INSTALLATION AND MAINTENANCE MANUAL

English

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CE

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1. Unpacking

The ***A15*** analyzer is a precision instrument. For this reason, special care must be taken with its installation and location. It is very important to connect the apparatus and the associated computer to an appropriate electrical system. It must be as exclusive as possible and it must be earthed. We recommend you read this chapter carefully before installing the apparatus. Non-fulfilment of the instructions given in this chapter may jeopardise the safety and functioning of the equipment.

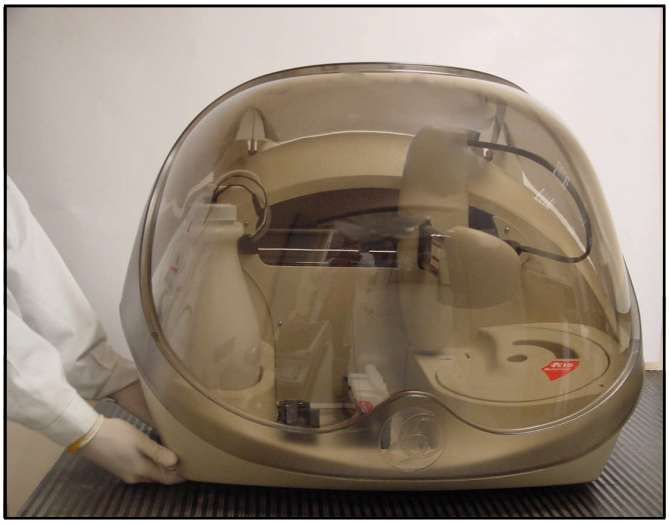
1.1. Unpacking

On receiving the instrument, check that the packaging is in perfect condition and that the sealing is intact. Open the box and carefully take out the contents. Follow the indications on the unpacking instructions sheet. The instrument weighs 45 kg and needs a minimum of two people to move it. When lifting it, keep your back straight to avoid injury. Grip it below the base, never by the top or by the housing or any other of its elements. The base of the analyser has two areas on each side, especially designed for gripping it while moving it. It is recommendable to use mechanical means, such as a fork lift, for transporting the analyser. Do not throw the packaging material away, since it may be necessary for ensuring safe transport if the analyser is reshipped or moved in a vehicle.

1.2. List of contents

The following is a list of the elements the user should find on unpacking the analyser. Visually check that none of them has been apparently damaged during transport.

1. Analyser
2. Unpacking instructions sheet.
3. Instrument Release Certificate
4. Boxes of accessories
5. Empty washing solution container with lid



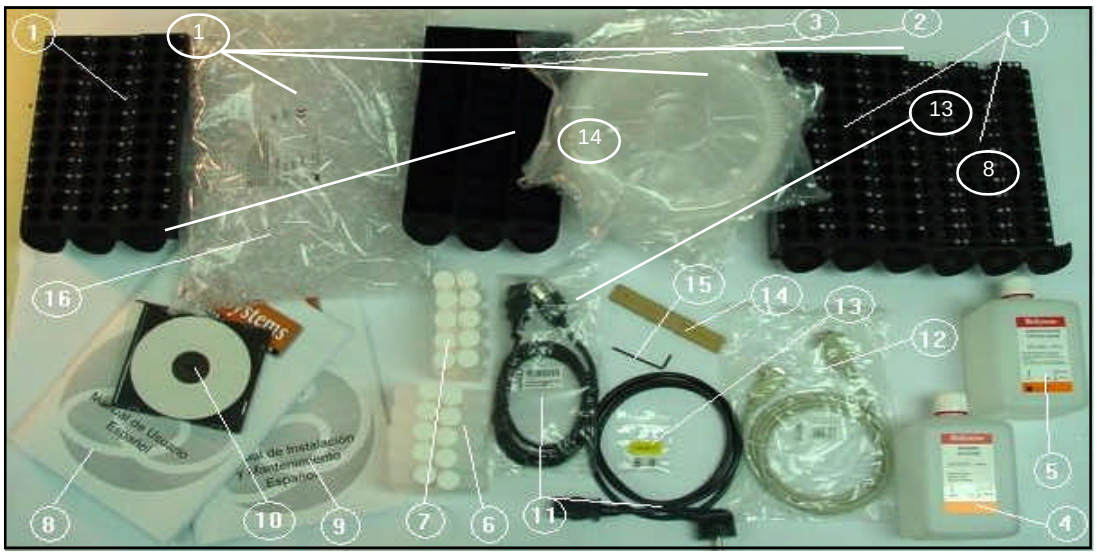
Content of the box of accessories

1. Racks of samples (3+3+3)
2. Rack of reagents (3)
3. Reactions rotor (5)
4. Bottles of concentrated washing solution (1 bottle of 100mL)
5. Bottle of concentrated system liquid (1l)
6. Empty 50 ml bottles (10)

7. Empty 20 ml bottles (10)

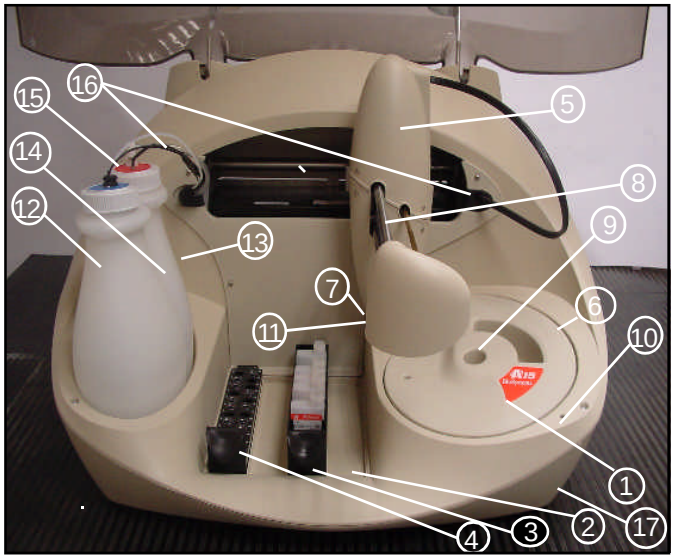
8. User manual
9. Installation and maintenance manual
10. CD ROM with User programme
11. Network connection cables (European and American)
12. Serial channel cable for connection to the computer
13. Fuses
14. Metal rod for cleaning the needle
15. 2 mm Allen key

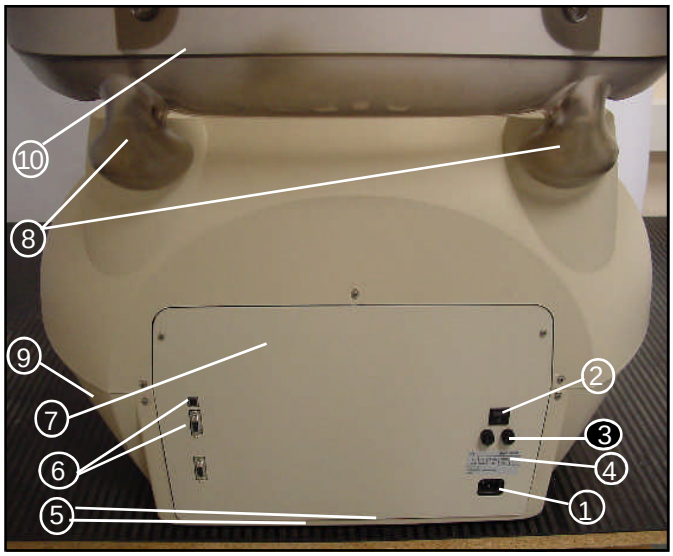
. Sample wells (1000)



1.3. Identification of the main components

The main parts of the analyser are identified and numbered in the following figures and their associated lists.





1. Label showing brand and model
2. Rack tray
3. Sample racks
4. Reagent racks
5. Arm protector cover
6. Reactions rotor and reading
7. Needle washing station
8. Operating arm
9. Rotor cover
10. LED status indicator
11. Needle self-adjustment sensor
12. System liquid container
13. Waste container
14. System liquid tubes
15. Waste tubes
16. Grommet
17. Adjustable leg

1. Power point
2. Switch
3. Fuses
4. Identification label
5. Fans
6. RS-232 serial connections (PC) and USB auxiliary connection
7. Back cover
8. Hydro-pneumatic elevators for the main cover
9. Base
10. General cover

2. Installation

With a view to guaranteeing optimum functioning of the analyser, follow the installation instructions given in this chapter carefully.

2.1. Warnings and precautions

The A15 analyser has been designed and constructed exclusively for professional use. The user must be adequately trained for work in a clinical analysis laboratory and to use an *in vitro* diagnostic analyser. Read this manual carefully together with the User Manual and take heed of all the warnings and precautions set forth in said manuals. The manufacturer accepts no liability for damage caused by incorrect use of the apparatus.

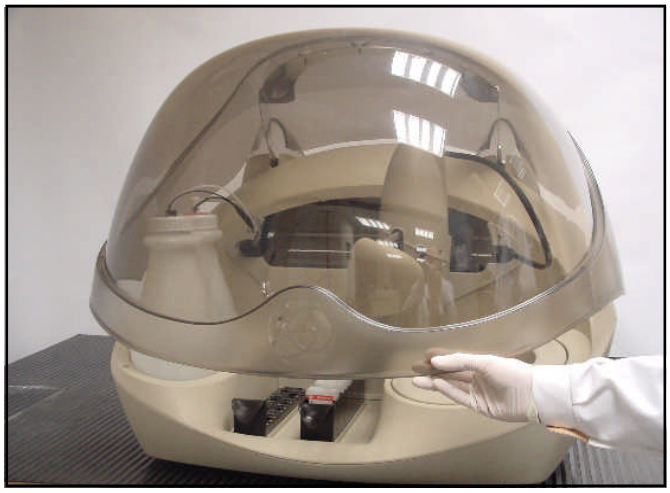
Warning

The user must check that the arm is completely in parked position before raising the cover of the analyser.

2.2. Location

The analyser must be located in a dry non-corrosive atmosphere. Relative humidity must not be higher than 75%. It is recommended that room temperature is below 28ºC. Avoid positioning it in draughts. Furthermore, the instrument must not be near sources of electromagnetic radiation (such as motors or centrifuges), or heat sources, or receive direct, intense sunlight or artificial light.

It must be placed on a flat, spacious surface (minimum of 110 cm x 60 cm), with particular being taken to ensure that there are no objects obstructing the air output of the ventilators (2 at the back and 1 on the base). Leave a minimum space of 10 cm between the back of the analyser and the wall or the nearest object. The surface must be sufficiently robust and rigid to support the weight of the analyser (45 kg) and the force resulting from the rapid movements of the operating arm. To adapt the analyser to the surface and level it correctly, the front right leg is adjustable.

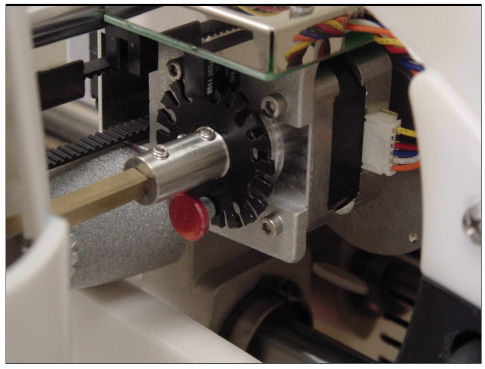


2.3. Opening the main cover

Lift the cover gently upwards by the front. The hydro-pneumatic hinge system enables the cover to be opened easily and it stays open while the user works with the different elements of the analyser. To close it, simply lower it gently to its lowest position. The cover has an open sensor which tells the analyser that it is open. In this case, the operating arm does not carry out any preparation and stays in the parked position to avoid injury to the user.

2.4. Unblocking the operating arm

To avoid damage during transport, the arm is immobilised by 1 screw and two foamm pipes . These elements must be removed for the arm to move freely. Simply unscrew it using your fingers (no tools are required) as indicated on the unpacking instructions sheet. Keep these screws and



the pipes next to the analyser so they can be repositioned if it has to be moved using a transport vehicle or reshipped.

2.5. Installing the waste and system liquid containers

On the left of the analyser are the waste and system liquid containers. The system liquid container, with its lid and blue mark, is at the front, i.e. in the position nearest to the user, and the waste container, with its lid and red mark, is at the back. The positions of these two containers cannot be swapped over.

To fill the system liquid container, unscrew the lid, extract the tubes and the lid and remove it from the analyser. Fill

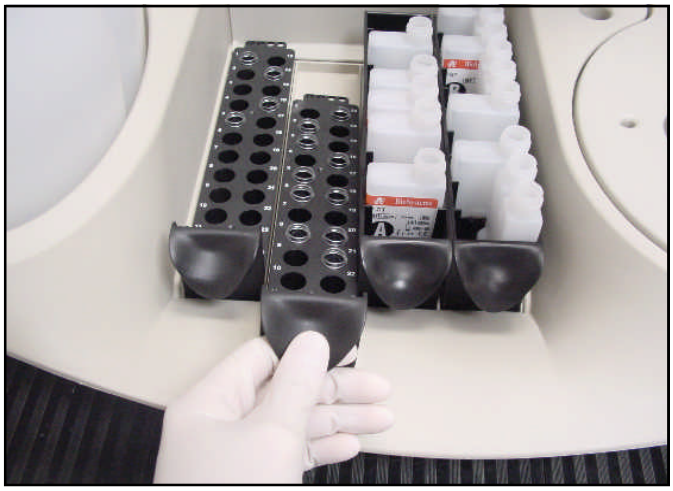
the container to the top with distilled water (approximately 3000 ml), add 6 ml of concentrated system liquid and shake the liquid gently.

To empty the waste container, disconnect the fitting and remove it from the analyser. The quick coupling fitting of the waste container has a valve which is closed when it is disconnected to avoid the spillage of waste. If, during the functioning of the analyser, said tube is not correctly connected, the needle washing station cannot be emptied and the waste is emptied to the outside of the analyser through the drainage points. The user must make sure that the fitting is correctly connected by pressing it until it clicks.

Also prepare the washing solution container, with the lid marked in green. Add 15 ml of concentrated washing solution to the container filled with distilled water (approximately 3000 ml).

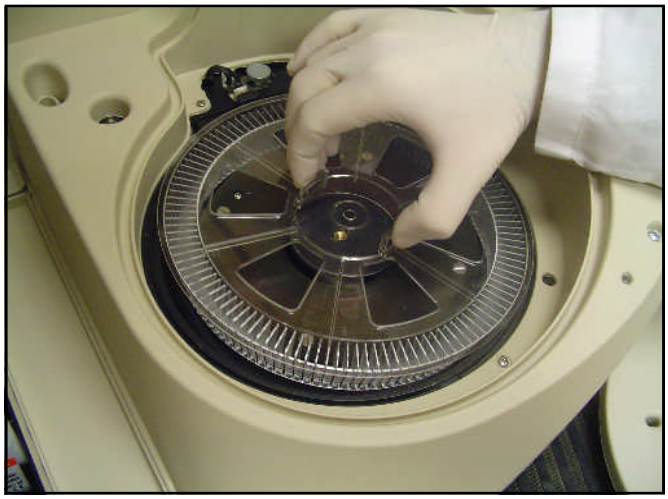
2.6. Installing the reagent and sample racks

The analyser has a tray with 4 positions for reagent and sample racks. To position a rack in the analyser, place it on one of the tray positions, push it to the back and gently lower it by holding it by the front tab until it is in position.



2.7. Installing the reactions rotor

Remove the rotor cover and extract the rotor fastening screw. Introduce the reactions rotor in the heater channel holding it by the top tabs and trying not to touch the channel walls. It has only one position and must fit perfectly in the support. Screw back up the rotor fastener and put the rotor cover in place. The cover also has only one position. Its position has a detector which tells the analyser it is in place. The analyser also detects the presence of the reac-



tions rotor. If the analyser detects that the cover or rotor are not in position, it does not take optical readings and gives alerts the user.

2.8. Connection to mains and start-up

It is very important to connect the apparatus and the associated computer to an appropriate electrical system. It must be as exclusive as possible and it must be earthed. The analyser and the computer must have the same earth connection. It is best to use the Uninterruptible Power Supply

(UPS) for the analyser and the control computer. We recommend you use a 1000 VA UPS with voltage stabilisation, sine-wave output and an input separation transformer. If any anomaly is observed in the functioning of the analyser or the computer (programme hangs or sporadic reboots occur), check that they are not close to centrifuges or equipment with motors or electromagnets that may cause strong electromagnetic interference. In this case, position the analyser at a distance from said equipment.

The A15 analyser has been designed for working within the 115 V - 230 V, 50 or 60 Hz range, with a maximum power of 150 VA. The analyser automatically adapts to the mains voltage, which does not need to be manually selected. Working outside the voltage range may cause incorrect functioning of the equipment and damage to it. The category of the electrical installation (overvoltage category) must be II.

To connect the analyser, proceed as follows:

a) Check that the switch at the back is in off position (0).

b) Connect the mains cable first to the apparatus and then to the mains.

c) Place the switch in on position (I).

It is recommended you always leave the switch on, unless maintenance work or breakdown repairs are to be carried out. The power consumption of the analyser in this position is minimal. In this way, the analyser can be started up or switched off from the user programme.

2.9. Connection to the computer

The computer must be dedicated fully to the analyser while it is in operation. No other programme can be used while the analyser is working. With the computer turned off, connect the supplied RS-232 cable to the COM1 B of the analyser and a series channel of the computer. The connectors have 9 pins.

COM 1: Main communications port
A – USB connection
B – RS-232 connection

COM 2: Auxiliary communications port

2.10. Installing the user programme on the computer

The user programme must be used on a compatible PC with the following minimum requirements:

- Pentium IV processor or higher
- Windows 98 or higher
- 256 Mb RAM
- 50 Mb free hard disk space
- CD-ROM
- VGA monitor, minimum screen resolution 800x600
- Mouse
- RS-232 serial channel connector or USB

To install the programme, proceed as follows:

a) Boot up the computer

b) Insert the CD-ROM
c) The installation programme launches automatically. Follow the indications given. If it does not launch automatically, click on *Start*, select *Run* and type… *CD-ROM drive letter*:\Setup (e.g. *D:**Setup*).

2.11 Installation of a code bar reader

The user manual section 2.2.6.1 explains how to introduce a patient's code. This code can also be introduced by a code bar reader. The reader is directly connected to the computer. In order to install the reader, you should follow the installation instructions of the code bar reader manufacturer.

2.12. Preparation before operation

The analyser is optimised for working with BioSystems consumables and reagents. The use of reagents by other commercial brand names is possible, but certain features may be affected. The use of accessories and spares that are not BioSystems original parts may seriously alter the functioning of the analyser as well as your personal safety. It also implies total loss of warranty for the analyser.

To prepare the system liquid, you must always use distilled water, never tap water. Automatic pre-diluting of the samples must be done with saline solution. To keep the analyser in perfect working order and obtain optimum performance, the entire dispensing system must be washed with BioSystems washing solution and system liquid on beginning and ending each working day. These washes are performed automatically by the analyser.

During start-up, the A15 analyser automatically performs all the checks required for correct functioning and no manual adjustment is necessary. If, for any reason, user intervention is necessary, the analyser issues the corresponding alert through the computer.

2.13. Transport

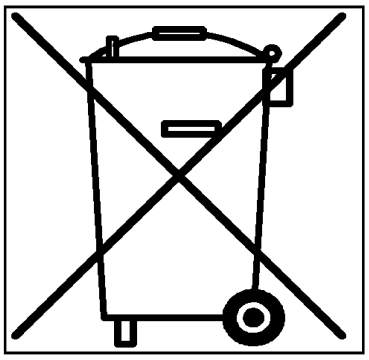
The instrument weighs 45 kg and needs a minimum of two people to move it. For easy transport, four people are recommended. When lifting it, keep your back straight to avoid injury. Grip it below the base, never by the top or by the housing or any other of its elements. The base of the analyser has two areas on each side, especially designed for gripping it while moving it. It is best to transport the analyser using mechanical means.

2.14. Handling, storage and reshipment

Although, thanks to its elaborate design, the analyser is robust and durable, it must be remembered that it is a precision instrument and, as such, must be handled with special care and attention.

If the analyser is to be stored for long periods, it is recommended that you completely clean all the fluid circuits with the corresponding utility on the user programme, first with washing solution and then with system liquid. The fluid system tubes must be left filled with system liquid. The system liquid container must be emptied and the waste container must also be emptied and washed. It is recommended that you throw away the used reaction rotors and use new rotors when you restart the analyser. The analyser must be duly protected from dust and other environmental aggressors such as direct sunlight or excessive humidity.

If the analyser is to be reshipped or moved using a transport vehicle, it is important to block the operating arm and use the original packaging to ensure that the apparatus is not damaged. To package the instrument, follow the indications on the unpacking instructions sheet.



The special "waste container crossed out" symbol indicates that the product in question is subject to the selective waste collection principle as established in European Union Directive WEEE (Waste Electrical and Electronic Equipment).
Once the instrument's lifetime is completed it becomes waste and, as established in the directive, the said waste must be separated from domestic waste for its proper recycling. To this end, the manufacturer facilitates its elimination.

3. Technical specifications

PLEASE NOTE
The manufacturer accepts no liability for damage caused by incorrect use of the apparatus.

GENERAL SPECIFICATIONS

Automatic random and continual access analyser aimed at giving results per patient, with direct photometric reading over a reactions rotor.

Preparation cycle time	24 s (up to 150 prep/h)
Warm-up time	25 mins
Reading time for each preparation	Every 24 s, up to 10 mins
Size	840x670x615mm (33,1´´ x 26,8´´ x 24,2´´)
	(length x depth x height)
Weight	45 kg (100 lb)

REAGENTS AND SAMPLES TRAY

Positions for racks	4
Capacity of the sample racks	24
Maximum number of samples	72
ø13 mm, ø15 mm sample tubes (max. height 100 mm),	ø13 mm paediatric well
Capacity of the reagent racks	10
Maximum number of reagents	30
20 ml and 50 ml reagent bottles	
Possible configurations	

Sample racks	Reagent racks	Number of samples	Number of reagents
1	3	24	30
2	2	48	20
3	1	72	10

DISPENSING SYSTEM

NEEDLE

Detachable tip	
Vertical length	110 mm
Capacity level detection	
Self-adjustment of position	

NEEDLE THERMOSTATATION SYSTEM

Actuator	1 Resistive
Control	PID
Thermostatation time	≤ 15 s
Dispensation temperature	37°C
Trueness	± 0.5°C
Repeatability	± 0.5°C

DISPENSING PUMP

Ceramic piston with PTFE-graphite seal	
Piston diameter	8 mm
Displacement	25 mm
Dispensing volume	3 µl – 1250 µl
Resolution	0.126 µl
Fuzziness	< 1% up to 3 µl
Dispensing speed	max. 880 µl/s
Programmable reagent volume	10 µl – 440 µl
Programmable sample volume	3 µl – 40 µl

NEEDLE WASHING SYSTEM

System liquid consumption	approx. 1.2 ml per preparation
System liquid container volume	3000 ml
Waste container volume	3000 ml
Waste and water level control per capacitive detection	

REACTIONS ROTOR AND READING

WELL ROTOR

Semi-disposable extractible methacrylate rotor	
Number of wells	120
Accepted reaction volumes	200 µl – 800 µl
Light path length	6 mm

ROTOR THERMOSTATATION SYSTEM

Actuators	4 Peltier cells
Control	PID
Working temperature	37°C
Trueness	± 0.2°C
Stability	± 0.1°C

OPTICAL SYSTEM

6 V, 10 W halogen lamp	
Wavelength selection with compensated interferential filters	
Detection system with silicon photodiode and 20-bit AD integrator-converter	
Measurement range	from -0.05 A to 2.5 A
Reading speed	1 readings
Maximum number of filters	9
Base configuration of the filter drum	340, 405, 505, 535, 560, 600, 635, 670 nm
Wavelength precision	± 2 nm
Bandwidth	10 ± 2 nm
Digital resolution	≤ 0.0001 A
Base line stability	max. 0.004 A in 30 mins, at 505 nm
Repeatability of the reading system (1 SD, 505 nm, with filter movement)	± 0.0005 A to 0.1 A (CV = 0.5 %) ± 0.003 A to 1.0 A (CV = 0.3 %) ± 0.005 A to 2.5 A (CV = 0.2%)
Optical repeatability between wells (bichromatic at 0A)	± 0.003 A at 340 nm ± 0.002 A at 505 nm
Accuracy	± 0.005 A to 0.1 A (± 5%) ± 0.015 A to 0.5 A (± 3%) ± 0.02 A to 1.0 A (± 2%) ± 0.04 A to 2.0 A (± 2%) ± 0.05 A to 2.5 A (± 2%) at 340 nm, 405 nm, 505 nm

MINIMUM COMPUTER REQUIREMENTS

Pentium IV processor or higher
Windows 98 or higher
256 Mb RAM
50 Mb free hard disk space
CD-ROM
VGA monitor, minimum screen resolution 800x600
Mouse
RS-232 serial channel connector or USB
The insulation level of the A15 analyser communications channel is reinforced (the insulation of the communications channel of the computer has also been reinforced)[(1)].

CHECKED REQUIREMENTS OF THE CODE BAR READER

Reading Speed	200 readings / second
Reading Width	80mm
Resolution	0.1mm
Light Source	Visible red LED of 660 nm
Sensor	Linear CCD of 2160 elements
Input Voltage	5VDC
Interface	Keyboard (PS/2 and AT), USB, RS232C

POWER REQUIREMENTS

Input voltage	115–230 V AC, 50/60 Hz
Power	150 VA
Electrical installation category (overvoltage category)	II
The mains power point must be approved and have an earth connection and cable with a minimum section of 1.5 mm².	

ATMOSPHERIC CONDITIONS

Interior use	
Height	< 2500 m
Temperature	10°C – 35°C
Relative humidity	< 75%
Contamination level	2

[(1)] Reinforced insulation is that which ensures protection that is equal to or higher than double that provided by the main insulation.
The main insulation is that whose failure could lead to the risk of electric shock (*EN 61010-1*).

COMPLIANCE WITH DIRECTIVES AND APPLIED STANDARDS

Directive 98/79/CE related with *In Vitro Diagnostic* products

- EN 61010-2-101:2002 “Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2 - 101: Particular requirements for vitro diagnostics(IVD) medical equipment”
- UNE EN 61326:1999+A1:2000+A2:2003+A3:2005+ERR:2002 “Electromagnetic equipment for measurement, control and laboratory use –ECM requirements.
  - UNE-EN 55022:2000+A1:2002+CORR:2002- Radiated emisions class B-continous interference class B”.
  - UNE -EN 61000-3-2:2002 «Harmonic current»
  - UNE -EN 61000-3-3:1997+Corr:1999+A1:2002-»Flckers»
  - UNE -EN 61000-4-2:1997+A1:1999+A2:2001
  - UNE -EN 61000-4-3:2003+A1:2004-»Radiated inmunity»
  - UNE -EN 61000-4-4:1997+A1:2001+A2:2002-»Fast transient /Burst»
  - UNE -EN 61000-4-5:1997+A1:2001-»Surge transients»
  - UNE -EN 61000-4-6:1998+A1:2001-»Conducted inmmunity»
  - UNE -EN 61000-4-11:1997+A1:2001-»Voltage disp short interruptions and voltage variations inmmunity»

· UNE EN 22233-1992 (ISO 2233-1986). Packaging — Complete, filled transport packages and unit loads — Conditioning for testing
· UNE EN 24180-2-1992 (ISO 4180-1980). Complete, filled transport packages — General rules for the compilation of

performance test schedules.
- UNE EN 22247-1992 (ISO 2247-2000). Packaging — Complete, filled transport packages and unit loads — Vibration tests at fixed low frequency
- UNE EN 22248-1992 (ISO 2248-1985). Packaging — Complete, filled transport packages — Vertical impact test by dropping

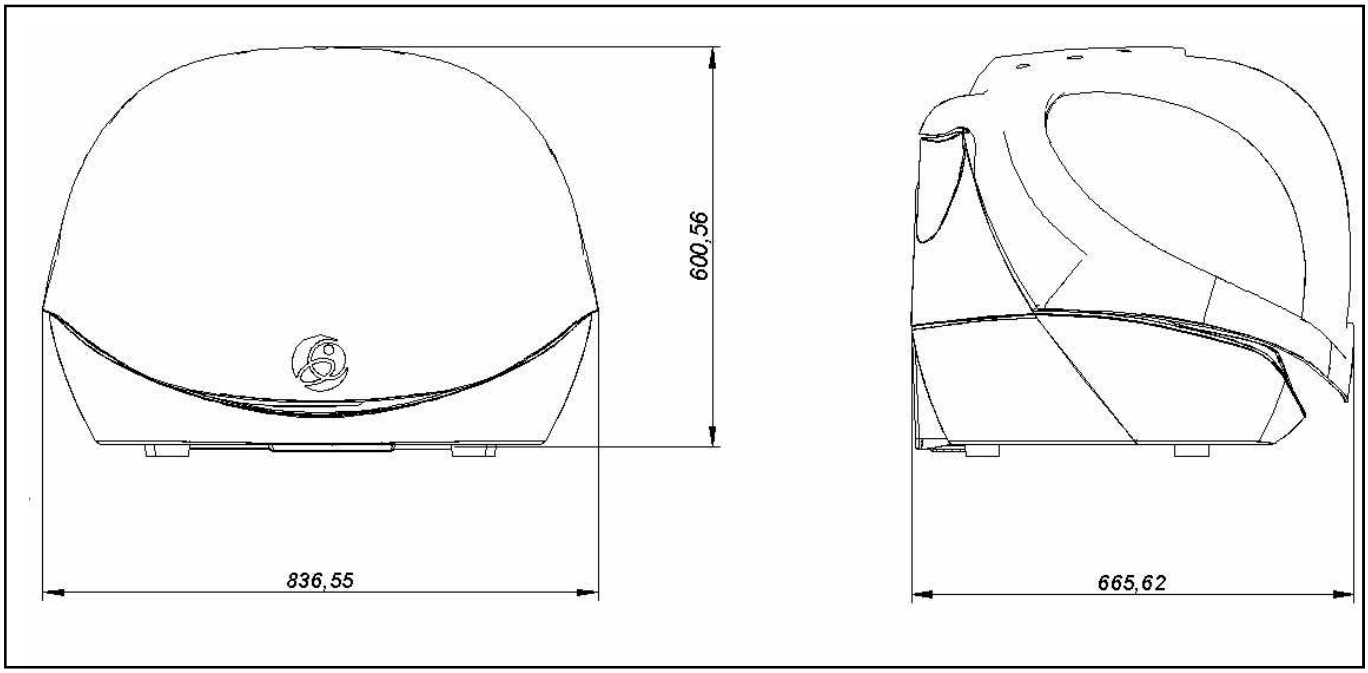
MAXIMUM SIZE OF ANALYSER

Closed cover :

Length: 840 mm. Depth: 670 mm. Height: 615 mm.

Opened Cover:

Length: 840 mm. Depth: 670 mm. Height: 1025 mm.



The manufacturer reserves the right to modify any technical specification without prior notice.

3.1. Behaviour limitations and criteria

The A15 analyser is optimised for working with the BioSystems A15 reagents line. The programmed manufacturing techniques correspond to measurement procedures that use these reagents, and which have been deeply and fully studied and validated to guarantee optimum performance of the reagent-analyser system. However, other reagents can be used whose measurement procedures are compatible with the specifications of the instrument, with the consequent loss in performance if the adjustment is not made correctly. In this case, BioSystems cannot guarantee the performance of the system. Updated information about the measurement procedures with BioSystems reagents can be obtained from your distributor or directly from the BioSystems website.
The use of accessories and spares that are not BioSystems original parts may seriously alter the functioning of the analyser as well as your personal safety. It also implies total loss of warranty for the analyser.
If problems exist in the power supply, the use of uninterruptible power supply (UPS) is recommended. In this way, time problems are avoided and the equipment is protected from possible anomalies.

4. Instrument care and maintenance

To achieve optimum functioning of the A15 analyser throughout its useful lifetime, minimum maintenance norms must be followed. This chapter sets forth these norms together with instructions for replacing different parts of the apparatus.

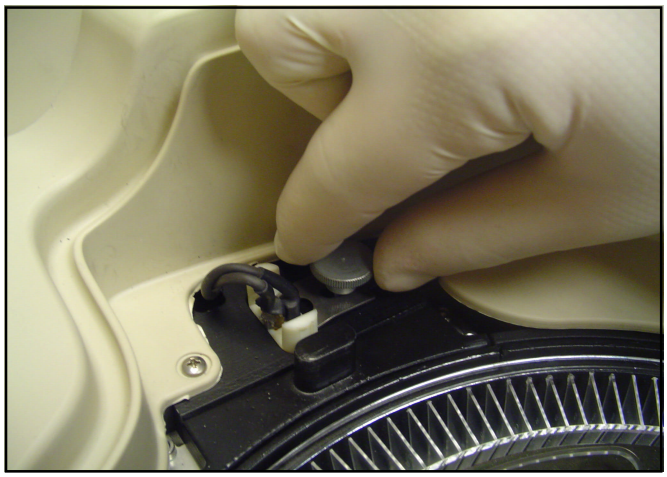
4.1. General recommendations

a) The analyser fluid system must always work using the system liquid, never with distilled water only. This liquid must be prepared by adding 6 ml of concentrated system liquid to the container filled with distilled water (approx. 3000 ml).
b) The analyser automatically washes its fluid system at the start and the end of the working day. In this way, optimum instrument performance is ensured. This liquid must be prepared by adding 15 ml of concentrated washing solution to the container washing solution(lid marked in green) filled with distilled water (approximately 3000 ml).
c) On ending the working day, once the analyser has been switched off, always empty the waste container.
d) Never leave a full reactions rotor in the analyser. Once the analyses have finished, remove it from the analyser immediately. If you wish to reuse the rotor, proceed as indicated in the section *Cleaning the semi-disposable reactions rotor*.
e) Never use detergents or abrasive products for cleaning the surface of the analyser. Use only a damp cloth with water and pH-neutral soap.
f) If a reagent or corrosive product spills or splashes onto the apparatus, clean it with a damp cloth and soap immediately. If necessary, protect your hands with appropriate laboratory gloves.
g) All the elements of the analyser have drainage conduits leading to the exterior to enable the elimination of any liquid spilled and to prevent the apparatus from flooding. If the spillage is significant, the liquid spilled onto the table through the drainage conduits and the analyser must be adequately cleaned.
h) When not in use, close the main cover of the analyser to protect it from dust.

4.2. Changing the lamp

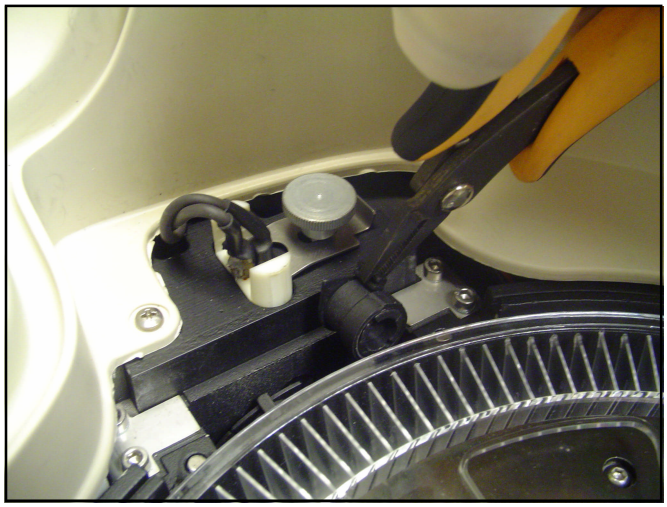
The analyser is fitted with a 6 V 10 W halogen lamp with an estimated average lifetime of 1,000 hours. It is recommended that you change the lamp every year even though its lifetime has not run out. When the lamp needs to be changed, access the *Change lamp* utility of the user programme and follow the steps indicated by the programme itself. To replace the lamp, proceed as follows:

a) Remove the rotor cover.
b) Loosen the screw that holds the fastening tab of the lamp holder.
c) Push the tab back.
d) Remove the lamp holder, loosen the Allen screw and take out the lamp.
e) Insert the new lamp, pushing the terminals to the back. Tighten the Allen screw until the lamp is securely in place. Do not touch the lamp bulb with your fingers. To handle the lamp, use the wrapping, cutting it at the terminal end and squeezing it until they come out.
f) Put the lamp holder back in place. Put the tab in position and fasten the screw.
g) Put the rotor cover back.
h) The lamp does not require any adjustment, but it can be placed in the analyser in two possible positions by turning it 180º around its longitudinal axis. The programme itself requires the user to place the lamp in



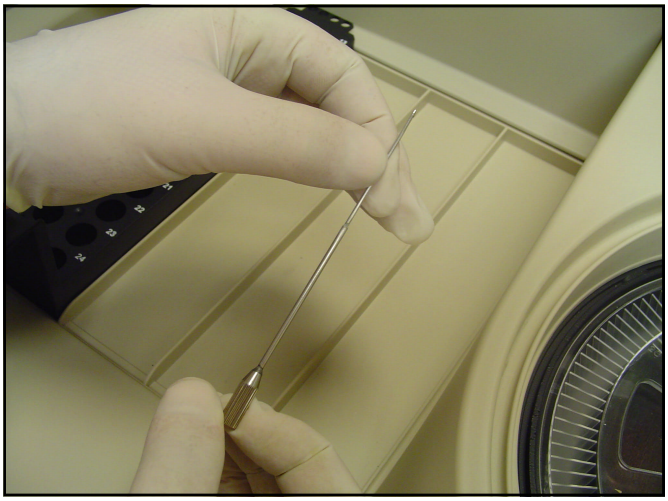
the two possible positions and check in which of the two maximum light intensity is obtained in the optical system.

4.3. Changing an optical filter



a) Access the *Filter Drum Configuration* screen of the user programme. Indicate which filter is to be changed (position 1-9) and click on the *Change filter* button.

b) Remove the rotor cover.
c) Remove the filter drum cover by simply pulling on it.
d) Remove the top filter using a pair of fine pliers.
e) Position the new filter by pressing down until it is correctly in place.
f) Do not leave the position free without putting a filter holder in place. If no filter is required in this position, put a covered filter holder in place.
g) Place the filter drum cover and the optics cover back in position. Put the rotor cover back.
h) If it is different, introduce the wavelength of the new filter that has been installed.



4.4. Cleaning the dispensing system

The dispensing system should be cleaned with washing solution at the start and end of each working day to ensure that it is completely free from air bubbles and is perfectly clean. Once the wash has been performed, the analyser asks the user to replace the container with system liquid and it automatically performs a wash and rinse of the dispensing system with system liquid. With the initial wash, the system is ready for working in optimum conditions during the entire working day, offering maximum performance. With the final wash, the analyser cleans the needle at the end of the working day, keeping it in optimum condition for future working days. The user can also wash the dispensing system whenever he wishes by means of the *Dispensing System Wash* tool on the user programme, while the analyser is in standby mode.

It is also appropriate to clean and check the filters of the system liquid container at least once every 3 months.
If the needle is obstructed by solid residue and needs cleaning with the metal cleaning rod supplied with the analyser, it can be disassembled for cleaning out of the analyser. For this, the *Disassemble dispensing needle* utility on the user programme must be used. It is also recommendable to periodically clean the outside surface of the needle with a piece of cotton or a soft cloth dampened with alcohol. When handling the needle, always wear laboratory gloves. The needle must be replaced if it noticeably deteriorates.

4.5. Cleaning the semi-disposable reactions rotor

When the reactions rotor is completely full, the user must change it for one that is empty, clean and dry. The reactions rotors can be reused if they are carefully cleaned immediately after use.The procedure is as follows:

- Remove the reagents from the rotor wells and rinse abundantly with running water
- Immerse the material in a 5% wash solution (Extrán Merck) for 30 minutes.
- Rinse thoroughly with running water.
- Deproteinize the rotor by adding a 3% nitric acid solution for 5 minutes.
- Rinse thoroughly with distilled water.
- Immerse in distilled water for 30 minutes and allow to dry at room temperature.

only deproteinize the rotor when tests for ions such as magnesium, calcium etc. are required. Organic solvents (alcohol, benzene) or alkaline solutions must not be used. They must be left to dry completely before being reused. High temperatures must not be used during drying. The rotors must be rejected if they are noticeably deteriorated. The optical status of a rotor must be verified by means of the *Reactions rotor verification* utility on the user programme.

The useful lifetime of each rotor depends drastically on its use and care.

4.6. Removing residue

The correct and safe way of removing the residue of the reagents is common practice in clinical laboratories. If there are any doubts about a BioSystems reagent, this information will be given in the safety data sheets that are at the user's disposal through the distributor.
For removing mixtures with waste samples, the general criteria based on good laboratory practice must be applied. These criteria must be familiar with the personnel of a clinical laboratory and set forth in the current legislation of the country where the instrument is installed. If user can not guarantee a correct cleaning of the rotor, we advise not to reuse it.

4.7. List of consumables, accessories and spares

If any of the components of the analyser deteriorate of if any of the perishable materials are required, always use original BioSystems material. The following table shows lists of components that may be required. To purchase said components, please contact your usual distributor and order each element using its corresponding code. This will simplify work and minimise errors.

CODE	DESCRIPTION
	User Manual/Installation and maintenance manual
AC13188	User program CD
AC11485	Reactions rotor (10 units)
AC11486	Reactions rotor fastening screw
BO13189	System liquid container with top
FI13190	System liquid container filters
BO13191	Washing solution container with top
BO13192	Waste container with lid and fitting
BO11493	50 ml bottle with top (10 units)
BO11494	20 ml bottle with top (10 units)
BO13416	Bottle of concentraded washing solution (100mL)
BO11524	Bottle of concentrated system liquid (1L)
AC10770	Samples wells (1000)
AC13193	Detachable needle
AC11501	20 ml/50 ml reagents rack
AC11502	13 mm tube sample rack
AC11503	15 mm tube sample rack
AC11504	Paediatric well samples rack
FU13194	Set of 2 A (F) fuses
CA10455	European network cable
CA10456	American network cable
FI10466	Serial channel cable for connection to PC
LA13195	6 V/10W halogen lamp
ZO13196	Lamp holder fastening system
FI11563	340 nm filter unit
FI11564	405 nm filter unit
FI11565	505 nm filter unit
FI11490	535 nm filter unit
FI11491	560 nm filter unit
FI11566	600 nm filter unit
FI11567	635 nm filter unit
FI11568	670 nm filter unit
FI11498	Covered filter unit
AC13197	Reactions rotor cover
AC13200	Filter cover

AC13198	Operating arm fastening for transport
AC13199	Height-adjustable leg
AC12222	Metal rod for cleaning the needle
AC12223	2 mm Allen key

5. Quick use guide

The basic routine operation method of the analyser can be summarised in the following instructions:

1. Check that the waste container is empty and that the fast fitting of said container is correctly connected. Fill the system liquid container.
2. Fit a reactions rotor.
3. Boot up the computer and launch the user programme.
4. From the *Monitor* screen, click on the *Warm up* button to switch on the analyser and start it up.
5. The initial wash is performed with washing solution, place the corresponding container in position when required to do so by the analyser.
6. It is recommendable to restart the work session daily by means of the *Restart session* button.
7. For each sample you wish to analyse, select the sample class and type from the *Introduction of New Samples* screen. If desired, introduce the patient code. Select the profiles and tests to be performed. Add the sample to the list of samples by clicking on the *Add (Arrow >)* button. Patient details can be introduced, if desired, while the analyser performs the analysis.
8. Click on the Position button to access the *Samples and Reagents Positioning* screen. Click on the *Position Reagents Automatically* and *Position Samples Automatically* buttons for the analyser to position all the elements required on the rack tray automatically. Click on the *OK* button.
9. Place the bottles of reagents and the tubes of samples physically on the tray of the analyser in keeping with the configuration shown by the computer. Place the bottle of distilled water and, if necessary, the bottles with washing solution and saline solution.
10. Click on the *Start* button to start the analyser working and to display the *Monitor*.
11. Each time you wish to introduce new samples for analysis, click on the *New Sample* button on the *Monitor* and repeat steps 7 to 10. If the analyser is still carrying out preparations, click on the *Sampling Stop* button to physically introduce the new samples or reagents in the analyser. Once in position, click on the *Continue* button.
12. Once the analysis is over, display and print out the reports from the *Results Reports* screen.
13. Remove the reactions rotor from the analyser. If you wish to reuse the rotor, proceed as indicated in the section *Cleaning the semi-disposable reactions rotor*.
14. From the *Monitor*, switch off the analyser using the *Shutdown* button.
15. The final wash is performed with washing solution, place the corresponding container in position when required to do so by the analyser.
16. When the analyser is off, empty the waste container.

6. Troubleshooting guide

Through the *Monitor* screen of the user programme, the analyser continually informs the user of all the incidences that occur by means of alarms and alerts. The *Alarms and alerts* section of the user manual sets forth the main alarms and alerts shown by the analyser, requiring user intervention, together with their possible cause and solution.

The following describes some additional anomalies and incidences, together with their possible causes and solutions. If any of the problems persist, contact the Technical Assistance Service.

The analyser does not start

1. *The analyser is not connected to the mains.* Check that the network cable is correctly connected to the instrument and to the mains.
2. *The switch at the back is off.* Turn the switch at the back of the instrument on (I).
3. *The safety fuses have jumped.* Replace the 2 fuses on the back cover of the instrument.
4. *The communications cable is not connected.* Check the cable is connected to the RS232 PC port of the analyser.
5. The computer does not function adequately. Reboot the computer and launch the user programme. Check communications with the test utility of the PC-Analyser communications channel.

The analyser or the computer hangs.

1. Another instrument is interfering with its functioning. Check the analyser and the computer are not near centrifuges or equipment with motors or electromagnets that generate strong electromagnetic interference. In this case, position the analyser at a distance from said equipment.
2. The computer is running other programmes. The computer must be dedicated fully to the analyser while it is in operation. No other programme can be used while the analyser is working.
3. The computer is unstable. Reboot the computer and

launch the user programme. If the unstable functioning persists, check that the computer complies with minimum requirements.

4. The programme has been incorrectly installed. Reinstall the user programme.

5. Other programmes have been installed on the computer and are causing the instability of the user programme. Uninstall all programmes and reinstall the user programme. It is highly recommended that the computer is used exclusively for controlling the analyser.

The results of the analyses are wrong

1. The fluid system is not being supplied correctly. Check the system liquid container filters If they are obstructed, replace them with new filters. Switch on and start up the analyser or manually wash the fluid system with washing solution from the utilities screen.

2. The dispensing needle is obstructed or incorrectly installed. Detach the needle, clean it and reinstall it. If noticeably deteriorated, replace it with a new one.

3. The reactions rotor is dirty or in poor condition. Replace it with a new one.

4. The reagents are incorrectly positioned. Check that the physical configuration of the reagents on the racks of the analyser is exactly as shown in the user programme.

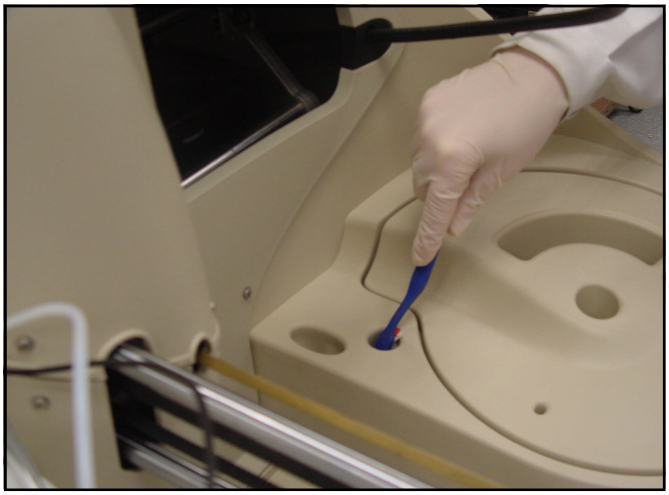
Contamination problems of the sample well

You have to bear in mind that it may be a transfer from a reagent to the sample well during a list. This transfer is not likely to affect the stability of a sample constituent. The best way to detect this problem is doing a good internal quality control, such as doing the quality control before and after the list. If you find a case as the one described, the solution is separating a sample aliquot to use only with the reagent suspected to cause contamination.

7. PREVENTIVE MAINTENANCE

A weekly preventive maintenance is advisable.

1. Carry out an outer cleaning of the needle. In order to access the needle, use the program option: *Remove dosing needle*. And with a piece of cotton soaked in 70° alcohol, clean the outer part of the needle.
   At the same moment, with a brush of bristles clean the L-shaped metallic part inside the instrument. You can



access through the origin hole of system XY, see the following photograph:

2. Carry out the following 3 steps one after the other:
   Use button NSL (New System Liquid) of the screen Monitor
   • Remove the tubes from the System Liquid bottle and carry out a cycle of NSL. In order to empty all the tubes.
   • Place the tubes in a bottle with Washing Solution and carry out a cycle of NSL.
   • Place the bottle with System Liquid and carry out the last cycle of NSL.
   This process is used to avoid the air bubble formation that alter the analytical results or that affect the dosing system.

3. It is also recommended to carry out an extra washing cycle once in a while, with button NSL, between two consecutive lists.

4. Carry out a weekly washing with Sodium Hypochlorite to the 1,5% to avoid the obstruction of the needle. Use the utility: Utilities\Wash dosing system

8. Supplementary information

8.1. List of uses and applications

The A15 analyser has been designed for biochemical analyses. It is optimised to function with the line of A15 Reagents by BioSystems. For further information about all the measurement procedures available, please contact your usual distributor. This information is also available on the BioSystems website.

8.2. Limitations to warranty

Any misuse (dropping, negligence, power conditions out of tolerance, inappropriate location or atmospheric conditions, etc.) together with internal manipulation of the instrument by personnel not authorised by BioSystems or the use of unoriginal consumables and spares (tubes, fuses, etc.) shall invalidate the warranty.

8.3. Requesting components and perishables

If any of the components of the analyser deteriorate of if any of the perishable materials are required, always use original BioSystems material. The *List of consumables, accessories and spares* section lists all the components that may be occasionally required. To purchase said components, please contact your usual distributor and order each element using its corresponding code. This will simplify work and minimise errors.

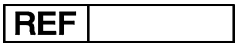
8.4. Technical assistance

Please contact your usual distributor for information about:

- Training for using the analyser
- After-sales Service Request Protocol
- User programme updates

8.5. Table of symbols and units

TABLE OF SYMBOLS AND UNITS	
SN	Serial number
FUS	Fuse
F	Fast
V	Voltage
Hz	Frequency
VA	Apparent power
A	Current

	In Vitro Diagnostic Medical Device
	Consult Instructions for Use
	Serial number
	Use By
	Batch code
	Catalogue number
	Temperature limitation
 xi	Irritant R36/38: Irritating to eyes and skin. S26: In case of contact with eyes, rinse imme-diately with plenty of water and seek medical advice.

8.6. Additional technical information

8.6.1 LIMS Communications

Specifications for the A15 programme communication with a computer management system (LIMS – Laboratory Information Management Systems software).

This section explains how to perform bidirectional communication from the A15 analyser to a centralised computer management system. This communication establishes a system for programming work sessions with the A15 and for exporting the concentration results obtained with the analyser.

Communication is by copying flat text documents into a system folder. To make the communication, the computer must have a network connection with the central system in order to be able to make copies of the documents.

The following folders show the locations of the documents in order to be able to make the communication:

C:\Program files\A15 Folder where the application is installed

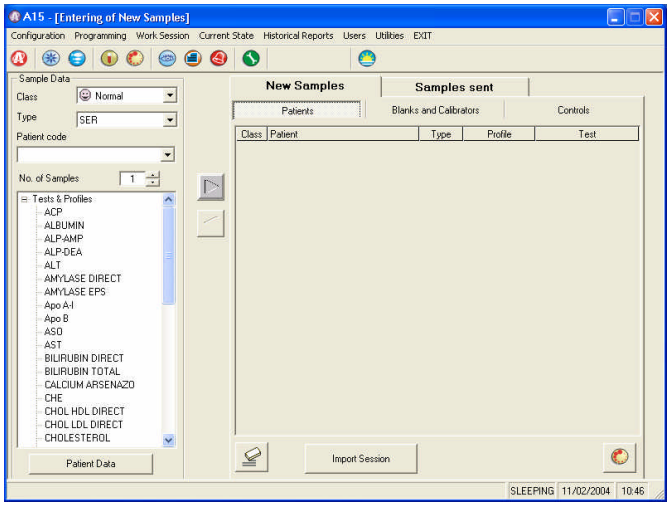
C:\Program files\A15\Import Folder where the document for import is copied

C:\Program files\A15\Export Folder where all the export documents are stored

C:\Program files\A15\Memo Folder where the memorised sessions are stored

Import process

To import a work session to the A15 analyser program, a flat text document must be copied into the *Import* folder with the name “import.txt”. On the screen for entering New samples, the Import session button is activated to load the import file samples when there is a new import document in the Import folder.



The format of the import document must be as follows:

Field	No. of characters	Values
Sample class	= 1	‘U’: Urgent Patient ‘N’: Normal Patient
Sample Type	=3	‘SER’: Serum ‘URI’: Urine ‘CSF’: Cerebrospinal liquid 'WBL'; Whole Blood ‘PLM’: Plasma
Patient identifier	≤16	Alphanumeric string (any character except #)
Technique identifier	≤16	Alphanumeric string (any character allowed)
Test tube type	=3	'PED': Paediatric tube 'T13': Tube 13 'T15': Tube 15

The import file must contain one row per test and the fields must be separated by a tab (ASCII code 09).

The size of the *Patient identifier* and *Test identifier* fields must be a maximum of 16 characters. The other fields must have the exact size indicated in the table.

Sample import file:

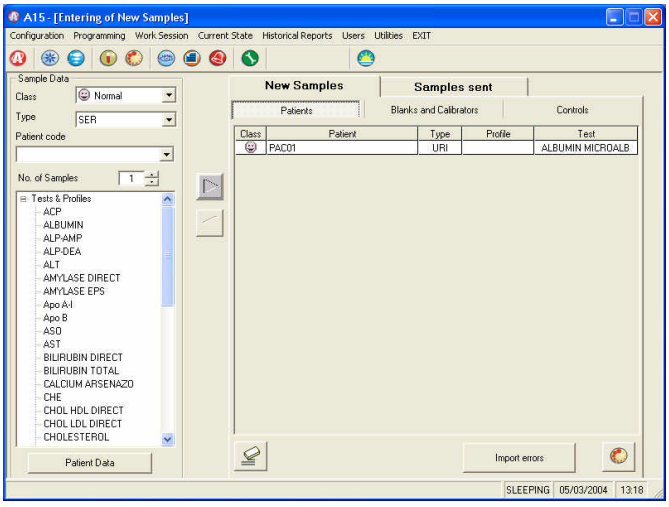
We have a patient PAC1234 considered urgent for ALT and GLUCOSE tests. The sample is SERUM type and is placed in a DIAMETER 15 tube.

U SER PAC1234 ALT T15

U SER PAC1234 GLUCOSE T15

Import file error control

The programme checks that the information in the *Import.txt* file is correct and generates a file (*Errors.txt*) in the \IMPORT folder if it detects an error in syntax or incompatibility with the tests programmed in the application. If an error is found in the import document, the *Import errors* button is enabled.



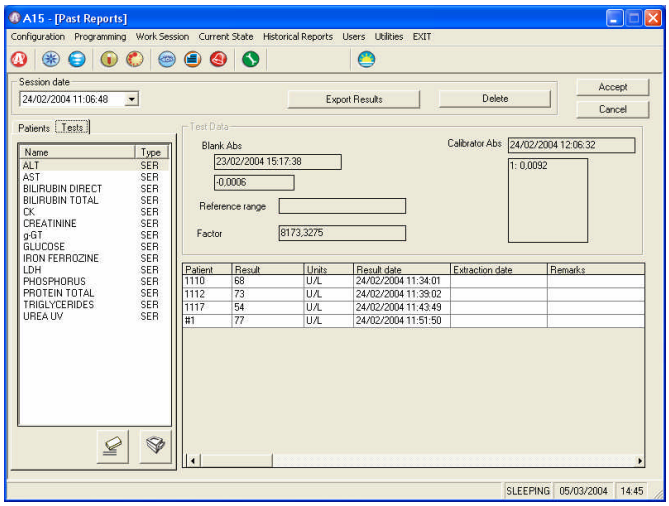
List of errors:

Error	Solution
Line > maximum length of 41 characters	Check the size of all fields and/or tabs
Incorrect CLASS	U (Urgent); N (Normal)
Incorrect TYPE	SER, URI, CSF, WBL, PLM
Incorrect tube	T15 (Diameter 15), T13 (Diameter 13), PED (Paediatric)
Incorrect PatientID size (> 16 chars.)	Reduce PatientID size
Incorrect TestID size (> 16 chars.)	Reduce TestID size
TestID DOES NOT exist in test programmed.	Check programmed test
Type indicated is NOT programmed for the test indicated.	Check Types programmed for the test.

Export process

Once it has been reset, an export document is automatically generated in the \Export folder (EXPAuto(DateSession).txt). This document is automatically deleted after one week.

If the user wishes to export a specific work session, he/she can use the *Export results* button, which generates a document called *Exp(aa-mm-dd hh-mm).txt*.



For example:

Exp(2005-01-28 14-24).txtfile exported on 28/01/2005 at 14:24

Said document has the following format

Field	No. of characters	Values
Sample class	= 1	'U': Urgent patient 'N': Normal patient
Sample Type	= 3	'SER': Serum 'URI': Urine 'CSF': Cerebrospinal liquid 'WBL': Whole Blood 'PLM': Plasma
Patient identifier	≤ 16	Alphanumeric string (any character except #)
Technique identifier	≤ 16	Alphanumeric string (any character allowed)
Concentration result	≤ 10	
Concentration units	≤ 10	
Result date	≤ 19	dd/mm/aa h:m:s

The export file has one line per test applied to each patient.

The export file has one line per test applied to each patient and the fields are separated by a tab and have the size shown in the table.

Sample export file:

PAC1234 ALT SER 121,4717 U/L 19/09/2005 12:19:46
PAC1234 GLUCOSE SER 261,3174 mg/dL 19/09/2005 12:19:46

8.6.2. Password working

You can create three types of user with different access levels:

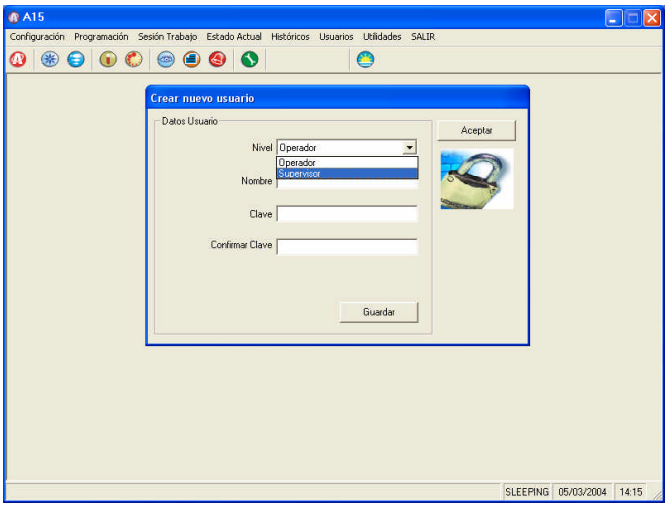
• Operator, is the user with a lower level of access to the application. He can only do working sessions, reports of current and historical results, and validate quality control results. In the screens of programming of techniques and contaminations, he can look up programming values, but he can not modify any parameter. He can not delete results or alarms. This user has total access to the rack and profile programming and to the analyser's configuration (except for changes of filters). He can change his own password.

Whenever you want, you can change the user by means of the option *Change of user* from the *User menu*.

Each user is capable of changing his password. All these options can be reached from the *user menu*.

• Supervisor, is the user with a medium access level. This user has got the same privileges as the operator user's and, in addition, he has got permissions to modify the programming of techniques in the calibration parameters and the control values. He can create a restricted number of new techniques, that is defined at the moment of creating such user and that it is a default setting of 5. He can also modify the programming of contaminations and change the analyser's filters. He can change his own password.

• Administrator, is the user with total access to the analyser's functions. He can create new users -as much at supervisor as at operator level-, eliminate or modify users. When



creating supervisor users, he has to indicate the maximum number of new techniques that can create. He can activate or deactivate Work Without Passwords (option within the Configuration menu). The administrator can only be the Technical Assistance Service.

When users are created, the access is limited to different parts of the program. When starting the program, an identification of the user is requested, by the user name and a password, and then the program will automatically restrict the different parts of the program depending on the access level permitted.