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.

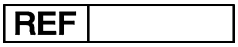
8.4. Technical assistance

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

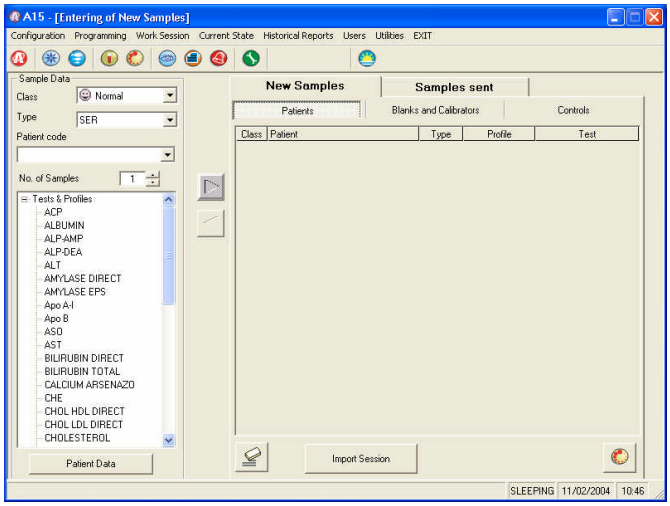
C:\Program files\A15\Import Folder where the document for import is copied

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:

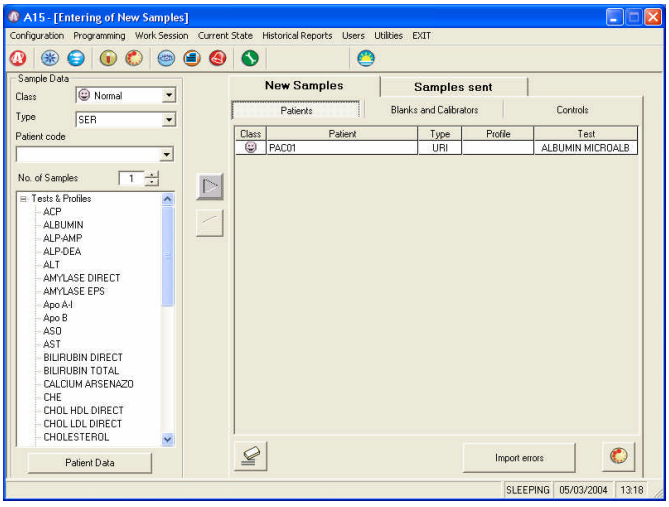
We have a patient PAC1234 considered urgent for ALT and GLUCOSE tests. The sample is SERUM type and is placed in a DIAMETER 15 tube.

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.



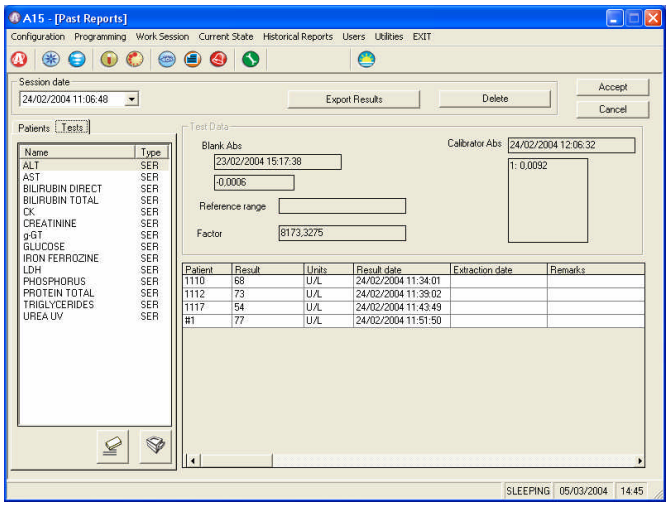
List of errors:

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:

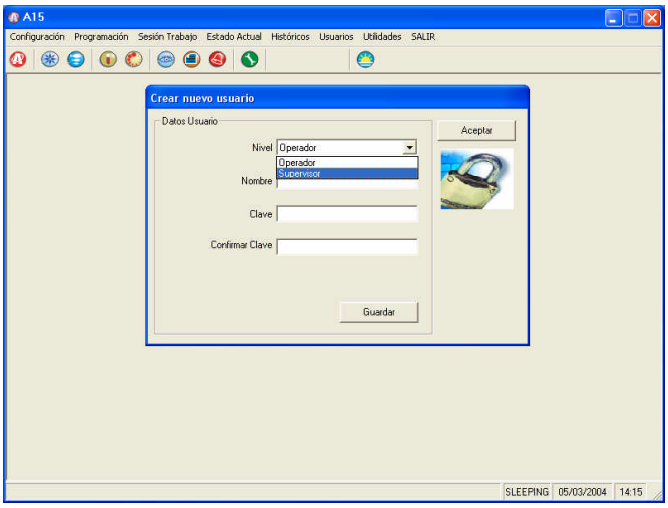
• Operator, is the user with a lower level of access to the application. He can only do working sessions, reports of current and historical results, and validate quality control results. In the screens of programming of techniques and contaminations, he can look up programming values, but he can not 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.