OPERATOR MANUAL

P/N: MO04444-00ING

SOFTWARE VERSION 14.0
Rev. 0, 10/2009

This manual is valid for the following BT analyzers: BT1000, BT1500, BT2000 Plus, BT3000 Plus, BT3500.

The differences among the analyzers are highlighted where necessary.









CE

This product conforms to the safety requirements of the Council Directives 98/79/EEC of 27 October 1998 (European Parliament) regarding the In-Vitro Diagnostic Medical Devices. This directive is in accordance with the Article 2, Paragraph 2 of the Directive 89/336/EEC, which ceases to apply to the products complying with the present directive. Refer to Paragraph 7, Article No.1 of the IEC Official Gazette No. L331 of Dec. 1998.

It also conforms to Italian Regulations CEI EN 61010-01 and CEI EN 61326-1 (EMC).

The conformity is attested when the equipment is installed in accordance with the conditions outlined in the manual

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY
Tel. +39-06-4112316
Fax +39-06-4103079
E-mail: *bt@biotecnica.it* **Website: www.biotecnica.it**

IMPORTANT NOTICE ON THE USE OF THE UPS DEVICE

ATTENTION!

BIOTECNICA INSTRUMENTS ANALYZERS MUST OPERATE ONLY IF CONNECTED TO AN UPS DEVICE.

BIOTECNICA WILL NOT BE RESPONSIBLE FOR ANY DAMAGE TO THE ANALYZER OR INJURY TO PERSONS IF THE ANALYZERS ARE OPERATED WITHOUT THE PROPER CONNECTION TO THE UPS DEVICE OR WITHOUT THE UPS ITSELF.

INDEX – Operator Manual

SECTION I: GENERAL INFORMATION

CHAPTER A		
1. INTRODUCTION	Page:	2
2. BASIC OPERATING PRINCIPLES OF THE ANALYZER	Page:	3
3. SYMBOLS: explanation of the used or applied symbols	Page:	4
4. BRIEF DESCRIPTION OF THE SYSTEM	Page:	9
4.1. Front view of the analyzer	Page:	9
4.2. Rear Panel Controls and Connectors	Page:	11
4.3. Modules	Page:	13

CHAPTER B		
1. INSTALLATION	Page:	2
1.1. Unpacking the Analyzer	Page:	2
1.2. Installation	Page:	4
1.3. Starting the instrument	Page:	8
1.3.1. Turning on the instrument for the first time	Page:	8
1.3.2. Preliminary checks	Page:	9

CHAPTER C		
1. FUNCTIONS	Page:	2
1.1. Description of the Program Menu	Page:	2
1.2. Operating Principles	Page:	5
1.2.1. Computations	Page:	5
1.2.2. Applied mathematical functions	Page:	7
1.2.3. Initial computation	Page:	9
1.2.4. Optimization techniques for Clinical Chemistry	Page:	9
1.2.5. Methods Description	Page:	10
1.3. Analyses Programming	Page:	15
1.3.1. Creating a New Code	Page:	15
1.3.2. Relation Tests	Page:	16
1.3.3. Primary Analytical Parameters	Page:	17
1.3.4. Check Parameters	Page:	23
1.3.5. Secondary Analytical Parameters	Page:	24
1.3.6. Automatic re-runs	Page:	27
1.4. Controls	Page:	28
1.5. Calibrations	Page:	29
1.6. Creating Profiles	Page:	34
1.7. Creating the Current Analyses' Tray	Page:	35

CHAPTER D		
1. PERFORMANCE AND LIMITS	Page:	2

INDEX – Operator Manual

CHAPTER E		
1. OPERATING PROCEDURE	Page:	2
1.1. Turning on procedure	Page:	2
1.2. Reagents: insertion and removal	Page:	2
1.3. Running Standard & Controls (on command or timed)	Page:	5
1.4. Samples	Page:	7
1.5. Work Lists	Page:	13
1.6. Turning off procedure	Page:	17
1.7. Access Password	Page:	18

CHAPTER F		
1. QUALITY CONTROLS	Page:	2
1.1. Inserting/modifying controls	Page:	2
1.2. Data management	Page:	4
1.3. Displaying and processing by lot pairs: Juden graph	Page:	6
1.3.1. Westgard Graph	Page:	7
1.3.2. Daily Chart	Page:	9
1.4. Additional Functions	Page:	10
2. POPULATION	Page:	11
2.1. Analysis Selection (How to run a Query)	Page:	12
2.2. Principal statistics formulas used in Population module	Page:	16
2.3. Inserting external analyses	Page:	18
2.4. Other menu functions	Page:	19
3. PATIENTS' ARCHIVE	Page:	21
3.1. Selection (How to run a Query)	Page:	23
3.2. Patients' report	Page:	25
3.3. Printing Reports	Page:	27
3.4. Other menu functions	Page:	29

CHAPTER G		
1. DISPLAYING AND PRINTING RESULTS	Page:	2
1.1. Results per Patient	Page:	3
1.2. Results per Test	Page	8
1.3. Displaying Real-Time data	Page:	9
1.4. Reaction graphs	Page:	11
1.5. Flags list	Page:	13
1.6. Sorting results in real time	Page:	14

CHAPTER H		
1. ANALYZER TECHNICAL FUNCTIONS	Page:	2
1.1. Service Functions	Page:	2
1.1.1. Analyzer Utilities	Page:	2
1.1.2. Mechanical Calibrations	Page:	4
1.2. Diagnostic Functions	Page:	6
2. ANALYZER SETUP	Page:	10

INDEX – Operator Manual

CHAPTER I		
1. BARCODE AND RELATED FUNCTIONS	**Page:**	**2**
2. USING THE BARCODE	**Page:**	**2**
2.1. Barcode on Samples	**Page:**	**2**
2.2. Reagent Barcode	**Page:**	**5**
CHAPTER K		
1. VACUUM PUMP SYSTEM INSTALLATION/OPERATION	**Page:**	**2**
1.1. Functional characteristics	**Page:**	**2**
1.2. System control functions	**Page:**	**3**
1.3. Waste container (external)	**Page:**	**3**
1.4. Installation & operation	**Page:**	**4**
1.5. Maintenance and care	**Page:**	**4**
1.6. Trouble-shooting	**Page:**	**4**
1.7. Spare parts for maintenance	**Page:**	**5**

CHAPTER L		
1. ISE MODULE	**Page:**	**2**
1.1. Introduction	**Page:**	**2**
1.1.1. Contents of the wooden crates: I.S.E.	**Page:**	**3**
1.1.2. Applied Mathematical Functions	**Page:**	**3**
1.2. Performance And Limits	**Page:**	**4**
1.3. I.S.E. Wash and system shut down	**Page:**	**5**
1.4. Mechanical Calibrations: I.S.E. Arm	**Page:**	**6**
2. Operating the I.S.E. Module	**Page:**	**7**
2.1. Parameters	**Page:**	**7**
2.2. Programming Standards and Controls	**Page:**	**10**
2.3. Replacing and Installing Electrodes	**Page:**	**13**
2.4. Preliminary steps before starting the system	**Page:**	**14**
2.5. Calibration procedure	**Page:**	**15**
2.6. Measuring unknown samples	**Page:**	**17**
3. Precautions, maintenance and Troubleshooting	**Page:**	**18**
3.1 Precautions for ISE Module usage	**Page:**	**18**
3.2. Suggestions for performance maintenance	**Page:**	**19**
3.2.1. I.S.E. Maintenance	**Page:**	**20**
3.3. Troubleshooting	**Page:**	**22**
4. Returning The Analyzer To The Tech. Assistance Service	**Page:**	**26**
5. I.S.E. Module Consumables	**Page:**	

CHAPTER M		
1. WARNINGS AND PRECAUTIONS	**Page:**	**2**
1.1. Potential risks during operation and maintenance	**Page:**	**2**
1.2. Warnings and precautions	**Page:**	**3**
1.3. Waste disposal	**Page:**	**6**
1.4. Returning the analyzer to the T.A.S.	**Page:**	**6**
1.4.1. Operating Analyzer	**Page:**	**6**

INDEX – Operator Manual

1.4.2. Not Operating Analyzer	Page:	7
1.5. Analyzer safe disposal	Page:	8
1.6. Electric and electronic devices disposal	Page:	9

CHAPTER N		
1. MAINTENANCE AND CARE	Page:	2
1.1. Preventive maintenance and Extra Wash	Page:	2
1.2. Replacing tubing and accessories	Page:	3
1.2.1. Clinical Chemistry	Page:	3
1.2.2. Extra wash cuvettes	Page:	5
1.2.3. Photometric lamp	Page:	5
1.2.4. Dilutors' piston o-ring	Page:	6
1.3. Cleaning the instrument	Page:	7
2. MALFUNCTIONS	Page:	8
2.1. Troubleshooting	Page:	8
2.2. Screen messages	Page:	9
2.2.1. Screen messages - Causes and remedies	Page:	10
2.2.2. Messages requiring technical assistance	Page:	12
2.2.3. Optical system verification messages	Page:	14

CHAPTER O		
1. TECHNICAL SPECIFICATONS	Page:	2

SECTION II: SUPPLEMENTARY INFORMATION

CHAPTER 1		
1. ABBREVIATED OPERATING INSTRUCTIONS	Page:	2
1.1. Turning on and preliminary procedures	Page:	3
1.2. Inserting Reagents for Clinical Chemistry	Page:	6
1.3. Analytical calibrations and Controls	Page:	7
1.4. Entering Patients and Work Lists	Page:	10
1.5. Running Tests	Page:	14
1.6. Displaying and Printing Results	Page:	15
1.7. Turning off the analyzer	Page:	19

CHAPTER 2		
2. WARRANTY CONDITIONS	Page:	2
• Notes from the manufacturer	Page:	3
• Parts/Instruments Return Authorization	Page:	4

CHAPTER 3		
3. ORDERING INFORMATION	Page:	2
3.1. GENERAL TERMS AND CONDITIONS FOR SALE	Page	2
3.2. Consumables for the analyzer	Page:	3

INDEX – Operator Manual

CHAPTER 4		
4. SOFTWARE EXTENSION: Serial communication analyzer <-> Host Computer	**Page:**	**2**
4.1. General	**Page:**	**2**
4.2. Patient transmission to analyzer	**Page:**	**2**
4.3. Results reception	**Page:**	**3**
4.4. Calculation of check-sum	**Page:**	**4**
4.5. Wiring diagram of interface cable	**Page:**	**5**
4.6. Variable communication protocol	**Page:**	**6**
4.7. Serial communication test programs	**Page:**	**17**
4.7.1. Program Comunica.exe	**Page:**	**17**
4.7.2. Program BTPLUS.exe	**Page:**	**17**
CHAPTER 5		
5. INSTALLATION OF THE OPERATING SYSTEM	**Page:**	**2**
5.1. Preliminary Phase	**Page:**	**2**
5.2. Setup of the Operating System	**Page:**	**5**
5.3. Completing the installation	**Page:**	**9**
5.4. Settings of the Operating System	**Page:**	**11**
5.5. Installation of analyzer Program	**Page:**	**15**
5.6. Upgrading the analyzer software	**Page:**	**16**
CHAPTER 6		
6. TECHNICAL ASSISTANCE	**Page:**	**2**
CHAPTER 7		
7. BIBLIOGRAPHY OF ALLIED SUBJECTS	**Page:**	**2**
CHAPTER 8		
8. LIST OF APPLICABLE METHODOLOGIES	**Page:**	**2**

INDEX – Operator Manual

ATTENTION: USE OF THE ANALYZER INTERNAL COMPUTER – DOES NOT APPLY TO BT1500

The computer box of BT analyzers is designed for long-term security and reliability and is virtually maintenance-free as long as the user does not install any third-party application programs. If these applications are installed, then they may damage the operating system registry and may also cause disastrous consequence for the computer's hard-drive. Biotecnica Instruments S.p.A. will not be responsible for any damage to the analyzer, its software and data in the hard-disk in case of improper use of the PC box. This includes also: installation of external programs, not properly secure net connections (intranet and internet) and the use of disks without the necessary verification for viruses presence. Biotecnica Instruments S.p.A. will not be responsible for any damage caused by non authorized third parties who may open and alter the PC box configuration.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER A

1. INTRODUCTION **Page: 2**
2. BASIC OPERATING PRINCIPLES OF THE ANALYZER **Page: 3**
3. SYMBOLS: explanation of the used or applied symbols **Page: 4**
4. BRIEF DESCRIPTION OF THE SYSTEM **Page: 9**
4.1. Front view of the analyzer **Page: 9**
4.2. Rear Panel Controls and Connectors **Page: 11**
4.3. Modules **Page: 13**

IMPORTANT NOTICE

The introduction of access passwords has been rendered mandatory since 2004 for safeguarding sensitive data (refer to CHAPTER E, paragraph 1.7.).

NOTE:

All pictures in this manual are referred to the BT3000 Plus. Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. INTRODUCTION

This instrument is an automatic analyzer for Clinical Chemistry and Immunoturbidimetry, it represents the technological evolution of the T.A.R.G.A. line ("***T**echnology **A**dvanced **R**andom **G**eneration **A**nalyzer*"), manufactured by Biotecnica Instruments S.p.A. Rome, Italy.

The analyzer software is based upon Windows 2000 NT® (Fig. 1). It is easy to learn and offers the operator (thanks to its selective random access) the maximum flexibility in the acquisition and performing of **ROUTINE and URGENT** ("**STAT**", "Single Test Actual Time") tests on *serum*, *plasma* and *urine*.

Designed for continuous use (*24 hours non-stop)*, the analyzer can perform **STANDARDS' CALIBRATION** and **QUALITY CONTROLS** upon operator's request or at programmed time intervals. An **AUTODIAGNOSTIC FUNCTION** is built into the operative software, continuously monitors the analyzer system for correct operation.

- Besides clinical chemistry and immunochemistry tests, the BT3000 Plus and BT3500 are equipped for ions determination with the **I.S.E. Module** (**I**on **S**elective **E**lectrodes).
- The methods used are: **End Point**, **Fixed Time**, **Kinetic**, **Initial-Rate (I.R.)**, **Sample Blank type A and B**, **Only Read**, **End Point 2 points**, **Sample Blank (A-b), Sample Blank (B-b), Absolute End Point** and **End Point Starter.** It is possible to store up to **500 different test codes**, plus **Relation Tests** with no limit. In the stored analyses list the operator can generate customized test codes sequence for the reagent tray in use, including the relation tests.
- During analyzer operation, the refrigerated reagents chamber (not available in the BT1000) ensures a longer stability of the products in use.
- The positive **barcode** identification of reagents position (not available in the BT1000), reduces the possible error during the positioning of bottles.
- It is possible to perform repetitions (**Re-run**) upon operator's request or automatically (pathological results).
- In case of hyperactive results, the test repetition can be performed with automatic dilution of the sample, as programmed in the parameters page. It is also possible to run tests on already diluted samples, thanks to the automatic data processing function.
- Random positioning of samples and positive barcode identification (not available in the BT1000). The bar-code feature and the connection to the Host Computer allow the system to be fully automated.
- An internal software manages the **QUALITY CONTROL** (statistics of control sera and population) and **PATIENTS' ARCHIVE** with data display and printouts.



Figure 1

2. BASIC OPERATING PRINCIPLES OF THE ANALYZER

The automatic analyzer is based upon the *spectrophotometry* principles.
The light absorption laws rule the performance of spectrophotometers.

- The amount of light radiation that passes through a homogeneous absorbing medium is defined as *transmittance*, *T*, where:

$$T = I / I_0$$

I_0 = *incident light radiation intensity*
I = *transmitted light radiation intensity*

The *absorbance*, *A*, (or *extinction, E)* is defined as:

$$A = \log (1/T) = \log I_0/I$$

- The Lambert-Beer law states the relation between absorbance, concentration of a compound absorbing light and sample thickness:

$$A = \varepsilon c d$$

ε = *molar extinction coefficient of the compound absorbing light at a certain (λ) wavelength.*
c = molar concentration of the compound absorbing light
d = optical path of the radiation into the solution

The absorbing spectrum of a compound is represented by a graph where the absorbed light (= absorbance) is related with the wavelength. For a colored solution, the graph will show one or more absorbance peaks. These may be in the visible part of the spectrum (400-700 nm) as in the ultraviolet (200-400 nm) region.

The analyzer uses a photometric system specially designed by the R&D Dept. of the Biotecnica Instruments S.p.A.
A light beam is sent through a cuvette that contains the solution that has to be read. The exiting light beam is transmitted to a photometer containing 10 interference filters of different wavelengths. The signal is amplified and then processed by the specific electronics and by the computer. The program then makes all the necessary calculations and controls, so that it can finally present the concentration of the compound in the sample and the any irregularities found in the reaction.

The general principle upon which the photometry in clinical chemistry is based is the following: the increasing or the decreasing of the color intensity in a specific solution is proportional to the searched compound concentration. Generally speaking, when a sample is added to a specific reagent, it starts a reaction carried out by specific enzymes or substrates. This reaction causes the increasing (or decreasing) of the solution color inside the cuvette. During the reaction process, the instrument “reads” it by means of its absorbance. The final data processing is done with reference to a calibration or a theoretical factor, so as to give at the end the concentration of the compound into the sample.

The ISE (Ion Selective Electrodes) module, where available, is a device dedicated to the determination in the samples of the electrolytes (see chapter L). This device is defined as ion selective as the used electrodes react with the corresponding ions in accordance with the following Nernst law:

$$E = E_0 + RT/nF \log aM^+$$

aM^+ = *M^+ ion activity*
E = *potential in Volt*
E_0 = *constant (H^+ electrode redox semi-reaction std potential)*
R = *gas constant*
F = *Faraday’s constant*
T = *temperature expressed in Kelvin degrees*
n = *ion charge*

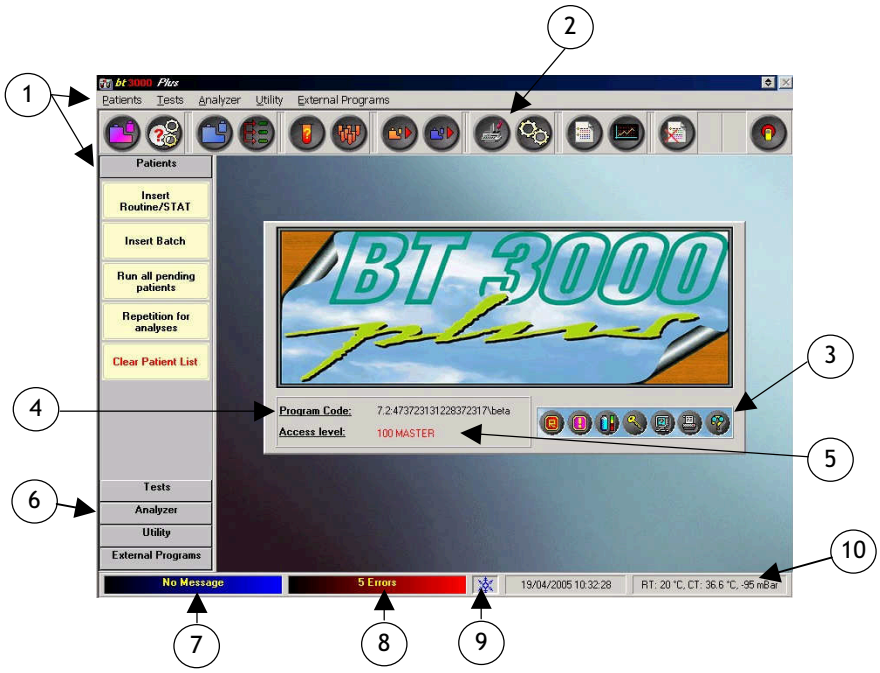
The electrodes life is dependent upon the number of sample runs and the routine maintenance procedures outlined in this manual.

3. SYMBOLS: EXPLANATION OF THE USED OR APPLIED SYMBOLS

As the analyzer software is based upon Windows, it uses the Windows style, icons, quick commands, function keys and curtain-shaped menus.

Every screen has its own icons and specific menus that will be described hereafter. The full meaning of each command will be explained in the corresponding chapters.

At the start-up, the program will display the following main window:



① **Main menu**: each menu generates other commands and/or options

② & ③ **Direct access icons**: selecting each icon the relative command is directly activated

④ **Program code:** operative program software version

⑤ **Access level**: is the access level of the operator: it is password dependent

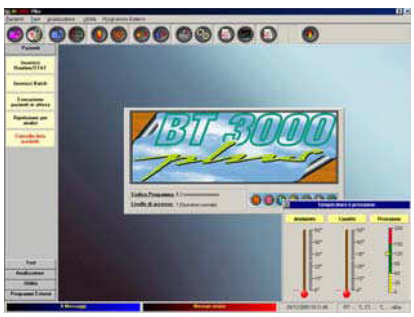
⑥ **Vertical Bar - Commands:** Direct access to function commands

⑦ **Messages bar**: clicking here opens a window showing the messages received by the program

⑧ **Errors bar**: by clicking here a window is opened showing the errors occurred during the work session.

⑨ **Refrigerator Status Indicator** (not available in the BT1000)

⑩ **Operating Pressure Indicator, Ambient Temperature (RT), Cuvette Temperature (CT)**



SERVICE ICONS BAR



Reset Analyzer (F5)



Stand-by Analyzer (F6)



Displays the Volumes' Status; Used to Insert/Remove Reagents (F10)



Password (F7)



Status Analyzer (F2)



Printer Setup (F4)



Help on line (F1)

FUNCTION ICONS BAR



1 - To Insert New Codes, Parameters, Standards and Controls for all Analyses



2 - To Create the On-Line Reagents' Tray



3 - To Insert Parameters/ Standard and Controls for the On-Line Reagents



4 - To Insert/Modify Profiles



5 - To Insert Routine - View Programmed or In-Run Patients



6 - To Insert Batch



7 - To Run Standards



8 - To Run Controls



9 - Analyzer's Utilities



10 - Mechanical Calibrations



11 - a) Results Listed per Patient b) Results per test in real time



12 - No Results



13 - Reaction Graphs



14 - Turning off the System

Simply positioning the cursor on the icons the "hint" will appear (where available), showing a brief description of the icon function. This is followed (when available) by the function key between brackets, which allows for the same function or command as the icon. For example, the hint "Reset (F5)" means that the function key F5 has the same function of the icon. In the same way, in each menu are shown (when available) the quick commands (e.g. "Insert Batch" (Ctrl+B) means that the same function is activated by typing simultaneously on the keyboard the keys "Ctrl" and "B").

GENERAL ICONS



Cancel (aborts the programming and closes the window)



Save (saves the program and closes the window)

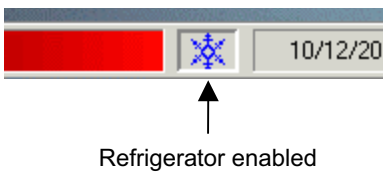


Print (prints the window's contents, i.e. parameters, graphs etc.)



Reduces the window to the upper bar where the analyzer's name appears.

An icon representing refrigeration system operation has been added to the status bar in the main menu. The "Refrigerator disabled" state may be necessary if the operator decides not to use the refrigerator for reactions or after a refrigeration operating error generated by the system.



IVD SYMBOLS: PRINTED PACKAGING ITEMS*



Caution, consult instructions for use



***In vitro* Diagnostic Medical Device**



Catalog number



Manufacturer



Lot number or Batch code



Storage temperature



Expiry date



Biological hazard



Risk symbols



CE Logo (Directive 98/79/CE)



Electrical and electronical devices: collect and dispose separately.

*** Not all symbols are listed here. These are only some examples.**

SYMBOLS APPLIED ON THE ANALYZER

A compilation of the main nameplate and warning symbols used for the IEC standards based on Table 1 of IEC 61010-1 Second Edition.



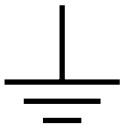
Direct current



Alternating current



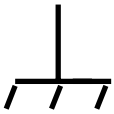
Both direct and alternating current



Earth (ground) Terminal



Protective earth conductor terminal



Frame or chassis (ground) terminal



Equipotentiality

ON (Main supply)



OFF (Main supply)



Equipment protected by double insulation or reinforced insulation



Caution, risk of electric shock
(black on yellow background)



Caution, refer to accompanying documents
(black on yellow background)

4. BRIEF DESCRIPTION OF THE SYSTEM

4.1. FRONT VIEW OF THE ANALYZER

BT3000Plus & BT3500

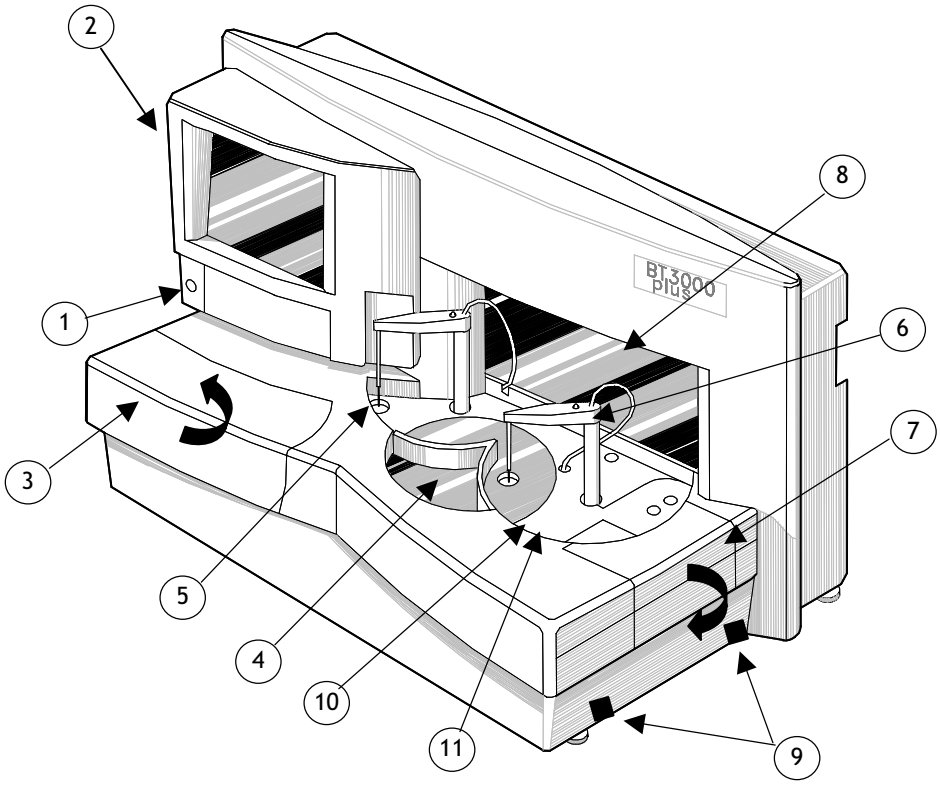


Figure 2

1 ON/OFF BUTTON FOR COMPUTER
2 LCD DISPLAY
3 REFRIGERATED REAGENT COMPARTMENT
4 SAMPLES TRAY
5 SAMPLING ARM FOR CLINICAL CHEMISTRY
6 SAMPLING ARM ISE
7 ISE MODULE
8 FLUIDIC CIRCUIT AND READING STATION
9 PUSH-PULL HANDGRIPS
10 ISE FUNNEL
11 DILUENT BOTTLE

BT1000, BT1500 & BT2000 Plus

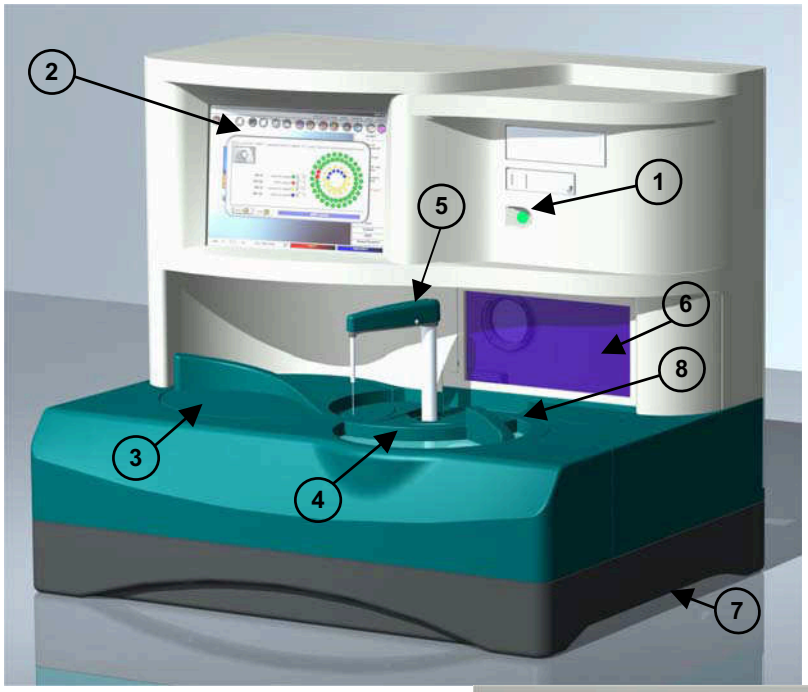
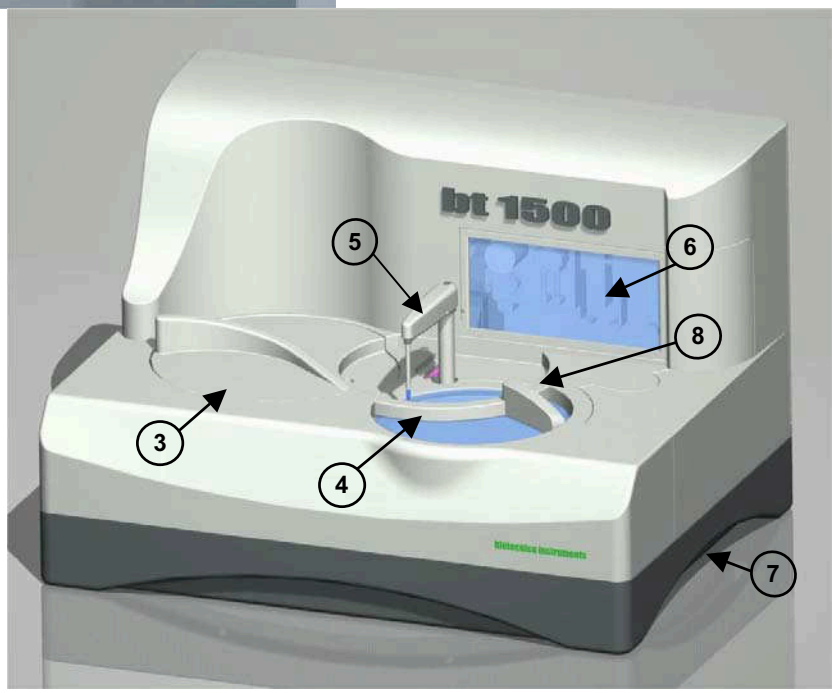
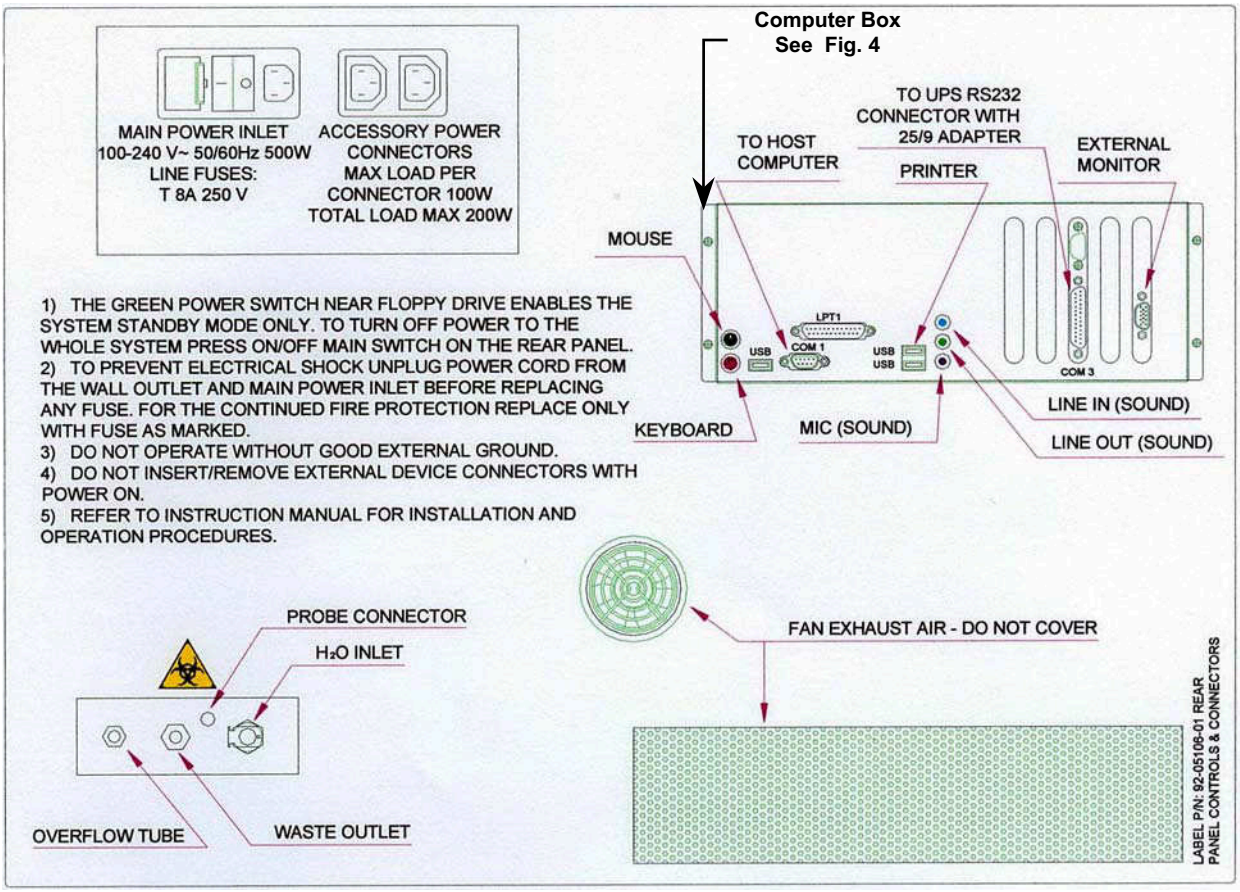


Fig. 3



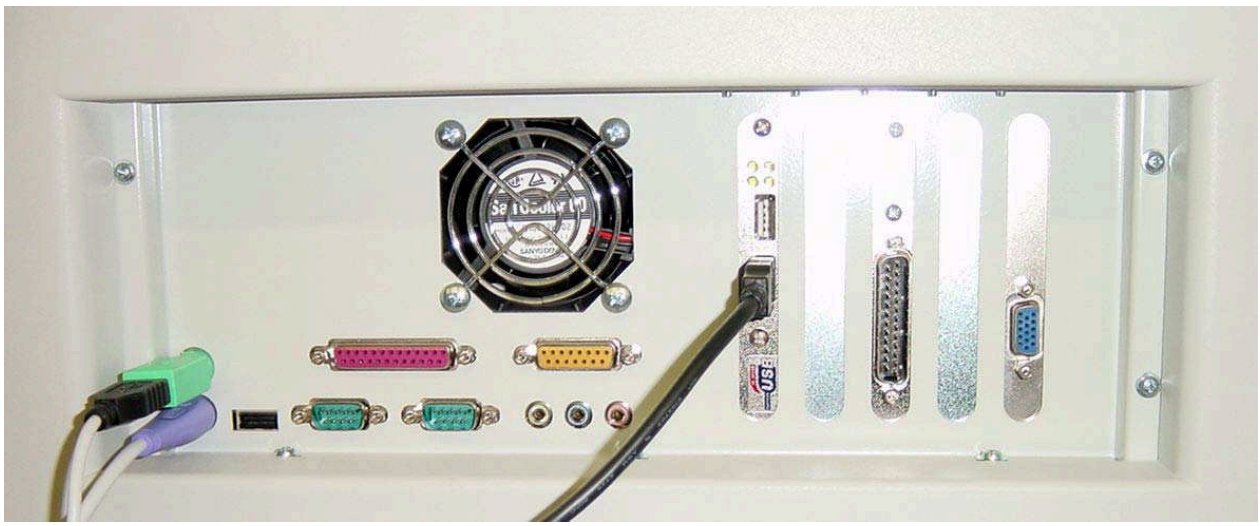
1 ON/OFF BUTTON FOR COMPUTER
2 LCD DISPLAY
3 REFRIGERATED REAGENT COMPARTMENT
4 SAMPLES TRAY
5 SAMPLING ARM FOR CLINICAL CHEMISTRY
6 FLUIDIC CIRCUIT AND READING STATION
7 HANDGRIPS
8. DILUENT BOTTLE

4.2. REAR PANEL CONTROLS AND CONNECTORS



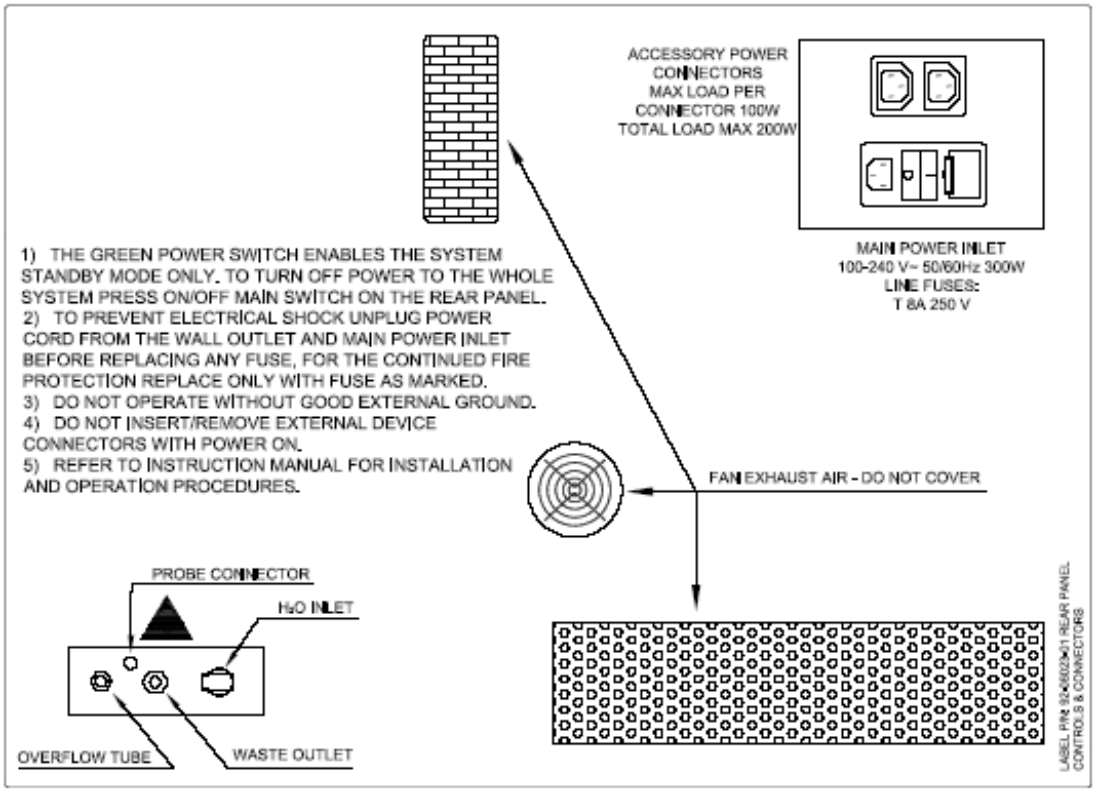
Rear Panel
Fig. 4

IMPORTANT NOTICE:
The illustrated connectors on the Computer Box (Fig. 4 & Fig. 5) may not be the exact representation due to possible design modifications without notice during the life of this manual. For correct configuration of the computer panel, please check the panel of Computer Box on the analyzer rear panel.



Connectors, Computer Box
Fig. 5

Connectors of BT1500 rear panel



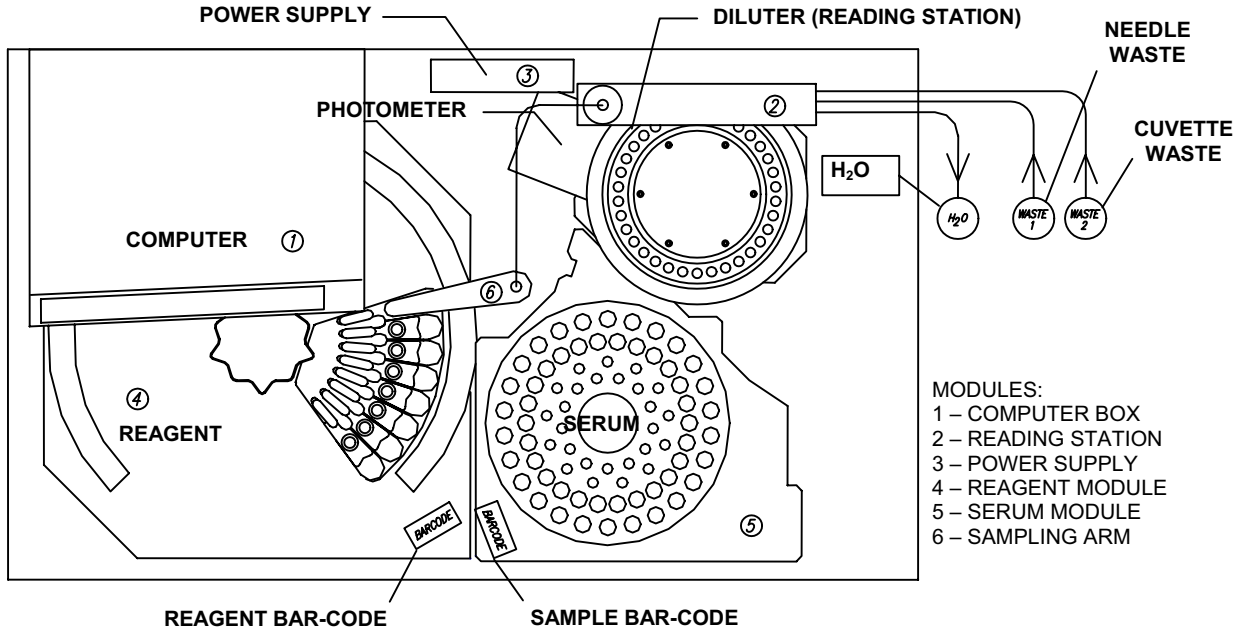
4.3. MODULES

The BT analyzers are constructed of a one-piece stainless steel structure. The injection-molded body (in Baydur®) is placed on the chassis to cover the instrument.
The following pictures show the modular composition of the instruments. Each module has its own specific function.

BT1000, BT1500 & BT2000 Plus

Modules definition

- **COMPUTER BOX**: it is not present in the BT1500. Consists of LCD Monitor, Touch screen, Main board, Power Supply and peripheral devices.
- **READING STATION MODULE**: comprises cuvette plate, photometer, diluter, reading unit, washing station, H_2O reservoir and electronics.
- **POWER SUPPLY MODULE**: houses the main power supply of the analyzer.
- **REAGENT TRAY MODULE**: is composed of the rotating reagent's tray, the refrigeration chamber, the bar-code reader and the electronics.
- **SAMPLE TRAY MODULE**: is composed of the rotating samples tray, the bar-code reader, the sample tube sensors, the washing wells and the control electronics.
- **SAMPLING ARM**: is composed of a two-axes based mechanical system accommodating sampling needle head with built-in electronics including correct position sensor (Encoder).

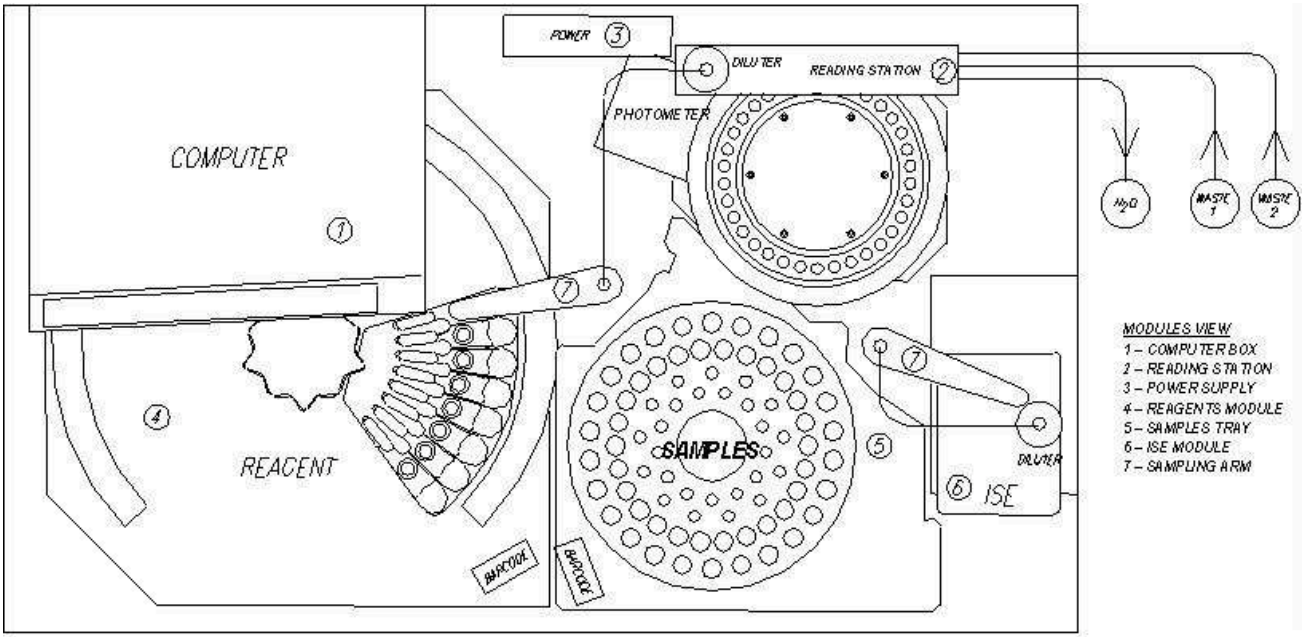


Modules Arrangement
BT1000, BT1500 & BT2000 Plus

BT3000 Plus & BT3500

Modules definition

- **COMPUTER BOX**: consists of LCD Monitor, Touch screen, Main board, Power Supply and peripheral devices.
- **READING STATION MODULE**: comprises cuvette plate, photometer, diluter, reading unit, washing station, H_2O reservoir and electronics.
- **POWER SUPPLY MODULE**: houses the main power supply of the analyzer.
- **REAGENT TRAY MODULE**: is composed of the rotating reagent's tray, the refrigeration chamber, the bar-code reader and the electronics.
- **SAMPLE TRAY MODULE**: is composed of the rotating samples tray, the bar-code reader, the sample tube electrodes, the washing wells and the control electronics.
- **ISE MODULE**: consists of the electrodes panel, hydraulic path and the electronics.
- **SAMPLING ARM (two)**: is composed of a two-axes based mechanical system accommodating sampling needle head with built-in electronics including correct position sensor (Encoder).



Modules Arrangement
BT3000 Plus & BT3500

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER B

1. INSTALLATION **Page: 2**
- **1.1. Unpacking the Analyzer** **Page: 2**
- **1.2. Installation** **Page: 4**
- **1.3. Starting the instrument** **Page: 8**
  - **1.3.1. Turning on the instrument for the first time** **Page: 8**
  - **1.3.2. Preliminary checks** **Page: 9**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.

Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. INSTALLATION

1.1. UNPACKING INSTRUCTIONS

♦ Unpacking the analyzer and the accessories

The crates can be easily opened by applying the lever action, with a large screwdriver, to remove all the spring clips at the base of the crate as shown in the Figure 1. Carefully remove the upper covering. Remove the analyzer and place it on a stable vibration-free surface. Carefully unpack all the accessories and place them in a protected place. Store the empty wooden crate in a safe place for future use.

CAUTION
The analyzer is provided with four integral handgrips (two handgrips for BT1000, BT1500 and BT2000 Plus) located on the left and right sides of the base frame. To lift or move the instrument from one location to another, always use the handgrips. ATTENTION: two persons are necessary to move the analyzer.

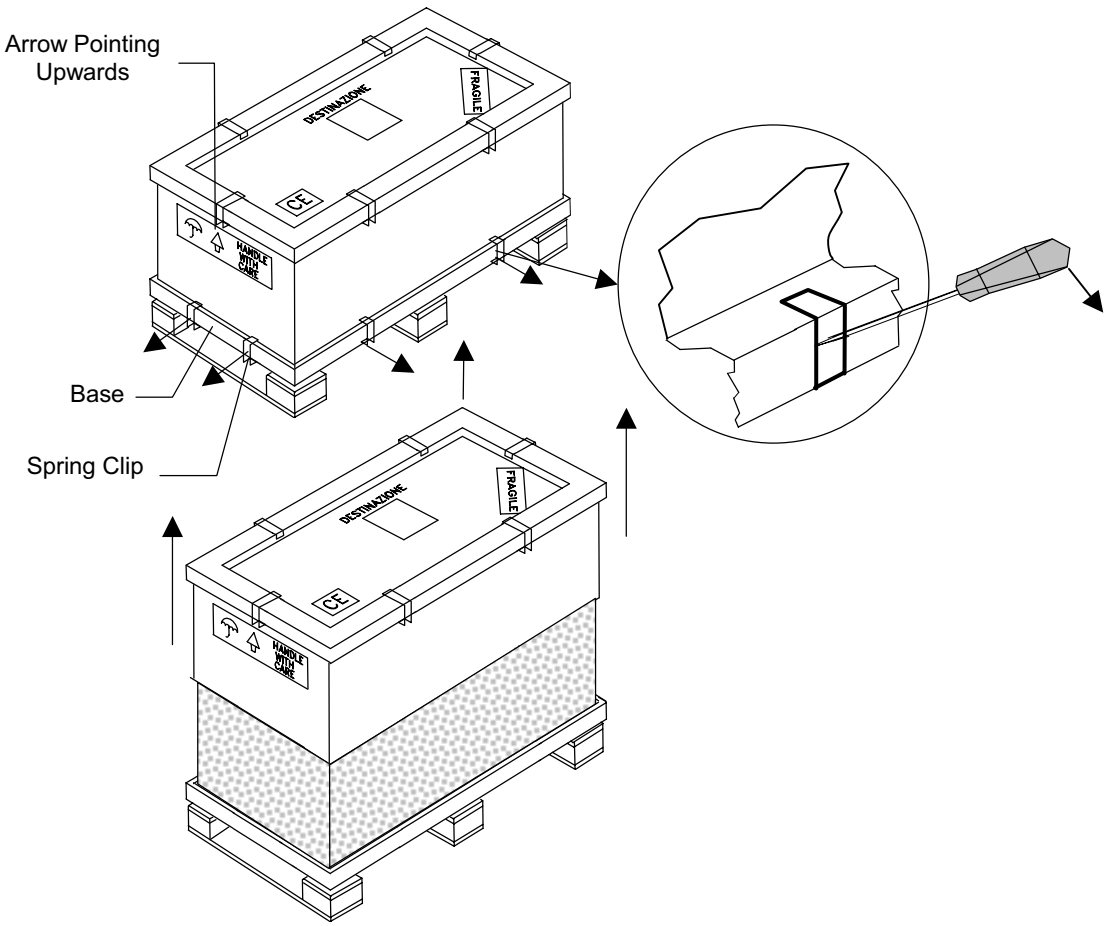


Figure 1

Verification Of the contents of the wooden crates

Verify upon receipt of the analyzer system that all parts are present and intact when opening the wooden crates and packaging. Please use **Mod. 05_28spr**, which is included in the shipment. This document is specific for each analyzer and lists in detail which items are present in the packages. The analyzer and accessories are contained in wooden boxes adequate for the shipment.

- **Verifying eventual damages occurred during shipment**

It is highly recommended to accurately verify the instrument and its accessories for any damages that could have occurred during shipment. In case there is a damage or missing items then please fill out all the sections of the **Mod. 05-35a** in this manual in the **SECTION II, CHAPTER 2 WARRANTY CONDITIONS**. Send it to your nearest sales/service office or directly to Biotecnica Instruments S.p.A. Rome, Italy. After appropriate evaluation, Biotecnica or its branch office will provide the best solution to the problem.

1.2. INSTALLATION

The analyzer must be placed on a stable vibration-free-surface, level table or cart. It should be easily accessible to the operator to load samples, consumables, reagents, etc. Ensure that the table can bear the instrument's weight and is large enough for its dimensions (refer to **Chapter O**, paragraph **1. Technical Specifications**). Avoid exposure to direct light, heat, air streams and draught. The instrument's left, right and rear sides must be left free (min. 20 cm from the wall) to ensure the produced heat dispersion and easy tubes and cables connection. Room temperature must not exceed 32°C. We recommend placing on the same table the analyzer and its peripherals (max allowed distance: 1.5 m). The printer can be placed in any location, always taking into consideration the paper feed, the connections with the instrument and the power supply needs. It is very important to place the analyzer away from strong electromagnetic fields, such as centrifuges, electric motors, big refrigerators, X-ray instruments, etc.
The table must be near a wall outlet with earthing and differential switch (life-saving)
The analyzer refrigerator produces water condensation in the reagent chamber. This is important for cooling the reagents in the bottles. In case of too much condensation, wipe it off with a clothe without drying it completely (never do this operation with the analyzer on). The instrument can be leveled by means of the four adjustable feet, to ensure the good drainage of the condensation.

CAUTION
The analyzer is provided with handgrips located on the left and right sides of the base frame. To lift or move the instrument from one location to another, always use the handgrips. For moving the analyzer at least two persons are necessary.

NOTE:
All the components, when present, shown in the following figures may undergo modifications over the time. Therefore, it is recommended to verify them accurately prior to any repair or installation (refer to eventual specific manuals included).

Attention: always verify the shipment check list Mod. 05_28spr, especially for what concerns accessories and peripherals, as not all analyzer's models are supplied with all accessories/peripherals. The following instructions are referred to the analyzers supplied with all accessories and peripherals. In case your analyzer is not supplied with complete equipment, please ignore the instructions related to the accessory/peripheral which is not present.

BT1500: as far as this analyzer has an external computer, please refer to its instructions for peripherals and electrical connections. The analyzer must be connected to the PC via the USB port located on the left side of the rear panel.

ELECTRICAL CONNECTIONS
Connect main power cable from the instrument to the UPS and connect the latter to the main wall outlet (**Figure 2**). Power circuit should respect current laws and have a good earth connection.

The printer and peripheral devices should be connected to the appropriate accessory power connectors on the analyzer rear panel (adjacent to main power inlet). See **Figure 2**.

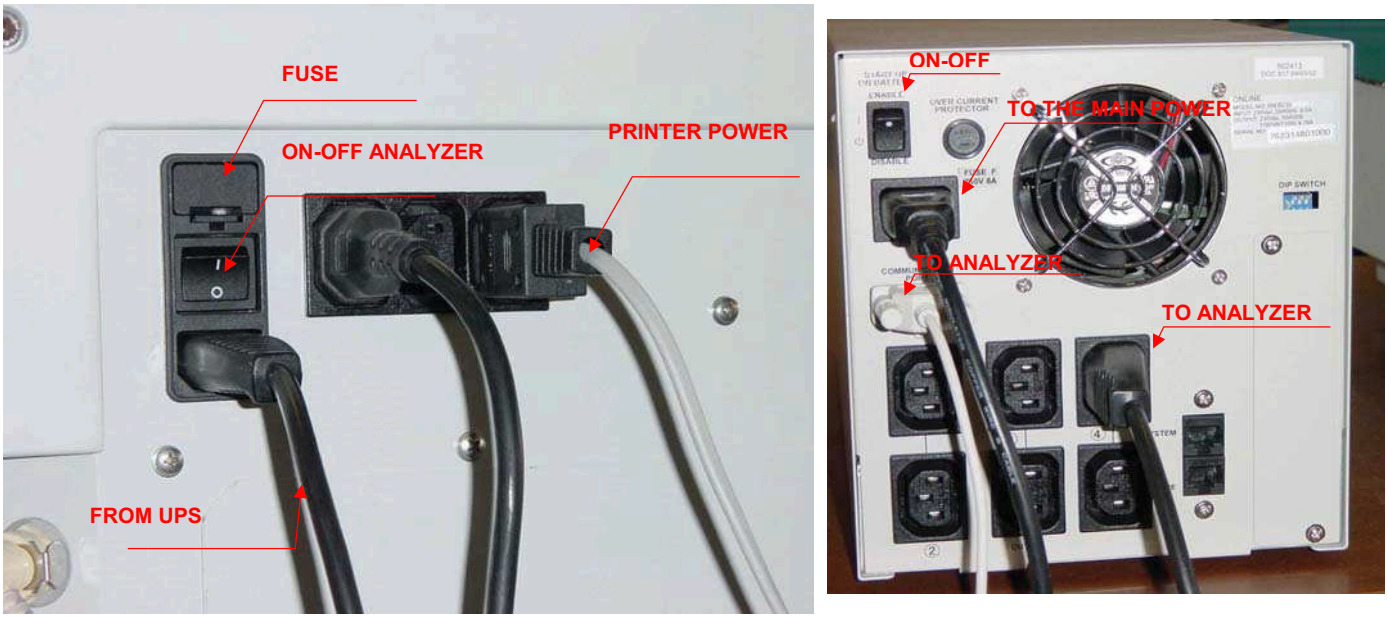


Figure 2

CONNECTING MOUSE AND KEYBOARD

Keyboard and mouse are cordless, and work by radio transmission. The receiver with PS/2 adapter should be plugged into the appropriate port on the rear panel.

The receiver has two cables with colored connectors that should be plugged into the respective ports of the same color. They are generally violet for keyboard and green for mouse (**Figure 3**).

Receiver, mouse and keyboard should be already tuned. If not, then observe the following procedure:

Turn on the analyzer, after program loading (system boot) is finished, press connect button on the receiver, and then press connect button on mouse. Next, press connect button on receiver again and press connect button on keyboard (rear). Refer to **Figure 4.** Connect buttons are generally located on the rear and can be pressed with the tip of the pen or pencil. Test mouse and keyboard and eventually repeat the tuning operation starting from the receiver. These devices need tuning only once.

PRINTER: Printer rear view.

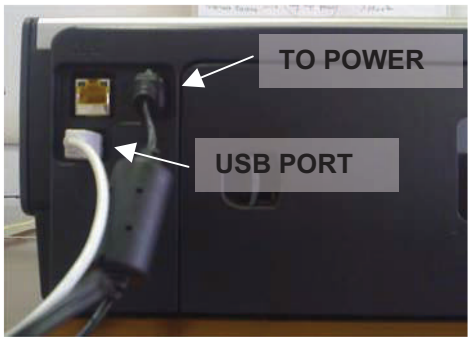


Fig. 5

Refer to **Figure 5** for connections.
Connect the USB/USB cable to the printer USB port and to one of the USB ports on the rear side of the analyzer. Connect at the same way the power cord, from the printer to one of the power connectors on the analyzer's rear panel (see figure 2).

FLUIDIC CONNECTIONS

The external fluidic manifold (**Figure 6 – BT1000, BT1500 & BT2000 Plus)** located at the bottom left of the rear panel has three connectors dedicated to H_2O intake, discharge of waste fluids, and a connector for transparent fluid overflow tube. A transparent tube supplies double distilled water from the external container. The waste probe tube discharges the analyzer waste (flowing from an internal vacuum pump) to the external waste container. In addition, the tubes are fitted with quick-connects having built-in shut-off valves, which in case of disconnection prevents liquid spillage.

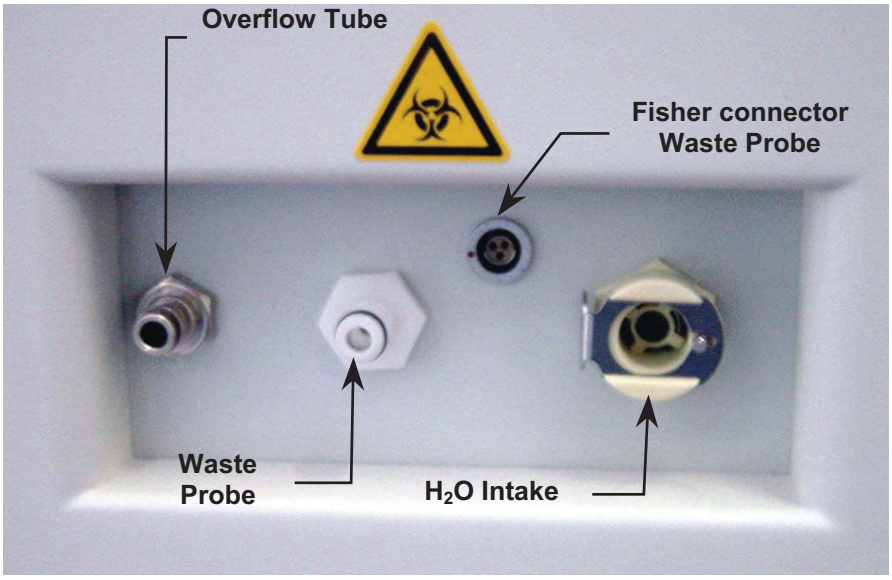


Figure 6 (BT1000, BT1500 & BT2000 PLUS)

The transparent tube (**double distilled H_2O plus Surface Active Agent i.e. tensioactive - 1ml every liter of water, ratio 1/1000**) must be connected to the right connector (**H_2O Intake**). Its other end goes to the external water container. Connect the liquid level detector cable (**Fisher connector**) and the drain tube of the waste probe to the middle connector (**Waste Probe**). Insert the waste probe in authorized external waste container (Fig. 7).



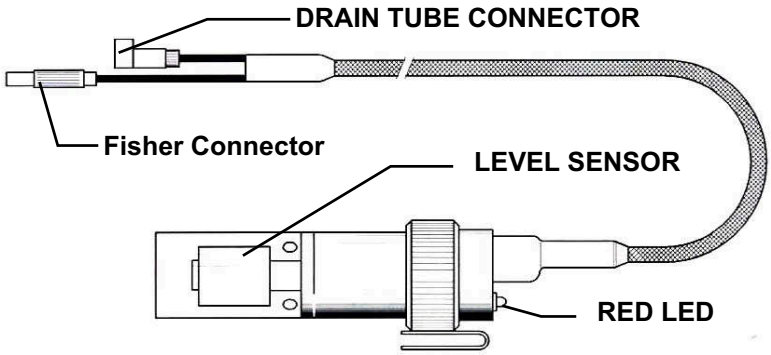
For BT3000 Plus and BT3500, the transparent, black, and blue tubes are fitted with quick-connects having built-in shut-off valves, which in case of disconnection prevents liquid spillage.

The transparent tube (**double distilled H_2O plus Surface Active Agent i.e. tensioactive - 1ml every liter of water, ratio 1/1000**) must be connected to the upper connector, identified by a white flange. Its other end goes to the external water container. The black tube for cuvettes waste fluid must be connected to the middle connector, identified by a black flange. Its other end goes directly into the second input connector of the vacuum pump. The blue tube must be connected to the lowest connector with blue flange on the fluidic manifold. Its other end goes directly into the first input connector of the vacuum pump system. For more info refer to **Chapter K – Vacuum Pump**.

Figure 6a

WARNING

1) **Do not use the internal vacuum pump system with any other fluid source except the analyzer. The unauthorized use may result in serious injury to the user and permanent damage to the vacuum pump system.**



WASTE PROBE (P/N 07-05165-01)

Figure 7

1.3. STARTING THE INSTRUMENT

1.3.1. TURNING ON THE INSTRUMENT FOR THE FIRST TIME

Turning on procedure for the first time:

1) Turn on the UPS device as described in the appropriate supplied manual.
2) Power on the printer (refer to the specific manual enclosed).
3) To switch on the analyzer, use the main power switch on the rear panel of the instrument. This button activates only the refrigerating system for the reagents, where available. To properly turn on the analyzer system, press once the green push-button placed on the front panel (**Fig. 8**). For what concerns the **BT1500**, verify first that the external PC is connected to the analyzer via USB, then turn the PC on and load the analyzer operative program.
   CAUTION
   Do not press this push-button during analyzer operation, because when pressed it stops the instrument, leaving only the refrigerating system on (refer to **Paragraph 1.6**., **Chapter E, Turning off procedure**).
   The start-up process includes the loading of the operating system (bootstrap) into the memory. At the end of the boot (loading of the operating system), the instrument activates all the devices and performs mechanical, hydraulic and electronic checks. The hydraulic check is represented by a graphical page "Auto Diagnostic" (**Fig. 9**) where the different phases of tests in progress are displayed sequentially. At the end of each test a message "**Passed**" or "**Not Passed**" appears. If all the tests had positive outcome (Passed) then this page automatically disappears. If one of the tests was followed by a message "**Not Passed**" then this indicates that the particular device is not functioning properly. This means that the instrument is not in the condition to perform analytic tests. By performing a manual reset (**F5**), the instrument will repeat the auto-diagnostic cycles in an infinite loop until the problem has been resolved.
4) Once turning on procedure has completed (lasting few minutes), wait for the system to warm up. During warm-up phase the temperature indicator flashes on the bottom right of the display until the appropriate temperature is reached. The instrument reaches the steady state after approximately 20 minutes.
5) After turning on the system, there is an access password requirement. Refer to **Chapter E**, paragraph **1.7. ACCESS PASSWORD** regarding the utilization of the password.
6) Prime the hydraulic circuit using the commands outlined in **Chapter H**, paragraph **1.1. Service Functions** (**Dilutor prime, Wash with water).**

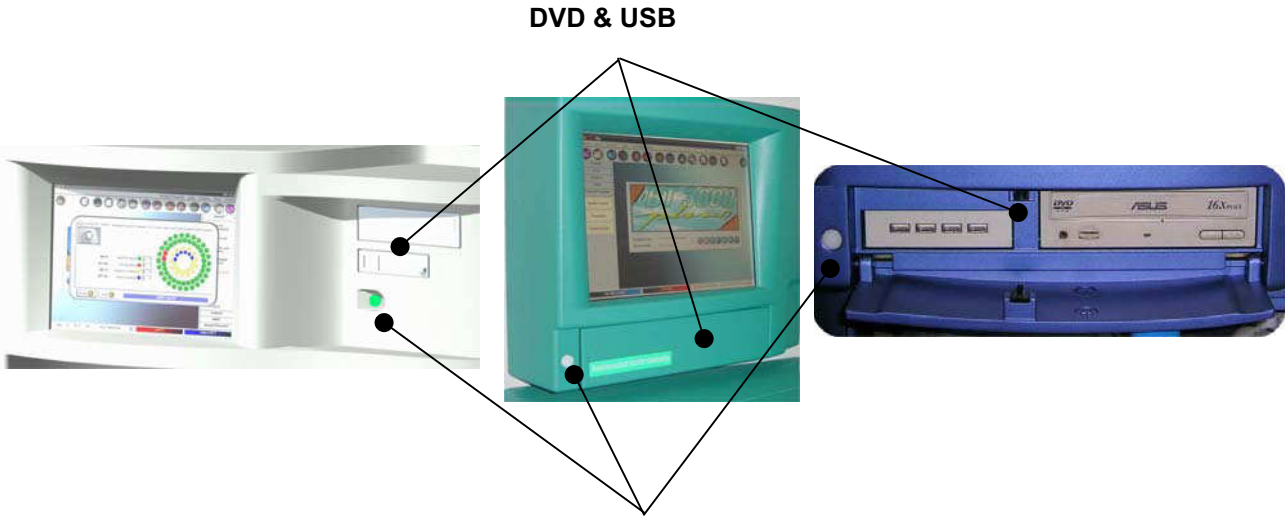


Figure 8

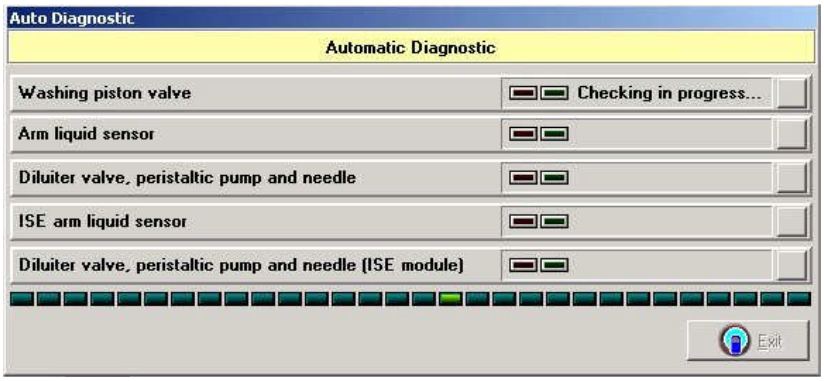


Figure 9

1.3.2. PRELIMINARY CHECKS

Before using the analyzer, it is recommended to perform the preliminary checks outlined below. Some of these checks should be performed daily and others are periodically.

DESCRIPTIVE TABLE

OPERATIVE CONTROL	PERIODICITY	NOTES
Verify that there is sufficient washing solution in the external tank for the needs of the working day. **The washing solution is prepared by adding to double distilled H_2O the Surface Active Agent – tensioactive - 1ml per liter of water (i.e. ratio 1:1000).** See technical specifications regarding double distilled water below.	Daily	
Check that the waste containers are empty or that they are of sufficient capacity for at least containing washing solution corresponding to the daily waste liquid volume.	Daily	
Zeroing of the photometer	Twice a day	A reminder message will appear 20 min after start up and then after 6 hours.
Wash the cuvettes with the proper solution	Daily	Before turning off
Extra wash of the cuvettes with acid solution	Weekly	When turning off
Wash I.S.E. module with proper solution	Daily	When turning off

DOUBLE DISTILLED WATER SPECIFICATIONS:

Resistivity: > 5 M Ω/m
Conductivity: < 1µS/cm
pH: 6,4
Residual Ions: < 1µg/l

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER C

1. FUNCTIONS **Page: 2**
- **1.1. Description of the Program Menu** **Page: 2**
- **1.2. Operating Principles** **Page: 5**
  - **1.2.1. Computations** **Page: 5**
  - **1.2.2. Applied mathematical functions** **Page: 7**
  - **1.2.3. Initial computation** **Page: 9**
  - **1.2.4. Optimization techniques for Clinical Chemistry** **Page: 9**
  - **1.2.5. Methods Description** **Page: 10**
- **1.3. Analyses Programming** **Page: 15**
  - **1.3.1. Creating a New Code** **Page: 15**
  - **1.3.2. Relation Tests** **Page: 16**
  - **1.3.3. Primary Analytical Parameters** **Page: 17**
  - **1.3.4. Check Parameters** **Page: 23**
  - **1.3.5. Secondary Analytical Parameters** **Page: 24**
  - **1.3.6. Automatic re-runs** **Page: 27**
- **1.4. Controls** **Page: 28**
- **1.5. Calibrations** **Page: 29**
- **1.6. Creating Profiles** **Page: 34**
- **1.7. Creating the Current Analyses' Tray** **Page: 35**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. FUNCTIONS

1.1. DESCRIPTION OF THE PROGRAM MENU

As already described in the Chapter A, the **BT** instruments are clinical chemistry automated analyzers for performing tests in Routine (programming per patient), Batch (samples per test) and STATs on *serum, plasma* and *urine.* The single samples are always accessed in random mode.
Besides the clinical chemistry, it is possible to perform turbidimetry tests (immunochemistry) for specific proteins, pharmaceuticals, drugs abuse and reading of electrolytes (where available, see Chap. L).
Once the program is loaded, the main page appears, where it is possible to enter all the menus. These are available in two variants: the horizontal and the vertical menu bars. Moreover, there is the icon bar that can be used for a rapid access to the most frequently used commands (refer to **Chapter A**, paragraph **3**.).
The analyzer provides access to the operating commands in the following three different ways:

- **Menus**
- **Shortcuts**
- **Icons**

Menu: move the cursor on the selected command and click once to access the function.

Shortcuts: the shortcut is a particular combination of the keys: "**Ctrl or Alt + one letter of the function's name"** (ex. "Ctrl+P" or "Alt+A"). It gives a direct access to the requested command. The **Shortcuts** are available for the menu items in **Patients** and **Tests.** These are always enabled, except for the external programs, the diagnostic page, and the parameters' programming pages or in case of errors' notification.

Icons: it is the symbolic representation of a given function. Move the mouse cursor on the desired icon and confirm by a single click to access the function.

The main menu contains five items: **Patients**, **Tests**, **Analyzer, Utility** and **External programs.**
Each item has a sub-menu that provides access to additional commands, some of which can also be selected through combination of keys corresponding to the desired shortcut.

Patients Menu

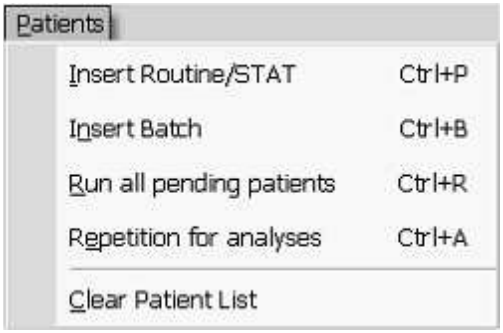


Figure 1

Insert Routine/STAT, Insert Batch: these items are used to enter samples for Routine/STAT and Batch mode.
Run all pending patients: Restarts the work list after an interruption.
Repetition for analyses: Selects the repetition by analyses upon operator's request.
Clear Patient List: Deletes the entire memorized patients list. The analyzer will request confirmation before deleting.

Tests Menu

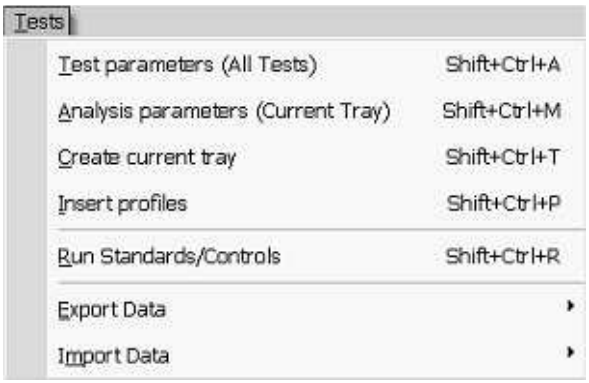


Figure 2

Tests' parameters (All Tests): It is used for programming and memorizing tests.
Analyses' parameters (Only In Tray): It provides direct access to the analyses on the current reagents' tray.
Create current tray: This item is used to create the list of analyses' in the current reagents tray.
Insert profiles: is used to create the analyses lists (profiles) which can be used for programming patients.

Run Standards/Controls: Activates the procedure for running standard/controls.
Export Data: Copies onto a floppy disk or any other desired location, the analytical parameters. There are two available options: Back-up (for exporting all the analyses) and Single Test (exports a selection of single tests).
Import Data Copies the above-mentioned parameters from a floppy disk or from any other location into the analyzer memory. There are two available options: Restore (will import all parameters) and Single test (imports the exported single tests). The function is allowed only if modify parameters password is given.
NOTE: when a back-up is imported, all data in the global and current analyses trays will be overwritten. When a single parameter is imported, it will be placed in the Global list of analyses. The operator will have then to correctly place it in the Current tray.

Analyzer Menu

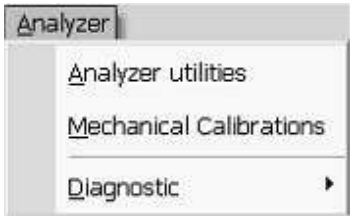


Figure 3

Analyzer's utilities: provides access to the service procedures of the analyzer.
Mechanical Calibrations: for making adjustments to mechanical devices.
Diagnostic: the technical assistance personnel mainly use this function (see Chapter H).

Utility Menu

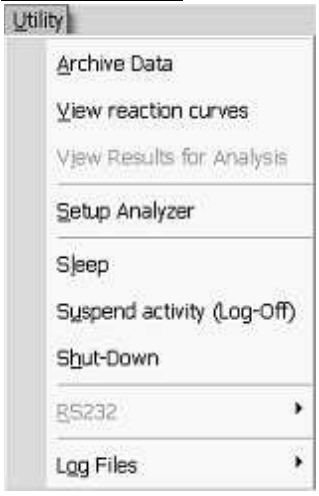


Figure 4

Archive Data: this command stores the processed patients' data into the patients' archive.
View reaction's curves: this command displays on a graph the reaction's curves of tests, with print capability.
View results for Analyses: displays results for test.
Setup Analyzer: it is used to define some system parameters. This command is disabled during analyzer operation. Refer to Setup Analyzer in Chapter H, paragraph 2.
Sleep: this command sets the analyzer to a standby mode, during which the cuvettes are washed and the monitor displays the screensaver. Press the button at the center of the display to exit from the sleep mode. A reset will occur and the analyzer will be immediately ready to operate. This option is useful when the analyzer is not being used for a while, but it must be kept on to resume work immediately.

Note: the analyzer switches automatically to the standby mode when left unused for more than thirty minutes.

Suspend activity (Log-Off): This command is used for programming the power on of the analyzer software on a specific date and hour. A small window will appear on the monitor where the restart time and date can be set. After the programming is confirmed, a guided procedure will lead to the system's washing procedure and afterwards the analyzer will suspend its activity. The system will be off except for the reagent refrigeration chamber. Approx 30 min. before the programmed turning on time, the lamp and the cuvettes' Peltier will be reactivated. At the expiry of programmed time and date the analyzer will exit the suspend mode by performing a system reset. To resume the analyzer activity before the programmed time, click on the left or right mouse button and press the **Exit** button on the window that appears. The system will reset and after approximately 20 minutes warm-up time the analyzer will be ready to operate (refer to Chapter E, paragraph 1.6.).

Shut-Down: to turn off the analyzer, it is important to observe the shutdown procedure (refer to Chapter E, paragraph 1.6.). The program, through a guided procedure, will perform the shutdown wash, and then the computer will turn off leaving only the reagent refrigeration chamber turned on. Press the ON/OFF button on the rear panel to turn also the refrigerator off.

Note: The analyzer's program will guide the operator through screen messages in the analyzer turning off procedures. He will be invited to place the solutions when needed and to ensure the correct execution of washing procedures. In case the washing procedures are not performed during shutdown, then at the next restarting of the analyzer (and before any sample run) the system will display a message inviting the operator to perform the required washings. Bear in mind that it is not possible to ensure data precision and accuracy if the normal washing and maintenance procedures are not observed.

RS232: This command is active only when the serial communication is enabled (see Analyzer Setup, Chapter H, paragraph 2). It allows the analyzer to send data to the host computer, upon operator's request.

When the serial port is active, two more commands will appear: **Accept result to be sent** and **Delete result to be sent**. The first one will send the results to the Host computer, the second will delete the results waiting to be send.

Log Files: gives access to the files where the operations performed by the analyzer are stored. This function is divided in two parts: the first part memorizes the performed operations; the second stores the errors and the incorrect procedures. This read-only area is very important for the Technical Assistance/service personnel.

External Programs Menu



The functions in this menu are outlined in the Chapter F.

Figure 5

1.2. OPERATING PRINCIPLES

Generally, adding a sample to its reagent determines a chemical reaction (involving enzymes and/or substrates) whose effect is to increase (or decrease) the color and thus the optical density of the solution in the cuvette. As the reaction proceeds, it is "read" by the analyzer in terms of "absorbance" ("A" or "Abs" for absorbance).
As every analyte has its own reagent with its proper characteristics; therefore it becomes necessary to use different methodologies (preparation and reading) based upon different wavelengths for each test. Many tests are based on similar principles, hence they will have in common the method and the wavelength, but not necessarily the incubation and reading times.
To obtain the concentration of an analyte in a sample, the analyzer multiplies the absorbance (or the absorbance delta ΔA = absorbance variation) developed by that sample reaction with a multiplication factor.
Besides some analyses for which a theoretical factor is used, usually the factor is calculated during a calibration. During the calibration the analyzer reads the reaction obtained with a known concentration sample called "standard". The factor is calculated by dividing the known concentration value by the absorbance read for the standard.
For the non-linear analyses (e.g. immunoturbidimetric tests) it is necessary to create an interpolation curve by means of several standards at different concentrations.

1.2.1. COMPUTATIONS

♦ COMPUTING ABSORBANCE (ABS)

End Point

ABS = Mean value of the last points in reading time- second phase - (max 3)
With subtraction of the Blank reagent.

Kinetics

- Linear regression computation
- ABS = (straight line coefficient) x 60 sec

Fixed Time

ABS = Δ ABS (last reading in second phase – first reading in second phase)

Initial-Rate

- Linear regression computation
- ABS = Straight line coefficient

In case test is unstable:

- Linear regression computation
- Elimination of 49% of the most distant points from the straight line
- ABS re-computation

Sample-Blank (A)

ABS = Last reading of the second phase – last reading of the first phase x K*

* K = Volumetric factor

Sample-Blank (B)

ABS = Last reading of the second phase – last reading of the first phase

End Point 2 Points

If readings are > 3:

- L1 = First reading in incubation time (phase 1)
- L2 = mean value of last three readings (phase 2)

If readings are > 2:

- L1 = First reading in incubation time (phase 1)
- L2 = mean value of last two readings (phase 2)

In the other cases:

- L1 = First reading in incubation time (phase 1)
- L2 = Last reading (phase 2)

ABS = L2 - L1

Sample-Blank A-b

Blank:	R1 + R2
1st phase:	R1 + Serum
2nd phase:	R2
Computation:	(Last Reading 2nd phase –Last Reading 1st phase) – blank

Sample-Blank B-b

Blank:	R2
1st cuvette:	R1 + serum
2nd cuvette:	R2 + serum
Computation:	(Last Reading 2nd cuvette –Last Reading 1st cuvette) – blank

End Point Starter

Dynamic:	As normal End Point with serum starter
1st phase:	Only reagent (R1 or R1+R2)
2nd phase:	Serum
Computation:	Last Reading 2nd phase –Last Reading 1st phase

Absolute End Point

This method is identical to the End Point but without subtraction of the Blank reagent.

♦ COMPUTING CONCENTRATION VALUE

Fnr

- If the External Dilution Factor is less than or equal to 1 then ***Fnr = 1***
- In other cases ***Fnr = External Dilution Factor***
- If sample is run with dilution then ***Fnr = External Dilution Factor***

Dynamic Blank Check

If Dynamic Blank is present and test is either a Kinetic, or a Fixed Time, then:

- ***ABS = ABS – Dynamic Blank Value***

If Dynamic Blank is not present and test is an End Point, then:

- ***ABS = ABS – Blank Value***

ABS = ABS x Fnr

- If the factor is used, then: ***Conc = ABS x Factor***
- Otherwise the concentration is extrapolated from the standard's curve, where:

Fnr : Internal Factor
ABS : Test ABS
Conc : Final concentration

1.2.2. APPLIED MATHEMATICAL FUNCTIONS

♦ **Correlation Coefficient**

$$CC = \frac{\sum_1^n (T_i - \overline{T})(L_i - \overline{L})}{\sqrt{\sum_1^n (L_i - \overline{L})^2 \sum_1^n (T_i - \overline{T})^2}}$$

where:

n : Number of readings
i : Number of reading (i)
T : Times
L : Readings

♦ **Linear Regression**

$$M = \frac{\sum_1^n (T_i L_i) - n \frac{\sum_1^n (L_i)^2}{n} \frac{\sum_1^n (T_i)^2}{n}}{\sum_1^n (T_i)^2 - \frac{(\sum_1^n T_i)^2}{n}}$$

$$Q = \frac{\frac{\sum_1^n L_i}{n} - \left(\sum_1^n (T_i L_i) - n \frac{\sum_1^n L_i}{n} \frac{\sum_1^n T_i}{n} \right)}{M}$$

where:

- **M** : Angular coefficient for the line
- **Q** : Final point for the line
- **n** : Number of readings
- **i** : Number of reading (i)
- **T** : Times
- **L** : Readings

♦ **Distance point-line**

$$D = | Y - MX - Q |$$

where:

- **M** : Angular coefficient for the line
- **Q** : Final point for the line
- **X** : Point Abscissa
- **Y** : Point Ordinate

♦ **Distance between two points**

$$Y = \frac{X - x_0}{x_1 - x_0}(y_1 - y_0) + y_1$$

where:

- **X** : X axis
- **Y** : Y axis
- **x_0** : First Point X Axis
- **x_1** : Second Point X Axis
- **y_0** : First Point Y Axis
- **y_1** : Second Point Y Axis

MATHEMATICAL FUNCTIONS FOR CLINICAL CHEMISTRY

♦ **Volumetric factor (used in sample blank A tests)**

$$K = \frac{vS + vR_1}{vS + vR_1 + vR_2}$$

where:

- **K** : Volumetric factor
- **vS** : Serum volume
- **vR_1** : First reagent volume
- **vR_2** : Second reagent volume

♦ **I.S.E. Module Functions**, see chapter L, par. 1.1.2.

1.2.3. INITIAL COMPUTATION

The initial computation is important for transforming the microprocessor data into compatible data for the program to generate the single absorbance value, which will be used afterwards for the final absorbance computation.

- **Clinical Chemistry**

$$V = \frac{Z - Log\left(\frac{F_1 - Fz_1}{F_2 - Fz_2}\right)}{Of} Op$$

where:

Z : Zeroing with water
F_1 : First Filter's Value
F_2 : Second Filter's Value
Fz_1 : First Filter's Zero-Value
Fz_2 : Second Filter's Zero-Value
Op : Optical path
Of : F.C.C.

1.2.4. OPTIMIZATION TECHNIQUES FOR CLINICAL CHEMISTRY

- **Searching for the right reading point (for Fixed Time test):**

If the point (P1) is not read exactly at (T_0), then the ABS value for P1 must be extracted with the following procedure:

with N < 3

1. Compute the Regression line y = mX+q from the reading points
2. Search for the point on the line at T_0

with N ≥3

1. Compute Best-Fit curve coefficients from the reading points
2. Search for the point on the line at T_0

N = number of points during reading time

- **Normalization of reading data (elimination of erroneous readings) (for Kinetics and Initial-Rate tests):**

If more than two points are obtained during reading time, then:

a. If CC is > 0.99, the procedure stops
b. If CC is ≤ 0.99:
1. NN = N / 3
2. Compute linear regression and store m and q
3. Compute the first most distant point from the line y = mX+q
4. Trace the point on the line
5. NN = NN – 1
6. If NN is > 0 go back to step (2)

where:

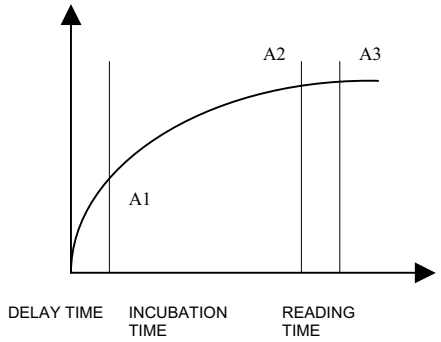
CC : Correlation Coefficient
N : Number of points during reading time
NN : Number of points to be traced
m : Angular coefficient for the line
q : Known line coefficient

1.2.5. METHODS DESCRIPTION

End Point

Once the sample has been added to its reagent, a reaction occurs first causing a variation in the solution's color i.e. the absorbance (usually during incubation time), followed by a phase in which the reaction's color is stable, defined as "plateau".
Generally, the absorbance value (A) is read from the first point after the incubation time. This value is then multiplied by the factor computed during calibration, to obtain the concentration of the analyte in the sample.

Conc. in sample = Factor x (A3 - Reagent Blank)



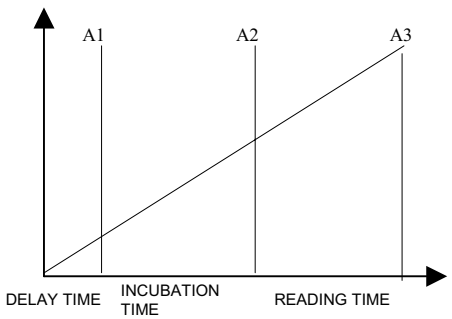
Absolute End Point

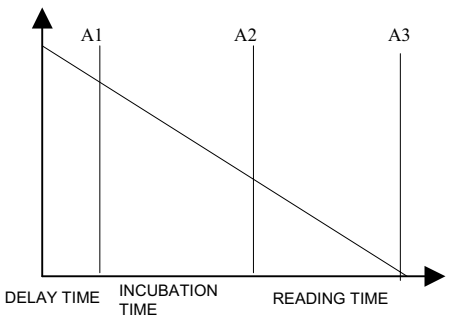
This method is identical to the End Point but without subtraction of the Reagent Blank.

Fixed Time

In this type of reaction, there is an increase (or decrease) of the absorbance during both incubation's and reading's phases. However, the slope of the line may not be the same during the two phases. The reaction graph displayed to the user is not always linear, but can also appear as piecewise linear. This is because the graph is obtained by the union of the read points that may not be aligned. A regression line is calculated during both incubation's and reading's phases. These provide the user with information about the correct evolution of the reaction. During reading time, the absorbance delta (ΔA) is also computed, which is used for calculating the final concentration for the analyte in the sample.
It may happen, due to a physical delay, that the instrument does not respect the timing and that tests are read at a different final time from the one set in the parameters. In this case the analyzer performs one more reading, traces the regression line between the last two points, moves to the exact reading time and derives the correct absorbance value from it.
Concentration is calculated by multiplying the absorbance delta (during reading time) by the factor obtained from the calibration:

Conc. In Sample = Factor x (A3 - A2) *(A3 - A2) = ΔA*

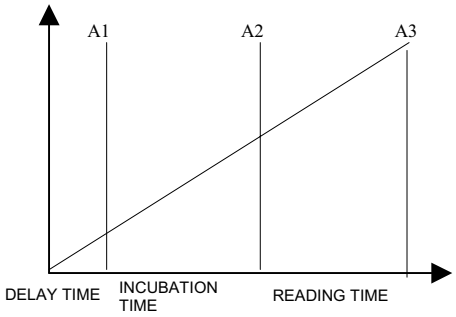


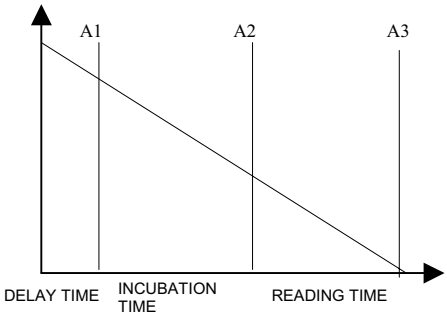


Kinetics

This kind of reaction is very similar to the previous one, with the difference that the reaction and the graph derive both from the computation of two regression lines: one for the incubation phase and the other for the reading phase. These two lines are often the same if the reaction has a good quality. The regression line for the reading phase is then scaled to minutes to compute absorbance delta (ΔA/min.). This value is then multiplied by the factor to compute the concentration of the analyte in the sample:

Conc. in Sample = Factor (A3 - A2) *(A3 - A2) = ΔA/min.*





Initial Rate (I.R.)

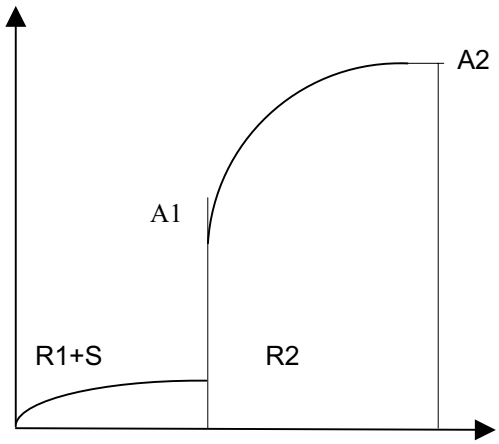
This type of reaction is very similar to the kinetic one. If the initial phase is stable, then it behaves exactly like a kinetic reaction. If the initial phase in unstable, the regression line is computed by eliminating the points outlying it from 49% to 100%. Thus, the calculation is identical to the one for kinetic reaction:

Conc. in sample = Factor x (ΔA/min)

Sample Blank (A)

This method is used whenever it is required to eliminate the photometric interference of the sample (for example turbid sera) from the reaction. These are double-reagent End Point reactions. The reaction and the computation are performed during two distinct phases: in the first phase (sample blank) the reaction between the first reagent and the sample (R1+S) takes place, while in the second phase the second reagent is added to R1+S (R1+S+R2). The final absorbance used for computing the concentration of the analyte is obtained from the difference in absorbance between the two phases:

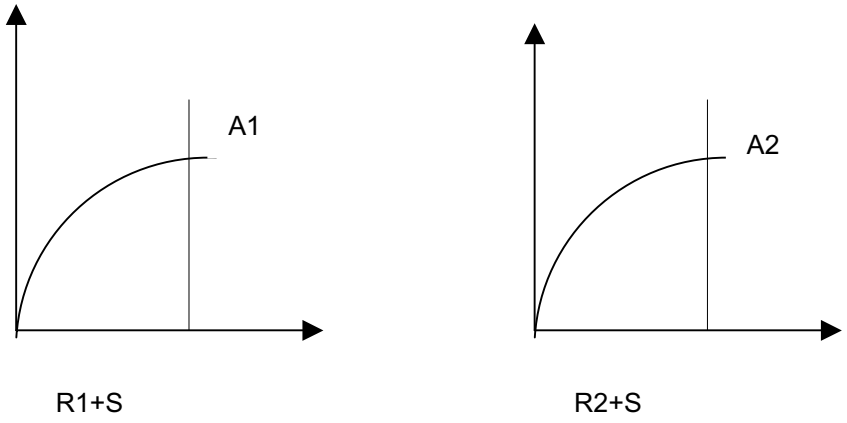
Conc. in sample = Factor x [A2 - (A1 x k)]



Sample Blank (B)

This kind of reaction is very similar to the previous one. The reaction always occurs in two phases: in the first phase (sample blank) the analyzer reads the final absorbance (A1) of the reaction between the first reagent and the sample (R1+S), in the second phase it reads the final absorbance (A2) of the reaction between the second reagent and the sample (R2+S). The two reactions are distinct and separate, and the sampling in the two phases takes place in two different reading cuvettes. The final absorbance used for computing is obtained from the difference between the two phases:

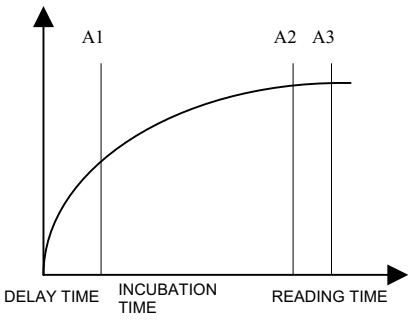
Conc. in sample = Factor x (A2 - A1)



End Point 2 Points

This method (only for single reagent tests) is used whenever it is required to eliminate from the reaction the interference due to the sample. The absorbance of the first reading in incubation phase is subtracted from the final absorbance:

Conc. in Sample = Factor x (A3 - A1)



Only Read

This method is used to read in End Point solely the sample, with a reagent blank. It can be used to read an already prepared (manually) solution. The factor for the computation can be either derived from calibration or set by the user:

Conc. in Sample = Factor x final A

For all the methods, except for Only Read, it is possible to work with one or two reagents. These reagents can be ready to use or concentrated (in this case the analyzer provides automatic dilution). The reagents can be placed in bottles of different volumes (50 ml, 20 ml and 10 ml) and in case of double reagent, the different size bottles are coupled together (e.g. 50 + 50, 50 + 20, 50 + 10, etc.).

The **End Point, Fixed Time**, **Kinetic** and **I.R.** methods allow, both with single and double reagent, the use of a special feature called Serum Starter. Normally, during test runs, the arm samples single or double reagents plus sample. By using the Serum Starter function, the reagents are placed into the cuvette **first** and then the sample is placed separately. In this way, the reagents can incubate in the cuvette for the programmed time, before the sample is added which starts the reaction.

The sampling dynamics of the above-mentioned methods are tabulated as follows:

NORMAL SAMPLING PROCEDURE			
Method	**Reagent**	**Blank Reagent**	**Dynamic**
End Point - Fixed Time Kinetic - I.R.	Single	R1	R1 + S ⇒Ta ⇒L
Only Read	Single	R1	S⇒ L
End Point - Fixed Time Kinetic - I.R.	Double	R1 + Ta + R2 + Tb	R1 +S + Ta + R2 + Tb ⇒ L
End Point - Fixed Time Kinetic - I.R.	Double	R1 + R2 + Tb	R1 + R2+ S + Tb ⇒ L
Sample Blank (A) Sample Blank (A-b)	Double	R1 + R2	R1 +S + Ta ⇒ L1+ R2 + Tb ⇒ L2 Sample Blank **(L2 –L1)**
Sample Blank (B) Sample Blank (B-b)	Double	R2	R1 +S + Ta ⇒ L1 R2 +S + Tb ⇒ L2 Sample Blank **(L2 –L1)**

Ta and Tb = Incubation times for R1 and R2, L = Reading

SERUM STARTER SAMPLING PROCEDURE			
Method	**Reagent**	**Blank Reagent**	**Dynamic**
End Point - Fixed Time Kinetic - I.R.	Single + S.S.	R1	R1 + Tr + S ⇒Ts ⇒ L
End Point - Fixed Time Kinetic - I.R.	Double + S.S.	R1 + Tr + R2 + Tr	R1 + Tr + R2 + Tr + S + Ts ⇒ L
End Point - Fixed Time Kinetic - I.R.	Double + S.S.	R1 + R2 + Tr	R1 + R2 + Tr + S + Ts ⇒ L

S.S. = Serum Starter, Tr = Delay Time for R1 and R2, Ts = Serum Incubation Time, L = Reading

The way the **Reagent Blank and the Reaction's Dynamics** are used is tabulated below:

End Point	Reagent blank. Final reaction datum detection (at the end of programmed time for incubation and reading) and concentration's value computation.
Fixed Time	Reagent's reading check. Data detection during programmed reading time, absorbance delta determination (ΔA) and concentration's value computation.
Kinetic	Reagent's reading check. Data detection during programmed reading time, determination of the absorbance delta per minute (ΔA/min.), processing of the linear regression and computation of the concentration's value.
Initial Rate	Reagent's reading check. Data detection during programmed reading time, determination of the absorbance delta per minute (ΔA/min.), processing of the linear regression and computation of the concentration's value.

Sample Blank (A)	Reagents' reading only for check (R1+R2); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) adding reagent 2 (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
Sample Blank (A-b)	Blank Reagent (R1+R2); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) adding reagent 2 (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
Sample Blank (B)	Reagent's reading only for check with R2 (Working Reagent); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) with reagent 2 and sample (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
Sample Blank (B-b)	Blank Reagent with R2 (Working Reagent); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) with reagent 2 and sample (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
Only Read * (End-Point)	Reagent blank. Final reaction data detection (at the end of programmed time for reading) and concentration's value computation.
End Point 2 points	Reagent's reading check. Data detection during programmed reaction time (first datum in incubation time and the last datum in reading time), absorbance delta determination (ΔA) and concentration's value computation.
End Point Absolute	Without Blank Reagent (reading only with reference to H_2O). Final reaction data detection (at the end of programmed time for reading) and concentration's value computation. However the Blank is read to verify the reagent.

***** During **Only Read (End-Point)** analyses, the analyzer uses the reactive just to prepare the reagent blank. The analysis' procedure requires then to sample at least 300 µl from the final solution in the sample cups and pour it into the cuvettes for the reading phase. Only single reagent use is allowed.

For the **End Point**, **Kinetic**, **Fixed Time**, **Initial-Rate** and **End-Point 2 Point** methods it is possible to use single and double reagent methodologies. The **Only read** method uses only a single reagent, and the **Sample Blank (A)** & **(B)** methods require exclusively double reagent methodologies.

1.3. ANALYSIS PROGRAMMING

The analyzer can store virtually endless analysis codes (with parameters). There are two different codes' lists: a "global" (**All Tests**) list where all programmed codes are stored, and an "on-line reagents tray" (**Current Tray**) list, where only the codes for the analyses that have their reagent in the tray are stored. Patients, standards and controls can be programmed and performed only for the on-line list.

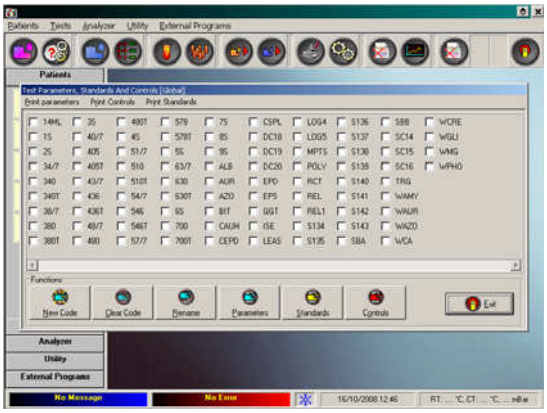


Figure 6

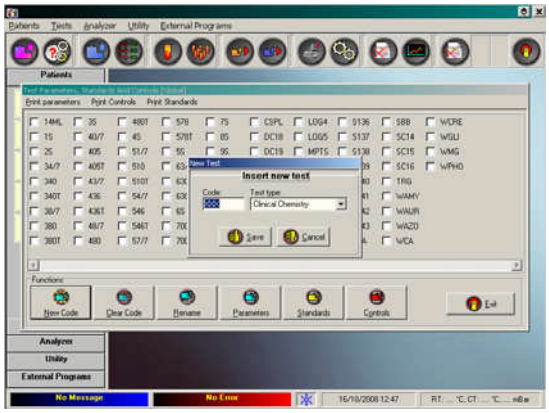


Figure 7

The analysis programming page can be accessed from the main menu (**Tests**) or from the specific icon that gives direct access (see Chapter A, paragraph 3., icon n°1 in the Function Icons Bar) (**Fig. 6**).
To set out new analyses it is necessary first to create the code (this function is enabled only in the **All Tests**) and then to assign the parameters, the standards and the controls (these are enabled also in the **Current Tray**). To perform any test it is necessary to move its code from the **All Tests** to the **Current Tray** by using the command **Modify Current Tray** (Function Icons Bar, icon n°2). Once the **Current Tray** is created, it will be possible to assign a position to each reagent bottle.

1.3.1. CREATING A NEW CODE

Open the analysis programming page and select **New Code**. Enter the test's code and select the **Test Type** among the options showed by clicking on the button"▼". The test type, defines whether the programmed test is a Clinical Chemistry, an I.S.E. (if enabled, refer to **Chapter L**) or a relation test (mathematical computation, refer to paragraph **1.3.2. Relation tests**). Use the button **Save** to memorize the test, or press **Cancel** to exit and abort programming. Any code can be deleted with **Clear Code** or modified with **Rename**. Once a code is set, it is possible to program the analytical parameters (see paragraph **1.3.3.** and the following).

1.3.2. RELATION TESTS

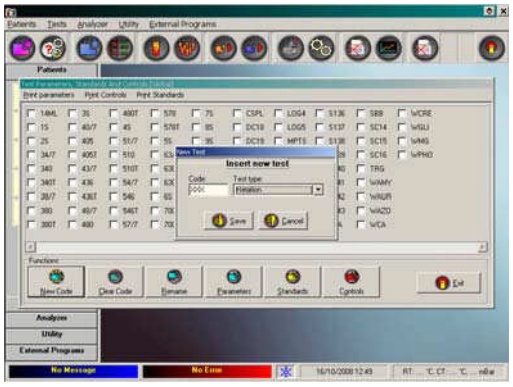


Figure 8

Once the code has been created for the relation test (as shown in **Fig. 8**), it is possible to program its general parameters and the related mathematical function. In the analyses list click on the code (the check symbol ✓ will be displayed), then select **Parameters**.

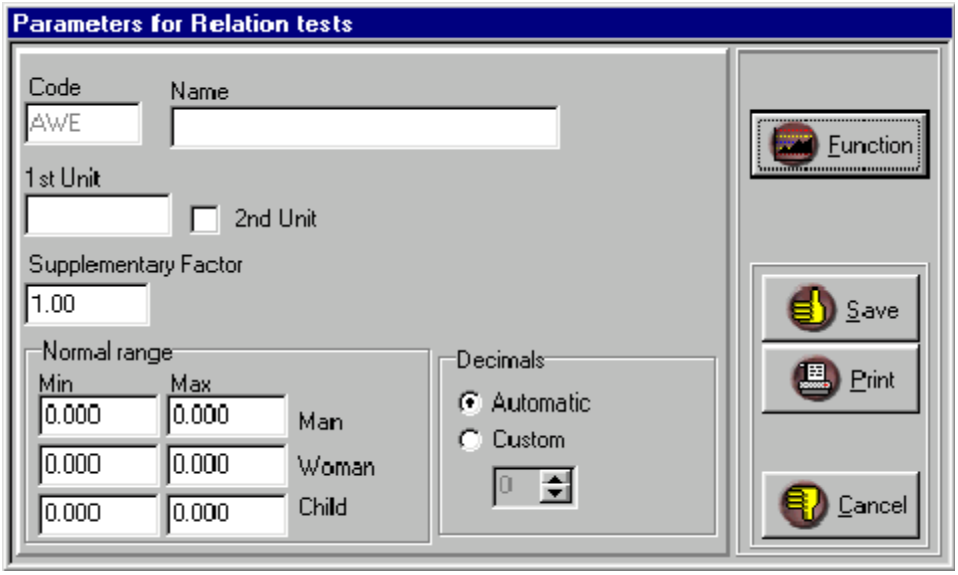


Figure 9

In the parameters window (**fig. 9**) enter the following information:
Name: complete test name
1st Unit: measurement unit. Clicking on the **2nd Unit** it is possible to enter a secondary unit, with its conversion factor (the analyzer will multiply the 1st unit by the given factor).
Supplementary Factor: The result of the mathematical function will be multiplied also by this value. This is simply an additional calculation offered by the analyzer.
Normal Range: insert the min. and max. values of the normal range for male, female and child.
Decimals: it is possible to choose the number of decimals after the point. Leaving the "Automatic" option the analyzer will follow this principle (floating point):

for values like 0.XXX	three decimals
for values up to 9.XX	two decimals
for values up to 99.X	one decimal
for values over 100	no decimals

To enter the mathematical function select **Function**

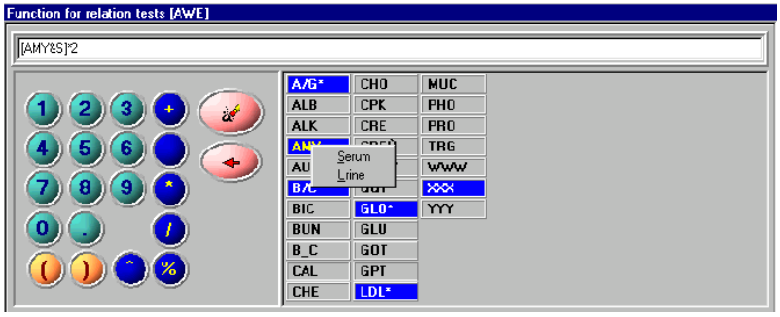


Fig. 10.a

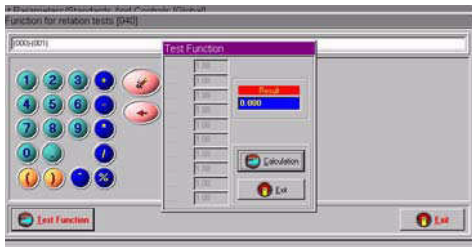


Fig. 10.b

A window divided in two parts will be displayed: one for the calculator and one for the analyses list (current tray), **Fig. 10**. The mathematical function can be composed of simple values and operations or can recall sample results acquired by the analyzer (serum and urine) on other tests (complex function). To enter a simple mathematical function avail yourself of the calculator. To enter a complex function, select the code of the test to be inserted into the function. A small field will appear, where it is possible to select between serum or urine results for that test. Then complete the function with the needed operations.
To create more complex functions (involving more than one test's result) it is advisable to use the parenthesis as for all normal mathematical functions. Ex. For the creatinine clearance with urine/24h = 900ml *[(urine CRE x urine ml 24/h)/(serum CRE x 1440)]* the formula would be: ([CRE&U] * 900) / ([CRE&S] * 1440).
The button **Test Function** (**Fig. 10.b**) is used for checking the relation test result from the analyzer, based on values given to the tests involved in the function. This option is useful for verifying the correct use of values and parenthesis in the formula.
The other options (**Figure 9**) available are:
Save: saves and exits from the window.
Print: prints parameters.
Cancel: exits without saving.

Note. The relation tests can be inserted into the available analyses' list for the current tray, even if they have no determined reagent position (refer to paragraph 1.7. Modify Current Tray). The result for a relation test can be returned only if both the test itself and all the other analyses involved in the function are present in the current reagent tray.

1.3.3. PRIMARY ANALYTICAL PARAMETERS

From the page **All Tests** or **Current Tray** select the desired test code, then move mouse cursor over **Parameters** and click to confirm.
In the displayed page, the analytical parameters for the chosen test are shown: they are divided into **Primary Parameters**, **Secondary Parameters** and **Check Parameters.** By clicking on the **>** or **<** buttons it will be possible to go to the next or previous test parameters.



The first screen shows **Primary Parameters**, to display the other screens click on the corresponding tags.

Primary Parameters

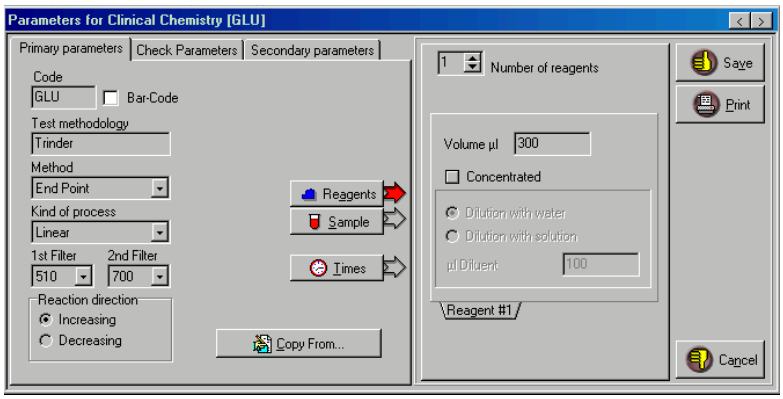


Figure 11

Code: The code of the selected analysis is shown in the text-box. It is not possible to write in this field.
Bar-Code: It is possible to assign a numerical code for positive barcode identification. It enables (if activated in the "Setup Analyzer") bar-code scanning to correctly identify the bottle during reagent's insertion phase.

Test methodology: In this field the reaction principle used for the test can be specified (for example: Jaffè, IFCC, etc.). This option is useful when recalling the tests from the Quality Control archive, in accordance with different principles, during the function **Data Processing**.

Method: This parameter defines the main methodology for the analysis. To program move the cursor over "▼" and select the chosen method. The available methods are detailed in paragraph **1.2.5.** of this chapter.

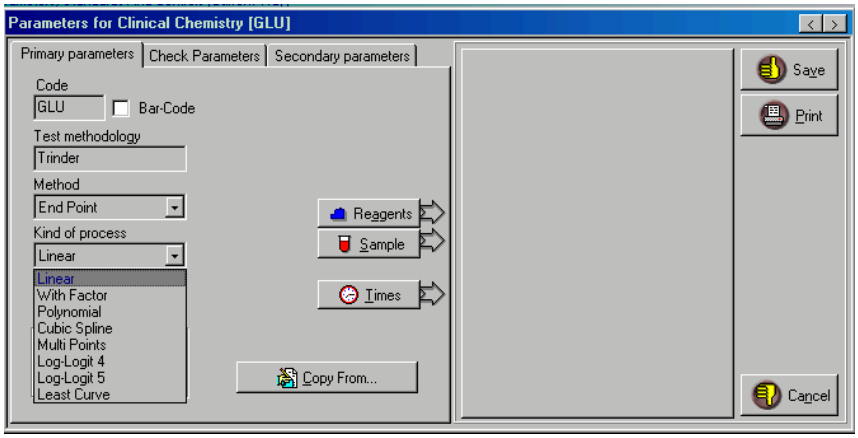


Figure 12

Kind of process: defines the kind of test's calibration: "linear", "with factor" or "with curve". The following choices are available:

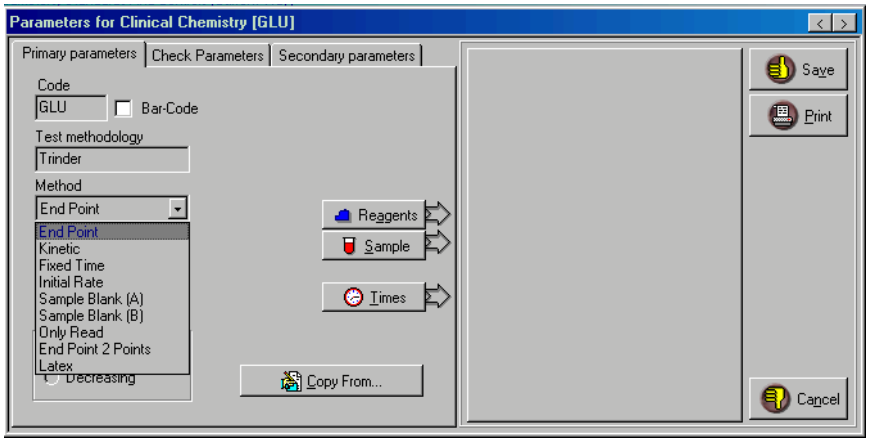


Figure 13

Available Methods (Fig.13)

End Point
Kinetic
Fixed Time
Initial-Rate (I.R.)
Sample Blank type (A)
Sample Blank type (B)
Only Read
End Point 2 Points
Sample Blank (A-b)
Sample Blank (B-b)
End Point Starter
Absolute End Point

linear: This function is used for linear reactions, it requires analytical test calibration to process computing factor.
with factor: It is used for linear reactions whenever the computing factor is known.
with curve: Non-linear tests, distinguished by:

- **Polynomial**: a third degree polynomial function is used. It has a very good approximation, but sometimes it may show anomalies
- **Cubic spline**: the typical cubic interpolation is used. There is a good connection between subsequent point couples. Approximation is perfect on single points, but is not flex point free.
- **Log-Logit 4** and **Log-Logit 5.** It is a logarithmic approximation on four or five points, used for non-linear tests.
- **Multi-point**: Linear interpolating function for several standard concentrations (max 6).
- **Minimum squares**: a second or third degree polynomial interpolation is used. It gives the best approximation to the minimum squares. It is a very simple curve, but sometimes may be distant from the standard points.
- **Line for two points:** Used for linear reactions. It requires analytic calibration of the test. Processes the passing line for two different concentrations. Represents FACTOR (SLOPE) and INTERCEPT (SHIFT).
- **Semi-log**: a second degree curve is used, which is function of the concentration logarithm, and gives the best approximation to the standard points minimum squares. It is asymptotical on the last point, has no flex points and well approximates the standard points. It may be used for highly non linear processes.

FILTER: The operator can select the desired filter value for the **1st Filter** and the **2nd Filter** (reference filter) from the available filter wavelengths**: 340, 380, 405, 436, 480, 510, 546, 578, 630, 700 nm** (**Figures 14 and 15**).
For the tests in **bichromatism**, click on the "**1st Filter**" and select the desired filter value from the cascading window and then go to "**2nd Filter**" and select the desired filter value from its cascading window (1st position has empty field).
For the tests in **monochromatism**, select the desired filter value in the "1st Filter" cascading window. Since the second filter is not used in this test, therefore select the first position (empty field) in the cascading window of "2nd Filter". In this case the analyzer will use a "reference filter" only to stabilize the readings.

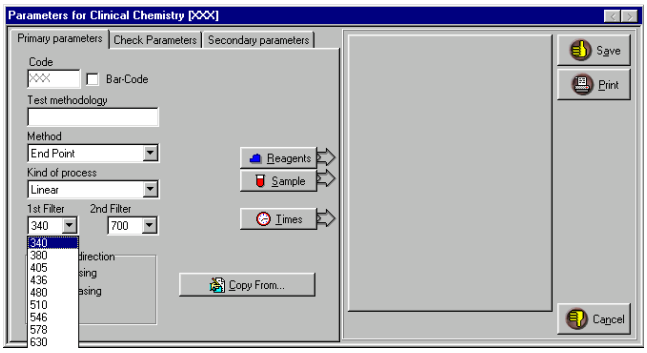


Figure 14

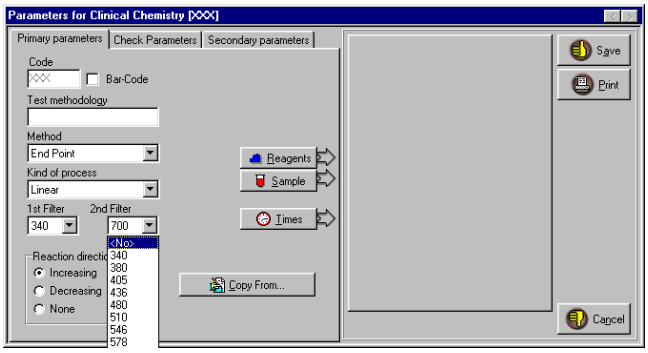


Figure 15

Reaction direction: select the kind of absorbance variation to be checked during reaction. The following choices are available:
(•) Increasing
(•) Decreasing
(•) None

Selecting "**None**" excludes the possibility of controlling the reaction direction, and in addition no control is performed on the flags of ABS Limit and out of range reagents. This function is useful when testing new methods.

Select correct option so that the parameters later described: **Final ABS**, **Initial ABS** and **Reagent Limit** have the necessary reference with reaction progress.
Reagents: click on this button to select the reagents' parameters (**Fig. 16**).
The user can enter the following information:

Number of reagents: Enter the number of reagents the methodology requires, max. 2. Use up/down arrow keys "⬍" or move the cursor directly on the box and enter the value. Insert the volume of each reagent by selecting the corresponding table (Reagent #1 & Reagent #2, see **Fig. 16**) in accordance with number of reagents programmed.

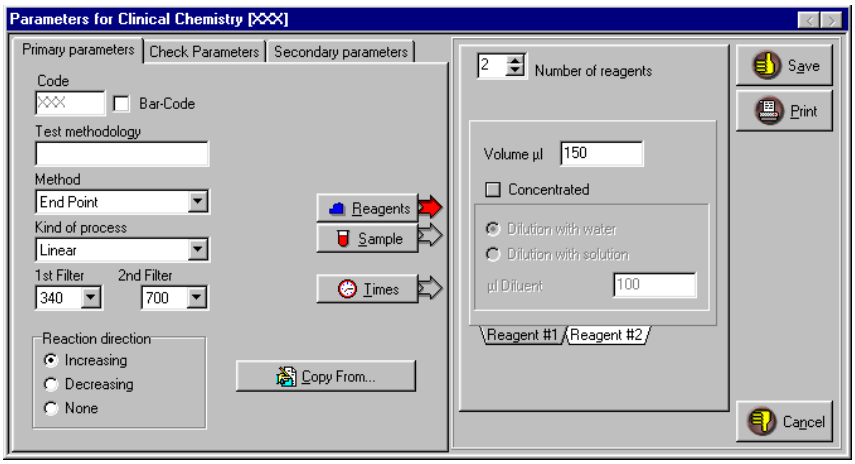


Figure 16

Volume µl: enter the reaction volumes for each reagent expressed in µl selecting the corresponding tag (Reagent #1 and Reagent #2, see **Fig. 16**). Always bear in mind that there are some limits for the final solution (reagent + sample) as well as for sample or reagents. See Table 1 at the end of this paragraph.

Concentrated: this field refers to concentrated reagents. If ready-to-use reagents are used this option should be disabled. If the program for volume of the **Concentrated** is enabled, then insert in the **Volume µl** text box, the volume of the concentrated reagent that the analyzer will withdraw for sampling, select the type of diluent to be used: if double distilled water **Dilution with water** or dedicated diluent **Dilution with solution**. Write in the apposite field **µl Diluent** the volume of diluent to be added to the concentrated reagent. For example: for a dilution ratio of 1:3 write 100µl for the concentrated reagent and 200µl for the diluent. The dedicated diluent is considered by the analyzer as a further reagent and will therefore take a position of its own in the reagents' tray. If the diluent is the distilled water, the analyzer will take it from the main reservoir.

Sample: clicking on the button will open the window where sampling parameters for **Serum** and **Urine** can be programmed (**Fig. 17** and **18)**. The **Serum** card is displayed first. To move between the **Serum** and **Urine** cards, click on the desired tag. The user can enter the following information:

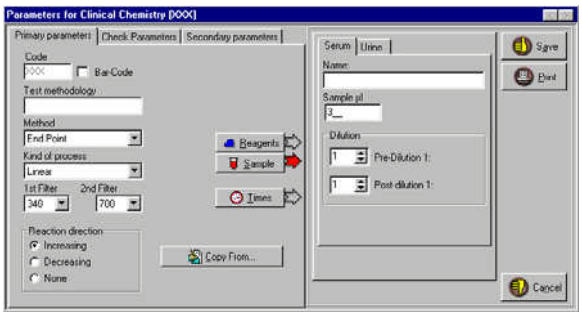


Figure 17

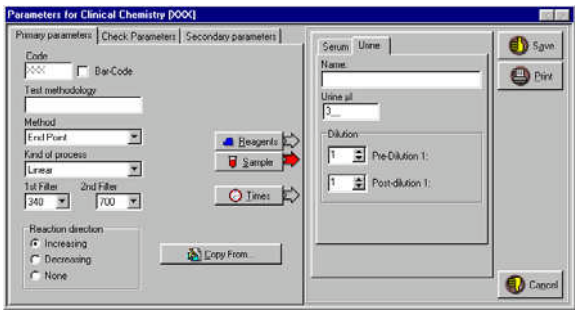


Figure 18

Serum Parameters (Fig. 17)

Name: Enter the complete name. The text written in this field will be used also to identify the test in the report printouts.

Serum µl: Sample volume expressed in µl (see Table 1).

Dilution: In this screen, two fields are available, ***Pre-Dilution 1*:** (predilution ratio) and ***Post-Dilution 1:*** (ratio of dilution repetitions). Maximum pre-dilution limit is 1/250. In case both ratios are set, the user can work within this limit, or in case a higher limit is necessary then an external dilution must be performed (refer to chapter **E**, paragraph **1.4. Samples**).

Pre-Dilution 1: Set sample's pre-dilution ratio only if required by the method. Otherwise enter 1, and no predilution will be performed.

Post-Dilution 1: Set the sample's dilution ratio to be used for automatic repetitions of tests, which during the determination have either **Max ABS Delta** or **Final ABS** or **Test Limit** values out of the programmed limits (see ensuing **Control Parameters**). The user can then set an adequate dilution ratio in order to bring the reaction into linearity limits.

Urine Parameters (Fig. 18)

Name: enter the complete name

Urine µl: sample volume expressed in µl (see Table 1).

Dilution: The programming of fields (text boxes) for **Pre-Dilution 1:** and **Post-Dilution 1:,** is identical to the above-mentioned **Serum Parameters**.

ATTENTION: for analyses on urine samples, it is recommended to read the Note on urine parameters at the end of paragraph 1.3.5. Secondary Parameters.

NOTE: for diluting serum samples the analyzer will use the diluent (saline solution) while for urine samples, the analyzer will use bi-distilled water.

Times: this command allows setting of incubation and reading times. Move the mouse cursor over **Times** command and click to confirm; a form appears on a side of the screen with programmable fields (**Fig. 19**). The user can then enter the following information:

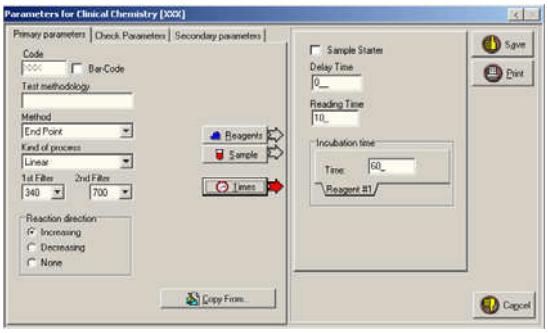


Figure 19

Sample Starter: This parameter, if enabled, allows separate dispensation between sample and reagent. This parameter can be used only for double reagents applications. See also par. 1.2.5. METHODS DESCRIPTION and the note at the end of this paragraph. To enable click on this box to confirm.

Delay Time: Parameter expressed in seconds preceding the incubation time, and it indicates a time gap available for the solution in the cuvette to become stable. During delay time no reading is performed (different from the incubation time) and it is useful in tests with "0" incubation time.

Incubation Time: This parameter expressed in seconds, indicates incubation time for the analysis (reagent and samples dispensed in the cuvettes) as required by the methodology. The possible values range from 0 to 999 seconds. For double-reagent methods, it is possible to enter different incubation times for the first and second reagent originating in different sampling dynamics. During incubation time the analyzer performs reading for capturing in advance the reactions that are out of linearity range (see later **Check Parameters).**

Reading Time: The user must enter the reading time (following the incubation time) in seconds, keeping in mind that the analyzer performs a reading approx every 10 seconds. The possible values range from 0 to 990 s.

Notes on the serum starter

When the serum starter is not activated the analyzer dispenses reagents and sample with different dynamics based on the programming:

Single-reagents: it takes the reagent and serum and dispenses both in the cuvette

Double-reagents: it takes the first reagent and serum and dispenses both in the cuvette; then it takes the second reagent and distributes it in the same cuvette. If the incubation time of the first reactive is zero, it takes both reagents and serum and dispenses everything together in the cuvette.

The method with the serum starter makes it possible instead to take the two reagents (even at different times) and dispense the serum in the cuvette last.

Indicative volumes

	BT1000 BT2000 Plus BT3000 Plus	BT1500 BT3500
Min / Max Sample Vol. µl	1 / 100	0.8 / 100
Min / Max Reagent Vol. µl	1 / 470	0.8 / 300
Min / Max volume in cuvette µl	280 / 700	180 / 400
Max diluter volume µl	470	300
Min / Max reaction (reag + sample) µl	300 / 700	180 / 400

Table 1

1.3.4. CHECK PARAMETERS

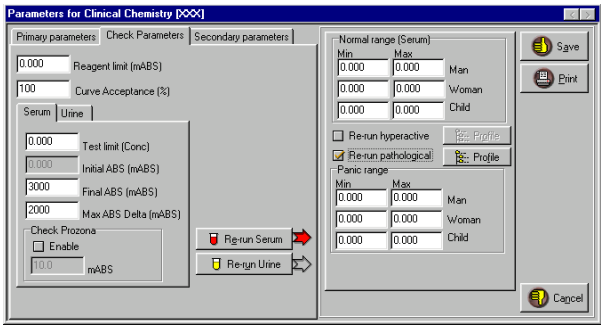


Figure 20

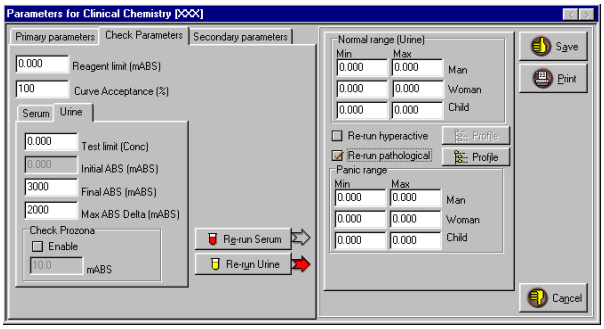


Figure 21

Select the **Check Parameters** table (**Fig. 20** and **21**). To set a given parameter, move the cursor on its corresponding textbox and click to confirm.
The user can enter the following information:

Reagent limit (mABS): this parameter indicates the limit absorbance (ABS) value that is acceptable for the reagent (maximum for increasing reactions, minimum for decreasing ones) and it is expressed in mABS. If reagent's absorbance is beyond this limit, the analyzer will check the results with **O flag** (**Reactive out of limit**). This parameter allows monitoring reagents quality as well as checking any variation from the specific techniques. The parameter is identical for the serum and urine.

> **Note:**
> This control has the highest priority on all the other check flags and inhibits the automatic repetition functions. In case of reagent out of limit, the blank will be repeated every time the test is performed in a run.

Curve Acceptance (%): C.C. = Correlation Coefficient. This is only applicable to kinetic type test (fixed time, kinetic and initial rate). The programmable values range from 0% to 100%. This parameter is identical for both serum and urine and indicates the acceptability limit for any data instability that is detected during programmed reading time. If this value is exceeded, the final result will be checked with a ± **flag** (**Unstable Sample – C.C.% greater than assigned value**).

Test limit (Conc): This parameter is used in all methodologies and it allows verification of the final concentration of the analyses. It represents a threshold value beyond which the analyzer detects an out-of-linearity condition (hyperactivity). With **Re-run hyperactive** check enabled (refer to paragraph 1.3.6. Automatic re-runs), the analyzer will automatically re-run the test, diluting the sample as programmed in the serum parameters, in order to bring the reaction into linearity range. The final result is automatically multiplied by the dilution factor and will be checked with **"I" flag** (= **Hyperactive Sample** – out of Test Limit-).

Initial ABS (mABS): This parameter is used only for the methods **Kinetics**, **Fixed Time** and **Initial-Rate.** It is expressed in mABS and defines the limit for the total absorbance (reagent + serum) expected for this test. The first reading of the incubation phase is compared with this value. If the read value is greater than the parameter, the analyzer will consider that as a possible interference of serum in the reaction (for example: lipemic serum), thus marking the final result with **~ flag** (= **Serum Interference**).

Final ABS (mABS): this parameter is used only for the methods **Kinetics**, **Fixed Time** and **Initial-Rate**. It is the last reading of the reaction expressed in mABS; it indicates the limit (upper limit for increasing analyses, lower limit for decreasing ones) beyond which the analyzer detects an out-of-linearity test (hyperactivity). With **Re-run hyperactive** check enabled (refer to paragraph **1.3.6. Automatic Re-runs**), the analyzer will automatically re-run the test diluting the sample (refer to Chapter E, paragraph 1.4. Samples) in order to bring the reaction into linearity range. The final result is automatically multiplied by the dilution factor and will be checked with **A flag** (= **Hyperactive Sample –** out of final ABS Limit-).

Max ABS Delta (mABS): This parameter expressed in mABS is used in all the methods, except **Only Read.** It represents the maximum Delta (∆) for the reaction detected during incubation phase. Test is considered out of linearity when this value is surpassed. The analyzer verifies the reaction process during the incubation phase for all the methods. The reaction is prolonged for a period equivalent to 60 seconds for the methods **Kinetics**, **Fixed Time** and **Initial-Rate**.
For the methods in **End Point**, **(End point, End Point 2 point, End Point Starter, Absolute End Point, Absolute End Point, Sample Blank A and B, Sample Blank A-b, and Sample Blank B-b),** the reaction is prolonged for a period equivalent to ¼ of the incubation time but never less than 20 seconds. The assigned Max ABS Delta is compared with the one calculated at the end of 60 seconds or one-fourth the incubation time, based on the type of test.

With the **Re-run hyperactive** check enabled (refer to paragraph 1.3.6. Automatic Re-runs), the analyzer will automatically re-run the test by pre-diluting the sample (see. **Samples**) in order to reenter the reaction into linearity range. The final result is automatically multiplied by the dilution factor and will be checked with **d flag** (= **Hyperactive Sample –** out of Max ABS Delta-).

Check Prozone (mABS): this parameter checks the ABS variation tendency during all processing time of the test. In case of inversion it is likely to be in a Prozone situation. The final result will be checked with **C flag.** This parameter is used for all methods, except for **Only read** and indicates the maximum allowable inversion in the reaction (expressed in mABS). If the prozone flag is activated in a sample, this will be repeated as if it was a hyperactive, if the repetition of hyperactives is enabled. In addition, for an inverse curve flag, the analyzer will also test the prozone.

Re-run serum and Re-run urine: these commands are used to enable automatic repetitions, for more information see paragraph 1.3.6 of this chapter.

Note. The parameters **Test limit**, **Initial ABS, Final ABS**, **Max ABS Delta** and **Check Prozone** are different for serum and urine (see **Fig. 19 and 20**).

1.3.5. SECONDARY ANALYTICAL PARAMETERS

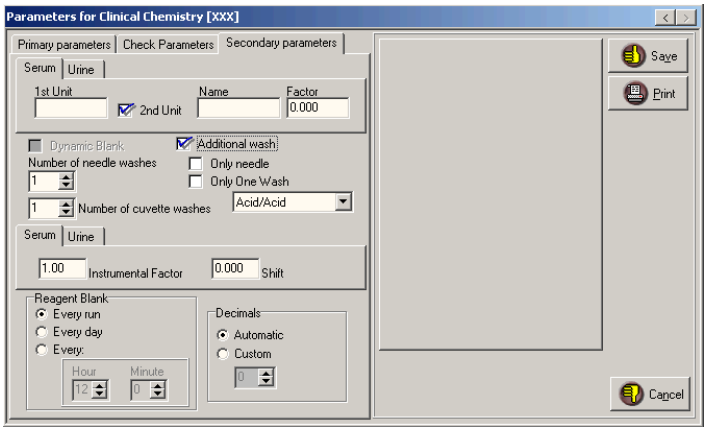


Figure 22

After selecting the **Secondary Parameters** (Figure 22) to program click inside the desired parameter textbox and confirm.
The user can enter the following information:

1st Unit: Enter the measurement unit in this field. Click on the **2nd Unit** to enable it for the second unit of measurement. Instantly a new textbox will appear where the operator can type in the second unit of measurement and the conversion factor between the two units. In case of two units of measurements, the test value is expressed in two results. In the analytical calibrations the **1st Unit** of measurement is used.

1St Unit (Urine): by selecting **Urine** it is possible to enter a specific unit of measurement and then the conversion factor between the unit of measurement expressed in serum and that expressed in urine.

N.B.: always remember that the calibrations are made with the parameters assigned to serum, so this should be taken into account for urine analyses.

The **Factor** field is only for urine and represents a multiplication factor. All the information must be entered in this field, which allows the analyzer to convert the serum units of measurement into those for urine, to convert the diuresis units of measurement and possibly compensate the different volume of urine compared to serum (see the note at the end of the paragraph).

Dynamic Blank: If the parameter is enabled, then the analyzer quantifies and memorizes the photometric drift of the reagent blank by processing only the reagent as sample. After the determination of the Reagent Delta ABS, this value is then subtracted from the Sample ABS value. The value of Reagent Delta ABS is then visualized in the "STANDARD" page adjacent to the absolute value of the reagent. The dynamic blank is only available for the Fixed Time, Kinetics and Sample Blank A tests.

Number of needle washes: With this command the user can set the number of washings to be performed after the dispensing of the reagent used for the test. Normally one washing is sufficient, however in case of highly contaminating tests more washings will be necessary. To set washing numbers (maximum 9 washings) in accordance with the contaminating force of the used product, press the up/down arrow keys "⇕" or move the mouse cursor inside the dedicated box and enter directly the value.

Additional washes: allows the operator to enter two additional special washes into the sampling dynamics. These additional washes may be useful when contamination between reagents is found. The two solutions used are a base to be put in position 24 of the reagent plate and an acid to put in position 23. The additional wash may be for just the sampling needle (check **Only needle**) or it can be for needle and cuvette. In both cases it is possible to select the additional wash to be performed with one (check **Only one wash**) or with two solutions: an acid and a base. The needle and cuvette wash will take place before dispensing the test. The normal water washing of the cuvette will still take place, it will then be washed with the (or both) additional solution and then rinsed again with water. In case of double reagents, the needle first wash will take place simultaneously to the cuvette wash.

If there is no additional solution in the reagent bottle, the test result will be marked with the **"W"** flag and the testing of the single analysis will be aborted.

Reagent Blank Timing: This parameter is used for automatic determination of the ABS value for the reagent. Select, among available choices present in the **Reagent Blank timing** list (see **Fig. 22**), one of the following:

> **(•) Every run:** The absorbance determination for the reagent will be performed at every work start-up.
>
> **(•) Every day:** The absorbance determination for the reagent will be performed once a working day (when the first working list of day is started).
>
> **(•) Every:** The absorbance determination for the reagent will be performed at the time intervals as programmed into the **Hour** and **Minute** boxes. For example, setting "02" hour and "00" minutes, determination will be performed every two hours. To set the value, press "⇕" or move the mouse cursor inside the dedicated box and enter directly the value.

Decimals: If this parameter is used with the **Custom,** then it sets the number of decimal places that should be used to represent numerical results of the tests. Alternatively, if the decimal places are not programmed **Automatic**, then the analyzer automatically sets the number of decimal places in accordance with "floating point" algorithm.

Instrumental Factor: This function introduces a constant correction of the final data of the executed test. It may be used for making adjustments to test data obtained from analytical methods or different type of instruments. Calculation: final result = value x instrumental factor
Shift: This function introduces a constant quantitative correction of final test data. It may be used for making adjustments to test data obtained through analytical methods or instruments of different types. Calculation: final result = value + shift.

NOTE: When the following parameters are used at the same time: Instrumental factor and Shift (in secondary analytical parameters), External dilution factor and Urine 24/h (in the patient's data), the calculation made by the analyzer will be as follows:
[(test result x External factor x Instrumental factor) + Shift] x Urine 24/h

ATTENTION: if the calculation of the result (with instrumental factor and shift) gives a value less than zero, **<NC>** (not calculable) will be displayed instead of the result and the associated flag will be **M**: Error in the parameters (instrumental factor and shift): By opportunely correcting the instrumental factor and shift parameters and running the calculation again (with the **Correction** function chap. G par. 1.1) it is possible to convert the <NC> result to a valid number.

NOTE ON THE URINE PARAMETERS

The analyzer always uses the parameters assigned to the serum when it runs the calibrations. It is necessary to bear this in mind when programming analyses on urine.
For tests dedicated solely to urine, it is advisable to program the serum parameters identically to those for urine. In this way the test calibration will be consistent with the urine parameters. For running the tests, urine can be regularly selected as sample, which will allow the use of all the fields assigned to it, both in the parameters and in patient entry (e.g. diuresis).
For tests on serum and urine, since the calibration is made on the serum parameters, it is necessary to take into account all the factors, which permit aligning the serum parameters to the urine ones.
a) Unit of measurement: if the unit for serum is mg/dl and the one for urine must be g/l, the factor will be: **100**
b) Sample volume: if the serum volume is 3µl, and that of the urine is 30µl, the factor will be **0.1***
The total conversion factor for cases a) & b) will be given by 100 x 0.1 = 10
These factors all go together in the **Factor** field relative to the first urine unit of measurement.
Diuresis: The diuresis field does not have a unit of measurement for greater flexibility, however, to avoid additional calculations, it is advisable to enter the diuresis volume already in the urine units of measurement.

* The factor will be around 0.1, since the exact relation is given by the relation of volumetric factors, however the relation vol. S / vol. U can be used as a good guideline.

OTHER COMMANDS IN THE PARAMETERS PAGE

Save: saves and exits from the window.
Print: prints parameters.
Cancel: exits without saving.

1.3.6. Automatic Re-Runs

The commands **Re-run Serum** and **Re-run Urine** are available (automatic repetition parameters for hyperactive or pathological tests) in the **Check Parameters** table.
To set, move the mouse cursor over the desired command and click to confirm. The following functions are available in the displayed table:

Normal range: **Min. Max. M**: **Min. Max. F**: **Min. Max. C**: normal reference values (min. and max.) for male (M), female (F) and children (C).

Re-run hyperactive: It allows automatic re-run for a hyperactive result, with dilution or not of the sample, according to the implemented programming (see par. 1.3.3.). Check the box to confirm and enable. The **Profile** (see below) is automatically enabled when selected.

Re-run pathological: it allows automatic re-run for a pathological test, without sample dilution. Check the box to confirm and enable. The **Panic range** box appears; similar to the **Normal range**, it allows programming the limits beyond which the analyzer performs test re-run. Values in the **Panic range** can be different from those in the **Normal range tests.**

Profile: it is available when automatic (hyperactive/pathological) re-run option is enabled and it allows automatic execution of analyses to be associated to programmed test. To set, move the mouse cursor over **Profile** command and click to confirm. The available analyses list will then appear, select the tests to be associated and store with **Save** command. The analyzer will automatically execute the profile associated to the hyperactive or pathological test.

For non-linear tests, the following fields will also appear:

Re-run out of curve "above": allows automatic re-running of the samples with an absorbance above the calibration curve by applying the same dilution relation required for hyperactive samples. The sample outside the curve is marked with the flag ">" if it is still outside the curve after re-running, the flag will be ">>".

Re-run out of curve "below": allows automatic re-running of samples with an absorbance below the calibration curve. In this case the analyzer applies a different relation between the serum and reactive in order to make the absorbance return within the curve limit. The sample outside the curve is marked with the flag "<" if it is still outside the curve after re-running, the flag will be "<<".

GENERAL CONSIDERATIONS ON TEST LIMIT, REACTION LIMIT AND MAX DELTA ABS

These three parameters are used to monitor a likely hyperactive situation in a sample, whether it is serum or urine. With automatic hyperactive samples re-run option enabled, the analyzer produces two results: the first value indicates the specific parameter that has been passed (for example, if Reaction Limit has been passed, the "A" flag is displayed), while the second one indicates what has been detected after repetition. In case the automatic sample's re-run has not been sufficient to restore the reaction within programmed limits, the user can insert a manually pre-diluted sample. For this purpose, a field called "Dilution Factor" has been added to the patient entry page. During check-in or sample's re-run phase, it is possible to set a pre-dilution parameter that will be used by the analyzer when calculating final result. For manually pre-diluted samples, if the result is hyperactive, this will be checked with the appropriate flag, but test won't be automatically re-run.

Note:
Reporting the first and second result when automatically re-running pathological and hyperactive tests: in case of automatic re-run of hyperactive and pathological tests, the analyzer displays and prints in real time a compressed report. The report shows the results obtained from the first and second determination naming them first and second result. However, one should bear in mind that in the patients archive only the second result is stored, the one obtained after the repetition. If printing is set in real time in "report" format (see Setup Chapter H, par. 2), the printed result will only be the second one, just like for the patient archives printing.

1.4. CONTROLS

In the pages **All Tests** and **Current Tray** select desired test code then move the mouse cursor to the command **Controls** and click to confirm. The parameters for the desired test are contained in the displayed page.
The controls are divided into **Known** and **Unknown,** where it is possible to program three levels for each one subdivided in tables:

Known: Level 1, 2, 3

Unknown: Level 1, 2, 3

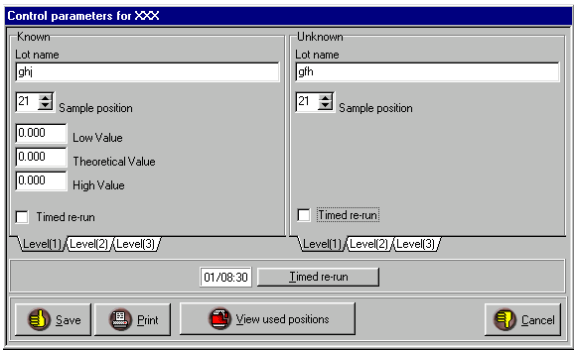


Figure 23

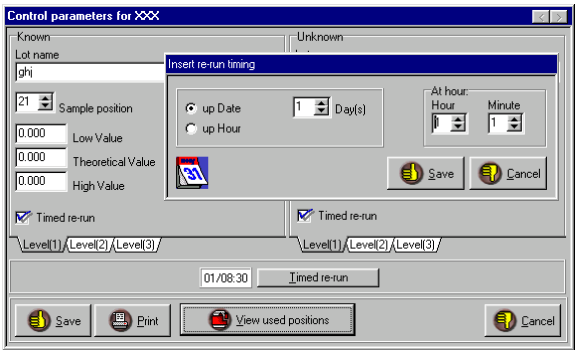


Figure 24

The first displayed tables are **Level 1** for **Known** and **Unknown** controls. To select move onto the desired tag title and click to confirm (**Fig. 23**).

Known: To program move the cursor over desired boxes and confirm. Enter **Lot name or number**, theoretical value, and low & high limits. Enter **Sample position**, already set to controls in the section **Setup Analyzer** included in the inner ring of samples' tray.

Unknown: Enter **Lot name or number** and **Sample position**. Reserved positions are those already set in the program **Setup Analyzer,** which are shared with known ones.
Timed re-run: With this program it is possible to set automatic controls run for a selected analysis. For each control it is possible to enter the time of automatic execution. Move over **Timed re-run** field and check the box.
It is possible to enter intervals of days and hours for automatic controls run **(Fig. 24):**

upon Date (daily interval): Select the function and set interval days, then enter test running time (for example 1 08,30 means every day at 08,30 or in any case at start up).

upon Hour (hour interval): Select the function and set the desired interval, hours and minutes.

Every day or when the preset time expires, the analyzer will automatically alert the user that there are controls to be run. If reagents and controls are present, then the user can directly confirm to execute the tests.

View used positions: This command displays the test disposition.

NOTE ON TIMED RE-RUN
Timed re-runs of controls or standards may expire while the analyzer is in the standby phase. In this case the expirations will be automatically delayed by 10 minutes.

1.5. CALIBRATIONS

Programming

The analytical calibrations that can be run by the analyzer are divided as follows:

Linear and **Non Linear**

Selection occurs during the programming of the analytical test parameters (refer to paragraph **1.3.3. Primary Analytical Parameters** and the following) and can be executed on user's request or automatically.

In the pages **All Tests** and **Current Tray** select desired test code then move the mouse cursor to the command **Standard** and click to confirm. The parameters of calibration, execution and verification of the preselected test are shown in the displayed page.

Always bear in mind that the serum parameters will be used for the calibrations, regardless of the sample that is going to be used.

Analyses With Factor

Calibration executed by the analyzer is not required for these tests, but a theoretical factor for calculation needs to be entered. This is a parameter to convert the absorbance values (ABS), determined by the analyzer, in final concentration values. A box appears where it is possible to enter a known factor value, declared in the method, while the reagent ABS value detected by the analyzer is represented at the same time.

Analyses with Linear Calibration

In this type of test the analyzer executes a calibration with a known concentration standard. Based on the absorbance values detected for the standard, the analyzer calculates the factor, which will be used to convert the absorbance values (ABS) of samples to final concentration values. After each new calibration the analyzer calculates and updates the factor. Alternatively, it is possible to directly enter a known value in the **Factor** field.

The following parameters also need to be set.

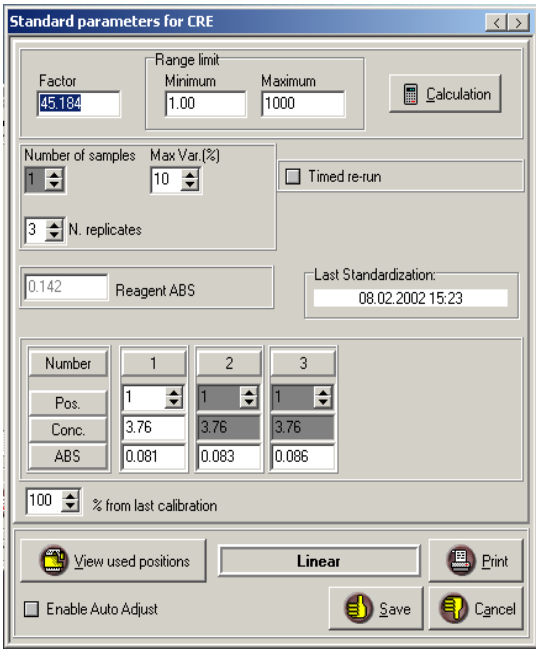


Figure 25

Range Limit – Minimum and Maximum: in order to verify the validity of the calibration, enter the minimum and maximum limits that the calculated factor must be within. After an out of range value, a warning is given and the previously memorized factor is not changed. If known concentration and absorbance values are available, it is possible to mathematically process the factor using the **Calculation** function key.

NOTE:
The used calibrators or standards must be placed in the positions assigned on the sample tray (bear in mind that the numbering is programmed in the **Analyzer Setup** program, par. 2, chap. H). In linear analysis it is possible to use up to 4 different standard concentrations or execute up to a maximum of 4 repetitions on a single point. It is possible to program the same positions for various analyses if a multi-calibrator is used.

Programming re-runs on a single point (see **Fig. 25**)
By entering 1 in the **Number of samples** box, the **N. replicates** box automatically appears. Enter the number of replicates to be executed, up to a maximum of four.
A programming box appears for the position and value of the standard concentration, plus other boxes which cannot be programmed related to replicates, for a total equal to the desired number of replicates. The values in the **ABS** boxes are automatically updated during the calibration phase. If known they can be entered by the operator. With this type of programming, the analyzer will execute a maximum of four samplings from the same sample cup, then calculate a factor for each sampling and update the calculation factor using the mean of factors obtained for the replicates.

Programming multiple standards (see **Fig. 26**)
Enter the number of standards to be used in the **Number of samples** box (maximum of 4). The programming boxes for the positions and concentration values of the standards are automatically displayed in the same quantity. The values in the **ABS** boxes are automatically updated during the calibration phase, if known they can be entered by the operator. With this type of programming, the analyzer will execute a maximum of four samplings of the standard from separate cups with different concentrations, then calculate a factor for each standard and update the calculation factor using the mean of factors obtained for the replicates.

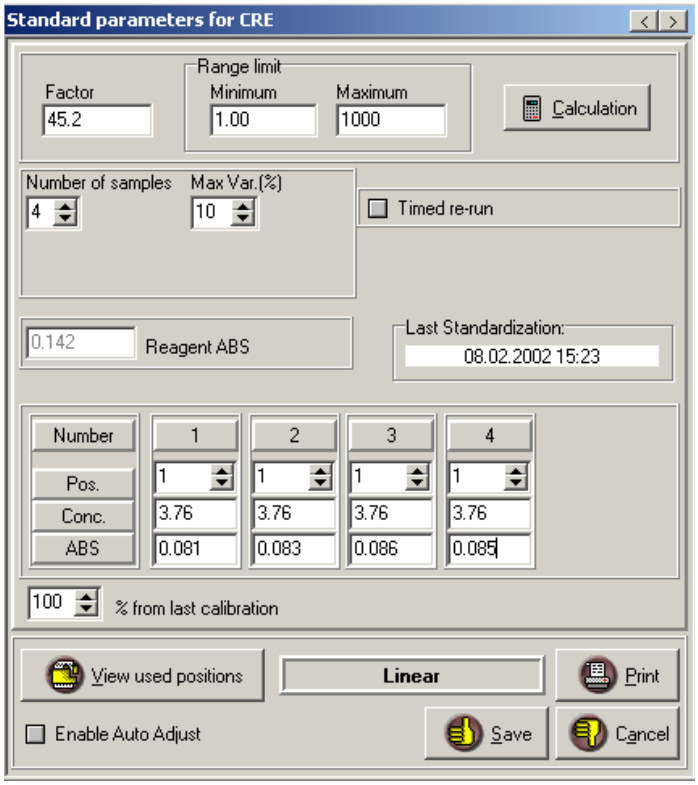


Figure 26

Max Var. (%) (Maximum percentage variation): calibration verification parameter. It represents the acceptable difference (in percentage) among the factors calculated if various standards are used or if replicates are executed on a single point. After a variation above the programmed limit, a warning is given and the previously memorized factor is not changed.

Reagent ABS: each time a reagent blank is executed for the analysis, the measured value is updated in this window. If **Dynamic blank** is enabled (subtraction of the reagent photometric variation, see par. 1.3.3. Primary Analytical Parameters and following paragraphs) the measured reagent ABS value is displayed, plus the variation determined during reading of the blank.

% from last Calibration: parameter which checks the percentage between the executed and previous calibration. It compares the determined factor with the memorized one. After a variation above the programmed limit, a warning is given and the previously memorized factor is not changed.

View used positions: opens a single box to represent the position of tests in relation to the sample tray.

Enable Auto Adjust: this parameter enables or disables automatic modification of the tests results if another calibration is executed when running patients. The user must be enabled to the access level (by password) to modify this parameter.

Last standardization: display box for the date and time of the last test calibration performed. By double clicking on the box it is possible to view the data of the previous calibration, factor, concentrations and absorbance.

Timed re-run: parameter used to program automatic calibration execution. Once the programmed standardization time has elapsed, the analyzer sends a warning message and if the reagents and standards are present, calibration can be directly executed. Enter the standardization time by enabling the check and program the intervals in days and hours:

By Date: select the function for programming the interval days, then indicate the test execution hour (e.g. 1 08.30 means every day at 8:30 or each time the analyzer is turned on).

By Hour: select the function and program the desired time interval, in hours and minutes.

Print: command for printing the programmed parameters.

Save: command for memorizing and exiting.

Cancel: program for exiting without memorizing changes.

Analyses with Non Linear calibration (see fig. 27)

Non Linear analyses require from 3 to 6 standards. If the process type is **Multi Point** the number to enter in the **Number of Samples** box varies from a minimum of 2 to a maximum of 6. In the analyses with **Log logit 4 & 5** curve, programming is the same by the required positions are 4 and 5, respectively.
Select the number of standards to be used to construct the curve. The fields for entering the position and concentration of the various standards appear automatically. The values in the **ABS** boxes are automatically updated during the calibration phase, if known they can be entered by the operator.
Programming is similar to that for analyses with factor, but here automatic standard dilution is also available.
To use the standard pre-dilution function program the positions of the standards and enter the calibrator concentration (the most concentrated point of the curve) at the first pre-selected position. Then click on the **Automatic Dilution** box. Three new fields will open:

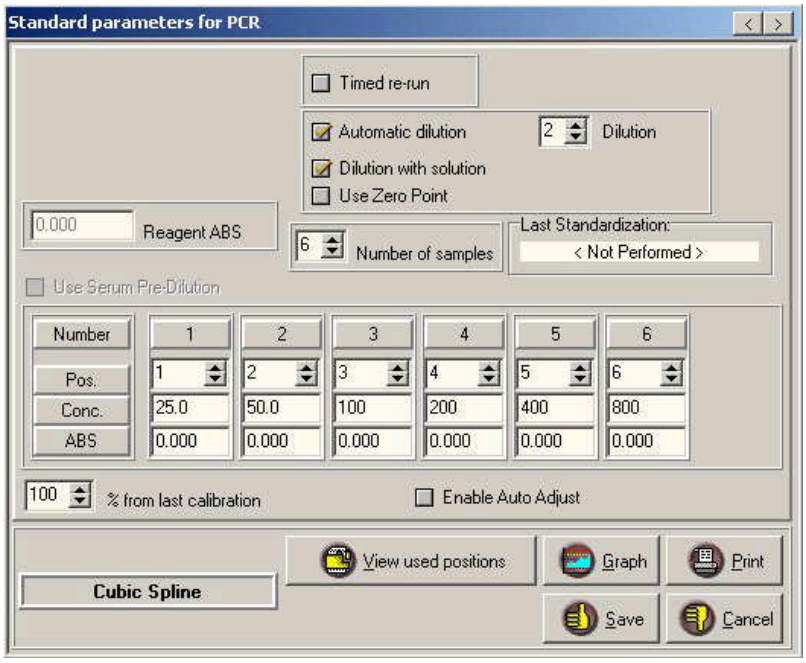


Figure 27

Dilution: sets the dilution relation. The analyzer will automatically calculate and update the scalar concentrations starting from the highest concentration value already present in the fields.
Place the cup with entire standard on the sample tray in the assigned position, plus a number of empty cups equal to the subsequent standards. The serial dilutions used to build the curve will be prepared in these cups.
Dilution with solution: used to select whether to dilute the sample with physiological solution (located in the specific test tube) or with bidistilled water taken from the external tank.
Use Zero Point: used to automatically reset the concentration of the lowest point of the curve to zero. During the predilution phase of the standards the analyzer will dispense the pre-selected diluent (physiological or water) in this position.

For all the tests with calibration curve, the analyzer will warn the operator if samples (patients) have results above or below the calibration curve with a flag (below curve "<" and above curve ">") next to the result. It is possible to select automatic re-running for samples outside the curve in the control parameters (see par. 1.3.6 Automatic repetitions). When the absorbance of the least concentrated point of the calibration curve (or point with 0.0 concentration) is negative, it will be automatically set to zero, in order to prevent false results, for example concentrations with a minus sign.
It is possible to normalize the memorized calibration curves, using a single calibration point (see below).

The fields **Reagent mABS, % from last calibration, View used positions, Enable auto adjust, Last standardization, Timed re-run, Print, Save** and **Cancel** have the same programming and functions described for linear calibrations.

Use serum Pre-dilution: if in the sample primary parameters (par. 1.3.3.) a pre-dilution ratio has been set, it is possible to perform the standards pre-dilution with the same ratio as for the sample.

Graph: command for displaying the interpolation graph of the memorized curve. The curve and data are represented on the graph display page.

NOTE ON TIMED RE-RUN

Timed re-runs of controls or standards may expire while the analyzer is in the standby phase. In this case the expirations will be automatically delayed by 10 minutes.

1.6. CREATING PROFILES

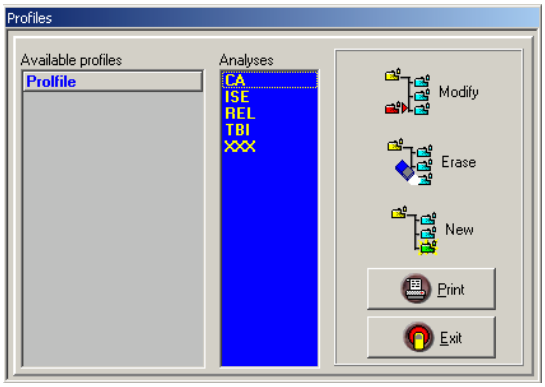


Figure 28

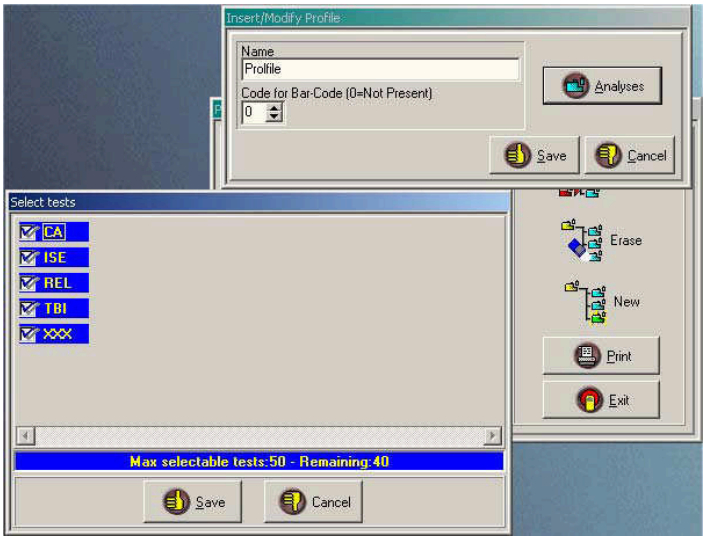


Figure 29

INSERT/MODIFY PROFILES: this function creates/modifies analyses groups, useful when checking-in patients. It can be accessed from **Tests** menu or from the specific icon that allows direct access (**Figure 28**).

It is possible to delete, update and print an already existing profile.

Creating a profile: click over **New** button: the **Profile Name** textbox will appear. Enter the name for the profile and click on **Analyses**: this will open a window where it will be possible to select the analyses for the profile. Click "Save" to store the selected analyses (**Fig. 29**). It is possible to enter in the **Code for Bar-Code** field a numerical code. The analyzer, when reading the bar-code labels of Patients, will recognize it. This code is used for completely computerized acquisition of the analyses assigned to the patient.

To update an existing profile, select it from the list and click on **Modify,** and then proceed as outlined previously. To delete an existing profile, select its name and press **Erase**, confirmation is requested prior to erasing.

Attention: during the patient acquisition, only the analyses present on the tray are displayed for each profile.

1.7. CREATING THE CURRENT ANALYSES TRAY

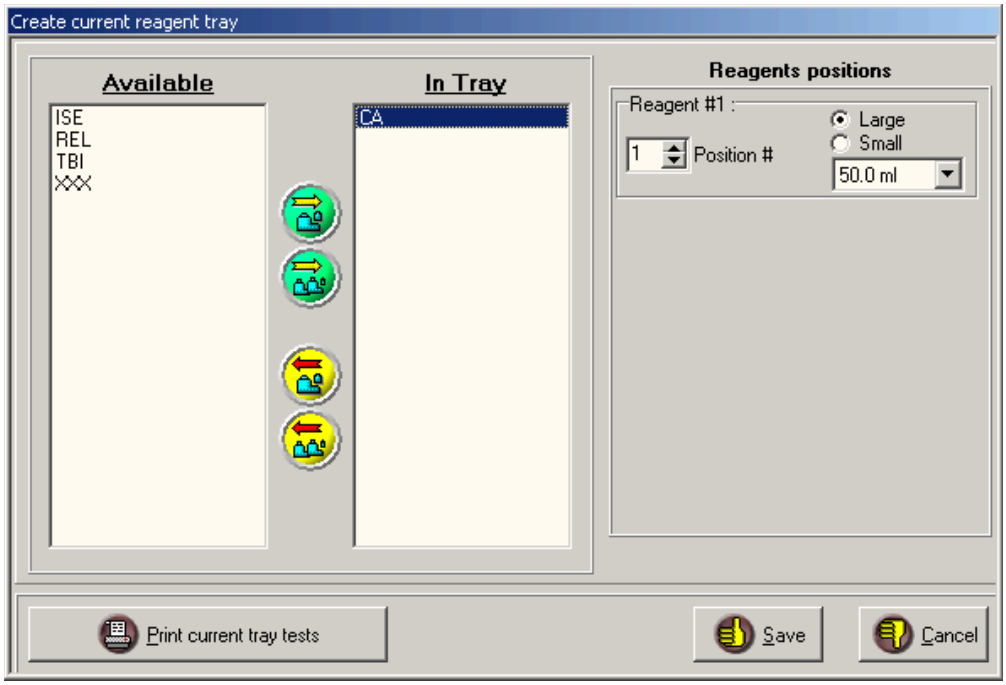


Figure 30

The function **Create/Modify current reagents' tray** creates the list for the reagents placed on the tray. It can be accessed from the **Tests** main menu or from the specific icon that allows direct access.

Into the window (**Fig. 30**) the "All tests" list **(Available)** is displayed and adjacent to it **(In Tray)** the tests for the current tray are listed.
To create the reagents' tray list, select one or more (CTRL+mouse for multiple selections) tests from the left window then transfer them with arrow commands "➢" (move single test or selection) or "➢➢" (move all available tests).
To remove from the current tray list select and transfer codes with commands "➢" (single or selection) or "➢➢" (all available). Once tests are transferred, the analyzer automatically assigns the positions and the type of bottles, but the user can modify both according to his needs.
To modify, select the desired test in "In Tray list" and then move the cursor in **Position #** textbox. Now enter directly the number or use up/down arrow keys "⇕" to scroll. Bottle size can be selected by checking • **Large** or • **Small.** There is also a field for selecting the volume of available bottles.
In case of **Double Reagents** or **Concentrated**, to be diluted with solution, positions and bottles' type are displayed for each product. It is possible to use the same reagent position for several analyses.
The creation of the current reagents list is automatic when the Bar-Code option is enabled (refer to **Chapter I**).
The Relation Tests can be entered in the analyses tray. They are placed at end of the generated list and no physical position is assigned to them.

Save: Memorizes data and exits.

Exit: To leave (exit) the program without saving.
Print: To print data in the current tray.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER D

1. PERFORMANCE AND LIMITS Page: 2

NOTE: for the I.S.E. module specifications, refer to the dedicated chapter (Chapter L)

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. PERFORMANCE AND LIMITS

GENERAL INFO

Operating Mode:	Random access
Methods:	Tests for Clinical Chemistry and Immune-Chemistry
Test Mode:	Routine, Batch, Emergencies (STAT), Profiles
Tests in memory:	500 single or double- reagent + unlimited Relation Tests
Test Re-runs:	automatic or on demand
Calibrations and Controls:	automatic or on demand
Automatic Profiles:	automatic execution of related profiles or on demand
Quality Control:	3 known levels and 3 unknown levels
Remote diagnostic:	Via Modem (optional)
Maintenance:	Automatic program

TIME REQUIRED TO REACH STEADY STATE

Ambient conditions:	21 °C R.T., 33% RH
Time required for the analyzer to reach steady state:	20 min.
Time required for refrigerated bottles to reach steady state:	approximately 2 hours

OPERATING AMBIENT TEMPERATURE 18 °C to 32 °C, 10% to 90% RH, Non condensating

PERFORMANCES

	BT1000	**BT1500**	**BT2000 Plus**	**BT3000 Plus**	**BT3500**
Tests on line:	48 reagents + relation test	48 refrigerated reagents + relation test	48 refrigerated reagents + relation test	80 refrigerated reagents + relation test	80 refrigerated reagents + relation test
Measurement:	direct reading of 25 cuvettes in optical glass	direct reading of 32 cuvettes in optical glass	direct reading of 25 cuvettes in optical glass	direct reading of 34 cuvettes in optical glass	direct reading of 45 cuvettes in optical glass
Samples Tray:	78 total positions 52 for Samples & STAT 26 for Standard and Controls	78 total positions; 62 for Samples & STAT, 16 for Standard and Controls	78 total positions 52 for Samples & STAT 26 for Standard and Controls	78 total positions 52 for Samples & STAT 26 for Standard and Controls	78 total positions; 62 for Samples & STAT, 16 for Standard and Controls
Sampling arm:	1 for Samples and Reagents	1 for Samples and Reagents	1 for Samples and Reagents	2 for Samples and Reagents	2 for Samples and Reagents
Bar code scanner:	Not available	Optional	2 distinct barcode scanners for positive identification of samples and reagents	2 distinct barcode scanners for positive identification of samples and reagents	2 distinct barcode scanners for positive identification of samples and reagents
I.S.E. Module:	Not available	Not available	Not available	See Chapter L	See Chapter L
Sampling cycle:	18 seconds	14.5 seconds	14.5 seconds	12 seconds	10 seconds
Analytical Throughput:	Up to 200 test/hour	Up to 250 test/hour	Up to 250 test/hour	Up to 300 test/hour	Up to 360 test/hour

VOLUMES

WORKING SOLUTIONS

	BT1000 BT2000 Plus BT3000 Plus	**BT1500 BT3500**
Min / Max Sample Vol. µl	1 / 100	0.8 / 100
Min / Max Reagent Vol. µl	1 / 470	0.8 / 300
Min / Max volume in cuvette µl	280 / 700	180 / 400
Max diluter volume µl	470	300
Min / Max reaction (reag + sample) µl	300 / 700	180 / 400

RESIDUAL VOLUMES OF REAGENTS BOTTLES

NEW SERIES

80 ml BOTTLES:	2 ml
50 ml BOTTLES:	1.5 ml
20 ml BOTTLES:	0.6 ml
10 ml BOTTLES:	0.6 ml

UTILITY EXECUTION TIMES

BT3000 PLUS	**TIME**	**USED WASHING SOL. (approx)**	**USED DEDICATED SOL. (approx)**
Wash with water	5’	200 ml	
Wash cuvettes	7’	250 ml	15 ml
Extra wash cuvettes	11’	500 ml	15 ml
Zeroing on water	6’	200 ml	
Sleep mode wash	5’	200 ml	
FCC Function	15’	300 ml	15 ml
Cuvette single wash		6 ml	
Needle single wash		2 ml	
Consumption per test		8 ml	

BT3500	**TIME**	**USED WASHING SOL. (approx)**	**USED DEDICATED SOL. (approx)**
Wash with water	5’	200 ml	
Wash cuvettes	7’	250 ml	15 ml
Extra wash cuvettes	11’	500 ml	15 ml
Zeroing on water	6’	200 ml	
Sleep mode wash	5’	200 ml	
FCC Function	15’	300 ml	15 ml
Cuvette single wash		2.5 ml	
Needle single wash		2 ml	
Consumption per test		4.5 ml	

BT1000 & BT2000Plus	**TIME**	**USED WASHING SOL. (approx)**	**USED DEDICATED SOL. (approx)**
Wash with water	5’	200 ml	
Wash cuvettes	7.5’	250 ml	15 ml
Extra wash cuvettes	11’	500 ml	15 ml
Zeroing on water	6’	200 ml	
Sleep mode wash	5’	200 ml	
FCC Function	15’	300 ml	15 ml
Cuvette single wash		6 ml	
Needle single wash		2 ml	
Consumption per test		8 ml	

BT1500	TIME	USED WASHING SOL. (approx)	USED DEDICATED SOL. (approx)
Wash with water	6’	140 ml	
Wash cuvettes	6’	230 ml	6.6 ml
Extra wash cuvettes	12’	350 ml	6.6 ml
Zeroing on water	8’	140 ml	
Sleep mode wash	6’	140 ml	
FCC Function	15’	300 ml	10 ml
Cuvette single wash		2.5 ml	
Needle single wash		2 ml	
Consumption per test		4.5 ml	

NOTE: stated times and liquid consumptions should be considered only as indicative as they may vary in different conditions.

Operating Limits

The instrument cannot guarantee the preceding performance specs in the following conditions:

1) Ambient conditions beyond the specified range.
2) Use of non-conformant clinical chemistry products such as washing solution, distilled water, and etc.
3) Maintenance schedule and expiry date ignored.
4) Use of non-original spare parts and consumables.

The manufacturer does not guarantee the correct instrument. In case of implementation of unanticipated methodologies. Consult your nearest sales/service office or factory for the use of different methodologies.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER E

1. OPERATING PROCEDURE **Page: 2**
- **1.1. Turning on procedure** **Page: 2**
- **1.2. Reagents: insertion and removal** **Page: 2**
- **1.3. Running Standard & Controls (on command or timed)** **Page: 5**
- **1.4. Samples** **Page: 7**
- **1.5. Work Lists** **Page: 13**
- **1.6. Turning off procedure** **Page: 17**
- **1.7. Access Password** **Page: 18**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. OPERATING PROCEDURE

1.1. TURNING ON PROCEDURE

Turn on the analyzer by pressing on/off switch on the rear panel (refer to Chapter B, paragraph **1.3. Starting the instrument.** This operation turns on only the refrigerating system for the reagents (not available in the BT1000). To properly turn on the analyzer, momentarily press the pushbutton located inside the panel at the right side of the LCD display **(Chapter B, Figure 11)**. Remember that if the same pushbutton is pressed again, it turns off the analyzer. Turning off the program in this way may permanently damage it. After this initial phase of power on, it will be necessary to enter the password (see paragraph **1.7. ACCESS PASSWORD** in this chapter). After the turning on procedure (lasting approx. 1 minute), allow the analyzer to warm-up. The instrument is ready for use after about 20 minutes, when the temperature in the cuvettes tray has reached the proper value and the photometric lamp is stable. At this point the analyzer will require a zeroing of the photometer. It is advisable to execute the photometer zeroing every time it is requested by the analyzer i.e. every six hours.
It is not advisable to keep the analyzer ON for more than one month as this may cause problems with Windows internal counters.

1.2. REAGENTS: INSERTION AND REMOVAL

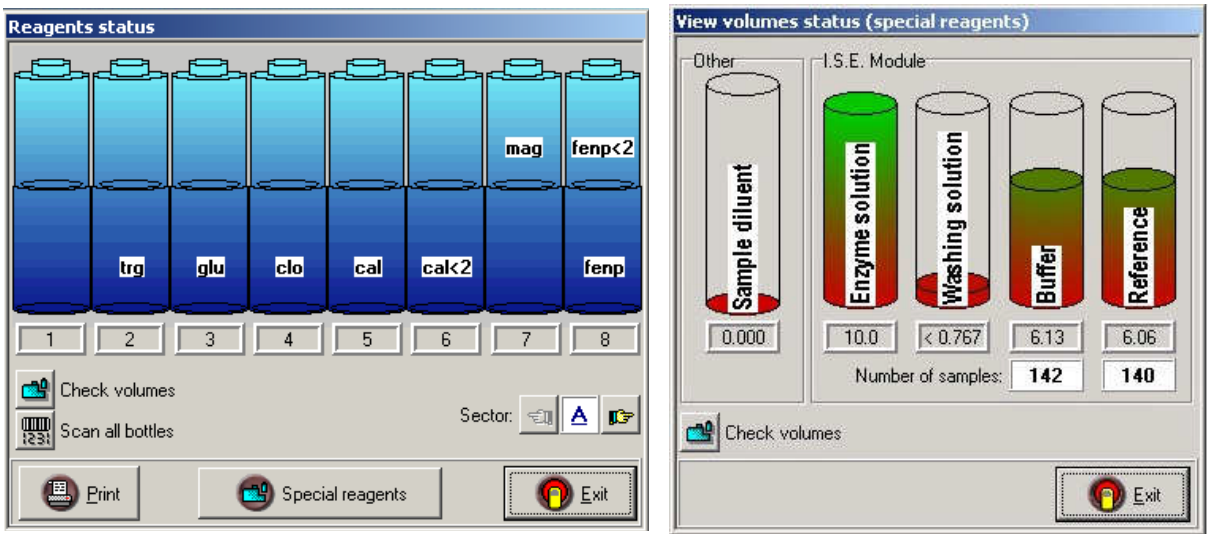


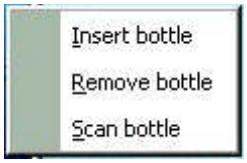
Figure 1

This function is accessed either by pressing F10 key or by clicking on the specific icon. It helps the user to correctly position the reagent bottles, as programmed in the current tray.
The reagent tray is divided into sectors, identified by the letters A, B and C for BT1000, BT1500&BT2000 Plus, while for BT3000 Plus and BT3500, the letters are A, B, C, D and E. Each sector has 8 positions. The screen displays the representation of 8+8 bottles (**Figure 1**). The analysis codes of large bottles are displayed on the lower positions, while the upper positions indicate the codes used for small bottles. By clicking on the **Special reagents**, the diluent and I.S.E. , where available, reagents volume status are displayed.
The symbols **+** or **XXX<2** can be displayed inside the code boxes (fields). The symbol **+** indicates that the position is used for many analyses, while the symbol **XXX<2** indicates the position of second bottle pertaining to the double-reagent analyses.
In the field **SECTOR** the belonging group is shown, and the default choice is "**A**". To change group click on the left and right hand buttons

ATTENTION: FOR THE USER SAFETY, NEVER ATTEMPT TO OPEN THE SAMPLES AND REAGENTS COVERS WITHOUT USING THE PROPER SOFTWARE-GUIDED PROCEDURE.

NOTE:all bar-code and scanning functions are not available in BT1000

Single bottle (available in alla analyzers):



Right-click over analysis code. A combo box asks the user to choose between "**Insert bottle**" or "**Remove Bottle**". After the choice has been made, the analyzer will correctly position the tray to match with the arrow at the base of the tray itself. The verification of fluid volume contained in the bottle is associated with the insertion procedure. With the barcode option enabled, identification is correctly achieved through the automatic scan of the barcode on the inserted bottle. The same function can be performed on command, by activating the "**Scan bottle**" command, near the insertion and removal commands.

Whole sector (available only in BT3000Plus and BT3500 analyzers):



Right-click over the "SECTOR" field. A combo box asks the user to choose between sector's insertion "Insert sector" or removal "Remove sector". After the choice has been made, the analyzer will correctly position the whole sector for insertion or removal. The verification of fluid volume contained in the bottles is associated with the sector insertion procedure. With bar-code option enabled, identification is correctly achieved through the automatic scan of the bar code of the inserted bottles. The same function can also be performed on command through "**Scan sector**", near the sector insertion and removal commands.

NOTE: if the bar-code function on reagents is not enabled, when using the "Remove" option (both for single bottle and for Sector), no functional control is performed: the existing volume and test code are not removed from the view volumes window.
In case the bar-code on reagents is enabled, when removing a reagent with the "Remove" function, the analyzer will perform a scan of the position (or the sector) to verify that the reagent has been removed. When closing the View volumes status window, the analyzer will perform a second verification scanning and then will move the removed test code from the on-line tray to the global list.

Check volumes
This option checks, on user's demand, the volume contained in all the bottles that are placed on the tray. Click with mouse on this command to confirm.

Scan all bottles
Enabled only when barcode option is on. It automatically performs the correct identification of all bottles' positions. Move cursor to this command and click.

Special reagents: command for checking the volumes of reagents and washing solutions for the I.S.E. module plus the diluent solution for the samples. With the **Check volumes** command the analyzer checks the volume contained in all the bottles. By clicking with the right mouse button, a window opens with the **Insert bottle** and **Check volumes** command, similar to those explained above (see Fig. 1).

Print
Performs a printout of the reagents status, with volumes and positions.

Volume's information

By clicking on the each analysis code, the volume of the reagent contained in the bottle is displayed as well as the number of tests that can be performed with it (Figure 2). For various tests in the same position, they will be listed individually. The count of the executable tests is made by single analysis, as if it was present alone in that given position. The Real samples field refers to the maximum number of samples which can be executed for the test when one of the reagents has a lower volume than the other. In this case the reagent with the lower volume determines the maximum number of samples that can really be executed.

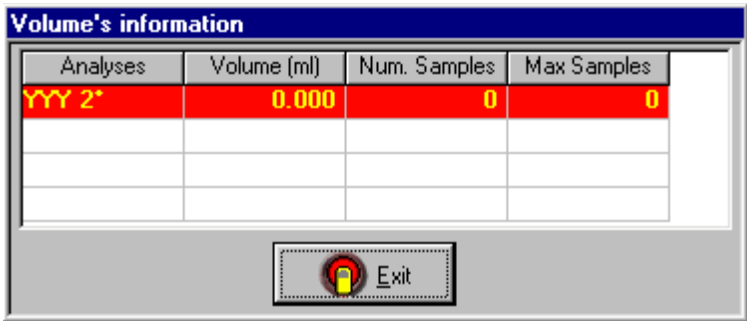


Figure 2

1.3. RUNNING STANDARDS & CONTROLS (ON DEMAND OR TIMED)

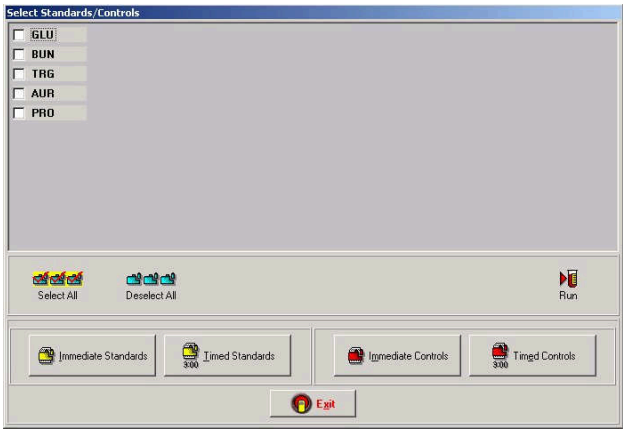


Figure 3

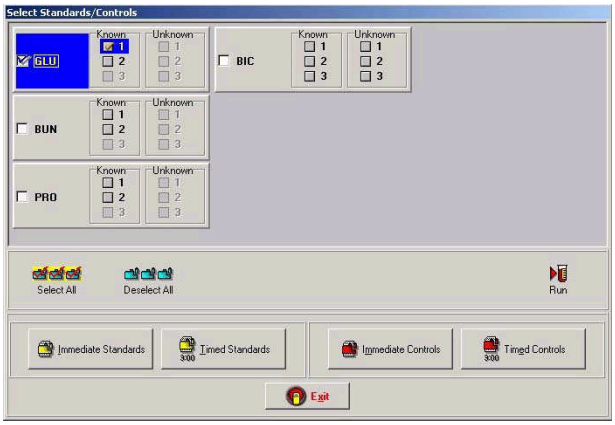


Figure 4

The **Run Standards** and **Run Controls** functions are available from the **Tests** main menu or through the specific icons that allow direct access.
The displayed analysis codes belong to the list generated in the **Current tray** list. Only codes with programming, even if incomplete, are displayed on the controls page. In this case the un-programmed levels will be displayed, even if not enabled. The entire list of tests present in the current tray is displayed for the standards (with the exception of relation tests).

RUNNING STANDARDS

Standards' calibration can be run either on command or automatically at pre-determined time intervals (refer to **Chapter C**, paragraph **1.5. Calibrations**). Both choices can coexist. The commands are **Immediate Standards** and **Timed Standards** (**Fig. 3**).

- **Immediate Standards:** Once the button is clicked a list of codes appears, select the desired tests and run by pressing **Run.** With **Select All** or **Deselect All** commands, it is possible to select or deselect the whole list. A message will ask the user whether the calibration standards are already present in the tray or not. If the samples are already present, click **Yes** and calibration procedure will automatically start. Otherwise, if calibration samples aren't already placed on the tray, click **No**; in this case a procedure will guide the user through samples' insertion. By clicking over sample's position, the tray moves itself to accommodate cup's insertion. Once the necessary cups have been inserted, it is possible to run the calibration.

Timed Standards: Only the codes with programmed times are enabled. After selection of tests, the calibrations can be run. In this case, the interval of the automatic calibration starts when tests are run. In case the calibrations aren't run, then the time count of calibration's interval starts from the moment the selection was made. Once the automatic calibration time has elapsed a message appears on the screen asking the operator if the tests need to be run. If the standards and reagents are on the tray answer yes. At this point the automatic calibration time restarts.
If the message is not answered or a negative answer is given, the calibration time count starts again. The previous calibration remains in the memory. If the timing expires while the analyzer is in standby, it will be automatically moved 10 minutes forward.

Running Controls

Controls Sera can be run on command or automatically, according to programmed time intervals (refer to **Chapter C**, paragraph **1.4. Controls**). The two modes can coexist. Commands are **Immediate Controls** and **Timed Controls** (**Fig. 4**).

Immediate Controls:
Clicking this button generates a list of codes. With **Select All** or **Deselect All** commands, it is possible to select or deselect the whole list.
The single levels for each type of control can be selected at the same time for all the tests present, by clicking on the relative button, which will change color from dark green to light green.



Select the desired tests and run by pressing **Run.**
A message will ask the user whether the control samples are already present in the tray or not. If samples are already present, click **Yes** and run will automatically start. Otherwise, if controls samples aren't already placed on the tray, click **No**; in this case a guided procedure is presented for samples' insertion. By clicking over sample's position, the tray moves itself to accommodate cup's insertion. After the insertion of necessary cups, run the controls.

Timer-driven Controls:
Only the codes with programmed times are enabled.
When the listed tests are selected the controls can be executed, in this case the automatic execution time interval starts from when the test begins, if the controls are not executed the execution time count starts from when the selection is carried out. When the automatic execution time has elapsed a message appears on the screen asking the operator if the tests need to be executed. If the operator answers yes, it checks for the presence of the controls and reagents and starts the tray.
If the message is not answered or a negative answer is given, the control time count starts again. If the timing expires while the analyzer is in standby, it will be automatically moved 10 minutes forward.

Standards, Controls and Patients Run

The analyzer allows the associated running of standards, controls and patients. The standards can be processed before, during or after patients' run. These three options provide the analyzer with maximum operating flexibility.
To run the calibrations during the patients determinations, proceed as described above. The analyzer will calculate the factors for the calibrations being run and update the result page in real time (by patient). If no errors occur in the calibrations, the results of the next patients will be calculated with the new factors at the end of the calibrations. The results of the patients before the calibrations will be calculated with the previous factors. When finished working it is possible to recalculate all the results based on the last executed calibration, again if there have not been any errors. This function is available on the result page in real time for patients (see Ch. G, par. 1. **Displaying and printing results)**.
Press the **Correction** button and select the correction with standard. This way all the results will be recalculated based on the last calibration.

NOTE:

In case of analytical errors during calibrations, the analyzer displays the error type and conserves the previous validated calibrations in the analyzer memory.

1.4. SAMPLES

Entering Samples (Routine, STAT, Controls and Batch)

Samples can be entered with **Insert Routine/STAT** or with **Insert Batch**. These can be accessed from **Patients** main menu or from dedicated icons. Select **Exit** to leave the program. The represented analyses codes pertain to the list generated in the **Create current tray**.

Insert Routine/STAT: The following options are available in this page **Global Insert/View Patients** (**Figure 5**):

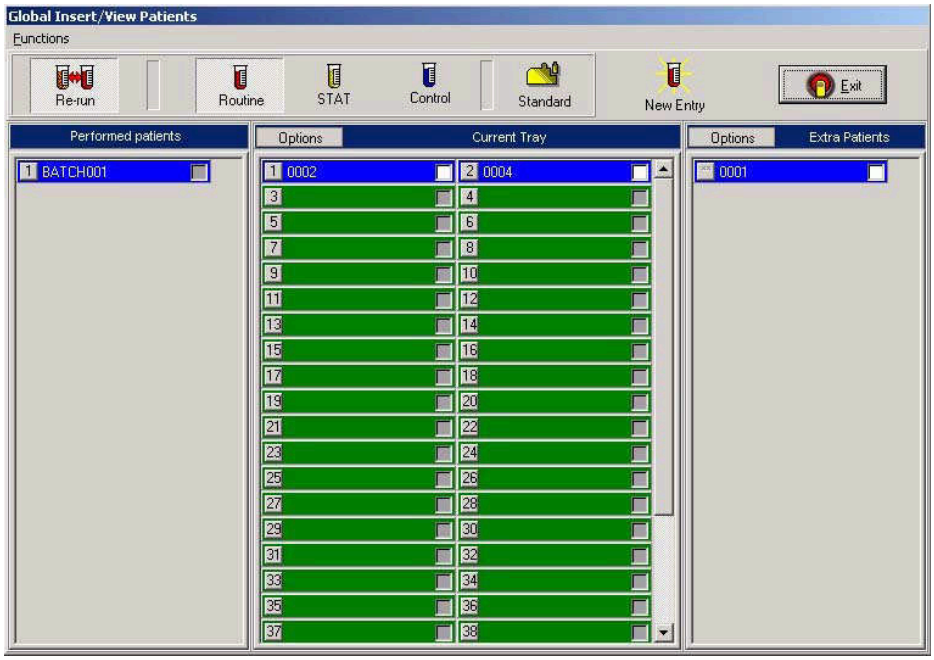


Figure 5

NOTE:
Point the cursor on the desired option and click to confirm.

Re-run: allows tests which have been run and not archived to be re-run (repetitions) on user's demand.

Routine: Default display of Patient positions.

STAT: Displays STAT (**S**ingle **T**est in **A**ctual **T**ime, i.e. urgent positions) positions.

Control: Displays Control positions.

Standard: Displays Calibrators positions.

New Entry: Enables data entry procedure for Routine, STAT and Controls.

Extra Patients: Displays the list of patients with no assigned position. Patients selected in the work-list may be moved here ("Options" menu, "Send to extra patients" command) and then back.

Exit: To leave program

New Entry Routine:
After the selection of **Routine** followed by confirmation through command **New Entry**, the patients acquisition frame is displayed (**Figure 6**). The programmed patient can be executed immediately or saved for later use. The programming fields and the functions are outlined below:

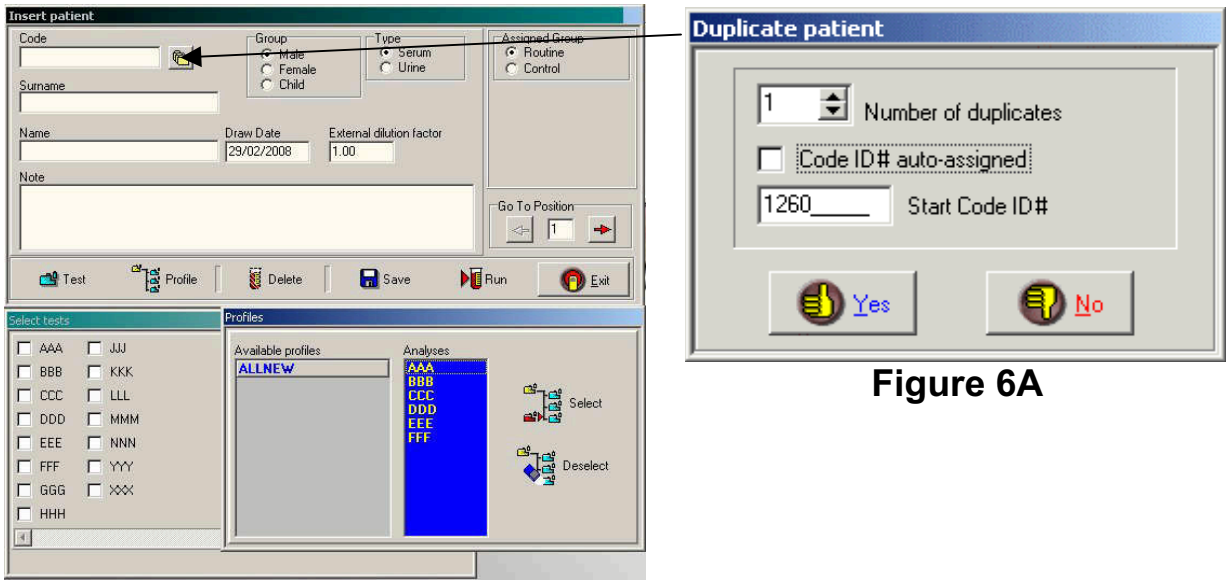


Figure 6A

Figure 6

Group: Select the group (Man, Woman, Child) for correct reference with normal values range.

Type: It is default set to **Serum.** The sample type (Serum or Urines) is selected here. If **Urine is selected, then** the volume of diuresis (in the 24h) is requested. This is required for processing data acquired with automatic calculation on 24 hours. If this processing is not required then leave the value at zero "0".

Assigned Group (Routine or **CTRL Routine):** The default setting is **Routine.** It is used for selecting the category (Patient or Control Serum) during sample programming. Selecting **CTRL Routine** the type (**Known or Unknown)** and levels (**Level 1, 2, 3**) must be specified.

NOTE:
With this type of acquisition, the controls belonging to the stored Q.C. will use the positions assigned to routine patients, not the dedicated ones.

Position: Displays the first free position from the available positions. To modify this field use horizontal arrows ⇐ ⇒ or type in the desired position. Do not modify to accept.

Code: It is the identification number assigned by the user to the patient. The user can also enter the code of a patient saved in the work list, even if in execution. In this case, a message asks the user to confirm patient's data cloning. In case of affirmative response, all the data relevant to the patient is instantly displayed and is linked to the current position. The cloning of a patient's code allows the user to obtain one report in case different samples are used. If this option is not used, then separate reports are obtained.

Duplicate patient: By clicking on the icon, it is possible to create a worklist with the same profile (**Autobatch**) or else a list with sequential codes. When the patients are entered using the duplication method, their codes may be assigned by the analyzer, or it may be a progressive number. In the case of progressive number, the operator must enter the first code to be used.

Surname, **Name:** Enter patient's personal data.

Draw Date: System date is automatically displayed. To modify, move mouse cursor on textbox, click and edit.

Note: Additional information to be added to the report.

External Dilution Factor: By default set to "1". It allows analysis determination on externally diluted samples. Enter in this field the external dilution factor ratio used in sample preparation. Final result is multiplied by the inserted ratio.

CAUTION!
IN THIS CASE THE PRE AND POST DILUTION FACTORS OF TEST PARAMETERS WILL NOT BE TAKEN INTO CONSIDERATION.

NOTE:
If a hyper-activity parameter value is surpassed (indicated by an appropriate flag) during determinations of externally diluted samples, the Automatic Re-run is not performed.

Test: Generates the Analysis List. Select each analysis to be performed on the sample.

Profiles, Select/Deselect Tests

Profile: The stored **Profiles** list (**Fig. 7**) is displayed through this command (refer to **Chapter. C**, paragraph **1.6. Creating Profiles)**. Two acquisition modes are available. The first one requires a double-click on profile's name. The second mode, after choosing the profile with one click, requires confirmation by activating **Select**.
The analyses programmed in this way can be modified. To add or remove tests, it is necessary to enter in the screen "Select tests" and confirm by clicking on the textboxes. With "Deselect", it is possible to delete an already selected profile.

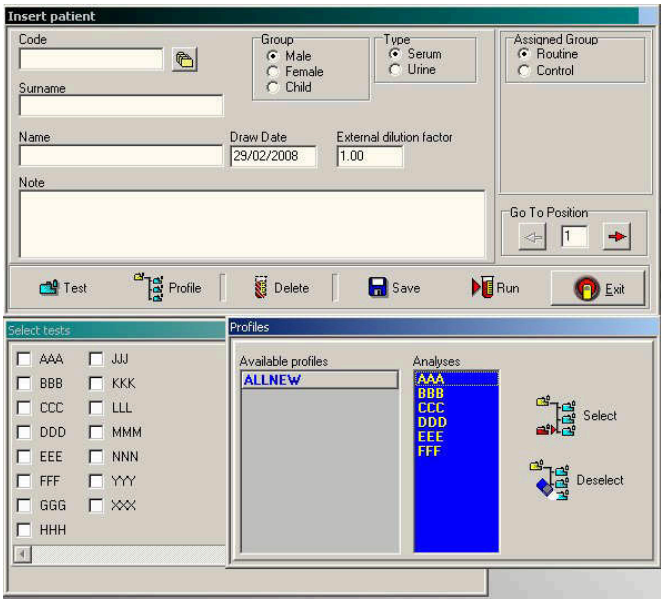


Figure 7

Delete: Cancels the programmed patient or the analyses of an already programmed (and saved) patient. Confirmation is requested.

Save: Saves patient's data and the associated analyses. With this command test execution is delayed.

NOTE:
In the routine programming, it is possible to acquire a greater number of patients than the available number of positions in samples' tray. All the patients acquired with no associated position are saved and displayed in the extra patients list and can be transferred to the main list on user's demand (refer to paragraph 1.5. Work Lists).

Run: This command immediately starts the execution of the programmed patient. The sample plate adjusts itself to match the position assigned to the patient, and a blinking red LED indicates the position for inserting cup or primary tube. If patient code is missing or no analyses have been selected then this command cannot be activated.

New Entry/STAT:

After the selection of **STAT** followed by confirmation through **New Entry**, the STAT acquisition frame is displayed (**Figure 8**). Bear in mind that the tray positions reserved for emergencies are the ones assigned in the **Analyzer Setup** (**Chapter H**, paragraph **2.**). An appropriate screen message alerts the user when a wrong position number is entered. Patients acquired as "STAT" can be saved as described in "Routine", but if sent for execution, they are analyzed immediately with highest priority.

All the acquired patients with no assigned position are saved and displayed in the temporary list **Extra Patients (STAT)**, from where they can be transferred back to the work-list on user's demand (refer to paragraph **1.5. Work Lists**).



Figure 8

New Entry/Controls:

*O*nce the icon "Controls" is selected, the list of control positions is displayed (**Fig. 9**). Controls acquisition frame is displayed by activating **New Entry** command or with aclick on a given position. A window identical to the one displayed in **Routine** appears but without the patient fields. Bear in mind that the tray positions reserved for controls are the ones assigned in the **Analyzer Setup** (**Chapter H**, paragraph **2.**). An appropriate screen message alerts the user when a wrong position number is entered. Patients acquired as "Controls" can be saved as described in "Routine", and are executed afterwards. All the acquired controls without assigned position are saved and displayed in the temporary list **Extra Patients (Control)**, from where they can be transferred on user's demand (refer to paragraph **1.5. Work Lists**).



Figure 9

Insert Batch:
In this page (**Figure 10)** select the desired analysis code and associate sample positions with it. Analysis list and routine numerations are displayed.The **Select** command (located next to the tray positions) automatically enables all the positions entered in the fields **From** and **To**, and the **Deselect** disables them all. Click on the check boxes to enable or disable a test. After entering one or more analysis code, enable test runand start working phase by pressing **Run. The enabled s**era positions are highlighted in red, while the analyses codes in blue. Press **Exit** to terminate and leave**.**
This check-in procedure is simplified as it doesn't require patients data entry and doesn't make any distinction between serum and urine. In the report, A progressive numerical identification is automatically assigned to the report, for example Batch # xx.

NOTE:
Even if the programming is based on analyses, the analyzer processing is always patient selective.

ATTENTION: when programming a batch, it is necessary to be sure that all the selected positions are free and not already programmed in the routine work-list. When "Run" is selected, the analyzer will ask confirm that the positions are free.
"Are you sure that the selected positions are all available?"
Answering "Yes", the batch will be run, answering "No", the run will be aborted in order to allow the operator to verify if the positions in the routine work-list are available or not.
If the operator runs a batch in which some of the selected positions are not available, the analyzer will skip on those positions and will keep the already programmed patients (in the same status these were before running the batch). The positions of the batch that have been skipped will not be considered at all, as if these were not programmed from the beginning.

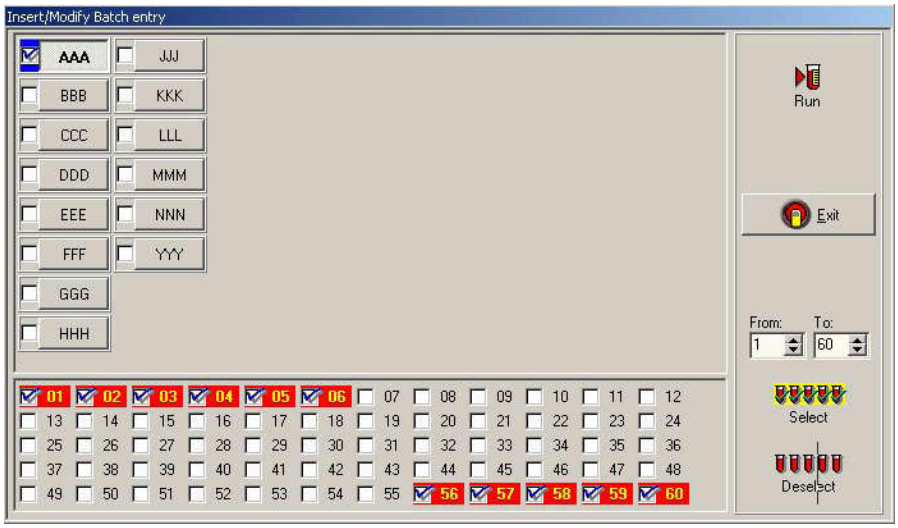


Figure 10

1.5. WORK LISTS

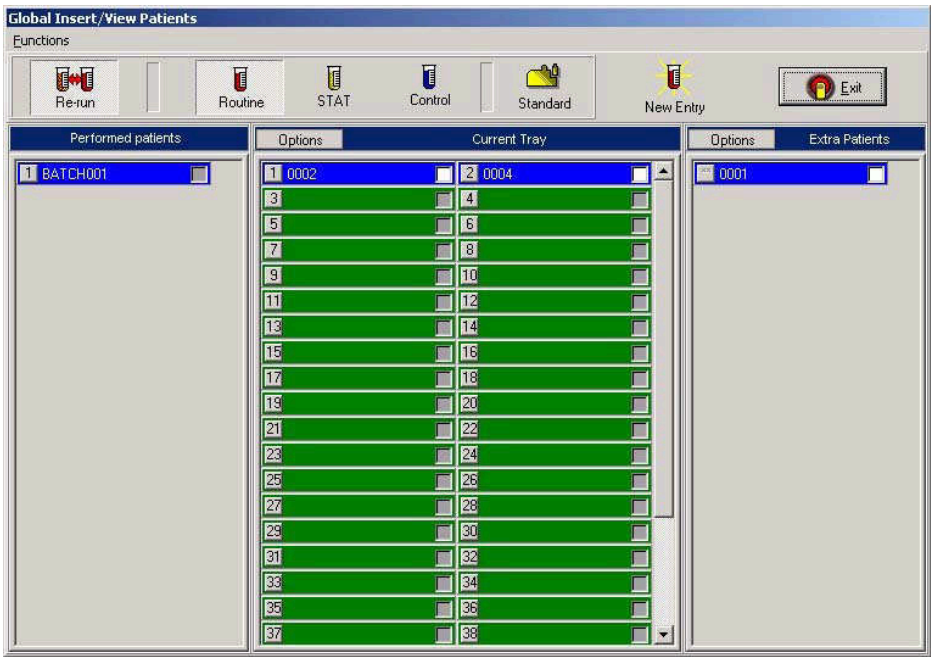


Figure 11

The Work Lists can be accessed through the menu "Patients" → "Insert Routine/STAT" or directly using its proper icon. The screen displays the "Current Tray (Routine)" in the center and the "Extra Patients (Routine)" on the right. During the working phase, it may be useful to display also the "Re-run" worklist.
Click on the **Routine, STAT**, **Control** and **Standard** buttons to view the corresponding work lists. For "Control" and "STAT", as for the patients, the screen displays the "Current Tray (Routine)" list and the "Extra Patients (Routine)" list. It is possible to run controls and calibrators even during the determination of patients. Thework-lists show the position number and test code: the samples being run are marked in red, the free positions in green, the samples which are programmed but in Stand By are marked in blue. If there is a lack of serum or reagent in the Performed Patients List they are marked in yellow. The patient codes have *Italics* characters for cloned samples and are underlined for determinations and repetitions. The characters are yellow for data being processed. The samples located in the Extra Patients List are graphically indicated in blue.
Work Lists are used to display the entered patients' codes or to verify the samples' state on the tray (**Fig. 11)**

Routine Tray List:
Inside this list it is possible to view in real-time the actual situation. The user, by clicking on an active position, enables the Registry situation with information on selected code and analyses. It is possible to modify if the sample is not being run. It is possible to enter new data by justclicking on a vacant position. During tray processing, as the samples are analyzed, the positions that were previously occupied become vacant (green).

Options: The "Options" menu is available in the **Current Tray** (Routine, STAT and Controls). It displays the following commands (Figure 11):



Send to extra patients: The selected patients are removed from current samples tray list for placement on **Extra Patients List**. Selection can be done by checking the appropriate boxes. Use "Select All" to select the whole list and "Deselect All" to deselect.

Print: Prints the partial (for selected items) or total samples list.

Select All: Automatically selects the whole list.

Deselect All: Automatically deselects the whole list.

Run: Work start command. If single patients or the whole list is selected, a message asks if the samples have been inserted. If the answer is affirmative, the analyzer automatically starts processing. In case of a negative answer, a guided procedure will assist the user to insert the samples. Confirming with cursor on the corresponding line performs the selection of the sample to be inserted. After the insertion of all the samples, activate "Run".

Delete: Removes selected or all the patients. Confirmation is required.

In case the serum barcode is enabled in the Options menu, then two additional commands are automatically added (Controls are excluded). The two commands are Scan Tray and Scan Tray and Run. Both commands allow further selection: All and Single Position.

Scan tray: Allows positive identification and saves present samples on the tray. It is subdivided into the following two functions:

All: The tray performs a rotation scan to make a positive identification, and saves all the samples (codes) in the sera tray.

Single Position: Allows positive identification and saving of only one single code. The analyzer requests the desired position and the tray accordingly positions itself for sample's insertion. Makes one rotation for reading the present code.

Scan tray and run: Performs reading rotation as before, but runs the tests immediately.

NOTE:

In patients' bar-code printing protocols it is possible to add Profile Number, which provides total automation in patient acquisition (refer to Chapter C, paragraph 1.6. Creating Profiles and Chapter I, paragraph 1. Bar-code and related functions).

During bar-code reading, the analyzer provides a list of likely errors that occurred. In this case the reading can be repeated by re-activating the command.

Extra Patients: It displays the acquired patients that haven't been inserted in the run list. The user by clicking on an active position enables Registry Situation with selected code and analyses information. It is possible to modify it.

Options: The "Options" menu allows the following functions:

Send to Current Tray: The selected patients are removed from **Extra Patients List** for placement on current samples tray list. The patients will be placed in the free positions starting from the first available. Use **Select all** or **Deselect all** commands to select or deselect the whole list. It is also possible to "drag and drop" single patients to the current tray in any available position.

Print: Prints the selected or total samples list.

Delete: Removes selected or all the patients. Confirmation is required.

Performed Patients List: This list displays the codes and positions for the completed patients that are available for repetition. The user, by double-clicking on an active code, enables patient's information page with assigned analyses and relevant results, while by clicking on a given analysis code, the reaction graph is presented.

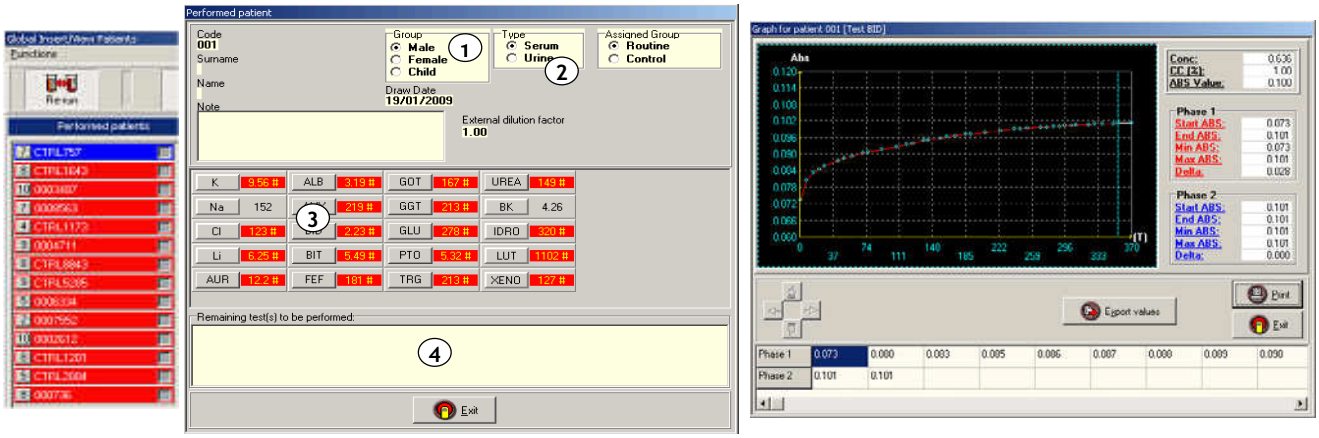


Figure 12

In the Performed patient window the following information are displayed:

① group which the sample belongs to.

② sample type.

③ already performed tests (the test graph can be displayed by clicking on the test code).

④ remaining tests (to be performed).

To re-run, the desired patient code must be transferred to Current Tray List and then run again. Confirm with a single click on the position number, confirmation is requested before transferring. If the answer is positive, then the screen "Select Repetition Position" is displayed. If available the previously used position is shown otherwise the first vacant position is presented, modify if necessary. Once the position is confirmed or modified, Registry Situation with related analysis is presented. Deselect the analysis that should not be repeated, add new tests if needed. Once programming has been terminated confirm with command "Run" to run the sample or "Save" for memorizing.

NOTE:

Confirmation is requested in all the patients' work lists, to perform Codes Transfer Commands. The analyzer verifies the availability of positions in the samples tray list and eventually prompts the user about the impossibility to complete the task.

Standards List:
Activation of **Standard** button displays a list (**Fig. 13)** of Calibrator Positions **Current Tray (Standards)**. This list is in a read-only format.

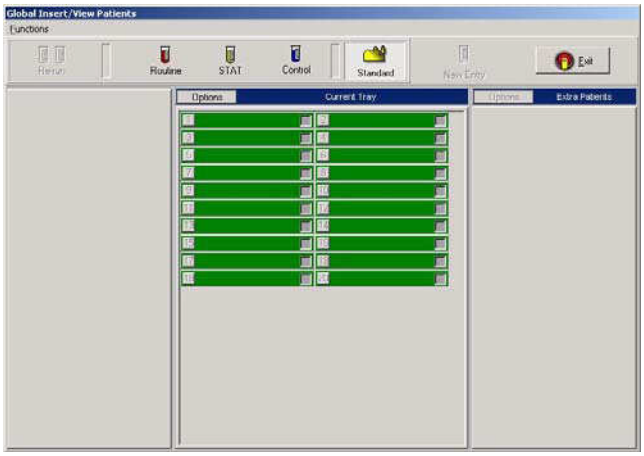


Figure 13

Global Insert/View patients

The "Functions" menu in the "Global Insert/View patients" (fig 14) bar provides access to the following commands:

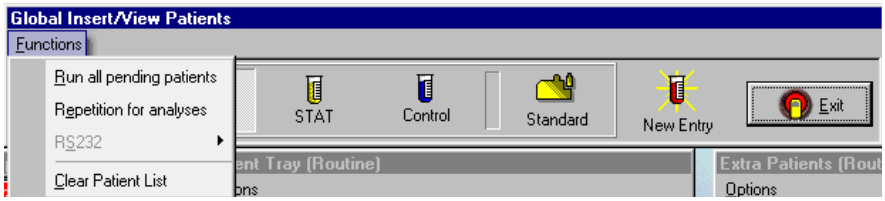


Figure 14

♦ **Run All Pending Patients:**
A sole command for running the already acquired patients and the partially processed patients (because of an interruption during tests execution). The analyzer will continue to process suspended patients. Confirmation is required.

♦ **Repetition for Analyses:**
This command re-runs test for samples. First the selection of the desired analyses codes is required and then the confirmation. The analyzer automatically searches for the samples which had already undergone determination of selected analytes, and performs the newly assigned work list and then updates patient reports with new data obtained from the repetition.

♦ **RS 232:**
This function is used for transferring data from the analyzer to the host computer. Data transfer can be automatic if enabled in the Setup. If it is not enabled, then the data transfer occurs on user's request through the command **Accept Result to be sent.** Confirmation is required. The function **Delete Result to be sent** allows deletion of the data to be sent to the host computer; confirmation is required (see also **Chapter H**, paragraph **2. Analyzer Setup**).

♦ **Clear Patients' List:**
This command allows deletion of the previously acquired patients list. Confirmation is required. It deletes the whole list.

1.6. TURNING OFF PROCEDURE

To turn off the instrument, the **SHUT DOWN** procedure must be performed. In this way the instrument is definitely turned off, except for the refrigerator for the reagents. The shut down procedure proposes the wash of the cuvettes with appropriate washing solution before turning off. The analyzer indicates the position where the detergent should be inserted (see also **Chapter. C**, paragraph **1.1.**). As regards the ISE Module, please refer to **Chapter L, par. 1.3.**

NOTE: if cuvettes are not properly washed at the shut-down, at the following start up the analyzer will ask for the cuvettes extra wash (with acid solution). Performing the normal cuvettes wash (with the cuvettes washing solution) will not prevent the analyzer from warning again that the extra wash is needed.

Conditions are:

a. If no test has been performed before the shut-down, at the following start-up of the program, no wash message will appear.

b. If no test has been performed before the shut-down and the shut-down wash has been started but it did not complete correctly, then at the following start-up of the program, the analyzer will warn the operator that the preceding wash was not correctly completed.

c. If tests have been performed and the shut-down wash was not performed, at the following start-up of the program, the analyzer will ask for the Extra wash cuvettes and will warn the operator that the preceding wash was not correctly completed.

NOTES:

1) Having performed a test: it means having performed either a single test with reagents and sample or any procedure involving colored solutions, such as the FCC.

2) The analyzer asks for the Extra wash cuvettes as it does not know how long the solutions were left inside the cuvettes before washing them.

The analyzer provides two other modes for interrupting its operation:

1) SLEEP-MODE

This mode can be manually activated, or it starts automatically when the instrument is left inactive for more than 30 minutes. The **Sleep-Mode** automatically performs the wash and fill up of the cuvettes with bi-distilled water and remains idle (waiting for user's commands for immediate operation).

2) LOG-OFF

The "Log-Off" mode represents a partial turning off of the analyzer. It disables some devices: halogen lamp of the photometer, cuvettes thermostat and drive motors. This mode is used for energy saving.

The Log-Off mode is utilized for programming automatic turning on at a desired date and time. The instrument will remain in a stand-by condition and it will automatically turn on 30 minutes before the programmed time. The turning on in anticipation allows the analyzer to reach steady state thus allowing immediate operation at the programmed time.

To exit ahead of time from a suspended activity, click on the left or right mouse button and press the **Exit** button on the window that appears. However, in this case it is necessary to wait for the devices to become operational.

NOTE

It is not advisable to keep the analyzer ON for more than one month as this may cause problems with Windows internal counters.

CAUTION!

If the SHUT DOWN procedure has not been observed, then do not ever stop the analyzer by turning off the main switch. This may cause irreparable loss of data in the archives and damages to the operative program.

1.7. ACCESS PASSWORD

To comply with the European law on privacy (processing of sensitive data) enacted with Italian Legislative Decree no. 196 of 30/6/2003 passwords have been implemented for the analyzer. This makes it possible to keep a record of the activity of each authorized operator.

To have access to the analyzer program, a sequence of USERNAME and PASSWORD needs to be entered.

When the analyzer is installed or first used, the Administrator or lab manager must assign each operator with a Username and password combination, associated with his own access level to the program.

The first window that appears is dedicated to the Administrator (a manager who takes care of archiving as well as password management of the users who have access to the analyzer).

The Administrator needs to enter the following in the Username field: ADMIN
The Administrator needs to enter the following in the Password field: Administrator

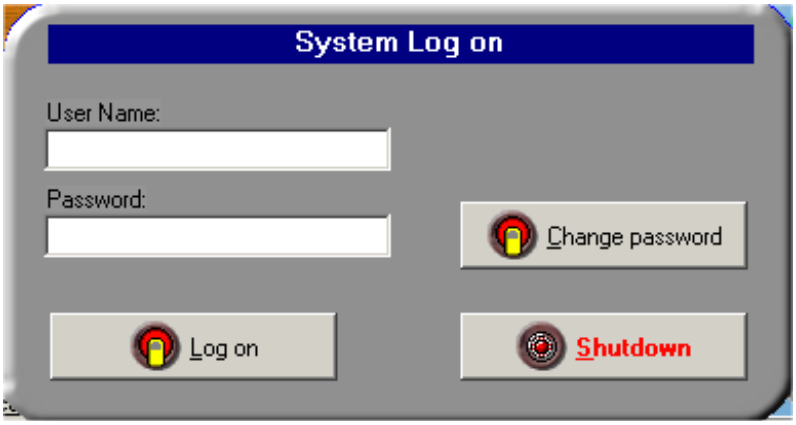


Figure 15

After pressing the Logon button, a window will open where the Administrator enters his new personal password.

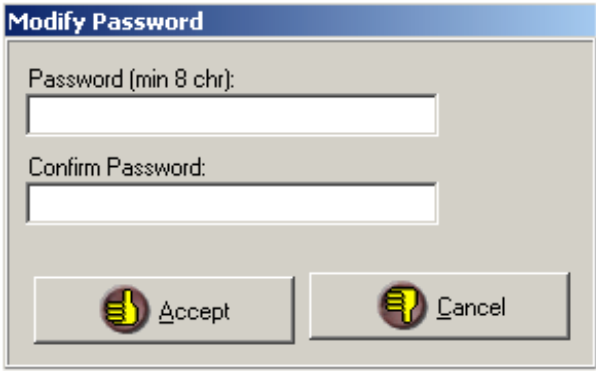


Figure 16

The Administrator password does not have an expiration date, while those assigned to operators need to be renewed every three months.

Do not forget the Username and Password sequence. If this happens, the Administrator will have to delete the operator profile and create a new one. If the Administrator forgets his own password, it will be necessary to delete the entire list of passwords using an external special program. If necessary, submit a request to the Technical Assistance Service.

Once access to the password entry page is obtained, the Administrator must assign each operator with his Username and Password combination. Press on **New User**. A window opens for typing the Username and password and confirming the password. Next, the Administrator needs to assign the access level allowed for the individual operator.

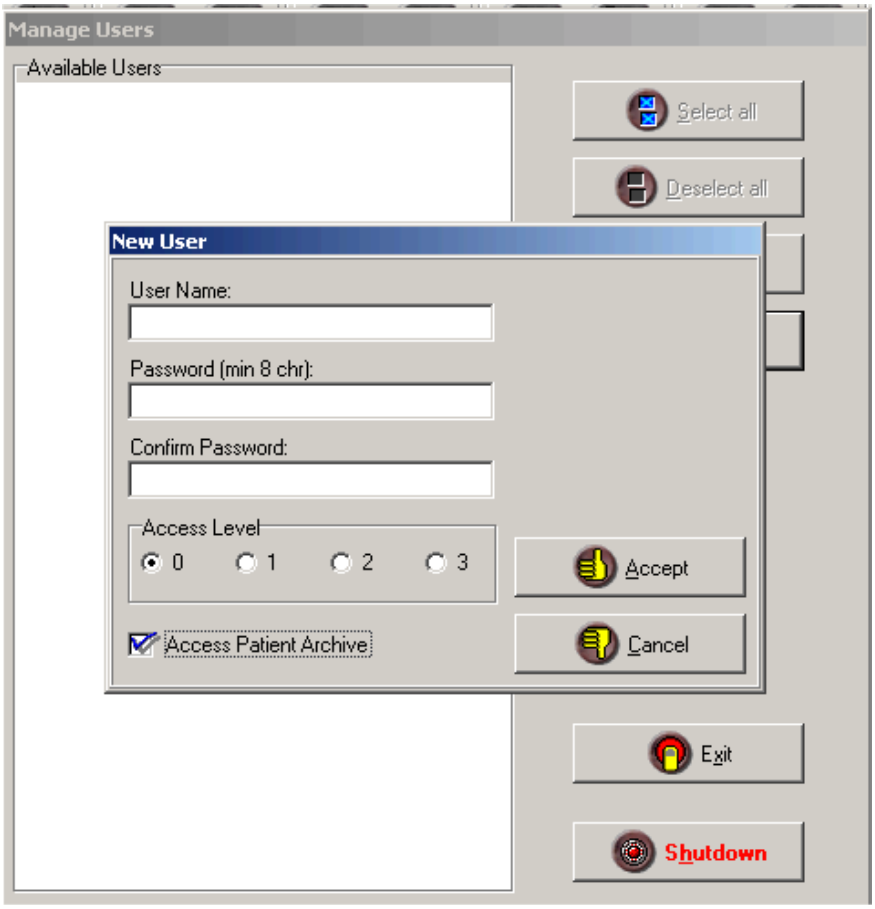


Figure 17

Each level allows access to normal analyzer operations (acquisition and running of patient lists, Calibrations, Q.C. program and Population, etc.) plus some specific functions that would otherwise not be available. Access to the patient archive is allowed by putting a check in the specific box.

L0: NO PASSWORD REQUIRED	
Modify Parameters	Not allowed
Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Not allowed
View Patients Archive	Not allowed
Modify Values In Patients Archive	Not allowed
Special Functions in General Diagnostic	Not allowed

L1: WITH PASSWORD	
Modify Parameters	Not allowed
Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Allowed
View Patients Archive	Allowed if operator is authorized
Modify Values In Patients Archive	Allowed
Special Functions in General Diagnostic	Not allowed
L2: WITH PASSWORD	
Modify Parameters	Allowed
Import/Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Not allowed
View Patients Archive	Allowed if operator is authorized
Modify Values In Patients Archive	Not allowed
Special Functions in General Diagnostic	Not allowed
L3: WITH PASSWORD	
Modify Parameters	Not allowed
Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Not allowed
View Patients Archive	Not allowed
Modify Values In Patients Archive	Not allowed
Special Functions in General Diagnostic	Allowed

To be able to allow a user to have an access level other than 0 it is necessary to know the system password that allows access to the same level. This is requested after selecting a level.
The system passwords can be changed in the analyzer Setup. Access is only allowed to the third level.
ATTENTION: if the new system passwords are forgotten, it is necessary to format the hard disk and reinstall the program. In this case any unsaved data will be lost. Biotecnica shall not be held liable for system passwords that are changed by the user.

NOTE: the users password MUST be at least of eight characters. It is advisable to use alpha-numeric passwords. Avoid using 8-times repeated characters such as YYYYYYYY or 33333333.
It is advisable to test the password every time a new password is programmed.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER F

1. QUALITY CONTROLS **Page: 2**
1.1. Inserting/modifying controls **Page: 2**
1.2. Data management **Page: 4**
1.3. Displaying and processing by lot pairs: Juden graph **Page: 6**
1.3.1. Westgard Graph **Page: 7**
1.3.2. Daily Chart **Page: 9**
1.4. Additional Functions **Page: 10**
2. POPULATION **Page: 11**
2.1. Analysis Selection (How to run a Query) **Page: 12**
2.2. Principal statistics formulas used in Population module **Page: 16**
2.3. Inserting external analyses **Page: 18**
2.4. Other menu functions **Page: 19**
3. PATIENTS' ARCHIVE **Page: 21**
3.1. Selection (How to run a Query) **Page: 23**
3.2. Patient's report **Page: 25**
3.3. Printing Reports **Page: 27**
3.4. Other menu functions **Page: 29**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. QUALITY CONTROLS

This is an external program used to enter, change and process quality controls. The program can process data from the analyzer (controls run in routine or dedicated positions) and from other instruments (with the **Insert / Modify Data** function).

NB: due to the large dimensions that the archive can reach, it is advisable to run a backup at regular intervals, even monthly.
It is advisable to use the "Export Data" function in the FILE menu to export the archive in CSV or Fixed length format (see par 2.4 OTHER MENU FUNCTIONS).
Once the archive is saved into a different location, please delete the internal archive to avoid the archive itself to crash.



Figure 1

The program is composed of three separate sections:

- **Insert/Modify controls**
- **Data Management**
- **Juden graph**

plus some Additional functions

1.1. INSERTING/MODIFYING CONTROLS

It makes possible to process data obtained **externally** at the analyzer. It requests a series of information used to statistically process the inserted values. Press the **Insert Modify Data** button.

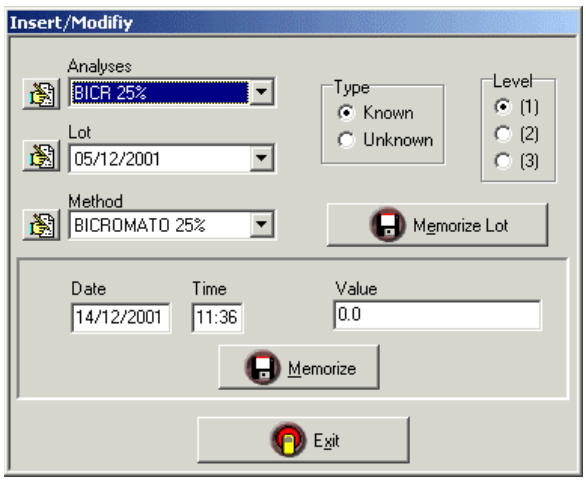


Figure 2

To enter a new name in the Analyses, Lot and Method field, click on the button 



To confirm and close the window, press MEMORIZE.

Analyses: insert a name for analysis or select one from the existing list.

Lot: insert the lot number or select one from the existing list.

Method: insert a method or select one from the existing list.

Type: select if the control is a known or unknown type.

Level: select the level to assign to the values.

The press the **Memorize Lot** button: a window will open for inserting the central control value and relative acceptability range.

After providing all the necessary data for unequivocal identification of the control data, the values can be inserted by pressing the **Memorize** button. The date and time proposed by the analyzer can be changed if necessary.

Once data insertion is finished, close the window in figure 2. At this point statistical processing of the data becomes available.

Data inserted manually will be managed exactly like the data from the analyzer (control execution).

1.2. DATA MANAGEMENT

Used to display and process data.

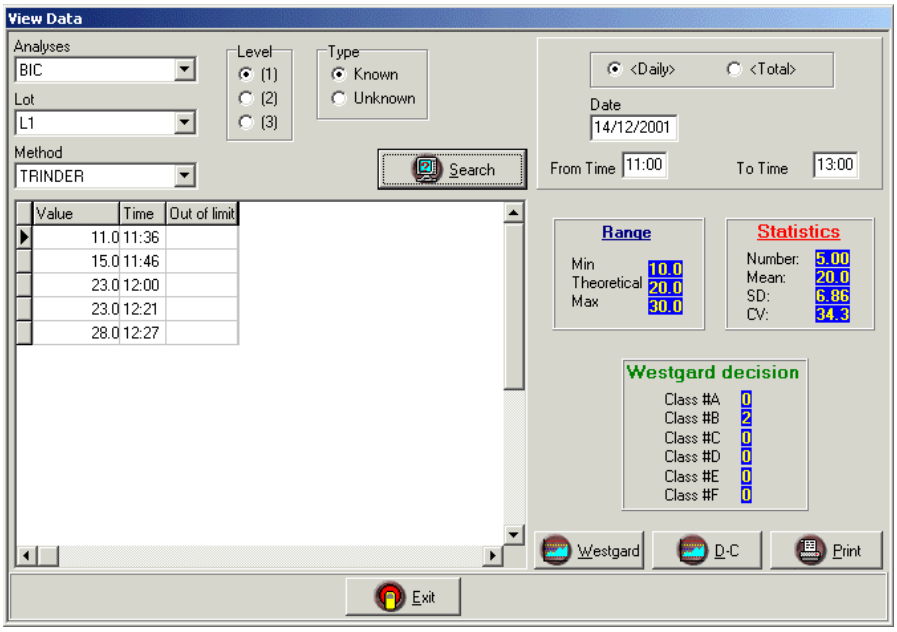


Figure 3

To obtain data processing it is necessary to provide the analyzer will all the information related to the control: **Analysis, Lot, Method, Control type – Known/Unknown –** and **Level.**

If the **All** option is left in the **Lot** and **Method** fields, the search will be done for all the lots and all the methods relative to the test selected in the **Analyses** field. In this condition the **Range** and Westgard **Decision** values will not be displayed (fig. 3a).

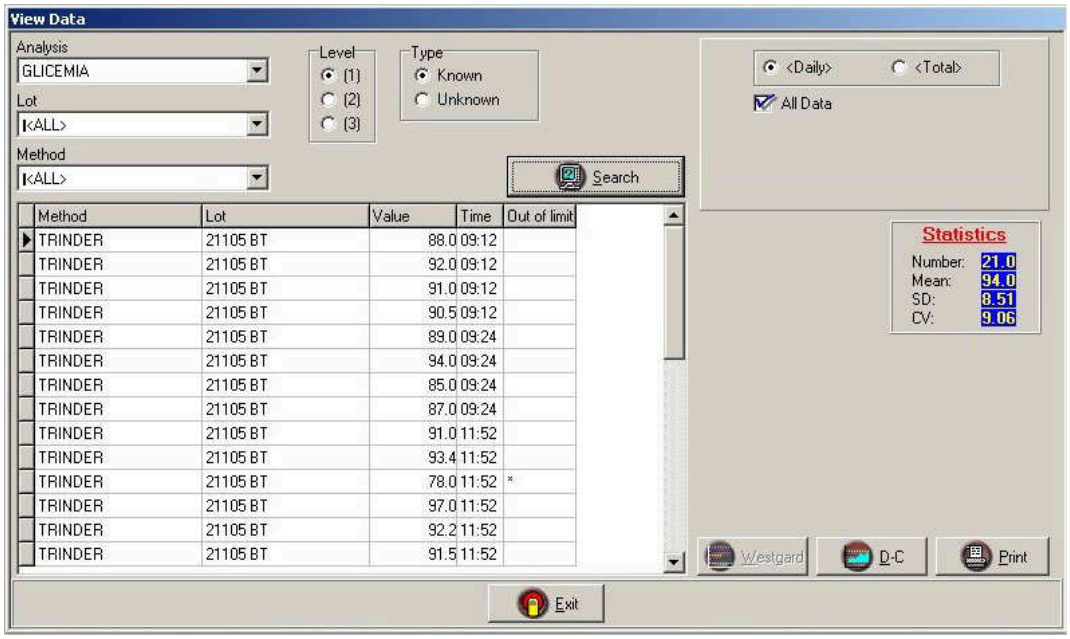
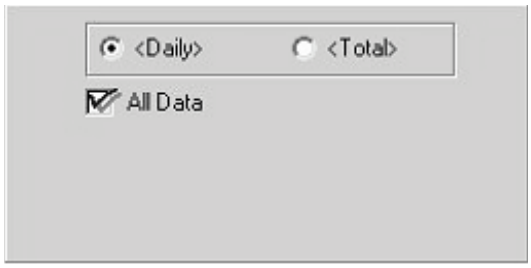
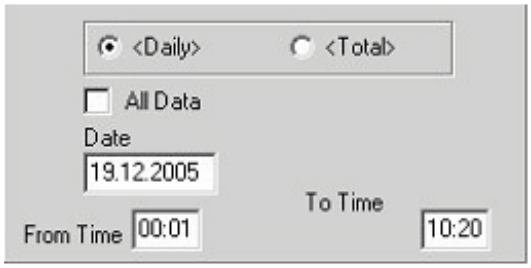


Figure 3a

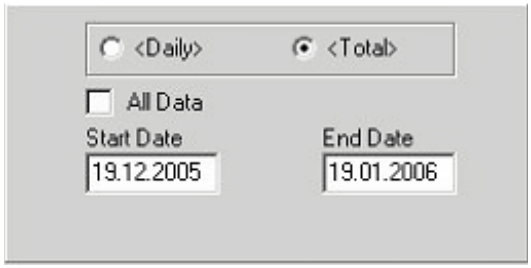
Data searches can be run for a single date (**Daily**) or for an interval of dates **(Total)**.



It is possible to select **All data** for both the Daily Q.C. and for the Total. In this case no additional range will be requested to further narrow the search field.



If only data for a precise time period in a work day are going to be processed, it is possible to disable the check on the **All data** field. At this point the analyzer proposes a date and time range. Enter the values within which to run the search.



If data for a precise time period in days are going to be processed, it is possible to disable the check on the **All data** field. At this point the analyzer proposes a start and end date for the search. Enter the values within which to run the search.

Make all the selections necessary for processing the data, then press the **Search** button.
The results will be displayed as shown in figure 3. The data are ordered by date and time. Out of range controls are indicated with an asterisk.
To delete a record, it must be first selected with the left mouse button, then it can be deleted by pressing the right mouse button. This is possible only if the search is Daily and not Total.

When the search is run on unknown controls the range and Westgard classes are not displayed.

Deleting data: see fig. 3 and 3a. After having performed a daily query, it is possible to delete one or more control values. To delete a control, first highlight it, then right click on it and confirm.

1.3. DISPLAYING & PROCESSING BY LOT PAIRS: JUDEN GRAPH

After selecting the key parameters **Analyses**, **Lot**, **Method**, **Type (Known/Unknown)** and **Level,** data processing and visualization is performed. The controls are ordered by date and only in case of known controls the **Out of limit** condition is indicated. Refer to Figure 4. This function relates two different levels for the same lot displaying distribution of controls within the limits of lots.

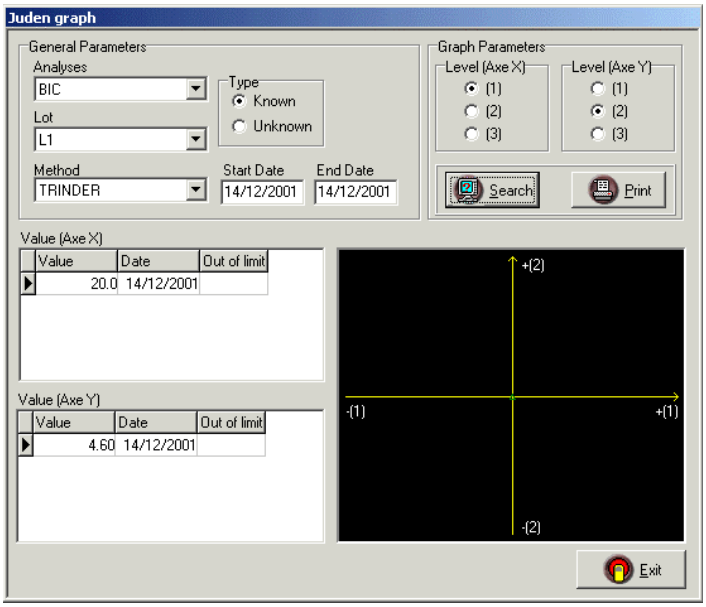


Figure 4

By clicking over a value plotted on the graph, the information relating the pair of values will be displayed.

1.3.1. Westgard Graph

The Westgard graph provides a global vision of a given lot by plotting data on a diagram having the origin at 0 line representing the lot mean value, calculated as (lot min + lot max)/2, which usually corresponds to the lot theoretical value. As division, are reported values such as Mean±1S ±4S (see Westgard table in Figure 5). All data within the given range will be displayed with a green triangle while the out of range data will be plotted using red squares.

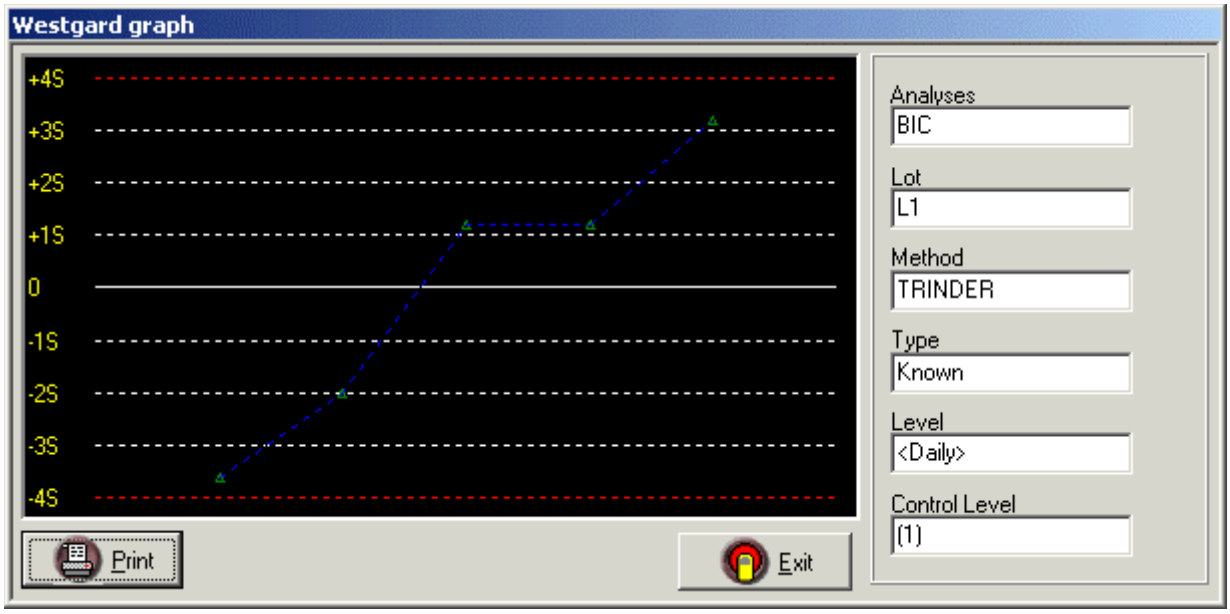


Figure 5

By clicking the mouse over a given value in the graph, its information will be displayed (fig. 6). Click on the "Print" button to print the graph.

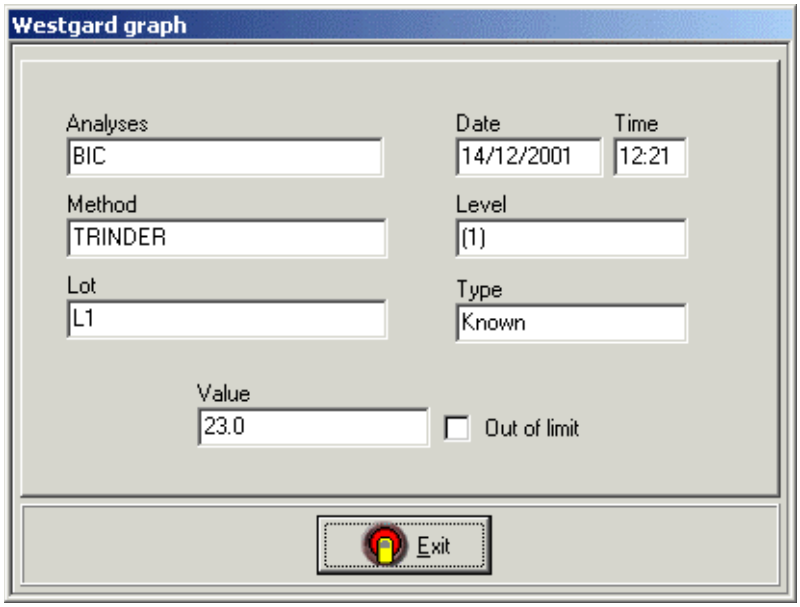


Figure 6

Westgard's Decision

It is a procedure for classifying values of a **Known** lot taken into consideration for processing.
Mean: mean between the maximum and minimum lot value
S: (Maximum lot value – Minimum lot value) / 8
The following procedure is observed for classification:

Class A (1-2S): One result exceeds Mean by +/- 2S.

Class B (1-3S): One result exceeds Mean by +/- 3S.

Class C (2-2S): Two consecutive results exceed mean by 2S in the same direction.

Class D (R-4S): Difference between two consecutive results is higher than 4S and at least one result exceeds mean by +/- 2S.

Class E (4-1S): Four consecutive results exceed mean by more than 1S in the same direction and at least one result exceeds mean by +/-2S.

Class F (10x): Ten consecutive results are all in the same direction of the mean value and at least one result exceeds the mean by +/- 2S.

Classes are controlled from F to A. The classes are mutually exclusive, that is, if a given value is mapped to one class then it can't be part of another class.

Example:
2 E classes means that **5** consecutive results exceed Mean by more than 1S in the same direction and at least one result exceeds mean by +/-2S; alternatively two groups of 4 consecutive results exceed the mean by more than 1S in the same direction and at least one result exceeds mean by +/-2S.

1.3.2. Daily Chart Graph

The "Daily Chart graph" provides a global vision of a given lot, plotting data on a diagram having the origin represented by the actual mean (not by the theoretical value) of the same lot and as divisions values such as Mean+Standard Deviation*1, Mean+Standard Deviation*2 to Mean+Standard Deviation*4. In addition the red dashed lines indicate the upper and lower limits of the lot. All data within the range will be represented by a green triangle, while the out of range data will be plotted using red squares.

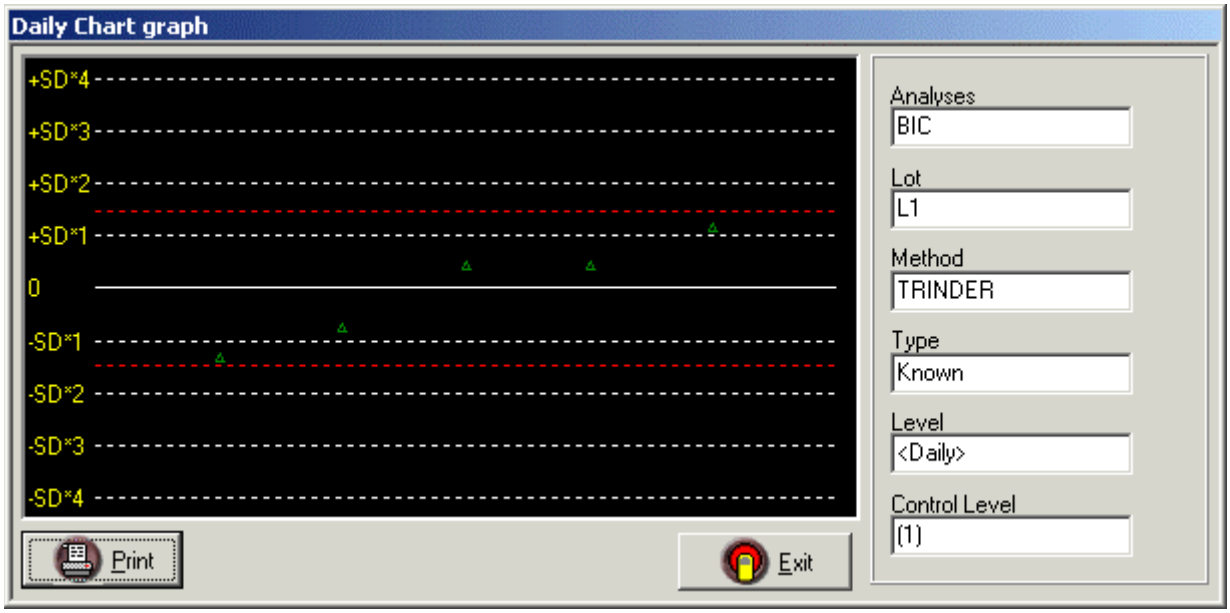


Figure 7

By clicking the mouse over a given value in the graphic, its information will be displayed. Click "Print" to print the graph.

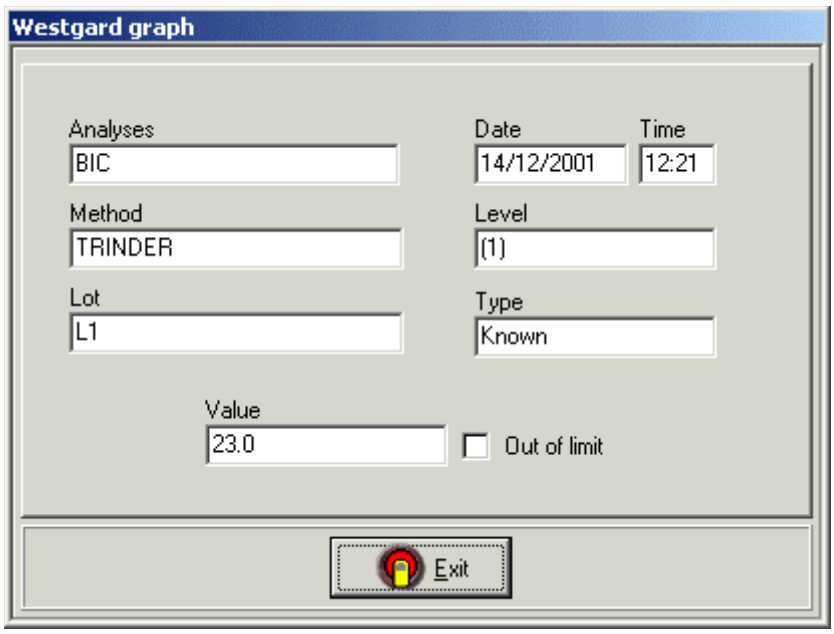


Figure 8

1.4. ADDITIONAL FUNCTIONS

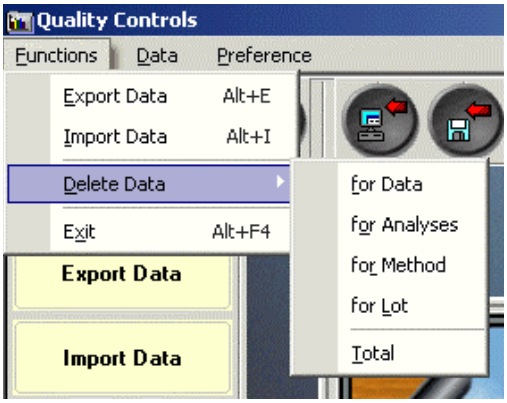


Figure 9

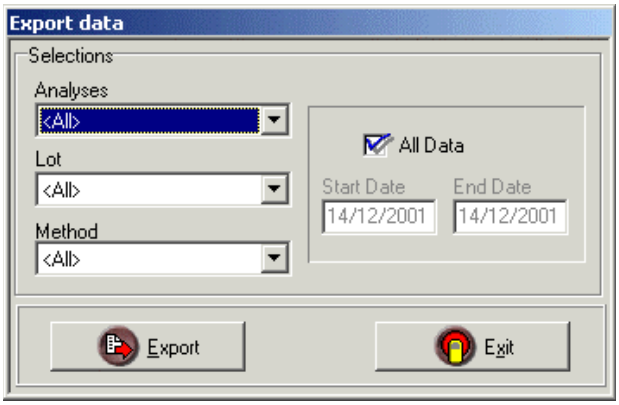
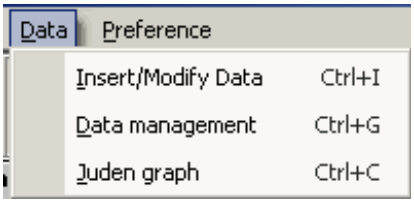


Figure 10

The **FUNCTIONS** menu contains the following:
Export Data: Saves memorized quality controls by selecting a particular "Method", "Analyses", "Lot", and "Date". If "All" is selected in the above-mentioned fields then all controls will be memorized. Refer to Figure 10. It is also possible to export the QC data in CSV (comma separated values) or Fixed length formats, compatible both with Word or Excel kind applicatives.
NOTE: the use of this function is very important to have constantly updated archives in a hard disk different from the analyzer's.
Once the *.csv or *.txt file has been created, it can be opened with Excel or Word. First open the appropriate program (both programs will open both kind of files, but the easier way is to use Excel for *.csv and Word for *.txt files). Then select "Open file" and in the "open" window, select in the field "File of type": "all files - *.*". Click twice on the file you want to open.
Import Data: Overwrites the actual stored data with the imported data. **CAUTION: It is not possible to restore overwritten data.**
Delete Data: it is possible to delete records in the archive by **Date, Method, Analyses, Lot** or erase the whole archive (**Figure 9**). **CAUTION: It is not possible to restore deleted data in the previous "Delete Data" command.**
- Reindex Data-Base: function used to reorder the **Quality Controls** archive.
- **Close**: closes the Q.C. program.

The **DATA** menu contains the functions explained in the paragraphs above.



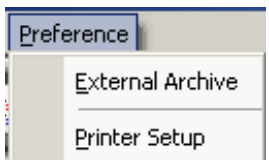


Figure 11

The **PREFERENCE** menu (fig. 11) contains the following:
External archive: used to view and print the quality controls memorized on the hard disk or on a floppy disk. A window opens where the position for opening the archive can be selected.
Printer Setup: used to set up the printer (heading, footnotes, etc.)

2. POPULATION

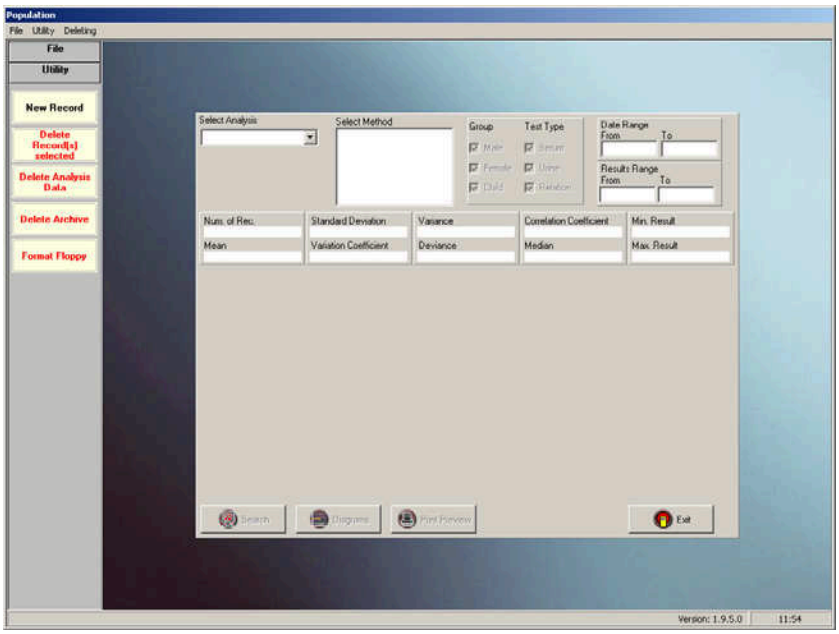


Figure 12

The Population module manages and displays graphs as well as data, and computes statistics on data of all the analyses performed by the instrument.
N.B.: due to the large dimensions that the archive can reach, it is advisable to run a backup at regular intervals, even monthly. It is advisable to use the "Export Data" function in the FILE menu to export the archive in CSV or Fixed length format (see par 2.4 OTHER MENU FUNCTIONS). Once the archive is saved into a different location, please delete the internal archive to avoid the archive itself to crash.
The main functions are:

- Display and data acquisition from updated analyses file.
- Update internal archives.
- Generate dynamic query that allows to sort and display data by analysis, analytical method, results' range, group, type and date.
- Statistical operations: display number of run tests, mean calculation, standard deviation, variation & correlation coefficients, variance, deviance, angular coefficient and known term of the minimum square line.
- Display data graphs: Trender (data with fitting line), L. Jennings, histograms with base zero and statistical (mean value represents the base).
- Printout of total and partial data, graphs, and statistics.

Moreover the program has the following built-in secondary functions:

- Total and partial "Back-Up" and "Restore" (selected by date and/or group and/or type and/or method and/or by results' range) functions.
- Total "Restore" function appends (adds) data to the existing archive.
- Printer setup.
- Deletion of the whole population archive.
- Addition of external tests for storing in the memory results belonging to different analyses than those performed by the analyzer: these results will be saved in the archive thus allowing data display and statistics generation.

2.1. ANALYSIS SELECTION (How to run a Query)

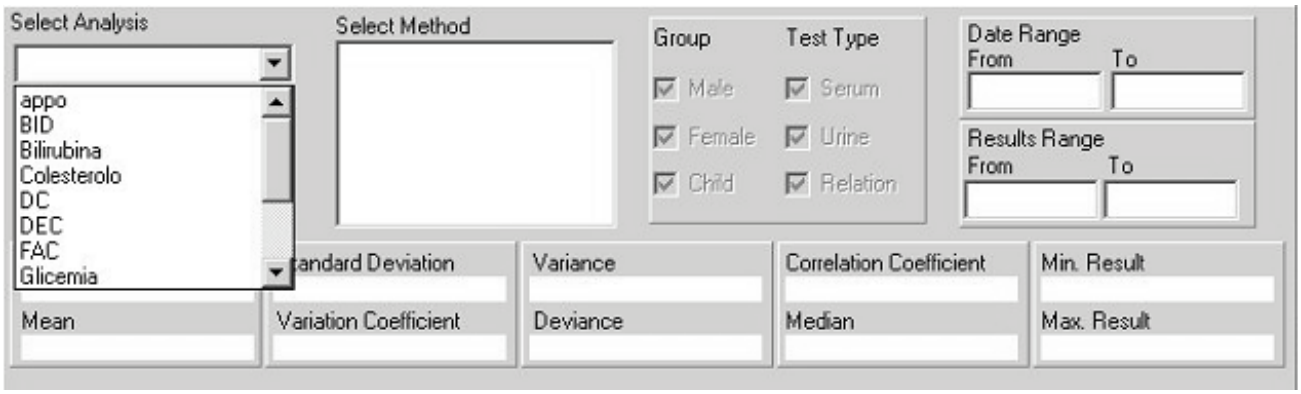


Figure 13

To perform any query it is necessary to select an analysis from the **Select Analysis** list (**Fig. 13**). Once selected all existing methods associated to the analysis (**Select Method**) are displayed. It is possible to select among the available methods by clicking on the check box. One can simultaneously enable the search for one or more groups "**Group**" (Man, Woman, Child) or **Test Type (Serum, Urine, Relation)**. Moreover it is possible to limit search within two dates **(Date range)** or according to a given data range **(Results range)**. Once the all query criteria have been selected, press the **Search** button to display the data and statistics referred to it (**Fig. 14**). This page shows the statistical processing for the query. They are also present on the pages for graphic processing (Diagrams)

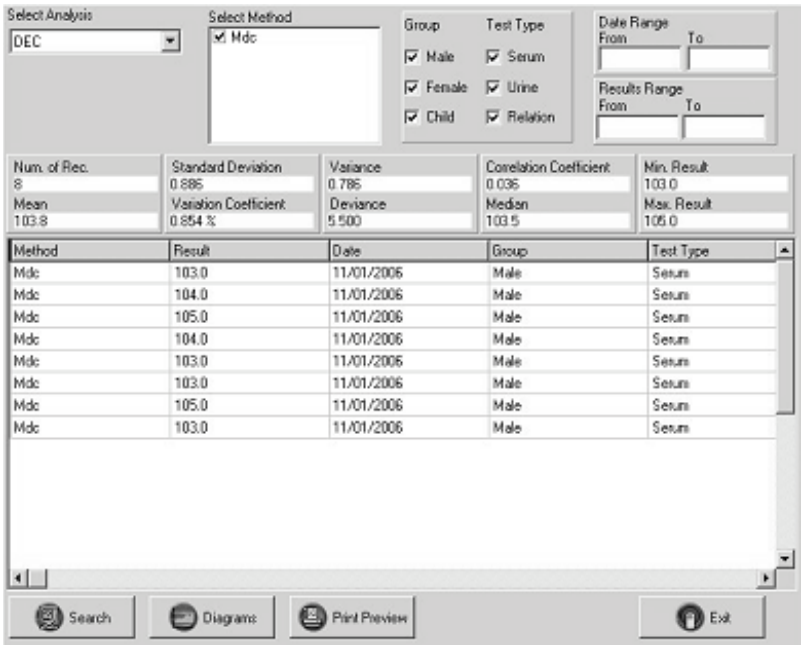


Figure 14

The statistical data presented for the query include:

- ✓ **Number of selected records**
- ✓ **Mean**
- ✓ **Standard Deviation**
- ✓ **Variation coefficient**
- ✓ **Variance**
- ✓ **Deviance**
- ✓ **Correlation coefficient**
- ✓ **Median**
- ✓ **Minimum result**
- ✓ **Maximum result**

The query data can be printed (**Print Preview**) in three different formats:

- Only values
- Only statistics
- Values and statistics

Once the selection is made the print preview page opens. To print, press the printer icon.

By pressing on the **Diagrams** button, a series of possible graphics processing is proposed for the executed query (**Fig 15**).

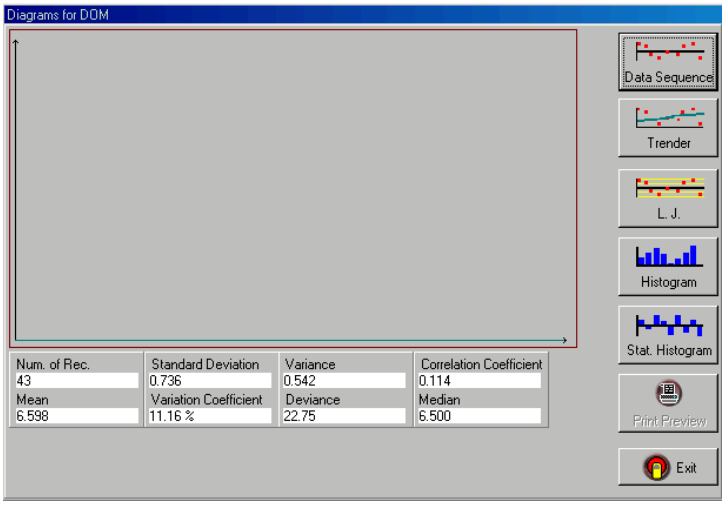
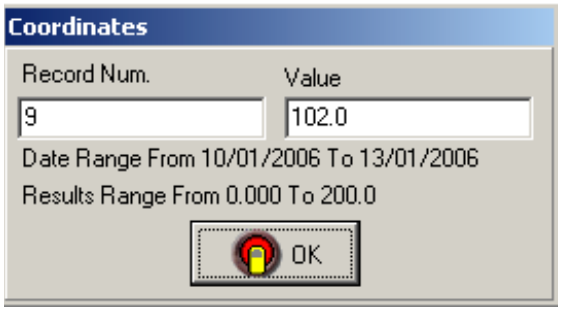


Figure 15

By clicking on one of the keys related to diagrams it is possible to view one of the graphs listed below.



In all available diagrams, by double-clicking the mouse on a given plotted point, information about its coordinates (position and value) is shown.
The specific criteria used for the query are also described, if present.

Data Sequence Graph

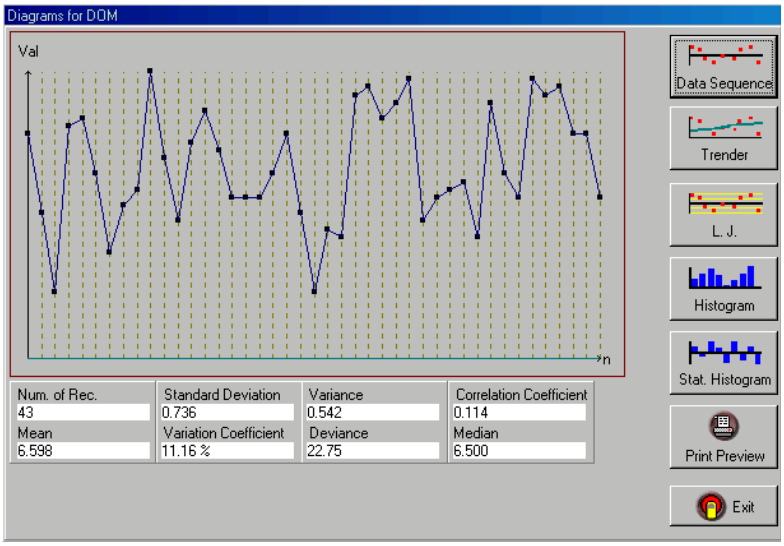


Figure 16

By clicking on **Data Sequence (Fig.16)** key, the data sequence is displayed.

Trender Graph

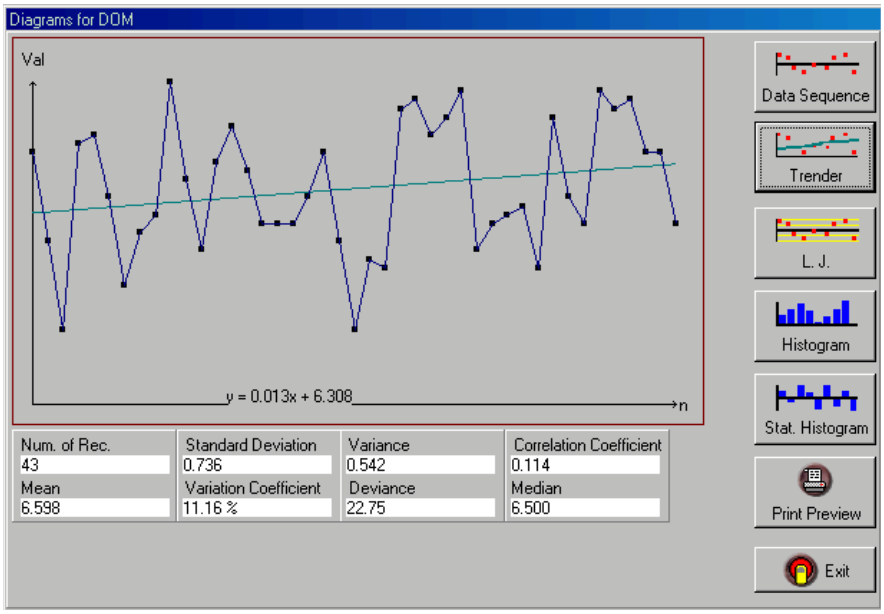


Figure 17

By clicking on Trender button, data sequence is displayed together with its related minimum square line (**Fig. 17**); in the lower part of the graph the equation for the line is shown.

L. Jennings Graph

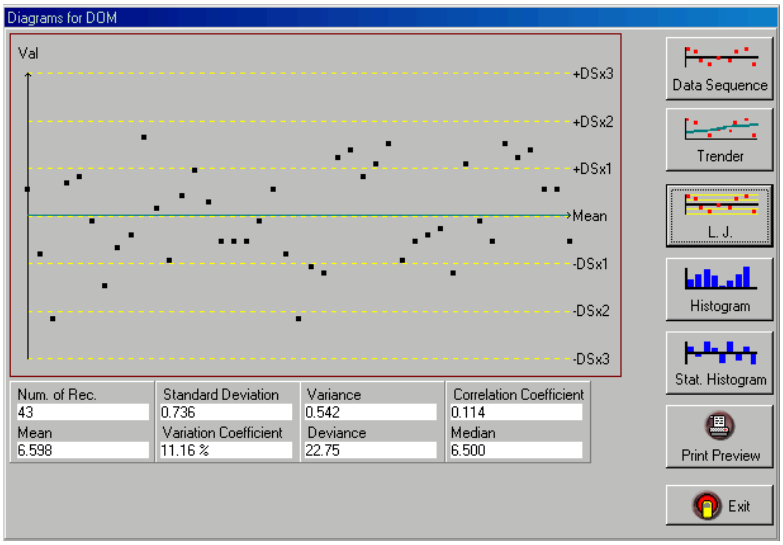


Figure 18

By clicking on **L. Jennings** button, L. Jennings graph is displayed for the selected data (**Fig. 18**).

Histogram Graph

By clicking on **Histogram** button, the histogram for the selected data is displayed (**Fig. 19**).

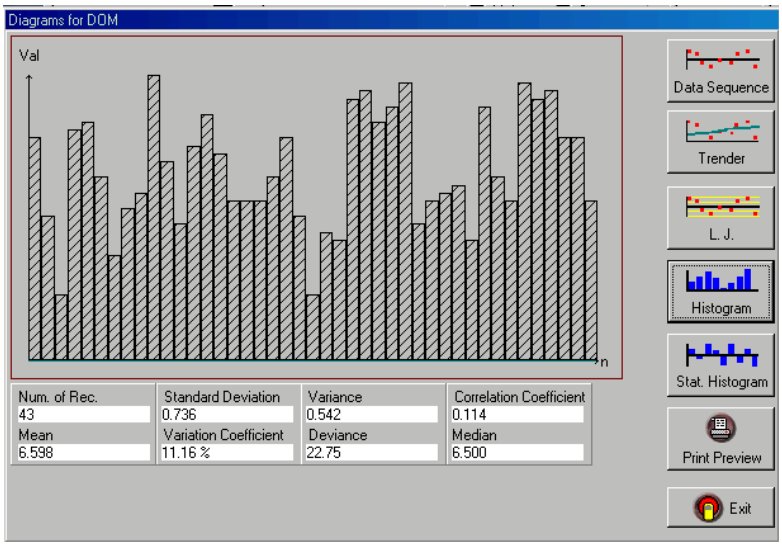


Figure 19

Statistic Histogram Graph

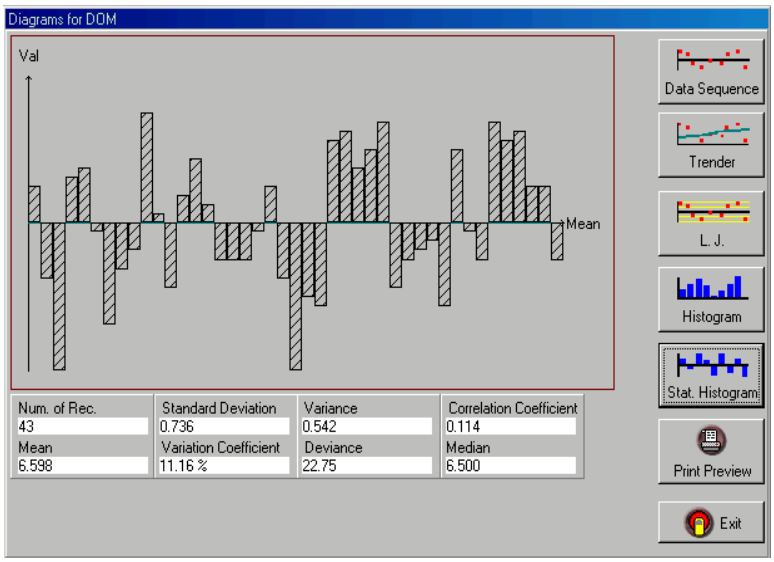


Figure 20

By clicking on **Statistic Histogram** button, the histogram for the selected data with respect to the mean value is displayed. (**Fig. 20**).

2.2. PRINCIPAL STATISTICS FORMULAS USED IN POPULATION

- ***Mean:***

$\bar{X}$: X1 ..Xn selected elements; being "n" the number of elements:

$$\bar{X} = \frac{X_1 + X_2 + \ldots + X_n}{n}$$

- ***Standard Deviation:***

SD: is a quantity that measures the spread of data across its mean value. If data is mostly located near the mean SD assumes a small value, otherwise a large value indicates large data spread.

$$DS = \sqrt{\frac{\sum_{i=1}^{n} (X_i - \bar{X})^2}{n-1}}$$

- ***Variation coefficient:***

CV%: is computed as the ratio between mean square error and arithmetic mean. CV% is a relative quantity and independent from the measurement unit used.

$$CV = \frac{DS*100}{\bar{X}}$$

- ***Minimum square line y = ax + b***

Where:

$$a = \frac{\sum XY - n\sum x\sum y}{\sum X^2 - n(\sum X)^2}$$

$$b = \sum Y - a\sum x$$

- ***Correlation Coefficient:***

$$CC = \frac{\sum[(Y-\bar{Y})*(X-\bar{X})]}{\sqrt{\sum(X-\bar{X})*(Y-\bar{Y})}}$$

- ***Variance:***

$$V = \frac{\sum X^2 - \frac{[\sum X*\sum X]}{n}}{n-1}$$

- ***Deviance:***

$$D = \sum X^2 - \frac{(\sum X)^2}{n}$$

Median:

The **Median** for an ordered ser of data is the central value or the arithmetic mean of the two central values, depending on the fact that the number of elements in the set be odd or even. In particular the median for N odd elements, is the X[(N+1)/2]th element.

Example.: given the following 9 elements set

1, 2, 2, 17, 21, 34, 34, 34, 67

Median = [X (N+2)]/2 = X[(9+1)/2] = X[5] = 21

median is 21, the fifth element.

The median for N even elements, is the { X(N/2) +X[(N+2)/2] }/2 element.
Ex.: be given the following 8 elements set

1, 2, 12, 24, 26, 45, 45, 46
{X[4]+X[5]}/2 = (24+26)/2 = 25

median is 25.

By comparing the median and the arithmatical mean, one can assume the existence of a measurement error or an asymmetry in the distribution function, in case these two quantities differ greatly.

2.3. INSERTING EXTERNAL ANALYSES

Press on the **New Record** in the **Utility** menu.

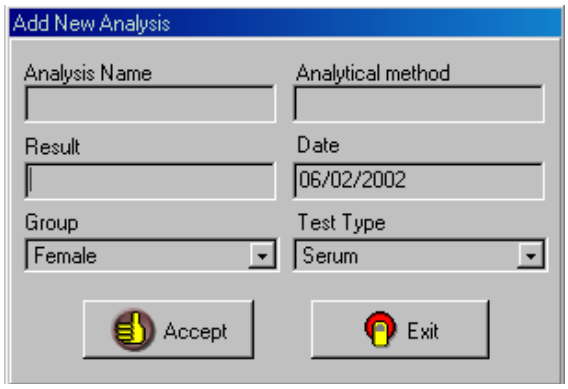


Figure 21

It is possible to store in the analyzer's memory results of other analyses not performed by the analyzer. These data will be saved into the archive and it will be possible to display statistics as well as analyses results.
The input screen **(Fig. 21)** shows the following fields:
Analysis Name, **Analytical Method**, **Result, Date**, **Group and Test Type**.
To insert a series of consecutive values for the new analysis, the results field should be programmed last. Then enter the results by pressing **Enter** on the keyboard (or the **Accept** button) to confirm each value.
By pressing the **Exit** key the external analysis insertion window closes and the entered data become available for statistical processing.
Data entry is case sensitive, meaning that an analysis name written in capital letters (YOU) is different from the one written in lower case letters (you) and is different from the one written with initial upper case letter (You).

2.4. OTHER MENU FUNCTIONS

The main menu contains three items, each of which has different commands. The most useful are also displayed in the navigation bar (Fig. 22)

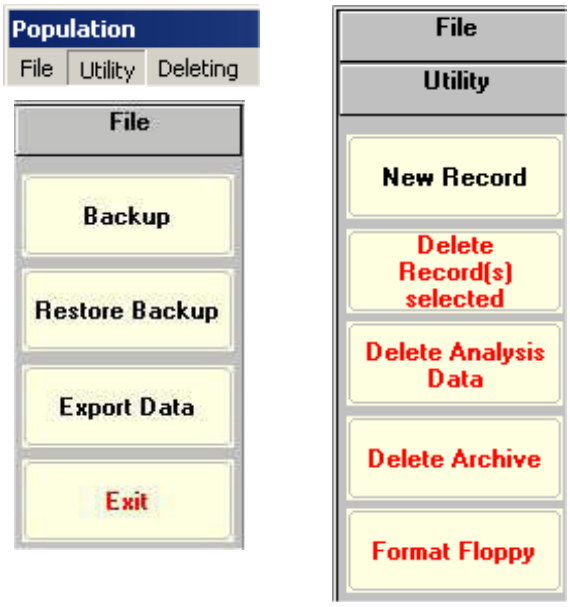


Figure 22

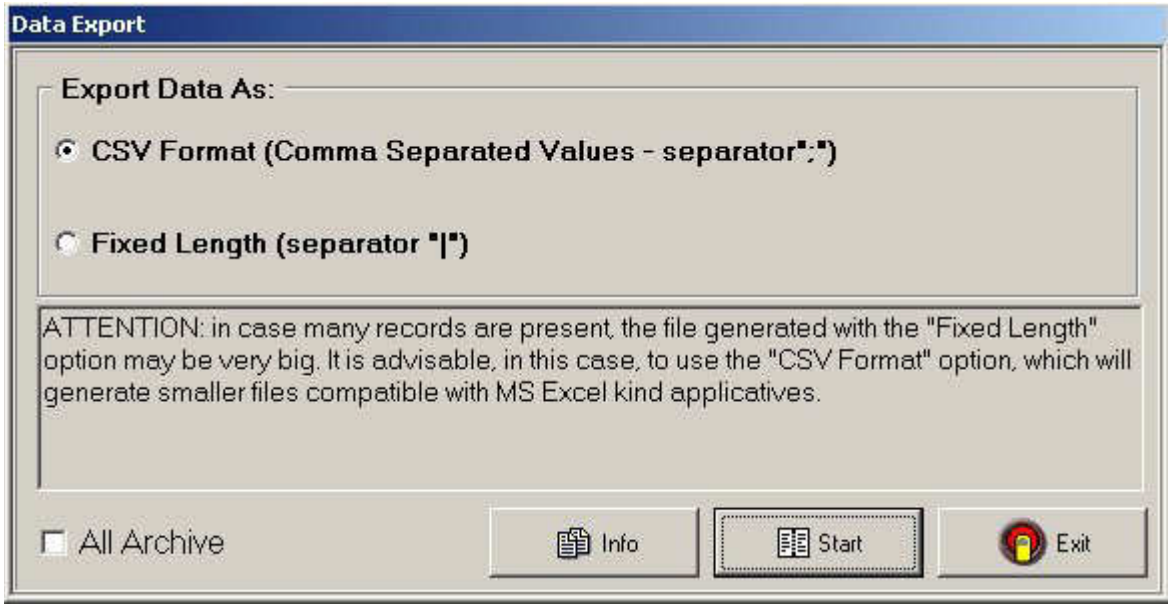
FILE MENU



Backup: creates a backup copy of the executed query. The backup copy can be saved on a floppy disk or the hard disk.

Restore Backup: used to restore the backup copy to its original position.

Export Data: this function allows exporting data in CSV (comma separated values) or Fixed length formats, compatible both with Word or Excel kind applicatives.

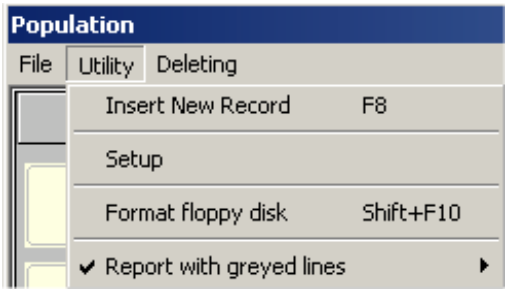


It is possible to export the whole archive (select **All archive**) or a query. To export a single query, it is first necessary to perform the query and then to click on the Export data option.
NOTE: the use of this function is very important to have constantly updated archives in a hard disk different from the analyzer's.
Once the *.csv or *.txt file has been created, it can be opened with Excel or Word. First open the appropriate program (both programs will open both kind of files, but the easier way is to use Excel for *.csv and Word for *.txt files). Then select "Open file" and in the "open" window, select in the field "File of type": "all files - *.*". Click twice on the file you want to open.

Exit: exits the application.

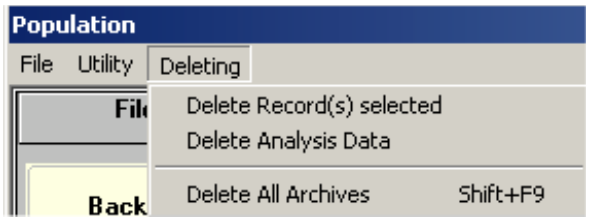
UTILITY MENU

Insert new Record: see the paragraph above (par. 2.3 and fig. 21)
Setup: opens the printer setup window (see also Ch. H Analyzer Setup, par. 2)
Format floppy disk: used to format a floppy disk.
Report with grayed lines: used to select whether to print the reports in "easy reading" format. Easy reading printing contains light gray lines alternated with lines the color of the paper.



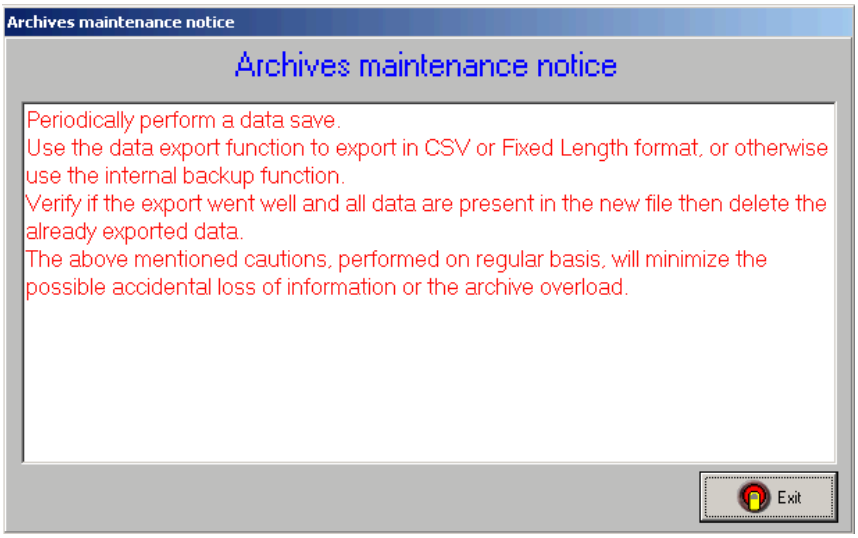
DELETING MENU

Delete Record(s) selected: it is possible to highlight several values in a query by holding down the CTRL key while selecting various results with the mouse cursor. These values can be deleted with this command.
Delete analysis data: deletes all the data related to the selected analysis and executed query. Selected analysis data that is not part of the query will be preserved.
Delete all archives: completely deletes the population archives.

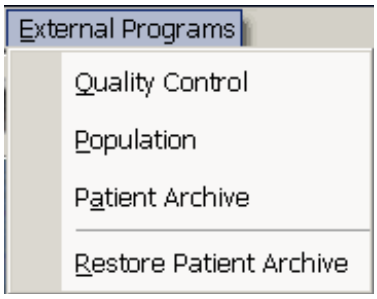


3. PATIENTS ARCHIVE

The **"Patients Archive"** module displays patients' information and allows report printing.
N.B.: due to the large dimensions that the archive can reach, it is advisable to run a backup at regular intervals, even monthly.
It is advisable to use the "Export Data" function in the FILE menu to export the archive in CSV or Fixed length format (see par 2.4 OTHER MENU FUNCTIONS). Once the archive is saved into a different location, please delete the internal archive to avoid the archive itself to crash.
An **automatic maintenance** has been added to the Patients Archive in order to avoid archive crash due to data overload. At periodical intervals, depending on the size of the Archive, the following maintenance message will appear.

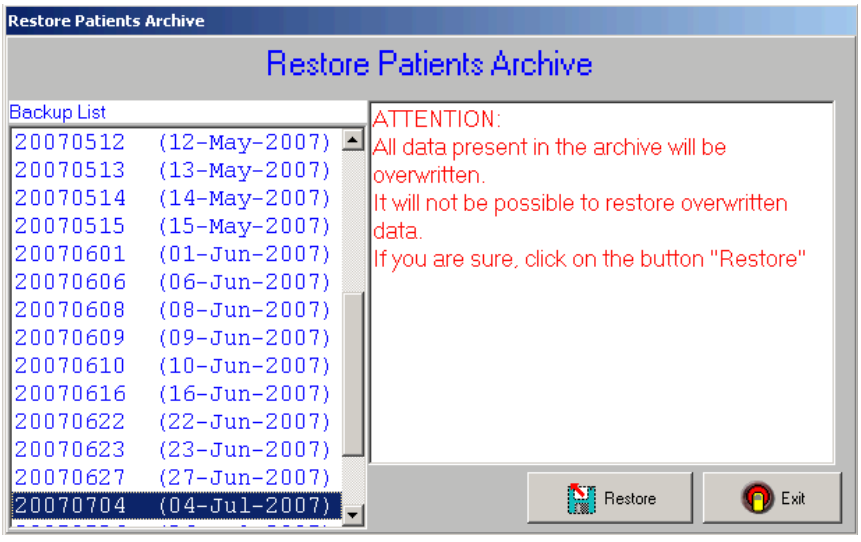


In case of Archive crash, it will be possible to restore one of the automatically performed backups.



Go to the External Programs menu, and select Restore Patients Archive.

The following window will appear. Select the file date you wish to restore and click on the Restore button. Pay careful attention: overwritten data can not be restored.



PATIENTS ARCHIVE

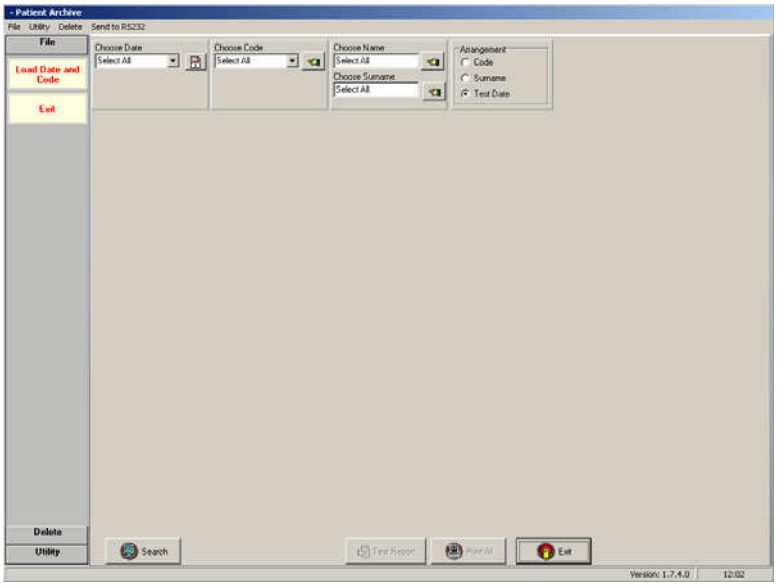


Figure 23

Its main features are:

- Displaying as well as data acquisition from updated analysis file.
- Innternal archives update.
- Internal and external archives display.
- Modifying values;
- Dynamic query that allows sorting, ordering and displaying data by date range, code, patient's name/surname,.

The program also contains other complementary functions:

- Archive backup;
- Printer set-up
- Deleting analysis file, query or the entire archive
- Floppy disk formatting

3.1. SELECTION (How to run a Query)

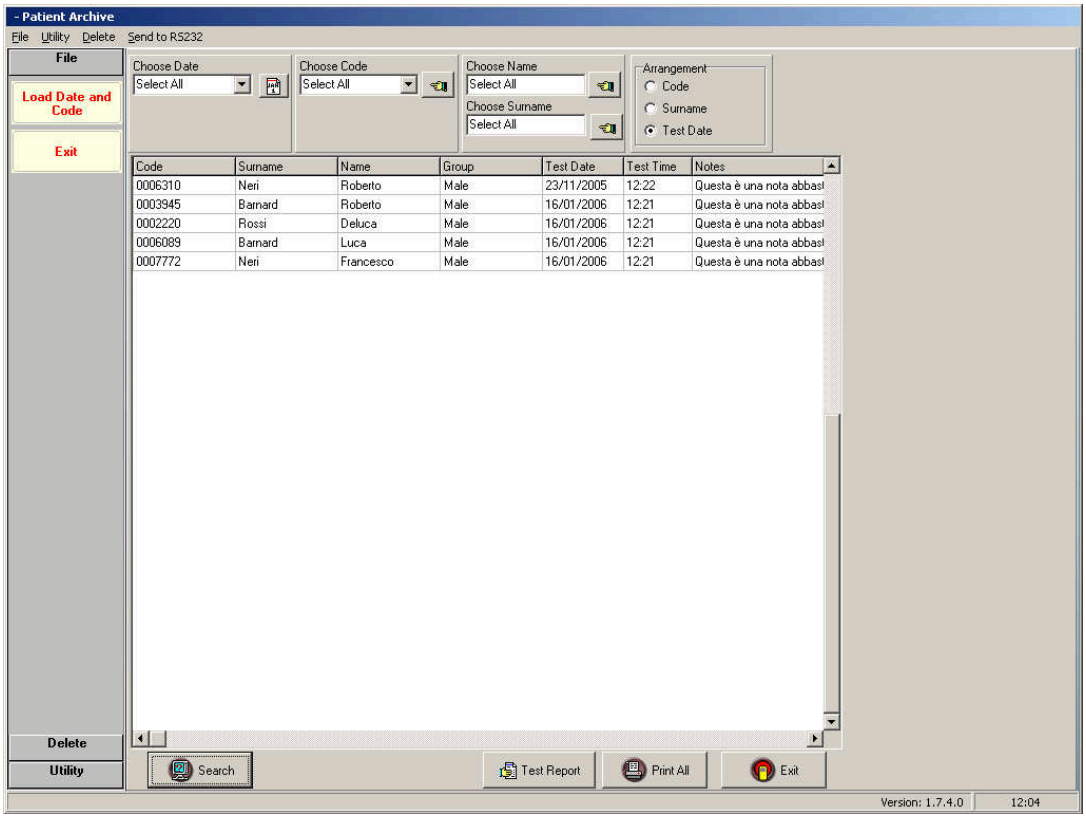
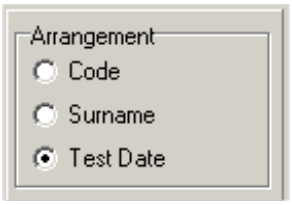


Figure 24

To run a query it is possible to specify various query criteria (Fig. 24) such as:

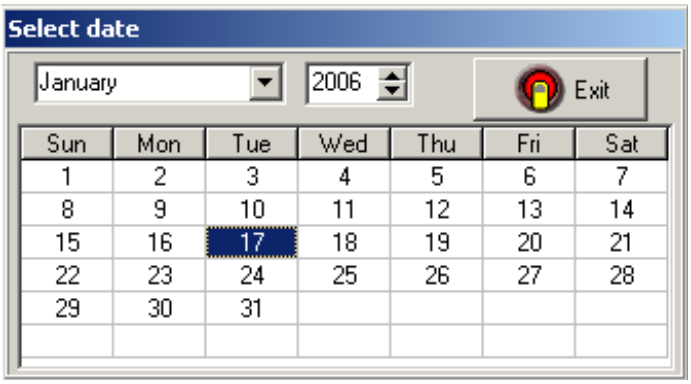
- Tests date range;
- Analysis code range;
- Name;
- Surname;
- Arrangement by code, surname, test date.

Select all is displayed by default in the fields. In this case, by pressing the **Search** button all the data present in the archive will be displayed.
Patients will be ordered by **Test Date** as long as the operator does not want to order by **Code** or **Surname**.

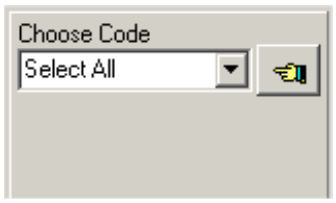


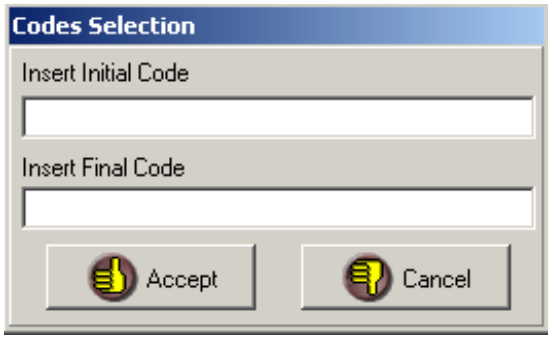
Choose date:
Clicking on the icon next to the editing window "Choose Date" for selection of tests date, it is possible to select the desired date range for search (query). It is possible to select the initial and final date with simple clicks in the window (shown at the left). Click on "exit" to save and close the frame. Press ESC to abort.



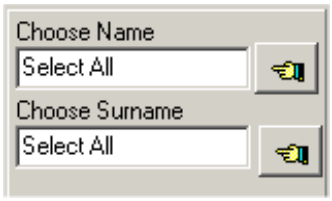


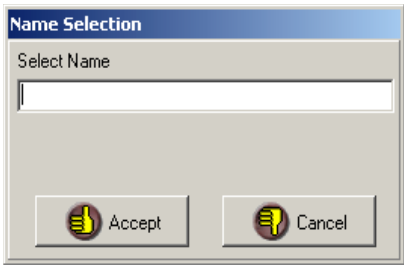
Choose code
It is possible to enter the information regarding the search range for desired analyses codes by clicking on the icon (hand) next to "Choose Codes". The search is case sensitive, meaning that the system distinguishes the capital letters (Upper case letters) from the small letters (lower case letters).
Clicking on the button "Accept" will save the values entered in the editing fields "Insert Initial Code" and "Insert Final Code". Pressing of "Cancel" will cancel the operation of the codes selection.

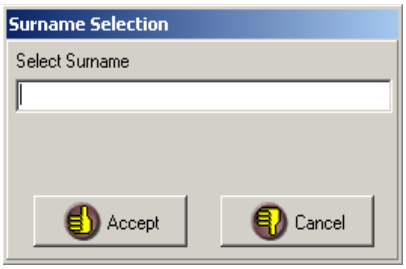




Choose Name/Surname
Click on the "hand" icon corresponding to "Choose Name" or "Choose Surname" to open the "Name Selection" window for searching by name or surname. Write name or surname in the dedicated field and click "Accept" to save the search or click "Cancel" to abort the operation. The search is case sensitive.







Once the search criteria have been fixed, click on **Search** button. The patients' data page will be displayed as in fig. 24.

3.2. PATIENTS REPORT

By clicking with the right button of the mouse on one of the records (Fig. 25) it is possible to select one of the functions described below.

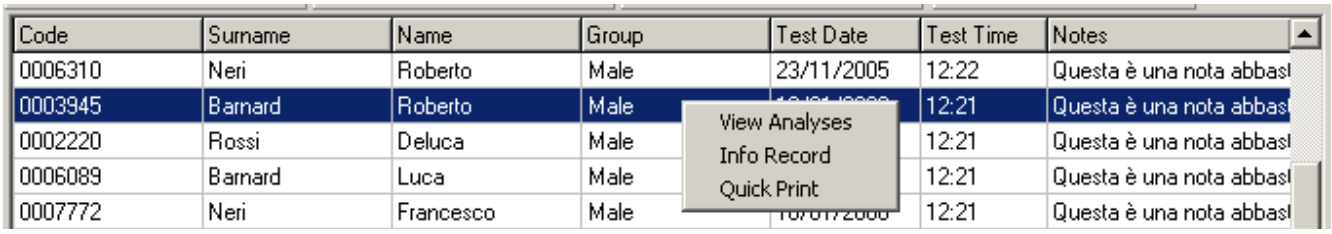


Figure 25

View Analyses: this can also be accessed with a double click and is used to display the information related to the selected patient (Fig. 26)
Info Record: displays the position of the selected record inside the executed query.
Quick Print: immediately prints the report for the selected patient.

View Analyses

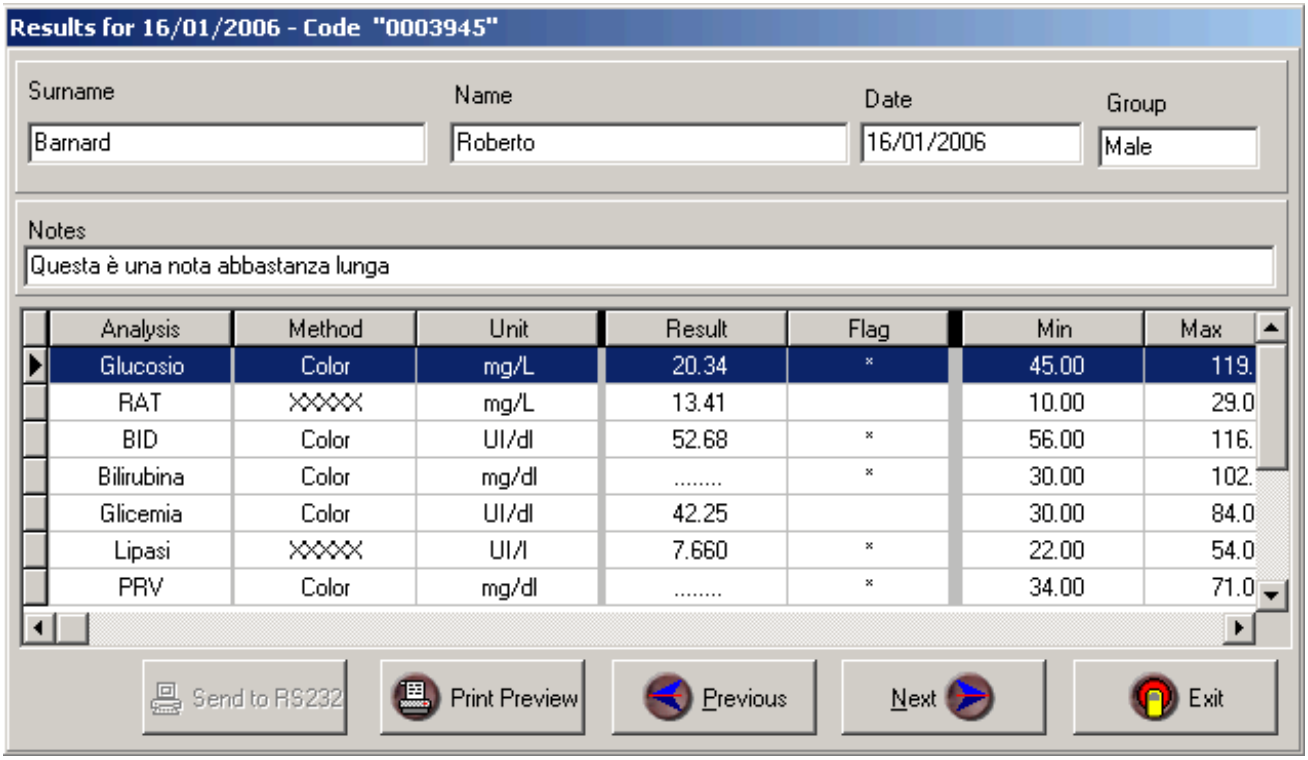


Figure 26

With the keys **Previous** and **Next** it is possible to scroll the entire patients list.
Send to RS232: sends the results to the Host Computer (when enabled)
Print Preview: opens the print preview of the patient's report.

In addition to the list of "Analysis" of selected code, the following informations are displayed: name, surname, test date, group, measurement unit, flags (an asterix identifies tests with flags; see flag page below), Min - Max range, and notes.

There is a possibility to change the analysis results by right-clicking with mouse on the relative line and selecting the option "Modify Value" (fig. 27). In the first field the "Old Value" of the result is shown, while in the second field "New Value" it is possible to insert the modified result. In case a wrong value is entered, then a screen message will alert the user to repeat the operation. Please pay careful attention to the correct entry of the decimal separator.

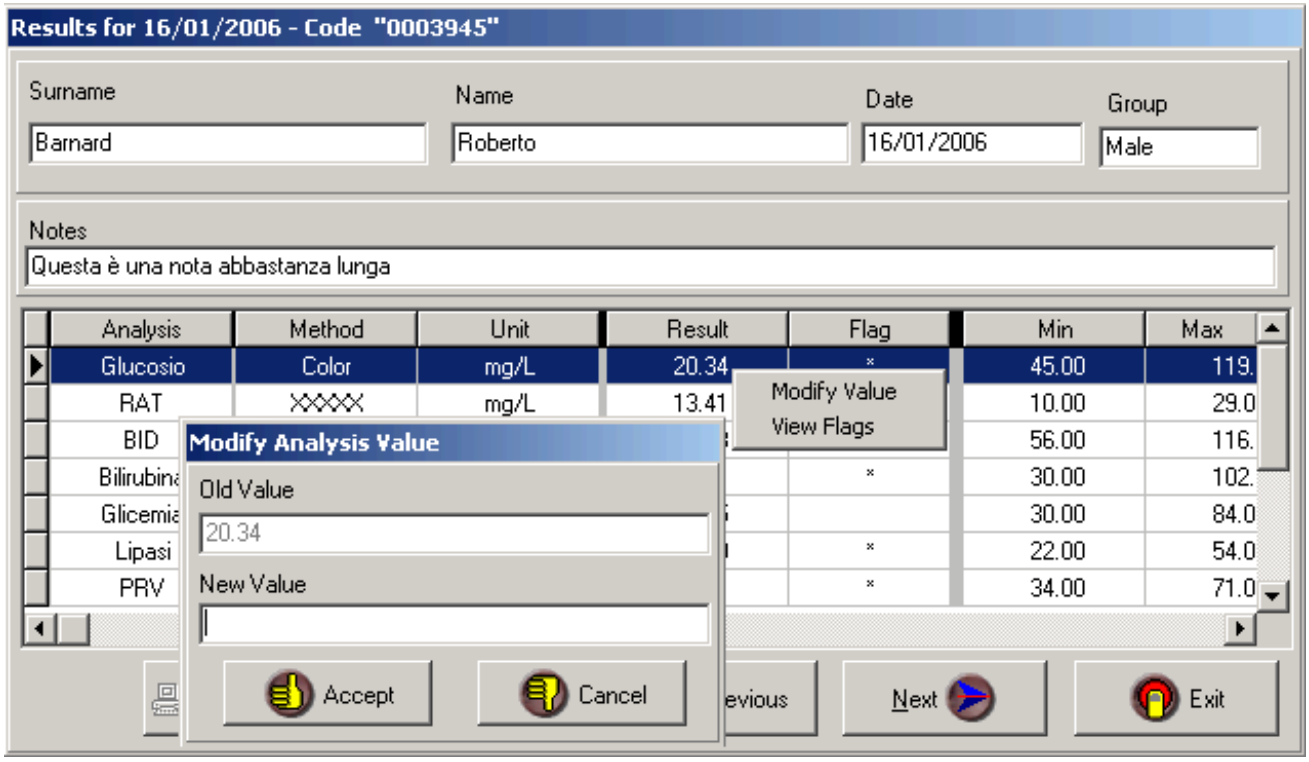


Figure 27

N.B.: the possibility of accessing the Patients' Archive module and modifying the analysis values is controlled by password and thus only accessible to authorized personnel.
See also Chapter E, Paragraph 1.7 Access Password.

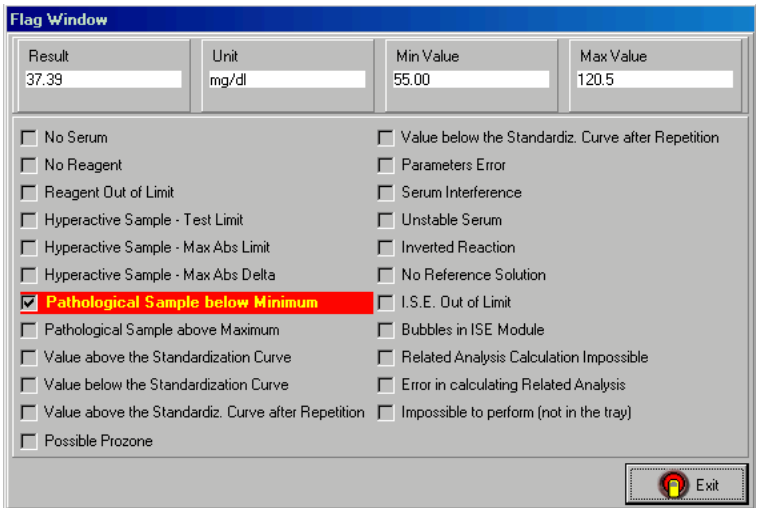


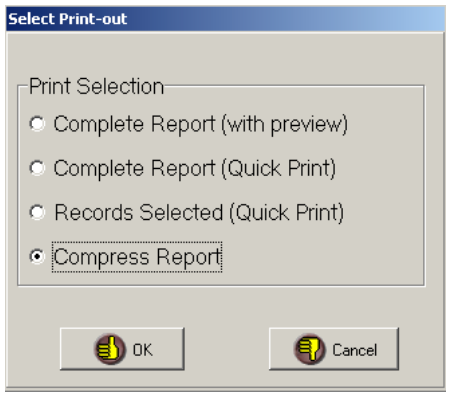
Figure 28

It is also possible to view the analysis flags by selecting the **View flags** option (Fig. 27) or with a double click on the analysis line (Fig. 28).

For more information on the meaning of the flags see Chapter G, paragraph 1.5.

3.3. PRINTING REPORTS

The **Print All** button in figure 24 is used for quick access to a print window with some options.



Complete Report (with preview): this option will allow printing of all patients' reports matching with the search criteria. A printing preview will be displayed.
The operator will start the actual printing of reports by for single patient.
Complete Report (Quick print): this option will allow printing of all patients' reports matching with the search criteria. Printing is immediate, with no preview.
Records Selected (Quick print): if only one or a few patients are selected, it will be possible from here to print only these reports
These three kinds of printings will produce reports as shown in Fig. 29.

Patient Archive

Code: 30002 **(Male)** **Test Date:** 23/04/2009
Surname: **Name:**
Notes:

Analysis	Method	Result (Result 2nd unit)	Range (Range 2nd unit)
ACIDO URICO DIALAB	TRINDER	4.748 mg/dl	3.400 - 7.000
BILIRUBINA DIRETTA	J.Grof.mod.	(*) 0.734 mg/dl	0.100 - 0.300
BILIRUBINA TOT.	J.Grof.mod.	(*) 1.317 mg/dl	0.500 - 1.200
COLESTEROLO DIALAB	TRINDER	(*) 95.34 mg/dl	140.0 - 220.0
D-CREATININA	JAFFE	1.065 mg/dl	0.800 - 1.400
FERENE DIALAB 2	FERENE	135.9 µg/dl	40.00 - 150.0
GLUCOSIO DIALAB	ColorimetricoGOD-PA	91.63 mg/dl	60.00 - 110.0
D-GOT	IFCC	(*) 42.75 UI/l	0.000 - 40.00
D-GPT	UI/l	42.79 UI/l	0.000 - 46.00
PROTEINE TOTALI	Biureto	(*) 6.417 g/dl	6.600 - 8.800
TRIGLICERIDI DIALAB	TRINDER	99.55 mg/dl	60.00 - 160.0
D-UREA	U.V.	40.46 mg/dl	10.00 - 50.00
ALBUMINA 4L	BCG	5.072 g/dl	3.500 - 5.500
GGT	Szasz	41.57 UI/L	0.000 - 50.00

Figure 29

In this kind of printout, all patient data are shown, followed by the analyses list with analytical method, result (with flags) and normal range.

Compress Report, will produce a different kind of report, where only analyses are listed, with no reference to the pertinent patient. A printing preview will be displayed (Fig. 30).

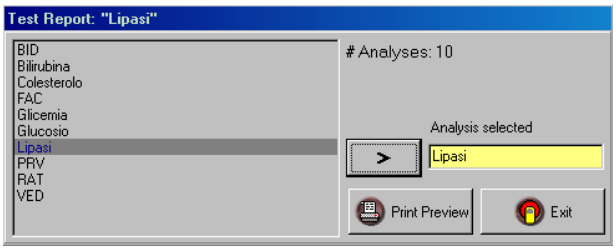
Lipasi	<Color>	(*)	<NC> UI/dl	24.00 - 86.00
Bilirubina	<Color>	(*)	<NC> UI/l	16.00 - 68.00
Glicemia	<Trinder>	(*)	<NC> UI/l	31.00 - 83.50
FAC	<Jundrassik>		60.91 UI/l	53.00 - 99.50
Colesterolo	<XXX>		48.50 mg/L	32.00 - 101.0
Glucosio	<XXXXX>	(*)	<NC> mg/L	57.00 - 108.5
BID	<Jundrassik>	(*)	<NC> mg/dl	56.00 - 132.0
RAT	<Jundrassik>		98.88 mg/L	52.00 - 108.0
Glicemia	<XXX>		53.51 mg/dl	18.00 - 72.00
Bilirubina	<Jundrassik>	(*)	<NC> mg/dl	25.00 - 63.50

Figure 30

There is another type of printing by test option in the main window of the Patient Archive (Fig. 24):



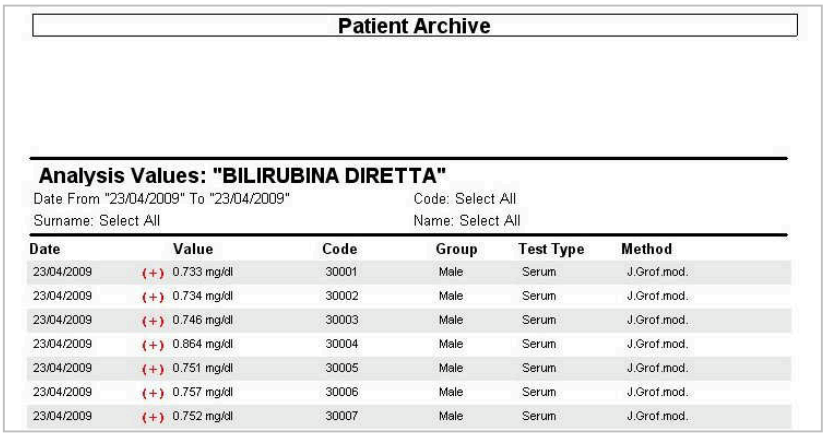
Test Report: from here it is possible to select one of the available tests and to print the corresponding results (Fig. 31 and 32)



Select the test, move it into the **Analysis Selected** field with **>** and click on **Print preview**

Figure 31

All results matching with the search criteria are displayed.



Patient Archive

Analysis Values: "BILIRUBINA DIRETTA"

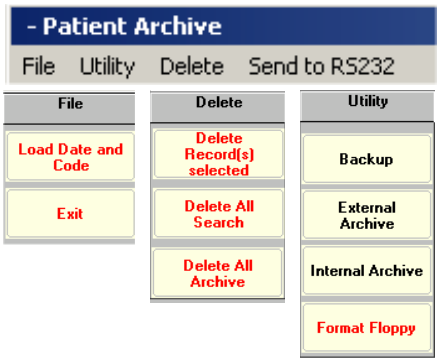
Date From "23/04/2009" To "23/04/2009" Code: Select All

Surname: Select All Name: Select All

Date	Value	Code	Group	Test Type	Method
23/04/2009	(+) 0.733 mg/dl	30001	Male	Serum	J.Grof.mod.
23/04/2009	(+) 0.734 mg/dl	30002	Male	Serum	J.Grof.mod.
23/04/2009	(+) 0.746 mg/dl	30003	Male	Serum	J.Grof.mod.
23/04/2009	(+) 0.864 mg/dl	30004	Male	Serum	J.Grof.mod.
23/04/2009	(+) 0.751 mg/dl	30005	Male	Serum	J.Grof.mod.
23/04/2009	(+) 0.757 mg/dl	30006	Male	Serum	J.Grof.mod.
23/04/2009	(+) 0.752 mg/dl	30007	Male	Serum	J.Grof.mod.

Figure 32

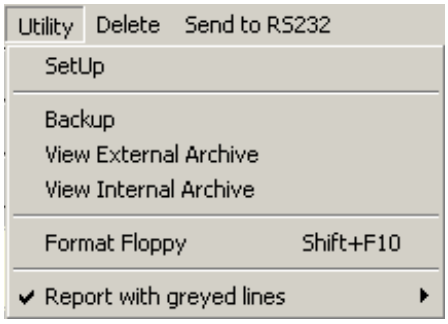
3.4. OTHER MENU FUNCTIONS



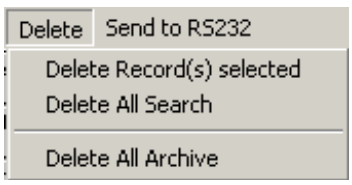
Other menus are available with relative command in the main page of the Patient Archive (Fig. 23), some of these are also present in the navigation bar.



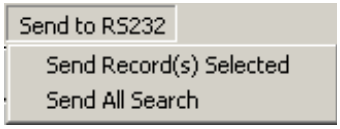
FILE
Load Date and Code: used to load the date for the test execution dates and patients codes so that they are available in the query criteria "scroll-box" (par. 3.1.).
Export Data: has the same function as in the Population archive: see par 2.4 OTHER MENU FUNCTIONS
Exit: is used to close the Patients Archive program.



UTILITY
SetUp: opens the printer setup.
Backup: creates a backup copy of the selected search, without deleting files from the HD. To create the backup it is necessary to first perform a search, then select a location for the backup files.
View External Archive: click on this button, select the location where the backup files are and then press the search button to view data.
View Internal Archive: press this button to go back to the internal archive after having viewed an external backup file.
Format Floppy: it is used to format a floppy disk.
Report with grayed lines: used to select whether to print the reports in "easy reading" format. Easy reading printing contains light gray lines alternated with lines the color of the paper.



DELETE
Delete Records Selected: Allows deletion of only the randomly selected records.
Delete All Search: it deletes the whole performed search.
Delete All Archive: it deletes the whole archive.



SEND TO RS232
Send Records Selected: sends randomly selected records to the host computer.
Send All Search: sends the whole performed search to the host computer.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER G

1. DISPLAYING AND PRINTING RESULTS **Page: 2**
- **1.1. Results per Patient** **Page: 3**
- **1.2. Results per Test** **Page 8**
- **1.3. Displaying Real-Time data** **Page: 9**
- **1.4. Reaction graphs** **Page: 11**
- **1.5. Flags list** **Page: 13**
- **1.6. Sorting results in RT** **Page: 14**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.

Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. DISPLAYING AND PRINTING RESULTS

The representation of the test results can be accessed through the specific icons (Fig. 1) for the two available options: **"View results for sample"** (results will be displayed for patient) and **"View results in real time"** (results will be displayed as the single tests are read).

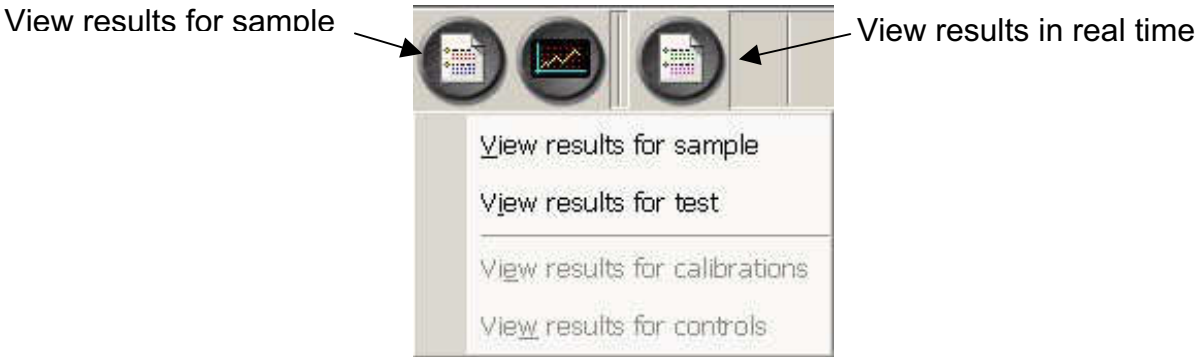


Figure. 1

By clicking on the icon for **View results for sample** the operator has the possibility of viewing the results **by sample** or **by test** (Fig. 1).

In the first case the patient data are displayed together with all the analyses run on that sample. In the second case the results of performed tests are displayed, grouped by analysis.

Moreover it is possible to view the results for the calibrations or the controls in the dedicated RT pages.

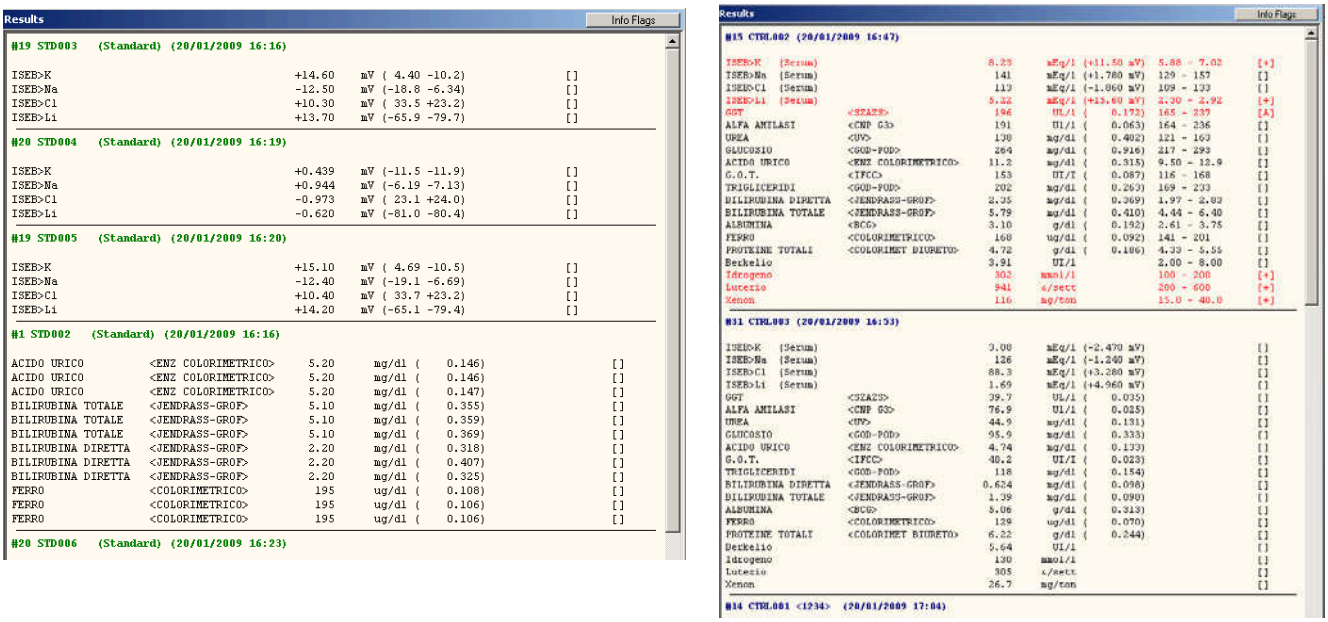


Figure. 2

<NC> WRITTEN INSTEAD OF THE RESULT

The paragraphs below (for example see fig. 4 or fig. 8) display the result pages in real time. It is possible to read **<NC>** "not calculable" in place of the value. This refers to values that cannot be calculated for one of the following reasons:

- no serum
- no reagent
- no washing solution
- no diluent
- no solution (I.S.E.)
- incorrect parameters
- expired reagent
- inverse curve

<NC> results can normally be archived (only in the patient archive) with the other results (see Ch. H, par. 2. Analyzer Setup) or they can be stored in the work lists to let the operator re-run the sample as soon as possible. In this case, the patient with the **<NC>** result will be regularly archived and a copy will be left in the work lists.

<NC> only appears on the result page in real time, it will be replaced by a series of dots "…." in the patient archive.

1.1. RESULTS PER PATIENT

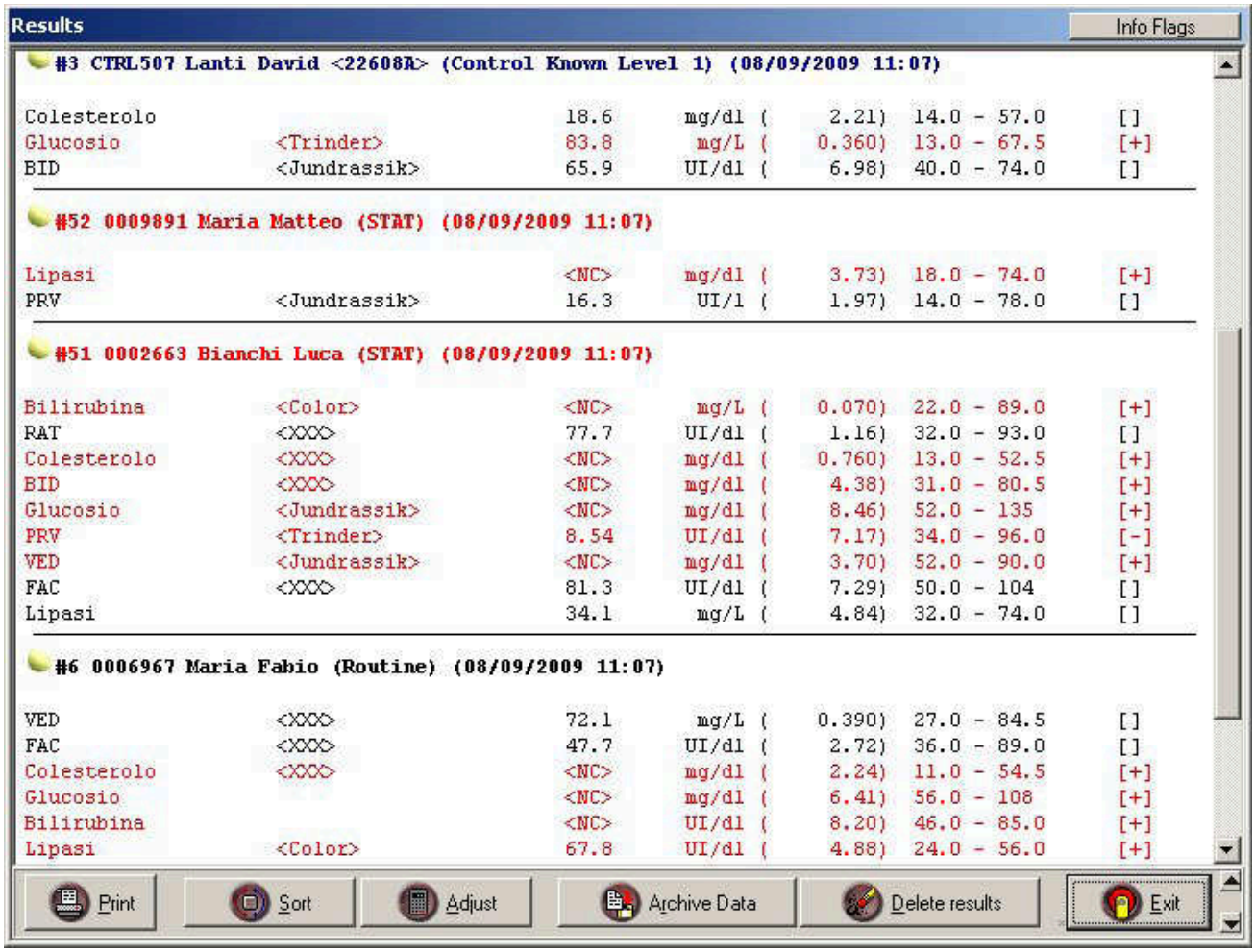


Figure 3

The "Patient's" data display page is shown in **Figure 3.** It can be accessed through the specific icon (Fig. 1).



In this area information related to calibrations is represented, like the values of calculated factors or any types of errors that occurred during execution.
If there is no data the page appears blank. A color code makes it possible to quickly identify the information:

- red text: presence of flags in at least one test of the sample
- blue text: controls
- green text: calibrations
- black text: no anomaly in the test or the entire sample

It is a brief representation of data and allows visualization of results of patient in execution as the tasks for the single patients are completed.
Once the results are archived, the information present in this page will no longer be available.
The following information are displayed for each sample:

a) Sample Position (#XX) Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.

b) Sample Code For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.
It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph **1. "Quality Controls"**).

c) Surname, Name Patient's personal data.

d) Sample Type The relationship of Sample to one of the groups: Routine, STAT, CTRL or STD is indicated between brackets.

e) Date and time Indicated when (date and time) the sample was performed.

f) Results The results of test attributed to patients are represented with:

```
FAC          <Color>          38.1     mg/L (    1.57)  53.0 - 102     [-]
VED          <Trinder>        19.7     mg/L (   0.910)  17.0 - 67.5     []
```

- full name of the analysis
- execution method
- result
- unit of measurement
- absorbance read (between parenthesis)
- range of normal values
- any flags (between brackets – see also par. 1.5)

For automatic re-runs the values of the first and second determination are represented.

INFO FLAGS

In both types of result displays (per patient and in real time) an **Info Flags** button is available on the upper right.



It provides access to a page where the flags are listed, with a short explanation of the meaning of each one (Fig. 4).

Info Flags

Flag	Information
S	No Serum
R	No Reagent
W	No Additional Wash Solution
O	Reagent Out Of Limit
I	Hyperactive Sample (Test Limit)
A	Hyperactive Sample (Final ABS)
d	Hyperactive Sample (Max ABS Delta)
-	Pathological Sample (Below)
+	Pathological Sample (Above)
<	Sample Out Of Calibration Curve (Below)
>	Sample Out Of Calibration Curve (Above)
<<	Sample Out Of Calibration Curve (Below - After Automatic Repetition)
>>	Sample Out Of Calibration Curve (Above - After Automatic Repetition)
P	Not Enough Data To Calculate The Result
~	Sample Interference (Initial ABS)
±	Unstable Sample (Curve Acceptance)
!	Invalid Reaction Direction
r	No Serum Diluent
D	ISE Unstable
B	Bubbles in ISE
?	Impossible To Calculate A Relation Test (Not Enough Data)
X	Impossible To Calculate A Relation Test (Negative Value)
T	Test Is Not In The Current Tray
C	Positive Prozone Check
N	Reagent Expired
E	Recalculated Test
M	Error in the parameters (Instrumental Factor and Shift)

Exit

Figure 4

ADDITIONAL COMMANDS

The following commands are available in the data display page (fig. 3):



PRINT: Print command. It allows two options: Normal print-out (will print the pages as they are displayed i.e. samples will be printed sequentially) or Printout for sample (will print one single patient for each page). However, this is not a print-out in report format.

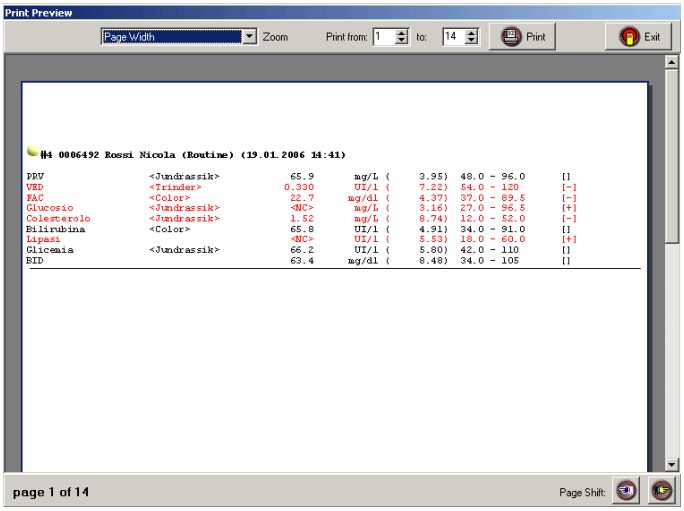
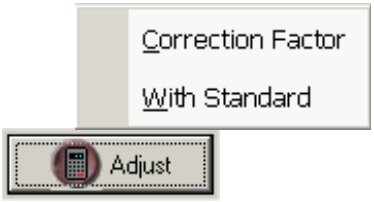


Figure 5

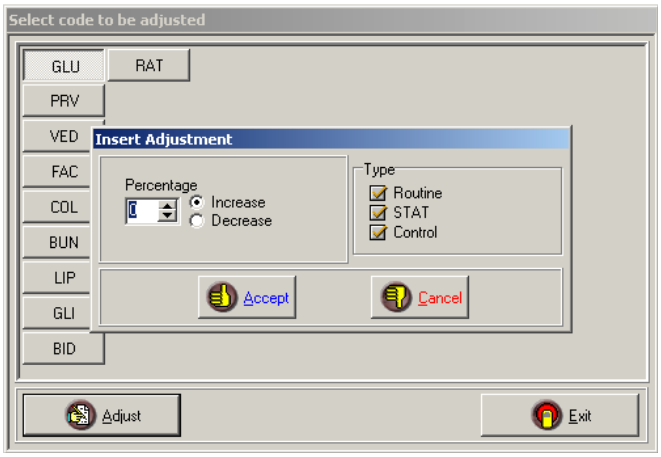
A print preview will be displayed (Fig. 5) where it is possible to select which and how many pages to print.

SORT: Data sorting command. This function is enabled only at the end of working session. The real-time data are displayed in random order as the analyzer returns them. The "Sort" command allows sorting based on the criteria selected in the Setup dedicated page (see par. 1.6 in this chapter).

ADJUST: Note: this parameter is not available in the US software version. Data re-reprocessing command. This function is enabled only at the end of working sessions. For patients re-run manually only the last result will be recalculated. The correction is made starting with the absorbance memorized for the single test.



Two types of data re-processing are possible. The first allows application of a percentage correction in increase or decrease. The second uses the last valid calibration as reference.



When recalculating the percentage or **Correction factor** (Fig. 6) a window is presented for selecting the test to recalculate, then by pressing the **Adjust** button, a mask appears for inserting the recalculation percentage (increase or decrease) and the type of sample to apply it to (routine, STAT and/or control). The maximum percentage allowed (both increase and decease) is 50%. By clicking on **Accept** the analyzer will make the adjustment.

Figure 6

In the correction **With standard** the analyzer runs the recalculation starting from the absorbance memorized for the test, thus the various analytical parameters and the last valid calibration are taken into consideration. In this case, if the instrumental factor and shift have been set in the analytical parameters, they will be used in calculating the new value.

N.B.: If a recalculation result returns a value of 1,000,000 or higher, **<NC>**, not calculable will be shown instead of the result. If the returned result is negative, the **M** flag will be assigned: error in the parameters (instrumental factor and shift).

NB: In the correction With standard, I.S.E. and Relation Tests results will not be recalculated.

The **E** flag (recalculated value) will be assigned to all tests that undergo recalculation.

Use of the correction functions is only for operators authorized with a specific password (see chap. E, par. 1.7 Access Password).

ARCHIVE DATA saves all the data present on the page on the hard disk. After archiving, the data will be available, based on type, in the three external programs: Quality Control, Population and Patient archive. Archive data also includes the deletion of the data from the visualization pages (per patients and in real time) as well as reaction graphs. Therefore, it is a good idea to print any pertinent graphs before archiving data.

DELETE RESULTS deletes all the data from the visualization pages (per patients and in real time) as well as the page of reaction graphs. The data cannot be recovered.

EXIT: closes the page and returns to the main program, without modifying the data.

1.2. RESULTS PER TEST

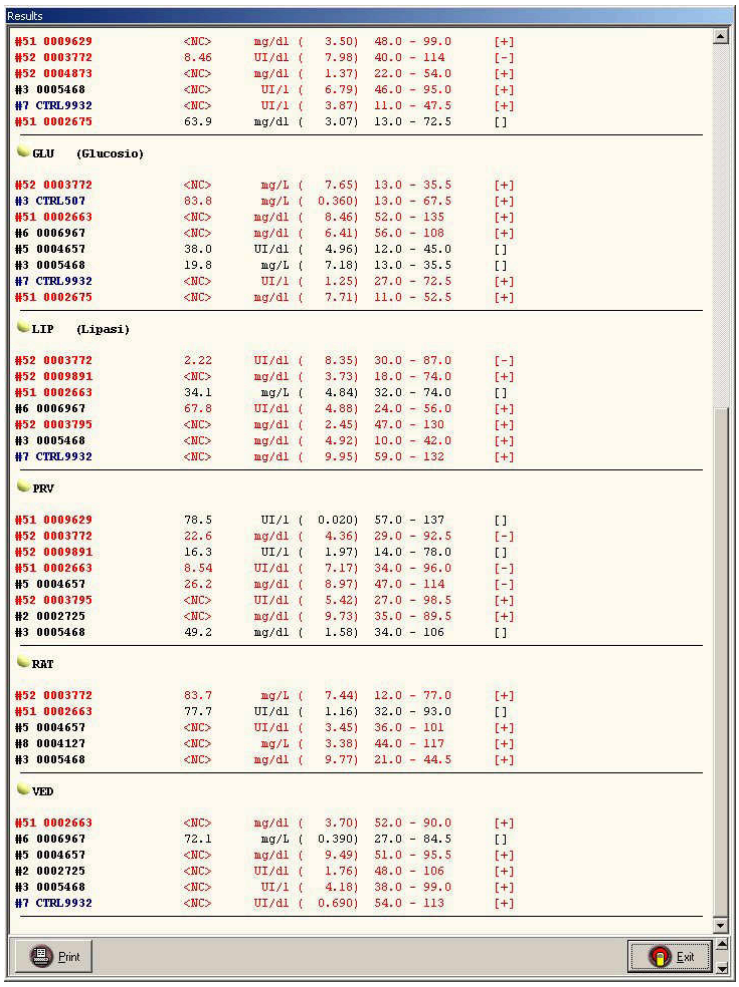


Figure 7

After the end of programmed task, the results can be viewed per **Test**. The test Results display page is shown in **Figure 7.**
The following information is displayed for each single test:

a) Code and test name The displayed code is the same read on the list of tests, while the full name between parenthesis is the one assigned by the operator in the analytical parameters (chap. C, par. 1.3.3.).

b) Sample Position (#XX) Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.

c) Sample Code For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.

e) Results The results of test attributed to patients are represented with:
- result
- unit of measurement
- absorbance read (between parenthesis)
- range of normal values
- any flags (between brackets – see also par. 1.5)

The following commands are available in the results display page:



PRINT: used to print the contents of the window. This is not a print-out in “report” format. A print preview will be displayed (Fig. 6) where it is possible to select which and how many pages to print.

EXIT: closes the page and returns to the main program, without modifying the data.

A window is also available on this page (**Info flag** button – see par. 1.1.) with information relative to the flags associated to the results.

PRINT-OUTS IN REPORT FORMAT

From the visualization pages mentioned in this chapter it is not possible to obtain print-outs for patients in report format. For more information on these type of print-outs, see chap. F par. 1.6 and chap. H, par. 2.).

1.3. DISPLAYING REAL-TIME DATA

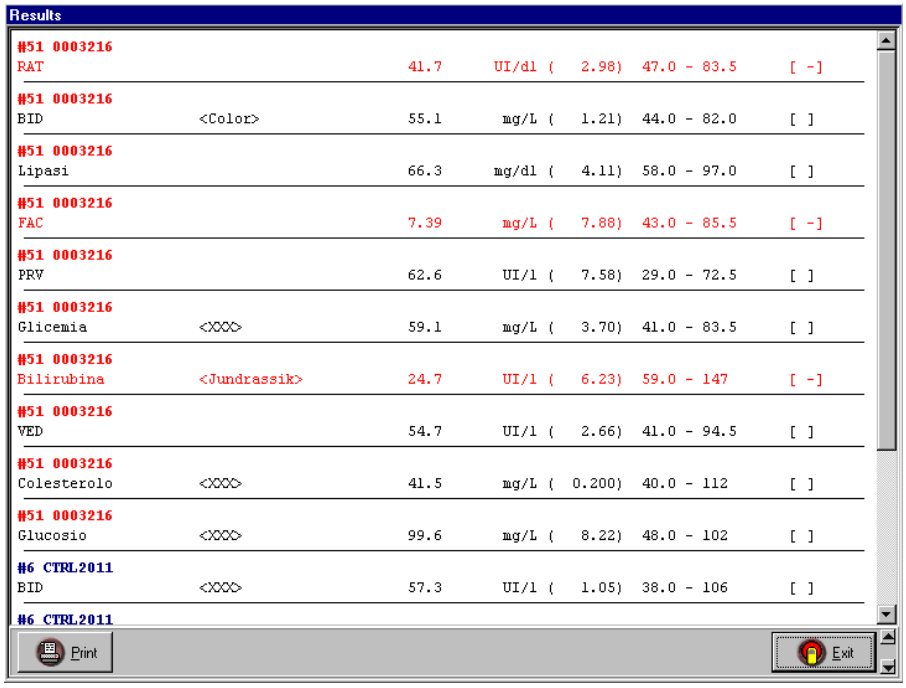


Figure 8

This page can be accessed through the specific icon (fig. 1). The data shown (Figure 8) refer to the results obtained by the analyzer in real time, i.e. as the tests are completed. For this reason the results of tests with a shorter incubation and reading time may appear first even if they belong to later patients. The results are not sorted in any way, not per patient, not for type of test. When no data is present this page is empty.
The data display is synthetic.

Once the results are archived, the information present in this page will no longer be available. The results of tests associated to flags are shown in red.

The following information are displayed for each single test:

a) Sample Position (#XX) Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.

b) Sample Code For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.
It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph **1. "Quality Controls"**).

c) Date and time The date and time the test was run is between parenthesis.

d) Results The results of test attributed to patients are represented with:

```
#1 0007685 (20.01.2006 09:36)
VED                <Color>          <NC>     mg/dl (    9.98)  33.0 - 77.5     [+]
#1 0007685 (20.01.2006 09:36)
Colesterolo        <Color>          49.8     UI/dl (    0.180)  40.0 - 106      []
```

- full name of the analysis
- execution method
- result
- unit of measurement
- absorbance read (between parenthesis)
- range of normal values
- any flags (between brackets – see also par. 1.5)

For automatic re-runs the values of the first and second determination are represented.

1.4. REACTION GRAPHS

This function can be accessed through the specific icon. It is used for displaying and eventually printing the graphs of the analyses. The page that opens displays the first available graph.

IMPORTANT: The graphic pages are available only after test runs and prior to data archival (par. 1.1.).

Graphs are divided into two parts by two dashed orthogonal axes. On the left part there is the incubation time graph, while on the right there is the reading time graph (Fig. 9).

On the right of the window, there are two frames containing the information concerning the absorbance determined during the two phases (incubation and reading times), Each division in the Time axis is approx 10secs.

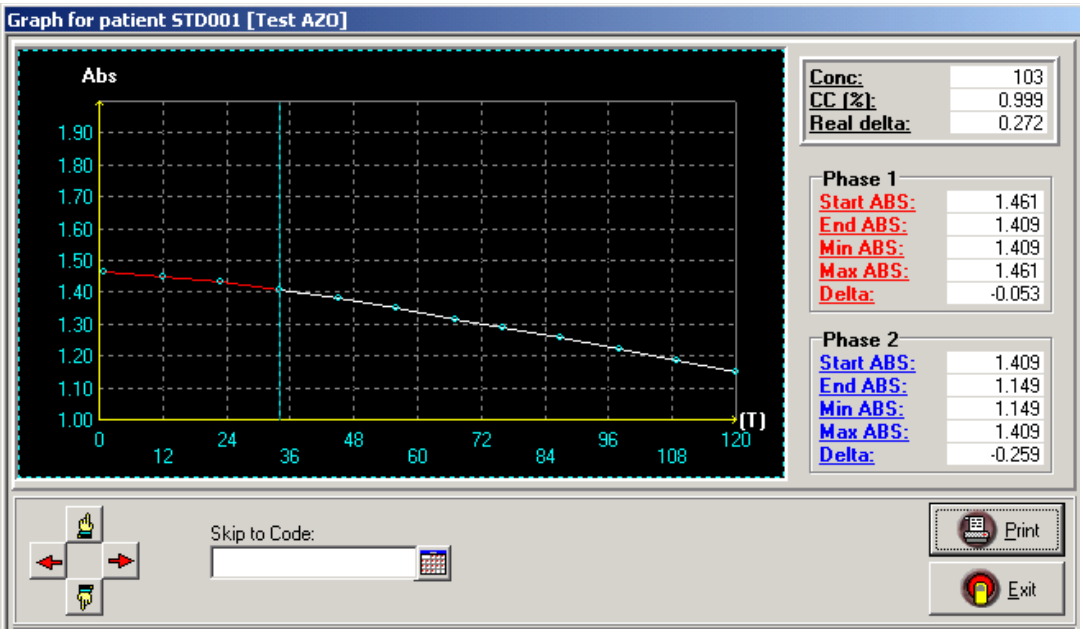
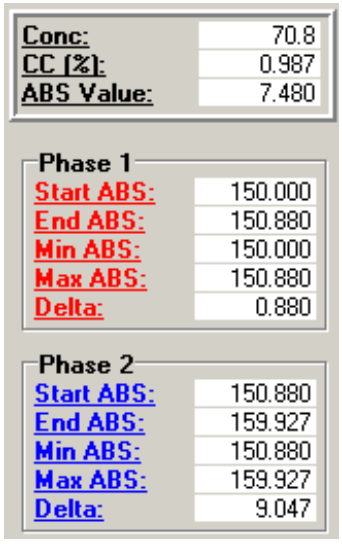


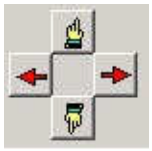
Figure 9



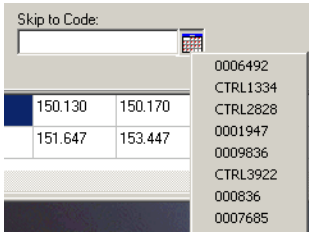
The following information is reported on the graph page (Fig. 9).

Conc: shows the test result.
CC%: shows the correlation coefficient compared to the test regression rate.
ABS Value: shows the test absorbance value.
Phase1: corresponds to the incubation phase for almost all the tests, with the exception of tests in two phases (such as sample blank). It shows the absorbance data detected by the analyzer during the test: start, end, minimum and maximum absorbance and the delta between the start and end absorbance.
Phase 2: corresponds to the reading phase or the second phase. The rest of the information is the same as phase 1.

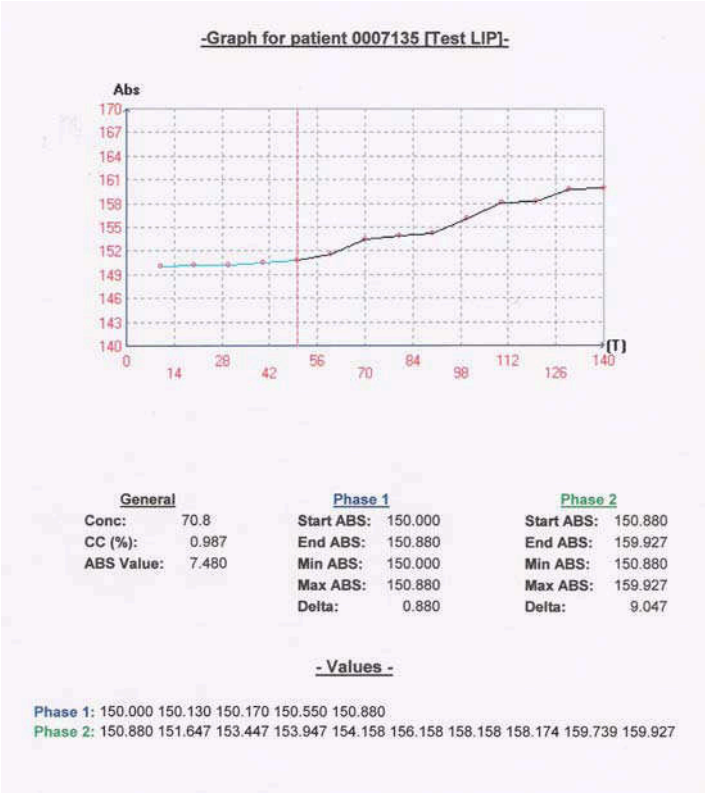
N.B.: The absorbance values read per single point in each phase are shown at the bottom, under the graph. This data can be exported into a file by pressing the **Export Values** button.



Using the up/down hand keys the user scrolls through different patients, while using left/right arrow keys, the different graphs for a single patient are shown (**Figure 9**).



By selecting an identification code, among the available in the **"Skip to code"** field, it is possible to go directly to the single patient.



Print: used to print the displayed graph. By accepting to print also thee data, all the absorbances corresponding to the reading points will be printed, otherwise only the information in the first part of the graph will be printed.

<- Absorbances of single points.

EXIT: closes the page and returns to the main program.

1.5. FLAGS LIST

The analyzer uses flag symbols to properly check analyses result. These symbols are printed adjacent to the result.
The following priority exists for the flags indicating hyperactivity:

I (Test Limit),

A (Reaction Limit)

d (Max ABS Delta)

The flags and their meanings are tabulated below:

FLAG	MEANING
+	Pathological above range
-	Pathological below range
I	Hyperactive sample (Test Limit exceeded)
d	Hyperactive sample (Max. ABS Delta surpassed)
A	Hyperactive sample (Reaction Limit exceeded)
O	Reagent Out of Limit
!	Inverse Reaction
S	Serum missing
R	Reagent missing
r	Dilution reagent missing (for diluting samples)
~	Serum interference
P	Errors in Parameters
±	Unstable sample (C.C. % greater than assigned value)
>	Sample above Calibration curve
>>	Sample above Calibration curve after repetition
<	Sample below Calibration curve
<<	Sample below Calibration curve after repetition
	No Error: result to be accepted
?	Impossible to calculate Relation Test, due to missing data (no Serum or Reagent)
X	Error in Relation Test (negative result)
C	Probable Prozone Effect (Prozone Check value exceeded)
T	Result processing impossible: analysis is not resident on the tray
N	Reagent expired - result set to 0 (zero), if the barcode is used
E	The test result has been recalculated
M	Error in the parameters (instrumental factor and shift)
W	Either one or both of the additional washing solutions is missing
	Only for BT3500
Z	Clot detection <ERROR> - A clot has been detected.
z	Clot detection <Warning> - Possible clot detected.

Note:
In report printing from patients' archive, all flags are replaced by the generic symbol ✸ (asterisk)**.**

In the patients archive active flags will be highlighted in red and will have the check in the corresponding box.



1.6. SORTING RESULTS IN REAL TIME

In the following chapter (chap.H), in the Setup section, it is explained how to get to the sorting page for the results in real time. It is possible to select the options as in the following picture.

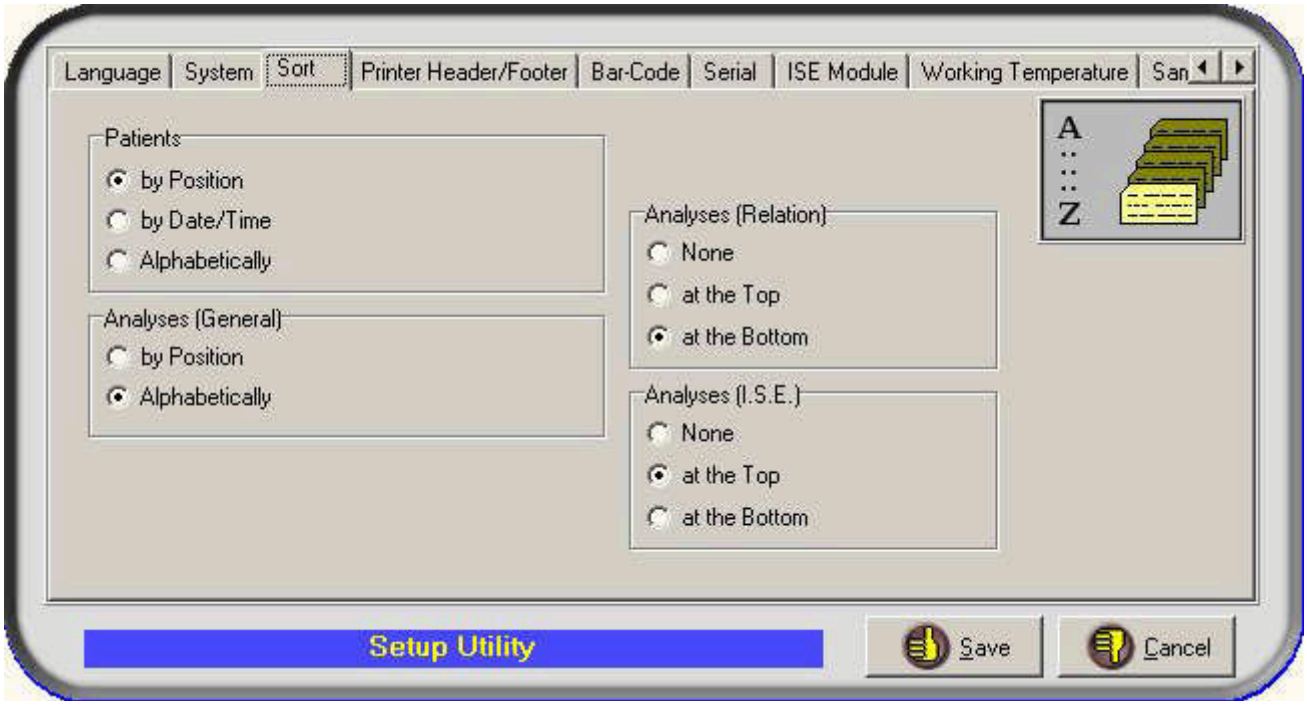


Figure 10

It is necessary first to select the desired options in the Setup and save. In the real time results page then, select the Sort button to arrange the results on the base of the selection performed in the Setup. The same arrangement will be performed both for the RT results and for the calibrations & controls dedicated pages.
Depending on the selection, the results in the real time page will be sorted as follows.

PATIENTS	ANALYSES	RELATION	I.S.E.	SORTED AS
BY POSITION	BY POSITION	None	None	ANALYSES – RELATION – I.S.E.
		At the bottom	None	ANALYSES – RELATION – I.S.E.
		None	At the bottom	ANALYSES – RELATION – I.S.E.
		At the bottom	At the bottom	ANALYSES – RELATION – I.S.E.
		At the top	At the top	I.S.E. – RELATION – ANALYSES
		At the top	At the bottom	RELATION – ANALYSES – I.S.E.
		At the top	None	RELATION – ANALYSES – I.S.E.
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION
		None	At the top	I.S.E. – ANALYSES – RELATION
	ALPHABETICALLY	None	None	ANALYSES, RELATION & I.S.E. all in alphabetical order
		At the bottom	None	ANALYSES and I.S.E. in alphabetical order - relation in alphabetical order
		None	At the bottom	ANALYSES and RELATION in alphabetical order – I.S.E.
		At the bottom	At the bottom	ANALYSES - RELATION – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	At the top	I.S.E. – RELATION – ANALYSES (ANALYSES & RELATION in alphabetical order)
		At the top	At the bottom	RELATION – ANALYSES – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	None	RELATION – ANALYSES & I.S.E. in alphabetical order
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION (ANALYSES & RELATION in alphabetical order)
		None	At the top	I.S.E. – ANALYSES & RELATION (ANALYSES & RELATION in alphabetical order)
Calibrations are sorted by position (on the tray), controls ran in the routine positions are listed before the controls ran from the dedicated positions.Both are sorted by position.				

PATIENTS	ANALYSES	RELATION	I.S.E.	SORTED AS
BY DATE/HOUR	BY POSITION	None	None	ANALYSES – RELATION – I.S.E.
		At the bottom	None	ANALYSES – RELATION – I.S.E.
		None	At the bottom	ANALYSES – RELATION – I.S.E.
		At the bottom	At the bottom	ANALYSES – RELATION – I.S.E.
		At the top	At the top	I.S.E. – RELATION – ANALYSES
		At the top	At the bottom	RELATION – ANALYSES – I.S.E.
		At the top	None	RELATION – ANALYSES – I.S.E.
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION
		None	At the top	I.S.E. – ANALYSES – RELATION
	ALPHABETICALLY	None	None	ANALYSES, RELATION & I.S.E. in alphabetical order
		At the bottom	None	ANALYSES & I.S.E. in alphabetical order - RELATION in alphabetical order
		None	At the bottom	ANALYSES & RELATION i in alphabetical order – I.S.E.
		At the bottom	At the bottom	ANALYSES - RELATION – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	At the top	I.S.E. – RELATION – ANALYSES (ANALYSES & RELATION in alphabetical order)
		At the top	At the bottom	RELATION – ANALYSES – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	None	RELATION – ANALYSES & I.S.E. in alphabetical order
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION (ANALYSES & RELATION in alphabetical order)
		None	At the top	I.S.E. – ANALYSES & RELATION (ANALYSES & RELATION in alphabetical order)
In the RT page, are listed: calibrations,– analyses – controls. Calibrations and controls are sorted by date/hour				

PATIENTS	ANALYSES	RELATION	I.S.E.	SORTED AS
ALPHABETICALLY	BY POSITION	None	None	ANALYSES – RELATION – I.S.E.
		At the bottom	None	ANALYSES – RELATION – I.S.E.
		None	At the bottom	ANALYSES – RELATION – I.S.E.
		At the bottom	At the bottom	ANALYSES – RELATION – I.S.E.
		At the top	At the top	I.S.E. – RELATION – ANALYSES
		At the top	At the bottom	RELATION – ANALYSES – I.S.E.
		At the top	None	RELATION – ANALYSES – I.S.E.
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION
		None	At the top	I.S.E. – ANALYSES – RELATION
	ALPHABETICALLY	None	None	ANALYSES, RELATION & I.S.E. in alphabetical order
		At the bottom	None	ANALYSES & I.S.E. in alphabetical order – RELATION in alphabetical order
		None	At the bottom	ANALYSES & RELATION in alphabetical order – I.S.E.
		At the bottom	At the bottom	ANALYSES - RELATION – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	At the top	I.S.E. – RELATION – ANALYSES (ANALYSES & RELATION in alphabetical order)
		At the top	At the bottom	RELATION – ANALYSES – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	None	RELATION – ANALYSES & I.S.E. in alphabetical order
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION (ANALYSES & RELATION in alphabetical order)
		None	At the top	I.S.E. – ANALYSES & RELATION (ANALYSES & RELATION in alphabetical order)
In the RT page, are listed: calibrations,– analyses – controls. Calibrations and controls are sorted alphabetically .				

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER H

1. ANALYZER TECHNICAL FUNCTIONS **Page: 2**
1.1. Service Functions **Page: 2**
1.1.1. Analyzer Utilities **Page: 2**
1.1.2. Mechanical Calibrations **Page: 4**
1.2. Diagnostic Functions **Page: 6**
2. ANALYZER SETUP **Page: 10**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.

Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. ANALYZER TECHNICAL FUNCTIONS

1.1. SERVICE FUNCTIONS

The analyzer has dedicated commands to allow **Service** and **Diagnostic** operations. The **Service** functions are divided into **Analyzer Utilities** and **Mechanical Calibrations.**
These functions are accessed from Analyzer's main menu or through the appropriate direct access icons**.**

The commands are available in the form of buttons. To access a function just push a button.
The **Exit** button on both pages closes the window and saves any settings.
The **Analyzer Utilities** include items (FCC Calculation, Lamp Setup, Temperature Test and Empty Fluidics) normally dedicated to technical assistance personnel. These functions should not be used unless they have been suggested by qualified personnel. Just like for the other parts of the program or analyzer, these functions must be used according to the intended use established by the manufacturer, failure to do so will result in warranty invalidation.

1.1.1. Analyzer Utilities



Figure 1



Direct Access Icon

To activate any of the following commands click on the corresponding button (**Figure 1**):
Wash with water: washes, with the washing solution (bidistilled water and surface active agent) the cuvettes and leaves them filled with water. This function is recommended when a work session has ended and the analyzer is not going to be used again immediately. However, after 20 minutes of inactivity, the analyzer goes into standby and automatically washes the cuvettes.

Wash cuvettes: is used for complete washing of the hydraulic circuit and reading cuvettes. Once the command is given, a message appears asking to insert the bottle (50 ml for BT1000, BT1500 & BT2000 Plus – 80ml for BT3000 Plus and BT3500) containing the dedicated washing solution (code 393) in the indicated position. This function must be run daily when the analyzer is shut off (using the guided shut down procedure) or at the end of the day if the analyzer is not shut off.

Extra wash cuvettes: is used for complete washing of the hydraulic circuit and reading cuvettes with a special solution. Once the command is given, a message appears asking to insert the bottle (20 ml for BT1000, BT1500 & BT2000 Plus in the upper reagent position – 80ml for BT3000 Plus and BT3500) with the special washing solution (code 393E) in the indicated position. This wash is run with an acid solution and is necessary at least once a week or if the analyzer returns inconsistent results for no apparent reason. This wash will reset the Diagnostic page maintenance counter.

Dilutor prime: Performs a filling-up cycle with distilled water of the hydraulic circuit and sampling system.

I.S.E. module prime: Fills up the fluidic circuit of the I.S.E. module (where available).

Extra wash I.S.E. Module: see Chapter L, par. 1.3.

Zeroing on water: Performs photometer zeroing with distilled water. This procedure can be performed either on request or automatically. In this second case, when the zeroing time has elapsed the analyzer will propose a message on the screen requesting zeroing.

When the analyzer is first turned on each day, it waits for the reaching of the steady state (stabilization of the Peltier temperature and lamp), then it requests the photometer zeroing. It is important to remember that zeroing is necessary to avoid any drift of the photometer zero.

Check volumes: The analyzer checks the volumes of reagents present in the reagent tray. These volumes are updated in the corresponding window **Reagents status** for the reagents insertion procedure (**F10** key).

Volumes calibration: used to allow the analyzer to create references used as a basis for determining the volume of reagents in the bottles and serum holder cups. A message will appear to guide the operator. Follow the instructions and place the empty containers in the correct positions. The bottles/cups are automatically filled with distilled water according to an internal procedure.

F.C.C. calculation: This procedure is for calculating the optical correction factor for the reading cuvettes. A screen message invites to insert a bottle with appropriate solution into the position #24 of the reagents tray. Generally a solution of Potassium Bichromate with absorbance around 0,500 Abs (read at 340 - 700nm) is used. The analyzer guides the user through the procedure. This function is password protected.

It is performed only when one or more cuvettes are replaced or after a thorough service is performed on the instrument computer (e.g. hard disk substitution) where correction factors may be lost.

Lamp Setup: this function is only necessary after the photometric lamp has been changed. It is used to align the new lamp to preset internal values. It also carries out photometer zeroing at the same time. It is advisable that only technical assistance personnel use this function.

Temperature test: Verifies thermostatic temperature of the reading cuvettes plate. For a correct measurement it is important that the thermometer of low temperature absorbance (miniature probe tip) is used. The measurement cuvette should be filled with 300 to 400µl of distilled water (between 200µl and 300µl for BT1500 & BT3500). It is also important that the measurements are taken approximately 20 minutes after the instrument has reached the steady state.

Empty Fluidics: This command completely empties the fluidic circuit. It is to be used exclusively as preliminary operation for maintenance or eventual moving of the instrument.

NOTE: if one of the analyzer functions is active, remember not to make modifications in the Setup program. This will cause a reset of the analyzer thus terminating the activated function.

1.1.2. Mechanical Calibrations

This function allows mechanical centering and adjustments for the different positions of the sampling arm, cuvettes plate, sample plate and reagents tray. Bear in mind that the analyzers are already factory-calibrated and a new adjustment is seldom necessary. To perform calibrations, move the mouse cursor on the desired function and click to confirm: the **[-] Dec.** and **[+] Inc.** command keys will be enabled on the screen, which determine the movement of the selected object either clockwise or counterclockwise, step by step. The **[*] Test** key lowers and lifts the sampling needle or the wash piston to check centering.

NOTE:
It is highly recommended to calibrate the trays (Sample/Reagent/Cuvette) first and then the positions of sampling arm. In addition the sampling needle must be centered on the required positions.



Figure 2



Direct Access Icon

The **Calibrations** menu is subdivided into three columns: **Clinical Chemistry Arm, I.S.E. Arm and Tray** as shown in **Figure 2**.
NOTE: bear in mind that only BT3000 Plus and BT3500 systems have two diluters, two sampling arms and the I.S.E. Module.

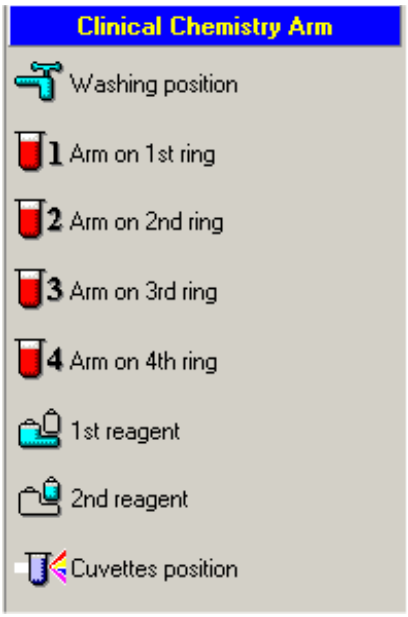
The following commands are available:



TRAY

Sample tray: centers the tray so that the arm is centered on the first position of the serum tray.
Reagents tray: It is recommended to insert a large reagent bottle matched with small bottle into position #4 prior to the calibration. By activating this command the reagents tray moves and puts position #4 below the hole for the first reagent. Center the bottle for the first reagent in this position. It is suggested to check also the position for the second reagent.
Cuvettes tray: The washing piston must be centered on the cuvette. Check correct centering through the piston up/down movement using the command **(*) Test**.

CLINICAL CHEMISTRY ARM



Washing position: Arm remains on the washing position upon which it must be centered.
Arm on 1st ring: The sampling arm moves to position #1 of the 1st ring (outer circle). Insert an empty cup into the tray to better observe the position. Center the sampling needle on the cup using the needle lower function **[*] Test** to better visualize the position.
Arm on 2nd ring: The sampling arm moves to the first position of the 2nd ring.
Arm on 3rd ring: The sampling arm moves to the first position of the 3rd ring.
Arm on 4th ring: The sampling arm moves to the first position of the 4thring.

Note: the first position for each ring is: #1, #27, #1 & #14 for BT1000, BT2000 Plus, BT3000 Plus. It is: #1, #27, #53 & #4 for BT1500 and BT3500

1st reagent: the sampling arm moves to the appropriate hole on the instrument's top for accessing 1 st reagent. Before starting the calibration a big bottle matched with a small one must be inserted in position n° 4. Center the sampling needle on the neck of the bottle.
2nd reagent: The sampling arm moves to the position for the second reagent corresponding to the appropriate hole for accessing small reagent bottle on the instrument's top. It is recommended to calibrate the reagent tray prior to calibrating the sampling arm.
Cuvettes position: The sampling arm moves over cuvettes tray. The sampling needle must be centered on the cuvette.

ISE ARM

The first five items and the **Cuvettes position (I.S.E.)** are the same as the corresponding button of the Clinical Chemistry Arm, see them for more information.
Arm on diluent: centers the I.S.E. arm above the tube containing the physiological solution for diluting the samples.
Arm on funnel: the I.S.E. arm moves above the I.S.E. mixing funnel. Center the sampling needle at the hole at the bottom of the funnel. It is very important that the needle is centered in this position to prevent it from touching the funnel walls during mixing.
For more info, see chapter L, par. 1.4.

1.2. DIAGNOSTIC FUNCTIONS

Diagnostic pages are accessible only from Analyzer's main menu (**Fig. 3**). The **Diagnostic** functions are partially reserved for approved service personnel only. Therefore the access to some of the functions is password protected.

It contains the following options: **Show F.C.C., Show Optical Transmission**, **Show Diagnostic** and **General Diagnostic**.

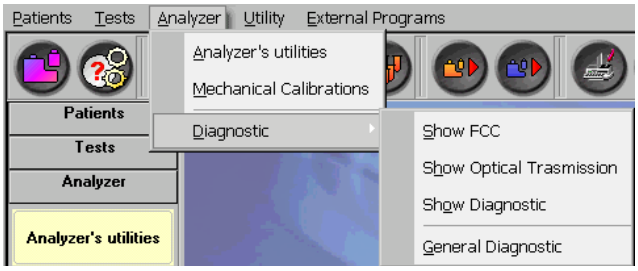


Figure 3

Show F.C.C.: It shows the optical correction factor calculated for all the reading cuvettes. For each cuvette, the mABS and the F.C.C. values (**Figure 4**) are reported. It also indicates the cuvettes with correction factor exceeding the preset limits (± 3%). It is possible to print this page.

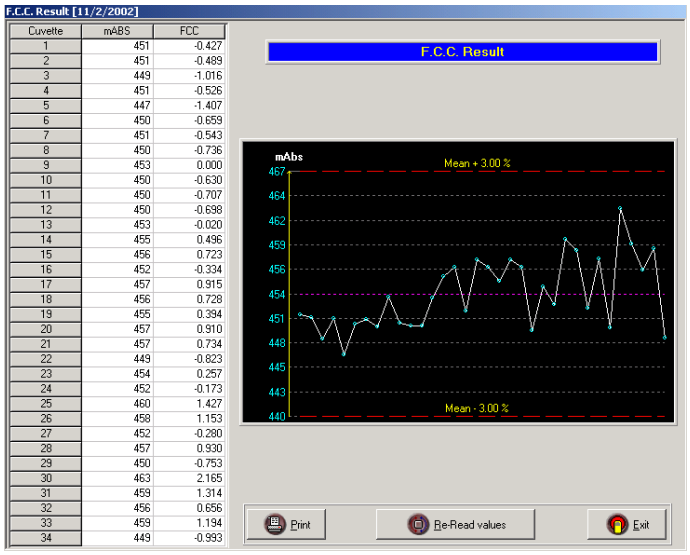


Figure 4

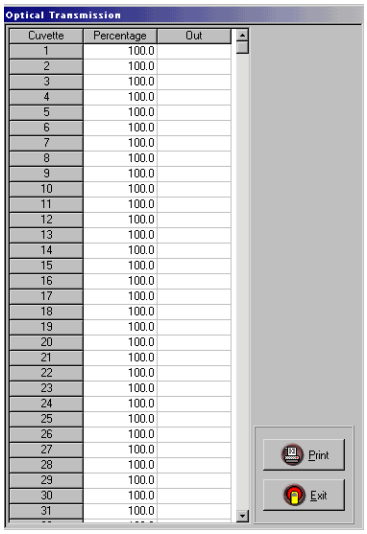


Figure 5

Show Optical Transmission: After each photometric zeroing, it indicates the percentage transparency of the cuvettes. The cuvettes with poor transparency are highlighted (**Figure 5**). If the optical transmission of a cuvette falls below a specific percentage (40% less than the mean of the calculated O.T.), the analyzer will eliminate it and will work with one less cuvette. If it becomes necessary to eliminate four or more cuvettes, the analyzer generates an alarm and will not allow work to continue. It is possible to continue to work with three damaged cuvettes.

Optical transmission of the cuvettes tends to decrease due to a series of factors, including lamp performance, opaque cuvettes etc.

Show Diagnostic: it shows the status of the various parts of the system that should be replaced regularly. This page shows the consumable parts, life cycles, remaining cycles and the possible replacement date (**Figure 6**). When at the analyzer start up, the message **There are the following obligations in diagnostic,** appears, it means that the indicated item has to be replaced or an action has to be undertaken. In the **Show Diagnostic** page there will be one or more red lines corresponding to the parts needing replacement (refer to **Chapter N**). Once the required maintenance has been performed, reset the internal counters of the analyzer, by clicking on the single voice described in the table on the right side.

Based on how the analyzer is used, the cycles may come to an end before the dates or vice versa. However, the maintenance requested by the analyzer should be carried out, even if the actual workload has been light. This guarantees perfect operation of the analyzer. If the analyzer has not been used for some time, it is advisable to replace the tube kits and possibly the seals, since they can deteriorate even if not used.

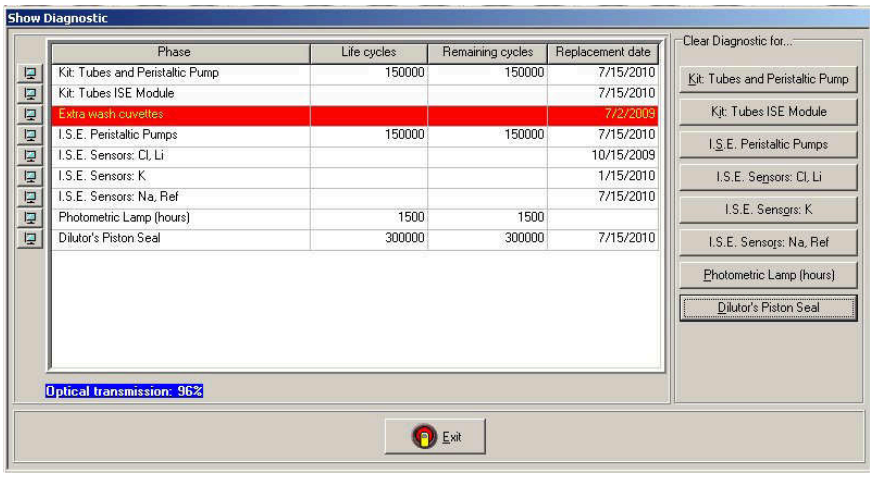


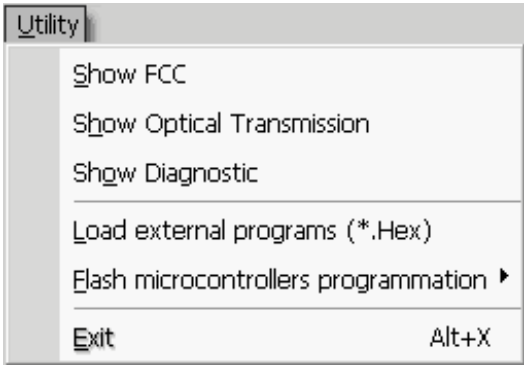
Figure 6

ATTENTION: the maintenance page shown in figure 6 is only an example. Check the consumable parts mentioned in the analyzer program, the cycles and replacement dates on the analyzer. Bear in mind that the replacement dates indicated on the maintenance page are a guideline as they are calculated on an average work day that may not reflect the needs of each lab.

General Diagnostic: This function is reserved for the Technical Assistance personnel for diagnosing problems that cause analyzer malfunction. There is free access to most of this program. However, the use of this program without the proper supervision of approved technical personnel, is under user's responsibility. Therefore it is highly recommended that the operator is assisted by the specialized technical personnel when using this program.
This page verifies the operation of the following devices and the operating phases:

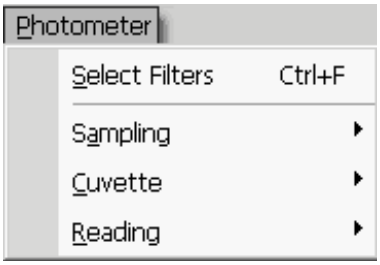
1) Photometer stability and operation.
2) Hydraulic functions: sampling, washing, and emptying of cuvettes.
3) ISE Module operation (where available).
4) Barcode operation and programming.
5) Stress program.

The **Diagnostic** page has four menus.

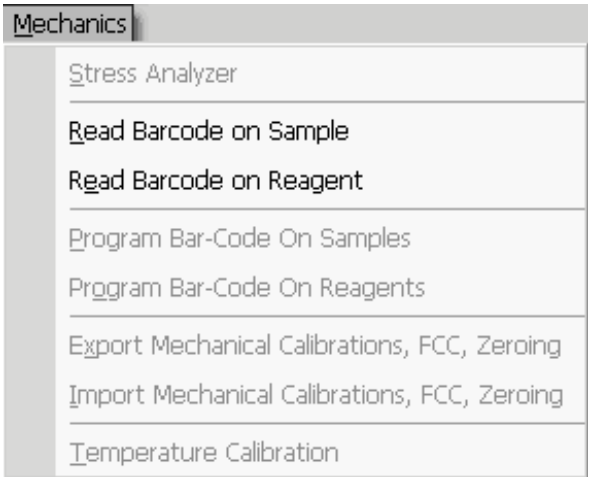


Utility: contains the same items previously explained at the beginning of the paragraph, plus the **Exit** command to close the diagnostic program.

Load external programs and Flash microcontroller programmation are options dedicated only to the Technical Assistance personnel, and may not appear at all in the menu.



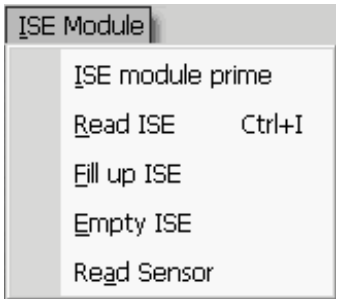
Photometer: is used to check the sampling and the readings executed by the photometer.
Select filters: used to select the filters for executing the reading.
Sampling: used to select whether to run a normal sampling or to use the serum as starter.
Cuvette: used to empty or fill a cuvette as selected by the operator. It runs a wash and fill cycle for the cuvettes.
Reading: used for reading the zero on filters, zeroing on water and reading (in mV and mAbs) of the contents of the cuvettes.



Mechanics: the items in this menu are not available. All the commands are only available with third level access (Technical Assistance).
Only read barcode on reagent and serum is available to operators.

Export / Import Mechanical Calibrations: the calibrations in the Diagnostic section can now be exported into a support different from the floppy.

Only for BT3000 Plus and BT3500



I.S.E. Module: all the items in this menu are available.
It is possible to run the I.S.E. module prime, read channels in mV, fill up I.S.E. hydraulic circuit with reference solution, empty I.S.E. and read the bubble sensor.

It is not advisable to use the commands in the **Diagnostic** program without the assistance of qualified personnel.

2. ANALYZER SETUP

This command is used for entering additional information on the various controls of the system. It can be accessed through the **Utility** ⇒ **Setup Analyzer** in the main menu. It is disabled during working sessions of the analyzer.
NOTE: if one of the analyzer functions is active, remember not to make modifications in the Setup program. This will cause a reset of the analyzer thus terminating the activated function.
By clicking on the **Setup Analyzer** command a screen displays various programmable items. Point the cursor on the desired title and click to confirm. After setup is done, click **Save** to save changes or **Cancel** to leave the program without saving (bear in mind that setup is an external program and must be closed once changes are made). It is highly recommended that operations in the setup program are performed by specialized personnel. It is advisable to keep track of the modifications made to the setup and the effects they can have on analyzer operation to avoid problems later on.



LANGUAGE: on this page (**Figure 7**) it is possible to select the language (for example English or Italian) from those available).

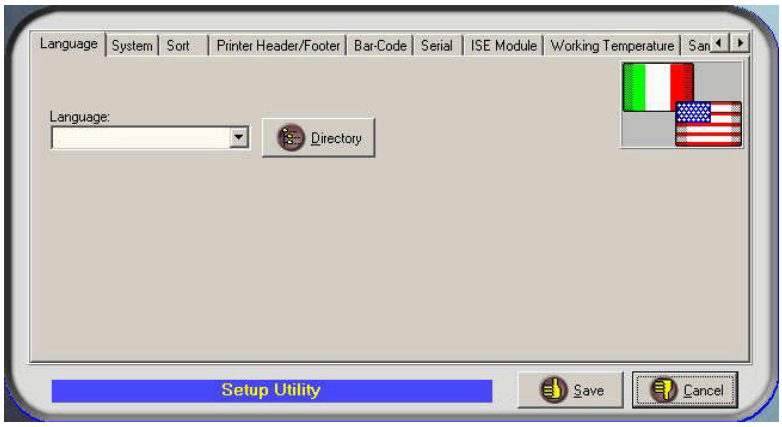
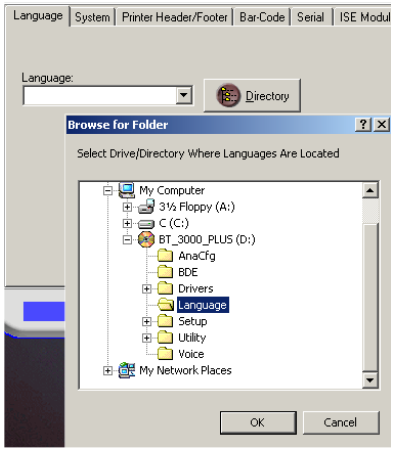


Figure 7

If there are no languages on the list they need to be installed. To view all the available languages, insert the installation disk of the operating program in the CD reader, then press the **Browse the Folder** button and browse the disk contents until finding the Language folder and click on **OK** (fig. 7a).



The Setup program will load the languages in an internal directory of the analyzer, then it will be possible to select the desired language from those available in the scroll box.

Figure 7a

SYSTEM: In this page it is possible to modify the following options (**Figure 8**):

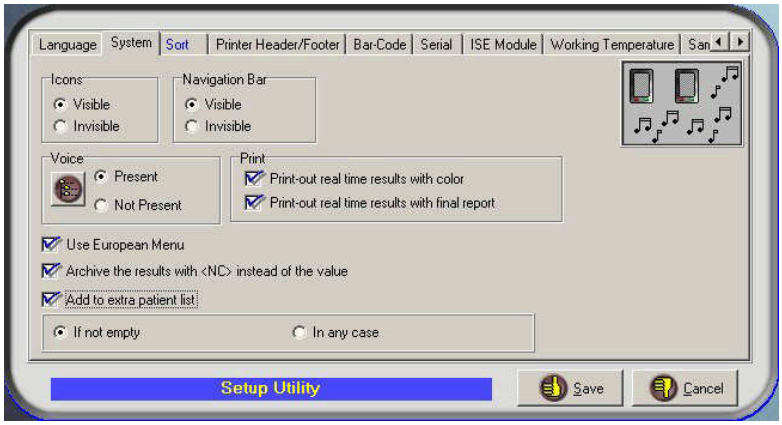


Figure 8

Icons: It enables or disables the displaying of the icons on top of the screen.

Navigation Bar: It enables or disables the displaying of the navigation bar on the left side of the screen.

Voice: it enables or disables vocal function (vocal messages). By clicking on the icon a mask appears for selecting and controlling the audio (reproduction speed and volume).

Use European Menu: If disabled, it changes the menu bar as well as the operating functions from European mode to the ones exclusively dedicated to USA mode.

NOTE: The USA operating modes are not outlined in the present manual.

Print-out real time results with color: When enabled, the real time print-out will be in colors, otherwise it will be in black and white. Bear in mind that in this way, the identification at glance of results associated to flags in printouts is lost, as they are normally printed in red.

Print-out real time results with final report: When enabled, it provides test results per patient in real time print-out in report format. However, remember that if it is necessary to execute a re-run, a new print-out would be obtained. This option may be costly in terms of paper and may cause confusion as there may be several reports printed for the same sample.

Archive the results with <NC> instead of the value: used to archive all the results, including those marked as not calculable in the Patient Archive. If this is not enabled, the results marked with <NC> will not be archived and they will be left on the work list to allow for re-running them (see Ch. G, par. 1. and Ch. F, par. 3.2.)

Add to extra patient list: during the patient programming phase in Routine, it is possible to have the analyzer memorize the patients directly on the extra patients list, instead of the normal work list (see Ch. E, par. 1.5. Work lists). This option is divided into: **If not empty** and **In any case**. In the first case, the patients are saved in the additional list only if it contains at least one other patient. **In any case**: the patients are saved directly on the extra patients list.

N.B.: The patients are transferred to the extra patients list only if the acquisition is via the **New Entry** button, and not by clicking directly on a free position on the sample tray (see Ch. E, par. 1.4.).

This option may be useful in cases where all patients are being programmed, before actually receiving the samples. As the samples are received the patients are moved from the extra patients list to the routine list and the work is started.

SORT: allows the operator to select the way to arrange the results in the real time results page. Select the desired combination of options and save. See also chapter G, par. 1.6.

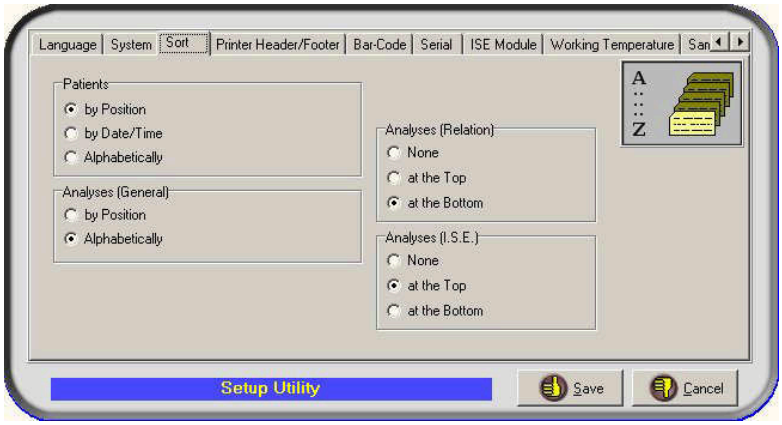


Figure 9

PRINTER HEADER/FOOTER: Customizes the printouts generated by the analyzer in the **Patient Archive, Population** and Quality Control Utilities (**Figure 10**). Two editable fields are displayed for programming of **HEADER** & **FOOTER**. Characters can be formatted (**B** for bold, **U** for underline, **I** for italic) as needed. Text format, font type, size and text color are also available. To print a test page click **Test** button.

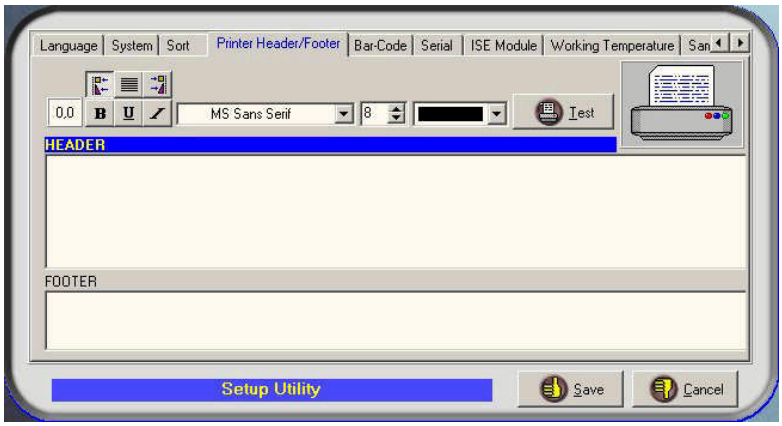


Figure 10

BAR-CODE: Enables bar-code scanning option (**Figure 11**). Confirm **Present** to enable it or **Not Present** to disable it. With bar-code enabled, further options are: **On Samples** and **On Reagents** (or just one of the two). The bar-code is not present in the BT1000 analyzer. The bar-code is optional on the BT1500.

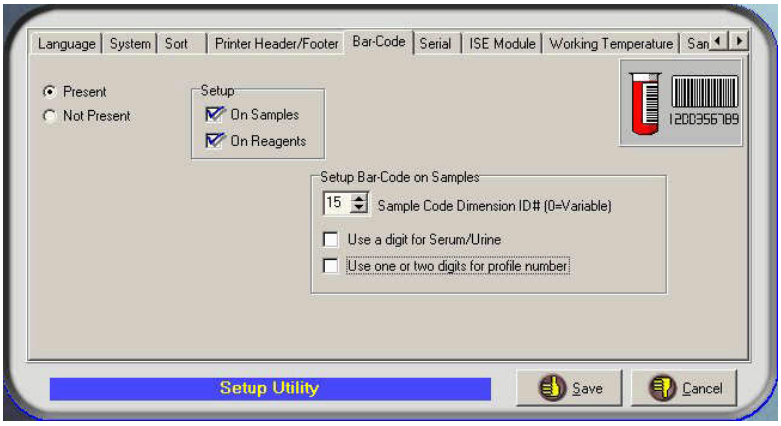


Figure 11

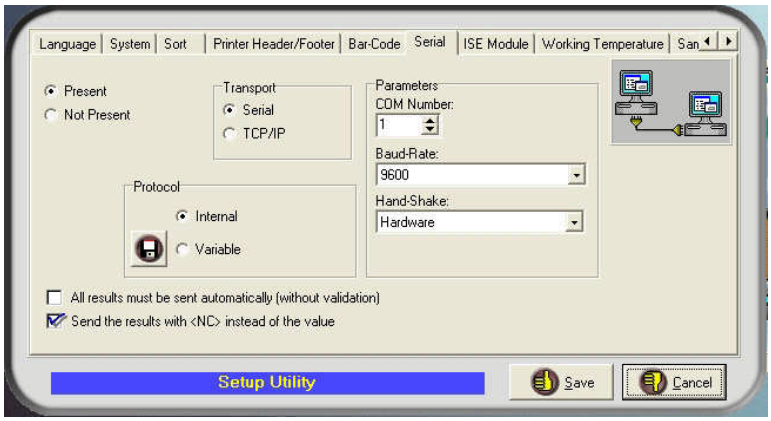
Setup Bar-code on Samples: This function customizes the contents of the patient code reported on the bar-coded label.

Dimension Sample Code: This field is used to define the number of characters dedicated to the patient code. If set to zero, the code length is variable (codes with a number of characters between 1 and 13 are accepted automatically). If as an example 10 is entered, then the patient code must have ten characters.

Use a digit for Serum/Urine: If enabled it is possible to use one character to automatically identify the type of sample (Serum/Urine) undergoing test.

Use one or two digits for profile number: When enabled it is possible to use one or two characters to identify automatically the profile number assigned during profiles programming (refer to **Chapter C**, paragraph **1.6., Creating Profiles**).

SERIAL: Enables communication with host computer (**Figure 12**).
Two communication ways are available: the **RS232** standard or the **TCP/IP**. Both use the same communication protocol (internal or variable), with the same control characters (STX, ACK, EOT)
Check **Present** to enable or **Not Present** to disable. Once the communication port is enabled, the **Parameters** functions will be enabled too.
Select the type of communication between Serial and TCP/IP.
TCP/IP Protocol: the default communication port is 8888. It can be set (by the technical assistance personnel with their password) in the setup. If the communication port is changed, it will be necessary to turn the analyzer (or the external PC) off and then on to activate the new port.
The TCP/IP protocol version used is version 4 (not version 6)
In the installation disk there are two programs (under the directory Utility) that can be used for testing the TCP/IP communication. One is TestTCPIP.exe and works under Windows, the other is TCPIPHost.exe and simulates a host computer under Windows.



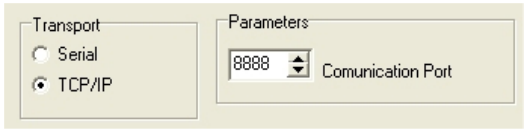


Figure 12

Serial: COM Number: Sets the serial port number (for example COM 1, COM 2 etc.)

Baud-Rate: Sets data transmission speed between the analyzer and the host computer. Click ▼ to view all the possible transmission speeds. To select, click on the desired value.

Hand-Shake: Enables Data Flow Control to be used during data transmission. Click ▼ to view the available options. To select, click on the desired option.

Protocol: it is possible to use the internal communication protocol or a variable protocol. When choosing the variable protocol, it will be possible to set the protocol options by clicking on the dedicated icon. Only expert operators should set the variable protocol (see **Chapter 4**, **Section II**, paragraph **4.2**).

All results must be sent automatically (without validation): When this option is enabled, all results from the analyzer are sent automatically and immediately to the host computer. If the option is not enabled, then the operator decides when to send the data (see **Chapter C**, paragraph **1.1. Description of the program Menu**). Analyzer will display the following options for sending patients to the host computer: accept results to be sent or delete results to be sent (see **Chapter. E**, paragraph **1.5. WORK LISTS**).

Send the results with <NC> instead of the value: by selecting this option the non-calculable results will also be sent to the Host Computer, if the option is not enabled the <NC> results will not be sent to the Host Computer and will be deleted. In this case the <NC> results that are not archived and are on the work lists can be run again by the analyzer and if there are valid results, they will then be sent to the Host computer.

I.S.E. MODULE: Only available in BT3000 Plus and BT3500. Activates the ISE module (**Figure 13**). Check Present to activate or Not Present to deactivate. When the ISE module is disabled, all relevant menu options will be disabled too or not visible at all.

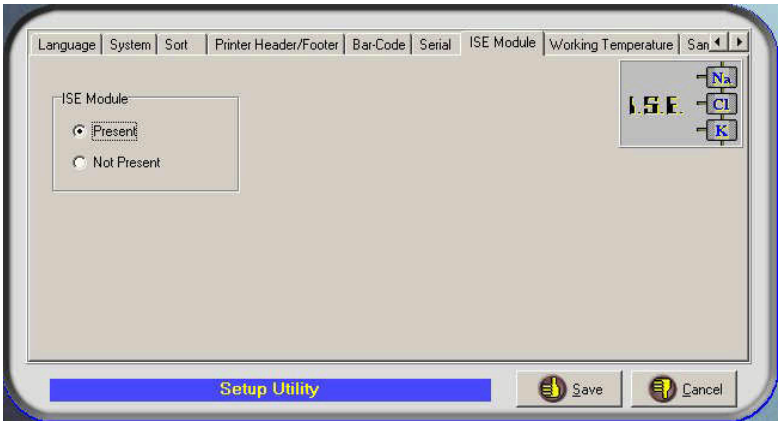


Figure 13

WORKING TEMPERATURE: Sets working temperature for reading cuvettes and activates the refrigerator for the reagents. Click to select the desired temperature among the available (**Figure 14**).

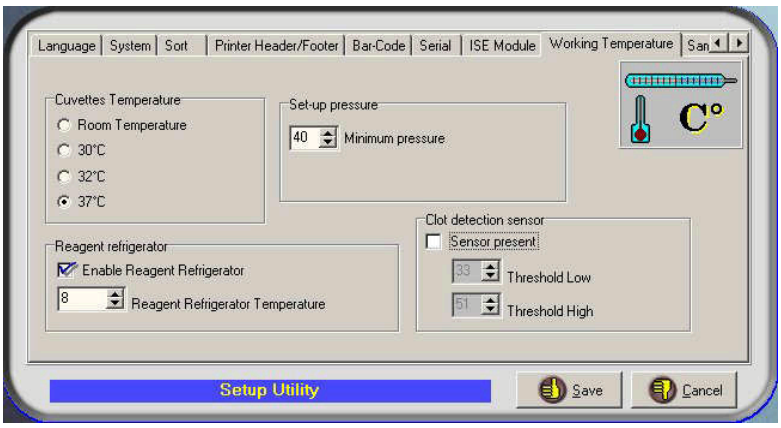


Figure 14

- Room Temperature
- 30°C
- 32°C
- 37°C

By selecting **Room temperature** bear in mind that when this is very high the temperature of the solution in the cuvettes will be high as well. The same thing is true even if the selected temperature is **37°C**, but the room temperature is 40°C, for example. The heating elements of the cuvette tray are able to heat but not cool if the room temperature is higher than the programmed temperature**.**

Enable Reagent Refrigerator: If not selected, it excludes the reagent refrigeration.

Clot detection sensor: Only available in **BT3500**. The clot detection sensor is used to verify whether there are total or partial occlusions in the sampling needle, due to proteins or else. It can be enabled or disabled. There are two thresholds, one high and one low, which values are set by default for the normal working conditions encountered in labs. It is possible to modify these values in case the used samples show, for instance, a higher density and therefore the system gives continuous errors.

If a clot is detected and the sampling arm is obstructed, the sampling for that patient is aborted, the sample will be flagged with the Z flag: Clot detection <ERROR>. If there is a possible obstruction of the sampling arm, the analyzer will go ahead sampling, but the results for that will be flagged with the z flag: Clot detection <Warning>

The clot sensor also detects malfunctioning of the hydraulic circuit, including detached tubes that cause a sudden drop in the hydraulic circuit pressure. In case this happens, the analyzer will immediately stop working and will display a proper warning message (Error on Arm hydraulic circuit...!)

Once an air bubble has entered into the hydraulic circuit, there is no way to fill the hydraulic circuit again without having the error message. It will be necessary to disable the clot sensor and perform some dilutor prime or to turn the analyzer off and on again.

SAMPLES' TRAY: Customizes samples' tray (**Figure 15)**. Here it is possible to change the number of positions dedicated to the samples of **Routine**, **STAT**, **Standards** and **Controls**.

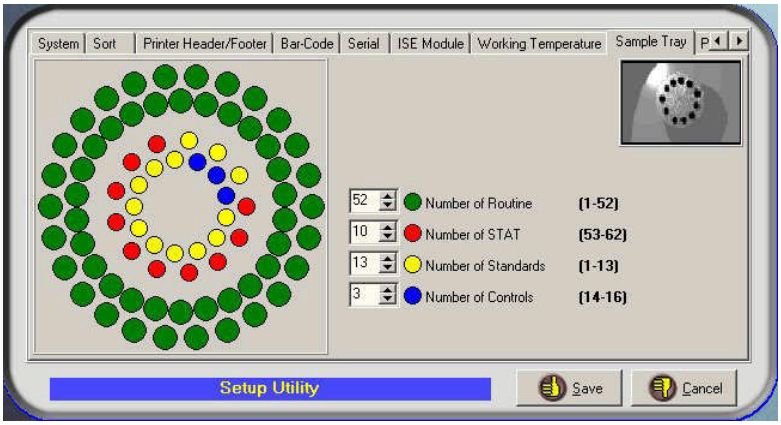


Figure 15

Customizes samples' tray (**Figure 15**). Here it is possible to change the number of positions dedicated to the samples of **Routine**, **STAT**, **Standards** and **Controls**.
Routine and STAT positions are included in the two outermost rings with progressive numeration from **1 to 52**. Standard and Controls positions are in the innermost rings with progressive numeration from **1 to 26**. It is not possible to exclude one typology to advantage of the other one. The minimum number of assignable positions is **1** for the Routine, STAT and Standards; and **3** for the Controls.
Click up/down arrows to increase/decrease the number of dedicated positions, or write the desired number into the textbox. The analyzer will automatically upgrade the positions for the second item of the pair every time the first one is changed.
Only for BT1500 & BT35000: Routine and STAT samples share the dedicated positions from number **1 to 62**. The two outermost rings with progressive numeration from 1 to 52 allow placing of primary tubes or cups. The positions from 53 to 61 will allow only cups. Standard and Controls shared positions are in the innermost rings with progressive numeration from **1 to 16** and allow placing of cups only.

PASSWORDS: on this page (**Figure 16**) it is possible to insert new passwords instead of the internal system ones. It is not advisable to change these passwords, since if they are forgotten or lost it will no longer be possible to access the system.

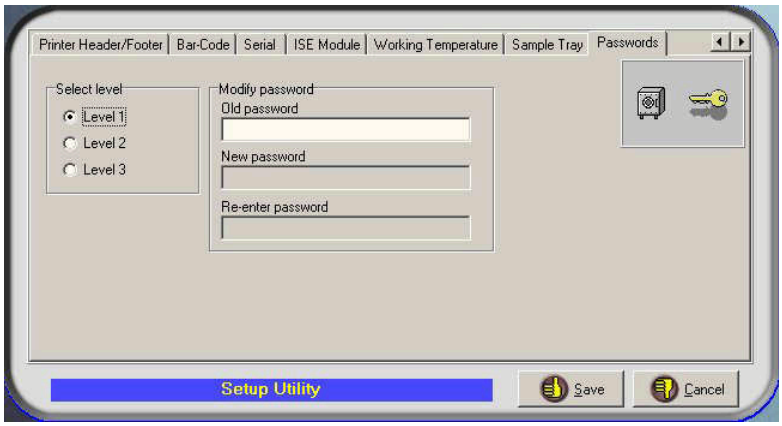


Figure 16

ATTENTION: when writing any of the passwords in one of the three appropriate field, it is necessary to confirm it by pressing Enter. This will also enable the following writing field. If the procedure is correct, the analyzer will display a message confirming that the password has been changed.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER I

1. BARCODE AND RELATED FUNCTIONS **Page: 2**
2. USING THE BARCODE **Page: 2**
2.1. Barcode on Samples **Page: 2**
2.2. Reagent Barcode **Page: 5**

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. BAR-CODE AND RELATED FUNCTIONS

The software for the analyzer allows independent enabling (and disabling) for bar-code scanning on Samples and Reagents (refer to **Chapter H**, paragraph **2. "Analyzer Setup"**). The enabling of barcode scanning on samples visualizes specific commands in the program (refer to **Chapter E**, paragraph **1.5. "Work Lists"**).
The analyzer uses as format a numeric code of max 13 digits (for example EAN 13). If the used format has a lesser digits, then the information space is reduced in the labels printing protocol. In fact it is not possible to add profiles number, serum and urine identification and besides the number of available characters for patient code are also reduced.

2. USING THE BAR-CODE

2.1. BARCODE ON SAMPLES

Entering Patients

Tests to be run can be acquired from the Host Computer, from those stored after manual input (refer to **Chapter E**, paragraph **1.4. "Samples"**) and through barcode scanning using the **"Profile"** utility (refer to **Chapter C**, paragraph **1.6. "Creating Profiles"**).

Manual programming: the patient is programmed manually (code and analyses), then his position on the sample tray is checked by barcode reading. In this case the samples can be inserted randomly on the tray, since the barcode reader will assign the position on the tray to the patient corresponding to each code read which has the same ID code.

Programming via Host Computer: The patient is programmed (code and analyses) on the Host Computer and transferred to the analyzer. The position on the sample tray is checked by barcode reading as described above.

Programming with Profiles function: this can be used with manual programming and programming via Host Computer. In this case when the barcode is created, the desired profile code also needs to be inserted (already assigned as described in chap. C, par. 1.6. **Create Profiles**). When the barcode is read the profile is automatically assigned to the read code. Once the patients are acquired it is possible to add or remove analyses. The samples can be randomly inserted in the sample tray and the barcode reader will assign the position.

Entering patients with and without bar-code on the same tray

Patients with barcode and those without can be run together. Patients without barcode must be inserted exactly into the positions assigned during programming. Patients with bar-code can be freely placed in any of the free position with no need to respect the assigned position number.

Bar-code Notes and Example

The bar-code on samples length and meaning can be programmed in the Setup program at the bar-code page.

The maximum number of digits that can be assigned to a sample is 15, depending also from the type of bar-code used.

See the following examples.

EXAMPLE 1

Patient ID# of digits: 10	With one digit for serum or urine: no	With two digits for profile: no
1234567890		
PRINTED CODE:	**1234567890**	**TOTAL 10 CHARACTERS**

EXAMPLE 2

Patient ID# of digits: 10	With one digit for serum or urine: yes	With two digits for profile: no
1234567890	**1**	
PRINTED CODE:	**12345678901**	**TOTAL 11 CHARACTERS**

EXAMPLE 3

Patient ID# of digits: 10	With one digit for serum or urine: yes	With two digits for profile: yes
1234567890	**1**	**99**
PRINTED CODE:	**1234567890199**	**TOTAL 13 CHARACTERS**

If in the Setup the number of digits for the patient ID is set to 15 and the printed code is of 10 characters, the analyzer will consider as ID# the 10 printed numbers.

If in the Setup the number of digits for the patient ID is set to 13 and the printed code is of 10 characters, the analyzer will consider as ID# the 10 printed numbers.

If in the Setup the number of digits for the patient ID is set to 13 (serum/urine digit and profile number are active) and the printed code is of 13 characters, the analyzer will not consider the digits for serum/urine and for profile number as it is expecting the patient ID to be of 13 digits. The patient ID always has the priority on the following numbers.

EAN13

If the bar-code used is an **EAN13**, the sample bar-code can be programmed as follows.

NOTE: with the EAN13 there are some limitations: the first number must not be 0; the actual number of digits is 12 as the last digit is the checksum **X** (automatically created).

EXAMPLE 1

Patient ID# of digits: 12	With one digit for serum or urine: no	With two digits for profile: no
123456789012		
PRINTED CODE:	**123456789012X**	**TOTAL 13 CHARACTERS**

EXAMPLE 2

Patient ID# of digits: 11	With one digit for serum or urine: yes	With two digits for profile: no
12345678901	**0**	
PRINTED CODE:	**12345678901X**	**TOTAL 13 CHARACTERS**

EXAMPLE 3

Patient ID# of digits: 9	With one digit for serum or urine: yes	With two digits for profile: yes
123456789	**1**	**99**
PRINTED CODE:	**123456789199X**	**TOTAL 13 CHARACTERS**

ANOMALIES IN BARCODE READING

There are some cases where the analyzer automatically makes modifications to the work lists acquired by barcode.

- **two identical barcodes are read in two different positions**: the analyzer deletes both codes since it has no way of knowing which one is incorrect. Thus, new programming becomes necessary.

- **a patient without a barcode and one with a barcode are found in the same position**: when the barcode is read the analyzer detects a sample with a barcode in a position where another patient was programmed without a barcode. The sample with barcode remains in the assigned position, while the patient without barcode is moved to the additional list (see chap. E, par. 1.5. **Work lists**).

Additional Information regarding types of barcodes:

The barcode scanner located inside the analyzer has ha the possibility of memorizing from one to six different codes in its flash ram memory.

At present the following codes are default set in the flash ram memory of the barcode scanner module:
Ean13, Code39, Codabar, Interleave 2 of 5 (6); Interleave 2 of 5 (8); Interleave 2 of 5 (10).

The scanner automatically detects the presence of one of the preceding codes on the barcode label.

Other codes can be programmed upon request. They are available in blocks of six and are uploaded by floppy disk.
Some of these codes available upon request include:
2/5 INTERLEAVED, CODE 39, CODE 39 FULL ASCII, CODABAR, CODE 128, EAN 128, CODE 93, PLESSEY, PHARMACODE, ALL EAN/UPC, EAN 13, EAN 8, UPC A, UPC E, EAN 13 ADDON 2, EAN 8 ADDON 2, UPC A ADDON 2, UPC E ADDON 2, EAN 13 ADDON 5, EAN 8 ADDON 5, UPC A ADDON 5, UPC E ADDON 5, EAN/UPC w/o ADDON, EAN/UPC ADDON 2, EAN/UPC ADDON 5, EAN/UPC ADDON N

Suggested dimensions for the labels:

Although the analyzer is equipped with a high quality barcode scanner, the labels of improper dimensions or defective labels may not be read. For correct readings the barcode label should be properly centered on the tube and should have a height between 2 cm and 3.7 cm. The barcode on the label should be completely visible after the tube has been inserted into the sample plate. It must not be partially covered on the top and the bottom. If the tube is partially covered by barcode, then the tube must be positioned in such a way that the barcode is facing outwards of the sample plate.

2.2 REAGENT BARCODE

The main objective of the reagent bottle barcode is the positive identification of the bottle to avoid position error. Moreover, upon request, a special program makes it possible to “close” the analyzer making it possible to use just reagents with barcode, introducing a series of additional controls.
However the barcode can be used only with specific labels produced by the manufacturer of the reagents.
At the installation of the instrument can be configured in the following three different modes of operation, in agreement between the manufacturer of the analyzer, the reagent supplier and the client:

1) Use of reagent bottles without barcode, independent use.
2) Use of reagent bottles with barcode (analysis code), only for positive identification of the bottle.
3) Use of reagent bottles with complex barcode, use of reagents bound by purchasing agreement.
   This mode allows for a barcode with customized reading key. The instrument doesn't accept bottles having unknown and incoherent barcode labels, thus preventing the execution of the tests. The applied algorithm provides for: analysis code, bottle type, test type (single or double), reagent lot and expiration date. The improper modification of any one of these parameters invalidates its applicability. There is also a built-in prevention against refilling of previously identified bottle.

NOTE:
Exclusively the Director General of the company manufacturing the analyzer releases additional information.

“Check volumes”

This command allows measurement of the volume of the reagent bottles (refer to **Chapter E**, paragraph **1.2. “Reagents: insertion and removal”**). With reagent barcode enabled, it is also possible to check the actual position of all the bottles in tray.
At the end of the reagent scanning, the analyzer sorts codes disposition and provides a list of all the errors found during reading phase. In case of detected anomalies, the procedure can be repeated once the problems have been solved. Every time a new reagent bottle is inserted, the analyzer will read the inserted codes.
When removing a reagent with the "Remove" function, the analyzer will perform a scan of the position to verify that the reagent has been removed. When closing the View volumes status window, the analyzer will perform a second verification scanning and then will move the removed test code from the on-line tray to the global list (see also Cap. E, page 3).

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER K

1. VACUUM PUMP SYSTEM INSTALLATION/OPERATION Page: 2
1.1. Functional characteristics Page: 2
1.2. System control functions Page: 3
1.3. Waste container (external) Page: 3
1.4. Installation & operation Page: 4
1.5. Maintenance and care Page: 4
1.6. Trouble-shooting Page: 4
1.7. Spare parts for maintenance Page: 5

NOTE:

The present chapter applies only to BT3000 Plus and BT3500 analyzers, which have an external vacuum system.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. VACUUM PUMP SYSTEM INSTALLATION/OPERATION

1.1. FUNCTIONAL CHARACTERISTICS

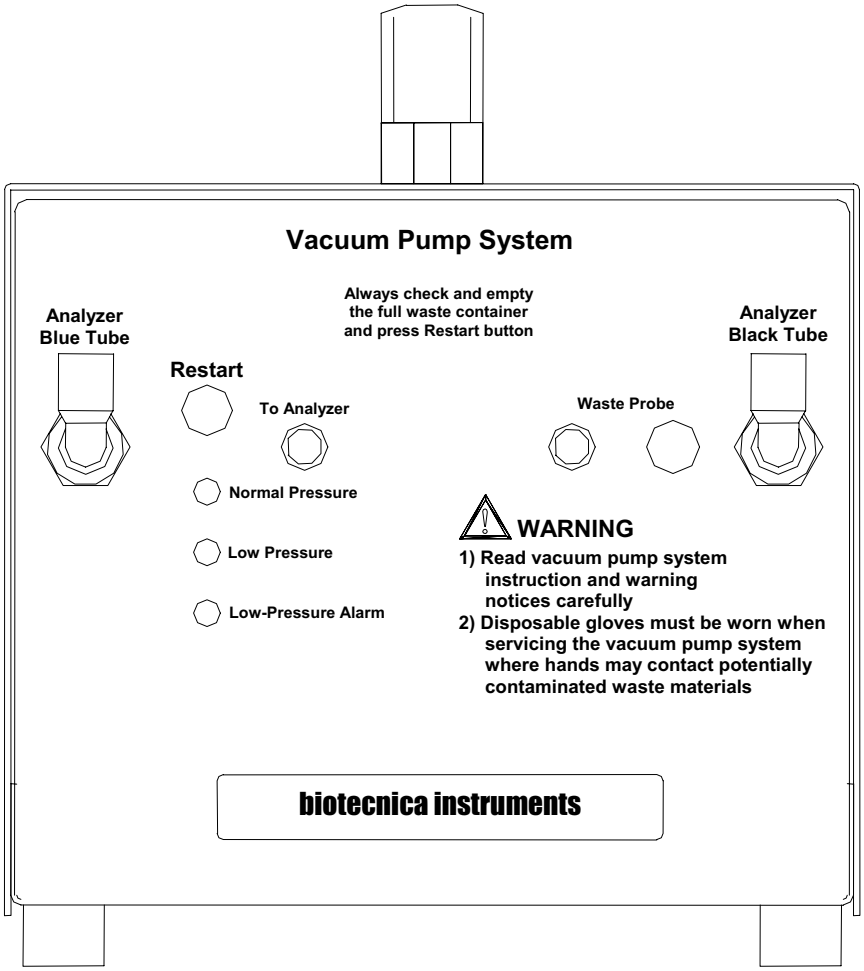


Figure 1
Vacuum Pump System P/N 06-05161-01

This silent and compact vacuum pump system has been specifically designed for use with this analyzers. It provides for an automatic and safe collection of waste liquids from analyzer's reaction cuvettes and sampling needle washing into the external waste disposal container in lab environment. The system consists of a metallic cabinet containing two membrane pumps controlled by a microprocessor, electronics, and the electrical and fluidic connections to the analyzer. The microprocessor manages three main functions: pressure measurement, waste container full check, and pump shutdown. The waste discharge has the following pathway (course):

A) The liquids aspirated by the pumps from the needle washing funnels (bowls) and the cuvettes washing through the two tubes (Blue and Black tubes) respectively are transferred to an internal waste chamber (made of transparent Pyrex). From here, the waste fluid is ejected to the external waste container through the waste probe equipped with liquid level sensor.
B) Whenever the external waste container is full, the waste liquid level sensor activates an audio/visual alarm that alerts the operator and instantly shuts down the pumps.

1.2. SYSTEM CONTROL FUNCTIONS

Pressure: Three LEDs on the front panel indicate the system vacuum level.
Green LED: Normal operating vacuum level (approximately –60 millibar).
Yellow LED: Low vacuum level (below 30 millibar).
Red LED: Vacuum level lower than –15 millibar

Simultaneous lighting of Green, Yellow, and Red LEDs: Indicate high vacuum level (higher than –150 millibar).

All LEDs turned off: Pumps disabled.
The green LED indicates that the system is functioning properly.
The yellow LED may indicate an operating limit condition, still satisfactory but signaling the beginning of vacuum level deterioration. The red LED indicates vacuum level failure due to various reasons.

The simultaneous lighting of Green, Yellow, and Red LEDs indicate excessive vacuum level probably caused by an occluded waste probe tube (from the vacuum pump system to the external waste container). If this condition occurs sporadically during washing then it must be considered normal.
All LEDs turned off condition is reached when the standby time (2 minutes) terminates without resetting the system (pumps disabled). In this case, the green LED of the Restart button flashes in quick successions.

1.3. WASTE CONTAINER (EXTERNAL)

The waste probe is placed into the external waste container to transfer liquid ejected from the waste pumps into the container. For safety reasons the waste probe is equipped with a liquid level sensor, which is activated when the external waste container is full. In this condition, the liquid level sensor transmits the signal to the microprocessor, thus putting the system in standby mode. In addition, the vacuum pump system generates an intermittent audible alarm and the red LED on top of the waste probe is lit. During the standby (lasting approximately 2 minutes) the waste fluid flow is deviated through a three-way solenoid valve into the internal waste chamber, thus continuing the waste aspiration function transitorily but the fluid flow to the external waste container is stopped. The purpose of this momentary deviation is to avoid any spillage during the transfer of the waste probe from one waste container to another empty container. After emptying or substituting the external waste container press Restart button on the vacuum pump system front panel to continue the operating procedure and reset the alarm. If the preceding step is not taken, after 2 minutes the system will enter in the alarm condition by turning off the aspiration pumps of the vacuum pump system. Simultaneously the analyzer enters the standby mode and a corresponding warning message LOW PRESSURE appears on the screen.

NOTE:
The liquid level sensor is magnetically actuated reed switch make and break type.

1.4. INSTALLATION & OPERATION

1) Connect the Blue and Black waste tubes from the right side of the analyzer to the appropriate quick connect on the vacuum pump cabinet front panel (Fig.1).
2) Connect the Waste Probe electric cable (liquid level detector) and the drain tube of to the vacuum pump cabinet front panel (Fig.1 and Fig.3).
3) Insert the Waste Probes in authorized external waste container.
4) Plug the power cord set to power inlet on the rear of vacuum pump cabinet and then into one of the accessory power connectors on the analyzer rear panel.
5) Now the system is fully installed and ready for operation.
6) Switch on the analyzer. The vacuum pump will start running

   NOTE:

   The vacuum pump system power inlet on the rear has no ON/OFF switch. The system turns ON and OFF simultaneously with the analyzer. The vacuum Pump System is equipped with a universal power supply of 100 to 240 Volt AC, 50/60 Hz similar to the power supply of the analyzer.

1.5. MAINTENANCE AND CARE

This compact pump system is virtually maintenance-free and offers continuous duty collection of waste liquids outside the analyzer. Does not require inconvenient peristaltic pump cartridge and filter changes. The theoretical operating life of the pumps is between 4000 to 5000 hours, after that the service technician should substitute the pumps.

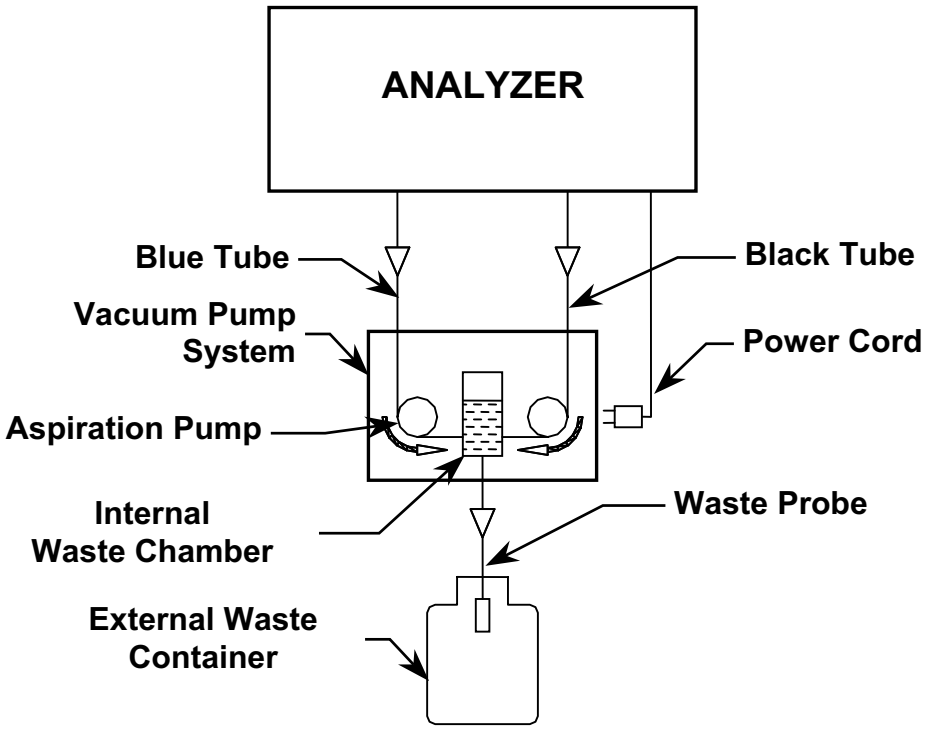
WARNING

a) DISPOSABLE GLOVES MUST BE WORN WHEN SERVICING THE VACUUM PUMP SYSTEM WHERE HANDS MAY CONTACT POTENTIALLY CONTAMINATED WASTE MATERIALS.

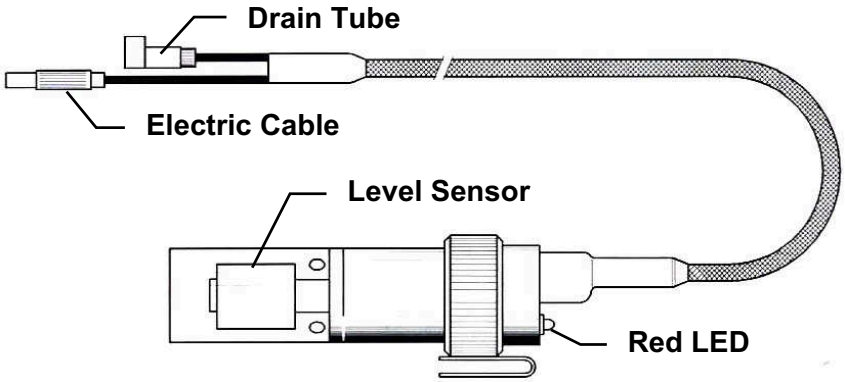
b) THE SAFE DISPOSAL OF THE WASTE MATERIALS IS THE RESPONSIBILITY OF THE USER. INSURE THAT THE DISPOSAL OF WASTE CONTAINER FLUIDS IS DONE ACCORDING TO ALL APPLICABLE LAWS AND REGULATIONS.

1.6. TROUBLE-SHOOTING

TROUBLE-SHOOTING GUIDE	
SYMPTOMS	**CORRECTIVE ACTIONS**
The vacuum pump is silent and Restart green LED not lit.	a) No power to the system. Power cord disconnected. Connect the power cord. b) Blown fuse/s. Replace with appropriate fuses as marked.
Audible alarm of intermittent frequency, some flashing LEDs and the instrument in standby mode.	Indicates vacuum level variation due to leakage in the hydraulic circuit connection/s. Ensure that the waste tubes (blue and black tubes connecting vacuum pump to the analyzer) are firmly connected. During the analyzer operation, this phenomenon may be considered normal, as there may be sudden variations in the vacuum level during emptying of the reading cuvettes.



Fluidic Pathway
Figure 2



Waste Probe (P/N 07-05165-01)
Figure 3

1.7. SPARE PARTS FOR MAINTENANCE

The following is listing of spare parts, which are available for field replacement:

PART NO.	DESCRIPTION
06-05161-01	VACUUM PUMP SYSTEM (COMPLETE) FOR THE ANALYZER
07-05165-01	WASTE PROBE
330.6338	FUSE 250 VOLT, 0.5 AT
330.6400	MAIN POWER SUPPLY CORDSET

OPERATOR MANUAL

ONLY FOR BT3000 PLUS & BT3500

SECTION I: GENERAL INFORMATION

CHAPTER L

1. ISE MODULE **Page: 2**
1.1. Introduction **Page: 2**
1.1.1. Contents of the wooden crates: I.S.E. **Page: 3**
1.1.2. Applied Mathematical Functions **Page: 3**
1.2. Performance And Limits **Page: 4**
1.3. I.S.E. Wash and system shut down **Page: 5**
1.4. Mechanical Calibrations: I.S.E. Arm **Page: 5**
2. Operating the I.S.E. Module **Page: 6**
2.1. Parameters **Page: 6**
2.2. Programming Standards and Controls **Page: 8**
2.3. Replacing and Installing Electrodes **Page: 11**
2.4. Preliminary steps before starting the system **Page: 12**
2.5. Calibration procedure **Page: 13**
2.6. Measuring unknown samples **Page: 15**
3. Precautions, maintenance and Troubleshooting **Page: 16**
3.1 Precautions for ISE Module usage **Page: 16**
3.2. Suggestions for performance maintenance **Page: 17**
3.2.1. I.S.E. Maintenance **Page: 18**
3.3. Troubleshooting **Page: 20**
4. Returning The Analyzer To The Tech. Assistance Service **Page: 24**
5. I.S.E. Module Consumables **Page: 26**

NOTE:

All pictures in this manual are referred to the BT3000 Plus. Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. ISE MODULE

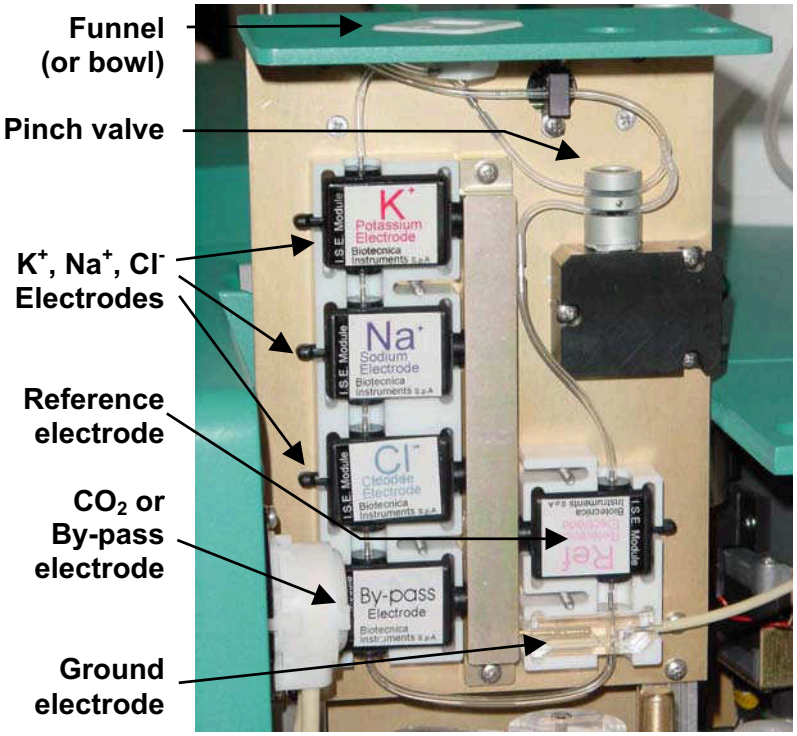
1.1. INTRODUCTION

In addition to the Clinical Chemistry and Immune-chemistry tests, the BT analyzers allow tests for the Na+, K+, Cl- and CO_2 ions with ion selective electrodes (ISE module).
The device consists of a reading module with a partially dedicated sampling arm and therefore can be considered as a stand-alone module of the instrument.
The system is called Ion Selective as the electrodes used respond to their respective ions in accordance with the Nernst equation:

$$E = E_0 + RT/nF \log aM+$$

aM+ = M+ ion activity
E = observed potential in Volts
E_0 = constant (standard potential for a redox semi-reaction referred to hydrogen electrode)
R = gases' constant
F = Faraday's constant
T = temperature in Kelvin degrees
n = ion's charge

It is highly recommended to carefully read this chapter before using the system. The user should also keep in mind that all the ISE components must be maintained in optimal operating conditions to ensure precise and accurate determination of results.
The correct use by the well-qualified personnel, assures quality test results as well as a longer duration of the electrodes. Lifetime for electrodes is about 1 year for sodium and reference, 3 months for potassium, chloride and carbon dioxide.
However, the electrodes lifetime depends upon the number of samples determined, and the observation of routine maintenance at proper intervals.
For a correct use of the system, the user must observe some basic functions such as initial restoring for electrodes conditioning, calibrations repeated every 4 hours or at any temperature variation that is greater than 3°C and at the substitution of working solutions (Buffer & Reference). When turning off the analyzer it is necessary to perform a washing procedure with appropriate detergent solutions.



This chapter gives some operating suggestions and GLP to help assure precision and accuracy of the system.
The ISE module is located inside the right side of the analyzer. The ISE reagents are positioned near the ISE module and are accessible through an appropriate panel. The module can be removed by opening the panel and extracting it upwards (all fluidic tubes must be disconnected before ISE module removal).
ATTENTION: when the I.S.E. module is removed the related sampling arm no longer works. If the I.S.E. module is not going to be used, it should be disabled from the Setup (chap. H).

1.1.1. Contents Of The Wooden Crates

In the small wooden create there are also the following items:

1	ISE STARTER KIT (P/N 947)	
1	Cl ELECTRODE CLEANING TOOL (P/N 03254)	
1	QUARTERLY I.S.E. MAINTENANCE KIT (*11-05668-01*)	

1.1.2. Applied Mathematical Functions

- **COMPUTING THE SLOPE**

$$S_i = \frac{(mV_h - BL_h) - (mV_l - BL_l)}{Log\left(\frac{C_h - BSF}{C_l - BSF}\right)}$$

where:

S : Slope
i : Electrodes
BSF : Base Line Factor
mV_h : mV High Standard
mV_l : mV Low Standard
BL_h : Base Line High Standard
BL_l : Base Line Low Standard
C_h : High Standard Concentration
C_l : Low Standard Concentration

- **COMPUTING THE RESULT**

$$Conc = \left(Cs_l + BSF \cdot 10^{\left(\frac{(mV_i - BL_i) - (mVs_l - BLs_l)}{S_i}\right)} \right) - BSF$$

where:

S : Slope
i : Electrode
BSF : Base Line Factor
mV_i : mV Electrode
mVs_l : mV Low Standard
BL_i : Base Line Electrode
Bls_l : Base Line Low Standard
Cs_h : Low Standard Concentration

1.2. PERFORMANCE AND LIMITS I.S.E. MODULE

Number of electrodes:	4 plus Reference Electrode	
Analytes:	K^+, Na^+, Cl^- and CO_2 (By-Pass)	
Analytical throughput:	up to 190 tests/h (K^+, Na^+, Cl^- and CO_2)	
Reagents:	Buffer and Reference Solution (concentrated)	
Sample Type:	Serum, Urine (whole)	
Sample Volume:	BT3000 Plus:30µl BT3500: 23µl	
Concentrated Reagents Dilution:	1/9 with H_2O (automatically)	
Dilution of Serum/ Buffer:	1/14 (automatically)	
Precision on Serum test:	± 1% for K^+ & Na^+, ± 2% for Cl^-, ± 3% for CO_2	
Precision on Urine test:	± 2% for K^+, Na^+ and Cl^-	
Linearity for Serum test:	Na=50-200mEq/L	K=1-20mEq/L
	Cl =50-400mEq/L	CO2=10-45mEq/L
Linearity for Urine test:	Na=20-400mEq/L	K =2-200mEq/L
	Cl =40-400mEq/L	
Accuracy for Serum test:		
Intra Run Serum (N°20 samples):	Na^+ and K^+	C. V. < 1%
	Cl^-	C. V. < 2%
	CO_2	C. V. < 5%
Inter Run Serum (N°20 samples):	Na^+ and K^+	C. V. < 2%
	Cl^-	C. V. < 2.5%
	CO_2	C. V. < 5%
Accuracy for Urine test:		
Intra Run Urine (20 samples):	Na^+, K^+ and Cl^-	C. V. < 2%
Infra Run Urine (20 samples):	Na^+, K^+ and Cl^-	C. V. < 2.5%
Life expectancy for electrodes:	Na^+ and Reference Electrode	12 months
	K^+	3 months
	Cl^- & CO_2	3 months

WORKING SOLUTIONS

BT3000 Plus

Concentrated Buffer Solution:	45 µl + 350 µl (H_2O) approx
Concentrated Reference Solution:	45 µl + 350 µl (H_2O) approx
Sample Volume:	30 µl
Concentrated Buffer 10 ml:	200 tests approx
Concentrated Reference Solution 10 ml:	200 tests approx

BT3500

Concentrated Buffer Solution:	34 µl + 280 µl (H_2O) approx
Concentrated Reference Solution:	34 µl + 280 µl (H_2O) approx
Sample Volume:	23 µl
Concentrated Buffer 10 ml:	300 tests approx
Concentrated Reference Solution 10 ml:	300 tests approx

RUNNING TIMES FOR UTILITY

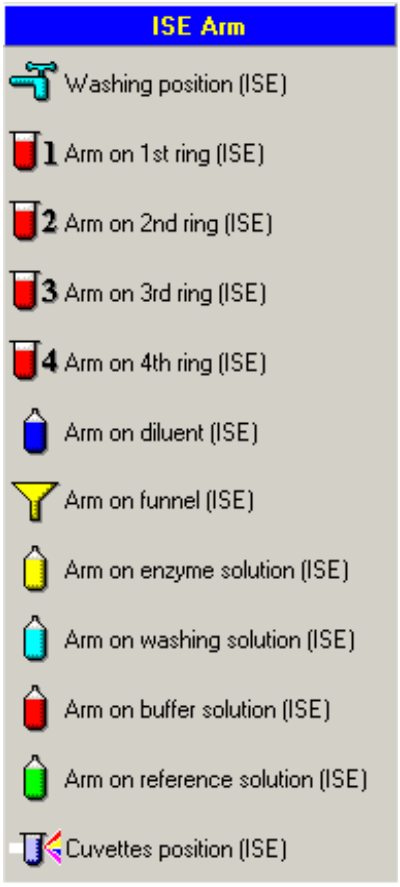
	TIME	*WASHING SOL. (approx)*
ISE wash	12'	20 ml
Consumption per ISE test		10 ml
NOTE: stated times and liquid consumptions should be considered only as indicative as they may vary in different conditions.		

1.3. I.S.E. Wash and system shut down

Wash I.S.E. Module: It is used for a complete extra wash with appropriate solutions (ISE Cleaning Solution and Enzymatic Solution) of the fluidic circuit of the ISE module. This washing procedure must be run daily, at the end of the day. This is to guarantee correct maintenance of the electrodes. Like wash cuvettes this procedure can be run when the analyzer is shut off (using the guided shut down procedure) or at the end of the day if the analyzer is not shut off.

1.4. MECHANICAL CALIBRATIONS: I.S.E. ARM

The first five items and the **Cuvettes position (I.S.E.)** are the same as the corresponding button of the Clinical Chemistry Arm, see Chapter H, par. 1.1.2. for more information.



Arm on diluent: centers the I.S.E. arm above the tube containing the physiological solution for diluting the samples.
Arm on funnel: the I.S.E. arm moves above the I.S.E. mixing funnel. Center the sampling needle at the hole at the bottom of the funnel. It is very important that the needle is centered in this position to prevent it from touching the funnel walls during mixing.
Arm on enzyme solution [ISE]: The sampling arm moves on to the appropriate hole corresponding to the enzyme solution, in the instrument's top.
Arm on washing solution [ISE]: Same as above, but for the washing solution.
Arm on buffer solution [ISE]: Same as above, but for the buffer solution
Arm on reference solution [ISE]: Same as above, but for the reference solution

2. OPERATING THE I.S.E. MODULE

2.1. PARAMETERS

Go to **the Global list** or the **Current Tray list** select **ISE**, and then click **Parameters** to display the screen showing analytical parameters: **General Parameters**, **Serum's Parameters**, and **Urine's Parameters**.

N.B.: the I.S.E. parameters have been optimized for this analyzer. The parameter fields marked with an asterisk should not be modified. Biotecnica Instruments S.p.A. shall not be held liable for unreliable results if the I.S.E. parameters are changed.

The **General Parameters** is displayed first (Figure 1), to access the other parameters click on the corresponding tags.

GENERAL PARAMETERS: In this page it is possible to program the general parameters for the ISE. The I.S.E. module test parameters are preset and should not be modified because the I.S.E. module has been designed to operate best with the parameters supplied by Biotecnica. The description and use of the parameters is very similar for what is described for clinical chemical parameters, see that section for more information.

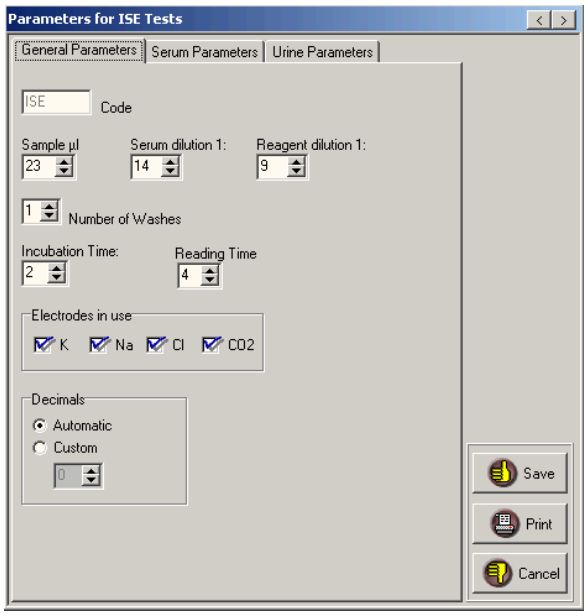


Figure 1

***Sample µl:** Sample volume expressed in µl, default value is 30µl for BT3000 Plus and 23 µl for BT3500.

***Serum dilution 1**:: Sets dilution ratio between sample and reagent, default value is set at 14.

***Reagent dilution 1:** Sets dilution ratio for concentrated reagent, default value is 9. Using this parameter the analyzer prepares (dilutes) the working reagents such as Reference (Baseline) Solution and Buffer Solution, which are CONCENTRATED.

1st Unit: Enter value in the corresponding field and enable **2nd Unit** to enter a second value and instantly a new textbox appears where the user can enter the second unit and the second unit's conversion factor. In case of double units, the test values are expressed with two results. In analytical calibrations, the first measurement unit is used.

Number of Washes: Normally one wash is usually sufficient. To set a different number of washes (maximum 9) use up/down arrow keys ⬍ or enter the value directly into the box. This option allows the user to set the number of washes that will be run at the end of dispensing the reagent used for the programmed test.

***Incubation Time:** Incubation time expressed in seconds, default value is 2 seconds.

***Reading Time:** Analysis' reading time, expressed in seconds, default value is set at 4seconds.

Decimals: For setting the number of decimal digits in test results (**Automatic** or **Custom**). If a value is not specified, then the analyzer automatically assigns number of decimal digits using the Floating point algorithm.

Electrodes in use (K Na Cl CO_2): Click the check boxes to select the electrodes to be used among those available here. This command selects or deselects electrode. When an electrode By-pass is used it is necessary to deselect the electrode which is not used to prevent continuous errors during calibration. If the selection of electrodes being used is modified, it is necessary to repeat the calibration.

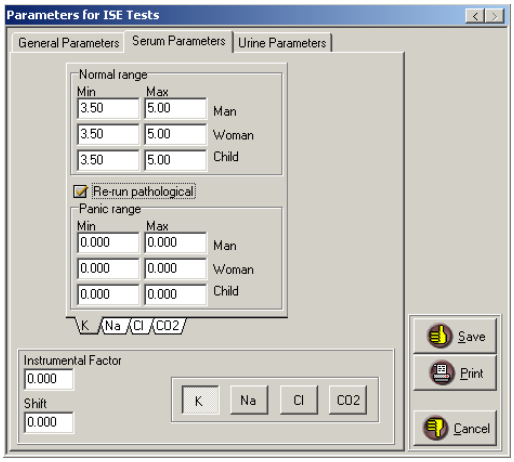


Figure 2

SERUM'S PARAMETERS: Here it is possible to assign the **Normal range** (**Figure 2**) for each electrode and, if needed the panic range for pathological repetition. The programming of the normal range values for Man, Woman and Child is assigned specifically to each electrode. To assign the normal (and panic) range to each electrode, click corresponding tag.

To visualize the Panic range, click **Re-run pathological** checkbox. If Re-run pathological option is selected, the analyzer will repeat all pathological results outside the given range.

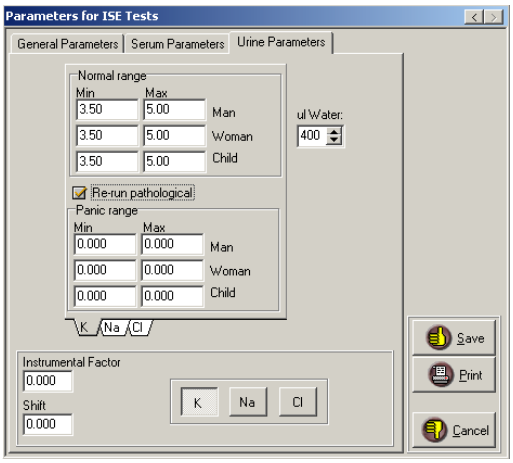


Figure 3

URINE'S PARAMETERS: In addition to the same functions as the Serum's Parameters, it also has the **µl Water** field (**Figure 3**). This is used for entering the volume in µl of water that must be used for washing the hydraulic circuit at the end of a test determination.

Note: The CO_2 electrode is automatically excluded In Urine's parameters (it does not appear even if it is present in the electrodes in use).

The Instrumental factor and Shift fields are available for both serum and urine, separated by single electrode.

- **Instrumental factor:** introduces a correction of the final datum of the executed test; it can be used to adjust the data of the executed test with different types or analytical methods or instruments. Calculation: final result = value x instrumental factor.
- **Shift:** the function introduces a quantitative correction of the final datum of the executed test; it can be used to adjust the data of the executed test with different types or analytical methods or instruments. Calculation: final result = value + shift.
-

NOTE: When the following parameters are used at the same time: Instrumental factor and Shift, External dilution factor and Urine 24/h (in the patient's data), the calculation made by the analyzer will be as follows:

[(obtained result x External dilution factor x Instrumental factor) + Shift] x Urine 24/h

At the end of programming press the **Save** button to save the inserted data, otherwise press **Cancel**.

2.2. PROGRAMMING STANDARDS AND CONTROLS

INSERTING STANDARDS: Go to **the Global list** or the **Current Tray list**. Select **ISE**, and then click **Standards** to display the **Standard parameters for ISE** (**Figure 4**). Standards programming (automatic or on request) follows the same procedure of Clinical Chemistry (**Chapter C**, **paragraph 1.5. Calibrations**). For system calibration, two known standards (Low and High) are required.

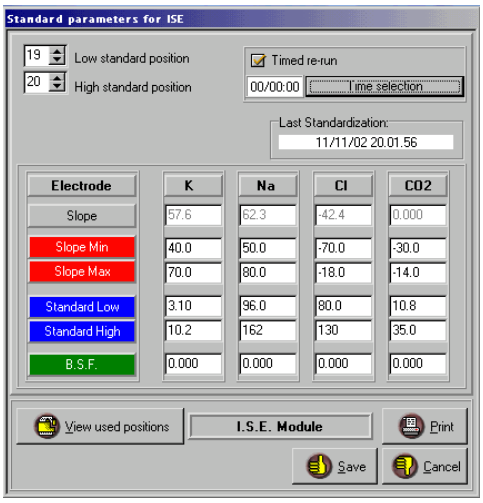


Figure 4

The Calibration parameters of the module and the relevant slopes calculated for each electrode are displayed together. Here it is possible to set an automatic standardization timer and assign two positions for low and high standards (same as clinical chemistry procedure outlined in Chapter C, paragraph 1.5.).

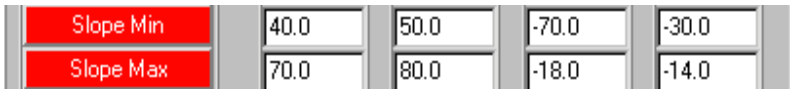
Low standard position and **High standard position:** write in these fields or select with up/down arrow keys ⬍ the positions for I.S.E. calibrators.

Timed re-run: It is possible to program automatic execution of calibration using this parameter. The analyzer will issue a warning message when the programmed standardization ends. If the reagents and standards are present, then one can directly perform the calibration. Insert the standardization time by enabling Time selection and program the corresponding field. One can enter interval of hours or days in this field.

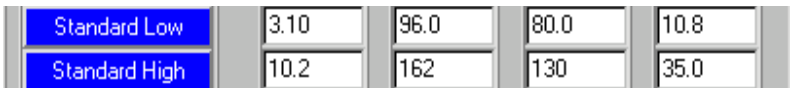
Last Standardization: The time and date of last test positive calibration are shown here.



Slope: After each calibration, the calculated values for the slopes are updated in these fields. Calculated slope values must be within the indicated ranges.



Slope Min / Max: By double-clicking the textboxes, slope ranges are individually set for each electrode. Refer to test methodology for correct values. The slope values are important for verifying a correct calibration and the electrodes status. When a slope is out of range, it will probably mean that the electrode must be replaced.



Standard Low/High: Double clicking in the appropriate fields it is possible to program the concentration values of the two standards for each electrode. Every time standards are changed, the set points must be changed as well. Refer to the kit insert or to the standards label for the correct values.



BSF: This parameter is a Base Line Factor and is used for Cl and CO_2. It must be set to 5. It is a linearity correction factor.

View used positions: This command shows all the positions used by standards.

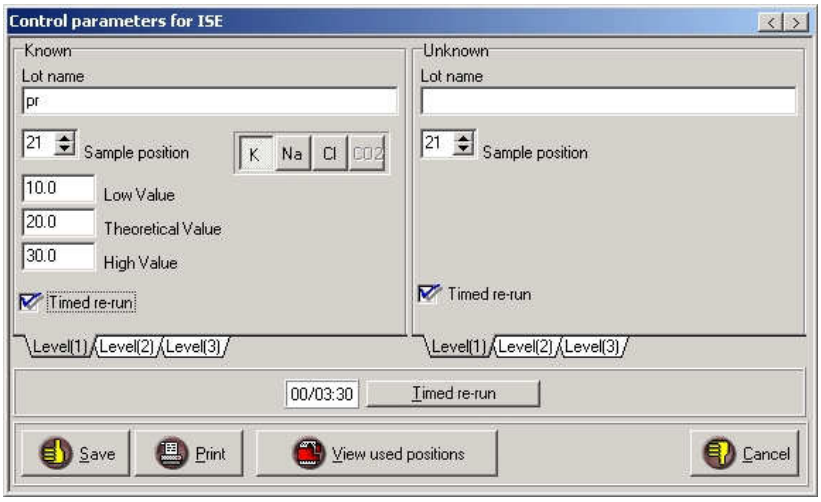


Figure 5

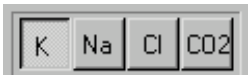
INSERTING CONTROLS

Go to **the Global list** or the **Current Tray list**. Select **ISE**, and then click **Controls** to display the **Controls parameters for ISE** (**Figure 5**). The Controls programming (automatic or on request) follows the identical procedure of Clinical Chemistry (**Chapter C**, **paragraph 1.4. Controls**). Selection of a single electrode is required prior to controls programming.

Use the command **Save** for memorizing data, **Cancel** for leaving the program without saving changes, and **Print** for hard copy printout.

The displayed page is divided into two parts, one for the **Known** controls and the other for the **Unknown** controls (**Figure 5**). The opening page is default set to **Level (1)** controls. To set parameters for Level 2 and 3, click corresponding tabs.

KNOWN CONTROLS



Known Controls: Select the electrode, prior to entering the control's range values**.**

Lot Name: Enter a name or a lot number.

Sample position: Enter the sample's physical position on the plate. The reserved sample positions are located in the inner circles of the sample plate and are dedicated to calibrators and controls. The numerical positions on the sample plate correspond to those established in the Setup Analyzer (refer to Chapter H, paragraph 2. Setup Analyzer).

Low value: Enter the lower value for the control's range.
Theoretical Value: Enter the theoretical value for the control.
High value: Enter the higher value for the control's range.

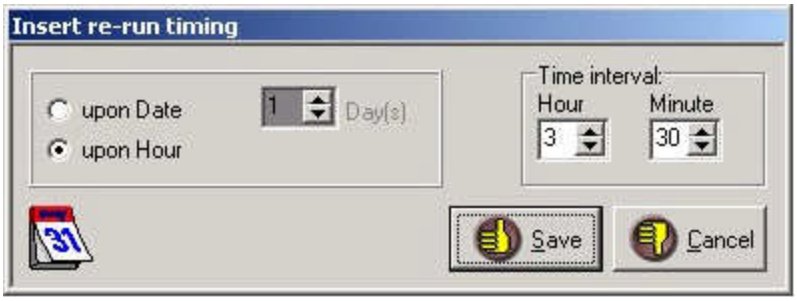


Figure 6

Timed re-run: This parameter allows programming of automatic execution of controls. It is possible to insert automatic execution time for each single control. Check **Timed re-run** box and then Click Timed re-run (just above the View used positions) to display Insert re-run timing screen (Figure 6).

Here one can enter interval of hours or days (refer to Chapter C, paragraph 1.4.) for automatic controls run.

upon Date (daily interval): Select the function and set daily interval, then enter test running time (for example 1 08,30 means every day at 08,30 or in any case at start up).

upon Hour (hour interval): Select the function and set the desired hour interval, hours and minutes.

Every day or when the preset time expires, the analyzer will automatically alert the user that there are controls to be run. If reagents and controls are present, then the user can directly confirm to execute the tests.

View used positions: This command displays the test disposition.

NOTE: Enter the same parameters also for Level 2 and 3 controls.

UNKNOWN CONTROLS

The only parameters to be set are the lot name or number, the sample position on the sample tray and the timed re-run for each level. Reserved positions are located in the inner circle of the sample plate and are dedicated to the calibrators and controls. The numerical positions on the sample plate correspond to those already set in the program **Setup Analyzer** (refer to Chapter H, paragraph 2. Setup Analyzer).

After programming all the parameters, save parameters by clicking **Save** button. Click **Print** for hardcopy printout of control parameters.

2.3. REPLACING AND INSTALLING ELECTRODES

The analyzer is supplied with the electrodes already installed in the ISE module.
To replace or install the electrodes the **analyzer must be turned off** and then the following steps must be observed:

WARNING
Do not touch with bare hands the small metallic tubes of the electrodes, the contacts of electrodes, or the sensor electronics, in order to avoid electrostatic discharges that may cause permanent damage or system malfunction.

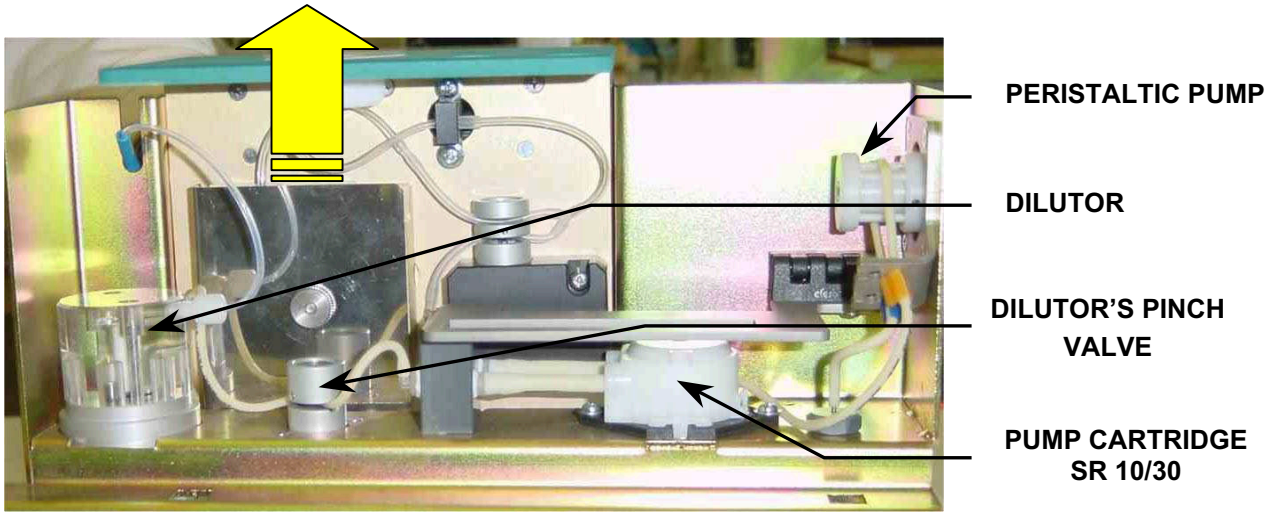


Figure 7

1. Before installing or replacing electrodes, remove the ISE module as shown in **Figure 7** and unscrew the thumbscrews securing the metallic shield.
2. Disconnect the tubes **2**, **3**, **4, 5** and **6** (**Figure 8**) from the electrodes. Remove the housing containing measurement electrodes (K, Na, Cl, By-pass or CO_2) by gently moving leftwards (**Figure 8**). Remove the housing containing Reference and Ground electrodes by carefully moving it rightwards. Keep these housings in vertical position when electrodes are present.
3. Carefully remove the electrodes from their respective housings by gently pressing on the backside. Always maintain the electrodes stack in vertical position.
4. It is recommended to immediately disconnect the first electrode (K) from the next one.
5. Replace the defective electrodes with new ones.
6. Reassemble the electrodes stack and place it into its housing.
7. Position the housing with the measurement electrodes on the ISE panel, and gently press fit to the right into the appropriate connecting pins of the detection electronics.
8. Carefully fit the housing with Ref & Ground electrodes by gently pushing to the left into the pins of the detection electronics.
9. Reconnect tubes **2**, **3**, **4, 5** and **6**.
10. Secure the metallic shield using the thumbscrews.
11. Insert ISE module into its appropriate slot.

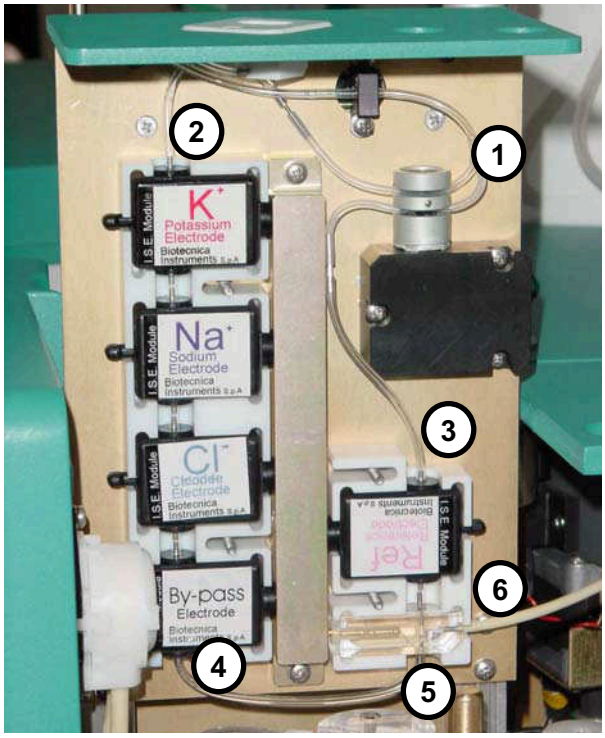


Figure 8

2.4. PRELIMINARY STEPS BEFORE STARTING THE SYSTEM

This procedure is necessary when installing the system or after replacing the electrodes. For normal operating functions, observe the following procedure:

a) Place the working solutions in their respective lodgings (**Figure 9**).

b) Make sure that the contents of the working solutions are sufficient for the necessary workload.

Caution

This verification of volumes (for necessary workload) is highly recommended. Whenever baseline or buffer solutions are changed, a new calibration of the system must be performed.

c) Run **Prime I.S.E.** (refer to **Chapter H**, paragraph **1.1.1.**) and repeat it for at least three times.

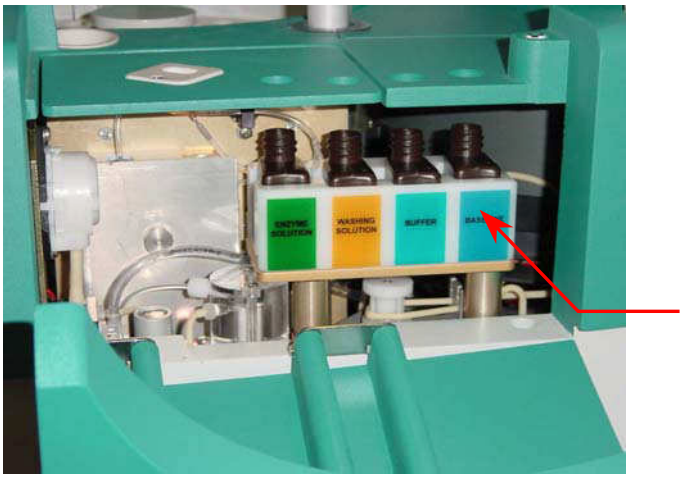


Figure 9

NOTES: if the device has just been installed, the electrodes have been replaced or if the I.S.E. module has not been used for some time, various system primes should be run. Wait around 30 minutes before using the I.S.E. module to let the electrodes by conditioned by prior passage of the reference solution.

d) Verify that programmed values for the standards (high level/low level) correspond to the used lot. Programming is performed as shown in **Figure 4**, where the values for two standards must be entered for the calculation of slope during the calibration.

e) To reduce the risk of contamination of baseline and buffer solutions through ambient air, it is suggested to remove and close the two bottles at the end of daily working sessions. Remember to open and replace these bottles at the beginning of every new working session.

The ISE module should be considered by the user as an ordinary test for Clinical Chemistry requiring a programming of its own for standards and controls. Calibration should be performed every four hours and it is essential for precise and accurate results. In addition, it is recommended to execute repeated calibrations until a stable slope value is obtained.

2.5. CALIBRATION PROCEDURE

Standards are automatically diluted with buffer solution (pH 8.6) with a ratio of 1:14. The mixed product is aspirated into the electrodes through the peristaltic pump. After an incubation period, the reading is performed.
At the end of calibration phase, the slope is calculated in accordance with **Nernst** equation:

Slope (s) = ΔE/(log STD high - log STD low)

where ΔE = difference in mV between STD high and STD low

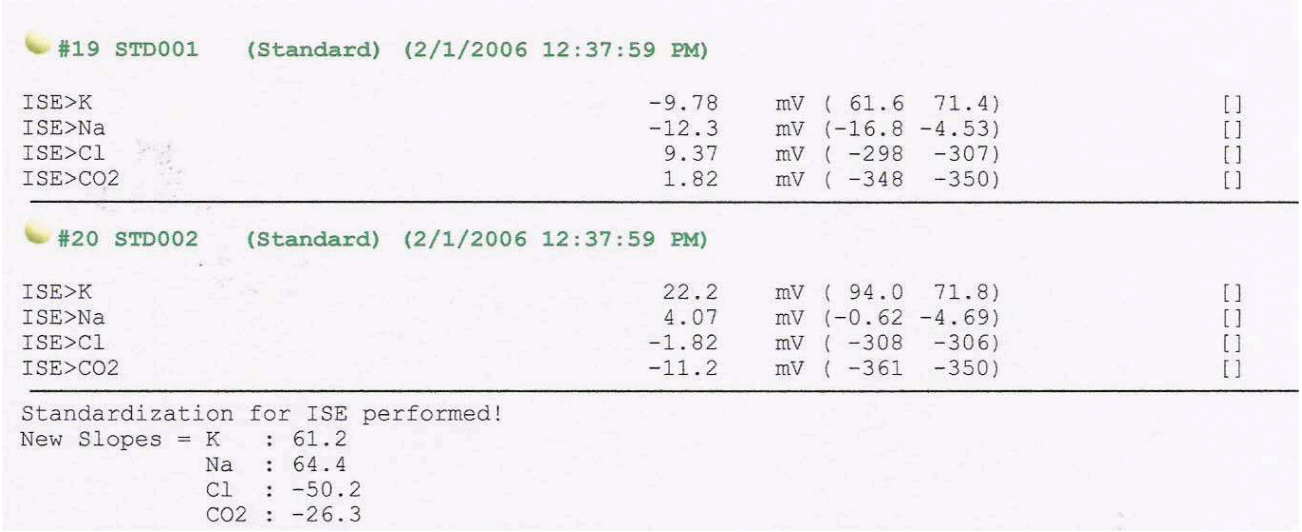
After calibrating each electrode, optimal slopes are obtained which should be within the following acceptance range:

	Optimal slopes		Range of slopes
K:	50 / 60 mV	K	40 / 70 mV
Na:	55 / 65 mV	Na	50 / 70 mV
Cl:	-45 / -35 mV	Cl	-70 / -25 mV
CO_2:	-30 / -22 mV	CO_2	-40 / -15 mV

NOTE:

In addition to the acquired slopes values, it is important to observe also the potential of the standards **mV STD Low** and **mV STD High** in the calibration printout.

In the optimal conditions, these values can be reproduced quite easily with slight variations around nominal value. The potential of the standards in association with the obtained slope values, are useful for evaluation of a correct calibration. When electrodes are not efficient, for example, when poor or no maintenance has been performed, or in case of contamination or degradation of the working solutions (Buffer, Baseline, or STD), the potential values vary considerably. This results in erroneous slopes indicating that the operating conditions are not optimal. However, in some cases, the potentials have incorrect values, but the slopes are apparently acceptable. Be cautious with this situation as the precision and accuracy of tests results will be affected by an incorrect calibration.



```
#19 STD001    (Standard)  (2/1/2006 12:37:59 PM)

ISE>K                                    -9.78    mV ( 61.6  71.4)          []
ISE>Na                                   -12.3    mV (-16.8 -4.53)          []
ISE>Cl                                    9.37    mV ( -298  -307)          []
ISE>CO2                                   1.82    mV ( -348  -350)          []

#20 STD002    (Standard)  (2/1/2006 12:37:59 PM)

ISE>K                                     22.2    mV ( 94.0  71.8)          []
ISE>Na                                    4.07    mV (-0.62 -4.69)          []
ISE>Cl                                   -1.82    mV ( -308  -306)          []
ISE>CO2                                  -11.2    mV ( -361  -350)          []

Standardization for ISE performed!
New Slopes = K   : 61.2
             Na  : 64.4
             Cl  : -50.2
             CO2 : -26.3
```

The potential values are related to standards, thus by changing standard's lot with another concentration, the different potentials will be observed with the same slope values. To optimize system performance it is fundamental that both the slope and potential values are always around established levels.
In case the slope values are out of range, an on-screen error message is displayed, even if there is an incorrect response from only one electrode. A check is also performed on the slopes reproducibility. The values obtained during current calibration are compared to the values of previous calibration. An error message appears during calibration if there is a variation greater than 3% for K and Na, 5% for Cl and 8% for CO_2.
Each standard measurement is followed by a baseline measurement. The baseline is a reference solution used for compensating any eventual drift of the system.

IMPORTANT NOTICE

a) After an incorrect calibration or in case of a calibration beyond the preset limits, the analyzer automatically performs a new calibration with up to 3 calibrations maximum.

b) Once the calibration standards are poured into the sampling cups, they are stable for no longer than 15 minutes. If calibrations, for any reason, last longer than this time, it is necessary to replace standards with fresh ones and repeat the calibration. The bottles containing buffer and reference solutions must be placed on the analyzer (open bottles - at room temperature) at least 30 minutes before operating phases begin and to allow for equilibrium with ambient temperature and with the carbon dioxide (CO_2) level in the air. If the thermal equilibrium is not reached, then the phenomena of drift effects and erroneous results can occur, while a lack of equilibrium with CO_2 may provide higher results for the latter test.

NOTE:
If slopes and potentials are constantly out-of-range, this indicates that the electrodes are exhausted, or there is an aspiration error of the reference (baseline) solution in the reference electrode, or the working solutions (buffer, baseline, STD) are contaminated or degraded. In case of contamination or degradation, replace in sequence the buffer solution, then the reference solution and at last the standard. Whenever a product is replaced, repeat the calibration procedure. In the other cases such as exhausted electrodes or a baseline aspiration error in the reference electrode, refer to the Troubleshooting guide.

2.6. MEASURING UNKNOWN SAMPLES

After a correct calibration, the samples are determined, which are prepared and read in similar manner to standards: dilution 1:14, aspiration into the electrodes, potential reading, and the reference (baseline) aspiration. The samples are calculated applying **Nernst** equation:

$$E - E_0 = s \log (Cx / C\ Std)$$

Considering the fact that the system requires a calibration, the measurement method is defined as comparative.
ISE tests are programmed in the same way as any other analysis of clinical chemistry.

Precision and accuracy errors when determining samples

NOTE:
In case of errors during samples determination, please follow indications outlined in the Troubleshooting guide.

Determined results can be associated to a flag that indicates eventual problems occurred during measurement.
The presence of **D** flag near a result, relevant to one or more electrodes, indicates drift during sample reading, i.e. the drift has exceeded ±2mV and thus the electrode may be unstable.
The flag **R** near the results indicates the absence of reagents.
The flag **B** adjacent to results indicates the presence of air (bubbles) in the hydraulic circuit during the transfer of the sample into the electrodes.
The sign **<NC>** in place of the results, indicates abnormal values (for example 9999999,999) or erroneous values (ex. No sample or reagent). Abnormal values may result from an interruption of the liquid flow into the electrodes during the test reading phases.

3. PRECAUTIONS, MAINTENANCE AND TROUBLESHOOTING

3.1. PRECAUTIONS FOR ISE MODULE USAGE

- The ambient conditions play an important role in the correct use of the ISE module. Room temperature must be between 20°C and 26°C, and the humidity between 35% and 75%.
- If the room temperature varies (even by 2°C or 3°C) during a working day, then it will be necessary to repeat the calibration of the ISE module just before running tests to avoid errors during next readings.
- It is suggested to insert the bottle containing buffer solution (open bottle - at room temperature) in the reagent tray at least 30 minutes before operating phases begin and to allow for equilibrium with ambient temperature and with the carbon dioxide (CO_2) level in the atmosphere. If the thermal equilibrium is not reached, then the phenomenon of drift and erroneous results may occur, while a lack of equilibrium with CO_2 may provide higher result values for the latter test.

  NOTE:

  ISE Module should be calibrated only after the above-mentioned equilibrium has been reached.
- When using the chemical standards, bear in mind that they are altered by air exposition. Therefore, it is recommended to fill the cups ¾ full (to minimize evaporation effect) and run the calibration immediately afterwards and then discard the remaining standard. In any case, do not leave standards exposed to air for longer than 15 minutes.
- It is recommended to run the standardization twice a day, in the morning and in the afternoon or in any case every four hours. To ensure a successful calibration, repeat it up to three times and verify if the results are stable. Standards and samples should be at room temperature before they can be used.
- Bear in mind that also the samples are altered if exposed to air for more than 30 minutes.
- The buffer bottle must always be closed (in case only a few samples per day are performed) after the ISE determinations, as the CO_2 in the solution degrades when exposed to air. If CO_2 slope should drop below 15, then replace the buffer solution and calibrate again. If the slope is still low even with a new buffer, then replace the electrode.
- If one of the two solutions, buffer or reference, is replaced, then the calibration should be performed again to avoid possible incorrect results.
- If the electrodes are removed for any reason, then carefully note down the electrodes sequence positions. The potassium electrode (K) must be immediately detached (by disconnecting tube) from the next electrode (Na) in the stack and maintained in vertical position, because even a small reflux of liquid from Cl and CO_2 electrodes can destroy it.
- The electrodes should be washed every day. This makes the electrodes more stable and guarantees a longer life.
- If only a few samples are run during the day, all the bottles containing I.S.E. solution should be closed (the enzymatic solution needs to be put in the refrigerator), in order to minimize contamination and evaporation.

3.2. SUGGESTIONS FOR PERFORMANCE MAINTENANCE.

To eliminate any problems during ISE operation, observe the following suggestions:

Before a long period of system's inactivity, proceed as follows:

a) Perform an ISE wash (refer to **Chapter H**, paragraph **1.1.1.**), even if no ISE determination has been performed.
b) Run **Prime I.S.E.** and repeat it three times (refer to **Chapter H**, paragraph **1.1.1.**).
c) At the end of this operation, release **tube 6** (**Figure 8**) from the peristaltic pump and remove the tubes 1 from the pinch valve to avoid sticking and collapsing of tubes.

NOTE: In case the ISE module has the **Cl** and **CO_2** electrodes, then also disconnect the tube 2 connected to **K** electrode (see **Figure 8**).

After a long period of system's inactivity, perform the following:

a) Connect tube 6 to the peristaltic pump, insert tubing 1 into the pinch valve and connect the tube 2 to **K** electrode.
b) Run **Prime I.S.E.** and repeat this procedure for three times (refer to **Chapter H**, paragraph **1.1.1.**).

CAUTION: refer to the Troubleshooting guide in case of problems during system restoring.

The analyzer alerts the operator in the following situations:

a) Every 24 hours the analyzer will ask for the ISE wash.
b) In case more than 150 ISE tests have been performed, then the ISE washing will be prompted.
c) If more than 300 ISE tests have been performed, then the preceding ISE washing message will be supplemented by an additional prompt requiring the cleaning of Chloride electrode.

Turning off the system equipped with ISE Module

During turning off procedure, the analyzer requests whether the cuvettes and the ISE Module should be washed (with Cleaning Solution and Enzymatic Solution). In case of an affirmative response, the analyzer will wash both cuvettes and electrodes, otherwise it is possible to wash the cuvettes only.

NOTE: It is important to wash electrodes everyday. This makes the electrodes more stable and prolongs their life. If the I.S.E. module is not going to be used any longer, run a complete wash. It is not necessary to repeat the wash after this until the I.S.E. module is used again.

3.2.1. I.S.E. Maintenance

PROGRAMMED MAINTENANCE

Item	**Replacement**
Kit tubes and peristaltic pump	Every 150000 cycles or 6 months
Kit tubes I.S.E. module	Every 6 months
Potassium electrode (K)	Every 3 months
Sodium electrode (Na)	Every 12 months
Chloride electrode (Cl)	Every 3 months
Carbon dioxide electrode (CO_2)	Every 3 months
Reference electrode (Ref)	Every 12 months

Note: the Kit tubes and peristaltic pump items are contained into the BT3000 Plus Six month maintenance kit (code 11-05337-01) and in the BT35000 Six month maintenance kit (code 11-05669-01). The other items are contained in the following dedicated kits.

BT3000 PLUS: QUARTERLY MAINTENANCE KIT (CODE 11-05338-01)		
ITEM	**QTY**	**DESCRIPTION**
1	1	REF - K Tube Manifold
5	1	Interconnection Tube for GND/Bypass OR CO2 Electrode
6	1	ISE Pump Tube

BT35000: QUARTERLY MAINTENANCE KIT (CODE 11-05668-01)		
ITEM	**QTY**	**DESCRIPTION**
1	1	REF - K Tube Manifold
5	1	Interconnection Tube for GND/Bypass OR CO2 Electrode
6	1	I.S.E.-Pump Tube

- To access the ISE Module, remove the plastic lodging for the reagents. Slide up the ISE electrodes panel to have an easy access to disconnect the waste tube connecting peristaltic pump to the ISE Module.
- Replace the Y-shaped tubing set (ref. 1 figure 7) by first inserting the single tube end into the bubble sensor, and then connect it to the funnel located above. Insert the remaining two tube attachments into the appropriate slots (K tube in the upper slot and the REF tube in the lower slot) of the pinch valve and then correctly connect their ends to the REF and K electrodes as shown in the figure. Verify correct tubing placement in the pinch valves.
- Replace the I.S.E.-peristaltic pump tube (ref. 6 figure 7) by connecting one end to the ground electrode, then around the pump head, and the other end to the waste liquid connector as illustrated. Then clip the tube holders to the tightener support.
- Connect interconnection tube (ref. 5 figure 7) to the CO2 electrode (or By-pass) and the ground electrode.
- Replace peristaltic pump cartridge (ref. 7 figure 7): remove both ends of the peristaltic pump tubing from the diluter manifold. Squeeze the locking catches and remove the defective cartridge. Place the new cartridge on the drive shaft and gently press to snap-fit. Carefully attach the pump tubing to both fittings in the diluter manifold.
- Replace tube (ref. 8 figure 7) connecting the peristaltic pump through pinch-valve to the dilutor.
- Carefully lower the ISE electrodes panel back into place ensuring that the tube (ref. 6 figure 7) is free and not pinched or crushed by the panel.

After replacing tubes and accessories, turn on the analyzer. Insert the plastic lodging with the reagent bottles containing appropriate products and run a few times the function Dilutor prime and Prime I.S.E. (refer to Chapter. H, paragraph 1.1.1.) to prime the hydraulic circuit.

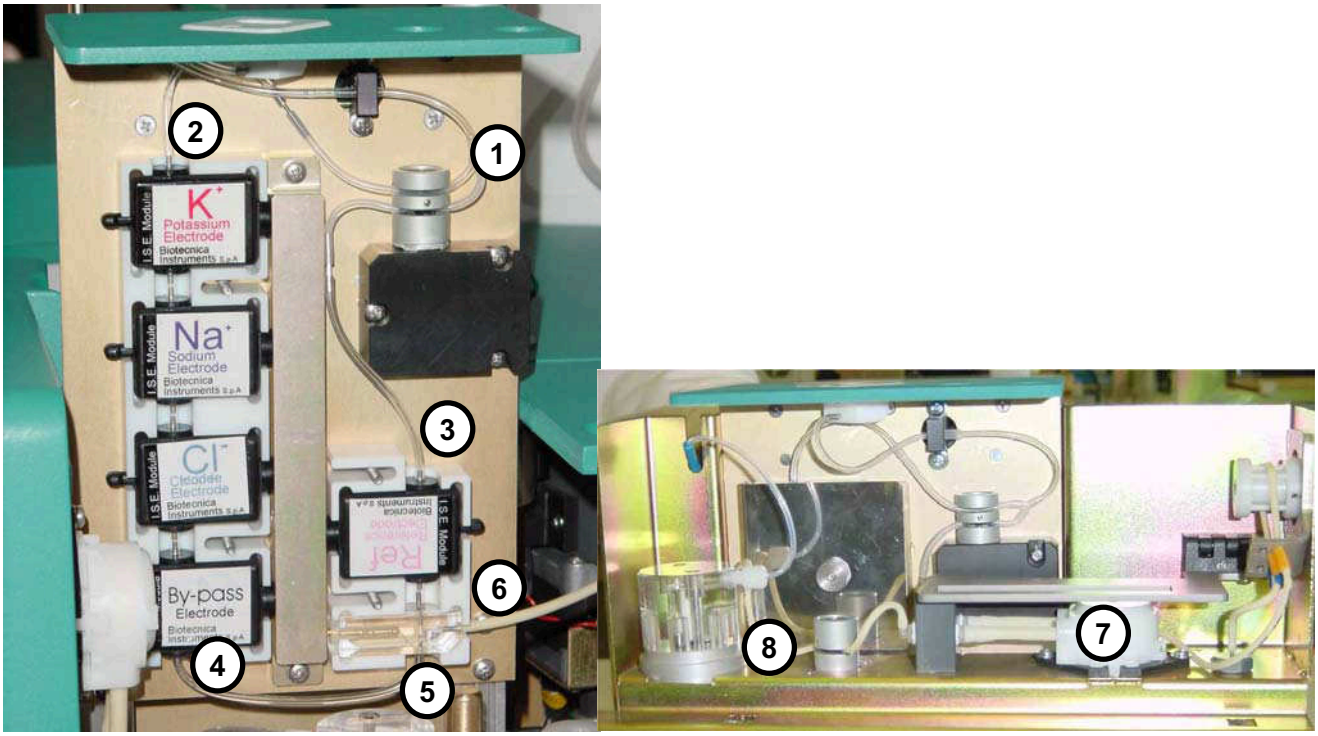


Figure 10

I.S.E. Electrodes

The I.S.E. electrode for sodium (Na) and I.S.E. reference electrode (Ref) need to be replaced on an annual basis. The I.S.E. electrodes for potassium (K), chloride (Cl) and carbon dioxide (CO_2) need to be replaced quarterly. The by-pass electrode, sometimes present in the place of another electrode not in use, does not require maintenance.

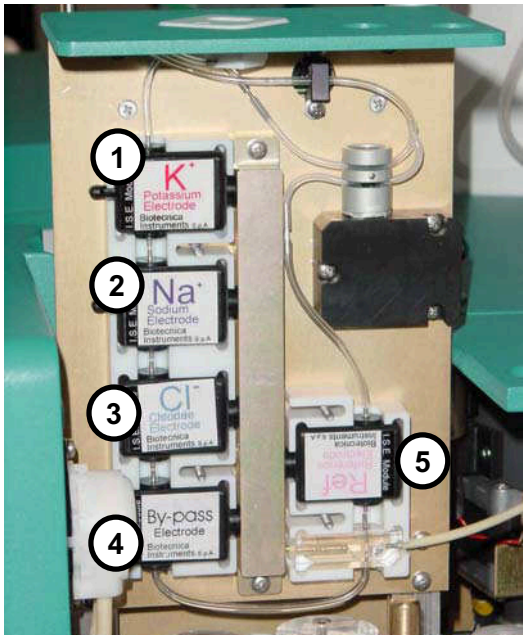


Figure 11

I.S.E. Electrodes			
Ref.	**El.**	**Code**	**Description**
1	K	662.0712	Potassium electrode
2	Na	662.0711	Sodium electrode
3	Cl	662.0713	Chloride electrode
4	CO2	662.0716	Carbon dioxide electrode
4	ByP	662.0709	By-Pass electrode
5	Ref	662.0710	Reference electrode

3.3. TROUBLESHOOTING

If the routine maintenance is performed regularly, the ISE module functions correctly. The most common problems encountered in the ISE Module are as follows:

a) Calibration errors.
b) Unreliable sample results with flags.
c) Error messages of air bubbles.

a) CALIBRATION ERRORS

The causes may be due to various reasons and can be diagnosed through close examination of mV values of slopes.

Typical values of calibration potentials in mV:

K std low = -8 mV
std high = +22 mV difference 30 mV (slope 57 mV)

Na std low = -10 mV difference 15mV (slope 63 mV)
std high= + 5 mV

Cl std low = +6 mV difference 10mV (slope 50 mV)
std high = -4 mV

CO_2 std low = +4 mV difference 10mV (slope 32 mV)
std high = - 6 mV

The above-mentioned values are indicative and may deviate due to the wear and tear of the electrodes.
A positional error or an incorrect concentration of reagents may determine a considerable variation of potentials and slopes.
The mV values (in brackets) in the calibrations printout can give additional indications, which are useful for the diagnostics.

For example:

Std low	-8mV	(-208 -200)
Std high	+22mV	(-178 -200)

One can observe in the above example the Baseline value (-200), which must be always included between two Std values. In fact the value -200 is between the two values -208 and -178.

Various combinations of error

a) Inversion of Buffer / Baseline
Considerable increase of potentials (up to 100mV), decrement of slopes.

b) Insertion of identical reagents: Buffer / Buffer or Baseline / Baseline.
The potentials are almost within norms but there is considerable decrement of slopes.

In the above items a) and b), the Baseline values shown in the preceding example shall not be coherent.

Obstructions caused by proteins in electrodes Cl &CO2

When running 150-200 I.S.E. samples per day, the **Cl** & **CO_2** electrodes may be periodically obstructed. In this case, one observes an increase in the slopes of **K** & **Na**, and decrement in the slopes of **Cl** & **CO_2**. Follow the instructions for the cleaning of electrodes.
A similar error may also be caused by a partially occluded Ground electrode. Generally, the obstructions in the ground electrode are caused by the foreign matter and not by protein. Carefully observe the cleaning procedures as outlined in the **Figures 10** and **11** on the ensuing pages.

NOTE:
A prolonged obstruction of the **Cl** electrode may progressively obstruct the electrodes below it (**CO_2** and **Bypass**). For cleaning these electrodes, use syringe for the **CO_2** and the cleaning tool on the **Bypass** as shown in the **Figure 11**.

b) BAD RESULTS OF SAMPLES:

Generally, this phenomenon occurs during sampling but it may take place afterwards. Observe the above-mentioned diagnostic procedures.

c) ERROR MESSAGES, AIR BUBBLES, FLAGS

During a calibration or a run an error message Air bubbles may appear. The error may be momentary and not appear afterwards. In this case, it means a casual formation of bubbles.
The bubble error in the I.S.E. is managed as follows:

a. If the bubble error occurs during the prime, the analyzer should give the bubble error warning, all the following I.S.E. samples will have to be flagged with B and will have <NC> instead of the result.
b. if the bubble error occurs during the sampling, while reading the baseline, the analyzer should display the bubble error message, should stop sampling and should give all the following I.S.E. samples results as <NC>, with flag B.
c. In case bubbles are detected while reading a sample, the warning message should be displayed. The sample will be flagged with B and will have <NC> instead of the I.S.E. result. The analyzer will go ahead with the following samples.

If the bubble error persists then it may be due to problems of hydraulic nature.

a) ISE funnel takes long time to empty. It may be caused by defective or worn peristaltic pump for draining or an obstruction in the electrodes stack. Repair or replace.
b) Prime operation failure. The Prime also calibrates the bubble sensor. Check that prime is performed properly.
c) Collapsed tube in the ISE pinch-valve. The Baseline solution doesn't enter the Reference electrode and the funnel doesn't empty. The Reference electrode is filled during the prime. Check and correct.
d)

Results with flag D

During the reading, the flag D on one or more electrodes indicates a drift of potential greater than 2 mV. The phenomenon may be determined by one of the following causes:

- Defective electrode.
- Electrode to be reconditioned.
- Partial occlusion of the electrode.
- Incorrect reagents.
- No washing after a consistent run.
- Correlation with general problems already explained.

Screen Messages - Causes And Remedies

NO SPECIAL REAGENTS	
NO I.S.E. BUFFER SOLUTION **NO I.S.E. REFERENCE SOLUTION**	The error message ***NO ISE BUFFER SOLUTION / NO ISE REFERENCE SOLUTION*** is displayed when the analyzer ***detects the absence of*** ISE buffer solution ***or reference solution needed for programmed tests.*** Immediately after this message the ISE sampling is interrupted. Insert new buffer / reference and perform a new I.S.E. calibration. It is possible to repeat interrupted tests using the **Re-run** option (**Chapter E**, paragraph **1.5**).
NO I.S.E. WASHING SOLUTION	The error message ***NO ISE WASHING SOLUTION*** is displayed when the analyzer ***detects through a built-in liquid sensor the absence of*** ISE washing solution and instantly the ISE sampling is interrupted. To restart washing insert new washing solution bottle.

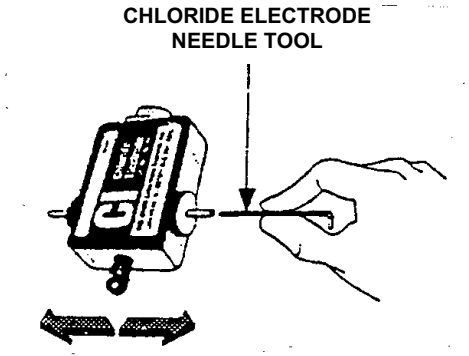
NOTICE

It is often possible to extend the life of a chloride electrode by using the supplied **CHLORIDE ELECTRODE NEEDLE TOOL P/N 03254.**

1. Grasp the NEEDLE TOOL as shown. Gently insert the tip of the needle tool into either end of electrode. Keeping your fingers off the opposite end of electrode, slowly but firmly push the needle straight through the electrode's inner core until the needle tip appears at the other end of the electrode (be careful not to bend the needle inside the electrode). Wipe off any debris on the needle tip and gently pull the needle back out of the electrode. Wipe off the needle and remove any debris or moisture from the electrode surface. Repeat on the other side of the electrode and until the needle tool tip is perfectly clean when exiting from the electrode.
2. Reinstall the electrode into the electrode housing in the correct order.
3. Install the electrode housing into the ISE. Connect tubing and prime the ISE module completely. If the electrode's performance does not improve, contact your local Technical Support.

WARNING

NEEDLE TOOL can damage all other electrodes (K, Na, CO2, REF). Do not use!

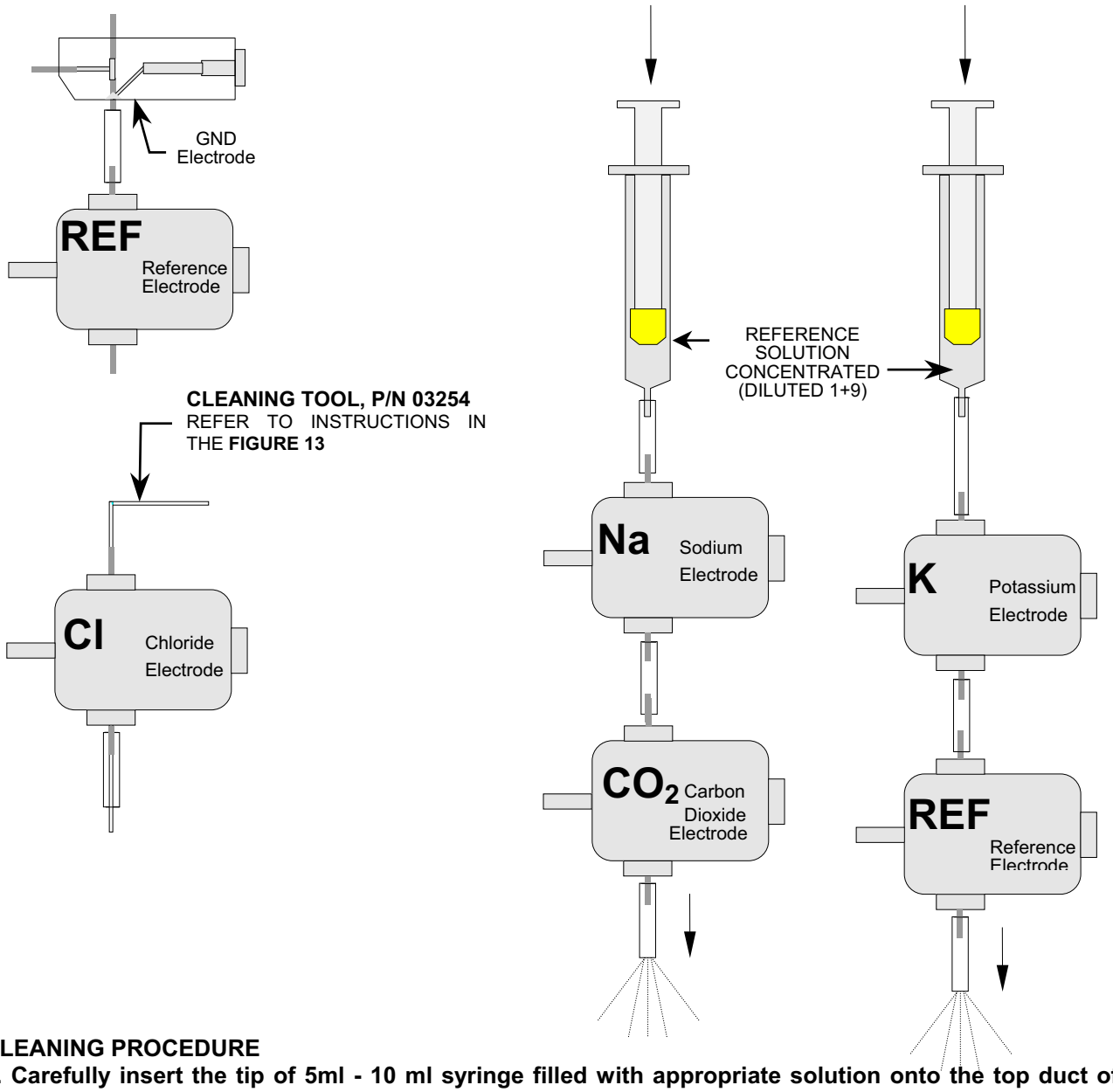


Chloride Electrode Cleaning Procedure

Figure 12

ISE ELECTRODES CLEANING PROCEDURE

NOTE:
FOR CONVENIENCE SAKE, IT IS IMPORTANT TO DETACH THESE ELECTRODES IN SMALL GROUPS FROM THE REST TO AVOID POSSIBLE ACCIDENTAL DAMAGE WHEN HANDLING A LONG STRING OF ELECTRODES. OBSERVE THE CLEANING PROCEDURE OUTLINED HERE FOR OTHER ELECTRODES.



CLEANING PROCEDURE

1. Carefully insert the tip of 5ml - 10 ml syringe filled with appropriate solution onto the top duct of electrode assembly as shown.

2. Inject solution until all the solution is forced through interconnecting bores of the electrodes and flows out from the bottom electrode, thus thoroughly removing any contamination.

WARNING

a. PUSH THE PLUNGER ONLY TO EJECT THE SOLUTION. DO NOT PULL THE PLUNGER TO ASPIRATE THE SOLUTION INSIDE ELECTRODES. THIS WILL CAUSE IRREPARABLE DAMAGE AND CONTAMINATION TO THE POTASSIUM ELECTRODE WITH Cl OR CO_2 PARTICLES.

b. DO NOT USE PLASTIC STRING FOR CLEANING THE REFERENCE OR Na ELECTRODES AS IT MAY DAMAGE THE ELECTRODES INTERNALLY

Figure 13

4. RETURNING THE ANALYZER TO THE TECHNICAL ASSISTANCE SERVICE

FOR MORE INFO REFER TO CHAPTER M

Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Put a suitable decontaminant (e.g. HCl 1N hydrochloric acid diluted at 3%) in a reagent bottle and place it in position no. 40 for BT3000 Plus & BT3500 (or in position 24 for BT1000 & BT2000 Plus).
3. Prepare a bottle of enzymatic solution for washing the I.S.E. and place it together with the other I.S.E. solutions in the specific housing.
4. Start a cuvette (Analyzer Utilities menu – Wash cuvettes) and I.S.E. (Analyzer Utilities menu – Wash I.S.E.) wash cycle.
5. Wait five minutes after the washes have finished and then remove the decontaminant bottle from the reagent tray and put the I.S.E. enzymatic solution back in the refrigerator. Remove all the other bottles of I.S.E. solutions.
6. Run a normal wash cycle with water (Analyzer Utilities – Wash with water).
7. Empty the hydraulic circuit (from the Analyzer Utilities menu - Empty fluidics).
8. Shut down the analyzer.
9. Clean off the entire sample tray with decontaminant and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

Analyzer Safe Disposal

When the instrument is no longer useable or needs to be decommissioned, follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.

Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Empty the hydraulic circuit (from the Analyzer Utilities menu: empty fluidics).
3. Remove the water tube from the external container and put it in a container with at least one liter of suitable disinfectant or decontaminant (e.g. hydrochloric acid HCl 1N diluted at 3%). Put disinfectant also in the four empty bottles in place of I.S.E. solutions and in a bottle in position 40 for BT3000 Plus & BT3500 (or in position 24 for BT1000 & BT2000 Plus) of the reagent tray.
4. Fill the hydraulic circuit again by running a reset and a series of prime of the clinical chemical diluter and the diluter of the I.S.E.
5. Run a wash of the cuvettes and I.S.E. (from the Analyzer Utilities menu - Wash with water and Wash I.S.E.)
6. Wait five minutes. Remove the disinfectant from the container and from the I.S.E. bottles and replace it with water. Put the water tube back in the container which has just been filled.

7. Run a wash of the cuvettes and I.S.E. again, and then empty the hydraulic circuit again.
8. Shut down the analyzer.
9. Remove all the cords connecting the UPS to the mains and peripheral devices from the analyzer.
10. Remove all the cables connecting the peripheral devices (keyboard, mouse, wireless connector, printer and UPS).
11. Carefully clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
12. Carefully clean the peripheral devices using a clean cloth and a disinfectant.
13. Remove the waste tubes from the analyzer and the vacuum system.
14. Remove the vacuum system discharge probe and soak it for five minutes in disinfectant (HCl 1N diluted at 3%). Then rinse it in water.
15. Remove all the tubes which are part of the washing, distribution and sampling hydraulic circuit and the I.S.E. circuit. Remove the I.S.E. electrodes as well.
16. Sort the material from decommissioning the instrument so that they can be recycled or disposed of as special waste in accordance with local laws.

If the analyzer is going to be returned to the Distributor, make sure all the removal parts of the system are bagged and separated after decontamination so that they can be disposed of as special waste.

5. ISE MODULE CONSUMABLES

PRODUCT	PART NO.	SIZE
I.S.E. Low Calibrator	943	2x20 ml
I.S.E. High Calibrator	944	2x20 ml
I.S.E. Starter Kit (Consists of: 943, 944, 947A, 947B, 947C, 947D)	947	1
I.S.E. Buffer (concentrated)	947A	3x10 ml
I.S.E. Reference (concentrated)	947B	3x10 ml
I.S.E. Washing Solution	947C	3x10 ml
I.S.E. Enzymatic Solution	947D	3x10 ml
By-Pass Electrode	662.0709	1
Reference Electrode	662.0710	1
Sodium Electrode (Na)	662.0711	1
Potassium Electrode (K)	662.0712	1
Chloride Electrode (Cl)	662.0713	1
Carbon Dioxide Electrode (CO_2)	662.0716	1
Cleaning tool for Chloride Electrode	03254	1

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER M

1. WARNINGS AND PRECAUTIONS Page: 2
1.1. Potential risks during operation and maintenance Page: 2
1.2. Warnings and precautions Page: 3
1.3. Waste disposal Page: 6
1.4. Returning the analyzer to the T.A.S. Page: 6
1.4.1. Operating Analyzer Page: 6
1.4.2. Not Operating Analyzer Page: 7
1.5. Analyzer safe disposal Page: 8
1.6. Electric and electronic devices disposal Page: 9

ATTENTION: USE OF THE ANALYZER INTERNAL COMPUTER – DOES NOT APPLY TO BT1500

The computer box of BT analyzers is designed for long-term security and reliability and is virtually maintenance-free as long as the user does not install any third-party application programs. If these applications are installed, then they may damage the operating system registry and may also cause disastrous consequence for the computer's hard-drive. Biotecnica Instruments S.p.A. will not be responsible for any damage to the analyzer, its software and data in the hard-disk in case of improper use of the PC box. This includes also: installation of external programs, not properly secure net connections (intranet and internet) and the use of disks without the necessary verification for viruses presence. Biotecnica Instruments S.p.A. will not be responsible for any damage caused by non authorized third parties who may open and alter the PC box configuration.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. WARNINGS AND PRECAUTIONS

1.1. POTENTIAL RISKS DURING OPERATION AND MAINTENANCE

- **USE**

  Although the BT analyzer system uses high performance components, which provide a high degree of safety, it is essential that the user takes the usual precautions to safeguard himself and to ensure a safe working environment.

  Biotecnica Instruments S.p.A. only guarantees the workmanship and materials of its products. It is the duty of the user to take care of safe operation and no amount of warnings can take place of such care.

  As regards the moving parts in the analyzer, these have been appropriately protected to avoid any potential risks to the user, and for proper instrument operation and safety. However, it is highly recommended to exercise extreme care during analyzer operation and especially when working close to the devices.

  To avoid accidental contamination, use suitable guards and/or personal protection, such as overall and gloves. When handling reagents, it is advisable to observe good laboratory practice (GLP) rules.

  Chemicals, serum samples and reagents must be handled with extreme caution. Patient samples may be biologically hazardous. The reagents or any other substances that may enter in contact with samples should be treated in the same way as samples themselves.

  The materials of human origin, such as control sera, are tested for the detection of HbsAg, anti-HCV anti-HIV-1 anti-HIV–2 antibodies. Even if the result is negative, as no known analytical method can exclude any infection's risk with certainty therefore these materials must be considered as potentially infective and thus must be handled with extreme caution. The reagents and any other substance entering in contact with samples must be treated in the same way. The reagents must be manipulated (before, during and after the use) by qualified personnel familiar with their characteristics in order to safeguard the user as well as the quality of the reagent itself.

- **MAINTENANCE**
  - It is of extreme importance that the instrument is fully turned off and the power cord unplugged from the wall outlet to safely perform any maintenance or service procedure.
  - During maintenance procedures (see **"Chapter L**, **"Maintenance"**), the safety and warning precautions must be observed as outlined in the preceding paragraph.
  - The exterior of the analyzer casing may be cleaned periodically to remove dust grease and other contamination. It is not necessary to clean the inside. Use soft cloth dampened with a mild solution of detergent with water.
  - The owner shall be responsible for maintenance of the analyzer. Wear or damage caused by lack of normal maintenance or by misuse of the analyzer shall not be considered as defective workmanship and material.

1.2. WARNINGS AND PRECAUTIONS

The following warnings will aid the user to provide adequate safeguards to assure safe trouble-free performance:

1. **BEFORE OPERATING THIS SYSTEM, BE SURE TO READ THE OPERATOR MANUAL THOROUGHLY AND CAREFULLY. AFTERWARDS, KEEP IT HANDY FOR FUTURE REFERENCE.**
2. **TAKE SPECIAL CARE TO FOLLOW THE WARNINGS AND CAUTIONS INDICATED ON THE SYSTEM REAR PANEL AS WELL AS IN THE OPERATOR MANUAL.**
3. **SYSTEM'S USE SHOULD BE RESTRICTED TO LAB'S QUALIFIED PERSONNEL ONLY.**
4. **SLOTS AND OPENINGS IN THE CASE, BACK PANEL, AND BOTTOM ARE PROVIDED FOR VENTILATION. THIS ENSURES RELIABLE OPERATION OF THE SYSTEM AND TO PROTECT IT FROM OVERHEATING. DO NOT BLOCK OR COVER THESE OPENINGS.**
5. **BEFORE USING THE SYSTEM, CHECK THAT THE VOLTAGE ON THE REAR PANEL LABEL MATCHES THE LOCAL LINE VOLTAGE.**
6. **TO GUARANTEE SAFETY THE SYSTEM MUST BE PROPERLY GROUNDED. THE WIRES IN THE MAINS POWER CORDSET ARE COLORED IN ACCORDANCE WITH THE FOLLOWING CODES:**

GREEN AND YELLOW:	**EARTH**
BLUE:	**NEUTRAL**
BROWN:	**LIVE**

   IN CASE OF DOUBTS CONTACT THE NEAREST QUALIFIED ELECTRICIAN.
7. **REPLACE FUSE AS MARKED** (see **Chapter N, "Maintenance"**). **PRIOR TO THE REMOVAL OF ANY FUSE, TURN POWER OFF AND UNPLUG THE CORDSET FROM THE WALL.**
8. **UNDER NO CIRCUMSTANCES IS THIS INSTRUMENT CASE TO BE OPENED. THIS INSTRUMENT IS NOT USER SERVICEABLE. DANGEROUS HIGH VOLTAGES INSIDE THIS INSTRUMENT CASE. IN EVENT OF DIFFICULTY, PLEASE NOTIFY YOUR DEALER FOR PROMPT SERVICE.**
9. **FOR OPERATING SAFETY, DO NOT INSTALL THE SYSTEM IN A LOCATION WHERE IT WILL BE EXPOSED TO HEATING EQUIPMENT OR RADIATORS, DIRECT SUN LIGHT, OR ANY OTHER SOURCE OF EXTREMELY HIGH TEMPERATURES.**
10. **DO NOT OPERATE THE SYSTEM IN THE PRESENCE OF FLAMMABLE FLUIDS OR GASEOUS ATMOSPHERE, DISINFECTING AGENTS, CLEANING AGENTS, ETC., DUE TO POSSIBLE FIRE OR EXPLOSION.**
11. **DO NOT KINK, BEND, LAY OBJECT ON, OR OTHERWISE DAMAGE OR RESTRICT CABLES AND TUBES.**
12. **BE SURE THAT THE POWER SWITCH ON THE BACK PANEL OF SYSTEM IS OFF WHEN PLUGGING IN, OR REMOVING THE POWER CORDSET FROM A WALL OUTLET.**
13. **TURN OFF THE MAINS POWER SWITCH ON THE REAR PANEL WHENEVER THE SYSTEM IS NOT IN USE. THIS PREVENTS DAMAGES DUE TO SURGE IN THE MAINS POWER.**

14. **DO NOT ATTEMPT TO ALTER THE SHAPE OF ANY PART OF THE SYSTEM.**

15. **IF THE SYSTEM IS NOT OPERATING PROPERLY AND THE TROUBLE-SHOOTING SECTION (**refer to **Chapter N, "Maintenance") DOES NOT PROVIDE A SATISFACTORY SOLUTION TO THE PROBLEM, THEN DO NOT USE THE SYSTEM UNTIL THE DEFECTS ARE REMEDIED.**

16. **INSPECT ALL ACCESSORIES AND SYSTEM CORDS. DO NOT USE IF DAMAGE CAN BE SEEN SUCH AS CUT INSULATION OR OUTER COVERING, FRAYED OR BROKEN WIRES, CORRODED OR BROKEN CONNECTORS ETC.**

17. **TO REDUCE THE RISK OF FIRE OR ELECTRIC SHOCK, DO NOT ALLOW FLUIDS OR ANY FOREIGN OBJECT TO ENTER THE SYSTEM. WIPE OFF SPILLS IMMEDIATELY.**

18. **DO NOT USE BENZENE, THINNER, ANY KIND OF SOLVENTS, OR ABRASIVE DETERGENTS TO CLEAN THE CASE. CLEAN WITH SOFT DUSTING CLOTH DAMPENED WITH DISTILLED WATER. IF NECESSARY USE ONLY NEUTRAL DETERGENT.**

19. **DO NOT STICK OBJECTS OF ANY KIND INTO THE SYSTEM THROUGH BACK PANEL OR CASE SLOTS AS THEY MAY TOUCH DANGEROUS VOLTAGE POINTS OR SHORT OUT PARTS THAT COULD RESULT IN FIRE OR ELECTRIC SHOCK.**

20. **INSTALL THE SYSTEM IN SUCH A WAY THAT ADEQUATE VENTILATION IS PROVIDED ALL AROUND TO PROPERLY DISSIPATE THE HEAT.**

21. **USE ONLY ORIGINAL BIOTECNICA'S TUBING REPLACEMENTS. DO NOT USE CONVENTIONAL TUBING. THIS WILL CAUSE MALFUNCTION OF THE SYSTEM.**

22. **MAKE SURE ALL FLUID LINES ARE FREE OF KINKS, NICKS, SHARP BENDS, PUNCTURES, OR OCCLUSIONS BEFORE INSTALLING ON SYSTEM.**

23. **DO NOT TWIST THE PERISTALTIC PUMP TUBING WHEN PLACING IN THE RACEWAY OF THE PUMP ROLLER.**

24. **RELEASE THE PERISTALTIC PUMP TUBING WHENEVER THE SYSTEM IS UNUSED FOR A PERIOD OF TIME LONGER THAN 36 HOURS.**

CAUTION

THE HYDRAULIC CIRCUIT SHOULD BE FULLY DISCHARGED AND THE WATER RESERVOIR DISCONNECTED FROM THE CIRCUIT PRIOR TO RELEASING THE TUBES FROM THE VALVES. IF THESE STEPS ARE NOT TAKEN, SERIOUS DAMAGE MAY BE CAUSED TO THE ANALYZER.

25. **THE HALOGEN LAMP MUST BE REPLACED SOME MINUTES AFTER THE INSTRUMENT HAS BEEN TURNED OFF AND POWER CORD UNPLUGGED (**refer to **Chapter N, "Maintenance").**

26. **ALWAYS ALLOW THE BURNT OUT LAMP TO COOL DOWN BEFORE HANDLING OR ATTEMPTING REPLACEMENT.**

27. **NEVER TOUCH THE LAMP OR THE REFLECTOR WITH BARE FINGERS. USE A RAG WHEN CHANGING.**

28. **IF THE LAMP IS TOUCHED INADVERTENTLY DURING INSTALLATION, CLEAN THE LAMP OR REFLECTOR WITH ALCOHOL AND DRY WITH A CLEAN, SOFT CLOTH BEFORE BURNING. CONTAMINATION OF THE LAMP OR REFLECTOR MAY REDUCE LAMP PERFORMANCE.**

29. **THIS LAMP (WHEN LIT) EMITS UV (ULTRAVIOLET) RADIATION. PROLONGED EXPOSURE TO THIS LAMP MAY CAUSE SKIN AND EYE IRRITATION.**

30. **THE ANALYZER SYSTEM MUST NOT BE DISMANTLED OR REPAIRED BY ANYONE WHO HAS NOT BEEN QUALIFIED BY THE MANUFACTURER. INCORRECT WORK MAY CAUSE FIRE OR IRREPARABLE DAMAGE TO THE SYSTEM.**

31. **DO NOT OVERLOAD ACCESSORIES POWER OUTLETS AND EXTENSION CORDS AS THIS CAN RESULT IN FIRE OR ELECTRIC SHOCK.**

32. **DO NOT PLACE THE SYSTEM ON AN UNSTABLE CART, STAND, OR TABLE; THE SYSTEM MAY FALL, CAUSING SERIOUS INJURY TO USER, AND SERIOUS DAMAGE TO THE APPLIANCE. PLACE THE SYSTEM ON A STABLE, VIBRATION-FREE, LEVEL TABLE OR CART.**

33. **USE ONLY SECURE POWER SOURCE TO PROTECT THE ANALYZER SYSTEM AGAINST POWER SURGES. DISCONNECT TEMPORARILY THE ANALYZER POWER CORD FROM THE WALL OUTLET IN CASE OF BAD ATMOSPHERIC CONDITIONS.**

34. **DO NOT OIL ANY PART OF THE SYSTEM.**

35. **EMPTY WASTE CONTAINERS WHENEVER THEY ARE FULL. ENSURE THAT THE CONTAINER LIDS ARE SCREWED ON TIGHTLY TO PREVENT LEAKAGE OR DISPERSION INTO THE ENVIRONMENT.**

36. **THE SAFE DISPOSAL OF THE ANALYZER WASTE MATERIAL WITH MINIMAL ENVIRONMENTAL IMPACT IS THE RESPONSIBILITY OF THE USER AND WILL HAVE TO MEET THE LOCAL LAWS AND DISPOSITIONS.**

37. **DO NOT ATTEMPT TO REMOVE ANY PANELS OR COVERINGS OF THE ANALYZER SYSTEM WHILE THE SYSTEM IS IN OPERATION.**

38. **AFTER OPERATION/SERVICING, COVER THE SYSTEM WITH A PROTECTIVE PLASTIC OR CLOTH SHEET.**

39. **DO NOT USE SOFTWARE DISKS OF UNKNOWN ORIGIN IN THE ANALYZER COMPUTER AS THEY MAY INTRODUCE VIRUSES.**

40. **DO NOT USE THE COMPUTER OF THE ANALYZER FOR ANY OTHER PURPOSE THAN THE ONE FOR WHICH IT IS DESIGNED FOR.**

41. **BE PARTICULARLY CAUTIOUS THAT NO PARTS OF YOUR BODY (e.g. FINGERS HAIR, ETC.) OR LOOSE OBJECTS (e.g. CABLES, TUBING, ETC.) CAN BE TRAPPED BY ANY MOVING OR ROTATING PARTS (e.g. SAMPLING ARM, PLATES, WASHER MODULE, PUMP ROLLERS ETC.) OF THE ANALYZER SYSTEM.**

NOTE:

a) ***The careful observation of the proceeding warnings should result in a long and satisfactory performance. If the above-mentioned notices are not fully observed, then any form of warranty is no longer valid and Biotecnica Instruments S.p.A. will not be responsible for any subsequent damage or loss. (see Section II, 2 "Warranty Conditions").***

b) ***The information in this manual is based upon the hardware and software currently in use. Biotecnica Instruments S.p.A. reserves the right to make software and hardware changes or improvements for product enhancement without notice and without imposing any obligation upon itself to install these changes or improvements on its products previously manufactured.***

1.3. WASTE DISPOSAL

- To ensure environment health and safety, it is recommended not to discard the used consumables, waste liquids or disposable maintenance kits into the environment.
- Insure that the disposal of waste material is done according to all applicable laws and regulations.

1.4. RETURNING THE ANALYZER TO THE TECHNICAL ASSISTANCE SERVICE

The Technical Service Assistance (S.A.T.) may intervene locally, at the Lab, or at Biotecnica Instruments S.p.A. for analyzers returned for repair.
In both cases it is necessary to decontaminate the analyzer and its parts to protect the health of technical assistance employees.

To decontaminate the analyzer follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.
Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.
The procedure described below is not considered to be complete and any other action taken by the Lab to ensure the safety of Biotecnica's technicians is appreciated.

1.4.1. Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. **To properly decontaminate the I.S.E. module, where present, refer to chapter L, par. 4.**
3. Put a suitable decontaminant (e.g. HCl 1N hydrochloric acid diluted at 3%) in a reagent bottle and place it in position no. 40 for BT3000 Plus and BT3500 or in position 24 for BT1000, BT1500 and BT2000 Plus.
4. Start a cuvette (Analyzer Utilities menu – Wash cuvettes) wash cycle.
5. Wait five minutes after the washes have finished and then remove the decontaminant bottle from the reagent tray.
6. Run a normal wash cycle with water (Analyzer Utilities – Wash with water).
7. Empty the hydraulic circuit (from the Analyzer Utilities menu - Empty fluidics).
8. Shut down the analyzer.
9. Clean off the entire sample tray with decontaminant and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

For shipping the analyzer to Biotecnica:

In addition to the instructions seen above, carry out the following:

1. Disconnect the waste tubes from the instrument.
2. Disconnect the water tube from the instrument, wind it up and put it in a bag.
3. Push the sampling needles all the way into their wash wells.
4. Put the cuvette and serum cover trays back in their places.
5. Make sure that all moveable parts are secured tightly.
6. Decontaminate the vacuum system, where present, and make sure there is no residual fluid.
7. Decontaminate the vacuum system discharge probe by soaking it for five minutes in HCl 1N diluted at 3%.
8. Wind up the waste tubes and put them in a tightly shut bag.
9. Pack up the peripheral devices and analyzer in their original packing.

1.4.2. Not Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
3. Unscrew the sampling needles from their arms and soak them for five minutes in decontaminant and then rinse them with water and put them aside or screw them back into place.
4. Decontaminate the vacuum system, where present, and make sure there is no residual fluid.
5. Decontaminate the vacuum system discharge probe by soaking it for five minutes in HCl 1N diluted at 3%.
6. Make sure the cuvettes are empty and then fill them manually with the decontaminant solution. After five minutes remove the solution and replace it with bidistilled water.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

For shipping the analyzer to Biotecnica:

In addition to the instructions seen above, carry out the following:

1. Disconnect the waste tubes from the instrument.
2. Disconnect the water tube from the instrument, wind it up and put it in a bag.
3. Push the decontaminated sampling needles all the way into their wash wells.
4. Put the cuvette and serum cover trays back in their places.
5. Make sure that all moveable parts are secured tightly.
6. Wind up the decontaminated waste tubes and put them in a tightly shut bag.
7. Make sure the cuvettes are empty.
8. Make sure there is no residual liquid in the hydraulic circuit or any other part of the instrument.
9. Pack up the peripheral devices and analyzer in their original packing.

1.5. ANALYZER SAFE DISPOSAL

When the instrument is no longer useable or needs to be decommissioned, follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.

Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.

Note: this procedure will make the I.S.E. electrodes unusable anymore.

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. **To properly decontaminate the I.S.E. module, refer to chapter L, par. 4.**
3. Empty the hydraulic circuit (from the Analyzer Utilities menu: empty fluidics).
4. Remove the water tube from the external container and put it in a container with at least one liter of suitable disinfectant or decontaminant (e.g. hydrochloric acid HCl 1N diluted at 3%). Put disinfectant also in a bottle in position 40 of the reagent tray for BT3000 Plus and BT3500 or in position 24 for BT1000, BT1500 and BT2000 Plus.
5. Fill the hydraulic circuit again by running a reset and a series of prime of the clinical chemical diluter and the diluter of the I.S.E, if present.
6. Run a wash of the cuvettes and the I.S.E. module.
7. Wait five minutes. Remove the disinfectant from all the containers and replace it with water. Put the water tube back in the container which has just been filled.
8. Run a wash of the cuvettes and I.S.E. again, and then empty the hydraulic circuit again.
9. Shut down the analyzer.
10. Remove all the cords connecting the UPS to the mains and peripheral devices from the analyzer.
11. Remove all the cables connecting the peripheral devices (keyboard, mouse, wireless connector, printer and UPS).
12. Carefully clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
13. Carefully clean the peripheral devices using a clean cloth and a disinfectant.
14. Remove the waste tubes from the analyzer and the vacuum system, if present.
15. Remove the vacuum system discharge probe and soak it for five minutes in disinfectant (HCl 1N diluted at 3%). Then rinse it in water.
16. Remove all the tubes which are part of the washing, distribution and sampling hydraulic circuit and the I.S.E. circuit. Remove the I.S.E. electrodes as well.
17. Sort the material from decommissioning the instrument so that they can be recycled or disposed of as special waste in accordance with local laws.

If the analyzer is going to be returned to the Distributor, make sure all the removal parts of the system are bagged and separated after decontamination so that they can be disposed of as special waste.

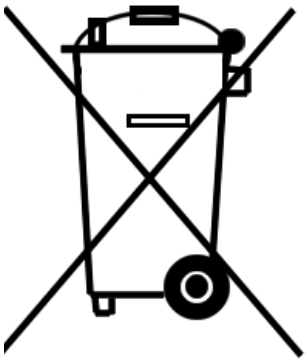
1.6. ELECTRIC AND ELECTRONIC DEVICES DISPOSAL

ATTENTION:
Waste Electrical and Electronic Equipment, called WEEE must be disposed of in accordance with **Italian Legislative Decree no. 151 of 25 July 2005**:

Implementation of EC directives 95/2002, 96/2002 and 108/2003, related to the reduction of hazardous substances in electrical and electronic equipment as well as waste disposal published in the Italian Official Gazette no. 175 of 29-7-2005- Ordinary Supplement no. 135.

The points below provide some instructions related to disposal of WEEE, however we recommend consulting the aforesaid Legislative Decree for additional information.

1. WEEE must not be disposed of as urban waste, it must be recycled.
2. Municipalities guarantee operation, access and suitability for recycling systems for WEEE, so that end users and distributors can return to collection centers all waste produced within their territories, at no cost.
3. WEEE can be returned to the distributor when new equipment is purchased, without prejudice the provisions of Legislative Decree 151/05.
4. The distributor has the obligation to take the WEEE, however pick up may be refused when there is a risk of contamination of personnel assigned to this job.
5. The presence of hazardous substances in electrical and electronic equipment requires separate disposal due to the potential effects on the environment and humans. Improper use of the same equipment or its parts may be potentially hazardous.
6. The symbol that indicate separate disposal of electrical and electronic equipment is a trash container on wheels with a cross over it as indicated below: the symbol is printed in a visible, readable and indelible manner



Editor's note: The picture is only for the purposes of example: see the printed version in the Italian Official Gazette no. 175 of 29-7-2005

7. Legislative Decree 151/05 includes a list of fines for illegal disposal of WEEE.

NOTE:
The manufacturer shall not be held liable for any failure to comply with regulations regarded to delivery of the instrument to third parties. Check the pertinent lists at specialized waster disposal centers.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATON

CHAPTER N

1. MAINTENANCE AND CARE **Page: 2**
1.1. Preventive maintenance and Extra Wash **Page: 2**
1.2. Replacing tubing and accessories **Page: 3**
1.2.1. Clinical Chemistry **Page: 3**
1.2.2. Extra wash cuvettes **Page: 5**
1.2.3. Photometric lamp **Page: 5**
1.2.4. Dilutors' piston o-ring **Page: 6**
1.3. Cleaning the instrument **Page: 7**
2. MALFUNCTIONS **Page: 8**
2.1. Troubleshooting **Page: 8**
2.2. Screen messages **Page: 9**
2.2.1. Screen messages - Causes and remedies **Page: 10**
2.2.2. Messages requiring technical assistance **Page: 12**
2.2.3. Optical system verification messages **Page: 14**

NOTE:

All pictures in this manual are referred to the BT3000 Plus. Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. MAINTENANCE AND CARE

1.1. PREVENTIVE MAINTENANCE AND EXTRA WASH

EXTRA WASH
This function is similar to the daily one but run with a stronger detergent. This operation is requested by the instrument on a weekly basis. See paragraph 1.2.2. The extra wash helps guarantee efficiency and long life for the reading cuvette.

Exercise extreme care to ensure that the system is regularly provided with proper maintenance and care to avoid any problems and malfunctions, which can potentially generate erroneous results. This will give longest life at lowest overall cost.
The maintenance is normally performed at regular intervals or whenever the operating conditions dictate it. The analyzer stores the number of run tests and a built-in maintenance software automatically alerts the operator through on-screen messages whenever any part needs attention or replacement. Failure to follow proper maintenance and replacement procedures may result in system malfunction.

The software programmed maintenance does not exonerate the user from neglecting any unexpected problems.
For the reasons just mentioned, we recommend that the operator follows the suggestions below:
The following simple steps serve as practical guidelines in establishing your care and maintenance program:

1) Replace the worn out component soon after the on-screen message from the maintenance software has been displayed (**Figure 1** "**Show Diagnostic**"). To access this function refer to chapter H.
2) Any consumable part showing signs of wear or damage should be immediately replaced, even if the appropriate on-screen message is not already displayed.
3) Use only original Biotecnica parts. Do not replace defective parts with non-original parts as this will cause malfunctioning of the analyzer. In case of any doubt, contact the Biotecnica Instruments S.p.A. or nearest service center.
4) Use only bi-distilled water for the washes performed during working phases.
5) Use only Biotecnica Instruments S.p.A. approved wash solution for the routine washing procedures and at the end of working session.
6) During routine maintenance, exercise extreme caution to avoid any contamination. When replacing tubing, needle, or handling waste container etc. accidental contact with potentially contaminating liquid is possible. For individual safety, use suitable protective garments, such as overalls and gloves (refer to **Chapter K**, paragraph **1.1.** "**Potential risks during use and maintenance**").



Figure 1

The components that are most subject to wear are the fluidic tubing used in the valves, the peristaltic pump cartridges and the photometric lamp.
The hydraulic circuit items, not mentioned in the maintenance table, should be considered as non-consumable and should be replaced only by the qualified technical personal during service.

1.2. REPLACING TUBING AND ACCESSORIES

CAUTION:

a) Completely empty hydraulic circuit, using the program outlined in the **Chapter H**, paragraph **1.1. Empty Fluidics** and wait until this operation terminates.

b) Always make sure that the mains power switch on the instrument is turned off and the power cord is unplugged from the wall outlet before performing any maintenance procedure.

The following figures show the position and indication of components to be replaced.
The maintenance kits include all that is needed for the ordinary maintenance of the analyzer. **For the I.S.E. module maintenance, refer to chapter L, paragraph 3.2.1.**

Phase	
Kit: Tubes and Peristaltic Pump	See paragraph 1.2.1.
Extra wash cuvettes	See paragraph 1.2.2.
Photometric Lamp (hours)	See paragraph 1.2.3.
Dilutor's Piston Seal	See paragraph 1.2.4.

PROGRAMMED MAINTENANCE

Item	**Replacement**
Kit tubes and peristaltic pump	Every 150000 cycles or 6 months
Kit tubes I.S.E. module	Every 6 months
Photometric lamp	Every 1500 hours of use
Dilutor's piston seal	Every 300000 cycles or 12 months

1.2.1. Clinical Chemistry

- Peristaltic pump cartridge (ref. 4 fig 2): remove both ends of the peristaltic pump tubing from the diluter manifold. Squeeze the locking catches and remove the defective cartridge. Place the new cartridge on the drive shaft and gently press to snap-fit. Carefully attach the pump tubing to both fittings in the diluter manifold.
- Tube for valves (ref. 1 fig 2): detach valve tube and discard it. Carefully attach ends of no-pinch valve tubing to appropriate fittings (Figure 2).
- Aspiration tube for washing module (ref. 2 fig 2): detach defective tube and replace with new aspiration tube.
- H_2O tube for washing module (ref. 3 fig 2): remove and discard the old tubing. It is possible that a small quantity of distilled water will flow out of the water reservoir. Immediately dry it after the tube replacement. Carefully attach the ends to the valve and to the appropriate fittings of the water reservoir and the washer.
- Tubular filter for water container (263 μ) (ref. 5 fig 2): maintenance includes annual replacement (or if the filter is completely clogged).
- Sampling arm: maintenance of the sampling arm includes annual replacement (or if the device does not work correctly) of the sampling needle (ref. 6 fig 2). To replace the needle, loosen and remove retaining nut with needle from the needle holder. Clean or substitute with new needle. Then gently push in needle into the needle holder until fully seated and screw it gently back into the needle holder.

Note: the reading cuvettes are also part of the reading station, but they do not need to be replaced unless it is impossible to wash them correctly or they break. If they need to be replaced contact the Technical Assistance Service.

The annual maintenance kit corresponds to the “Tube and Peristaltic Pump Kit” on the Diagnostic page (fig. 1)

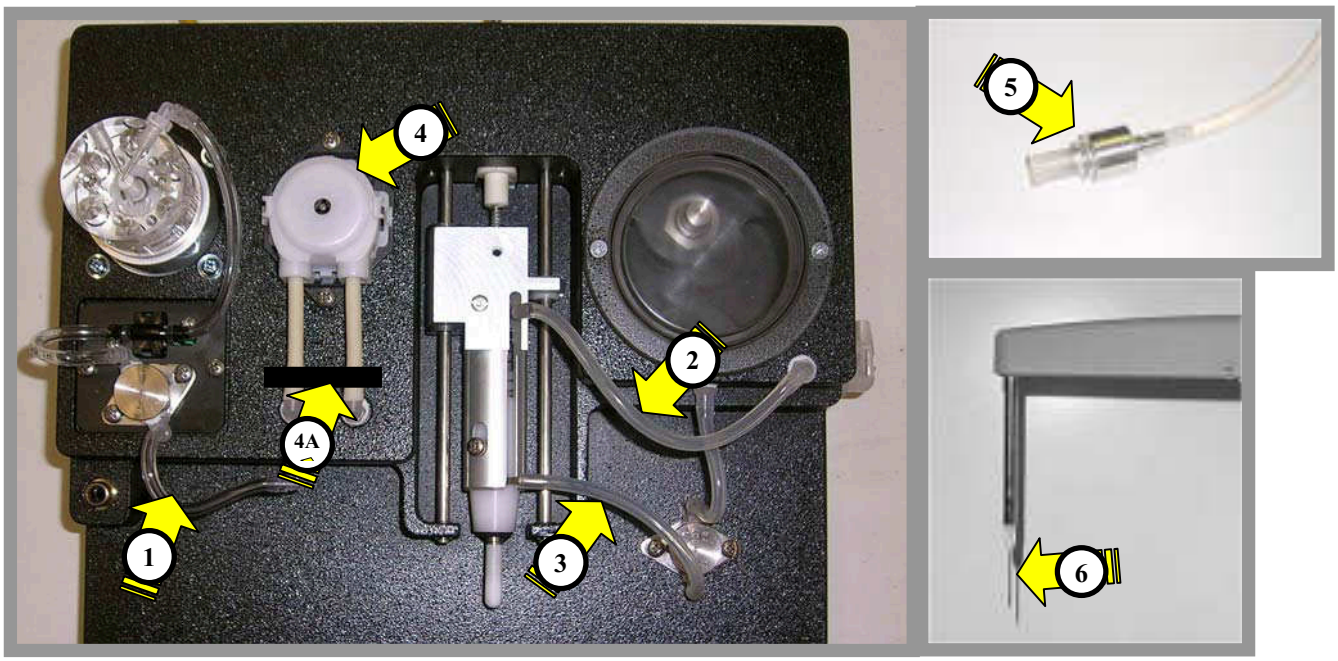


Figure 2

BT1000, BT1500 & BT2000 PLUS: ANNUAL MAINTENANCE KIT (CODE 662.2001)		
ITEM	**QTY**	**DESCRIPTION**
1	2	Diluter/Valve Tube
2	1	Aspiration Tube for Washing Module
3	1	H_2O Tube for Washing Module
4	1	Peristaltic Pump Cartridge
4A	1	Peristaltic Pump Tray
5	1	Tubular Filter for Water Container
6	1	Sampling Needle

BT3000 PLUS: SIX MONTH MAINTENANCE KIT (CODE 11-05337-01)		
ITEM	**QTY**	**DESCRIPTION**
1	1	Diluter/Valve Tube
1A	1	Diluter/Valve Tube I.S.E. (see chapter L)
2	1	Aspiration Tube for Washing Module
3	1	H_2O Tube for Washing Module
4	2	Peristaltic Pump Cartridge
4A	1	Peristaltic Pump Tray
8	1	Tubular Filter for Water Container
9	2	Sampling Needle

BT35000: SIX MONTH MAINTENANCE KIT (CODE 11-05669-01)		
ITEM	**QTY**	**DESCRIPTION**
1		Diluter/Valve Tube - Does not need any maintenance
2	1	Aspiration Tube for Washing Module
3	1	H_2O Tube for Washing Module
4	2	Peristaltic Pump Cartridge
4A	1	Peristaltic Pump Tray
5	1	Tubular Filter for Water Container
6	2	Sampling Needle

1.2.2. Extra Wash Cuvettes (solution code 393E)



This is requested by the analyzer on a weekly basis.
Insert a bottle with washing solution code 393E in the position indicated in the message and activate the command.
It is highly advisable to run this operation any time the efficiency of the cuvettes is questionable. A progressive accumulation of contaminants in the cuvettes may lead to serious release problems when running tests.

Analyzer Utilities menu

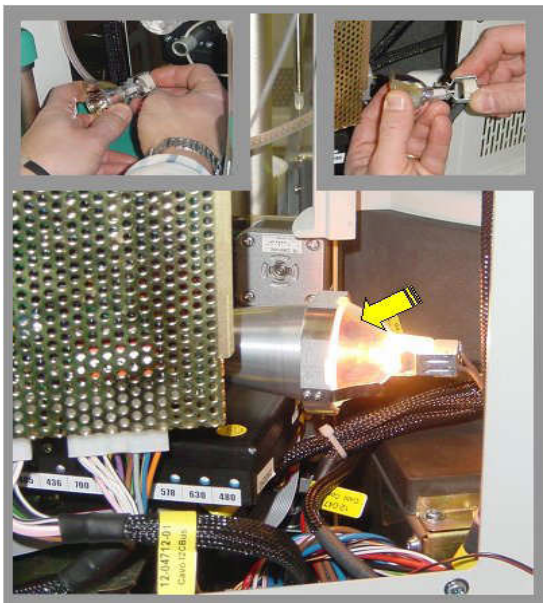
Figure 3

1.2.3. Photometric Lamp (code 330.9321)

The analyzer controls the Halogen lamp condition, and it should be replaced every 1500 hours or when there is a faulty operation. The analyzer verifies lamp efficiency and stability, and alerts the user through appropriate messages in case of fault.

Precautions for handling the halogen lamp:

- Turn off power and remove the power cord from the wall outlet before servicing. The replacement of the Halogen lamp can be done by the removal of the rear panel, or by sliding the transparent shutter on the front panel and then removing the access cover from the deck **Figure 4**.
- Always allow the burnt out lamp to cool down.
- Never touch the reflector or the lamp with bare fingers. Use a rag when changing.
- If the lamp is touched inadvertently during installation, clean the lamp or reflector with alcohol and dry with a clean, soft cloth before burning. Contamination of the lamp or reflector may reduce lamp performance.
- It is recommended to initially burn the new lamp for about 30 minutes before analyzer operation.
- Release the lamp assembly by gently sliding downwards and remove the burnt out lamp.
- Insert a new halogen lamp fully into the socket. It is recommended to slightly press both of the lamp retaining spring clips before fitting the lamp.
- Slide the lamp assembly onto the light cone and orient the lamp socket in the vertical position as shown in the **Figure 4**



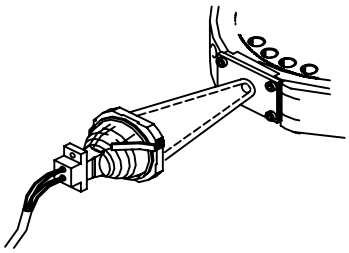


Figure 4

1.2.4. Dilutors' Piston o-ring

The dilutor o-ring needs to be replaced annually. Since this replacement operation is very difficult it is advisable to ask for intervention from the Technical assistance service.



BT dilutors maintenance consists in the o-ring replacement and greasing of the stepping motor lead screw.
In the kit there are the o-ring and grease necessary for one dilutor.

For the sole BT3500 it is only necessary to replace the o-ring, without greasing the lead screw. See section II, chapter 3 for consumables list.

Figure 5

Code	Description	
11-05283-01	Dilutor piston o-ring kit (contains what is necessary for one dilutor)	**BT1000, BT2000 Plus** **BT3000 Plus**
330.5741	Ring-flon for diluter piston	**BT3500 & BT1500**

1.3. CLEANING OF THE INSTRUMENT

It is a Good Laboratory Practice (GLP) to maintain the instrument in optimal operating conditions. The instrument should be fully turned off and the power cord unplugged from the wall outlet prior to performing any cleaning procedure. Always wear suitable protective devices such as protective gloves, protective glasses, white coat, etc.

The exterior of the analyzer casing may be cleaned periodically to remove dust, grease and other contamination. Use soft dusting cloth dampened with distilled water or a mild solution of detergent with water. Do not use alcohol, solvents, or abrasives.

Use appropriate soft lint less cloth or tissues for LCD Display cleaning. Clean gently and avoid excessive rubbing to prevent damage to the LCD surface. Do not use any liquid that may damage the invisible matrix of the touch screen.

Protective gloves and laboratory coats/gowns should be worn to prevent contamination when cleaning the inside of the reagent chamber or serum plate chamber because of liquid contaminants. Use appropriate disinfectant for the thorough cleaning and elimination of biological residues.

Clean the cuvettes thoroughly with approved washing solution.

Immediately eliminate any traces of serum drops or liquid contaminants using appropriate disinfectant to avoid difficulties associated with removal of dry and tenacious contaminations.

2. MALFUNCTIONS

2.1. TROUBLESHOOTING

The risk of encountering system malfunctions is very low if the routine care and maintenance procedure (outlined in the previous chapter) and the instructions in the operating manual are strictly observed. Refer to the troubleshooting guide below and the subsequent text regarding symptoms and corrective actions.

The instrument or one of its peripheral devices does not turn on
Verify that the UPS group is turned on, the electrical cables are correctly connected and check the fuses. If fuses need replacement then observe the following procedure:
1) Turn off the instrument by pressing the main switch on the rear panel and unplug power cord.
2) Extract the fuse-holder (located above the main switch on the rear panel) by gently opening the latch with a tool. Discard the old fuses and replace with new fuses, which match the selected voltage rating indicated on the rear panel label. Insert the fuse-holder into the compartment and push until its latch snaps back into the position (see Figure 3, Chapter B).

Results are invalid or cannot be reproduced due to residues in the dilutor.
1) Disconnect dilutor tubes
2) Remove the two mounting screws on the transparent dilutor chamber and clean the piston with soft lint less cloth dampened with alcohol. Rinse the chamber and reassemble. Connect the tubes to appropriate ports.

Results are invalid or cannot be reproduced due to air in the sampling system.
Sampling imprecision due to the presence of air in the hydraulic circuit. Probably caused by the clogged tubular filter in the external water container:

- Check, replace **Filter** if necessary (**ref. 5 Fig. 2**).

Sampling imprecision due to deteriorated tube in the dilutor valve:

- Inspect and replace **Tube** (**ref. 1 Fig. 2**).

Sampling imprecision due to reagent or sample residues in the sampling tube or in the needle:

- Inspect and replace **Peristaltic Pump Cartridge** (**ref. 4 Fig. 2**).
- Check and replace the **Sampling Needle** (**ref. 6 Fig. 2**).
- Check and replace the **Sampling Tube**. To be replaced by qualified service technician only.

Sampling imprecision due to reagent or sample residues on the external surface of the needle, with consequent contamination during preparation:

- Remove **Needle** and clean externally using gauze soaked with alcohol (**ref. 6 Fig. 2**).
- Check the efficiency of built-in devices for needle cleaning. In case of vacuum pump malfunction or if there are any obstructions in the cleaning devices, contact immediately the nearest Biotecnica sales/service office.

Results are imprecise due to insufficient cleaning or drying of the reading cuvettes.

Vacuum pump malfunction or occluded washing piston.

- BT1000 & BT2000 Plus: In case of vacuum pump malfunction or if there are any obstructions in the washing piston, contact immediately the nearest Biotecnica sales/service office. Check sampling/washing hydraulic circuit for leaks, which may affect system performance
- BT3000 Plus & BT3500: In case of vacuum pump malfunction refer to items in VACUUM PUMP SYSTEM chapter K. If the problem with vacuum pump still persists or if there are any obstructions in the washing piston, contact immediately the nearest Biotecnica sales/service office.

NOTE:

Check sampling/washing hydraulic circuit for leaks, which may affect system performance.

Invalid results or results cannot be reproduced.

Defective or burnt-out lamp.

Inspect and replace the lamp, refer to par. 1.2.3 in this chapter.

Invalid results or results cannot be reproduced without any evident reason.

Perform all maintenance procedures and check all possible causes described earlier in this chapter.

2.2. SCREEN MESSAGES

2.2.1. Screen Messages - Causes And Remedies

The BT analyzers software has a built in Auto-diagnostic function, which is enabled during normal working sessions. This function allows verification of any system malfunction or lacking of any solution necessary for running the tests.
In presence of any system malfunction, an appropriate message is displayed on the screen indicating the type of error and the suggested solution. The system stops until the causes of error are eliminated and then the operation can be resumed from where it stopped.
When anything necessary for test run is lacking (for example reagent or sample) an appropriate message is displayed on the screen, sampling procedure for the missing element is interrupted while the analyzer continues with the next working phases.

SAMPLE IS MISSING ***NO ROUTINE #XX*** ***NO STAT #XX*** ***NO STANDARD #XX*** ***NO CONTROL #XX***	The error ***"SAMPLE IS MISSING"*** is displayed when the analyzer detects the absence of sample through a built-in liquid sensor. It is subdivided into ***NO ROUTINE***, ***NO STAT***, ***NO STANDARD***, ***NO CONTROL***. After this message the sampling of the missing sample is interrupted. It is possible to run remaining tests using the rerun commands (**Chapter E**, paragraph **1.5**) after the problem is solved.
REAGENT IS MISSING ***NO REAGENT XXX*** ***POSITION XX***	The error ***"REAGENT IS MISSING"*** is displayed when the analyzer detects the absence of reagent needed for test run. After this message the sampling of the missing reagent is interrupted. It is possible to run remaining tests using the rerun commands (**Chapter E**, paragraph **1.5**) after the problem is solved.
NO SAMPLE DILUENT	The error message ***"NO SAMPLE DILUENT"*** is displayed when the analyzer detects the absence of sample diluent solution. The testing of samples to be prediluted is interrupted. To solve the problem add fresh diluent solution and re-run the sample (**Chapter E**, paragraph **1.5**).
NO I.S.E. SOLUTIONS	**See Chapter L, par. 3.3**
VACUUM SYSTEM: ***- WARNING –*** **LOW PRESSURE**	**BT1000, BT1500 & BT2000 Plus** This message appears when the vacuum pump inside the analyzer has lost efficiency and the vacuum level is below -40 mbar. It is possible to continue the tests if the vacuum level is -35 mbar and by setting the minimum threshold in the setup to -20 mbar. If the problem persists contact nearest sales service department. After resolving the problem, the analyzer can be restarted and continue testing from where it stopped. The message "**-WARNING- LOW PRESSURE**" may also appear when waste liquid container is full. Empty or replace it. **BT3000 Plus & BT3500** The message **-WARNING- LOW PRESSURE** may

	also appear when waste liquid container is full. See chapter K in this manual **Operative steps sequence in case of alarm:** First alarm on (slow intermittent beeps) and the waste probe LED is lit. External waste container full. Empty or replace it and press **RESTART** button (Green) to continue the operating procedure and to reset the alarm. Second alarm on (rapid intermittent beeps) with the LED on the waste probe lit. The external waste container and the internal waste chambers are full. The vacuum system stops itself, the analyzer interrupts working phases and displays the message ***Low pressure…***. Empty or replace the waste container and press the green **RESTART** button on the vacuum pump cabinet to continue the operating procedure and to reset the alarm. If the audible alarm is still activated, it means that the peristaltic pump for draining is not efficient and that the internal waste chamber is still full. The vacuum system stops itself, the analyzer interrupts working phases and displays the message ***Low pressure…***. Consult your nearest sales/service office regarding repair. After resolving the problem, the analyzer can be restarted and continue testing from where it stopped. The message "**-WARNING- LOW PRESSURE**" may also appear when waste liquid container is full. Empty or replace it.
- WARNING - **NO WATER**	The message **"No Water …"** appears when washing water does not reach the analyzer because the external water container is empty or defective loading pump. When this message is displayed, the sampling procedure for programmed tests is stopped. Fill the external water container to continue the tests. Check, replace if necessary, the tubular filter on the intake tube inside the water tank (par. 1.2.1. and ref. 5 Fig. 2). The analyzer will start working from where it stopped (see **Chapter E**, paragraph **1.5.**). If the error message persists, because of defective loading pump, contact the approved technical assistance.
THERE ARE THE FOLLOWING OBLIGATIONS IN DIAGNOSTIC: EXTRA WASH	The message is displayed during normal working sessions seven days after the last Extra wash was performed. Execute an Extra wash procedure. This message does not stop test execution, but it is not possible to guarantee correct results if an effective Extra Wash is not performed. The extra wash message is displayed also if the analyzer is turned off without washing the cuvettes with the correct daily procedure.

2.2.2. Screen Messages Requiring Technical Assistance

SCREEN MESSAGE	CAUSES & REMEDIES
ERROR RESETTING SAMPLE TRAY	This message stops the execution of programmed tests. The message is generated by an incorrect home position of the sample tray. This error can be caused either by an absence of sample tray, or defective position sensor. In case of a wrong positioning or absence of sample tray, correctly position the sample tray in its chamber and then press **"F5"** (**"Reset"**) key to restore correct analyzer operation. In case of defective position sensor contact qualified technical assistance to solve the problem.
ERROR RESETTING REAGENT TRAY	This message stops the execution of programmed tests. The message is activated by an incorrect zero positioning of the reagent tray. This error can be caused either by an incorrect placement of reagents tray into the analyzer or by a defective position sensor. Verify and correctly place the reagents tray and then press **"F5"** (**"Reset"**) key to restore correct analyzer operation. In case of defective position sensor contact qualified technical assistance to solve the problem.
ERROR RESETTING DILUTOR	This message stops the execution of programmed tests. The message is generated by an incorrect zero positioning of the dilutor piston. This error can be caused either by an excessive piston friction or a defective position sensor. In the event of friction it is sufficient to disassemble and clean the piston with a soft cloth dampened with alcohol, reassemble and then press **"F5"** (**"Reset"**) key to restore correct analyzer operation. In case of defective position sensor contact approved technical assistance to solve the problem.
ERROR RESETTING CUVETTE TRAY	This message stops the execution of programmed tests. The message is generated by a position sensor error of the cuvette tray. Press **"F5"** (**"Reset"**) key to try to restore the correct operation of the analyzer. If this does not solve the problem, then it will be necessary the to contact approved technical assistance.

SCREEN MESSAGE	CAUSES & REMEDIES
ERROR RESETTING ARM ARM (HORIZONTAL) **ERROR RESETTING I.S.E. ARM (HORIZONTAL)**	This message stops the execution of programmed tests. The message is generated by a defective position sensor of the arm. Press **"F5"** (**"Reset"**) key to restore the correct analyzer operation. If the problem persists, then contact approved technical assistance.
ERROR RESETTING ARM (VERTICAL) **ERROR RESETTING ARM I.S.E. (VERTICAL)**	This message stops the execution of programmed tests. The message is generated by an error during up/down motion the sampling needle. This error may be caused by a deformed needle, obstructions (i.e. improper placing of the reagent bottles) or a defective position sensor. If the needle is deformed, replace it. As regards obstructions, just place the bottles correctly. Afterwards press **"F5"** (**"Reset"**) key to restore correct analyzer operation. In case of defective position sensor, contact approved technical assistance.
ERROR RESETTING WASHING STATION	This message stops the execution of programmed tests. A defective position sensor of the washer module generates this message. Press **"F5"** (**"Reset"**) key to restore correct analyzer operation. If the message persists, contact approved technical assistance.
IMPOSSIBLE TO RESET ANALYZER	The message **"Impossible to reset analyzer"** indicates a system error. It does not allow the continuing of working phases. Restart the system computer by pressing the start button. If the message persists, contact approved technical assistance.
SYNCH ERROR	The message **"Synch error"** indicates a system error. It does not allow the continuing of working phases. Restart the system computer by pressing the start button. If the message persists, contact approved technical assistance.
SYSTEM BLOCKED CALL ASSISTANCE	The message **"System blocked"** indicates a total blockage of the system. Restart the system computer by pressing the start button. If the message persists, contact approved technical assistance.

2.2.3. Optical System Verification Messages

ERROR MESSAGE	CAUSES & REMEDIES
- WARNING - **LAMP PROBABLY OFF**	The message is displayed after a photometric zeroing, when the analyzer detects that the optical system has a lower efficiency than the minimum value stored. When this message is displayed it is not possible to continue sampling tests. Replace photometric lamp (see par. 1.2.3 in this chapter) and perform Photometric Zeroing (refer to **Chapter H** paragraph **1.1.1.**). In case the error message still persists, contact approved technical assistance.
- WARNING - **LAMP PROBABLY EXHAUSTED**	The message is displayed after a photometric zeroing, when the analyzer detects that the optical system has at 340nm a lower efficiency than the minimum value stored. The sampling tests are not stopped after this message. It is necessary to replace the lamp (see par. 1.2.3 in this chapter) and repeat the **"Photometer zeroing"** command (refer to **Chapter H** paragraph **1.1.1.**). If after observing these steps, the message no longer appears, then it is possible to continue testing. In case the error message still persists, contact approved technical assistance.
ERROR IN OPTICAL GROUP	The message is displayed after resetting the analyzer and indicates an optical group malfunction. Contact approved technical assistance.
CUVETTES TRANSMISSION OUT OF LIMITS	The message is displayed after a photometric zeroing, when the analyzer detects optically unusable cuvettes. After this message the unused cuvettes (up to a max. of three) are rejected by the analyzer that continues to work with the remaining ones. An "**Extra wash**" should be run followed by a new "**Photometer zeroing**". If more than three cuvettes are unused operation is stopped and intervention of the specialized technical personnel is required.

IMPORTANT NOTICE:

The above-mentioned messages are only a partial representation of all the possible warnings that the analyzer may output to the user. In case of any messages that are not covered here or are not clear, please contact Technical Assistance Dept. at Biotecnica Instruments S.p.A.

OPERATOR MANUAL

SECTION I: GENERAL INFORMATION

CHAPTER O

1. TECHNICAL SPECIFICATONS **Page: 2**

NOTE:
Specifications are subject to change without notice

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. TECHNICAL SPECIFICATIONS

CUVETTE OPERATING TEMPERATURE

Programmable Temperatures:	room temperature, 30°C, 32 °C, or 37 °C
Precision:	± 0,2°C
Accuracy:	± 0,2°C

Temperature Monitoring Device based on Peltier Effect

REAGENT CHAMBER TEMPERATURE

Nominal Temperature:	Between 5°C and 15°C Approx. (depending upon the setting)

Temperature Monitoring Device based on Peltier Effect

OPERATING AMBIENT TEMPERATURE 18 °C to 32 °C, 10% to 90% RH, Non condensating

DILUTORS Dilutors Type: Biotecnica Dilutor

TECHNICAL SPECIFICATIONS	**BT1000&BT2000 Plus BT3000 Plus**	**BT1500 BT3500**
Max Volume:	470 µl	340 µl
Linearity F.S.:	± 0.1% F.S. (Full Scale)	± 0.1% F.S. (Full Scale)
Accuracy at 3 µl:	± 3%	± 1%
Accuracy (Full Scale):	± 0.1% from 10 µl to 470 µl	± 0.1% from 10 µl to 340 µl
Reproducibility	± 0.7% at 3 µl; ± 0.6% at >3 µl	± 0.7% at 3 µl; ± 0.6% at >3 µl
Average Life:	3 million operating cycles	1 million operating cycles
Maintenance:	Every 300,000 operating cycles (O-ring seal replacement)	Every 300,000 operating cycles (O-ring seal replacement)

PHOTOMETER

Optical System	Solid state photometry, (patented by Biotecnica Instruments S.p.A.)
Detectors	10 UV/VIS photodiodes + reference channel

PRECISION AND ACCURACY

Spectral Response:	340, 380, 405, 436, 480, 510, 546 578, 630, 700 nm
Bandwidth:	± 5 nm max
Photometric precision:	± 1% from 0 to 2.000 O.D., ± 2.5% at 2-3 O.D.
Photometric Sensitivity:	± 0.001 ABS
Drift:	± 0.005 ABS/h (steady state)
Optical path:	7 mm for BT1000, BT2000 Plus & BT3000 Plus 5.9 mm for BT1500 & BT3500
Photometric Lamp:	Tungsten Halogen Lamp with Dichroic Reflector
Beam Angle:	9º
Power:	35 Watts
Input voltage:	12 VDC
Avg Rated Life:	Approximately 2000 hours

NOTE: For optimal result the lamp can be used for about 1,500 hours.
The long-term use will result in the gradual deterioration of the UV emission.

ANALYZER POWER REQUIREMENTS

	BT1000	**BT1500**	**BT2000 Plus**	**BT3000 Plus**	**BT3500**
Universal Input:	100 / 240 V~ 50-60 Hz	100 / 240 V~ 50-60 Hz	100 / 240 V~ 50-60 Hz	100 / 240 V~ 50-60 Hz	100 / 240 V~ 50-60 Hz
Power:	250 Watt	300 Watt	370 Watt	590 Watt	590 Watt

PFC Unit (Power Factor Correction) included.

VACUUM PUMP POWER REQUIREMENTS P/N 06-05161-01

	BT3000 Plus	**BT3500**
Input:	100 / 240 V~, 50-60 Hz	100 / 240 V~, 50-60 Hz
Power:	40 Watts	40 Watts

PRINTER POWER REQUIREMENTS

Universal Input: 100 / 240 V~, 50-60 Hz
Power: 50 Watts

UPS

Input: 220 V~, 50-60 Hz (110 V~ on request)
Output: 220 V~, 50-60 Hz (110 V~ on request)
Power: 1100 VA (710 Watts)

DATA MANAGEMENT **(Except for BT1500)**

Computer	≥ Pentium M ≥ 1.6 GHz or more, IBM compatible
DVD/CD Rom Player	≥ 16X
Hard disk	>40 Gb
Floppy Disk Drive	1,44 Mb
Monitor	LCD Display Module TFT 12 with integrated touchscreen
Interface	2 Serial Ports RS232C + 2 USB PORTS
Printer	Ink-jet Color IBM compatible or other
Mouse & keyboard	Cordless
External Modem	Optional
Error Messages	Visible (Vocal optional)

EXTERNAL PC MINIMUM REQUIREMENTS FOR BT1500	
Operative system:	Windows 2000® Professional Windows XP Windows Vista
Computer:	IBM compatible
Processor:	Pentium Dual core duo
RAM:	1Gb (2Gb for Windows Vista)
Video:	SVGA or compatible, 32K colors
Display:	Color min. resolution 800x600
Mouse:	Serial, PS2 or USB, 2+1 buttons
Host communication:	RS232 or LAN (TCP/IP)
USB:	1, version 2.0 for communication with the analyzer
Parallel port:	1, if the printer has a parallel port
Printer:	Windows compatible (the printer must be installed on the PC before installing the operative software) Deskjet, Inkjet or Laser
CD ROM:	DVD reader
HD:	5Gb free
Note: use a standard theme for all the windows and font 96 DPI.	

DIMENSIONS & WEIGHT	**BT1000**	**BT2000 Plus**	**BT1500**
Instrument	60 Kg (132lb)	72 Kg (159lb)	53 Kg (116lb)
Instrument dimensions	L=78cm (30.7") D=58cm (22.8") H=68cm (26.7")	L=78cm (30.7") D=58cm (22.8") H=68cm (26.7")	L=78cm (30.7") D=58cm (22.8") H=51cm (20")

	BT3000 Plus	**BT3500**
Instrument	135 Kg (297lb)	135 Kg (297lb)
Instrument dimensions	L=100cm (39.4") D=58cm (22.8") H=68cm (26.7")	L=100cm (39.4") D=58cm (22.8") H=68cm (26.7")

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This instrument has passed all tests related to Electromagnetic Compatibility (EMC), and Safety requirements for electrical equipment for measurement, control, and laboratory use performed by the OCE Lab (EMC & Electrical Safety Compliance Test Laboratory), Ministry of Communication - Italy accredited EMC certification body, No. 051 of 21 October 1998. Certificate's documentation is available on request. This analyzer is in conformity with the following normative/standards:
EN 61326: EMC
EN 61010-1: ELECTRICAL SAFETY

NOTE:

1 **As regards the technical specifications for the system "instrumentation + reagent" used in the applications of kit, these are the responsibility of kit's manufacturer and will be stated in the applications (refer to the instructions accompanying the kits).**

2 **The analyzer BT PLUS does not require (after sales) any routine electrical or mechanical readjustments. There are mechanical and electronic adjustments performed by the manufacturer (Biotecnica Instruments S.p.A.) during assembly and quality controls. These adjustments may be performed again in case required by a particular technical service and in any case are at the discretion of the authorized technical personnel only. However, It is highly recommended to check the system periodically to prevent any faults or malfunction of the analyzer.**

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 1

1. ABBREVIATED OPERATING INSTRUCTIONS Page: 2
- **1.1. Turning on and preliminary procedures Page: 3**
- **1.2. Inserting Reagents for Clinical Chemistry Page: 6**
- **1.3. Analytical calibrations and Controls Page: 7**
- **1.4. Entering Patients and Work Lists Page: 10**
- **1.5. Running Tests Page: 14**
- **1.6. Displaying and Printing Results Page: 15**
- **1.7. Turning off the analyzer Page: 19**

FOREWORD

This quick guide gives a global view of the system operation by outlining the sequence of fundamental operating phases. It is highly recommended to carefully read the whole manual in order to have a deeper knowledge of each argument.

ATTENTION: USE OF THE ANALYZER INTERNAL COMPUTER – DOES NOT APPLY TO BT1500

The computer box of BT analyzers and by-products is designed for long-term security and reliability and is virtually maintenance-free as long as the user does not install any third-party application programs. If these applications are installed, then they may damage the operating system registry and may also cause disastrous consequence for the computer's hard-drive. Biotecnica Instruments S.p.A. will not be responsible for any damage to the analyzer, its software and data in the hard-disk in case of improper use of the PC box. This includes also: installation of external programs, not properly secure net connections (intranet and internet) and the use of disks without the necessary verification for viruses presence. Biotecnica Instruments S.p.A. will not be responsible for any damage caused by non authorized third parties who may open and alter the PC box configuration.

NOTE:

All pictures in this manual are referred to the BT3000 Plus. Figures may be different for the other analyzers.

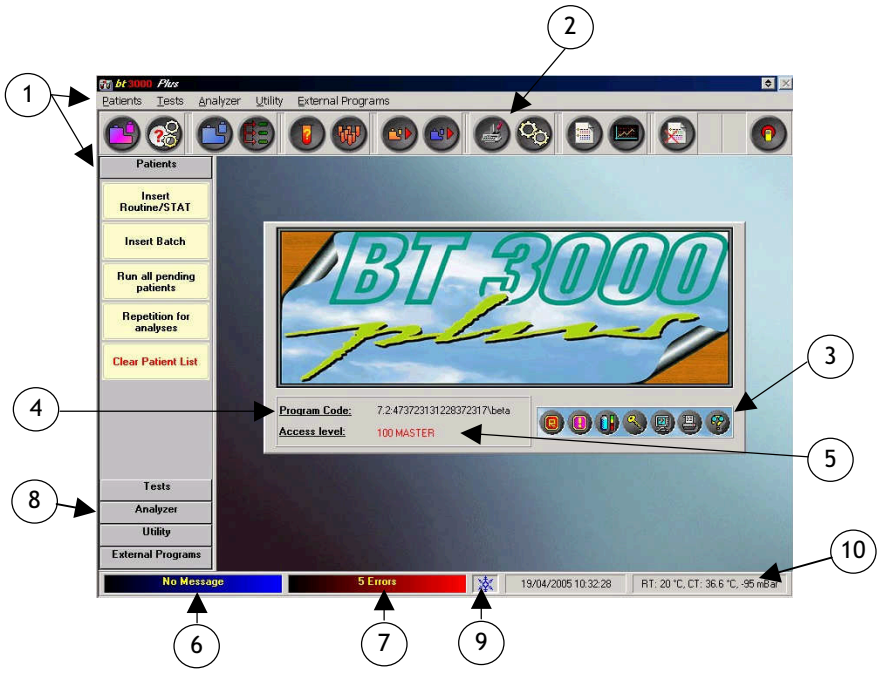
Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

1. ABBREVIATED OPERATING INSTRUCTIONS

The BT instruments are automatic analyzers for clinical chemistry, immunochemistry analyses, and, where available, for electrolytes determination through Ion Selective Electrodes (**I.S.E. Module)**.
The analyzer can be divided into the following two distinct operative parts:
a) **Sampling Unit**: It prepares for tests the samples and single or double reagent.
b) **Reading Unit**: Cuvette plate with integral automatic washing system.

SYMBOLS

As the BT analyzers software runs under Windows, it uses the same philosophy with windows, icons, quick commands, function keys and curtain-shaped menus.
Every window has its own icons and specific menus that will be described hereafter. The full meaning of each command will be explained in the corresponding chapters.
At the start-up the program will display the following main window:



① **Main menu**: each menu generates other commands and/or options

② **& ③ Direct access icons**: selecting each icon the relative command is directly activated

④ **Software version:** operative program version

⑤ **Access level**: is the access level of the operator: it is password dependent

⑥ **Vertical Bar - Commands:** Direct access to function commands

⑦ **Messages bar**: clicking here opens a window showing the messages received by the program

⑧ **Errors bar**: by clicking here a window is opened showing the errors occurred during the work session

⑨ **Refrigerator Status Indicator**

⑩ **Operating Pressure Indicator, Ambient Temperature (RT), Cuvette Temperature (CT)**

1.1. TURNING ON AND PRELIMINARY PROCEDURES

Turning on procedure for the first time:

1) Turn on the UPS device as described in the appropriate supplied manual.
2) Power on the printer (refer to the specific manual enclosed).
3) To switch on the analyzer, use the main power switch on the rear panel of the instrument. This button activates only the refrigerating system for the reagents. To properly turn on the analyzer system, momentarily press the green push-button placed on the front panel (Fig. 1). For what concerns the **BT1500**, verify first that the external PC is connected to the analyzer via USB, then turn the PC on and load the analyzer operative program.
   CAUTION
   Do not press this push-button during analyzer operation, because when pressed it stops the instrument, leaving only the refrigerating system on (refer to Paragraph 1.6., Chapter E, Turning off procedure).
4) Once turning on procedure has completed (lasting few minutes), wait for the system to warm up. During warm-up phase the temperature indicator flashes on the bottom right of the display until the appropriate temperature is reached. The instrument reaches the steady state after approximately 20 minutes.

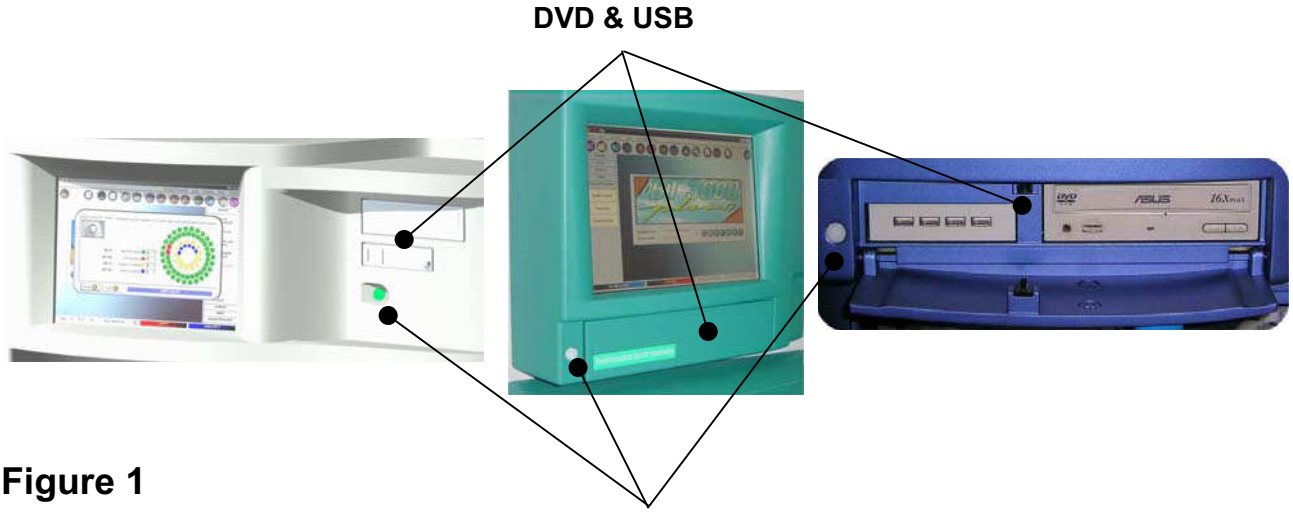
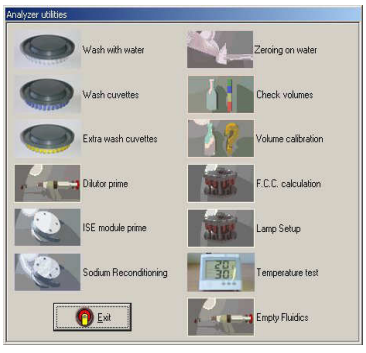


Figure 1

5) Verify the presence of the washing liquid (at least for the daily needs). It consists of bi-distilled H_2O plus surfactant (1ml/l of water - ratio 1/1000).
6) Verify that waste liquid containers are empty or at least have the capacity to contain the quantity of liquid produced during the working day.

NOTE:
It is important to observe steps 5) and 6) to ensure a continuous operation of the analyzer without interruptions.





Direct Access

Figure 2

- Run a dilutor prime by the command **Dilutor prime** (**Fig. 2**).
- Run a wash by the command **Wash with water**.

SERVICE ICONS BAR



Reset Analyzer (F5)



Stand-by Analyzer (F6)



Displays the Volumes' Status; Used to Insert/Remove Reagents (F10)



Password (F7)



Status Analyzer (F2)



Printer Setup (F4)



Help on line (F1)

FUNCTION ICONS BAR



1 - To Insert New Codes, Parameters, Standards and Controls for all Analyses



2 - To Create the On-Line Reagents' Tray



3 - To Insert Parameters/ Standard and Controls for the On-Line Reagents



4 - To Insert/Modify Profiles



5 - To Insert Routine - View Programmed or In-Run Patients



6 - To Insert Batch

 **7 - To Run Standards**

 **8 - To Run Controls**

 **9 - Analyzer's Utilities**

 **10 - Mechanical Calibrations**

 **11 - a) Results Listed per Patient b) Results per test in real time**

 **12 - No Results**

 **13 - Reaction Graphs**

 **14 - Turning off the System**

Simply positioning the cursor on the icons the hint will appear (where available), showing a brief description of the icon function. This is followed (when available) by the function key between brackets, which allows for the same function or command as the icon. For example, the hint Reset (F5) means that the function key F5 has the same function of the icon. In the same way, in each menu are shown (when available) the quick commands (e.g. Insert Batch (Ctrl+B) means that the same function is activated by typing simultaneously on the keyboard the keys Ctrl and B).

GENERAL ICONS



Cancel (aborts the programming and closes the window)



Save (saves the program and closes the window)



Print (prints the window's contents, i.e. parameters, graphs etc.)

 Reduces the window to the upper bar where the analyzer's name appears.

An icon representing refrigeration system operation has been added to the status bar in the main menu. The Refrigerator disabled state may be necessary if the operator decides not to use the refrigerator for reactions or after a refrigeration operating error generated by the system.



1.2. INSERTING REAGENTS FOR CLINICAL CHEMISTRY



Direct Access Icon

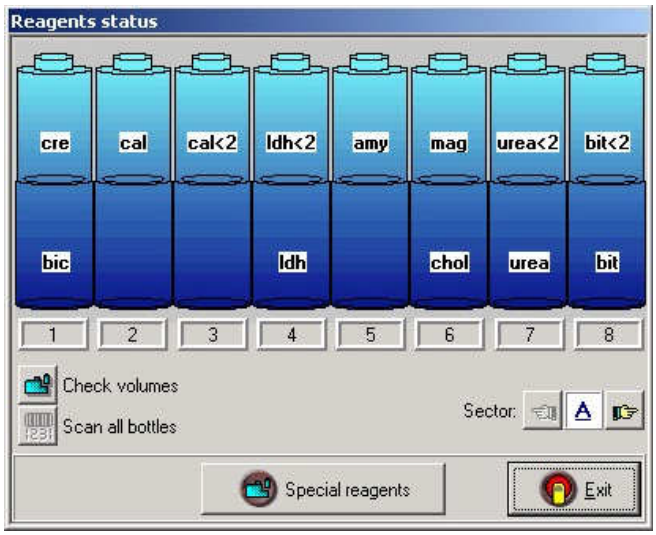


Figure 3

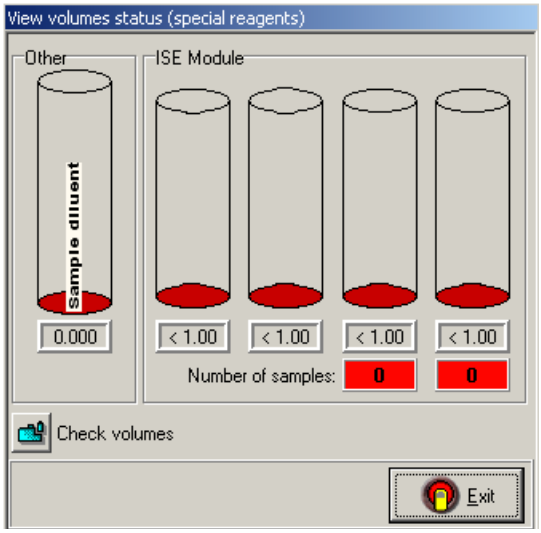


Figure 4

This function is accessed either by pressing F10 key or by clicking on the specific icon. It helps the user to correctly position the reagent bottles, as programmed in the current tray.
The reagent tray is divided into sectors, identified by the letters A, B and C for BT1000, BT1500&BT2000 Plus, while for BT3000 Plus and BT3500, the letters are A, B, C, D and E. Each sector has 8 positions. The screen displays the representation of 8+8 bottles (**Figure 3**). The analysis codes that use large bottles are displayed in the lower positions, while the codes using small bottles are displayed in the upper positions. The reagents volume status for the **I.S.E.** Module and the sample diluent are illustrated in the **Figure 4**. The insertion of reagents in the reagent tray for clinical chemistry, and in the **I.S.E.** Module is explained below.
Single bottle: Right-click over analysis code. Choose between bottle's insertion or removal. The analyzer will correctly position the tray to match with the arrow at the base of the tray itself. With bar-code option enabled, identification is correctly accomplished through the automatic scan of the bar code on the inserted bottle. The same function can be performed on demand, by activating the Scan Bottle command (near the insertion/removal commands). **Figure 5**

Whole sector: Right-click on the SECTOR field. Choose between bottle's insertion or removal. The analyzer will correctly position the whole sector for insertion or removal. With bar-code option enabled, identification is correctly achieved through the automatic scan of the bar code for the inserted bottles. The same function can be performed on demand through Scan Sector (near the sector insertion/removal commands).
In both cases, after insertion of the reagents, the analyzer will run a control of the volume of the liquid present. **Figure 5**



Figure 5

NOTE: when using the Remove option, no functional control is performed: the existing volume and test code are not removed.

1.3. ANALYTICAL CALIBRATIONS AND CONTROLS

CALIBRATIONS

The analytical calibrations that can be run by the analyzer are divided as follows: **With Factor**, **Linear** and **Non Linear**. The selection occurs during the programming of the analytical test parameters (refer to **Chapter C**, paragraph **1.3.3. Primary Analytical Parameters**) and can be executed on user's request or automatically.

Linear and With factor analyses

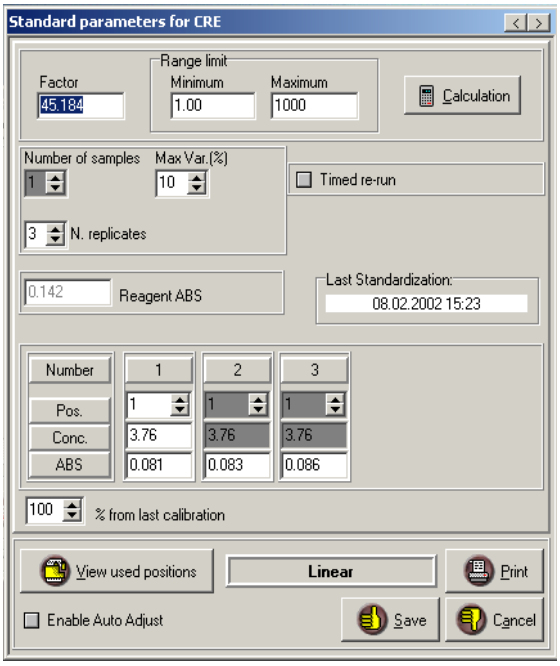


Figure 4

Factor: This parameter converts absorbance (ABS) values detected by the analyzer into final concentration values. When a theoretical factor is used (i.e. With Factor methodologies), enter in this field the known factor. The analyzer, when calibrating, calculates and updates the factor value.

Range limit: In order to verify calibration's validity, enter the Minimum and Maximum range in which the factor must be included. If an out-of-limit factor is detected, a message informs the user and the previously stored value is not modified.

Calibrators or standards used must be placed into dedicated positions on the samples' tray. It is possible to use up to 4 different standard concentrations or run up to 4 repetitions on a single title (and position) in the linear analyses.

Programming replicates on a single title

Enter 1 into the **Number of samples**, then enter the **N. replicates** (up to 4 max). Select the actual position (**Pos.**) on the tray for the replicated standard and then the concentration (**Conc.**). The values are automatically updated in the ABS boxes during the calibration and the factor will be automatically calculated.

Programming several standards

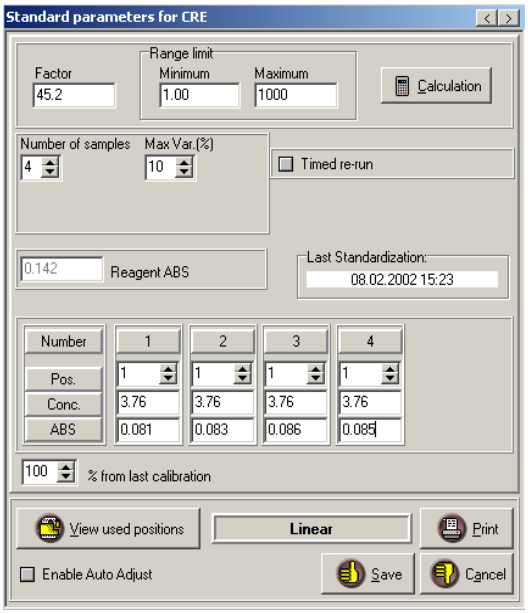


Figure 5

Enter the number of standards to be used in the **Number of samples** textbox. Enter the actual positions (**Pos.**) on the tray for each standard and then the concentrations (**Conc.**). The values are automatically updated in the ABS boxes during the calibration and the factor will be automatically calculated.

Calibration parameters

Max Var. (%) (Maximum percentage variation): This parameter is for verifying percentage variation. It represents the acceptable difference between the ABS values calculated for the different calibration points, in case more calibrators are used or repetitions are performed on a single title. When an out-of-limit variation occurs, a message informs the user and the calibration will not be stored (the previous positive calibration will remain in memory).

Reagent mABS: It is a read-only field and it is updated every time the blank reagent is performed.

% from last calibration: It is a percentage check made between current and previous calibration. It compares the newly determined ABS with already stored data. If the programmed limit is surpassed, then a message informs the user and the previous positive calibration will remain intact in memory.

Automatic adjust: It is a password-protected parameter that enables or disables automatic modification of test results in case of an additional calibration run during patients' execution.

Last Standardization: This field displays date and time for the last stored positive calibration. By double-clicking over the date textbox it is possible to display the previous calibration parameters.

Save: This command saves data and then closes the window.

Non Linear analyses: These tests require from 3 to 6 standards. Enter the number of standards to be used in the **Number of Samples field.** Enter the actual positions (**Pos.**) on the tray for each standard and then the related concentrations (**Conc.**). The values are automatically updated during calibration into the **ABS** boxes.

To use standards pre-dilution function, enable the **Automatic Dilution**. It is then possible to select whether dilution must be performed with water or physiological solution (**Dilution with solution**). In the **Dilution** field enter the required dilution ratio. If automatic dilution is not required, then appropriate concentration of the corresponding standard must be entered in the each concentration field.

Graph: This command displays the graph of the stored interpolation curve. In the graphic display page, data and curve are displayed together and can be printed.

CONTROLS

The controls are divided into **Known** and **Unknown,** where it is possible to program three levels for each one subdivided in tables:

Known: Level 1, 2, 3

Unknown: Level 1, 2, 3

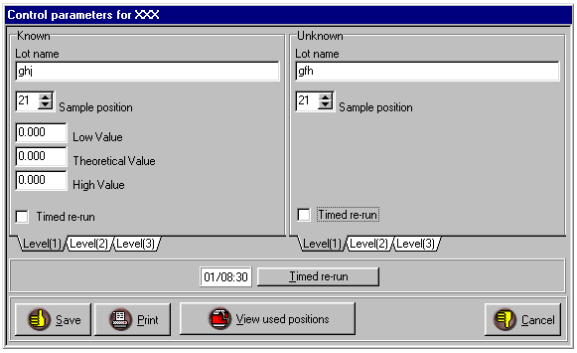


Figure 7

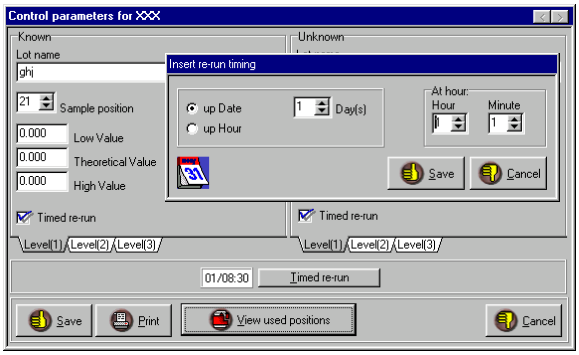


Figure 8

Known: Enter lot name or number, mean value, and min & max limits. Enter tray's position, already set to controls in the section **Setup Analyzer** included in the inner ring of samples' tray.

Unknown: Enter lot name or number and tray's positions. Reserved positions are those already set in the program **Setup Analyzer,** which are shared with known ones.

RUNNING STANDARDS AND CONTROLS

The functions **Run Standards** and **Run Controls** can be accessed from Tests main menu or through the specific icons that allow direct access (**Fig. 9 and 10**).
The displayed analysis codes pertain to the list generated in the **Current tray**. To run standards and controls, select the desired tests and then click on the **Run button.** To leave program press Exit.



Run Standards
Direct access icon

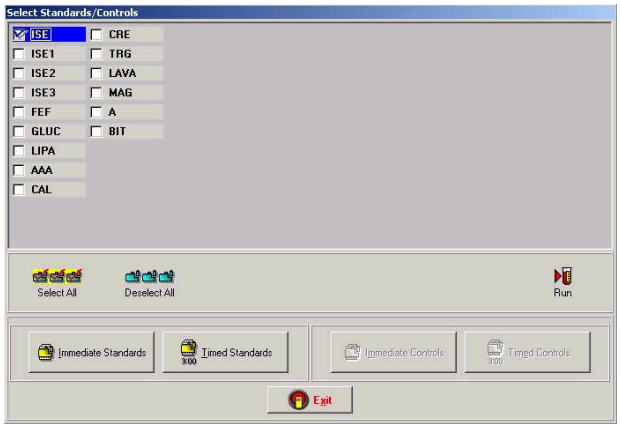


Figure 9



Run Controls
Direct access icon

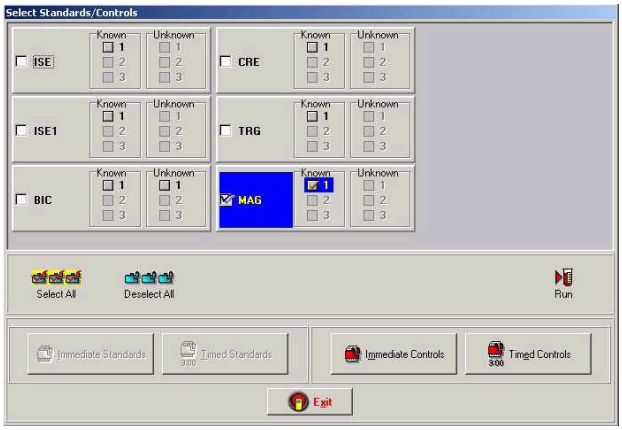


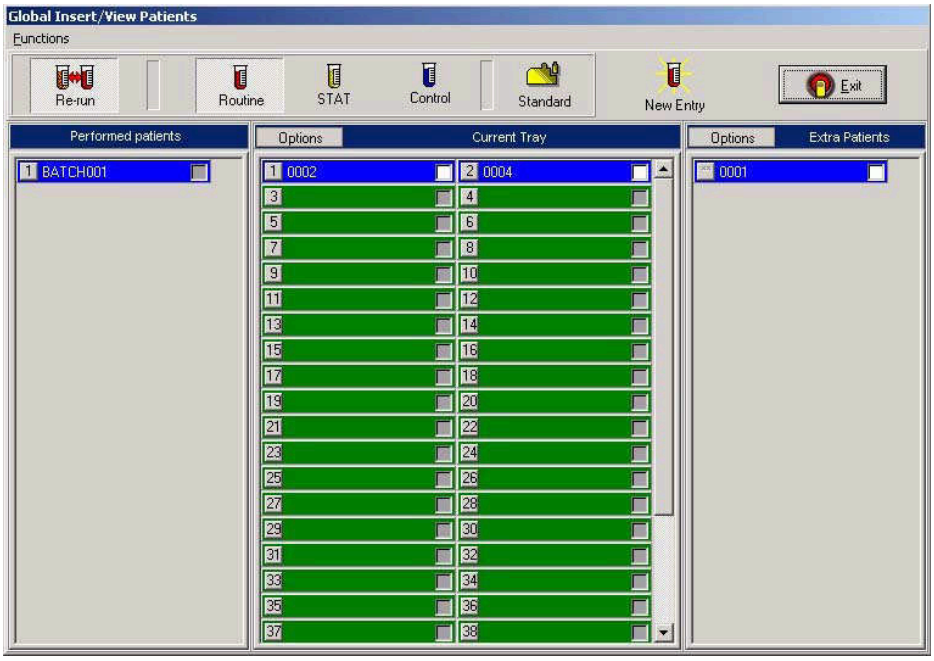
Figure 10

1.4. ENTERING PATIENTS AND WORK LISTS

Entering Samples (Routine, STAT, Controls and Batch)

Samples can be entered with **Insert Routine/STAT** or with **Insert Batch**. These can be accessed from **Patients** main menu or through appropriate direct access icons. Select **Exit** to leave the program. The represented analyses codes pertain to the list generated in the **Create current tray**.

Entering Patients: The options outlined below are available in this page **Global Insert/View Patients** (**Figure 11**). Point the cursor on the desired option and click to confirm. To leave program press Exit.





Direct access icon

Figure 11

Re-run: allows tests re-run (repetitions) on user's demand.

Routine: Default displays of Patient positions

STAT: Displays STAT (**S**ingle **T**est in **A**ctual **T**ime, i.e. urgent positions) positions.

Control: Displays Control positions.

Standard: Displays Calibrator positions.

New Entry: Displays window for entering data of Routine, STAT and Control samples.

Extra Patients: Displays the list of patients with no assigned position. Patients selected in the work-list may be moved here (Options menu, Send to extra patients command) and then back.

Exit: To leave program

Example of entering samples

New Entry Routine:

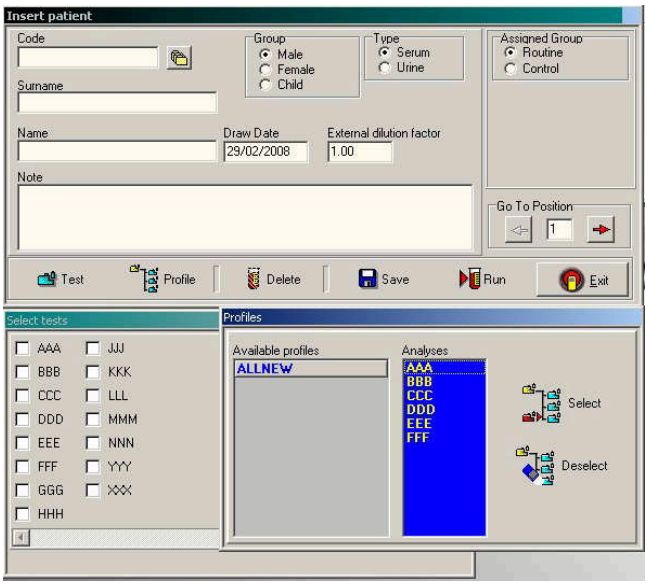


Figure 12

After the selection of **Routine** followed by confirmation through command **New Entry**, the patients acquisition frame is displayed (**Figure 12**). The programmed patient can be executed immediately or saved for later use. The programming fields and the functions are outlined below:

Code: It is the identification number assigned by the user to the patient. It is possible to assign an already given code thus creating a clone of the patient. The cloning of a patient's code allows the user to obtain one report in case different samples are used. If this option is not used, then separate reports are obtained.
It is also possible to create multiple **duplicates** of the same patient, where the codes will be automatically assigned and identified by the name Autobatch. These will have individual reports.

Surname, **Name:** Enter patient's personal data.

Date: enter the test date**.**

Notes: enter additional notes.

External Dilution Factor: By default set to 1. It allows analysis determination on externally diluted samples. Enter in this field the external dilution factor ratio used in sample preparation. Final result is multiplied by the inserted external dilution factor.

Group: Select the group (Man, Woman, Child) for correct reference with normal values range.

Type: It is default set to **Serum.** The sample type (Serum or Urines) is selected here. If **Urine** is selected, then the volume of diuresis is requested.

Assigned Group (Routine or **CTRL Routine):** The default setting is **Routine.** It is used for selecting the category (Patient or Control Serum) during sample programming. Selecting **CTRL Routine** the type (**Known or Unknown)** and levels (**Level 1, 2, 3**) must be specified.

Position: Displays the assigned position on the sample tray.

Test: Generates the Analysis List. Select each analysis to be performed on the sample.

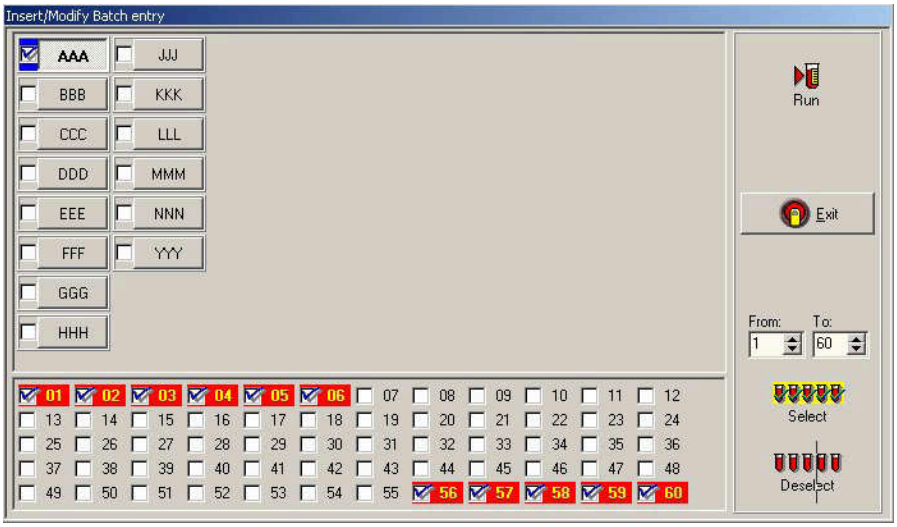
Profile: Select the desired profile among the available. The analyses programmed in this way can be modified. To add or remove tests, it is necessary to enter in the screen Select tests and confirm by clicking on the textboxes. With Deselect it is possible to delete an already selected profile.

Save: Saves patient's data and the associated analyses. With this command test execution is delayed.

NOTE:
In the routine programming, it is possible to acquire a greater number of patients than the available number of positions in samples' tray. All the patients acquired with no associated position are saved and displayed in the extra patients list and can be transferred to the main list on user's demand (refer to paragraph 1.5. Work Lists).

Run: This command immediately starts the execution of the programmed patient. The sample plate adjusts itself to match the position assigned to the patient, and a blinking red LED indicates the position for inserting cup or primary tube.

Entering samples in Batch





Direct access icon

Figure 13

Batch Entry: Click test code, then click each desired position (selected positions are highlighted in red). Finally click on the checkbox by the code to activate the programmed batch. Select the **Run** button to perform the patients. Refer to Figure 13.

Work Lists

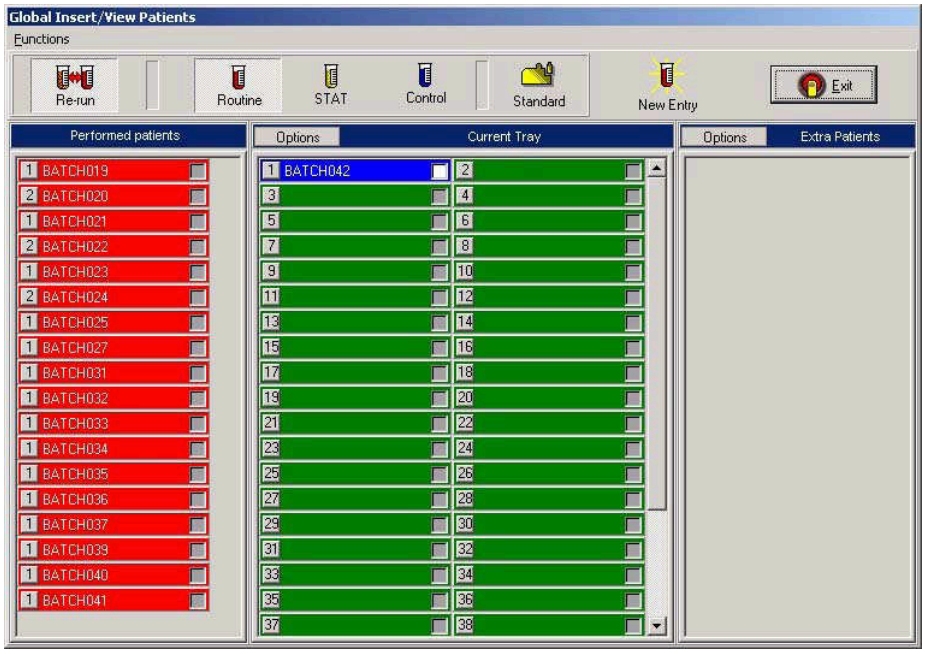


Figure 14

Work Lists (**Figure 14**) are used to display the patient codes or to verify the status of the samples in the tray together with the situation of Routines, STAT, Controls and Calibrators. The Work Lists can be accessed through the menu **Patients** → **Insert Routine/STAT** or using its direct access icon. The screen displays the **Current Tray (Routine)** in the center and the **Extra Patients (Routine)** on the right. During the working phase, the **Re-run** is also shown.

Click on the **STAT**, **Controls** and **Standard** buttons to view their worklists. For each the Current Tray and the Extra Patients lists will be displayed. It is possible to perform patients while running calibrations.

1.5. RUNNING TESTS

Once the data has been entered, insert the samples into the tray (**Figure 15**) and then place the tray into the analyzer (**Figure 16**).



Figure 15



Figure 16



Options:
The Options menu is available in the **Current Tray** (Routine, STAT and Controls). **It** displays the following commands:

Send to extra patients:
The selected patients are removed from current samples tray list for placement on **Extra Patients List**. Selection can be done by checking the appropriate boxes.

Print:
Prints the partial (for selected items) or total samples list.

Select All:
Automatically selects the whole list.

Deselect All:
Automatically deselects the whole list.

Run: Work start command. If single patients or the whole list are selected, a message asks if the samples have been inserted. If the answer is affirmative, the analyzer automatically starts processing. In case of a negative answer, a guided procedure will assist the user to insert the samples. The selection of the sample to be inserted is performed by confirming with cursor on the corresponding line. Use Select All to select the whole list and Deselect All to deselect it but in this case confirmation is required. After the insertion of all the samples, activate Run

Delete: Removes selected or all the patients. Confirmation is required.

Scan tray – Scan tray and run: performs a reading of the samples' tray and updates the patients worklist. Selecting "scan and run" the analyzer will read tha samples' tray and start the patients run.

1.6. DISPLAYING AND PRINTING RESULTS

Displaying Patients Results

The representation of the test results can be accessed through the specific icon (shown on the right) for the two available options: **View results for sample** (results will be displayed for patient) and **View results for test** (results will be displayed for test).

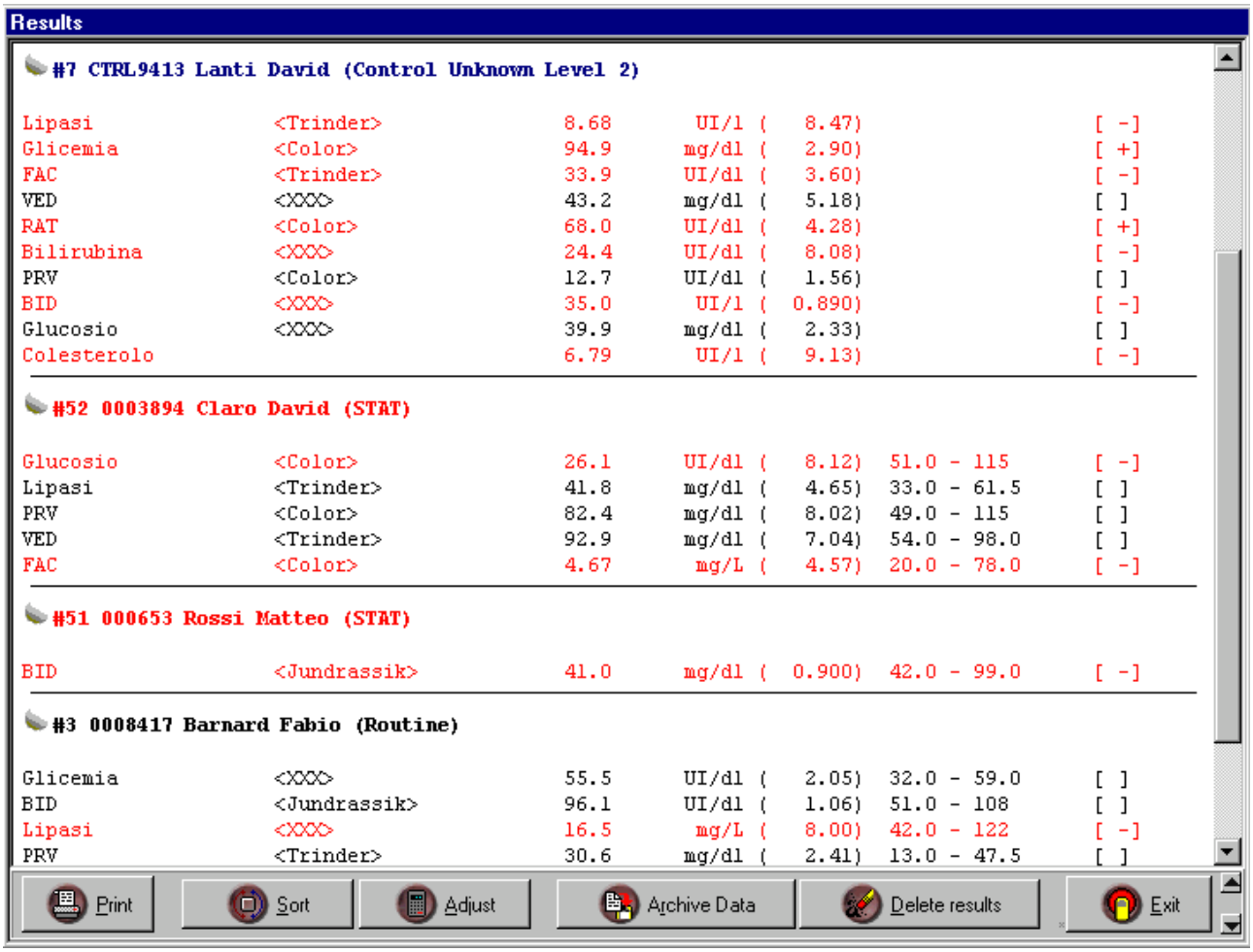


Figure 17

The Patient's data display page is shown in **Figure 17.** It can be accessed through the specific icon (shown on the right). It is a brief representation of data and allows visualization of results of patient in execution as the tasks for the single patients are completed. Once the results are archived, the information present in this page will no longer be available.

In this area information related to calibrations is represented, such as the values of calculated factors or any types of errors that occurred during execution.

If there is no data the page appears blank. A color code makes it possible to quickly identify the information:

- red text: presence of flags in at least one test of the sample
- blue text: controls
- green text: calibrations
- black text: no anomaly in the test or the entire sample

The following information are displayed for each sample:

a) Sample Position (#XX) Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.

b) Sample Code For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.
It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph **1. "Quality Controls"**).

c) Surname, Name Patient's personal data.

d) Sample Type The relationship of Sample to one of the groups: Routine, STAT, CTRL or STD is indicated between brackets.

e) Results The results of test attributed to patients are represented with:

```
FAC          <Color>          38.1     mg/L (     1.57)  53.0 - 102     [-]
VED          <Trinder>        19.7     mg/L (    0.910)  17.0 - 67.5    []
```

- full name of the analysis
- execution method
- result
- unit of measurement
- absorbance read (between parenthesis)
- range of normal values
- any flags (between brackets – see also par. 1.5)

For automatic re-runs the values of the first and second determination are represented.

The following commands are available in the data display page:



Print: Print command. If enabled, it prints the entire contents of the data display page. However, this is not a print-out in report format.

Sort: Data sorting command. This function is enabled only at the end of working session. The real-time data are displayed in test execution order. The Sort command allows sorting based in the following criteria, in this order: date, time, position on tray. The controls are places last and the calibrations first.

Adjust: Data re-reprocessing command. This function is enabled only at the end of working sessions. For patients re-run manually only the last result will be recalculated. The correction is made starting with the absorbance memorized for the single test. After confirming the command and selection of the desired analysis, two data re-processing modes are available. The first mode allows a positive or negative percentage correction and the second mode uses the latest valid calibration

Archive Data: This command saves data into the patients archive.

Delete Results: deletes all the data from the visualization pages (per patients and in real time) as well as the page of reaction graphs.

Exit: Exits from data display page.

INFO FLAGS

In both types of result displays (per patient and in real time) an **Info Flags** button is available on the upper right.
It provides access to a page where the flags are located, with a short explanation of the meaning of each one.

RESULTS PER TEST

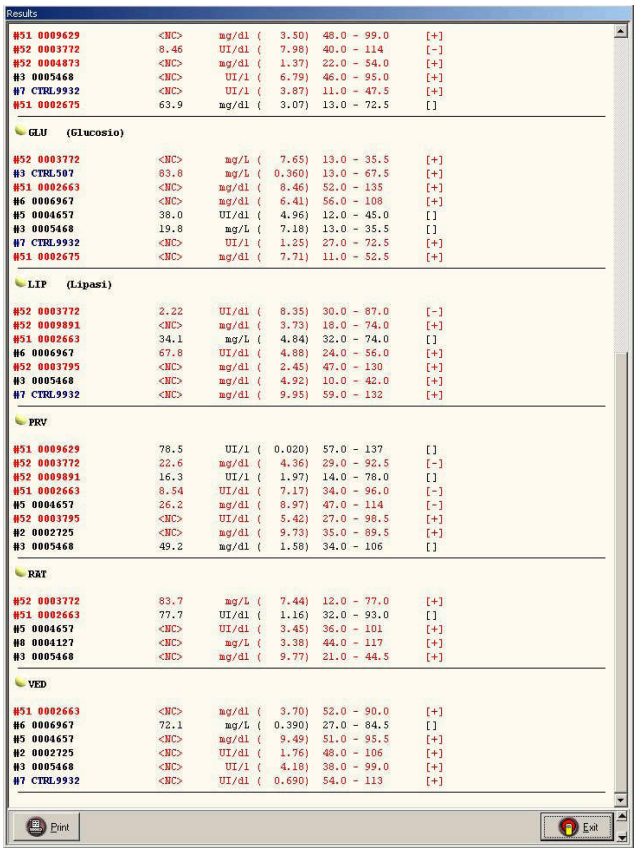


Figure 18

After the end of programmed task, the results can be viewed per **Test**. The test Results display page is shown in **Figure 18.** Test results with flags are highlighted in red.
The following information is displayed for each single test:

a) Code and test name — The displayed code is the same read on the list of tests, while the full name between parenthesis is the one assigned by the operator in the analytical parameters (chap. C, par. 1.3.3.).

b) Sample Position (#XX) — Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.

c) Sample Code — For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.

e) Results — The results of test attributed to patients are represented with:
- result
- unit of measurement
- absorbance read (between parenthesis)
- range of normal values
- any flags (between brackets – see also par. 1.5)

The following commands are available in the results display page:

PRINT: used to print the contents of the window. This is not a print-out in report format. A print preview will be displayed where it is possible to select which and how many pages to print.

EXIT: closes the page and returns to the main program, without modifying the data.

DISPLAYING REAL-TIME DATA

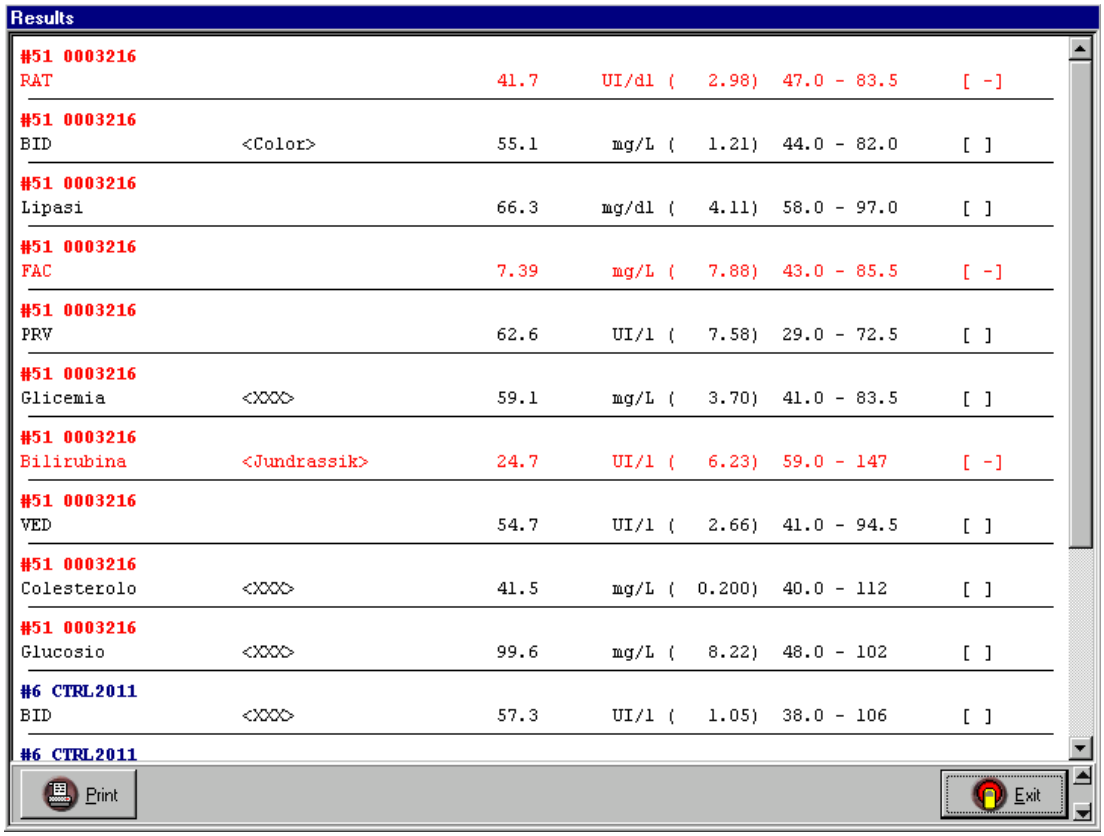


Figure 19

The data shown refer to the results obtained by the analyzer in real time (fig. 19), i.e. as the tests are completed. The results are not sorted in any way, not per patient, not for type of test.
The data display is synthetic. The results of tests associated to flags are shown in red.

Once the results are archived, the information present in this page will no longer be available.

The following information is displayed for each single test:

a) Sample Position (#XX) Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.

b) Sample Code For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.
It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph **1. "Quality Controls"**).

c) Date and time The date and time the test was run is between parenthesis.

d) Results The results of test attributed to patients are represented with:
- full name of the analysis
- execution method
- result
- unit of measurement
- absorbance read (between parenthesis)
- range of normal values
- any flags (between brackets – see also par. 1.5)

For automatic re-runs the values of the first and second determination are represented.

A window is also available on this page (**Info flag**) with information relative to the flags associated to the results. The Print and Exit buttons are also present, their functions have already been described in the previous paragraph.

1.7. TURNING OFF THE ANALYZER

To turn off the instrument, the **SHUT DOWN** procedure must be observed. In this way the instrument is turned off, except for the reagent refrigerator. The shut down procedure proposes the wash of the cuvettes with appropriate washing solutions before turning off. The analyzer indicates the position where the detergent should be inserted for the cuvettes washing (see also **Chapter. C**, paragraph **1.1.**). As regards the I.S.E. Module, please refer to Chapter L, par. 1.3.

There are two additional modes for interrupting analyzer operation:

1) SLEEP-MODE

This mode can be manually activated, or it starts automatically when the instrument is left inactive for more than 30 minutes. The Sleep-Mode automatically performs the wash and fill up of the cuvettes with bi-distilled water and remains idle (waiting for user's commands for immediate operation).

2) LOG-OFF

The Log-Off mode represents a partial turning off of the analyzer. It disables some devices: halogen lamp of the photometer, cuvettes thermostat and drive motors. This mode is used for energy saving. The Log-Off mode is utilized for programming automatic turning on at a desired date and time. The instrument will remain in a stand-by condition and it will automatically turn on 30 minutes before the programmed time. The turning on in anticipation (30 minutes before the programmed time) allows the analyzer to reach steady state thus allowing immediate operation at the programmed time.
To exit ahead of time from a suspended activity, click on the left or right mouse button and press the Exit button on the window that appears. However, in this case it is necessary to wait for the devices to become operational (around 20 minutes).

CAUTION!

a) **Do not ever stop the analyzer by turning off the main switch prior to performing the correct SHUT DOWN procedure.**

b) **Improper shutdown may cause loss of data and programs and will necessitate reinstallation of the operating software.**

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 2

2. WARRANTY CONDITIONS **Page: 2**
- **Notes from the manufacturer** **Page: 3**
- **Parts / Instruments Return Authorization** **Page: 4**

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

2. WARRANTY CONDITIONS

- Biotecnica Instruments S.p.A., after having accurately tested this analyzer, guarantees the instrument for 1 (one) year starting from invoice or goods delivery.
- The warranty includes the repairing and the replacement for free of the faulty parts due to wrong manufacturing. Warranty is not extended to the normally consumable parts of the system.
- The warranty is not valid in case of improper use, negligence, improper or lack of maintenance and cleaning, tampering or repairing by third parties not authorized by Biotecnica Instruments S.p.A. and in any case when the cause cannot be stated as original manufacturing fault.
- The costs of shipment and transport to Biotecnica Instruments S.p.A. for repair or substitution, and the risks deriving from this is the responsibility of the buyer, including all the costs of onsite technical service at client's location (transport, board and lodging) as well.
- If the stated defects will result to be out of warranty limits, the buyer will pay repair or replacement costs.
- Biotecnica Instruments S.p.A. is not responsible for any unforeseen technical problem that might occur. If the requested technical assistance is outside the terms of warranty a charge will me made to the customer as per current rates in force.
- Biotecnica Instruments S.p.A. is an internationally known for its high quality standards in production. Biotecnica Instruments S.p.A. is thus responsible for providing to the customer clear and effective information for use of it's products, including all the precautions and warnings for a secure and risk-free use.
- Service personnel must also refer to the warnings and cautions notices in this manual. It is the duty of the service engineer of Biotecnica to instruct the customer’s personnel to take all necessary precautions during repair and handling of products.
- Biotecnica Instruments S.p.A. is not responsible for any damage that may be caused directly or indirectly to persons or things due to a lack of observance of all the warnings and cautions outlined in the user's manual, and concerning the warnings and cautions during the different working phases of the instrument (see chap. M). Direct, indirect, incidental, special, moral damages as well as other damages of any type (including, with no limitation, those deriving from profit’s loss, business interruption or information loss) cannot be ascribed to Biotecnica Instruments S.p.A. even in the case in which the possibility of the event had been explicitly stated.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY
Tel. +39-06-4112316
Fax +39-06-4103079
E-mail: bt@biotecnica.it
Web: www.biotecnica.it

NOTES FROM THE MANUFACTURER

- The Biotecnica Instruments S.p.A. reserves the right to revise this manual without notice, for any reason. This includes but is not limited to, utilization of advance in the state-of-the-art and changes thereof. Product enhancement resulting from our continuing quality improvement effort may necessitate changes in specifications without notice. This fact doesn't oblige the company to inform its actual customers because the information included in the present manual refers to state of the product when shipped, thus no warranty about notification of future changes is given.
- The information contained in this manual is proprietary with "Biotecnica Instruments S.p.A.". Reproduction of any part or whole may only be performed with written permission from "Biotecnica Instruments S.p.A.".

Mod.05-35a-ing Rev. 1

biotecnica instruments

Parts / Instruments Return Authorization

DATE: _____/_____/____

From:			
To: Technical Assistance – Export Manager			
Client information			
Instrument model:		Serial number:	
Defective part			
Part description:			
Code:			Serial number:
Bar-code number:			Quantity:
Under warranty: Yes ❑ No ❑		Invoice number:	Date:
Description of the problem:			
Request for:			
Repair ❑	**Exchange ❑**	**Quotation ❑**	**Urgent ❑**
Name:		Signature:	
Biotecnica Instruments response			
Return authorization number: **/ 200_**			Date:
Approved: Yes ❑ No ❑			
Repair ❑	Exchange ❑	Destroy ❑	Quotation:
Note:			
Approved by: Technical Assistance Dept.		Signature:	
Checked by: Quality Assurance Manager		Signature:	

NOTE: No parts or instruments will be accepted for repair or replacement without a Return Authorization number that can be obtained from Biotecnica Instruments S.p.A. Fax this Return Authorization form to +39 06 410 3079 to the attention of Technical Assistance/Export Manager, who will then evaluate and issue a Return Authorization number.

WARRANTY EXCTRACT: Biotecnica Instruments S.p.A. warrants its instruments to be free from defective parts and workmanship for a period of one (1) year from the date of purchase. Liability under this warranty is expressly limited to repair or replacement of defective parts at the option of Biotecnica Instruments S.p.A. This warranty does not cover the results of misuse, accident or abuse of any parts of its instruments which have been repaired, tampered with or altered by anyone other than personnel authorized by Biotecnica Instruments S.p.A. This warranty does not apply to fluid handling devices, consumables or reagents.
Products returned to Biotecnica Instruments S.p.A. for repair or replacement shall be sent with transportation prepaid.
If found not to be defective under the terms of warranty, a charge will be made for repair or replacement and freight costs will be at customer's expense.

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 3

3. ORDERING INFORMATION **Page: 2**
3.1. GENERAL TERMS AND CONDITIONS FOR SALE **Page 2**
3.2. Consumables for BT analyzers **Page: 3**

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

3. ORDERING INFORMATION

For technical or ordering assistance start with our convenient ordering check list located in the ensuing paragraphs **3.2.** and **3.3.** For further assistance, don't hesitate to call the Biotecnica Instruments S.p.A. or your local sales/representative office.
To obtain accessories/spare parts, address order or enquiry to your Biotecnica Instruments S.p.A. sales/service representative or to Biotecnica Instruments S.p.A. and supply the following Information:

a) Instrument Model and Serial Number
b) Quantity of parts desired
c) Part Number
d) Description

Biotecnica Instruments S.p.A.
Via Licenza, 18
00155 - Rome (ITALY)

Phone: +39 06 411 2316 Fax: +39 06 410 3079 E-mail: bt@biotecnica.it

NOTE:
DUE TO IMPROVEMENTS IN DESIGN AND/OR SPECIFICATIONS, SOME PRODUCTS MAY DIFFER SLIGHTLY FROM THE PREVIOUS DESCRIPTION.

3.1. GENERAL TERMS AND CONDITIONS FOR SALE

ORDERS: All telephone or written orders placed by the customer are considered a binding contract created with the Company, when a written order acceptance has been sent by the Company or the ordered goods have been shipped. For orders with a value over Euro 250,00, the goods including the packing cases are shipped carriage paid. All prices listed exclude VAT and all similar taxes and the purchaser will be liable for such taxes if applicable.
SHIPMENTS: In accordance with the general provisions of law, the goods are shipped at the customer's risk even where shipped carriage free.
The goods with cold storage temperature between 2 - 8° are shipped at controlled temperature.
CLAIMS: Any claims must be made within 10 days from the receipt of goods.

PAYMENT TERMS: The terms of payment indicated on the invoice are valid. In the event of overdue account, interest and expenses will be applied as per the regulations introduced by Italian Legislative Degree 231/2002 of 7 November 2002 implementing EC directive 35/2000 (official ECB rate plus the rate established annually by the Italian government).
JURISDICTION: For any judicial contest, legal venue for both parties is Rome (Italy).

For additional information please visit our website at the following URL:
www.biotecnica.it

3.2. CONSUMABLES FOR BT ANALYZERS

PRODUCT	**PART NO.**	**SIZE**
Surfactant Concentrate	392	2x50 ml
Cuvettes washing solution	393	1 liter
Cuvettes' extra wash solution	393E	2x100 ml
Fuse RVT 8A, 250 Volt *(for Analyzer)*	330.6342B	1
Power Cord *(for analyzer)*	330.6391	1
Power Cord *(for peripheral devices)*	330.6400	1
Peristaltic Pump Cartridge	11-05209-01	1
Halogen Lamp 12V/35W for Photometer	330.9321	1
Tubular Filter for H_2O container	330.9614	1
Distilled Water container 5 lt Cubitainer	660.4002	1
Cleaning Tool for Arm Needle	662.0629A	1
Waste Container 10 lt Cubitainer	662.1010	1
Sampling Needle	662.1011	1
Sample Cup 2 ml	667.1040	1 (min. 1000)
Reagent Bottle 50 ml (white)	667.1084	1
Reagent Bottle 20 ml (white)	667.1085	1
Reagent Bottle 10 ml (white)	667.1086	1
Reagent bottle cap	667.1075	1
BT1000 & BT2000 PLUS	**PART NO.**	**SIZE**
Annual Maintenance Kit	662.2001	1
10 ml Test-tube	667.1081	1
Dilutor piston o-ring kit (ring flon + grease for 1 dilutor)	11-05283-01	1
BT1500	**PART NO.**	**SIZE**
Annual Maintenance Kit	662.2001	1
10 ml Test-tube	667.1081	1
Dilutor Ring Flon Φ 5mm	330.5741	1
BT3000 PLUS	**PART NO.**	**SIZE**
Reagent Bottle 80 ml (white)	667.1083	1
Quarterly I.S.E. Maintenance Kit	11-05338-01	1
Six-Monthly Maintenance Kit	11-05337-01	1
Dilutor piston o-ring kit (contains what is necessary for one dilutor)	11-05283-01	1
Fuse RVT 0.5A, 250 Volt *(for Vac Pump P/N 06-05161-01)*	330.6338	1
BT3500	**PART NO.**	**SIZE**
Reagent Bottle 80 ml (white)	667.1083	1
Quarterly I.S.E. Maintenance Kit	11-05668-01	1
Six-Monthly Maintenance Kit	11-05669-01	1
Dilutor Ring Flon Φ 5mm	330.5741	1
Fuse RVT 0.5A, 250 Volt *(for Vac Pump P/N 06-05161-01)*	330.6338	1

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 4

4. SOFTWARE - Serial Communication: BT Analyzer <-> Host Computer — Page: 2
4.1. General — Page: 2
4.2. Patient transmission to BT analyzer — Page: 2
4.3. Results reception — Page: 3
4.4. Calculation of check-sum — Page: 4
4.5. Wiring diagram of interface cable — Page: 5
4.6. Variable communication protocol — Page: 6
4.7. Serial communication test programs — Page: 17
4.7.1. Program Comunica.exe — Page: 17
4.7.2. Program BTPLUS.exe — Page: 17

Important Notice:

Any modification to the Variable Serial Protocol is restricted to qualified personnel only. The Biotecnica Instruments S.p.A. guaranties the correct performance of the internal serial protocol. The responsibility for any malfunction arising out of any modifications to the scripts of the Variable Serial Protocol rests with the customer.

WARNING

This information regards the setting up of the barcode for sample tubes identification. The reading of the sample barcode label has the same progression as patient code.
For example: Once a patient code of 15 characters has been entered, then a code of 8 characters followed by 7 empty spaces to reach the 15 characters is sent.
The code read on the barcode label must have the same sequence 8 + 7 for correct detection.

IMPORTANT NOTICE ON DATA TRANSMISSION.
Any character below the "space" (value 32 decimal or 0x20 hexadecimal) at the beginning or at the end of a patient code will be deleted. In this way it will be possible to have a patient code shorter that 15 characters, without being obliged to use the variable protocol. In case, after eliminating these characters, the resulting patient code is empty, it will automatically be changed into '{0}'

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

4. SOFTWARE - SERIAL COMMUNICATION: BT ANALYZER <-> HOST COMPUTER

4.1. GENERAL

The analyzer allows bi-directional communication through RS 232C serial connection with any host computer.
The particular feature of the dialog is that it is always the host computer, which initiates the communication for either transmitting patient list or for receiving the results.
To initiate any communication the host computer will have to send to analyzer the character STX (0x02) and expect the character ACK (0x06) as a response. At this point the host computer will send data to the analyzer and terminate the communication by sending the character EOT (0x04).
It is important to remember that any communication is followed by a response from the analyzer.
It must be noted that if the parameter to be transmitted is shorter in length than the length requirement of the communication protocol than a space must be added before or after. For example the analysis have length 4, therefore to send a code GLY one must add a space after to reach the length of 4 characters.

4.2. PATIENT TRANSMISSION TO BT ANALYZER

- ► Start communication with sequence STX<->ACK.....
- ► Send patient code..... (15 characters)
- ► Send list type for patient insertion..... ("T" for Routine or "R" for STAT)
- ► Send type of serum..... ("S" for Serum or "U" for Urine)
- ► Send if the patient is a clone..... ("Y" for Yes or "N" for No)
- ► Transmit position of cup..... ("00" unknown)
- ► Send number of tests to be executed..... (from "01" to "99")
- ► Send codes of tests to be performed..... (4 characters)
- ► Send Check-Sum..... (3 characters)
- ► Send end transmission character EOT.....
- ► Wait for response from the analyzer..... (2 characters)

If the communication is successful then the analyzer responds with character "Y" followed by a byte, which identifies the position where patient has been inserted. In case the communication was unsuccessful, then the analyzer responds with "N" followed by a byte identifying the type of error. The possible errors generated by the analyzer in response to the invalid insertion of patient are as follows:

0x01	Check-Sum Error
0x02	Unknown Command
0x03	Routine/STAT field Error
0x04	Serum/Urine field Error
0x05	Clone Yes/No field Error
0x06	Cup position Error
0x07	Number of Analysis field Error

0x08	Wrong Number of Test
0x09	Position already in execution
0x0A	Cloning impossible
0x0B	Code duplicated
0x0C	One or more analysis not present in the analyzer
0x0D	One or more analysis not present in the current plate
0x0E	Too many analysis for the patient
0x12	No patient to repeat
0x13	The serum field in the patient to be repeated is different from the memorized one
0x14	Patient to be repeated, but the list is already full
0x15	Patient to be repeated, but the list is different
0x16	The assigned position is already in use
0x17	Already existing or performed patient, it is not a clone and belongs to a supplementary (extra) list
0x18	Already performed patient, but no repetitions or clones are active

For example to send a patient with code 000000000000001, serum type and with analysis GLY, BUN and CHO onto the STATS list, then one must send the following sequence of characters (excluding initial sequence STX<->ACK):

000000000000001RSN0003GLU BUN CHO 134<EOT>

Where:

000000000000001.....	Patient code
R.....	Identifies STATS list
S.....	Identifies the type of patient (in this case: Serum)
N.....	Identifies that the patient is not a clone
00.....	Unknown position (the analyzer will insert the patient in a convenient position)
03.....	Identifies the number of test to be executed.
GLY, BUN, CHO.....	Test codes (observe the space after each code to reach the 4 characters limit)
134.....	Identifies the Check-Sum
<EOT>.....	This character ends communication

4.3. RESULTS RECEPTION

There are three commands for receiving reports from the analyzer:

R.....	Reception of next available report
L.....	Reception of the last report sent (in case of reception problems)
A.....	Reception of the first available report (in case one desires to receive again all the reports)

The commands R, L, and A require standard communication or the procedure STX<->ACK and the character EOT to end communication.
As a response to one of these three commands the analyzer sends the requested report (if

available) or the character NAK (0x15) if there is no report to be sent. It must be borne in mind that after a run test the reports are not immediately available for transmission as these need validation. To do this, go to Utility menu, RS232 and enable the option "Accept result to be sent". This operation must always be performed after each run test or groups of run test.
There is also an additional option for performing validation operation automatically. Go to Setup of the analyzer (Menu Utility, Setup Analyzer), go to the Serial (fourth from the left) and enable the option "All results must be sent automatically (without validate)" at the bottom of the page.
In case of positive response to the request for a report the analyzer transmits:

Patient code.....	15 characters
List type.....	"T" for Routine or "R" for STATS
Sample type.....	"S" for Serum or "U" for Urine
Number of reports.....	3 characters

For each report:

Analysis code.....	4 characters
Result.....	7 characters
Check-Sum.....	3 characters
<EOT>	

The following is an example of eventual response to the data sent in "Sending a patient to BT ":

000000000000001RS003GLU 000.000BUN 0010.10CHO 00100.0245<EOT>

Where:

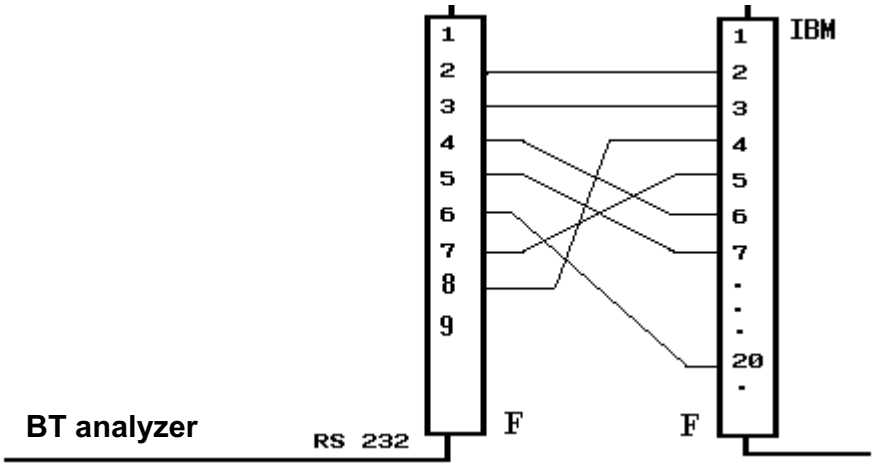
000000000000001.....	Patient code
R.....	Identifies STATS list
S.....	Identifies the type of patient (in this case: Serum)
003.....	Identifies numbers of reports
GLU.....	First test code
000.000.....	GLU test result
BUN.....	Second test code
0010.10.....	BUN test result
CHO.....	Third test code
00100.0.....	CHO test result
245.....	Identifies the Check-Sum
<EOT>.....	This character ends communication

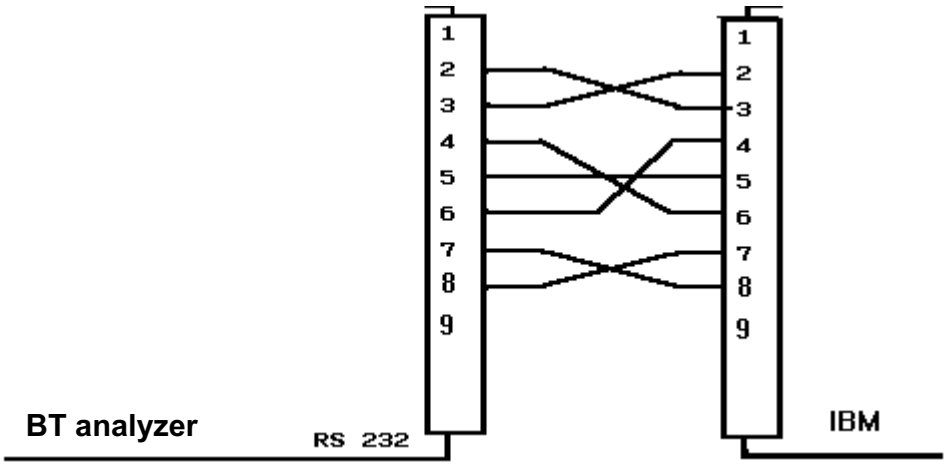
4.4. CALCULATION OF CHECK-SUM

This procedure calculates a Control code in accordance with the transmitted or received data. An algebraic sum of ASCII values of all the sent characters is executed. For example the character "A" has ASCII value 65 - 0x41.
Consequently the module 256 of the found value is executed (balance of dividing the value by 256). This is the Check-Sum to be sent.

IMPORTANT NOTE FOR VARIABLE COMMUNICATION PROTCOL
THE TERMINATING CHARACTERS OF VARIABLE LENGTH STRINGS DO NOT ENTER INTO THE CHECKSUM CALCULATION

4.5. WIRING DIAGRAM OF INTERFACE CABLE





4.6. VARIABLE COMMUNICATION PROTOCOL

Introduction
The variable serial protocol has been designed to provide the user with possibility to personalize the transmitted and received data from the analyzer.

ATTENTION: WHEN A VARIABLE COMMUNICATION PROTOCOL IS CREATED OR MODIFIED (BOTH IN TRANSMITTING AND/OR RECEIVING), IT IS ABSOLUTELY NECESSARY TO SAVE BOTH TRANSMITTING AND RECEIVING SCRIPS AND TO COMPILE AGAIN BOTH OF THEM, EVEN THOU ONLY ONE HAS BEEN MODIFIED.

The user can transmit or receive in addition to preset data (patient code, analysis code, results etc.), also the simple text strings and/or characters in order to meet the personal requirements.

Not only the user can decide to send or receive numerical information (for example number of tests) not as single byte but as a preset numerical string or vice versa.

For example the user can decide to receive something like:

"Initiate analysis data"
<Analysis data true and typical>
"End analysis data"

Where the phrases "Initiate analysis data" and "End analysis data" do not refer to any preset data by the analyzer but serve only for monitoring communication process (can be useful for inserting specific markers on those programs which obtain information from text files).

It is obvious that the protocol of initiation and end of communication, the commands for the request of report, and the analyzer responses in case of error or success remain identical to the usual preset serial communication.

NOTE:

a) If a check-sum is omitted in a communication then the analyzer will not control it.
b) The following numbers have been used to represent the error codes relevant to sending a patient to the analyzer as regards the parameters not part of the standard serial communication:

0x0F	Data (constant) sent to a TAG #Char, #String or #Stringn does not fall within the possible values range
0x10	Data (variable) sent to a TAG #Char, #String or #Stringn is not valid
0x11	An analysis variable is outside the **SET BEGIN/END** relative to the analysis

Notes regarding Scripts

A script is a text document. Each one of the single commands must each reside in a different line and be complete. In other words a single command cannot be divided into more lines.

Stringn 'Name'|$10 -> *Valid line*
Stringn 'Name'|$10 **char** 'A' -> *Invalid line*

Stringn 'Name' -> *Invalid Command*
|$10

An editor for writing, modifications, saving and compiling of one or more scripts is accessible inside the program (setup function). In any case it is possible to write a script with any text editor (DOS or Windows) like Notepad of Windows or the EDITOR of the DOS. It is not possible to import documents written with UNIX as the characters used for going to the next line are different from the ones used by the DOS or Windows.

CAUTION!

If one wants to use the script stored in a removable disk (for example floppy disk) then it will be necessary to copy it on the hard disk.

TYPE OF DATA

Character: Identifies a single character, can pass as printable character (enclosed between single apostrophes), as decimal ASCII value (followed by symbol **$**) or else hexadecimal ASCII value (followed by **0x**).
If for example we want to identify the character **A** (decimal value **65** or hexadecimal value **41**) then we can write **'A', $65** or **0x41.**

String: Identifies a sequence of printable characters enclosed in single apostrophes, for example: **'this is a string'**.

Comment: Identifies a portion of test (preceded by a character **;** which will not be compiled but will serve as note only for the programmer.

Variables: These are particular sequence of characters preceded by the symbol **#**, which will be used by the program for storing internal information (patient code, analysis name and etc.), refer to "TABLE 1 - TRANSMISSION/RECEPTION".
There are also variables for direct uses, which allow for identification of any character below ASCII 32 (space) to facilitate the writing of the script (for example, one can use the variable **#EOT** to identify the character **$4**), see "TABLE 2 - INTERNAL VARIABLES".

SCRIPT FUNCTIONS

String: Identifies a string of variable length ending with a particular character.

Syntax:
String <string>**|**<Terminator>

Where
<String> Transmit/receive string
<Terminator> End character

Note:
It is not possible to use the variables like parameter <Terminator>

Example:
String 'Hello Word'**|**$0
String 'My String'|'@'
String #Variable1**|**0x10

Stringn: Identifies a string of fixed length

Syntax:
Stringn <*String*>**|**<*Length*>

Where
<String> Transmit/receive string
<Length> String length

Note:
If the length of the text strings is less than the data length then a series of spaces will be added on the right to reach the data preset length. In case the text string is longer than the data length then the string end will be cut off to match the data length.

If the length of the numerical values is less than the data length then a series of characters '0' will be added to the left to reach the preset data dimension. In case the length of the numerical values string is longer than the data length then the string will be truncated to match the data length.

It is not possible to use variables as parameter <Length>.

Example:
Stringn 'Hello Word'**|**$40
Stringn #Variable1**|**0x10

Char: Identifies a single character (or single byte)

Syntax:
Char <*Character*>

Example:
Char 'H'
Char $20
Char 0x10
Char #STX

Set: Identifies the beginning and the end of the group of repetitive commands

Syntax

Set Begin<*Name of group*>
Begin repetitive group

Set End<*Name of group*>
End repetitive group

Note:
Actually the **ANALYSESDATA** is the unique SET present, which identifies the analysis in transmission/reception.
Only one command **SET BEGIN** and one command **SET END** can be present in a script.
A script must always contain the command **SET**.
The variable **PATIENTNUMBERTEST** must be present before the command **SET**.

COMPILATION ERRORS

One or more errors due to incorrect script writing or the system error may show up during compilation of a script. The compiler shows the error code, the description of error, and the line where it has been detected.
The following table shows the error codes, description, and the possible causes:

Error Code	Description	Possible Causes
1	Unknown command	An invalid command has been inserted in the commands of script.
2	A string request	A string as first parameter for String or Stringn command has not been inserted.
3	A number request	A string like parameter <lunghezza - length> of command Stringn has been inserted.
4	Invalid number format	Inserted invalid decimal or hexadecimal number.
5	Excessive data	a) Inserted more than two parameters for command String or Stringn. b) Inserted more than one parameter for the command Char or Set.
6	Invalid data	A string for command Char has been inserted.
7	String Terminator Request	The end (') character of a string not found.
8	Too little data	a) Inserted less than two parameters for command String or Stringn. b) No parameter inserted for command Char or Set.
9	Invalid String Length	The string length for Stringn command is less than 0 or more than 128.
10	Empty string	a) An empty string inserted for the command String or Stringn. b) Inserted a character identified as "
11	Unknown variable	a) Tried to transfer an invalid variable in the list of internal variables. b) Tried to use a transmission variable in the script of reception or vice versa.
12	Damaged file	Hard disk error. Contact Sales/Service.
13	Unknown file	Internal error. Probably damaged program. Reinstall the program. If the problem persists contact sales/service.
14	Incorrect identifier in the SET command	a) The text SET BEGIN or SET END not written. b) A different value from ANALYSEDATA transferred as <Group name> for the SET command.
15	Damaged exit file	Hard disk error. Contact sales/service.
16	SET command not closed	The SET END not inserted in the script.
17	Too many SET commands	More than one SET BEGIN command inserted.
18	SET command not found	The SET BEGIN command not found in the script.
19	Incorrect variable for SET command	A different value from ANALYSEDATA transferred as <Group name> for the SET command.
20	Variable not found before the SET command	The highlighted variable required in the script before the SET BEGIN command.
21	The variable must be String type	The highlighted variable must be String type, not Char
22	Already occupied position	An already occupied position on the plate has been entered
23	Patient exists but in different lists	An already existing code (or already executed) on the plate has been entered, but the list is different.
24	Patient executed but no repetition	An already processed code has been entered without indicating a repetition or a clone.

TABEL 1 – TRANSMISSION

The following variables are used for the transmission of a report from analyzer to the host computer:

Variable	Usage	Type of valid data
PATIENTCODE	Patient Code	String
PATIENTNAME	Patient Name	String
PATIENTSURNAME	Patient Surname	String
PATIENTGROUP	Group (1)	String Character
PATIENTLISTTYPE	List (2)	String Character
PATIENTTYPE	Method Type (3)	String Character
PATIENTNOTE	Descriptive Note	String
PATIENTNUMBERTEST	Number of Results	String Character
CHECKSUM	Check-Sum	String Character
ANALYSESCODE	Analysis Code	String
ANALYSENAME	Analysis name	String
ANALYSESTYPE	Analysis Type (4)	String Character
ANALYSESCONCENTRATION1	1st Concentration	String
ANALYSESCONCENTRATION2	2nd Concentration	String
ANALYSESFLAGS1	Flag 1st Result	String
ANALYSESFLAGS2	Flag 2nd Result	String
ANALYSESMINVALUE	Minimum Value	String
ANALYSESMAXVALUE	Maximum Value	String
ANALYSESUM1	1st Unit of Measurement	String
ANALYSESUM2	2nd unit of measurement	String
ANALYSESUMFACTOR	Unit Factor	String
ANALYSES2RESULT	Does the 2nd result exists? (5)	String Character
ANALYSESSERUMTYPE	Method Type (3)	String Character
ANALYSESURINE24H	Urine in 24/h	String

(1) Identifies Male, Female or Child (Select one of these):
'M' : Male
'F' : Female
'C' : Child

(2) Identifies Routine or STAT (Select one of these):
'R' : Routine
'S' : STAT

Transmitting patient from archive will always have identifier of Routine.

(3) Identifies Serum or Urine (Select one of these):
'S' : Serum
'U' : Urine

(4) Identifies Clinical Chemistry, or Relation Analysis (Select one of these):
'C' : Clinical Chemistry
'R' : Relation Analysis

(5) Identifies if the 2nd result exists or not (Select one of these):
'Y' : 2nd result exists
'N' : 2nd result does not exist

- If only the final result is desired then always refer to variables pertaining to 2nd result.
- In case of the absence of 2nd result then its variables will have the same values of the 1st result.

TABLE 1 – RECEPTION

The following variables are used for reception of a patient by the analyzer:

Variable	Usage	Type of valid data
PATIENTCODE	Patient Code	String
PATIENTNAME	Patient Name	String
PATIENTSURNAME	Patient Surname	String
PATIENTLISTTYPE	List (1)	String Character
PATIENTGROUP	Group (2)	String Character
PATIENTTYPE	Method Type (3)	String Character
PATIENTURINE24H	Urine in 24/h	String
PATIENTNOTE	Descriptive Note	String
PATIENTISCONTROL	If the patient is a control (4)	String Character
PATIENTCONTROLKNOK	If it is a known control (5)	String Character
PATIENTCONTROLLEVEL	Control Level (6)	String Character
PATIENTCLONE	If it is a clone (7)	String Character
PATIENTCUPPOSITION	Vial (Cup) position	String Character
PATIENTNUMBERTEST	Number of test	String Character
CHECKSUM	Check-Sum	String Character
ANALYSESCODE	Analysis Code	String

(1) Identifies Routine or STAT (Select only one of these):

$0 : Routine
$1 : STAT
'0' : Routine
'1' : STAT
'R' : Routine
'S' : STAT
'ROUTINE' : Routine
'STAT' : STAT

(2) Identifies Male, Female or Child (Select only one of these):

$0 : Male
$1 : Female
$2 : Child
'0' : Male
'1' : Female
'2' : Child
'M' : Male
'F' : Female
'C' : Child
'MAN' : Male
'FEMALE' : Female
'CHILD' : Child

(3) Identifies Serum or Urine (Select only one of these):

$0 : SERUM
$1 : URINE
'0' : SERUM
'1' : URINE
'S' : SERUM
'U' : URINE
'SERUM' : SERUM
'URINE' : URINE

(4) Identifies a Control or a Sample (Select only one of these):

$0	: Sample
$1	: Control
'0'	: Sample
'1'	: Control
'N'	: Sample
'Y'	: Control
'S'	: Sample
'C'	: Control
'NO'	: Sample
'YES'	: Control
'SAMPLE'	: Sample
'CONTROL'	: Control

(5) Identifies a Known or Unknown Control (Select only one of these):

$0	: Unknown
$1	: Known
'0'	: Unknown
'1'	: Known
'N'	: Unknown
'Y'	: Known
'U'	: Unknown
'K'	: Known
'NO'	: Unknown
'YES'	: Known
'UNKNOW'	: Unknown
'KNOW'	: Known

(6) Identifies Control Level (Select only one of these):

$1	: Level 1
$2	: Level 2
$3	: Level 3
'1'	: Level 1
'2'	: Level 2
'3'	: Level 3
'L'	: Level 1
'N'	: Level 2
'A'	: Level 3
'LOW'	: Level 1
'NORMAL'	: Level 2
'ABNORMAL'	: Level 3

(7) Identifies if it is a Clone (Select only one of these):

$0	: Normal
$1	: Clone
'0'	: Normal
'1'	: Clone
'N'	: Normal
'Y'	: Clone
'NOCLONE'	: Normal
'CLONE'	: Clone

TABEL 2 – INTERNAL VARIABLES

Variables	Decimal	Hexadecimal
NUL	$00	0x01
SOH	$01	0x02
STX	$02	0x03
ETX	$03	0x04
EOT	$04	0x05
ENQ	$05	0x06
ACK	$06	0x07
BEL	$07	0x08
BS	$08	0x09
TAB	$09	0x0A
LF	$10	0x0B
VF	$11	0x0C
FF	$12	0x0D
CR	$13	0x0E
SO	$14	0x0F
SI	$15	0x10
DLE	$16	0x11
DC1	$17	0x12
DC2	$18	0x13
DC3	$19	0x14
DC4	$20	0x15
NAK	$21	0x16
SYN	$22	0x17
ETB	$23	0x18
CAN	$24	0x19
EM	$25	0x1A
SUB	$26	0x1B
ESC	$27	0x1C
FS	$28	0x1D
GS	$29	0x1E
RS	$30	0x1F
US	$31	0x20

SCRIPT EXAMPLES

The examples outlined here are the transformation in script of the standard routine of the patient reception by the analyzer.

Stringn #PatientCode|$15
Char #PatientListType
Char #PatientType
Char #PatientClone
Stringn #PatientCupPosition|$2
Stringn #PatientNumberTest|$2

Set #BeginAnalysesData
Stringn #AnalysesCode|$4
Set #EndAnalysesData

Stringn #CheckSum|$3

The following are the details of the above Scripts:

Stringn #PatientCode|$15
Patient Code of fixed length equal to 15 characters

Char #PatientListType
Type of list (Routine/STAT) as single character

Char #PatientType
Serum type (Serum/Urine) as single character

Char #PatientClone
Identifies if the patient is or is not a clone (single character)

Stringn #PatientCupPosition|$2
Position of serum cup (string of fixed length equal to 2 characters)

Stringn #PatientNumberTest|$2
Number of tests to be executed (string of fixed length equal to 2 characters)

Set #BeginAnalysesData
Beginning of analysis codes

Stringn #AnalysesCode|$4
An analysis code of fixed length equal to 4 characters. It must be entered for each type of test as per qty indicated in the #PatientNumberTest.

Set #EndAnalysesData
End of analysis codes

Stringn #CheckSum|$3
Check-Sum (transferred as a string of fixed length equal to 3 characters)

The following examples are the transformation in script of the standard routine for the transmission of a report by the analyzer to the host computer:

Stringn #PatientCode|$15
Char #PatientType
stringn #PatientNumberTest|$3

Set #BeginAnalysesData
Stringn #AnalysesCode|$04
Stringn #AnalysesConcentration2|$7
Set #EndAnalysesData

Stringn #CheckSum|$3

The details of the above scripts are as follows:

Stringn #PatientCode|$15
Patient Code of fixed length equal to 15 characters

Char #PatientType
Serum type (Serum/Urine) as single character

stringn #PatientNumberTest|$3
Number of results to be sent (a string of fixed length equal to 3 characters)

Set #BeginAnalysesData
Beginning of zone repeated for the number of results to be sent (see #PatientNumberTest)

Stringn #AnalysesCode|$04
An analysis code of fixed length equal to 4 characters

Stringn #AnalysesConcentration2|$7
Concentration referred to the analysis code as per #AnalysesCode (a string of fixed length equal to 7 characters)

Set #EndAnalysesData
End of zone repeated for the number of results to be sent

Stringn #CheckSum|$3
Check-Sum (transferred as a string of fixed length equal to 3 characters)

4.7. SERIAL COMMUNICATION TEST PROGRAMS

4.7.1. Program COMUNICA.EXE:

It is a simple communication program for sending command characters to the analyzer and receive any response.
At the start the only input to the program is the number of the communication port (from 1 to 4).
A blue screen divided into two sections is displayed. In the upper section the characters coming from the analyzer are displayed, while the lower section displays the characters sent to the analyzer.
The only special keys used are F1 to clear the screen and F10 for exiting the program.
The special characters (with values less than 32) are displayed in ASCII notations along with their values.
For example the Character EOT - value 4 - will be shown as EOT (4).
To send a special character (with values less than 32 or higher than 124) it is necessary to keep pressed the ALT key and simultaneously to write the value of the character to be sent using numerical keys. For example to send EOT it is necessary to keep the ALT key pressed and simultaneously enter the value 4 through the numerical key and then release the ALT key.

4.7.2. Program BTPLUS.EXE:

It is a simple communication program that simulates the host computer. At the start it is necessary to identify the number of communication port (from 1 to 4) and the desired procedure (Transmission or Reception).
In case the Transmission is selected the program will ask for patient code (from 1 to 15 characters), the test number (from 1 to 9) and the relevant analysis code for each test (for example: BUN).
It is a good practice to use the same analysis codes, which the analyzer has memorized in the plate actually in use, if otherwise then an error will result in the transmission phase.
Now the program will execute an initialization procedure of communication with the analyzer, will send patient data and wait for the outcome of transmission.
At the end the screen will display the outcome of the operation or show the position number of the plate where the patient has been inserted or explanation of error code sent by the instrument (for example: Patient Code Duplicated).
If the Reception procedure is selected, then the program will begin initialization of communication with analyzer, will ask for data of the next report ready for serial dispatch and show data of relevant downloaded report.
If there are no reports to be received, then a relevant message will be displayed.
Every time the program waits for a response from the analyzer, in case of problem it is possible to abort the current operation by simply pressing the Esc (Escape) key.

NOTE:
Both the programs must reside in the computer connected serially to the analyzer through appropriate cable indicated in the Operators Manual.
The computer must be an IBM compatible equipped with DOS operative system: Windows 95, Windows 98, or Windows 2000. The operating systems such as MAC, UNIX, Windows ME or XP are not supported.
Since the programs operate in DOS ambience, therefore in case the Windows operating system is used then it will be necessary to open a DOS shell (the command Prompts of MS-DOS is found in the menu Programs, Accessories - accessed through the Start button on the bottom left of the screen).
Both the programs use serial port with the following setups:

Baude-Rate.....	9600
Stop-Bits.....	1
Parity.....	None
Hand-shake.....	Hardware

IMPORTANT NOTICE: These two programs are in the installation disk under Utility folder.

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 5

5. INSTALLATION OF THE OPERATING SYSTEM **Page: 2**
- **5.1. Preliminary Phase** **Page: 2**
- **5.2. Setup of the Operating System** **Page: 5**
- **5.3. Completing the installation** **Page: 9**
- **5.4. Settings of the Operating System** **Page: 11**
- **5.5. Installation of BT analyzers Program** **Page: 15**
- **5.6. Upgrading the BT analyzers software** **Page: 16**
- **5.7. Installation with Image Disk** **Page: 17**

NOTE:

All pictures in this manual are referred to the BT3000 Plus.

Figures may be different for the other analyzers.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

5. INSTALLATION OF THE OPERATING SYSTEM (OS)

CAUTION!

INSTALLATION OF THE OPERATING SYSTEM MUST BE DONE BY EXPERT PERSONNEL, AND ONLY IN CASE THE OS HAS TO BE RE-INSTALLED EX-NOVO.
BEFORE STARTING ANY SOFTWARE INSTALLATION PROCEDURE, CONTACT THE AUTHORIZED TECHNICAL PERSONNEL ONLY.

FOR ALL ANALYZERS EXCEPT BT1500
For the installation of BT1500 operative program, follow ONLY the instructions at par. 5.5. & 5.6. When installing the operative program on the BT1500 external PC, it is mandatory to have administrator rights.

5.1. PRELIMINARY PHASE

1) Ensure that the BIOS has the following Boot configuration:

- ***Hard-Disk***
- ***CD-ROM***
- ***Drive A***

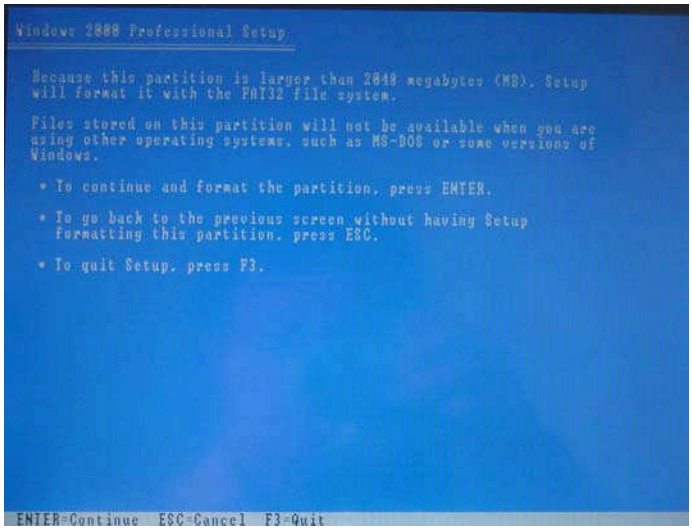
2) Check that the mouse and the keyboard are properly connected.

3) Ensure that the following supplementary hardware has been correctly installed:

- ***Additional Serial***
- ***Audio Card (optional)***
- ***Network Interface Card (optional)***
- ***Touch Screen***
- ***Connecting cable between IBM & 552***

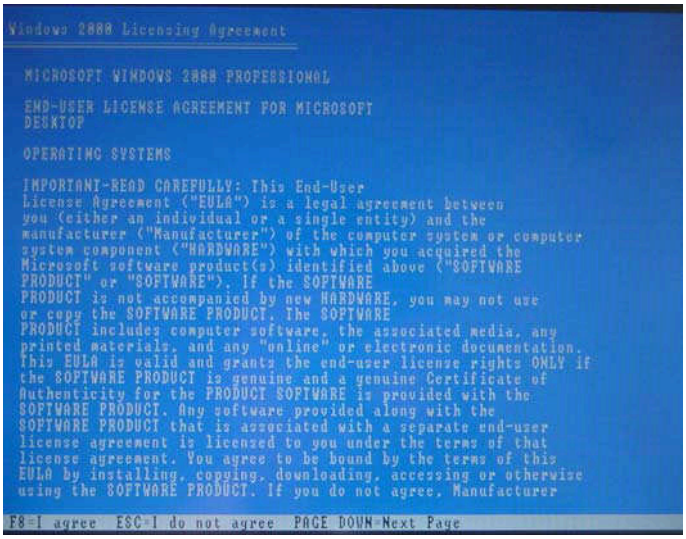
4) Turn on the instrument and insert Windows 2000 disk in the CD-ROM drive

The following screen appears:



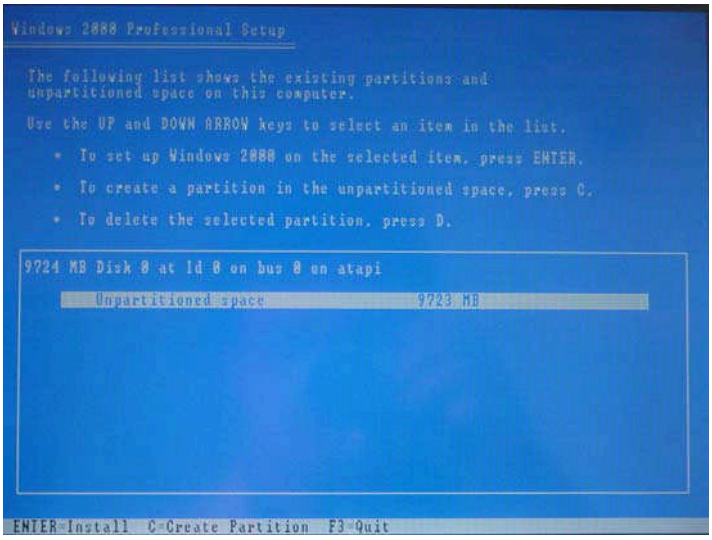
Press enter to initiate installation.

Now the screen displays the end-user license agreement for Microsoft Windows:

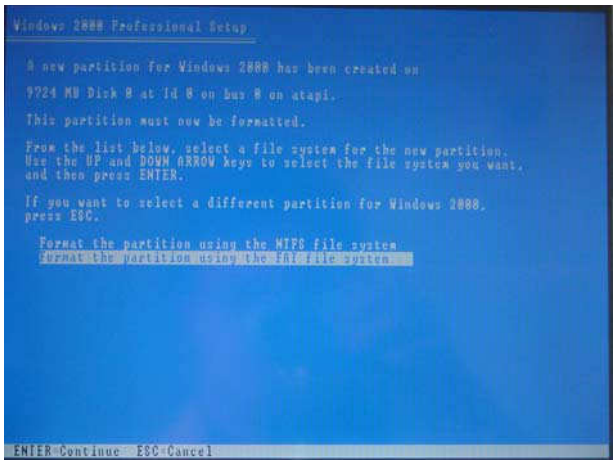


Press "**F8**" (**I agree**) to accept it.

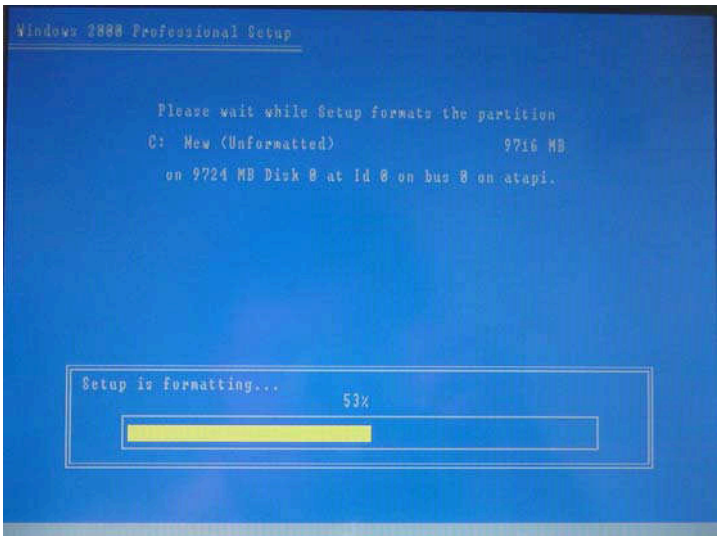
Windows displays the existing partition of the hard disk:



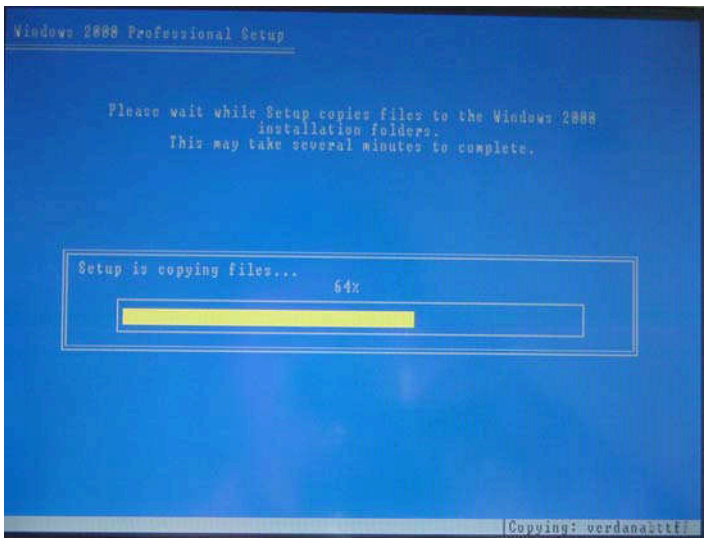
Press "**ENTER**" to use the default partition.
Select "**Format the partition using the FAT file system**":



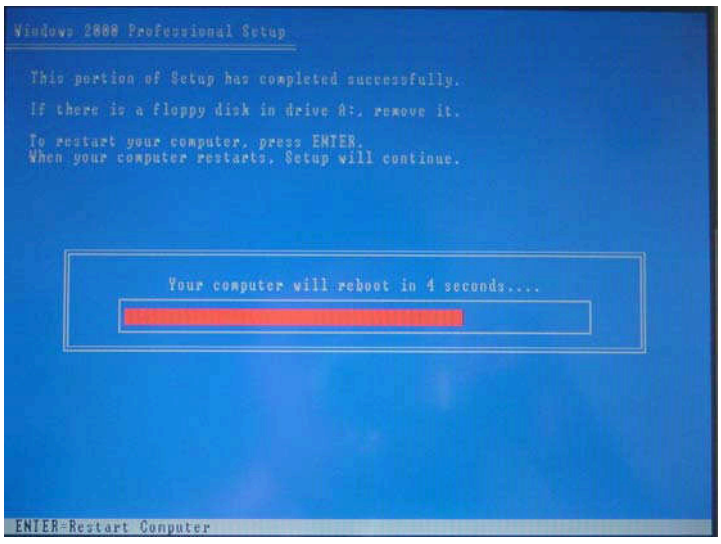
Press **"ENTER"** to continue.
Now the Setup formats the hard disk and this phase may last for a few minutes:



Now the Setup copies files to the Windows 2000 installation folders in the hard disk and this may take several minutes to complete:



At the end of preceding phase the system will restart (**DO NOT REMOVE CD-ROM FROM CD-ROM DRIVE**).

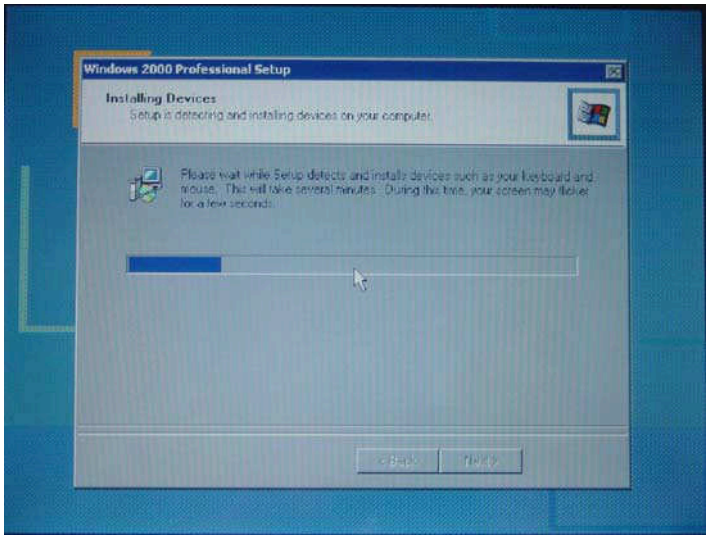


5.2. SETUP OF THE OPERATING SYSTEM

After the restart, the system displays the "Setup Wizard" which will guide the user during Setup of the Operating System:

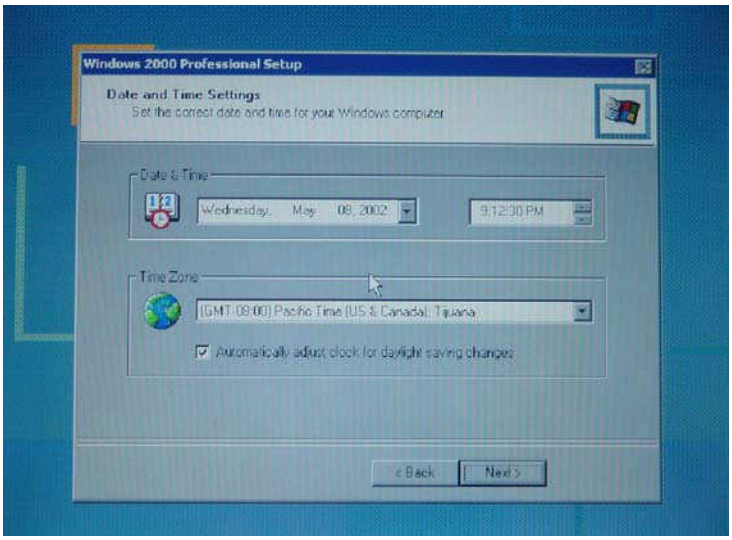


Click **"NEXT"** key to continue with Setup.
Now the Windows Setup detects the existing hardware and installs devices in the system. This will take several minutes. In case the system halts (crash), that means some hardware is not compatible with the system and/or the board utilized.

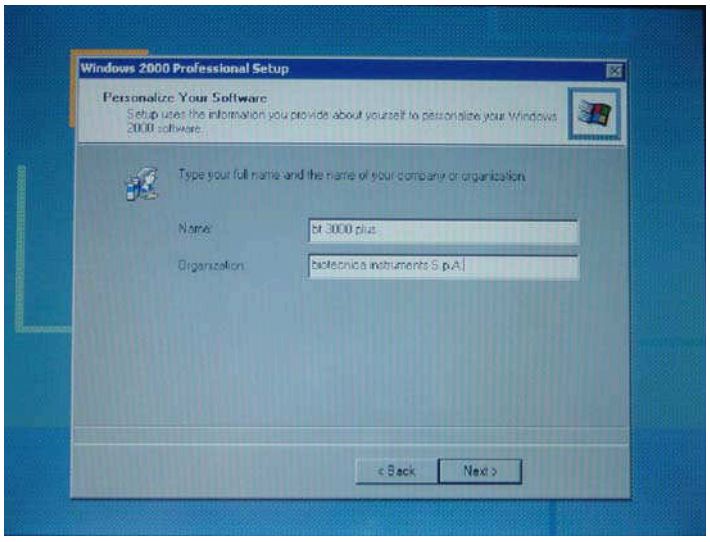


CAUTION
DO NOT INTERRUPT THIS OPERATION!!!

Now the Setup asks for setting the correct date and time for the system. One may skip this now and set the date & time later.

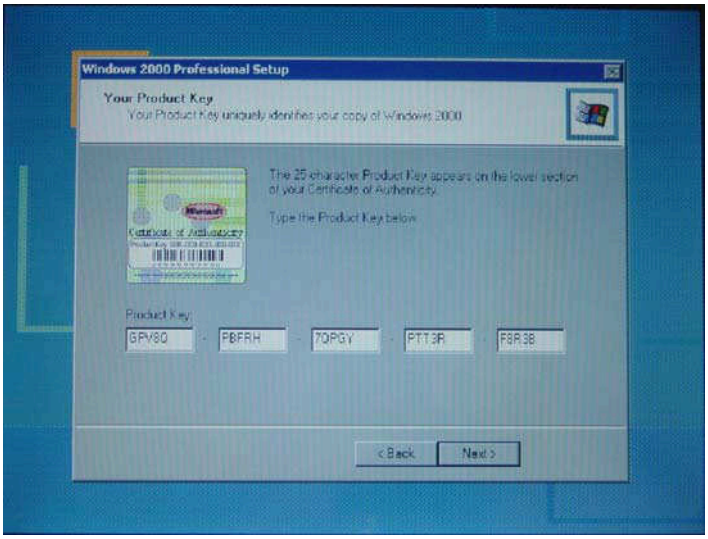


After making appropriate corrections, click **"NEXT"** key.
The Setup requests to enter **Name** of instrument and **Organization**:

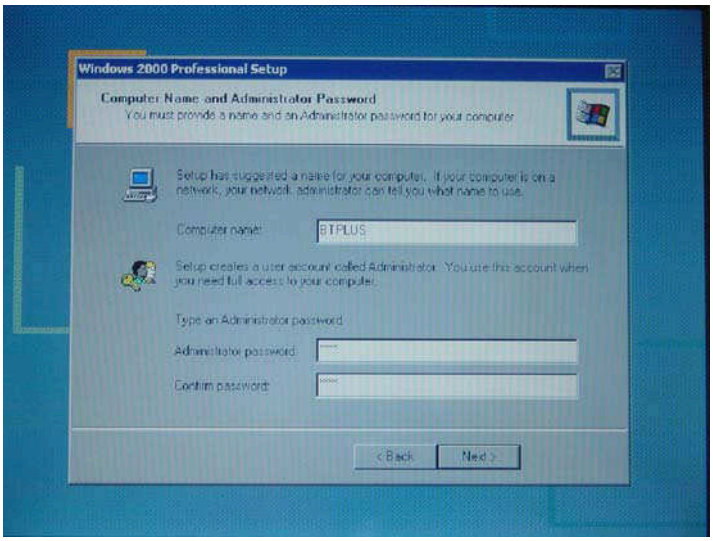


Enter **"bt plus"** as **"Name"** and **"biotecnica"** as **"Organizzazione"**.
Click **"NEXT"** key.

Now type the Product Key of Windows (the Product Key is composed of 5 groups of 5 characters each):

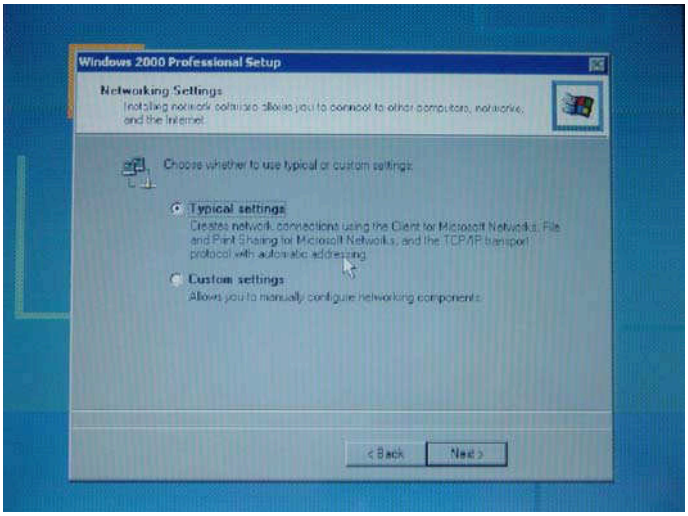


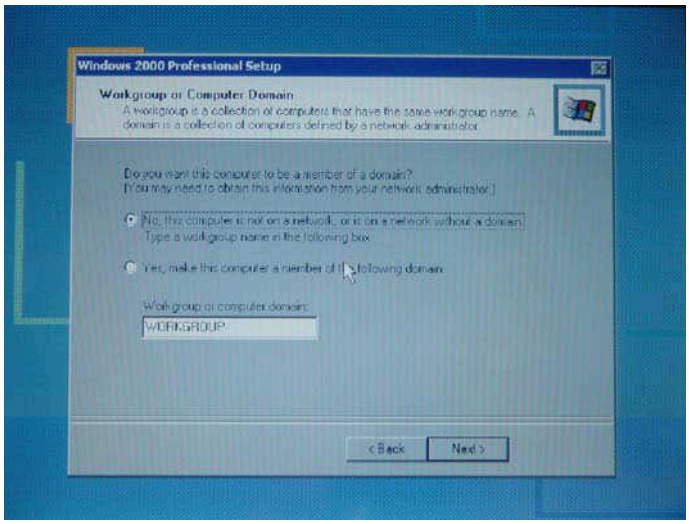
The 25 characters Product Key appears on the installation CD-ROM cover.
After typing the Product Key click "**NEXT**" key.
In case of incorrect Product Key entry, a message will alert the operator to enter the correct Product Key.
Now provide the Administrator Password for your system:



In the field **"Administrator Password"** type **"ENZO"** and rewrite it in the field **"Confirm Password"**.

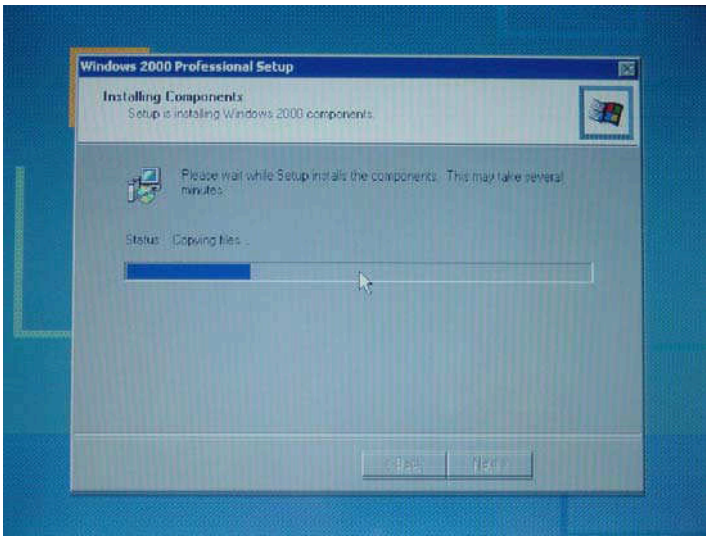
In case the board has a LAN (network) communication hardware, then the following screens will be displayed:

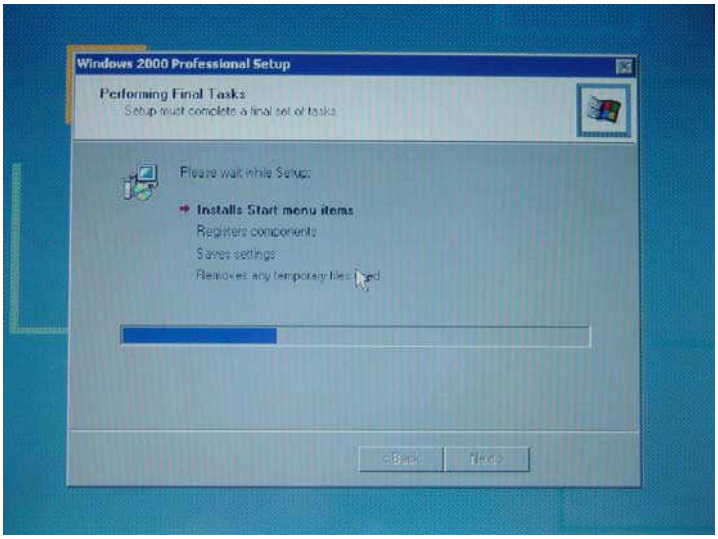




Do not change the default parameters and click **"NEXT"** in both the screens.

Now the Setup installs the Windows components and then completes the final set of tasks, which may take several minutes:



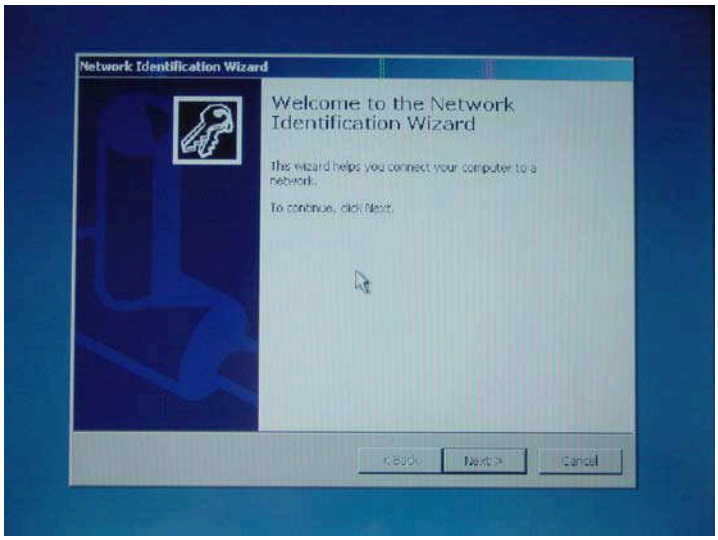


The second phase of the installation has been successfully completed. Remove CD from the drive. Click "**Finish**" to restart the system:

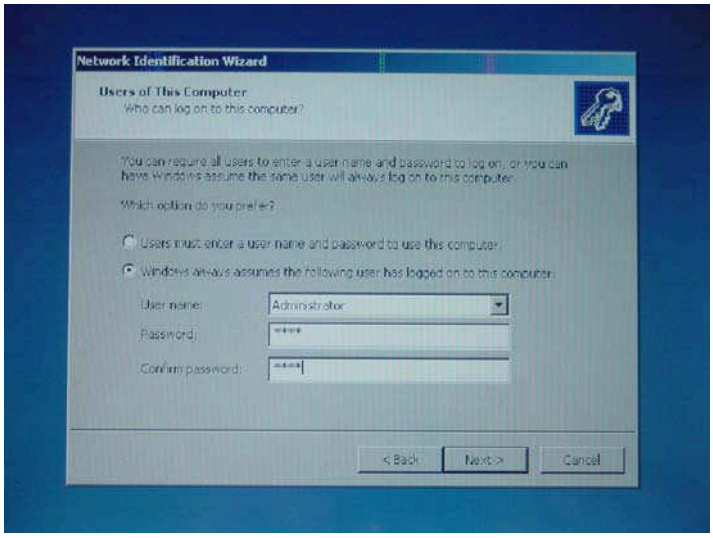


5.3. COMPLETING THE INSTALLATION

This is the most delicate phase of the whole process. If it is not performed correctly then it will be necessary to repeat the whole installation procedure of the operating system.
A welcome message is displayed:

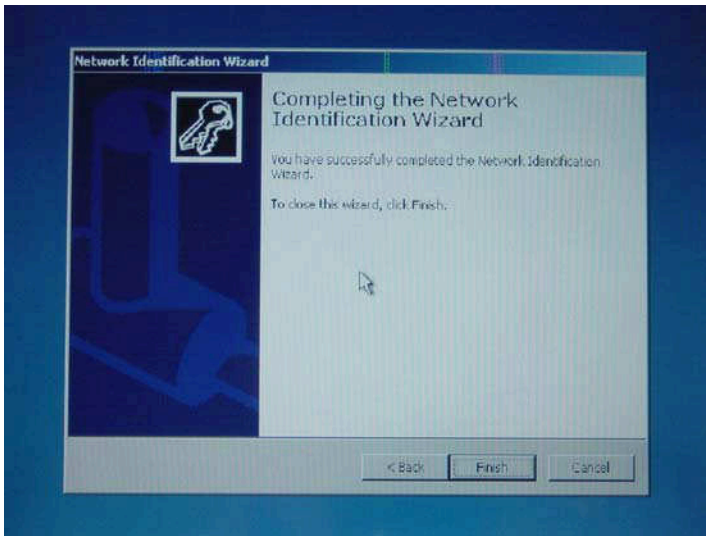


Click **"NEXT"** key.
Enter user name that will log on to the system **(STRICTLY OBSERVE THESE INSTRUCTIONS)**.



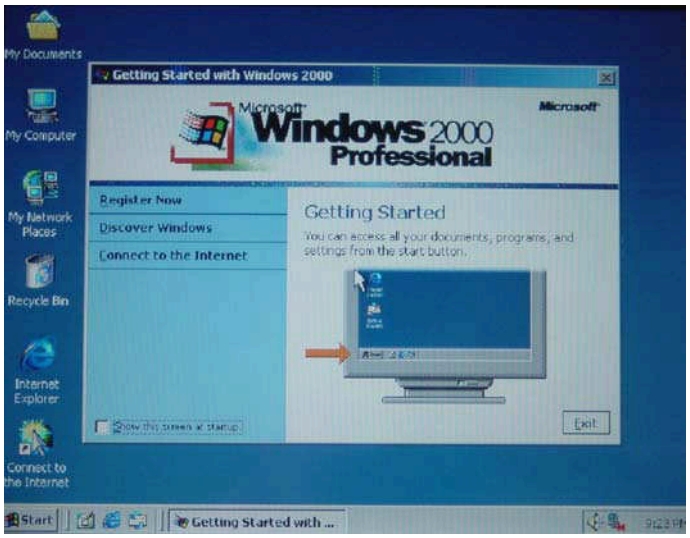
Enter **"Administrator"** as **"User Name".**
Enter "**ENZO**" as "**Password**", which was also used in the previous installation phase.
Confirm password by rewriting it.
Click "**NEXT"** to continue.

The Windows installation has been completed. Click **"Finish"** to exit.

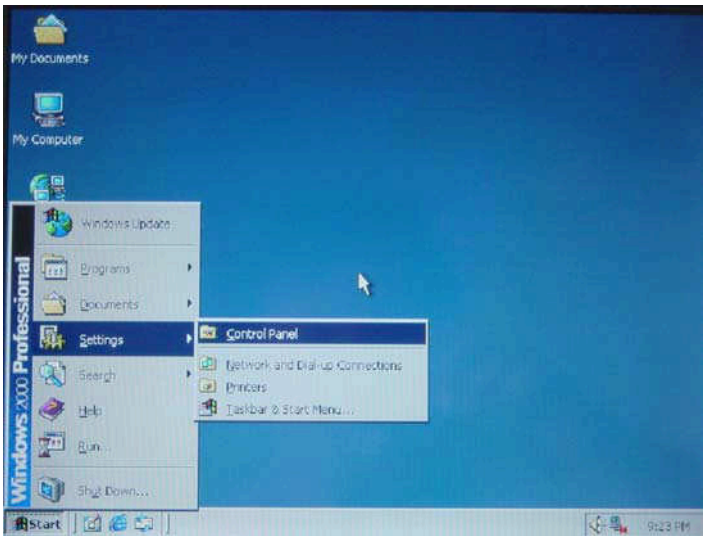


5.4. SETTINGS OF THE OPERATING SYSTEM

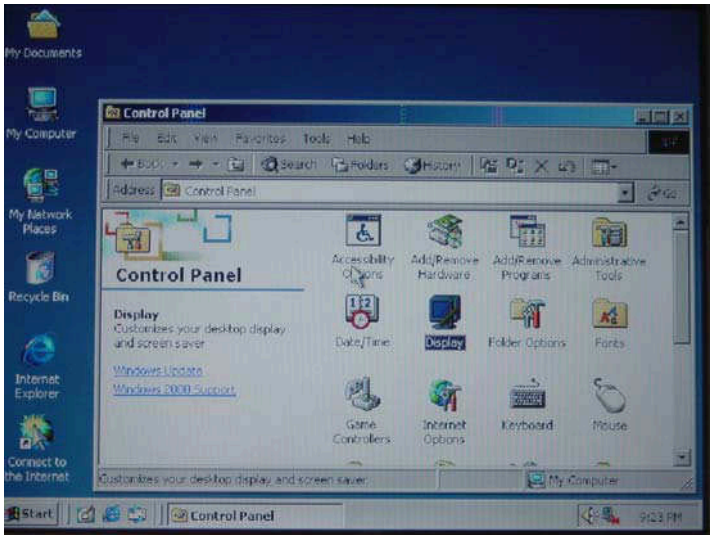
Uncheck the box **“Show this screen at startup”** (at the bottom left of the screen) and click "**Exit**" (at the bottom right of the screen).



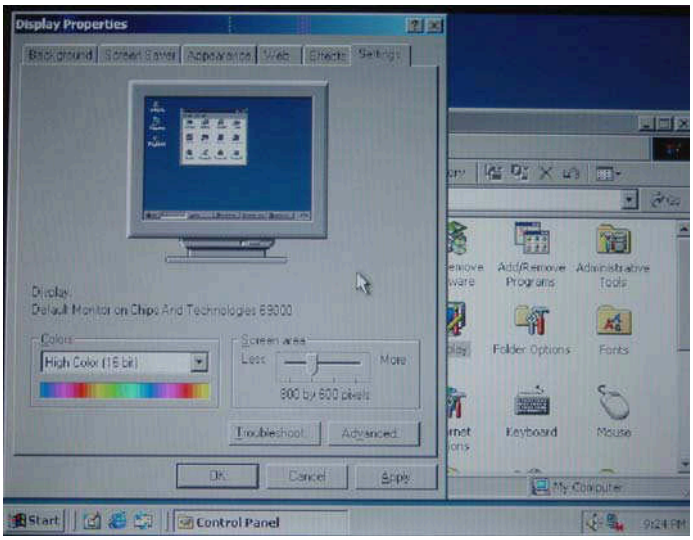
Open Control Panel: Click “**Start”**, point to **“Settings”**, and click **“Control Panel”**.



Double click on “**Display”** icon.

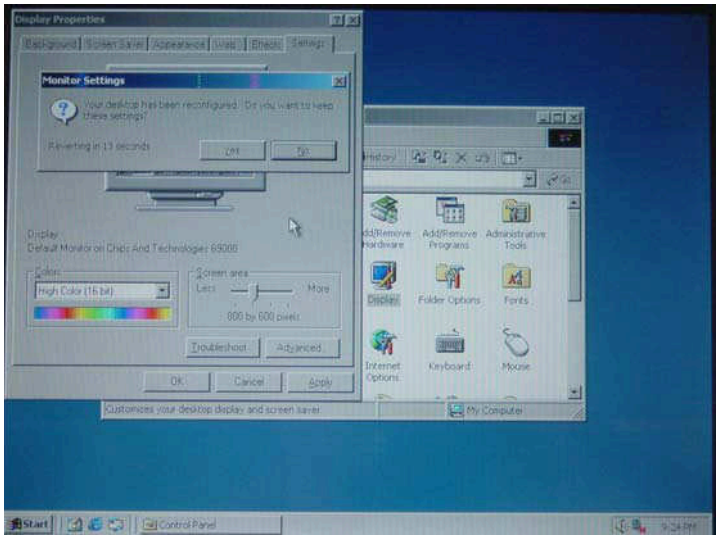


Select **“Settings”**:

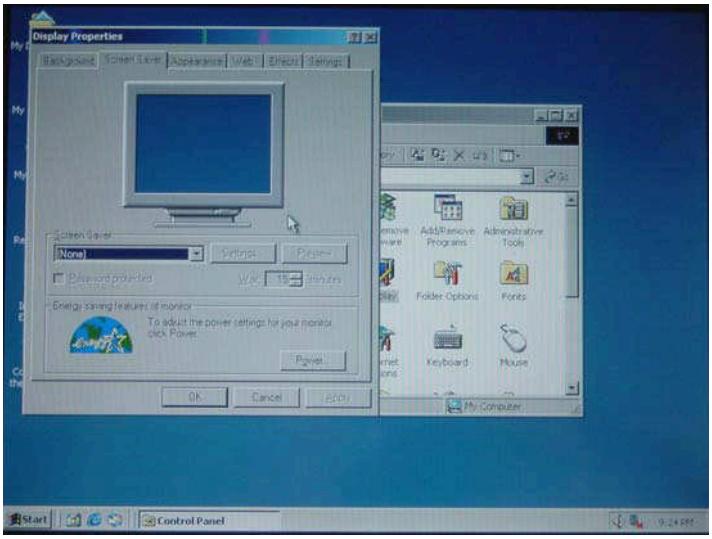


Set **“Screen area”** to 800 by 600 pixels.

Click **“Yes”** on the "**Monitor Settings**".

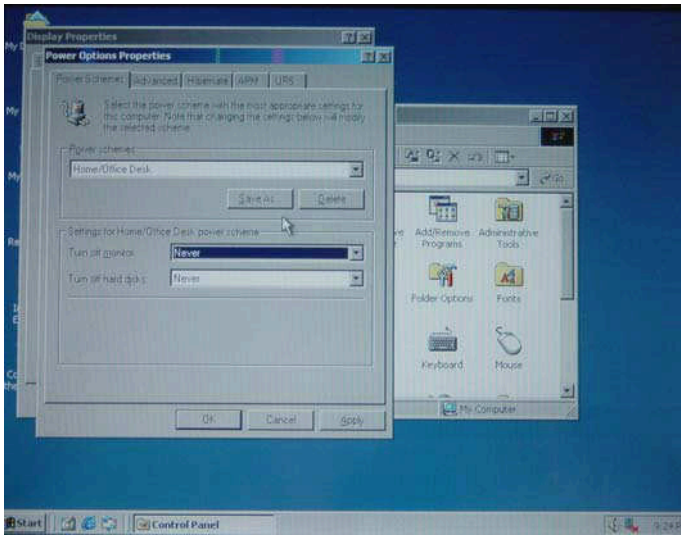


Go to **“Screen Saver”**:



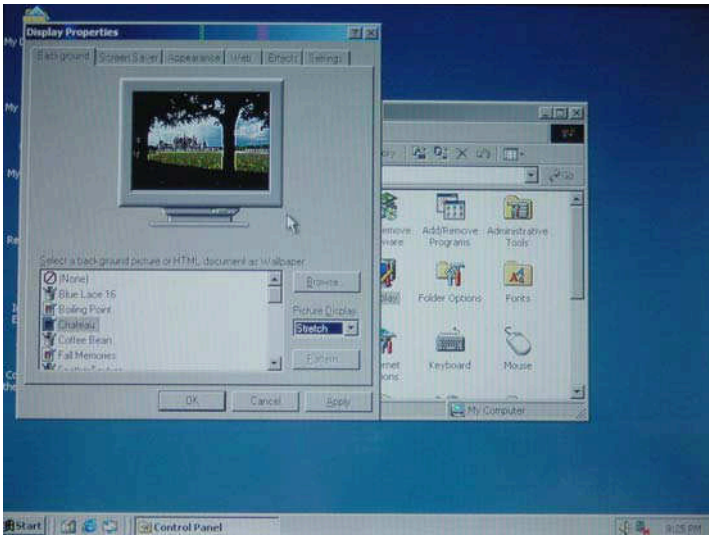
Click **“Power”** (at the bottom right).

Select the settings "**Never**" in **“Turn off monitor”** and **“Turn off disks”**:

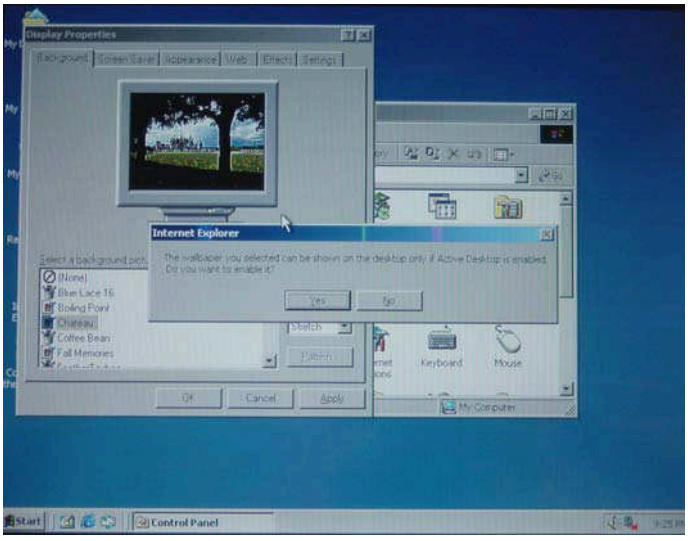


Click **“OK”**.

If one desires to select a background picture go to "**Background**" page.



Select the desired background picture and set **“Stretch”** in the "**Picture Display**".
Click **“OK”**.
If a question is asked then respond by clicking **“Yes”**:



The Operating System is now configured correctly and one may proceed to the installation of the drivers of the peripheral devices (e.g. Additional Serial port, Touchscreen, and printer).

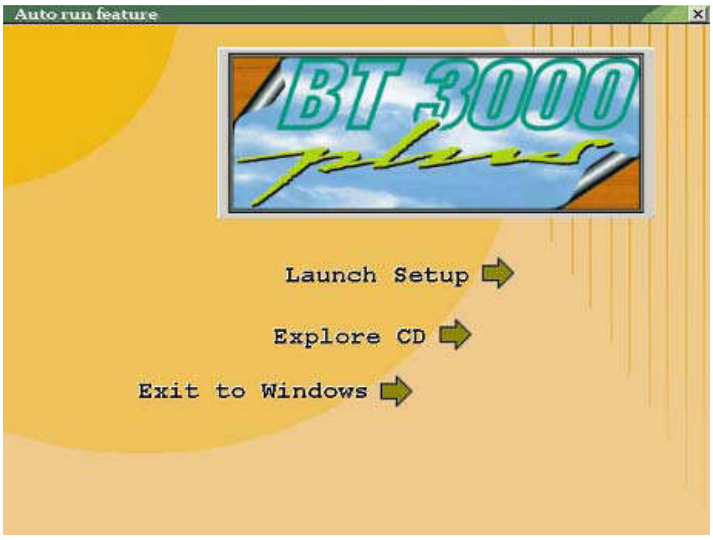
CAUTION:
The supplementary drivers must be installed prior to installation of the BT operating program in the system.

THE PRINTER MUST BE INSTALLED BEFORE THE OPERATIVE PROGRAM!
Open the Printers window ("Start" button, "Settings", "Printers") and click on "New Printer", then follow instructions. Otherwise, insert the printer's installation disk into the driver and follow the printer's setup instructions.

5.5. INSTALLATION OF THE BT ANALYZERS OPERATING PROGRAM

FOR ALL ANALYZERS

Insert the CD-ROM containing the operating program of the BT analyzers in the CD-ROM drive.
The following screen appears:



Click **"LAUNCH SETUP"**.
Now the installation procedure begins, which will guide the user during operating program installation.



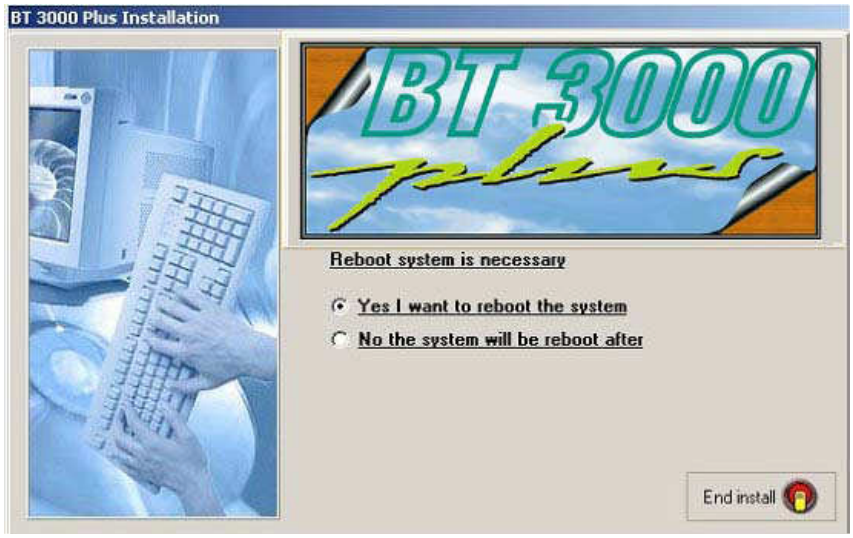
Click **"NEXT"**.

The installation procedure automatically checks the communication port (**COM**) used for communication with the 552. In case the communication port not found (cable disconnected, no processor, etc.), the following screen "**Select communication port**" will appear:



Here the operator will manually select the Com port used for communication (normally "**Com4**" is utilized).
Select **Com4** and click **"Accept"**. Now the installation of operating programs begins.

CAUTION:
DO NOT INTERRUPT THE ONGOING INSTALLATION, UNLESS FOR SERIOUS REASONS.



After the termination of previous phase, a message "**Setup has finished installing bt Plus on your computer**" will be displayed:
Click **"Finish"**.
Now a screen with various options for "**End installation**" (with restart or without restart of the system) is displayed.
In case of the new installation, select "**Yes, I want to restart my computer now**" (first option).

Now the operating program has been installed correctly in the system.

5.6. UPGRADING THE BT ANALYZERS SOFTWARE

Proceed with installation as for a new instrument.

5.7. INSTALLATION WITH IMAGE DISK

BT analyzers are supplied, among the others, with analisi Image Disk, which is a "copy" of the original hard disk (HD). With the Image Disk, it is possible to install and configure easily the operative system.

ATTENTION:

The Image Disk can be used only if the hardware (IMB hardware, excluded the hard disk) in the analyzer is the original one.

If the HD has been replaced, it is possible to use the Image Disk, but if the printer, the video board, or other hardware has been changed, it will be necessary to use the standard installation procedure, not the Image Disk.

First of all, verify that the IBM mother board, the LCD, mouse and keyboard are working correctly. Then install the Image Disk by following the procedure below. Note: to enter into the BIOS program, follow the instructions displayed, as these may be different from analyzer to analyzer.

IMAGE DISK INSTALLATION PROCEDURE

- insert the Image Disk DVD (containing the HD file) into the reader
- enter into the mother board BIOS and let it read the installed HD by means of the function **IDE HDD AUTO DETECT**
- set the Boot sequence, in the Setup, as follows CDROM ► C ► A.

Verify the correct sequence, save and exit from the Setup.

At this point the DVD will be read and a menu will appear.

Select:

⇨ **Local-Disk- from Image**

In the displayed options, select:

⇨ **File name o load Image from**

here select **CDROM** and click on the file with extension "**GHO**"

The following question will appear:

⇨ **Select Local Destination Drive by clicking on the drive number**

select ⇨ OK;

The following question will appear:

⇨ "**Destination Driver Detail**

select ⇨ OK;

The following question will appear:

⇨ **Proceed with disk clone? Destination drive will be overwritten**

answer ⇨ Yes;

Wait for the end of this process which may last from1 to 3 hours approx.

The following question will appear:

⇨ **Clone completed successfully Continue**

⇨ exit from the program with **Quit**

The analyzer will start a new bootstrap. Enter again into the BIOS and set again the correct Boot sequence in the Setup:

- ***Hard-Disk***
- ***CD-ROM***
- ***Drive A***

Exit again from the BIOS saving the modifications. The bootstrap will start again. The Windows program will be loaded. Once done, start the analyzer operative system installation as indicated at paragraph 5.5. in this chapter.

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 6

6. TECHNICAL ASSISTANCE **Page: 2**

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

6. TECHNICAL ASSISTANCE

In case of need for the Technical Assistance Service, before calling Biotecnica, please make sure that the following information is available:

- analyzer model
- serial number
- program code (at the center of the main screen)
- analyzer configuration (printable from the External programs menu, with third level password)

For operative and applications problems, make sure all possible information is available (in addition to the above mentioned), such as:

- analytical parameters printout
- calibration parameters printout
- calibration results in RT printout
- calibration reaction graphs printout
- samples reaction graphs printout
- real time pages printout
- possible errors or messages from the analyzer printout

Please do not return any equipment or part of the system to Biotecnica before discussing your problem with an authorized technical assistance representative or Biotecnica own technical assistance. The Technical Assistance Service at Biotecnica Instruments S.p.A. will provide a Return Authorization Number for the **Parts/Instruments Return Authorization module** available in Section II, chapter 2.

Reference numbers for Biotecnica Instruments S.p.A. Technical Assistance Service:

✉ BIOTECNICA INSTRUMENTS S.p.A.
Via Licenza, 18
00156 – ROME
ITALY

☎ Tel. +39.06.4112316 Fax +39.06.4103079

Technical Assistance E-mail ***mciucci@biotecnica.it***

Biotecnica E-mail ***bt@biotecnica.it***

www.biotecnica.it

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 7
7. BIBLIOGRAPHY OF ALLIED SUBJECTS Page: 2

NOTE:
The following bibliography is given to supplement this manual, whose scope as an operator manual permits only the mention or brief explanation of some subjects.

Biotecnica Instruments S.p.A.
Via Licenza, 18
00155 Rome – ITALY

7. BIBLIOGRAPHY OF ALLIED SUBJECTS

- **Burtis C.A., Ashwood E.R.: "Tietz Textbook of Clinical Chemistry" IInd Ed. W.B. Saunders Company, 1994**

- **Press W.H., Flannery B.P., Teukolsky S.A., Vetterling W.T.: "Numerical Recipes" - The Art Of Scientific Computing -, Cambridge Univ. Press, 1986**

- **EN 591 (1994): In vitro diagnostic systems – Requirements for user manuals for in vitro diagnostic instruments for professional use (ital. UNI 96)**

- **EN 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (amendment to IEC 1010-1:1990 + A1:1992)**

- **EN 1658 (1996): Requirements for marking of in vitro diagnostic instruments**

- **Directive 98/79/EC on in vitro diagnostic medical devices (1998)**

- **EN 980:2002: Graphical symbols for use in the labelling of medical devices**

- **2002/95/EC: Restriction of the use of certain hazardous substances in electrical and electronic equipment**

- **2002/96/EC: Waste electrical and electronic equipment (WEEE)**

- **Decreto Legislativo 30 giugno 2003, n. 196 Codice in materia di protezione dei Dati Personali (Privacy and sensitive data dispositions).**

OPERATOR MANUAL

SECTION II: ADDITIONAL INFORMATION

CHAPTER 8
8. LIST OF APPLICABLE METHODOLOGIES Page: 2

Biotecnica Instruments S.p.A.
Via Licenza, 18
00156 Rome – ITALY

8. LIST OF APPLICABLE METHODOLOGIES

Some examples of available applicable methodologies are resident in the analyzer's hard disk.
Updated Biotecnica applications are available inside each reagent kit.

For further details on the applied methodologies, please address to the following e-mail:

bt@biotecnica.it