VIDAS® PC

User's Manual

EN

BIOMÉRIEUX

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Done...

This……....................day of ....

Signature and User's stamp:

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General warnings

⚠️ *DANGER !*   *All biological fluids should be considered as potentially infectious.*

Powderless protective gloves must be worn when manipulating blood, products derived from blood or objects contaminated with blood.

Qualified laboratory personnel should use acceptable procedures for biohazardous material.

IMPORTANT!   *The configuration that you have purchased is adapted to the legislation and standards of the different countries it will be sent to. For this reason, it may differ from the one presented in this document. However, it will not prevent VIDAS® from operating correctly.*

This product is an in vitro diagnostic medical device. It complies with the directives and standards mentioned in the certificate supplied with it.

You are advised to read and understand all the instructions in this manual to be able to derive the best performance from your VIDAS.

bioMérieux® SA recommends that you observe the different warnings inscribed on the instrument itself and indicated in the documentation supplied.

The equipment may also cause inteference if not installed in accordance with the instructions given in this manual.

Electromagnetic Compatibility (EMC):
This is a Class A product.
In a residential area, this product may cause harmful interference in which case the user may be required to take adequate measures at his own expense.

IMPORTANT! *Never download into the computer, programs other than those provided by bioMérieux®. If these instructions are not complied with, the computer could become infected with computer viruses. Any intervention directly or indirectly resulting from the presence of such a virus cannot be covered by the warranty or the maintenance contract.*

This statement only applies to European countries and instruments bearing the symbol with regard to the waste electrical and electronic equipment European directive.

You can play an important role in contributing to reuse, recycling and other forms of recovery of waste electrical and electronic equipment. Sorting this type of waste significantly reduces potential negative effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment.

At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. Please contact bioMérieux or its distributor in order to organize its collection.

Revisions

The list of revisions below summarizes replacements or additional pages in your *VIDAS PC* User's Manual.

Manual	Reason	Page(s)
V.C 08.2003	Update of a few screens + text	1-7,1-8, 1-11, 2-3, 3-7, 3-8, 4-2, 4-5,5-21, 6-6, 6-7, 11-17
V.D. 03.2005	Modification relating to the new *VIDAS* model	All
V.E. 12.005	New *VIDAS* software version	All
V.F 05.2008	Addition of a backup mode	Chapter 9

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Note: *The copies of **VIDAS PC** software screens are only given as examples.*

1 How to use this manual

Introduction

This manual covers the procedures for the major functions of the *VIDAS* as well as its software and consumables.

It also deals with the various procedures relating to the *VIDAS* installation and start-up.

The instruments are described in the *VIDAS* Instrument User's Manual.

CAUTION!　　*The software must be used by trained personnel only, who are authorized to do so.*

You are advised to read and understand all the instructions in this manual to be able to derive the best performance from your VIDAS.

Finding topics and procedures

This manual is divided into fourteen chapters. The first eleven chapters are used for the description and procedures. Chapter 13 contains the glossary and chapter 14 the index.

Table of contents
The main table of contents of the manual is located on pages V-1 to V-6.

It lists each chapter and the procedures and/or topics contained in the chapter.

List of figures
Pages VI-1 to VI-3 contain a list of the figures in this manual.

Graphic symbols
The standard symbols used for bioMérieux instruments, and their meanings, can be found in the list on page 1-4.

Warnings
The warning messages are used throughout the procedures for use.

All the warnings in this manual should be read carefully before using *VIDAS PC* in any way.

Page headers and page footers
Apart from the first page of every chapter, each page of the manual includes a page header and footer.

Each page header includes the chapter title and the title of a procedure or its corresponding description.

These titles are located on the outside of the page so that you can thumb through the pages to quickly locate a chapter or a procedure.

The footers contain the title of the manual, the name of the product and the page number.

Glossary
The glossary is located in Chapter 13 at the back of the manual. It gives the definition of the main technical terms used in the manual.

Index
The index is located in Chapter 14 at the back of the manual. It is used to locate a particular description or procedure.

Typographic conventions

These conventions are used in the different chapters of the manual.

• Click on...	A bullet point is used to denote an action to be performed.
"Calibration…"	Quotation marks are used for information which appears on the screen: messages, menu options, functions.
< >	Keyboard keys are represented in angle brackets.
"O" and "I"	are letters.
"ø" and "1"	are the digits zero and one.

Warnings

The following warnings are used throughout the manual:

− for safety reasons (***DANGER!***),

− to ensure that ***VIDAS*** is maintained in good working condition (***CAUTION!***),

− or to allow optimum use of your ***VIDAS*** (***IMPORTANT!).***

Graphic symbols

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The standard symbols used for the bioMérieux systems and their meanings can be found below:

	Direct current
	Alternating current
	Both direct and alternating current
	Three-phase alternating current
	Earth (ground) TERMINAL
	PROTECTIVE CONDUCTOR TERMINAL
	Frame or chassis TERMINAL
	Equipotentiality
	ON (power supply)
	OFF (power supply)

1

"ON" (only for a component of the system equipment)

"OFF" (only for a component of the system equipment)

Equipment protected throughout by DOUBLE INSULATION or REINFORCED INSULATION (equivalent to Class II of IEC 536)

Risk of electric shock

Caution, consult accompanying documents

High temperature

Potential pinch point

Biological risks

Consult Instructions for Use

LOT   Batch code
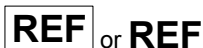
REF or **REF**   Catalogue number

Temperature limitation

EC REP   Authorised Representative in the European Community

☂	Keep dry
▲▲▲	Manufacturer
◹◹	Date of manufacture
IVD	In Vitro Diagnostic Medical Device
SN or **SN**	Serial number
⊗	Keep away from magnetic field
⌧	Separate collection for waste electrical and electronic equipment

2   Functional description

Introduction

This chapter describes the main features of the *VIDAS*® *PC* software.

Description / Aim

The *VIDAS* software is multi-task.

It enables:

− Entry of patient data and analyses via the keyboard or the bidirectional connection with or without the bar code reader,

− Printing of results via the printer, the screen or the uni/bidirectional connection (on request).

− System operation and self-tests.

− Management of calibrations and controls in memory.

− Display and validation of results.

− Management of patient records.

− Running of one or two analytical modules.

The computer contains software programs and various files which enable it to run the *VIDAS* system.

VIDAS PC software: This software contains all the elements and information required to run the system.

Protocol software: **PTC**   **P**rotocol **T**est **C**hange: this software contains all the protocols and tests required to perform assays.

Bidirectional   Interface Software: **BCI**   **B**idirectional **C**onnection **I**nterface**:** this is an optional software which controls the bidirectional interface with the Laboratory Information System (LIS).

General features

Hardware
- Refer to Chapter 2 of the *VIDAS* Instrument User's Manual in which the analytical and computer modules are described.

Consumables
- Refer to Chapter 2 of the *VIDAS* Instrument User's Manual in which the consumables are described.

Principle of operation

2

- Refer to Chapter 2 of the *VIDAS* Instrument User's Manual in which the following are described:

    – Methods for immunoassay.

    – Protocol concept.

    – The optical system.

3   Getting started

Introduction

This chapter covers the first steps you need to take before you can use the *VIDAS PC* :

- safety instructions,

- precautions for use of reagents,

- starting and shutting down the software,

- defining and using user groups.

Safety instructions

This manual contains information and warnings which you must respect in order to ensure that the software runs properly.

IMPORTANT!   *Never download into the computer, software programs other than those provided by bioMérieux[®].*

If these instructions are not complied with, the computer and software provided by bioMérieux could become infected with computer viruses.

Any intervention directly or indirectly resulting from the use of a software program other than the one provided by bioMérieux shall not be covered by the warranty or the maintenance contract.

Do not install a screen saver on the computer.

CAUTION!   *The system must be installed and brought into service by or under the guidance of bioMérieux Technical Assistance.*

The computer media containing the VIDAS PC software programs or the user's backups used for installation or reinstallation, must be stored in an appropriate location.

The different elements composing your VIDAS: hardware, software programs, software configuration (especially date and time format, language, type of keyboard …), are part of a configuration validated by bioMérieux. Any modification or addition resulting in a different configuration to the one validated may cause incorrect operation.

Precautions for use of reagents

IMPORTANT!   *Reagent kits must be stored between 2 and 8°C.*

Bring reagents to room temperature before use (refer to the package insert in the reagent kits).

To ensure that the standard duration of temperature control is respected, the strips should not be kept in the trays, or the SPR®s in the SPR block, for any longer than it takes to prepare or normally perform the tests. Strips and SPRs should not be loaded into the instrument in advance, but just before the corresponding test is performed.

Do not use the reagents after the expiration date.

Do not mix reagents from different lots.

Carefully reseal the SPR pouch with the desiccant inside after use.

Powderless gloves should be worn when using the reagents.

Homogenize the standard, controls and samples before use.

Check that each SPR has a color-coded dot. If a SPR does not have its color-coded dot:

- *Reject the result corresponding to the defective SPR.*
- *Clean the SPR block.*
- *Repeat the assay corresponding to the defective SPR.*
- *Inform bioMérieux® Technical Assistance.*

3

Control devices

You can access most of the *VIDAS PC* software functions using the mouse. However, you can also use the keyboard to run the software.

Main function keys

This key is always combined with another one (on the keyboard or on the mouse). Both keys should be pressed simultaneously.

(E.g.: <CTRL> + <left mouse button> enables you to select one or several lines on the screen).

Caps Lock key. This is used to lock the keyboard in upper case characters. Combined with the left mouse button, it allows you to select data lists in a table.

This key must be activated (light on) if you want to use the numeric keypad.

Left and right arrow keys are used for moving the cursor in the entry zones.

This key enables you to delete a character to the right of the cursor.
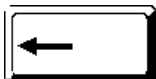
This key enables you to delete a character to the left of the cursor.
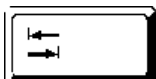
In certain windows, the tabulation key enables you to move the cursor from one entry field to another.

These function keys at the top of the keyboard correspond to keyboard shortcuts which are used in the "Loading" menu.

The mouse keys

The left button is used for selecting.

The middle scroll wheel is used for rapid scrolling. The right button is not used in the **VIDAS PC** software.

Note: Left-handed users can invert the mouse buttons. To do so, please refer to the Windows user's manual.

Main computer terminology

Enable/disable boxes

enabled **disabled**
− Small boxes which correspond to one or several options which can be enabled or disabled.

enabled **disabled**
− Small circles corresponding to one or several options which can be enabled or disabled. Only one option at a time can be enabled.

Enabled/disabled icon
− When a function or a menu represented by an icon is accessible, the icon is colored (enabled).
− When a function or a menu is not available, the icon is a bluish color (disabled).

3

List zone
− In a dialog box, this zone lists available options. If all the options do not fit in the zone, a scroll bar can be used.

Entry zone
− In a dialog box, this zone can be used to enter information.

Text zone
− A zone in which you can enter information required to carry out a command. When the dialog box opens, the text zone may be blank or already contain text.

Recommendation for use of the bar code reader

To read a bar code:

- Hold the reader about 5 cm from the bar code.

- Check that the reader is perpendicular to the bar code (maximum 5° tilt).

- Depress the trigger.

A red beam of light will appear on the bar code.

- Hold the trigger and slowly scan the bar code from top to bottom or bottom to top until the code has been read completely.

A beep and a green LED indicate that reading has been performed correctly.

When reading is complete:

- Release the trigger.

If reading does not occur immediately:

- Slowly move the reader away from and/or towards the bar code until the optimal position for reading has been reached.

- If the problem persists, refer to Chapter 7 "Troubleshooting" of the *VIDAS* Instrument manual.

Starting *VIDAS PC*

- Turn on the instruments in the following order:
    - UPS (if necessary),
    - *VIDAS* analytical modules,
    - printer and screen,
    - computer.

The configuration initializes.

- Wait for the Windows® welcome window to appear.

- Enter the user's name and password.

Note: *Your user name, your password and the user group you are a member of, must be pre-defined in your laboratory.*

This information will determine the level at which you can use your **VIDAS PC** software.

A user who is a member of the VIDAS_ADMIN group has access to all the software functions and certain administration functions such as programming backups, changing the system time etc.

A user who is a member of the VIDAS_ROUTINE group can access the main functions of the software, except the "Configuration" menu. The administration functions, however, are not available.

Group membership is predefined for each user by a bioMérieux® Field Service engineer, the local bioMérieux representative or your laboratory system admininstrator.

3

The Windows® desktop is displayed.

- Wait for 2 minutes before starting the **VIDAS PC** application.

- Double click on the **VIDAS PC** icon,

The **VIDAS PC** initialization screen displays.
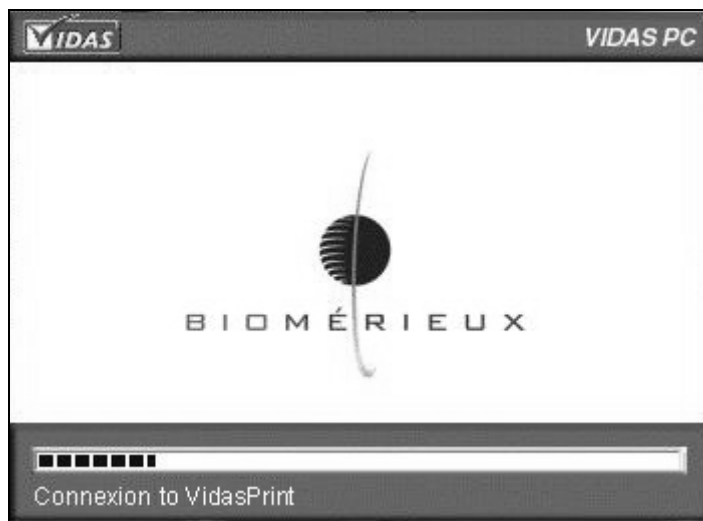
Fig. III 1: VIDAS PC initialization screen

After a short time, the *VIDAS PC* main screen appears.
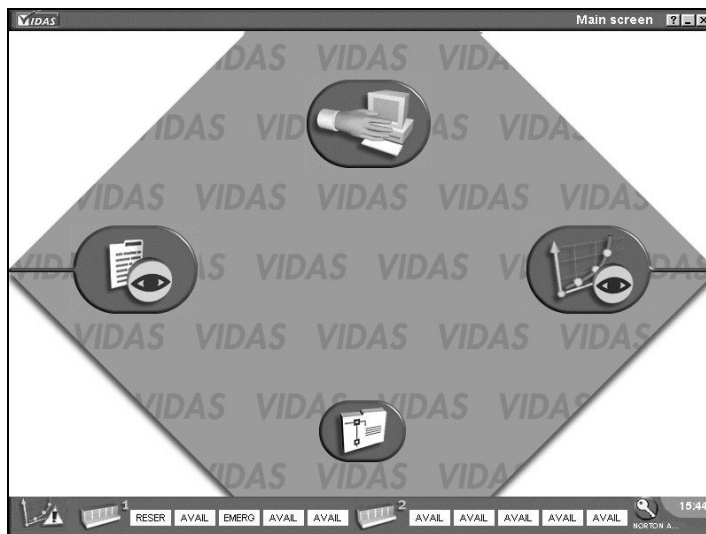
Fig. III 2: Main screen

Note: *For optimum performance of the VIDAS PC software, only one application can be started at a time. If you try to start a second application, the following error message appears.*
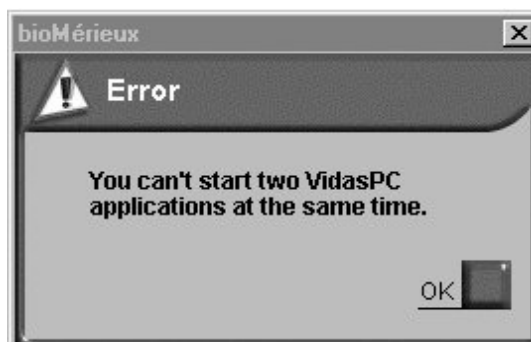
• Click on "OK" to close the window.

When you turn on the analytical module, **leave it to warm up for 45 minutes**.

When the analytical module initializes, it automatically calibrates according to a solid standard which reacts to temperature.

Note: *If the room temperature is too low when the analytical module is turned on, an error is generated (error 160) by **VIDAS PC** after the self-calibration phase (see "Error 160 – Self-calibration drift", on page 12-15).*

After the instrument has warmed up for 45 minutes, turn it off for one minute and then turn it back on again. This operation enables the instrument to store in memory the solid standard value after temperature stabilization.

Note: *If error 160 was generated when the analytical module was turned on for the first time, another error 160 will appear after the new self-calbration phase. Turn off the module and then turn it back on again. If error 160 persists call your bioMérieux ® Technical Assistance Service.*

CAUTION! ***Never connect or disconnect cables when the computer is switched on.***

Shutting down *VIDAS PC*

- Make sure that:
  - no assays are running,
  - no reagents (strips and SPR®s) remain in the strip sections and SPR blocks,
  - printing is not in progress.

To quit the **VIDAS PC** software,

- Click on the stop icon in the top right-hand corner of your work window.

The following dialog box displays.
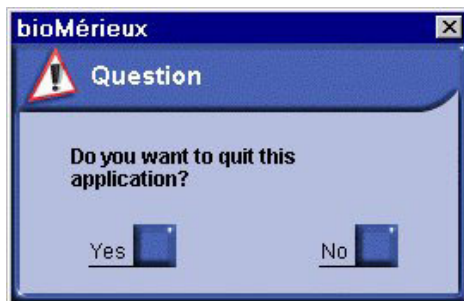
- Click on "Yes".

The Windows® desktop displays.

To quit the *BCI RS232* or *BCI NET* software (if necessary),

- Click on the stop icon ![X] in the top right-hand corner of the BCI window.

Note: *For more information on BCI RS232, see chapter "Bidirectional Computer Interface (BCI)" in this manual.*

For more information on BCI NET, see the BCI NET User's Manual.

The Windows® desktop displays.

To shut down the computer,

- Click on the ![start] button in the bottom left-hand corner of the screen or press one of the Windows key situated either side of the space bar.
- Select "Shut Down".
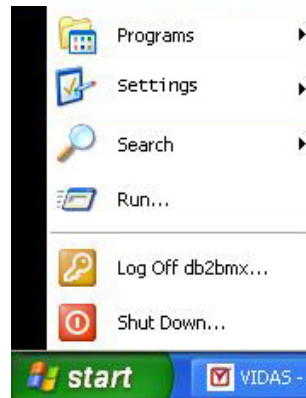
Fig. III 3: Shutting down Windows®

The following window appears.

Fig. III 4: Shutting down the computer

- Select "Shut down"
- Click "OK".

The computer will stop and shut down.

Note: *For optimum operation of your PC, it is recommended to shut it down once a week.*

- Turn off the other instruments:
    - screen,
    - printer,
    - analytical module(s),
    - UPS (if necessary).

Changing the system date and time

CAUTION!   *Incorrect setting of the date and time can lead to incorrect running of programs and loss of data.*

IMPORTANT!   *In order to change the system date and time, you must be logged on with a user identifier which gives administration rights over the operating system.*
For additional information, contact your laboratory system administrator.

- Go to the Windows® desktop.

- Double click in the bottom right-hand corner of the window where the time is displayed.

The following dialog box appears :
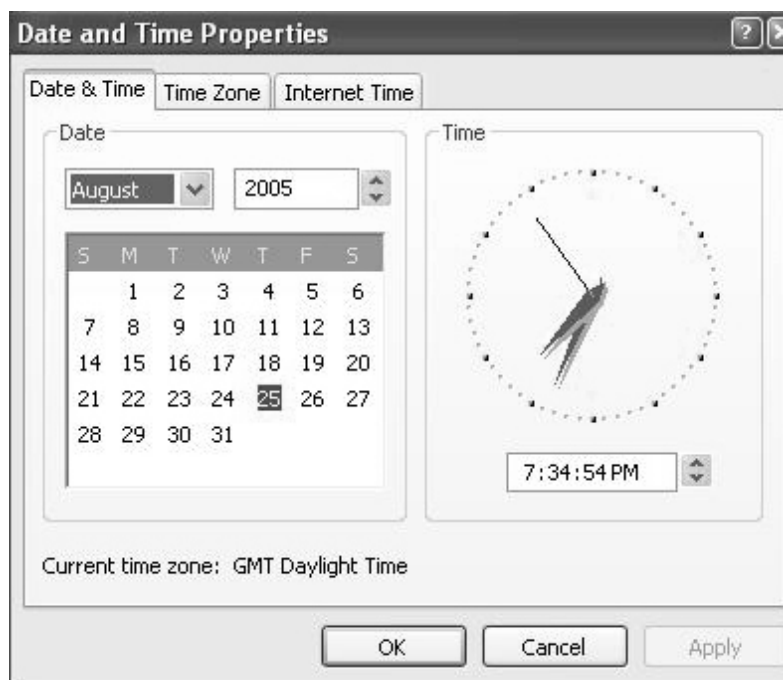
Fig. III 5: Date/Time Properties window

- Change the date and time.
- Click "Apply ".
- Click "OK".

The new date and time are displayed in the bottom right-hand corner of the Windows® desktop.

User management

The "User Manager" utility developed by bioMérieux® SA enables the laboratory administrator to:

- manage user accounts for Windows® XPe, *VIDAS PC* and *BCI RS232* or *BCI NET* created with previous versions of the *VIDAS PC* software;

- create and manage new user accounts.

Note: *User management operations can only be performed by the laboratory system administrator or another person qualified to do so.*

The following table presents the user groups and their rights for for Windows XPe, *VIDAS PC* and *BCI RS232* or *BCI NET*.

GROUP	WINDOWS	*VIDAS PC*	BCI RS232 or BCI NET
Users	**ORDINARY**	/	/
Administrators	**FULL**	/	/
VIDAS_ROUTINE	/	**ORDINARY**	/
VIDAS_ADMIN	/	**FULL**	/
BCI_ROUTINE	/	/	**ORDINARY**
BCI_ADMIN	/	/	**FULL**

The "Users" group can use Windows XPe, but not modify its properties.

The "Administrators" group gives full access rights to the Windows software.

The "VIDAS_ROUTINE" group gives access rights to the main *VIDAS PC* menus, except the "Configuration" menu and the Maintenance/Instrument run menu.

The "VIDAS_ADMIN" group gives full access rights to all the *VIDAS PC* software menus **except the Maintenance/Instrument run menu.**

The BCI_ROUTINE group allows you to view the BCI.

The "BCI_ADMIN" and "BCI_ROUTIN" groups give full access rights to the *BCI RS232* or *BCI NET* software menus.

Example: To have full access rights to Windows® XPe, *VIDAS PC* and *BCI RS232* or *BCI NET*, you must be a member of the "Administrators", "VIDAS_ADMIN" and "BCI_ADMIN" and "BCI ROUTINE" groups.

To have limited access rights to Windows XPe but full access rights to *VIDAS PC* and *BCI RS232* or *BCI NET*, you must be a member of the "Users", "VIDAS_ADMIN" and "BCI_ADMIN" and "BCI ROUTINE" groups.

To have limited access rights to Windows XPe, *VIDAS PC* and *BCI RS232* or *BCI NET*, you must be a member of the "Users", "VIDAS_ROUTINE" and "BCI_ROUTINE" groups.

IMPORTANT! *Each user must belong to a VIDAS group (VIDAS_ADMIN or VIDAS_ROUTINE) and a Windows XPe group (Users or Administrators) to be able to use the VIDAS PC software.*

If a bidirectional connection interface is used, each user must belong to a BCI group ("BCI_ADMIN" or "BCI_ROUTINE") to be able to use BCI RS232 or BCI NET.

3

Creating a user

Note: *During user management, you must close the **VIDAS PC** interface.*

- If necessary, open the session using the administrator's identifier and password.

On the Windows® desktop:

- Double click on the "User Manager" icon.

The "Vidas user manager" menu opens and the following window is displayed.
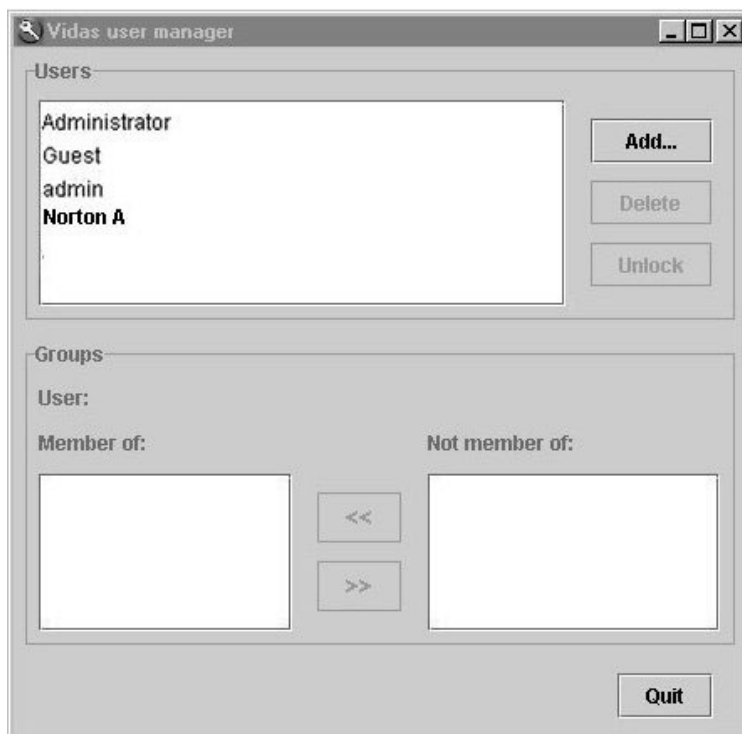
Fig. III 6: Opening the VIDAS user manager window

To create a new user account,

- Click on "Add".

The following window displays:
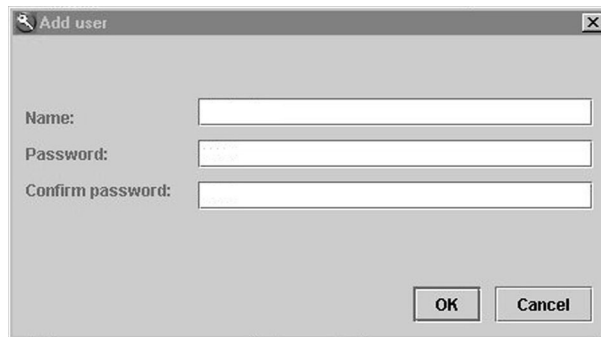
Fig. III 7: Add user window

- Enter the user's name in the "Name" text box.

- Enter the password in the "Password" text box.

- Confirm the password in the corresponding text box.

- Click on "OK" to confirm creation of the new user account.

3

The following window displays:
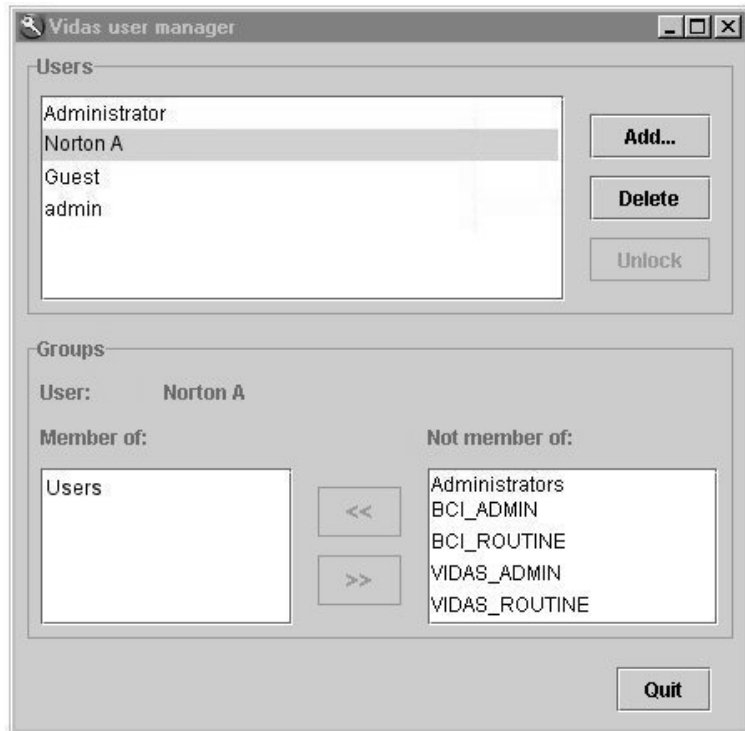
Fig. III 8: Group membership window

The name of the new user account is displayed at the top of the "Vidas user manager" window.

- Select the user group(s) (Users, Administrators, VIDAS_ADMIN, VIDAS_ROUTINE, BCI_ADMIN, BCI_ROUTINE) in the "Groups" field according to the permissions or rights assigned to the new user.

- Click on the [<<] button to assign permissions or rights, or on the [>>] button to remove them.

Note: *A user can belong to several user groups, for example:*
- VIDAS_ADMIN and BCI_ADMIN.
- VIDAS_ROUTINE and BCI_ROUTINE.

- Proceed in the same way to create other user accounts.

- Click on "Quit" to close the "Vidas user manager" window.

The following dialog box opens:
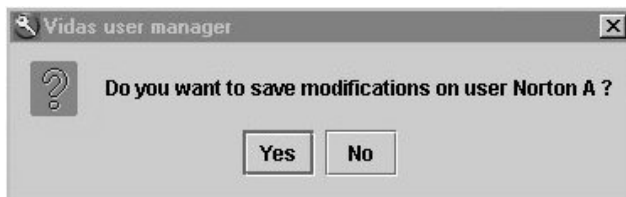
- Click on "Yes" to confirm creation of the new user account.

Note: *A new user must be assigned a default printer (see section Selecting a default printer, on page 3-26).*

For a new user opening Windows XPe® for the first time, see section Opening a session for a new user, on page 3-25.

3

Modifying a user

Note: *During user management operations, you must close the **VIDAS PC** interface.*

- Open a session by entering the administrator's identifier and password (if necessary).

On the Windows® desktop:

- Double click on the "User Manager" icon.

The "Vidas user manager" menu opens and the following window is displayed.
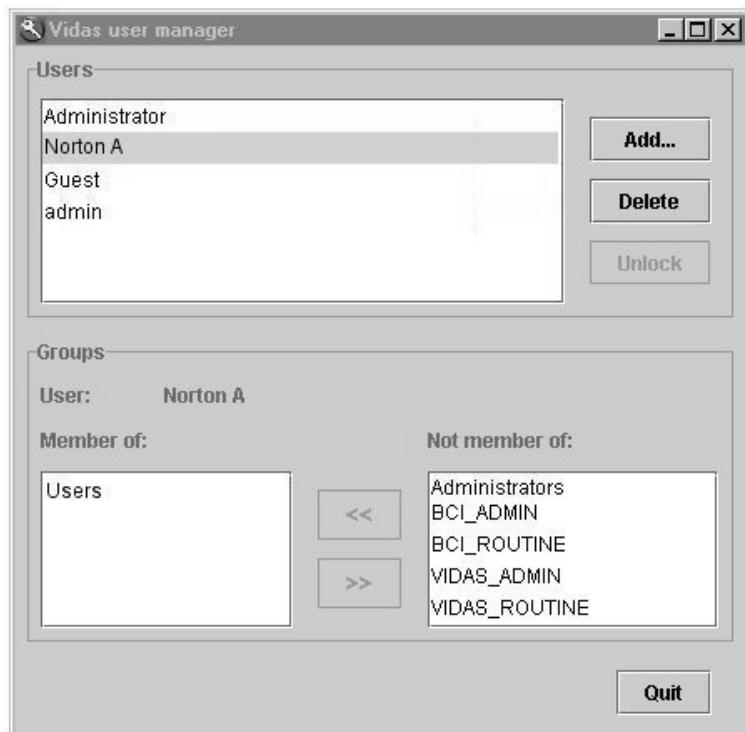
Fig. III 9: Group membership window

In the "Vidas user manager" window,

- Select the user whose rights you want to modify.

In the "Groups" field,

- Select the group to be removed or added using the add button ⟨⟨ or the remove button ⟩⟩.

- Click on "Quit" when modification is finished.

The following window is displayed.
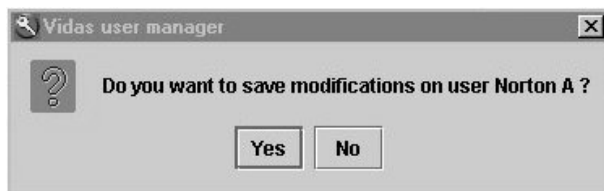
- Click on "Yes" to confirm the modifications.

The user's permissions and rights are now modified.

3

Deleting a user

Note: *During user management operations, you must close the **VIDAS PC** interface.*

- Open a session by entering the administrator's identifier and password (if necessary).

On the Windows® desktop:

- Double click on the "User Manager" icon.

The " Vidas user manager" menu opens and the following window is displayed.

Fig. III 10: Deleting a user account

- Select the user you want to delete in the list of users.

- Click on "Delete".

The following window is displayed.
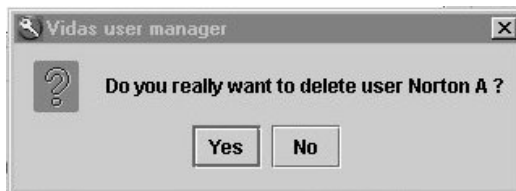
- Click on "Yes" to confirm deletion.

The user account is definitively deleted.

- Click on "Quit" to close the "Vidas user manager" window.

Note: *This operation has no effect on the results or calibrations that the user obtained in the application. When the user is deleted, the user data remain in the **VIDAS PC** database and can be consulted by any other users who have access rights to this information.*

3

Unlocking a user account

After three unsuccessful attempts to connect, the software will lock.

To unlock it:

- Open a session by entering the administrator's identifier and password.

On the Windows ® desktop:

- Double click on the "User Manager" icon.

The "Vidas user manager" menu opens and the following window is displayed.
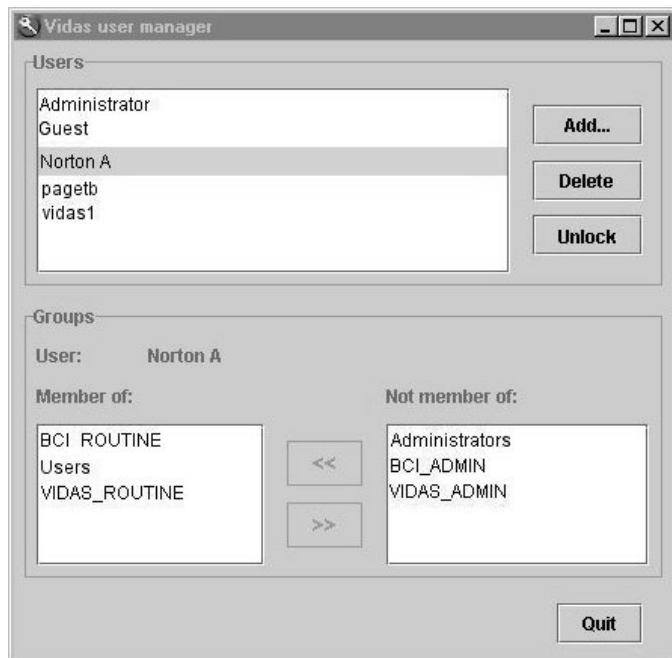
Fig. III 11: Unlocking a user account

- Select the user account you want to unlock.

The "Unlock" button is activated.

- Click on "Unlock" to unlock the account.
- Click on "Quit" to close the "Vidas user manager" window.

The user account is now unlocked.

Opening a session for a new user

When Windows$^®$ XPe is opened for the first time by a new user, various screens appear for modification of the password.

- Click on OK.

A dialog box is displayed.

- Enter your new password.

- Confirm your new password.

- Click on "OK".

A message is displayed informing you that your password has been changed.

- Validate by clicking on "OK".

The Windows session opens.

Note: *The numeric keypad is disabled when a new session is opened. Press* [Verr num] *to enable it.*

3

Selecting a default printer

When a new user account is created, the administrator must select a printer using Windows® Xpe. To do so, on the Windows desktop:

- Click on the **start** button in the bottom left-hand corner of the screen or press one of the "Windows" keys situated either side of the space bar.

- Select "Settings" and then "Printers and Faxes".
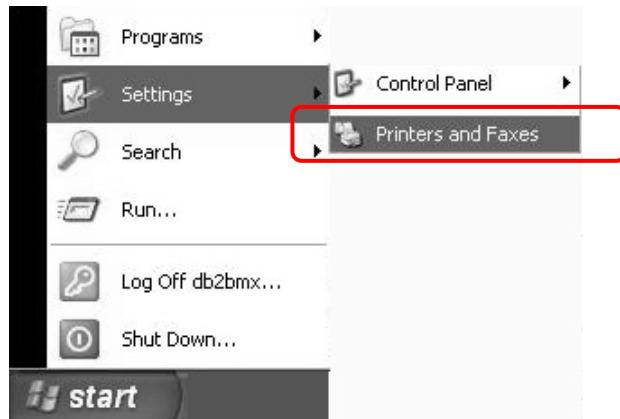
Fig. III 12: Selecting a printer

In the "Printers and Faxes" menu,

- Click on the icon of the printer to be selected by default.

- Click on the right mouse button and select "Set as default printer".
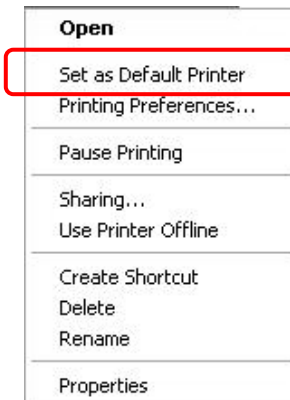
This printer will be selected by default for the user's print-outs.

Logging on with a user group after opening a session

To log on using a different user group ("Routine" or "Administrator") to the one you initially logged on to the *VIDAS PC* software with, you have to quit the *VIDAS PC* software and open a Windows® session using your own user identifier .

CAUTION!   *If you need to open a new Windows session, you must shut down the connection and quit the BCI software before closing the current Windows session.*

Proceed as follows:

- click on the **start** button in the bottom left-hand corner of the screen or press one of the "Windows" key situated either side of the space bar.

- select "Log Off…".

3
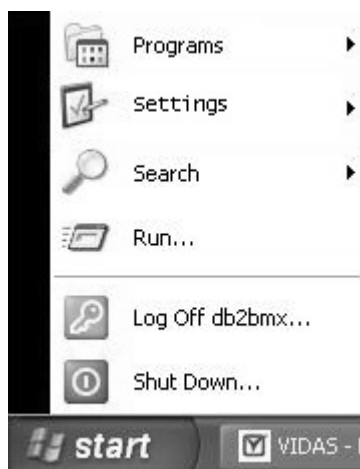
The "Log Off Windows" dialog box displays.
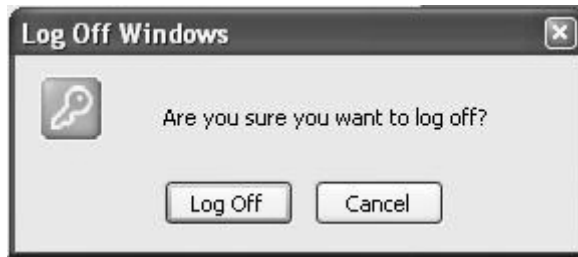
- Select "Log off" .

The session closes and a new session opening screen is displayed.

- Enter the data required to open a new Windows® session corresponding to the desired user group.

Changing the password

Changing the password when opening Windows®

When you enter your password, a dialog box will inform you if your password has expired.

- Click on "OK".

A dialog box displays.

- Enter your new password.

- Confirm your new password.

- Click on "OK".

A message will appear to inform you that your password has been changed.

Changing the password when starting *VIDAS PC*

When you enter your password in the *VIDAS PC* prompt screen, a dialog box will inform you if your password has expired.

- Click on "OK".

- Simultaneously press <Ctrl>, <Alt> and <Del>.

The Windows security window displays.

- Click on "Change password".

- Enter your old password.

- Enter your new password.

- Confirm your new password.

- Click on "OK".

You can also change your password at any time using the above procedure.

3

Locking and unlocking the *VIDAS PC* software

After 30 minutes of inactivity, or if requested by the user (by clicking on the key icon in the bottom right-hand corner of the screen), the *VIDAS PC* software locks. This has no effect on assays in progress.

Note: *The default time is 30 minutes, but it can be modified by any user who has sufficient rights to access the "Routine" submenu in the "Configuration" screen.*

The following window is displayed on the screen:
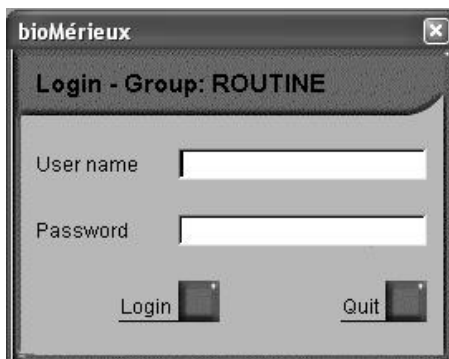
Fig. III 13 : *VIDAS PC* login window

To unlock the software,

- Enter your user name.
- Enter your password.
- Click on "Login".

When you unlock the software, you can also log on as a different user but from the same group, i.e. "Routine" or "Administrator".

To do so,

- Enter your user name.
- Enter your password.
- Click on "Login".

When you unlock the software, you can also log on as a different user but from another group. Refer to "Logging on with a user group after opening a session" on page 3-27.

CAUTION!   *After 3 unsuccessful attempts, the software will lock. To unlock it, call your laboratory system administrator.*

CAUTION!   *To log on as a different user, you must be a member of the same user group ("Routine" or "Administrator"). If this is not the case, a warning message will appear on the screen. You will therefore have to quit the VIDAS PC software and open a Windows ® session using your own user identifier.*

CAUTION!   *If you need to open a new Windows session, you must shut down the connection and quit the BCI RS232 software before closing the current Windows session.*

Locking and unlocking the BCI RS232 software

After 10 minutes of inactivity, the *BCI RS232* software locks. This has no effect on the assays or the interface with the LIS.

The following window appears on the screen:
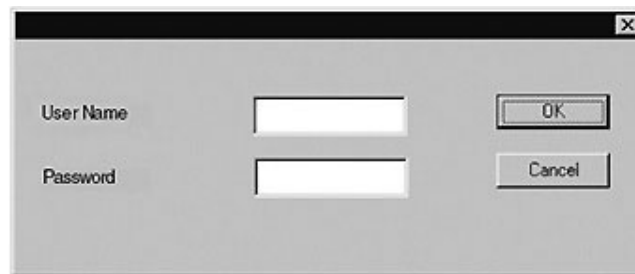
Fig. III 14 : BCI RS232 login window

To unlock the software,

- Enter your password.
- Click on "OK".

When you unlock the software, you can also log on as a different user but from the same group, i.e. "Routine" or "Administrator".

To do so,

- Enter your user name.
- Enter your password.
- Click on "OK".

CAUTION!   *If you need to open a new Windows session, you must shut down the connection and quit the BCI RS232 software before closing the current Windows® session.*

Note: *For the BCI NET software, see the BCI NET User's Manual.*

4   Instructions for use

Introduction

This chapter deals with the use of the *VIDAS*® *PC* software for preparing and starting assays.

Theory of operation

VIDAS is a multiparametric system for immunoassay. It is composed of hardware, software and consumables.

- The *VIDAS* analytical module is divided into 5 sections each containing up to 6 assays with compatible protocols.

- The *VIDAS PC* software can manage two *VIDAS* modules.

- The reagent kits of 60, 30 or 10 tests are composed of:

  - the reagent strips and SPR®s (Solid Phase Receptacle),

  - the necessary additional consumables such as standard(s), control(s), diluent,

  - the master curve in the form of bar codes (MLE card),

  - the package insert.

The theory of operation on *VIDAS* consists of*:*

- creating predefined sections,

- running assays,

- performing calibrations and controls.

Step 1
Prepare the sample

Step 2
Create a predefined section
and then reserve a section.

Step 3
Fill the sample well

Step 5
Place the reagent strips in their
positions and fill them.

Step 4
Place the SPR®s in their slots.

Step 6
Close the door of the SPR® block.

Step 7
Lower the section's cover.
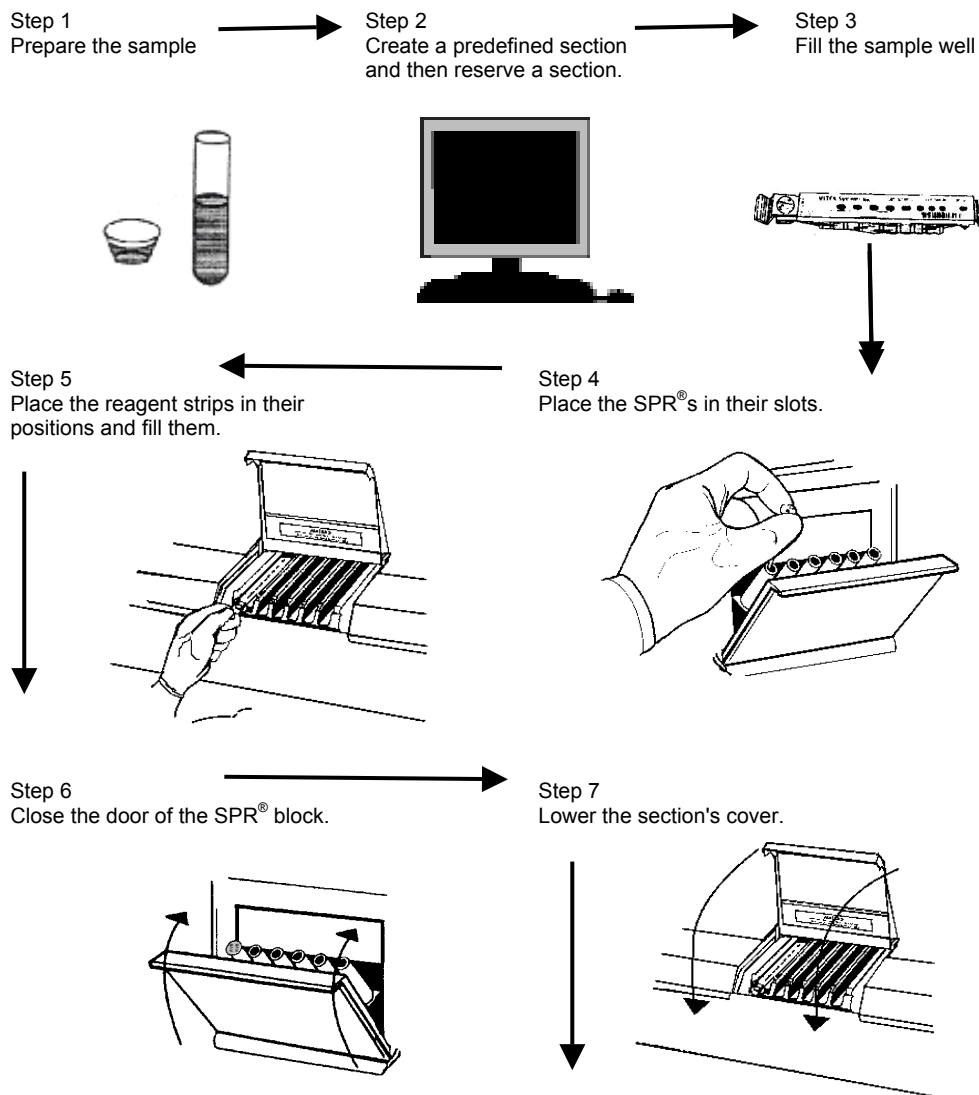
Fig. IV 1: Basic *VIDAS* workflow

(continued on next page)

Step 8
Run assays.

Step 9
Results are printed (depending on the software configuration).

Step 10
When assays are completed, remove the reagent strips and SPRs.
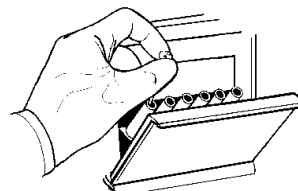
Fig. IV 2: Basic *VIDAS* workflow (cont'd)

IMPORTANT!   *Always observe good laboratory practices and universal safety precautions when handling VIDAS reagents.*

CAUTION!   *Check that each SPR® has a color-coded dot.*
If a SPR® does not have its color-coded dot :

−   *Reject the result corresponding to the defective SPR®.*

−   *Check that the dot has not become stuck on the SPR® block or the SPR® seal and if it has, then remove it.*

−   *Repeat the assay corresponding to the defective SPR®.*

−   *Inform bioMérieux® Technical Assistance.*

User interface

Presentation of the main screen

When you start the *VIDAS PC* software, the following window displays:

1. **Navigation tree**

2. **Three main menus**

3. *VIDAS* **status summary**
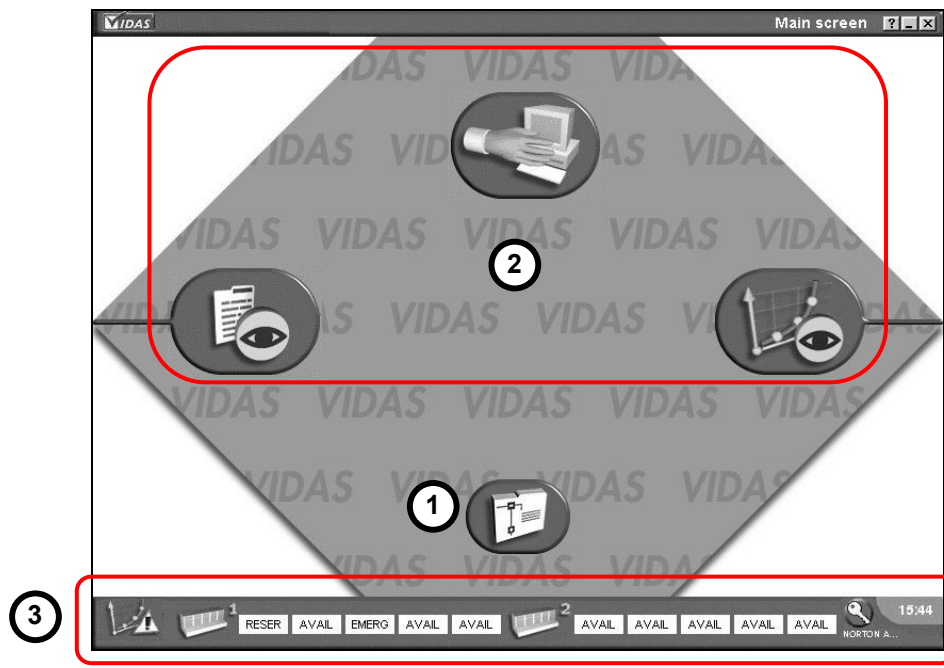
Fig. IV 3: Main screen

The main window is divided into two parts:

−   the navigation tree and the three main menus,

−   the *VIDAS PC* status summaries.
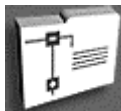
•   Click on the navigation tree in the main window to display the list of *VIDAS PC* menus. The following window appears :
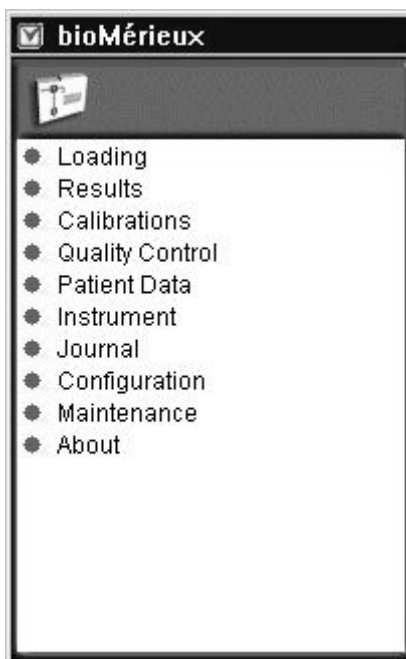
Fig. IV 4: List of *VIDAS PC* menus

The navigation tree

You can access 10 menus through this window :

- LOADING menu

- RESULTS menu

- CALIBRATIONS menu

- QUALITY CONTROL menu

- PATIENT DATA menu

- INSTRUMENT menu

- JOURNAL menu

- CONFIGURATION menu

- MAINTENANCE menu

- ABOUT menu

The three main menus

Loading menu   Enables you to prepare and run assays.

Calibrations menu   Enables you to display and access the various procedures for calibration.

Results menu   Enables you to display and validate assay results.

The *VIDAS PC* status summaries

Calibration status
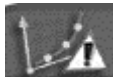
Recently expired calibrations

The flashing icon in the bottom left-hand corner of the screen indicates that at least one calibration has expired (see page 6-18).

Instrument status
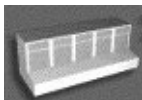
Analytical module affected by the error

Instrument error 101 to 163 : the icon corresponding to the analytical module affected by the error is circled in red (see page 12-8).

Section status

Enables you to view the status of the various sections.

The statuses are the following:

| AVAIL (white) | The section is available. |

| EMERG (white) | The section is reserved for emergencies. |

| RESER (white) | The section has been reserved for a predefined section (see Reserving sections page 4-22). |

| VERIF (green) | Verifications are in progress in this section (reading of bar codes, strips, verification of calibrations, etc.). The section number is displayed below the section concerned, under the status bar. |

| 04:07 PM (green) | The section is running an assay. The time indicated corresponds to the time of completion of the assay. |

| UNLOAD (green) | Strips and SPR®s are waiting to be unloaded from the section. |

| RESET (white) | The section is being reset. |

| ERRINST (red) | An error has occurred in a section. |

| DISCO (black) | The section is disconnected. |

User identification

The identification icon shown opposite gives access to the *VIDAS PC* login window (see Fig. III 13). The user name is displayed below the icon.

To lock the *VIDAS PC* software,

- Click on the identification icon.

The *VIDAS PC* login window displays. The *VIDAS PC* software is now locked. Assays continue normally.

It is possible to enter a user name and a password that are different to those initially entered.

This can be useful when several users work routinely with the *VIDAS*.

- Enter the desired user name.

- Enter the corresponding password.

- Click on OK.

The new user name is displayed below the icon.

CAUTION! *To log on as a different user, you must be a member of the same user group ("VIDAS_ROUTINE" or "VIDAS_ADMIN"). If this is not the case, a warning message will appear on the screen. You will therefore have to quit the VIDAS PC software and open a Windows® session using your own user name.*

Minimize button

This button in the top right-hand corner of the window enables you to minimize a window to the size of an icon in the task bar.

To restore the window,

- click on the icon in the task bar.

Presentation of a typical menu

All the *VIDAS PC* menu and submenu screens are divided into several zones with a similar architecture.

1. **Menu bar**. The menu bar enables you to access the three main menus (Loading, Calibrations and Results) and to return to the main menu. The icon of the current menu is shaded.

2. **Menu name**. The name of the current menu or submenu is displayed.

3. **Tool bar**. The tool bar enables you to access the specific tools for the current menu or submenu.

4. **Menu screen**. This is the specific screen for the current menu or submenu.

5. **Sub-menu bar**. The submenu bar enables you to access the different submenus of the current menu.

6. **Status bar**. The status summary indicates the following information:
- section status,
- presence of errors,
- system time,
- name of the technician currently using the software.
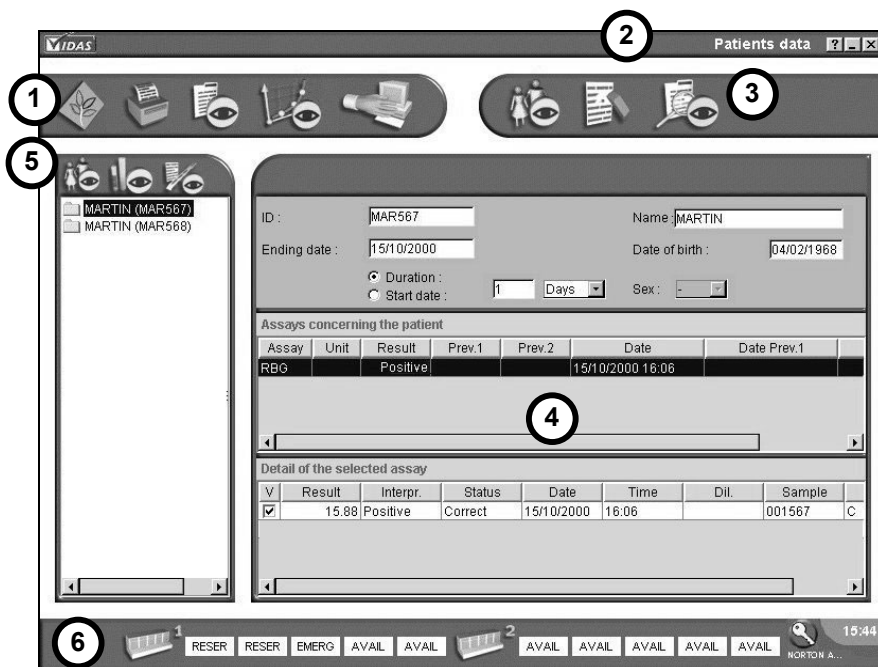
Fig. IV 5 : A typical menu

Entering assays (or assay requests)
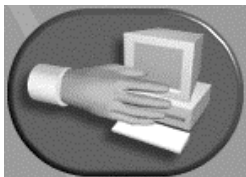
In the main window, or any other window,

- Click on the "Loading" button,

or,

in the main window,

- click on the navigation tree and then,

- select the "Loading" button.

The following window is displayed.

1. **Job list**. List of entered assays waiting to be run, and assay requests received from the LIS.

2. **Predefined sections**. List of the predefined sections waiting to be reserved and then started.

3. **Entry zone**. Entry of data according to the entry mode selected (simplified, complete, industrial). The fields of this zone are detailed in each entry mode.

4. **Section number**. The number of a predefined section is displayed below the reserved section to which it corresponds.

5. **Clear**. **The "Clear" button enables you to delete all the fields (including the "Dilution" field).** When you do this, the "Multiplier" check box returns, by default, to 1. You can also press <F12> to do so (keyboard shortcut).
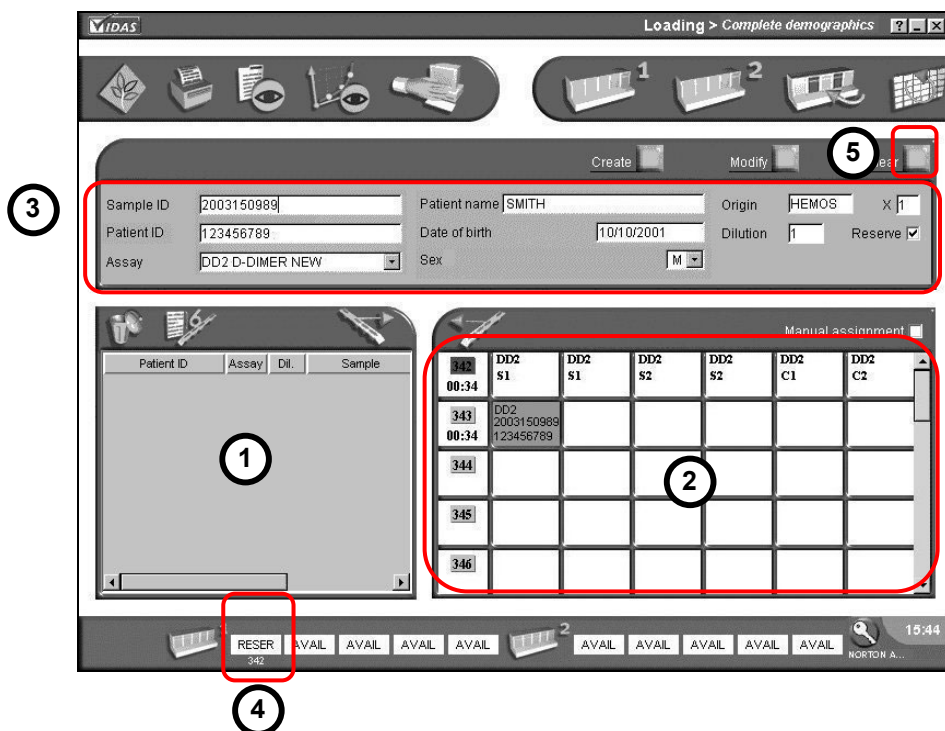
Fig. IV 6: "Loading" window (complete demographics mode)

Before entering assays, you can select one of the following three entry modes:

– simple demographics mode (see page 4-14).

– complete demographics mode (see page 4-15).

– industrial context mode (see page 4-16).

The selection of these modes is described in Chapter 8 - The different **VIDAS PC** menus.

Summary table for the different entries

Description of fields *(Maximum number of characters)*	Simple demographics	Complete demographics	Industrial context
Assay code *(obligatory field)*	**Yes**	**Yes**	**Yes**
Dilution *(3 characters)*	**Depending on type of assay**	**Depending on type of assay**	**Depending on type of assay**
Sample ID *(12 characters - obligatory field)*	**Yes**	**Yes**	**Yes**
Origin *(5 characters)*	**Yes**	**Yes**	**Yes**
Patient ID *(12 characters)**	**No**	**Yes**	**No**
Patient's name *(30 characters)*	**No**	**Yes**	**No**
Patient's sex	**No**	**Yes**	**No**
Patient's date of birth	**No**	**Yes**	**No**
Specimen*	**No**	**No**	**Yes**
Transfer mode ("Reserve" box to be enabled)	**Depending on work method**	**Depending on work method**	**Depending on work method**

* This ID must be unique and specific for a patient or a specimen.

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Entry in simple demographics mode

1. **Assay selection**. Manual entry or selection of an assay code from a pull-down entry list.

2. **Sample ID**. Sample ID (12 characters maximum).

3. **Dilution**. Dilution factor for a defined assay. This window is only for quantitative assay codes (from 1 to 999).

4. **Origin**. Five characters indicating the origin of the assay (laboratory, specimen location, etc).

5. **Multiplier**. Enables you to repeat an assay up to 30 times.

6. **Reserve**. 2 work modes :
   "Reserve" box enabled:
   This enables automatic recording of an assay in a predefined section.
   "Reserve" box disabled:
   This enables automatic recording of an assay in the job list.

7. **Create**. The "Create" button enables you to validate entry of an assay. You can also press <F10> to do so (keyboard shortcut).

8. **Modify**. The "Modify" button enables you to modify an entry in the job list or a predefined section (see Modification - Deletion page 4-37). You can also press <F11> to do so (keyboard shortcut).

9. **Clear**. The "Clear" button enables you to delete all the fields (including the "Dilution" field). By default the "Multiplier" check box resets to 1 when this is done. You can also press <F12> to do so (keyboard shortcut).

Fig. IV 7: Entry zone (simple demographics)

To enter an assay request,

- Select the assay.

- Enter the necessary information in the entry zone according to the patient data.

- Click on "Create" or press <F10> (keyboard shorcut).

The assay request is displayed as a list or predefined section, depending on the recording mode selected ("Reserve" box enabled or disabled).

Note: *The cursor for entering the next assay request is automatically positioned in the "Sample ID" text box.*

Entry in complete demographics mode

1. **Date of birth**. Patient's date of birth (depending on the configuration: dd/mm/yyyy or mm/dd/yyyy).

2. **Sex**. Patient's sex (M, F, -).

3. **Patient name**. Patient's name (max. 30 characters). **The patient's name will only be taken into account if a Patient ID has also been entered**.

4. **Patient ID**. Patient ID (max. 12 characters).

Fig. IV 8: Entry zone (complete demographics)

To enter an assay request,

- Select the assay.

- Enter the necessary information in the entry zone according to the patient data.

See "Entry in simple demographics mode" on page 4-14 for entry of basic information.

- Click on "Create" or press <F10> (keyboard shortcut).

The assay request is displayed as a job list or predefined section, depending on the recording mode selected ("Reserve" box enabled or disabled).

Note: *If a patient ID has previously been used, the patient's data will appear by default.*

Entry in "Industrial context" mode

1. **Specimen**. Specimen type (max. 30 characters).
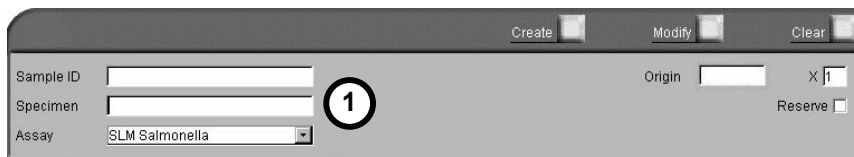
Fig. IV 9: Entry zone (industrial context)

To enter an assay request,

- Select the assay.

- Enter the necessary information in the entry zone.

See "Entry in simple demographics mode" on page 4-14 for entry of basic information.

- Click on "Create" (or press <F10>.).

The assay request is displayed as a job list or a predefined section, depending on the recording mode selected ("Reserve" box enabled or disabled).

Modifying and deleting assay requests

The methods for modification and deletion of assay requests which have been entered and queued are described in "Modification - Deletion" on page 4-37.

Managing creation of predefined sections for two connected *VIDAS*® analytical modules
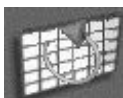
– If compatible assays have been assigned to different ***VIDAS***® analytical modules (***VIDAS 1***, ***VIDAS 2*** in the Configuration menu) during the creation of an analysis including these assays, separate predefined sections are automatically created.

– The "Reorganize all sections by compatible tests" icon does not allow you to group these tests together in one section.

4

Transferring assays

The following window shows assays and indicates the commands used to transfer them to a predefined section or the job list.

1. **List of predefined sections**. List of the predefined sections ready to be reserved or run by the *VIDAS* module(s) (up to 20 predefined sections displayed at the same time).

2. **One predefined section**. Predefined section composed of a maximum of 6 assays with compatible protocols. The *VIDAS PC* software assigns a number to the predefined section and displays the expected time for completion of the assay.

3. **Job list**. The job list is composed of up to 200 lines. Each line is a request for a given assay.
You can sort by category by clicking on the column header (eg : Patient ID). The width of the columns can be adjusted. To do so,

- Click on the ←→ arrows of the column header while holding down the left button of the mouse until you obtain the width you want.

4. **Selection of compatible assays**. Selection of the first 6 compatible assays in the job list. They will display in inverse video.

5. **Entry commands for loading assays**. Entry commands required to load assays in a predefined section or the job list.

Note: *It is possible to automatically perform a search for identical sample numbers in the job list. To do so, use the bar code reader to scan a tube bar code corresponding to the sample number you are searching for.*
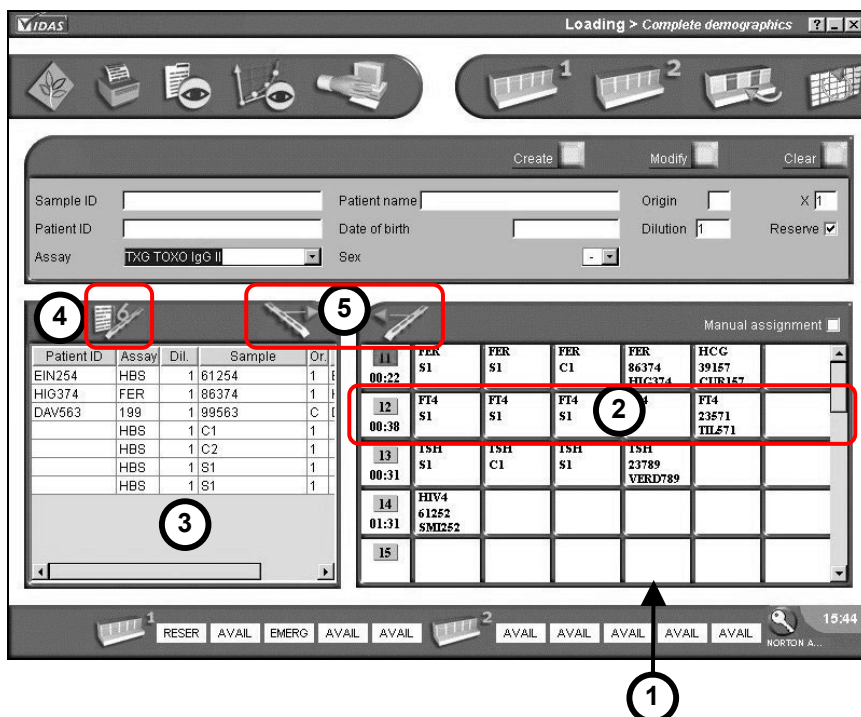
Fig. IV 10: Transfer to predefined sections

Transferring an assay from the job list to a predefined section

Transfer of assay requests can be manual or optimized.

Manual transfer

Creating a predefined section in manual mode

- Select an assay in the job list (the assay is in inverse video).

- Transfer the assay by clicking on the "Transfer" button.

The assay appears in a predefined section numbered by *VIDAS PC* (if the "Manual assignment" box has not been selected).

If a predefined section has already been created for the same protocol, the assays will automatically be assigned to this section until all six positions have been filled.

Manual assignment ☐

If you want to transfer an assay to a predefined section of your choice, select the "Manual assignment" box beforehand.

If the "Manual assignment" box has been selected, a dialog box is displayed which will enable you to either use a new section or select the predefined section to which you want to transfer the assay.
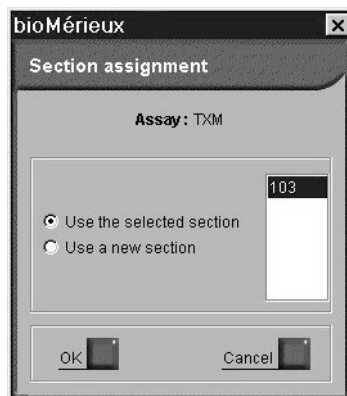
The time required to run the assay (in minutes) is displayed below the number of the predefined section.

An assay that is transferred to a predefined section will disappear from the job list.

Optimized transfer

Optimized transfer enables you to rapidly fill the positions of predefined sections by selecting the first six assay requests with compatible protocols from the job list.

This function can only be used if assays with compatible protocols have been assigned to the same *VIDAS* module (see "Assay assignment" submenu on page 8-43).

The "Select 6 compatible assays" button is enabled (colored).

- Click on this button.

The selected assays appear in the job list in inverse video.

- Transfer them to the predefined section by clicking on the "Transfer" button.

Note: *If two assays with compatible protocols are assigned to two different VIDAS instruments, two predfined lists will be created.*

Transferring assays from predefined sections to the job list

Transferring an assay

- In the predefined section to be modified, select the assay you want to transfer (the assay is displayed on a blue background).

- Click on the "Transfer" button.

The assay disappears from the predefined section and is returned to the top of the job list.

Sorting is possible by clicking on the column header.

Transferring a predefined section

- Select the predefined section by clicking in the white background of the predefined section button.

The assays and the predefined section appear on a blue background.

- Click on the "Transfer" button.

All the assays loaded in this predefined section are returned to the top of the job list and the predefined section is cancelled.

Reserving sections

Reserving a section consists of loading a previously created predefined section in a section defined by *VIDAS PC* or the user.

You must then physically load the strips, SPR®s and samples into the sections indicated on the loading plan provided by *VIDAS PC*. The instrument will then run the assays.

Two types of reservations are possible:

− by *VIDAS PC* :

  − individual reservation

  − grouped reservation

− by the user:

  − manual reservation

The window of the "Loading" menu displays the various functions used for the reservation of sections.

1. **Individual reservation**.

2. **Grouped reservation**.

3. **Manual reservation**.
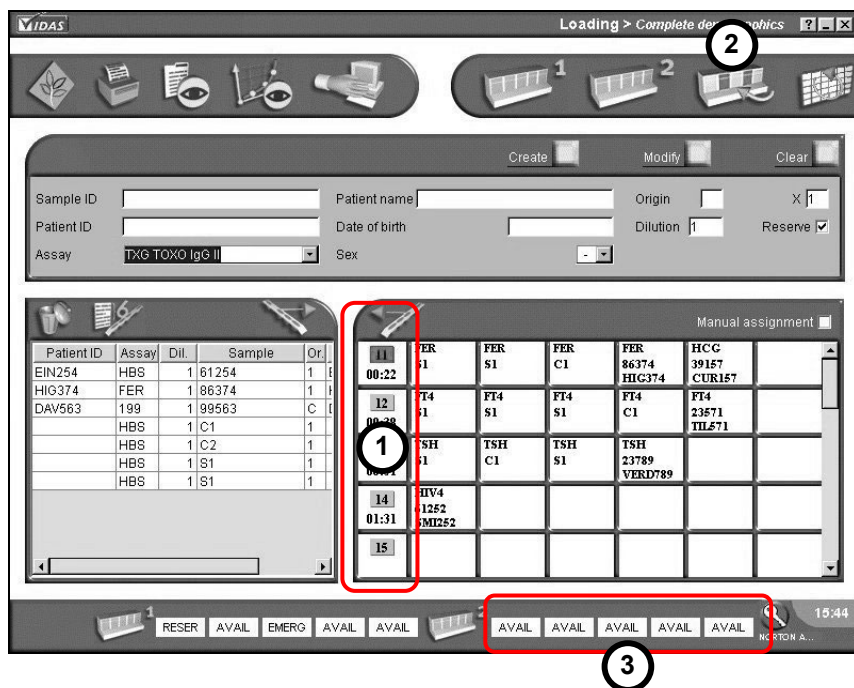
Fig. IV 11: Main reservation commands

Individual reservation

Individual reservation is performed section by section.

• Click on the predefined section number.

The number is displayed in red.

VIDAS PC automatically assigns a predefined section to an available section.

The status of one of the sections of the *VIDAS* which is still available changes to reserved in the status bar.

When all the sections of each *VIDAS* module are loaded, you can no longer reserve sections.

A warning message alerts you when the *VIDAS* module is full (or modules if there are several).
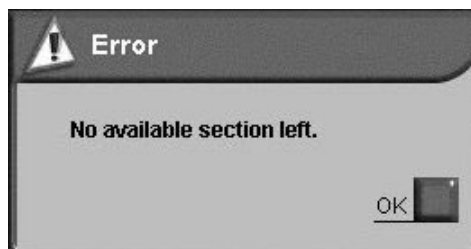
Grouped reservation

Grouped reservation is managed by *VIDAS PC*. This procedure enables you to load all the predefined sections into the available sections of each *VIDAS* module in numerical order (except the sections dedicated to emergencies "EMERG." (see "Emergencies" on page 4-35).
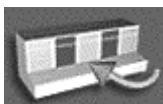
• Click on the "Reserve all" button.

Note: *Individual and grouped reservations take into account the assignment of assays by module (see the "Assay assignment" submenu on page 8-43).*

Manual reservation

To perform manual reservation, proceed as follows:

| AVAIL | / | EMERG |

- Click on an "AVAIL" or "EMERG." button corresponding to the desired section (the "Emergency" mode is described on page 4-35).

The "Section reservation" window appears.

1. **The section reservation window** displays the number of the *VIDAS* analytical module and the selected section.
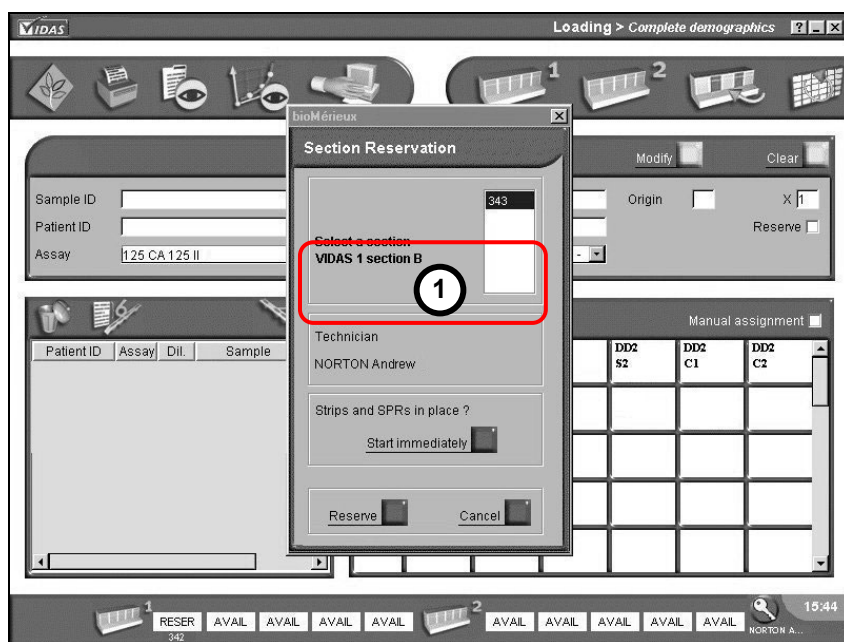
Fig. IV 12: Manual reservation window

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• In the "Section reservation" window, click on the number of the predefined section to be reserved.

Technician

NORTON Andrew

The technician's name is displayed.

Reserve

• Click on the "Reserve" button if you only want to reserve a section (the "Section reservation" window disappears).

RESER

The section status changes to "RESER",

or,

Start immediately

• Click on the "Start immediately" button if you want to reserve a section and run it immediately (the "Section reservation" window disappears).

Note: *Check that reagents and samples have been inserted before starting the assay.*

Printing

It is possible at any time to print information on assays and predefined sections.

• Click on the "Print" button.

The following window appears:
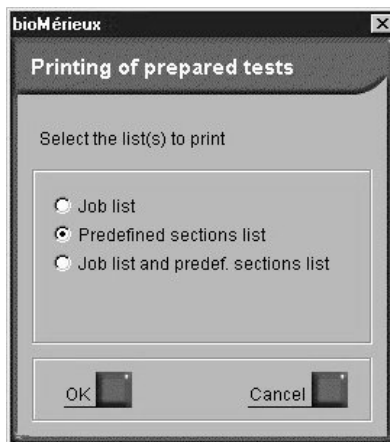
• Click on "Cancel" to close the window without printing,

or

• Select the option you want and click on "OK".

Note: *If you select "Job list and predef. sections list" the 2 reports are printed one after another.*

4

```
Pending VIDAS patients                    Pending patients tests on Aug 02 2005  13:56:19

Patient ID              Test        Dilution    Sample ID          Origin          Name
----------------        -------     ----------  --------------     --------        --------
MIL849                  RSV                     127848             C               MILLER
MOR564                  TXG                     123564             M               MORTON
                        TXG                     C2
                        TXG                     C1
                        TXG                     S1
                        TXG                     S1
Total number of pending assays : 6
```

Fig. IV 13: Job list report (example)

```
                                    Predefined sections

                                                              16 juil. 2005 18:55:23

Section     Position      Test      Dilution      Patient ID        Sample ID
----------  -----------   ------    ----------    ------------      -------------------
   107      1             RSV                     MIL849            127848
            2             TXG                     MOR564            123564
            3             TXG                                       C2
            4             TXG                                       C1
            5             TXG                                       S1
            6             TXG                                       S1


Section     Position      Test      Dilution      Patient ID        Sample ID
----------  -----------   ------    ----------    ------------      -------------------
   108      1             OPT                                       OPT
            2             OPT                                       OPT
```

Fig. IV 14 : Predefined sections list report (example)

Running assays

The assay is performed from start to finish by *VIDAS PC*.

Loading is made easier by the loading plan provided by *VIDAS PC*.

Loading plan

The following procedures were defined for one or two *VIDAS* modules.

You can access the *VIDAS PC* loading plan by clicking on one of the icons shown in the figure below.

1. **Loading plan**. These icons enable you to access the loading plan for module 1 or module 2 before the start up phase.
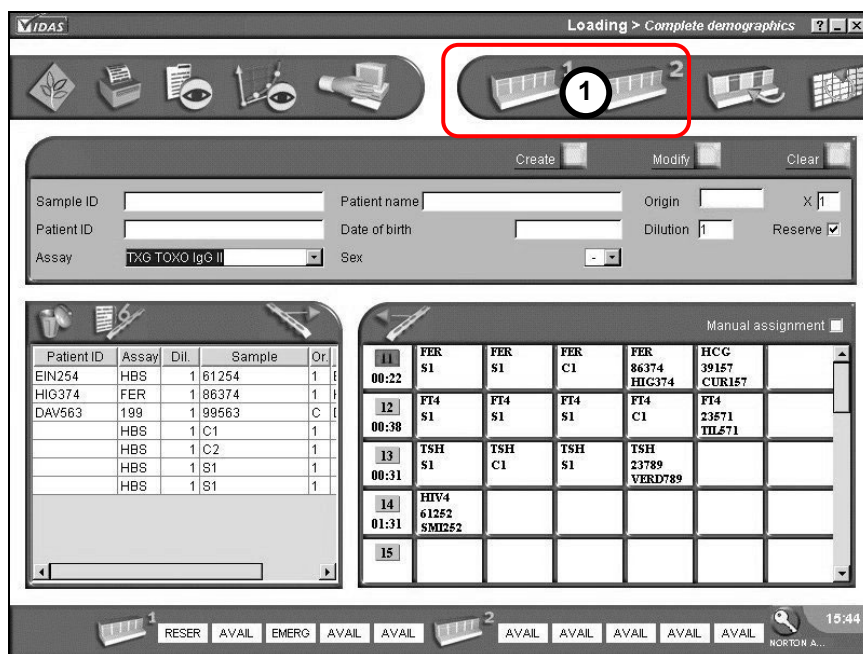
Fig. IV 15: Loading plan commands

Note: *If two **VIDAS** modules are used, assays can be assigned specifically to one or another of the modules (see "Assay assignment" page 8-43).*
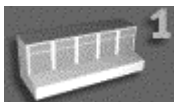
- Click on the "Access to loading plan" icon on the **VIDAS 1** module,

or
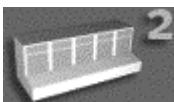
- Click on the "Access to loading plan" icon on the **VIDAS 2** module.

Note: *If only one **VIDAS** module is connected, the button giving access to the loading plan of the other module is disabled (blue).*

The loading plan window appears.

1. **Load help zone**. Enables you to find an assay which has been reserved or is being run, by searching for the patient ID or the sample ID.

2. **VIDAS module**. Indicates the **VIDAS** analytical module currently running.

3. **Number of predefined reserved section**. Displays the number of the predefined section that has been reserved.
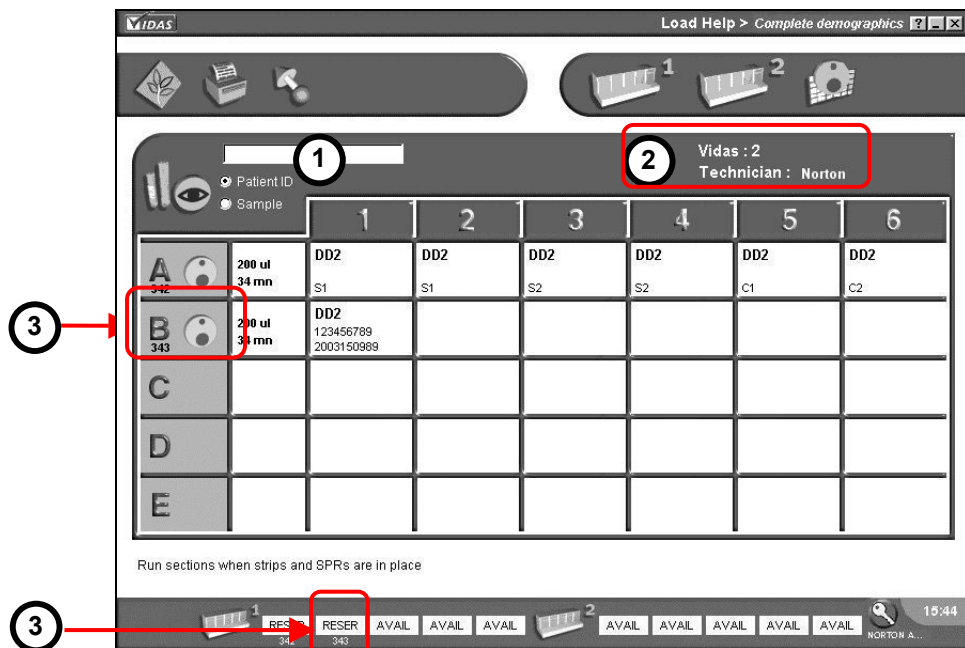
Fig. IV 16: Loading plan window

You can now view the loading plans of the *VIDAS 1* or *VIDAS 2* modules with their sections labeled A to E.
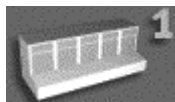
• In the *VIDAS 2* loading plan, click on the *VIDAS 1* icon (colored and enabled) to view the *VIDAS 1* loading plan.
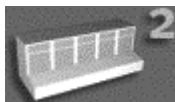
• In the *VIDAS 1* loading plan, click on the *VIDAS 2* icon (colored and enabled) to view the *VIDAS 2* loading plan.

You must then load each chosen section with the appropriate reagents and samples using the loading plans shown on the screen.

Load help screen

The load help screen (mark **1**) enables you to find an assay which has been reserved or is being run, by searching for the patient ID or the sample ID.

• Select the "Patient" or "Sample" option box.

• Enter the information manually or using the bar code reader. You must respect upper case and lower case characters.

• Press <TAB> to quit.
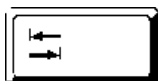
The corresponding section is automatically selected and displayed on the screen.

The "Run" icon is used to start a section.

The "Run all" icon is used to start all the reserved sections in the *VIDAS* module.

Printing
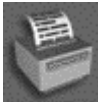
- To print the loading plan displayed on the screen, click on this icon.

```
                                    Loading report
VIDAS : 2   Technician : Robert                           Printed on Aug 02 2005 13:57:14
Section    Position    Assay     Dilution   Patient ID    Patient name              Sample
----------  ---------   --------  ----------  ------------  ------------------        ----------
A:497      1           HCG                                                            S1
           2           HCG                                                            S1
           3           HCG                                                            C1
           4           HCG                    MOR564        MORTON                    123564
           5
           6
B:498      1           HBS                                                            S1
           2           HBS                                                            S1
           3           HBS                                                            C1
           4           HBS                                                            C2
           5           HBS                    MIL251        MILLER                    659251
           6
C          1
           2
           3
           4
           5
           6
D          1
           2
           3
           4
           5
           6
E          1
           2
           3
           4
           5
           6
```

Fig. IV 17: Loading report (example)

Quitting the menu

- You can return to the loading menu at any time by clicking on this icon.

Running assays

There are three different ways to run assays:

- − at the time of reservation of a section (see "Manual reservation" on page 4-25).

- − using the individual mode,

- − using the complete mode.

Individual mode

In the loading plan,

- • click on the "Run" icon next to the desired section.

The icon disappears.

The status button of the section concerned switches from "RESER" to "VERIF".

04:07 PM   It then changes to "busy" (analysis end time is displayed).

Complete mode

In the loading plan,

- • click on the "Run all" icon to start all the reserved sections in the *VIDAS* module.

The "Run" icons of each section disappear.

The status button of all the sections of the *VIDAS* module switch from "RESER" to "VERIF".

If an error occurs on one of the sections run in complete mode, only the section with the error will be jammed. To correct the error:

- • Check what type of error has occurred (see the instructions on page 8-30, "Error window").

- • Reset the section to enable the assay to continue (see the instructions on page 8-28, "Resetting a section").

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Errors

The instrument and reagents are checked for errors. If an error occurs, the section concerned changes to red and displays the type of error.

Operating errors or errors occurring during analysis, are described in "Error window" on page 8-30 as well as in Chapter 12 "Troubleshooting".

Halting an assay

You can halt an assay that is being run in one or several sections. This procedure is described in the "Instrument" menu on page 8-28.

Emergencies

The "emergency" configuration consists in assigning one or several sections that remain at the user's disposal for use when one or several assays have to be run rapidly before the others.

A section assigned to emergencies can only be loaded manually.

How to assign sections to emergencies is described in "Assay assignment" on page 8-43. The aim of this operation is to enable you to use sections reserved for emergencies only in the case of manual reservation of a section. The complete and individual reservation modes will not affect sections reserved for emergencies.

A section assigned to emergencies is shown in the figure below (mark **1** - example of section C of the *VIDAS 1* module).

Fig. IV 18: Section assigned to emergencies

Reserving a section and running an assay

- Load the assays in predefined sections.

EMERG

- Click on the "EMERG" status button corresponding to the desired section.

The "Section Reservation" window appears.
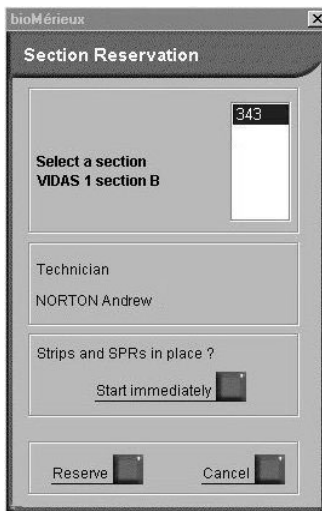
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- In the "Section Reservation" window, click on the number of the predefined section to be reserved.

Technician

NORTON Andrew

The technician's name is displayed.

Reserve

- Click on the "Reserve" button if you only want to reserve a section (the "Section Reservation" window disappears).

The section status changes to "RESER".

RESER

or,

Start immediately

- Click on the "Start immediately" button if you want to reserve a section and run it immediately (the "Section Reservation" window disappears).

Note: *Check that reagents and samples are in place before starting the assay.*

Modification - Deletion

Modification of an assay

The "Modification" function enables you to modify an assay in the job list or in a predefined section.

This function is shown in the following figure.

1. **Selection of an assay**. Assay selection zone: from the job list or a predefined section.

2. **Entry zone**. The assay data are displayed in the entry zone and can be modified.

3. **Modification**. Validation of the new entry.

Fig. IV 19: Modification of an assay

- Click on the assay to be modified in the job list or in a predefined section.

The assay appears in inverse video in the job list or on a blue background in the predefined section.

- The assay data are displayed in the entry zone and can be modified.

- Enter the new data.

- Click on the "Modify" button or press <F11> to validate the new entry.

If you try to modify information such as the patient's name or date of birth, the following dialog box will display.
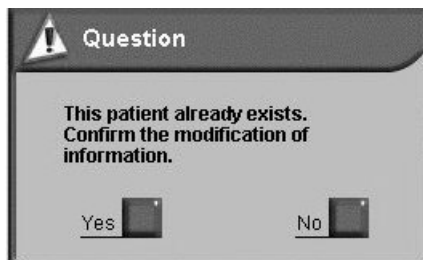
- Click "Yes" to confirm the modification.
- Click "No" to cancel.

Deletion

The "Deletion" function enables you to delete one or several assays in the job list or in a predefined section.

An assay in a predefined section cannot be deleted without first having been transferred to the job list.

1. **Transfer of assays to the job list**.

2. **Deletion**.
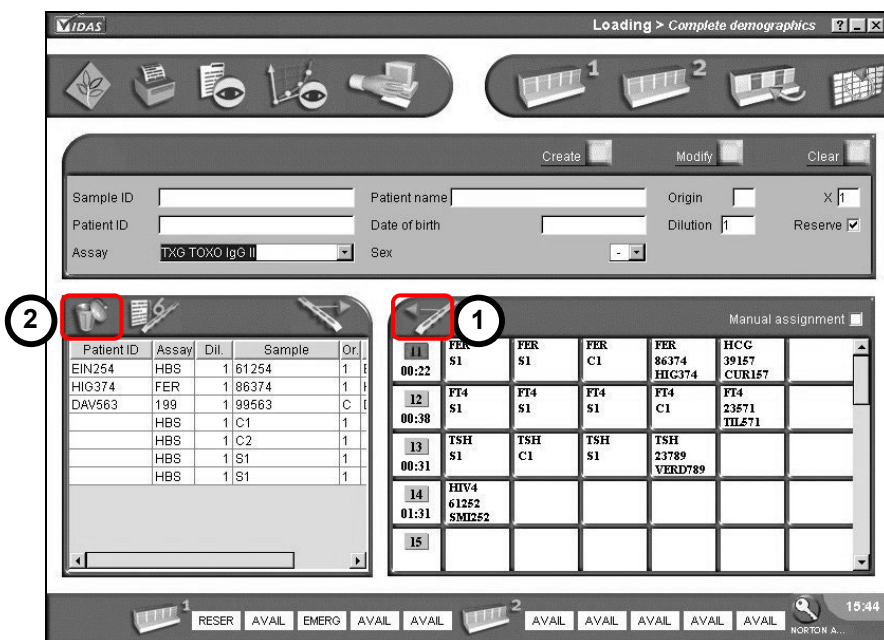
Fig. IV 20: Deletion of an assay

Deletion of an assay from the job list

- Select the assay you want to delete (it will appear in inverse video) and click on the "Delete" icon.

To delete a continuous list of assays:

- Click on the first assay and then on the last assay holding the "Shift" key pressed down. The list to be deleted appears in inverse video.

- Click on the "Delete" button.

To delete several assays:

- Click on the first assay and then on the other assays holding the "Ctrl" key pressed down. The selected assays appear in inverse video.

- Click on the "Delete" button.

Regardless of the deletion mode, a confirmation message is always displayed to enable you to confirm the deletion.
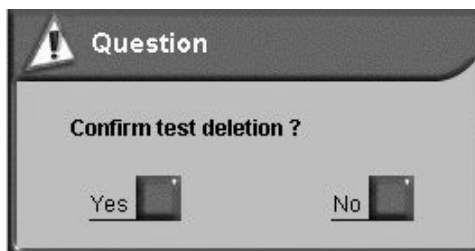
Deletion of an assay in a predefined section

Transferring an assay from a predefined section

- Select the assay to be transferred in the predefined section you want to modify (the assay appears on a blue background),

- Click on the "Transfer" button.

The assay disappears from the predefined section and returns to the top of the job list where it can now be deleted.

Transferring a predefined section

- Select the predefined section by clicking in the white background next to the predefined section button.

- Click on the "Transfer" button.

All the assays loaded in this predefined section are returned to the top of the job list and the predefined section is cancelled. The assays can now be deleted.

You can select several predefined sections and/or several assays simultaneously.

Halting an assay

You can halt an assay that is being run in one or several sections. This procedure is described in the "Instrument" menu on page 8-26.

5 Updating a VIDAS assay

Introduction

This chapter describes how to perform the **VIDAS** PTC (Protocol Test Change) update.

Purpose of the PTC update

This update enables you to transfer assay data to the *VIDAS* instrument when a new assay is used or when an existing assay is updated.

Updating

IMPORTANT!   *The update is stored in the VIDAS for further use of the assays*

Preliminary instructions

Note: *This update can only be performed by the laboratory administrator.*

- Before performing the update, make sure that:

    - no assays are running,

    - no reagents (strips and SPRs) remain in the strip sections and SPR blocks,

    - printing is not in progress,

    - the printer is turned on,

    - the bar code reader has been installed and configured.
      If not, see Chapter 4 in the *VIDAS* Instrument User's Manual and follow the installation instructions,

    - the reagent kit package insert is in good condition; to be readable the bar codes must be complete, unstained, and untorn.
      If they are not, call bioMérieux[®] Technical Assistance or your local bioMérieux representative.

  Once you have checked all these points,

- Open a *VIDAS PC* session using a user name and password belonging to the "VIDAS_ADMIN" group.

Reading PTC update cards

The PTC update cards are printed at the back of the assay package insert.

To read the PTC update cards:

From the main screen,

- click on the navigation tree,

- select the "Configuration" menu.

The "Configuration" menu window is displayed.

1. Select the "Assay Activation" function.

2. The assays are displayed on the screen.

3. Click on the PTC card reading button.
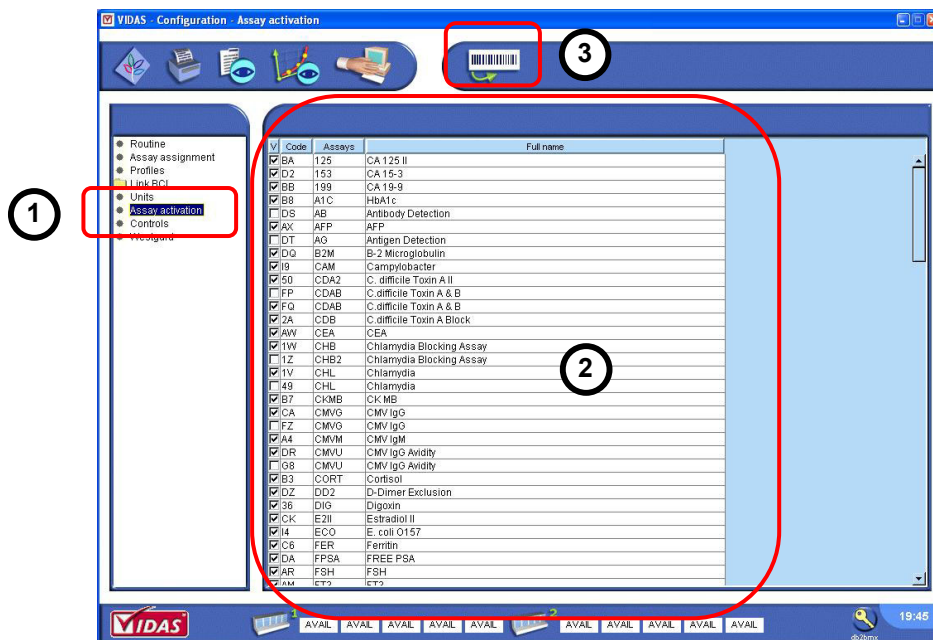
Fig. V 1 : "Assay activation" function

The update cards reading screen is displayed. It is divided into two parts:

1. **Reading status**. Describes the status of the current reading.

2. **Reading instructions:** follow these instructions as they appear during the update procedure.
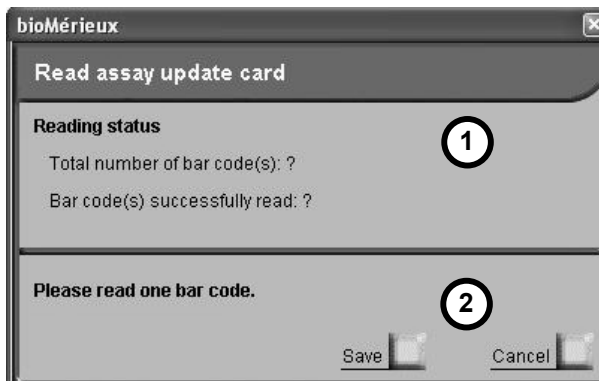
Fig. V 2 : Assay update card reading screen

- Take the page in the package insert that includes the bar codes (back of the package insert).

- Read the first bar code using the reader: slowly scan the bar code from top to bottom and from bottom to top until the code has been read completely. The reader emits a beep and a green LED lights up when reading is finished.
  For further information, see section "Recommendation for use of the bar code reader" in Chapter 3.

Fig. V 3 : Examples of bar codes

- Wait for a few moments to allow data to transfer.

Note: *The first reading may take a while as you need to become familiar with the use of the reader. Continue until reading is sucessful.*

When reading is performed correctly, the reading screen is updated. It shows:

1. The total number of bar codes to be read and the number of the code already read.

Note: *If the codes are not read in numerical order, the software indicates the number(s) of the missing bar code(s) which need to be read to complete the update.*

2. The number of the bar code(s) still to be read to complete the update.
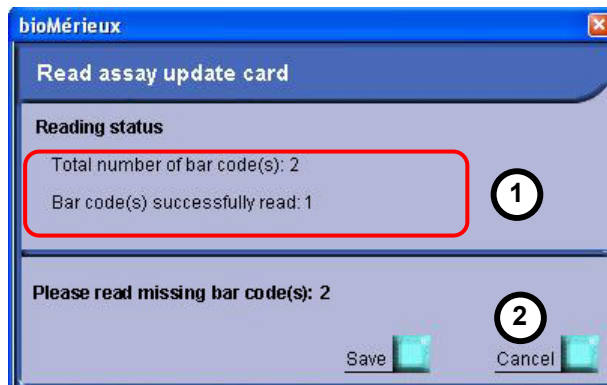
Fig. V 4 : Status after reading of the first bar code (example)

- If necessary, read the following bar code(s) using the bar code reader.

- Wait for a few moments to allow transfer of the data.

- Repeat the reading and waiting steps until all the codes required to update the protocol have been read.

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Bar code reading may fail if

- The code was not correctly read by the reader.

- The code is unreadable (incomplete, stained, or torn).

- The code read does not belong to the series of codes for the current update. You should only read codes belonging to the same series. If code reading fails, the following message is displayed :

- Click on "OK".

- Solve the problems described in the above message.

- Repeat the bar code reading.

When reading is complete, the reading screen summarizes the status of the update.
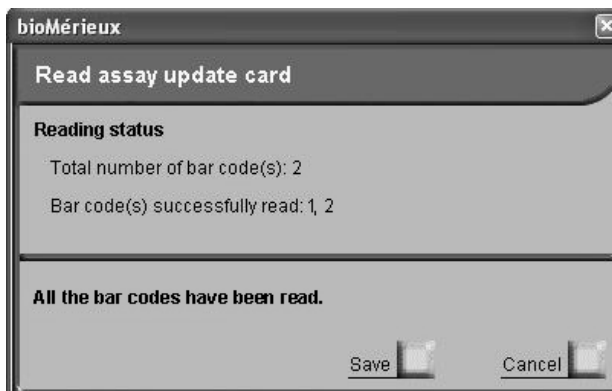
Fig. V 5 : Status after reading of the last bar code (example)

- Click "Save" to save the update.

- Wait a few moments for the data to be saved.

An assay update report is printed. It contains the information about the assay update.

```
                     Assay update report

Completed: Printed on: Aug 29 2005  12:19:23

Short assay name : TXG
Unique assay code : FK
Full name : TOXO IgG IV
Assay version : 1
Update card version : 1

Units :
      1. UI/ml
      2. IU/ml

Low detection limit: 0
High detection limit: 300

Messages and interpretation thresholds:
      Refer to the package insert

Please keep this report. Communicate data to your LIS
Administrator


Page 1/1
```

Fig. V 6 : Assay update report (example)

The following message is displayed to confirm that the update was performed sucessfully.
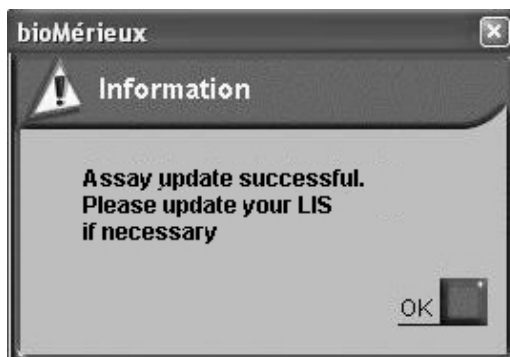
- Keep the update report.

- Inform the LIS of the update (if this service is used by the laboratory).

The protocol can now be used for the analyses.

Note: *If a user repeats a protocol update, it will not have any effect on the initial update.*

6   Calibration

Introduction

This chapter deals with the calibration and recalibration of the *VIDAS*.

Calibration / recalibration

Calibration of the **VIDAS** reagents is performed at the factory.

Recalibration is performed upon receipt of a new lot of reagents and then every 14 days. This operation enables the master lot curve or the initial reference parameters to be readjusted.

If the configuration used includes two **VIDAS** modules, the calibration will apply to one single **VIDAS** module (calibration of the **VIDAS 1** module will not be applied to the **VIDAS 2** module).

The calibration and recalibrations for a same lot are all stored in the **VIDAS** memory.

The following are required to perform calibration and recalibrations on the **VIDAS**:

–   the MLE (Master Lot Entry) card,

–   one or several calibrators (replicates or standards) called **S1** and **S2**,

–   the control(s) identified by **C1**, **C2** and **C3**.

VIDAS PC can store up to 4 calibrations for a particular lot and a particular assay. Only the last calibration is used.

IMPORTANT!   *Controls must be systematically performed at the time of recalibration.*

Calibrators

Calibrator(s) are reagent bottles provided with each reagent lot.

They are identified by *VIDAS PC* as **S1** and/or **S2**.
This identification is indicated on each bottle.

6

The calibrator must be tested in single, duplicate or triplicate (depending on the procedure) upon receipt of a new lot of reagents, and then every 14 days. It must be dispensed in the sample well (same volume as the sample).

A single RFV or the mean RFV of the calibrator duplicates or triplicates is stored in memory and is printed on each result sheet. This value is used for the calculation of results.

For certain assays, calibration is not required. The controls are recommended to check that the kit is intact.

How to calibrate

For each new lot:

- Enter the MLE card data (see page 6-9).

- Run the calibrator in single, duplicate or triplicate (according to the procedure).

Note: *In the Loading menu, the calibrators should be grouped together, but not necessarily in a new section.*

The controls included in the kit must be performed at the same time as they enable verification of the calibration accuracy.

Every 14 days,

- Rerun the standard(s) and controls included in the kit.

The *VIDAS* automatically checks the standard and control values ; this verification validates the calibration.

Obtaining the master lot curve

The principle consists of determining the mathematical equation which represents the calibration curve, i.e. the relationship between the RFV and the concentration of the standards.

Well-defined reference solutions (standards) are used to make this determination. The calibration curve is established using 5 to 11 standards. It is valid between zero and the standard with the highest titer.

Three mathematical models can be used to establish the master lot curve:

1. 4 logistic parameters or Rodbard model

$$RFV = \frac{a1 - a4}{1 + (c / a3)\, a2} + a4$$

2. polynomial

$$\ln (c) = a1 + a2\ RFV + a3\ RFV2 + a4\ RFV3$$

3. semi-log

$$RFV = a1 + a2\ \ln(c)$$

c, represents the concentration

a1, a2, a3, a4 are the mathematical parameters of the model. They are recalculated for each calibration.

6

For the *VIDAS*, calibration is performed during the production of each new lot of SPR®s and reagents. Each lot is associated with a particular mathematical model.

To determine the master curve, the standards are tested in seven different runs on the same *VIDAS* instrument.
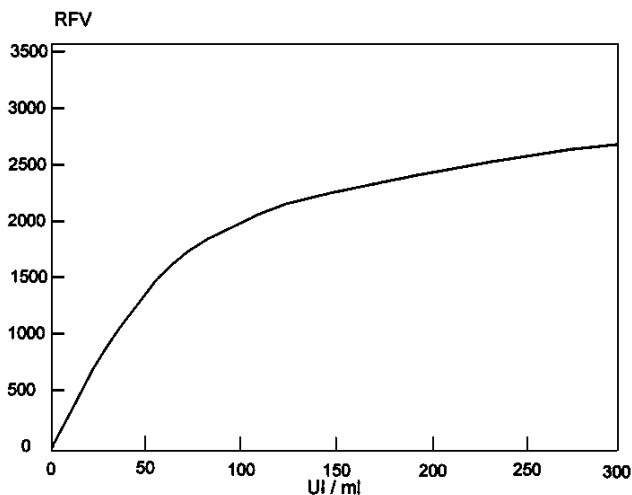
Fig. VI 1: Master curve

The mean curve of these seven runs becomes the master curve. The master curve is specific for a certain manufacturing lot and biological parameter.

Establishing the Master Curve

Each kit includes the Master Curve in the form of bar codes containing the following information:

– Several RFV levels, corresponding to several standards (generally 4) defined in the software. The master curve is restored using several points; mathematically, this is sufficient in all cases. The levels of concentration of these standards are known to the **VIDAS PC** software and are specific for each assay.

For instance, for FER, Std1 = 5, Std2 = 150, Std3 = 500, Std4 = 1200 ng / ml.

The **VIDAS PC** software calculates the total curve from the concentrations and RFV.

In case of dual calibration, two master curves are obtained for a same test.
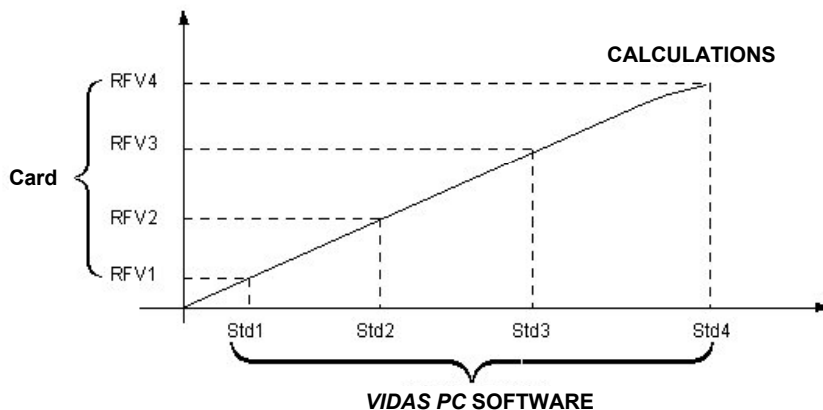
Fig. VI 2: Establishing the master curve

6

Recalibration

Recalibration consists of establishing a calibration curve from a reference curve and a standard. The reference curve is the master curve used to calibrate reagent lots.

Before use, it must be readjusted to compensate for any minor variations in assay signal between the *VIDAS* modules and any possible alteration of the reagent kit.

This readjustment is called recalibration. It brings into play the factory master curve and the calibrator RFV level.
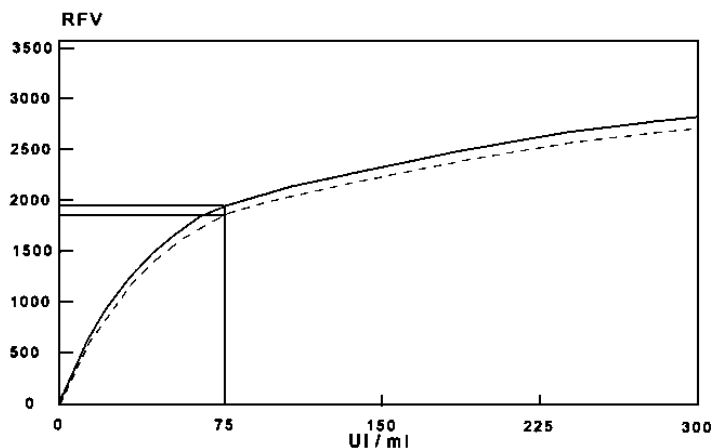
Fig. VI 3:Recalibration of the master curve

Recalibration is valid for 14 days, after which, the software requests another calibration (reading of the standard). To avoid any deviation, the master lot curve is the one set in the factory and not the last curve readjusted. The software can perfectly manage simultaneous use of several master curves corresponding to different lots.

A CV% for each duplicate or triplicate is calculated to ensure coherence of the recalibration.

Controls

Controls are included in each reagent kit.

They must be performed immediately after opening a new kit to ensure that reagent performance has not been altered.

Up to 3 controls (C1, C2 and C3) can be run together with the calibrators S1 and S2 every 14 days to validate the calibration.

In general, the positive control is identified by **C1** and the negative control by **C2** (for qualitative assays only).
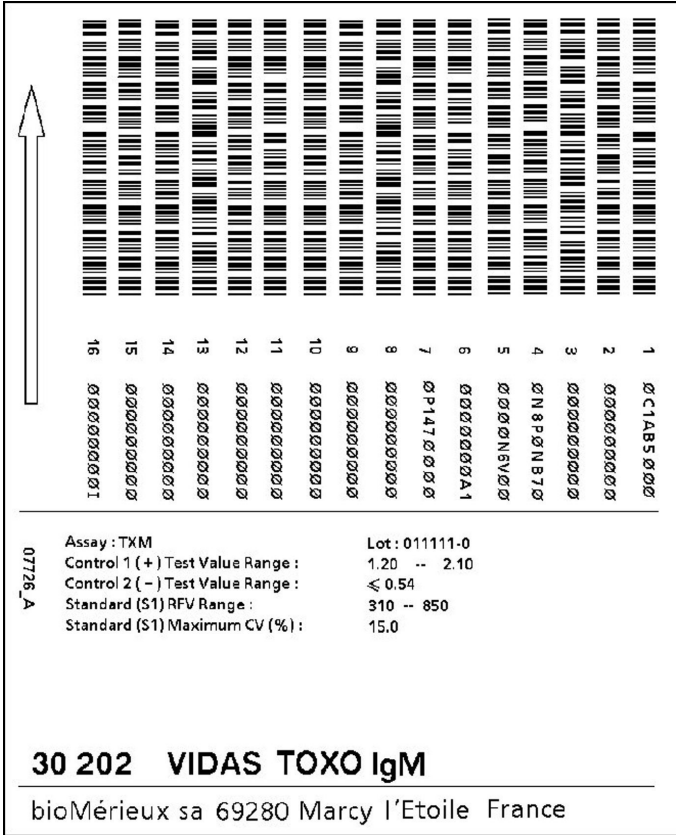
The identification of the calibrator(s) and controls is indicated on each bottle.

MLE card (Master Lot Entry) or specifications sheet

The MLE card contains all the information required to perform calibration, as well as data which enables the reagents' shelf life to be checked.

Presentation

6

The MLE cards are shown in the figures below.

Assay : TXM   Lot : 011111-0
Control 1 (+) Test Value Range :   1.20 -- 2.10
Control 2 (−) Test Value Range :   ≤ 0.54
Standard (S1) RFV Range :   310 -- 850
Standard (S1) Maximum CV (%) :   15.0

30 202   VIDAS TOXO IgM

bioMérieux sa 69280 Marcy l'Etoile France

Fig. VI 4: MLE card (qualitative assays)

Fig. VI 5: MLE card (quantitative assays)

Composition

The MLE card is specific for an assay and a reagent lot and includes:

− For qualitative assays,

- − assay code *(Assay),*

- − reagent lot number *(Lot)*,

- − range values for the calibrator RFV (fluorescence) *Standard RFV Range*,

- − range values for the controls included in the kit (*Control Test Value Range*),

- − maximum variation coefficient of the calibrator RFV duplicates or triplicates (*Standard Maximum CV (%)*).

− For quantitative assays,

- − assay code *(Assay)*,

- − reagent lot number (*Lot*),

- − RFV values corresponding to calibrators defined in the software and enabling the master curve to be restored *(Standard RFV Values)*,

- − the calculation method used to plot the master curve (*Calibration method*),

- − concentration level of the calibrator (this level, which can vary slightly from one lot to another, is essential for the calculation of the correction factor), (*Calibration Dose Value*),

- − range values of the control(s) included in the reagent kit (*Control Dose Value Range*),

- − range values for the calibrator RFV (fluorescence) (*Calibrator RFV Range*),

- − maximum variation coefficient of the calibrator RFV duplicates or triplicates (*CV (%)*).

− For dual reagent strips (without calibrator),

- − assay code (*Assay*),

- − reagent lot number (*Lot*),

- − range values for the control(s) included in the reagent kit (*Control Dose Value Range*).

"Calibrations" menu

In the main window, or another window,

- click on the "Calibrations" icon,

or,

in the main window,

- click on the navigation tree and then,

- select the "Calibrations" menu,

or,
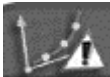
- click on the flashing icon which indicates an expired calibration.

Note: *This command selects the display mode for expired calibrations.*

The calibrations window shows the different operating commands for the "Calibrations" menu and enables you to view the status of calibrations stored in each *VIDAS* module.

1. **Deletion of stored calibrations**. See Deleting calibrations on page 6-24.

2. **Recalibration of expired calibrations**. See Calibrations to do on page 6-18.

3. **Entry of MLE card data**. Gives access to the menu for entry of the MLE card data (see Entry of MLE on page 6-14).

4. **Display of calibrations**. Three groups of calibrations can be viewed (see Displaying Calibrations on page 6-18) :

− expired calibrations displayed as "To do",

− valid calibrations,

− all calibrations.

5. **List of calibrations.** This table can be selected using the display mode buttons.

Fig. VI 6: Calibrations window (example)

Entry of MLE card data

MLE card data can be entered in three different ways:

− automatically by the *VIDAS*,

− manually,

− using a hand-held bar code reader.

Automatic reading by the *VIDAS* analyzer

In the calibrations menu,

• Click on the "MLE card entry" button.

The "Read MLE card " window in Fig. VI 7appears.
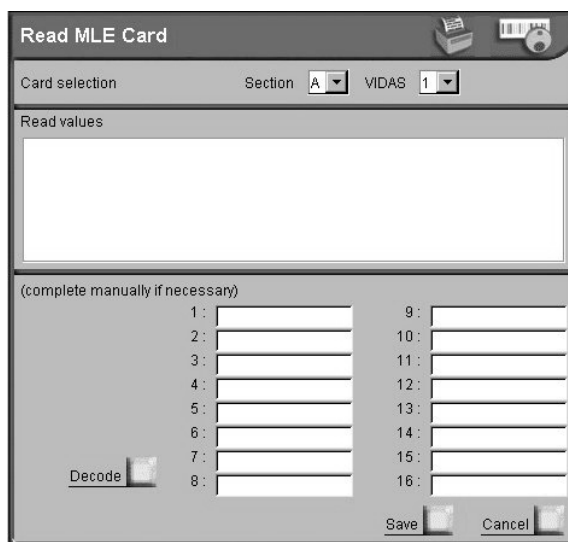
Fig. VI 7: Read MLE card window

6

- In the "Selection" zone, select the **VIDAS** into which the MLE card will be inserted (**VIDAS 1** or **VIDAS 2**).

Note: *If two **VIDAS** modules are connected, the MLE card can be read by either one of the modules regardless of the module to which the assay has been assigned.*

- In the "Section" pull-down menu, select the section of the module into which the MLE card will be inserted (A to E).

- Click on the "Reading" button after having placed the MLE card in the card stand of the **VIDAS** module section.

If the result of the reading is correct, all the MLE card data will be displayed in the "Read values" zone (see Fig. VI 7).

- Check that this master lot data corresponds to that of the MLE card.

- Click on "Save" to save the MLE card data, before returning to the "Calibrations" menu. The MLE card data are then automatically printed.

The calibration will be displayed in the expired calibrations window.

or

- Click on "Cancel" to stop entry of MLE card data and return to the "Calibrations" menu. The MLE card data will not be saved.

If the result of the reading is not correct, an error message will inform you that the **VIDAS** was not able to read and interpret the MLE card data.

In this case, you must either enter the missing data manually, or reperform automatic reading of the MLE card data.

If an incorrect value is entered, **VIDAS PC** will delete the content of the entry zone concerned and the corresponding alphanumeric code will have to be entered manually.

CAUTION! *"O" and "I" are letters.*
"Ø" and "1" are the digits zero and one.

Manual entry or entry using the bar code reader

Manual entry of the MLE card data, or entry using the bar code reader is performed if:

−   the **VIDAS** cannot read the MLE card,

−   none of the **VIDAS** sections are available.

In the calibrations menu,

•   Click on the "MLE card entry" button.

The "Read MLE card " window in Fig. VI 7appears.

•   Enter the MLE card bar code data manually (data numbered from 1 to 16).

CAUTION!   *With manual entry of the MLE card there is a risk of error. Make sure that you enter the lines in exactly the same order as they appear on the MLE card. Letters should be typed in upper case.*

•   Click on "Decode" to display the data entered manually.

•   Make sure that the data displayed on the screen correspond exactly to the data printed on your MLE card.

If data entry is not correct, an error message will inform you that the **VIDAS** was not able to read it. You will then have to reenter the data. If the data is still not correct, **VIDAS PC** will delete the content of the entry zone concerned.

Once they have been decoded,

•   Click on "Save" to save the MLE card data. MLE card data will then be automatically printed.

The calibration will be displayed in the calibrations to do window.

or

•   click on "Cancel" to stop entry of the MLE card and return to the "Calibrations" menu.

Printing

Data on the MLE card are automatically printed when you save them; nevertheless, they can be printed manually.

In the MLE card reading window (see Fig. VI 7), before saving the data,

- click on "Print" to print the MLE card data displayed on the screen.

MLE Card Data

Printed on Aug 02 2004   14:08:01

Strip lot : 050509-1
Assay : TXG
Standard RFV Values : 448, 1869, 3183, 3852
Calibration Method : 7
Calibrator (S1) Dose Value : 70.00 UI/ml
Control C1 Dose Value Range   : 25.00 - 40.00 UI/ml
Control C2 Dose Value Range   : <= 7.00 UI/ml
Calibrator (S1) RFV Range : 1350 - 2900 Max CV % :   15.0

1 : 0C8G9B0DV	9 : 000000000
2 : 1HC2HU30F	10 : 000000000
3 : 705EG0000	11 : 000000000
4 : 0P2T0Q8H0	12 : 000000000
5 : 0000NOT00	13 : 000000000
6 : 00000012X	14 : 000000000
7 : 29Z470000	15 : 000000000
8 : 000000000	16 : 00000000A

Fig. VI 8: MLE Card report (example)

Displaying Calibrations

Calibrations to do
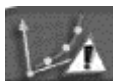
The list of calibrations to be done can be accessed in two different ways:

- In the "Calibration" menu, click on the "Calibrations to do" button.

or
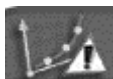
- In any menu, click on the flashing "Expired calibrations" icon if it appears (to the left of the status bar at the bottom of the screen).

The following window appears.
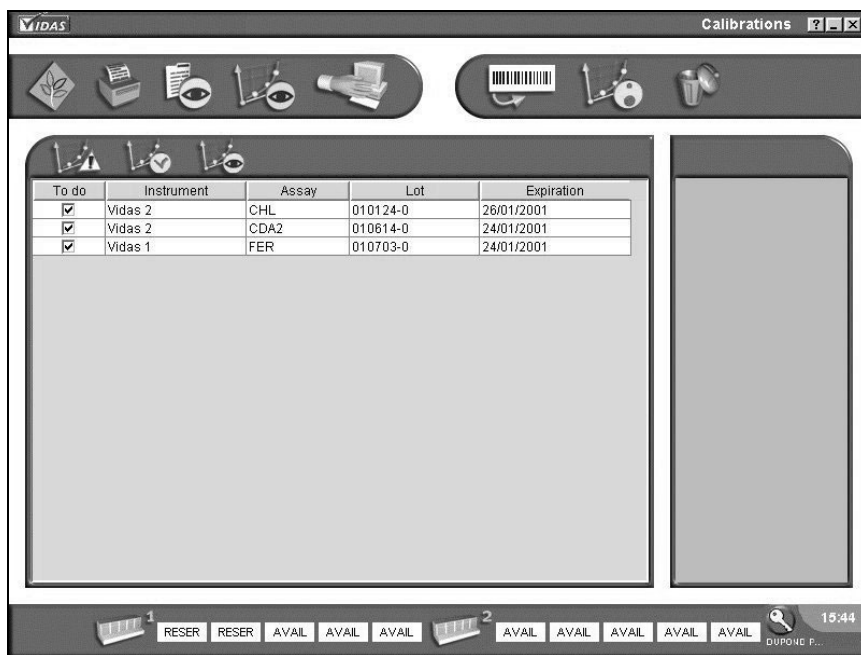
Fig. VI 9: "Calibrations to do" window

6

The data displayed for calibrations to be done are the following:

–   the "To do" box which you have to select if you want to recalibrate the lot for which the calibration has expired,

–   the *VIDAS* module in which the calibration takes place,

–   the assay code,

–   the lot number,

–   the calibration expiration date.

Note: *This menu displays the tests for which only the MLE card has been read. In this case, only the assay code and lot number are displayed.*
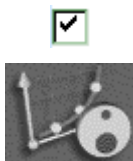
☑   The "To do" box is deselected by default for each of the calibrations to be done.

•   Select the test(s) to be recalibrated.

•   Click on the "Recalibration" icon.

All the necessary standards/calibrators and controls are automatically created in a predefined section if the "RESERVE" check box is enabled. If not, they are created in the job list.

Note: *The "Delete"* icon *enables one or more expired calibrations to be deleted (See Deleting calibrations on page 6-24).*

VIDAS PC disabled the deleted calibrations. On the "All Calibrations" screen their status is "Archived" and they can no longer be used. All the associated results are stored.

Current calibrations

• In the "Calibrations" menu, click on the "Valid calibrations" button.

The list of valid calibrations appears in a table and includes all currently valid calibrations.

Instrument	Assay	Status	Lot	Date	Time	Expiration	Conf.	S1 RFV	S2
Vidas 1	HBCT	Valid	010228-0	07/27/2000	16:56 PM	08/10/2000	No	712	
Vidas 1	CKMB	Valid	000629-1	07/26/2000	15:03 PM	08/09/2000	Yes	425	
Vidas 1	ST	Valid	010123-0	07/26/2000	14:49 PM	08/09/2000	Yes	1175	
Vidas 1	CMVG	Valid	010117-1	07/27/2000	16:33 PM	08/10/2000	Yes	2425	
Vidas 1	HAVT	Valid	010503-0	07/23/2000	15:03 PM	08/06/2000	Yes	2900	
Vidas 1	RBG	Valid	000813-1	07/26/2000	14:23 PM	08/09/2000	Yes	2450	
Vidas 1	153	Valid	000607-0	07/26/2000	12:13 PM	08/09/2000	Yes	2225	
Vidas 1	FPSA	Valid	010413-0	07/26/2000	16:09 PM	08/09/2000	Yes	3900	
Vidas 1	TES	Valid	010113-0	07/26/2000	14:09 PM	08/09/2000	Yes	1625	
Vidas 1	P24	Valid	001005-0	07/26/2000	09:22 AM	08/09/2000	Yes	900	
Vidas 1	TNI	Valid	010321-0	07/26/2000	14:04 PM	08/09/2000	Yes	2725	
Vidas 1	CAM	Valid	000707-0	07/28/2000	14:43 PM	08/11/2000	Yes	2400	

Curve 1
CMV IgG
Conf. : Yes
Mean S1:2425

RFV S1:2400
RFV S1:2450

RFV
3793
2528
1264
100 200 300
UA/ml

RESER RESER EMERG AVAIL AVAIL AVAIL AVAIL AVAIL AVAIL ERRINST
NORTON A...
15:44

Fig. VI 10: "Valid calibrations" window

The table includes the following information:

– the **VIDAS** module in which the calibration takes place,

– the assay code,

– the status of the calibration,

IMPORTANT! ***The calibration status can either be, VALID if calibration was performed <u>less than 14 days ago</u>, or INITIALIZED for assays using dual reagent strips, as they do not require a standard.***

6

– the lot number,

– the date on which the current calibration took place,

– the time at which the current calibration took place,

– the expiration date of the current calibration,

– the conformity of the current calibration,

Note: *A calibration is said to be "conform" if it was performed according to the specific recommendations of bioMérieux® (see the package insert for each assay).*

– the mean RFV of the standard(s).

Each calibration can be selected to obtain further information or for deletion (see Deleting calibrations on page 6-24).

The following window shows the type of data obtained after selecting a calibration.

1. **Select a calibration**. Click on the calibration you want to select (the selection is displayed in inverse video).

2. **Calibration details**. Including:

- the type of standard used,

- the full name of the assay,

- the conformity of the calibration to procedures established by bioMérieux®,

- the mean fluorescence value (or RFV) of the calibrator duplicates or triplicates,

- the standard RFV values,

- the calibration curve and the recalibration point reported on the curve.

Note: *The fluorescence curve only exists for quantitative assays. Certain assays can have two calibration curves.*
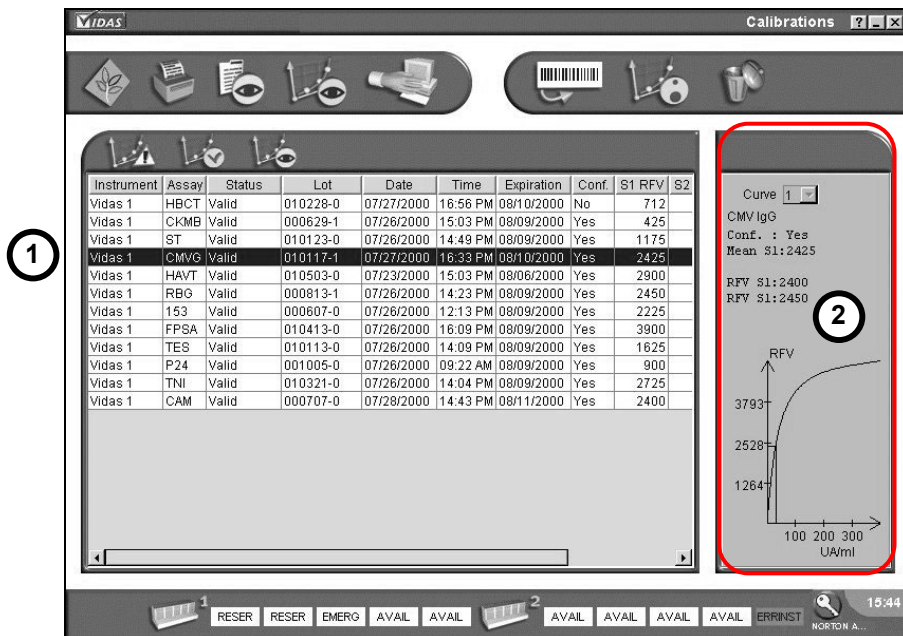
Fig. VI 11: Calibration details

All calibrations (valid and expired)

- In the "Calibrations" menu, click on the "All calibrations" button.

The "All calibrations" table includes the list of current and expired calibrations.

You can obtain additional information for each of the calibrations listed in the table.

The *VIDAS PC* software stores in this table, the current calibration and the last three calibrations used for a same lot (valid or expired).

6

Deleting calibrations

To delete a calibration,

- Select one or more valid or expired calibrations.

- Click on the "Delete" icon. A confirmation message will enable you to validate the deletion command.
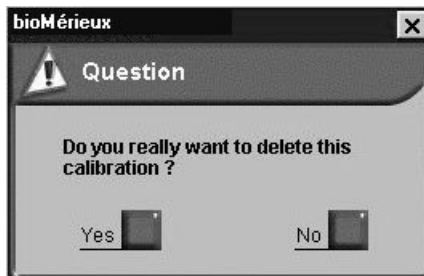
- Click on "Yes".

The calibrations selected are deleted from the list.

Note: *For certain assays that use the same type of strip (eg: HBE, HBET), it is not possible to delete one calibration without deleting the other.*

The following dialog box displays when one of these two calibrations is valid.
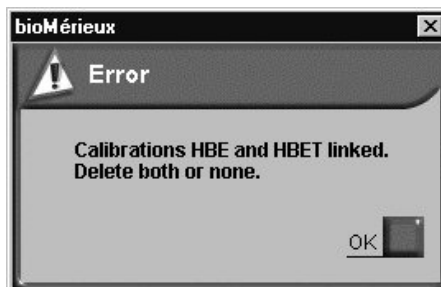
Other recalibration methods

First method :

If the assay requested has not been calibrated or if it has no valid calibration, **VIDAS PC** automatically creates the calibrators and controls required and records them in a predefined section if the "RESERVE" box is selected, or to the job list if the "RESERVE" box is not selected.

Second method:

In the "Loading" menu, you can perform a calibration regardless of the current validity.

Sample ID ⬛

- In the "Sample ID" entry zone, enter the letter "S",

Assay TXM TOXO IgM ▾

- In the pull-down assay list, enter the assay to be recalibrated,

Create

- Click on the "Create" button " or press <F10> (keyboard shortcut).
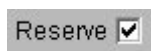
Reserve ☑

VIDAS PC automatically creates the necessary calibrators and controls and records them in a predefined section if the "RESERVE" box is selected, or to the job list if the "RESERVE" box is not selected.

7   Results

Introduction

This chapter describes the "Results" menu.

Calculating results

Qualitative assays

The result of a qualitative assay is determined by comparing the test value to one or two preprogrammed thresholds. This test value is calculated in relation to the calibrator which is retested every 14 days.

Depending on the test value after comparison to the thresholds, the result is considered to be:

− negative,

− positive,

− equivocal …

There are two different types of configurations for qualitative assays:

− single reagent strips,

− dual reagent strips.

Quantitative assays

Reading of the MLE card data enables a master curve to be determined.

This master curve must be adjusted using a calibrator each time a new lot of reagents is used and then every 14 days.

At the end of an assay, the fluorescence value of the sample is recorded on the stored calibration curve for each assay and each lot.

This fluorescence (or RFV) is interpreted as a concentration. The result is given in the unit chosen by the user (see "Units" on page 8-46).

Serologic tests are interpreted in comparison with thresholds stored in the memory.

Results menu

The results menu enables you to display and run the assay results stored in the *VIDAS* memory.

To get to this menu,

In the main window, or in any other window,

- click on the "Results" icon,

or,

In the main window,

- click on the navigation tree and,

- select the "Results" menu.

7

The following window appears.
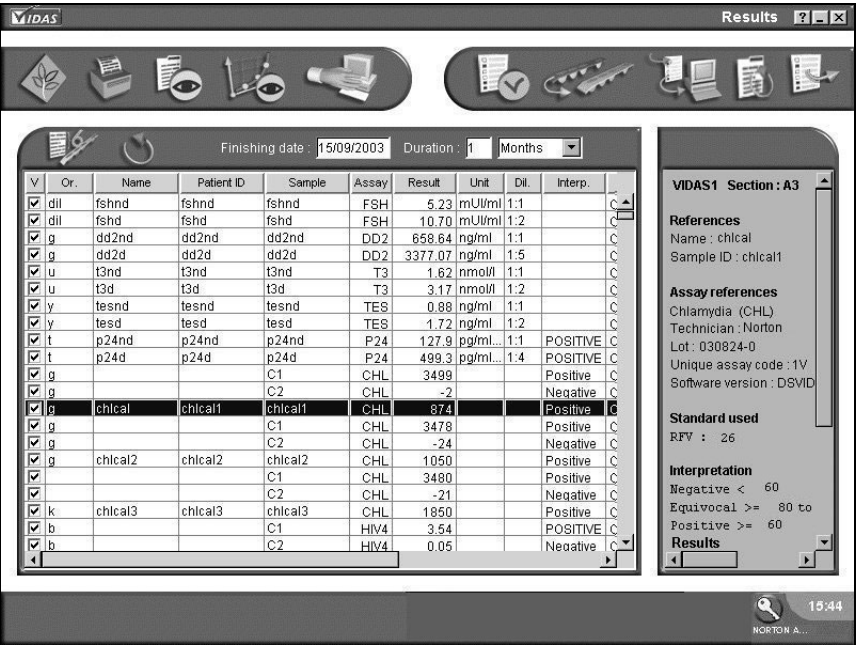
Fig. VII 1: "Results" menu window

"Results" menu commands

Finishing date	Date on which the search ends.
Duration	Search period in days, weeks or months for which you want to display results.

Refreshes the lists of assay results.

Selects all the assay results for one run (one single section or several sections if they have not been run in complete mode) after previous selection of an assay.

Validates and transmits the selected result(s) to the Laboratory Information System (LIS).
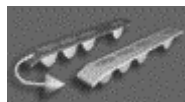
Reloads selected assays in the job list to enable them to be reanalyzed.

Retransmits selected assay results to the LIS (in case the first transmission failed).

Recalculates an assay result using the calibration defined by the user as reference.

Prints the results of the search.

This function is used to export selected results (see Exporting results on page 7-10).

Details of a result

V	Or.	Name	Patient ID	Sample	Assay	Result	Unit	Dil.	Interp.	
☑	dil	fshnd	fshnd	fshnd	FSH	5.23	mUI/ml	1:1		C
☑	dil	fshd	fshd	fshd	FSH	10.70	mUI/ml	1:2		C
☑	g	dd2nd	dd2nd	dd2nd	DD2	658.64	ng/ml	1:1		C
☑	g	dd2d	dd2d	dd2d	DD2	3377.07	ng/ml	1:5		C
☑	u	t3nd	t3nd	t3nd	T3	1.62	nmol/l	1:1		C
☑	u	t3d	t3d	t3d	T3	3.17	nmol/l	1:2		C
☑	y	tesnd	tesnd	tesnd	TES	0.88	ng/ml	1:1		C
☑	y	tesd	tesd	tesd	TES	1.72	ng/ml	1:2		C

Fig. VII 2: Example of results

Assay results listed in the "RESULTS" menu contain the following:

−   the validation check box (*V*),

−   the origin *(Or.)*,

−   the patient name *(Name)*,

−   the patient ID or specimen (*Patient ID*),
    With the "Industrial context" mode, the specimen appears in both the *Patient ID* and the *Name* columns.

−   the sample name *(Sample)*,

−   the assay code (*Assay*),

−   the result (*Result*):

    −   quantitative assay: the value indicated corresponds to a concentration. It is obtained by recording the sample RFV on the calibration curve stored in the memory for each assay and each lot.

    −   qualitative assay: the value indicated corresponds to a test value (TV). Please refer to the package insert for the calculation method.

$$TV = \frac{\text{Sample RFV}}{\text{Calibration RFV}} \quad \text{or TV = Sample RFV} - \text{Calibration RFV}$$

Note: *If an assay is run using dual reagent strips, the calibrator RFV corresponds to the RFV of the reference strip.*

−   result unit (for an assay) depending on the selected configuration (*Unit*),

−   the dilution rate of the sample (*Dil.*) (for a quantitative assay),

−   the interpretation (*Interp.*) (for a qualitative assay and a quantitative serologic assay),

−   status of the calibration and controls used for the lot (*Status*),
    This status indicates any problems relating to the standards or controls (out of range, not run etc.).

−   the date and time of completion of an assay (*Date*),

−   the section number (*Section Nr.*),

−   the position of the test in the section (**VIDAS** 1 or 2, section A to E, position 1 to 6) (*Position*).

IMPORTANT! *The results of the reagent for checking pipette mechanisms are not displayed on the screen. To analyze the results of the reagent for checking pipette mechanisms, you must refer to the printed report and the package insert included in the reagent kit, which indicate the acceptable ranges for each lot.*

Selecting an assay result enables you to display additional data relative to the selected result.

• Click on the line you want to select.

The following window shows (on the right) the additional data concerning the selected assay result (displayed in inverse video).

1. *VIDAS* **used**, the section number and the assay position (e.g.: D2),

2. **Patient's references**,

3. **Assay references**,

4. **Standard used**:
   − the fluorescence value of the standard.

5. **Interpretation** (according to the type of test),

6. **Raw results**:
   − BKG (Background) corresponds to the value of the fluorescence of the substrate before assay.
   − RFV (Relative Fluorescence Value) fluorescence value at the end of the assay minus the background value.

Fig. VII 3: Additional assay data

List of functions

Validate

If *VIDAS PC* is connected to the laboratory information system, this function enables you to validate and transmit results to the LIS (function enabled or disabled during configuration by the user of the BCI) (see chapter 9 Bidirectional Computer Interface (BCI)).

To validate:

• Click on one or more assay results in the list to select them.

• Click on the "VALIDATE" icon.

The "V" check boxes are automatically enabled. Each assay result can be validated or invalidated by clicking on the corresponding check box.

Retest
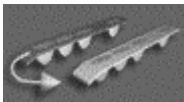
Recreates assay requests in the job list with the same characteristics as the selected results.

To retest:

• Click on one or more assay results in the list to select them.

• Click on the "RETEST" icon.

The assays are created in the job list or the list of predefined sections depending on whether the "Reserved" check box is enabled or not.

Recompute

The "Recompute" function enables you to recalculate the assay result using a calibration that you have defined as a reference.

To recompute:

• Click on one or more assay results in the list to select them.

• Click on the "RECOMPUTE" icon.

The "Recompute" submenu window appears and displays all the assays in the same predefined section as the result previously selected.

1. **Calibrations available**. This zone displays the list of valid and available calibrations that is different to the one currently selected.

2. **Assays performed**. The assays with the same lot performed in the same section as the selected result appear in this zone.
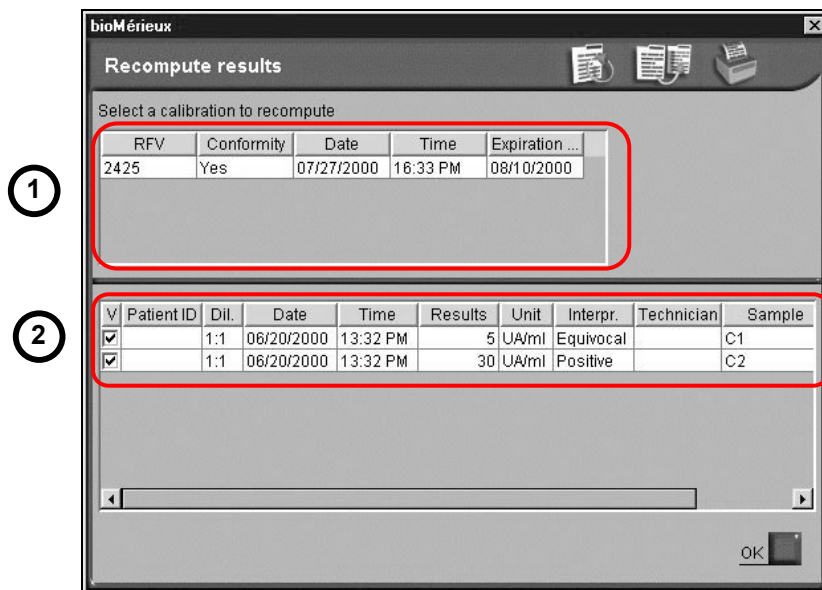
Fig. VII 4: "Recompute" submenu

- Click on the assay to be recalculated.

- Click on the "Recompute" icon.

The result of each assay will be modified according to the new parameters used for the recalculation.

- Click on "Print" to print the recalculation result.

Note: *This function enables you to print the recalculated results of all the assays performed in a specific section.*

- Click on the "Replace" icon to replace the previous result with the recalculated result and save it.

All the results of the section will be recalculated.

- Click on "OK" to return to the "Results" menu.

CAUTION!   ***It is important to take into account the conformity of the selected calibration. If it is not conform, an alarm will be generated when the results are printed.***

Retransmit

Retransmits selected assay results to a host computer (LIS) (in case the first transmission failed).

Exporting results

The "Exporting results" function is used to save results to a chosen directory.

- Click on one or more assay results in the list to select them.

Note: *If you do not select any results, all the results will be exported.*

- Click on the Export selected results icon.

The "Save" window is displayed.

1. Select the folder in which you want to save the data.

2. Enter a file name.

3. Click on the "Save" button.
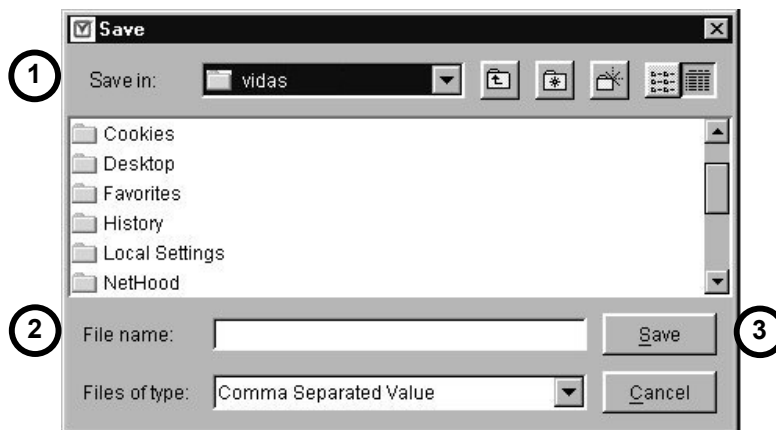
Fig. VII 5: Exporting data from the Results Menu

The file is saved in ".csv" format (Comma Separated Value) and is usable through a spreadsheet (e.g. Excel®).

IMPORTANT!   This file must be opened using the Windows® explorer.

Print

- Select one or more results in the list. It appears in inverse video.

The following dialog box displays.
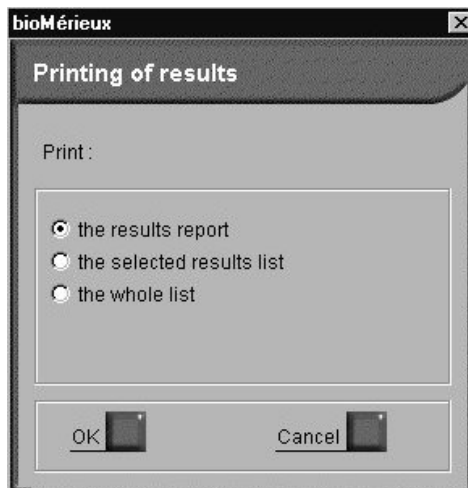
Different print options are available:

- − Print "**the results report**": this is only possible if a single result has been selected.

- − Print "**the selected results list**": this is possible if one or more results have been selected.

- − Print "**the whole list**": this option is used to print the whole list of results.

- Select the desired option.

- Click on "OK" to print.

Or,

- Click on "Cancel" to quit this window without printing.

Note: *If no results are selected, the whole list will be printed.*

If all the assays are printed for a specific patient, the results of quantitative assays and interpretation of qualitative assays will appear on the same report.

```
                                         Results list


                                                             Printed on Jan 19 2005 11:21:24


V.    Name      Test  Dil.  Result   Unit    Interpr.        Status   Date                        Or  Sample  Section  Pat. ID
----- ---------- ----  ----  --------- ------  ----------------  -------  --------------------------  --  ------  -------  -------
No    Simon     HCG   1:1   3.02     mUI/ml                    Correct  19/01/2005 07:42 PM         A   S243    259      SIM243
No    Albert    TSH   1:1   0.11     µUI/ml                    Correct  19/01/2005 12:47 AM         B   A249    260      ALB249
No    Bertold   TXM   1:1   0.82     UI/ml   Positive          Correct  19/01/2005 07:42 PM         A   B673    261      BER67
No    Perez     RBG   1:1   151      UI/ml                     Correct  19/01/2005 12:47 AM         B   P554    261      PER55
No    Martin    FSH   1:1   5.03     µUI/ml                    Correct  19/01/2005 12:45 PM         M   M451    262      MAR45
No    Norris    HIV   1:1   0.12     UI/ml   Negative          Correct  19/01/2005 12:47 AM         M   N279    263      NOR27


Page 1 of 1
```

Fig. VII 6: Results report (list of results)

```
                                         BioMérieux
                                    Quality control laboratory

                          Genevrier / Juniper (ST6) - DSVID  R2.3.0  DSPTC R5.5

VIDAS : 1 - Section 453                                                                    Page 1 of 1
Technician : Judy                                                                          Completed :
Lot number : 060123-0                                                                      Jul 26 2005 16:53:37

                                    Standard used for this analysis :
                                    Completed : Jul 26 2000  14:49:02
                                    S1 RFV : 1175

-----------------------------------------------------------------------------------------------------------
Position        Sample ID          Dilution        Seq#                 Test              Result       Interpretation
                                                            BKG          RFV              KUI / I
-----------------------------------------------------------------------------------------------------------
Patient name : SMITH
A-3             123845S                            01373    100          1400             12.03
Patient name : MILLER
A-4             352775M                            01373    100          1400             12.03
```

```
                                         BioMérieux
                                    Quality control laboratory

                                RSV (RSV) - DSVID  R2.3.0  DSPTC R5.5

VIDAS : 1 - Section 136                                                                    Page 1 of 1
Technician : Judy                                                                          Completed :
Lot number : 060704-0                                                                      Jun 05 2005 16:53:37

Negative < 1.40                       Equivocal >= 1.40 to 1.80                           Positive >= 1.80

-----------------------------------------------------------------------------------------------------------
Position      Sample ID      Seq#          Reference              Test          Test Value   Interpretation
                                           BKG      RFV      BKG      RFV
-----------------------------------------------------------------------------------------------------------
A-1           459003J        01373         100      1000     100      1390          1.39     Negative
A-3           987223X        01373         100      1000     100      1800          1.80     Positive
```

Fig. VII 7: Results reports (one result)

8   The different *VIDAS PC* menus

Introduction

This chapter describes the different *VIDAS PC* menus.

Functions

The different *VIDAS PC* menus enable you to set up and manage the data stored in the memory.

You can access the *VIDAS PC* menus from the main window.

To return to the main window from any other menu,

- Click on the "Return to main window" icon.

- Click on the navigation tree (see Fig. IV 3: Main screen and Fig. IV 4: List of *VIDAS PC* menus on pages 4-5 and 4-6).

The menus are the following :

Loading

The "Loading" menu is described in chapter 4 "Instructions for use".

Results

The "Results" menu is described in chapter 7 "Results".

Calibrations

The "Calibrations" menu is described in chapter 6 "Calibration".

Quality control

The "Quality Control" menu enables you to perform quality controls on all quantitative assays.

Three types of controls are possible:

− kit quality control (controls performed systematically during recalibration) (C1 to C3).

− external quality controls (frequency is defined by the laboratory (QC1 to QC6)).

− linearity controls (L1 to L8).
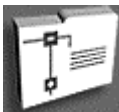
In the main window,

• Click on the navigation tree,

• Select "Quality control".

8

The following window appears.

1. **Select type of control**. Enables you to select the type of control you want to display:

– kit quality control (Control Result),

– external quality control (Levey Jennings),

– linearity control (Linearity).

2. **Select data**. Selection of the different data relative to the type of control selected.
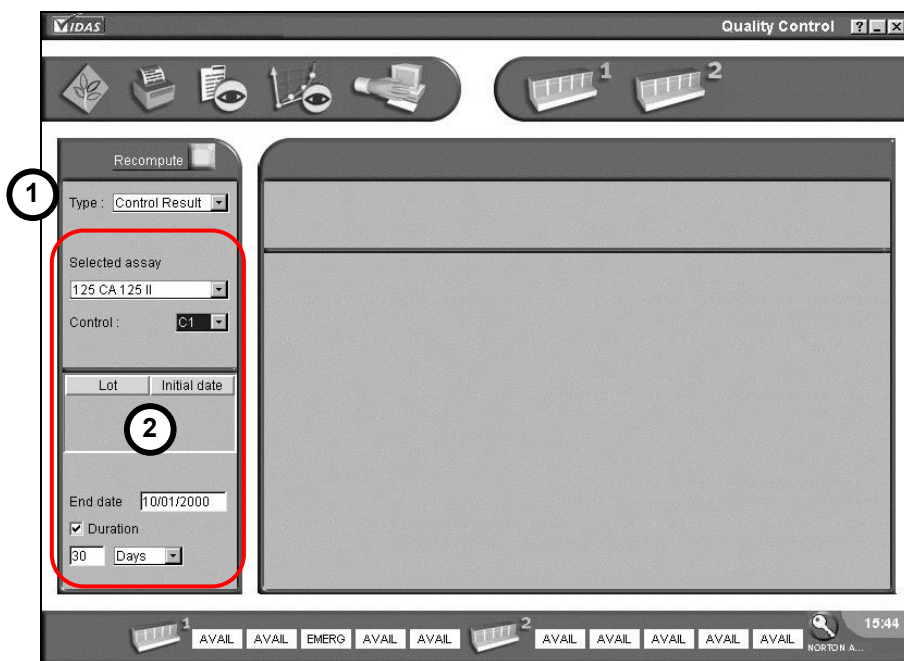
Fig. VIII 1: "Quality control" menu window

Kit quality control reports
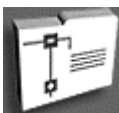
In the main window,

- Click on the navigation tree,
- Select "Quality control".

In the Quality Control menu window:

- In the "Type" pull-down menu, select "Control Result".

Select data
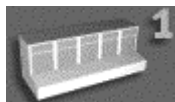
- Select the icon of the *VIDAS* for which you want a report: *VIDAS 1* or *VIDAS 2*.

- In the "Selected assay" pull-down list, select the assay you want.

8
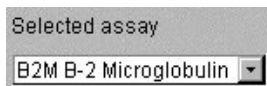
Selection of a kit quality control:

- In the "Control" pull-down list, select the control to be displayed (C1, C2 or C3).

Selection of a lot:

Lot	Initial date
000503-0	06/08/2000
010503-0	06/21/2000

The list of lots and the date of their first use are displayed.

- Select the lot you want.

The search can take place over a period of time (end date / period of time) or between two dates (start date/ end date).
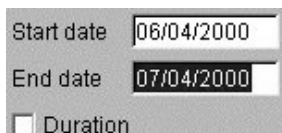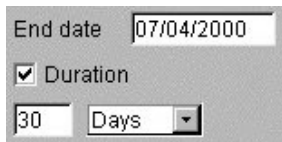
You can select the search time from:

End date   07/04/2000

☑ Duration

30   Days   ▼

−   end of search date (current date by default).

By default, the search will take place over a period of 30 days. This interval of time can be modified in the selection fields (days, months or years).

Start date   06/04/2000

End date   07/04/2000

☐ Duration

•   To select a start date, disable the "Duration" check box.

The current date is displayed by default.

Recompute

When you have made your choice,

•   Click on "Recompute" : the results of the search are displayed.

Display

When recomputing is finished, the following window is displayed. It includes the information shown below.

1. *VIDAS* **module in use**. The number of the *VIDAS* analytical module in use is displayed.

2. Kit control limits. The limits for the kit control are displayed.

3. Summary. This zone displays statistical data for the selected quality control. It indicates:

− the number of results used for the calculation of statistics,

− the mean of all the selected results,

− the standard deviation for the selected results,

− the variation coefficient (Standard deviation/Mean) x 100).

4. List of control results. When the "Used" column check box is selected (selected by default) the result is taken into account for the calculation of statistics.

5. Comment zone. This text zone enables you to enter comments for the whole of the current list (text or graphic mode display).

Fig. VIII 2: Window for the result of a kit quality control

Results can be removed from the statistics calculation, particularly when they are erroneous.

- Disable the "Used" check box of the result to be removed.

  − The updated number of results used for the calculation is displayed in the "Summary" zone.

External quality control report

When an assay request is created, the external quality controls must be identified as QC1 to QC6 in the sample ID field.

In the main window,

- Click on the navigation tree,
- Select "Quality control".
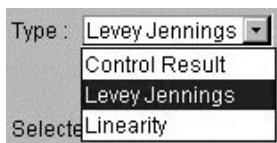
In the Quality Control menu window:

- In the «Type» pull-down menu, select "Levey Jennings",

- Select an external quality control.

Select data
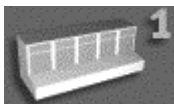
- Select the *VIDAS* for which you want a report: *VIDAS 1* or *VIDAS 2*.
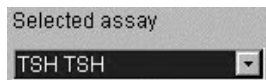
- In the "Selected assay" pull-down list, select the assay you want.

Selection of an external control:

- Select the external control to be displayed (QC1 to QC6) in the "Quality Control" pull-down list.

The list of external control identifiers and the date of their first use are displayed.
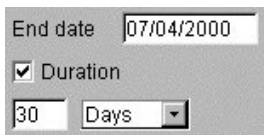
Selection of an identifier:

- Select the identifier you want.
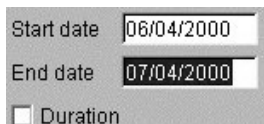
The search can take place over a period of time (end date / period of time) or between two dates (start date/ end date).

You can select the search time from:

End date	07/04/2000
☑ Duration	
30	Days ▾

− end of search date (current date by default).

By default, the search will take place over a period of 30 days. This interval of time can be modified in the selection fields (days, months or years).

Start date	06/04/2000
End date	07/04/2000
☐ Duration	

• To select a start date, disable the "Duration" check box.

The default date displayed is the current date.

Recompute

When you have made your choice,

• Click on "Recompute". The results of the search are displayed.

For each quantitative assay, you can select up to 6 external controls.

You therefore have to define parameters for each control (see the "Controls" submenu on page 8-49).

Note: *The controls in the **VIDAS** kit can also be used as external controls. In this case, identify them as QCx (x = 1 to 6) and reperform them.*

8

Display

When recomputing is finished, the following window is displayed.

1. *VIDAS* **module in use**. The number of the *VIDAS* analytical module in use is displayed.

2. **The external quality control limits**, recorded in the Configuration menu (QCx), are displayed.

3. **Summary.** This zone displays the statistical data for the external control selected. It indicates the mean of the standard deviation for:

– the total of the identifier values (*Total for identifier*),

– the period of time selected (*Between dates*),

– the values defined by the user (*User*).
Entry of the target value and the standard deviation helps to situate the result in relation to the expected values.

4. **List of control results**. Displays the results for each quality control. Each line includes :

– the date of the control,

– the value obtained,

– the Westgard rules and their status.

5. **Deselection of values**. It is possible to deselect values. The mean and the standard deviation are immediately recalculated and a new curve is plotted.

6. **Comment zone**. This text zone enables you to enter comments on the whole of the current list (text or graphic mode display).

Fig. VIII 3: Window for the result of an external control (text mode)

Graphic mode display

- Click on the "Display curve" button to obtain a graph of the external quality control results.

To return to the previous screen (text mode display),

- Click on the "Text mode" button.

The "Recompute" button enables you to recalculate the curve following a change of data.

1. Graph. The results curve enables you to directly analyze the various control variations as well as the standard deviation overflows observed. The standard deviation overflows are defined according to the configuration chosen in The "Westgard" submenu on page 8-51.
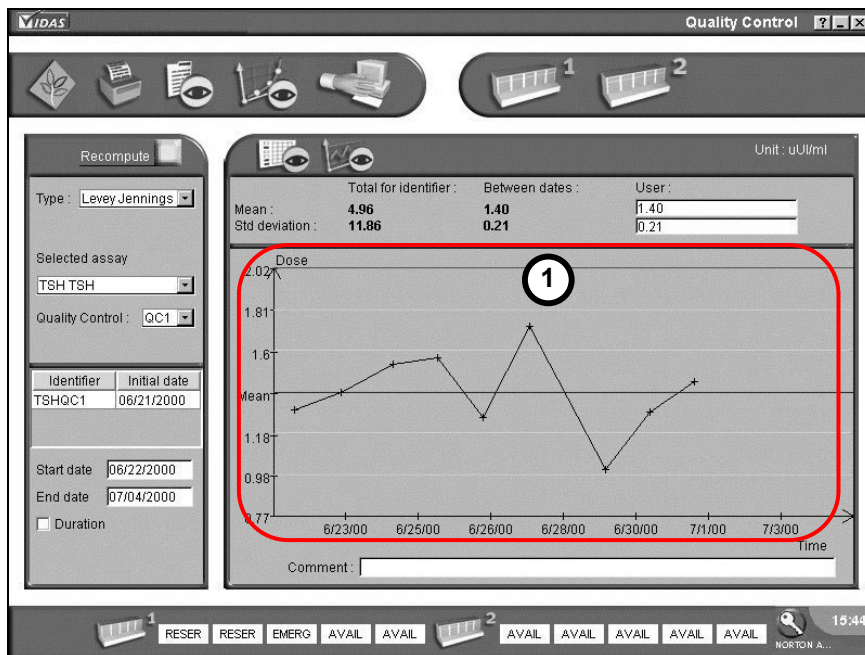
Fig. VIII 4: Result of an external quality control (graphic mode)

The graph

Displaying the curve enables you to locate the standard deviation overflows. The graph is tagged with definable rules called "Westgard" rules.

The standard deviation overflow caption is the following:

1st Westgard rule - (1*2s)

– Overflow of a control beyond 2 standard deviations.

2nd Westgard rule - (1*3s)

– Overflow of a control beyond 3 standard deviations.

3rd Westgard rule - (2*2s)

– Overflow of 2 consecutive controls beyond 2 standard deviations.

4th Westgard rule- (1*2s and 1*3s)

– Overflow of a control beyond 2 standard deviations followed by the overflow of a control beyond 3 standard deviations.

8

Linearity report

When an assay request is created, each level of concentration must be identified as L1 to L8 in the sample ID field.

Note: *The number of concentration levels must be between 4 and 8.*

The number of replicates must be between 2 and 10.

- Start all the assays using the "Run all" icon.

Selecting data
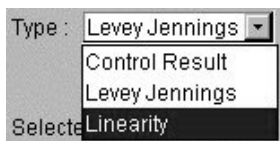
- Select "Linearity".
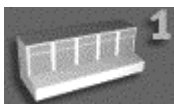
- Select the **VIDAS** for which you want a report: **VIDAS 1** or **VIDAS 2**.
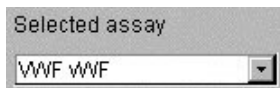
- Select the assay in the "Assay" pull-down list.
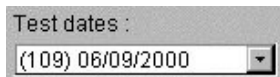
- Select a date in the "Assay dates" pull-down list. The digits that appear in parentheses represent the section number.

If several sections are run at the same time, the section number which appears in parentheses corresponds to the lowest number in the group of sections.

Text mode display

- Click on the "Recompute" button.

The window for entry of expected concentrations of each dilution is displayed.

If assays have just been completed, the window will not contain data.

- Enter the expected concentrations for each sample.

IMPORTANT! *You should only enter concentrations in the L1 to L8 text zones. Data entered in the L9 and L10 text zones will not be taken into account.*

8

Fig. VIII 5: Expected concentrations

For a test which has already been calculated, the window will contain data.
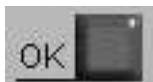
- Validate the entry using the "OK" button.

The following window appears.

1. **Linearity table**. This list contains all the concentrations obtained with the *VIDAS* compared to the expected concentrations entered in L1 to L8.

2. **Comment zone**. This text zone enables you to enter general comments on the whole of the current list.

Fig. VIII 6: Result of a text mode linearity report

The linearity table

Each line includes:

- the sample ID (Lx : x = 1 to 8),
- the expected concentration,
- the obtained concentration,
- the reagent lot number,
- the position in the selected ***VIDAS*** section.

Clearing the check box at the beginning of each line enables you to remove a concentration from the global calculation.

Note: *The zone above the linearity table indicates the confidence and coverage intervals for the concentrations.*

__The confidence interval__ defines the limits between which the concentration, predicted by the curve, has a 95% chance of falling (see Graphic mode display on page 8-18).

__The coverage interval__ defines the limits between which 90% of the concentrations measured with the VIDAS PC linearity test should be situated, with a confidence level of 90%.

When the concentration list is displayed, it is possible to reenter a list of expected concentrations by clicking on the "Recompute" button.

The   expected   concentrations   entry   window   appears   (see   page 8-15).

Graphic mode display

You can access this display mode either directly or through the text mode display.

- Click on the "Display curve" button to obtain a graph of the linearity results.

The following window appears:
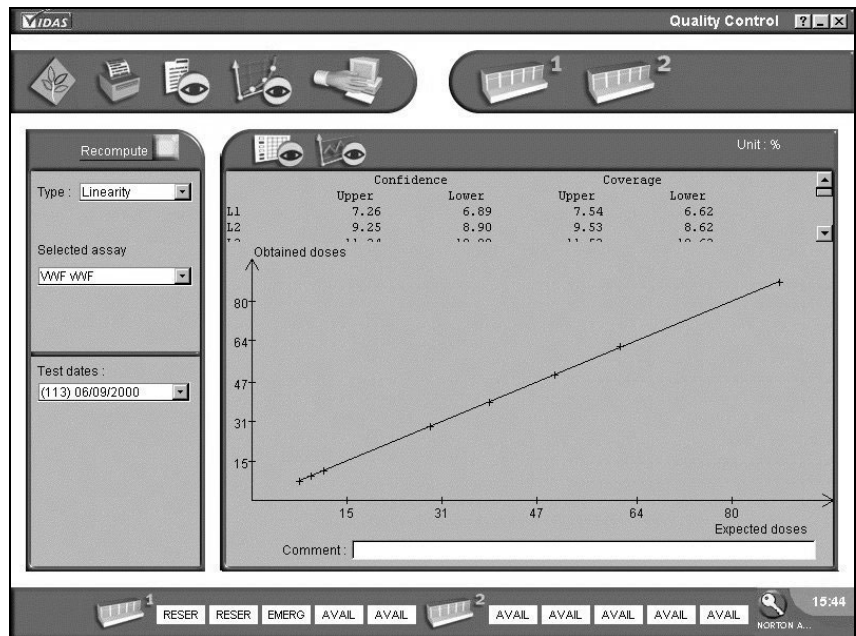
Fig. VIII 7: Result of a linearity control (graphic mode)

To return to the previous screen (text mode display),

- Click on the "Text mode" button.

Patient data

The "Patient data" menu enables you to search for information in the database stored in memory.

This menu can be used when a complete demographics configuration has been selected (Patient ID entered) or in an industrial context (specimen entered).

This database contains all the assays carried out by each *VIDAS* module.

In the main window,

- Click on the navigation tree,

- Select "Patient data".

8

The following window displays.

Fig. VIII 8: "Patient data" menu window

"Patient data" menu commands

The first 3 commands can be found in the tool bar.

Starts the search once you have selected the search criteria.

Clears the patient list displayed on the left of the screen as well as the search criteria on the right of the screen.

Displays detailed results.

The following commands can be found in the submenu bar.

After a search phase, this command displays the patient list only (patient's name and patient's ID in parentheses).

After a search phase, this command displays the list of patients and the sample IDs for each one.

After a search phase, this command displays the list of patients, the sample IDs for each one and the assays performed for each one.

Prints the patient files.

8

Search procedure

The following window shows the different fields enabling you to search for results and use them.

1. **Search criteria**. Entry of patient ID **and** name.

2. **Date criteria**. Enables you to enter an interval of time for the search (search period).

3. **Results of search**. Displays the result of a search.
It is then possible to obtain more details on the result displayed either using the buttons described in "Patient data" on page 8-21 or by clicking directly on the files.

4. **Summary of the assays performed**. Displays the result of a search.
The complete list of assays carried out for a patient over a given period of time, as well as the last two assays performed for the patient are displayed (Prev. 1 = Patient case history1).

5. **Detailed assays**. Gives a more detailed list of assays selected in the assay summary table.

Fig. VIII 9: Detailed patient data

Procedure for patient search

- Enter the search criteria:

  − in the "NAME" text zone,

  and,

  − the "ID" text zone (patient ID).

Note: *In each zone, it is possible to perform an intuitive search by entering only the first character followed by the character *. You can also obtain all the patients for preselected dates by entering the character * **in the "ID" and "NAME" text zones.***

- Select the search period:

  − In the "Date criteria" option boxes, select the option "Duration" or "Start date",

    - "Start date": enter the date on which the search should start (e.g: 01/01/2000). The default date displayed is the current date.

    - "Duration": select a time unit: "Days", "Months" or "Years" and enter a value in the previous text zone (e.g: 6 months).

- Start the search by clicking on the "Search" icon in the menu bar.

The patients are displayed in the list of results.

You can improve the search using one of the following icons:

To display the details of assays carried out for a patient,

- Click on the patient's name.

The assay summary is displayed in the top table.

- Click on one of the assays in this list.

The details of the assay are displayed in the bottom table.

To obtain more details on this assay,

- Select an assay in the bottom table, then,
- Click on the opposite icon.

A window containing detailed information on the assay is displayed.

VIDAS1 Section : B6

References
Name : MARTIN
Sample ID : MAR234

Assay references
TOXO IgG (TXG)
Technician :
Lot : 000509-1

Standard used
RFV : 1700

Interpretation
Negative <   8
Equivocal >=   8 to < 10
Positive >= 10

OK
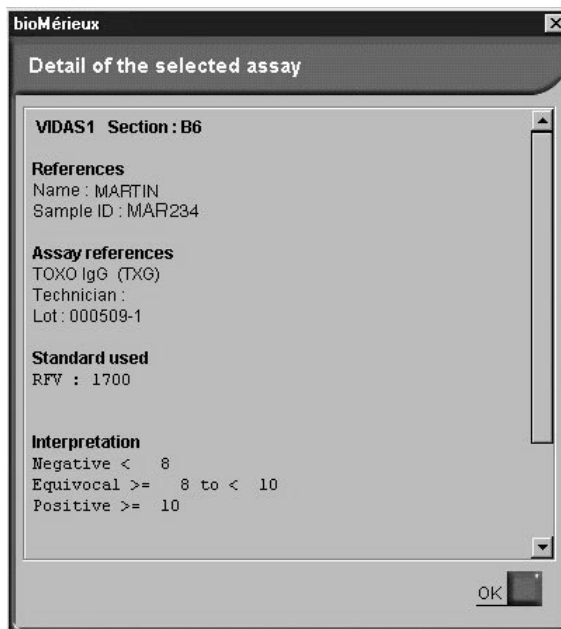
Printing of results

In the main window,

- Click on the navigation tree.
- Select "Patients data".

- Perform a search for patient data (see Chapter 8, "Search procedure" in the User's Manual).

- Select a patient in the "Results of search" window on the left of the screen.

- Click on the "Print" button in the menu bar.

The following window displays.
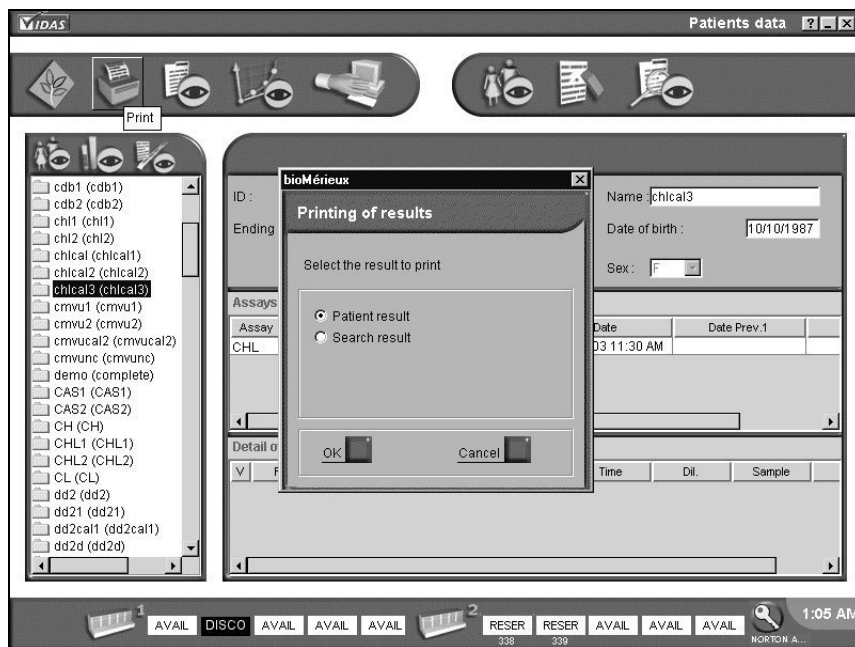
Fig. VIII 10: Printing of results

Two print options are available:

− "**Patient result**": for printing the patient report (results of the selected patient).

− "**Search result**": for printing the list of all the patients corresponding to the search criteria (left side of the Patients data window).

This list contains the following information:

− Patient ID,

− Patient name,

− Sample ID,

− Test performed,

− Unit used.

Instrument

The "Instrument" menu enables you:

- to halt an assay running in one or more sections,
- to carry out procedures for initialization of sections,
- to connect or disconnect a section,
- to display temperatures,
- to analyze and correct the various errors that occur during operating phases.

In the main window,

- Click on the navigation tree.
- Select the "Instrument" menu.

The following window displays:

1. **Section status screen**. Indicates the status of each section (available, running, disconnected or in error), as well as the temperature of the trays and SPR® blocks.

2. **Section content screen**. Displays the list of assays loaded in each section.

3. **Error screen**. Displays current errors (see Error window on page 8-30).
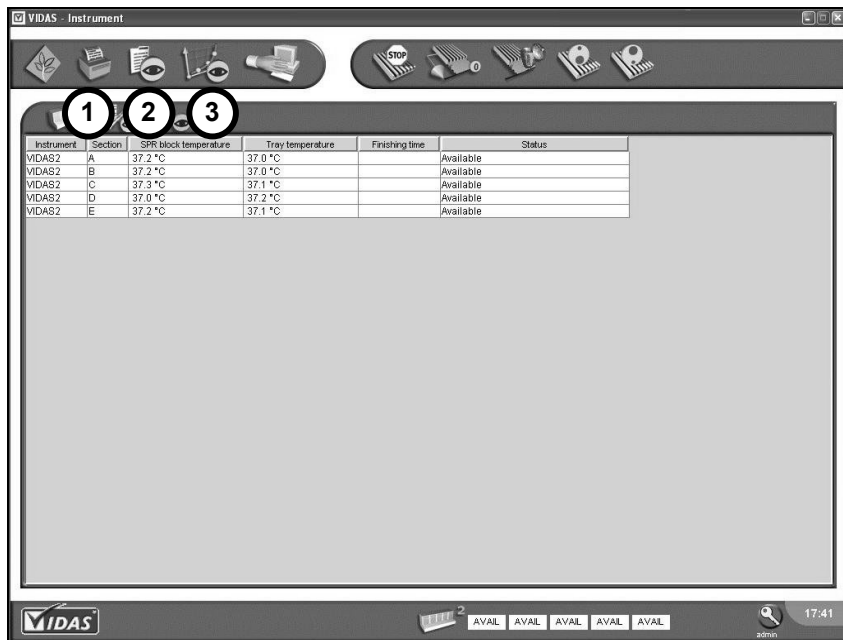
Fig. VIII 11: "Instrument" menu status window

Section status window

Statuses

The temperatures of the SPR$^®$ blocks and trays of each section are displayed.

The status of each section is displayed (see Fig. VIII 11).

Managing sections

Halting an assay

The following function enables you to halt the selected sections.

- Select a section in which an assay is running (the section appears in inverse video).

- Click on the "Stop" button to halt the assay.

The time of completion of the halted assay disappears and the section status button at the bottom of the screen changes to "RESET" and then to "RESER"

CAUTION!   ***You must discard the strips and SPRs that are in the halted section.***

Note: *The "Stop" function is disabled in "AVAIL" or "RESER" sections.*

Resetting a section

This function enables you to reset a section.

- Select a section (the selected section appears in inverse video),

- Click on the "Reset" icon to reset the selected section.
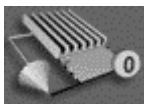
The section status changes from "RESET" to its initial status.

Note: *The reset function is disabled on a section which is running or in which an error has occurred.*

Freeing a section

CAUTION! **It is imperative to discard the strips and SPR®s of assays in a section which has been halted.**

This function frees and resets the section.

- Select the section to be freed (the selected section appears in reverse video).

- Click on the button to free the section.

A dialog box appears :

- Confirm that you want to free the section.

The section status button in the status bar becomes "FREE".

Note: If the section you want to free is being processed, the data will be lost.

Disconnecting a section

If an operating problem occurs in one of the sections, it can be disconnected.

- Select an "AVAIL." or "ERRINST" section (the selected section appears in inverse video).

- Click on the "Disconnect" button to disconnect the section.
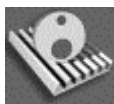
"DISCO" is displayed in the section status zone and the section status button in the status bar becomes black.

Connecting a section

- Select a disconnected section (the selected section appears in inverse video),

- Click on the "Connect" button.

"DISCO" disappears from the selected section status zone and the section status button in the status bar changes to "AVAIL".

Error window

ERRCB

In any menu, if you click on the status button of the section where an error has occurred (red background), you will directly access the error display window in the "Instrument" menu,

or,

In the "Instrument" menu, if you click on the "Error display" button, the error display window will appear.

The following window is displayed :

1. **List of errors**. This window informs you of the type of error occurring in a section of a *VIDAS* module.

2. **Error description**. The "Description" window describes the problem encountered after you select the error in the previous window.

3. **Error correction**. The "Error correction" button enables you to correct errors according to their type.
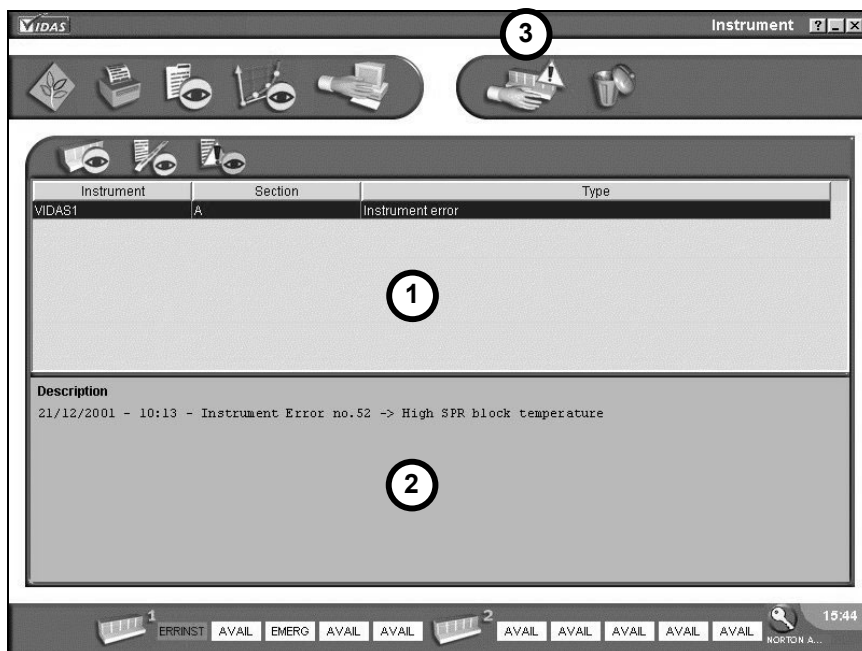
Fig. VIII 12: Error display window

List of errors

The following errors may occur:

- Instrument errors,
- Reagent errors:
    - calibration errors,
    - substrate errors,
    - bar code errors,
    - lot errors.

For further information refer to the Troubleshooting chapter on page 12-1.

8

Instrument errors

ERRINST

- Select the error (the "Description" window gives you the origin of the error).

To delete the error,

- Click on the delete icon.

Online help for correcting instrument errors is currently not available.

If you click on the "Error correction" icon, the following window is displayed.
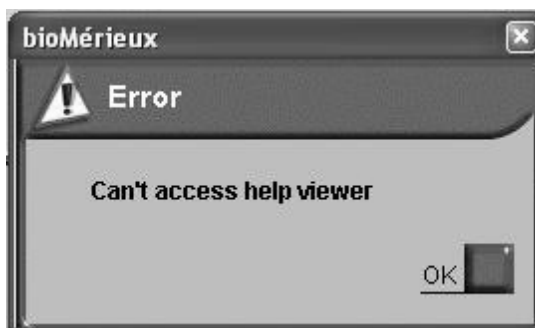
Fig. VIII 13: Online help window

- Close this window by clicking on ⊠ in the top right-hand corner of the screen.

Reagent errors

Calibration error

- Select the error (the "Description" window gives you the origin of the error).

- Click on the "Error correction" button.

A window similar to the following one is displayed:
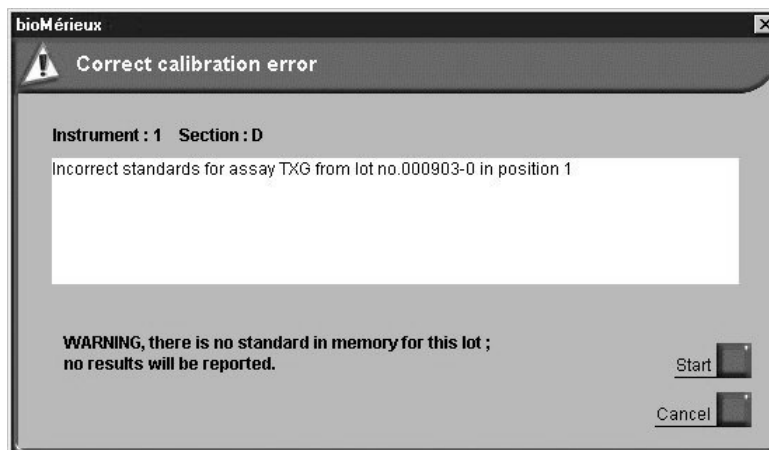
The causes are usually the following:

- no MLE card entered,

- no standard,

- the calibration has expired.

CAUTION!   *Results will not be calculated for assays affected by a calibration error. Nevertheless, results can be recalculated at a later date once the necessary calibrations have been performed (see chapter 7).*

Correcting calibration errors

- Click on "Cancel" to close the calibration error display window (see previous figure).

- Select the calibration error to be corrected.

- Click on the "Delete" icon to delete the error messages.

- Correct the error (see chapter 6 – "Calibration").

Starting assays without correcting the error

- Click on "Start".

Note: *The "Start" button enables you to start the assay regardless of the error message.*

Substrate error

ERRSUB

- Select the error (the "Description" window gives you the origin of the error).

- Click on the "Error correction" button.

The following window displays:

bioMérieux ☒

⚠ Correct substrate error

Instrument : 1   Section : E

Low substrate error for assay TXG from lot no.000903-0 in position 1

RFU values

Position 1 : 18

Position 2 : 6

Position 3 : 6

Position 4 : 6

Position 5 : 6   Start again

Position 6 : 5   Cancel
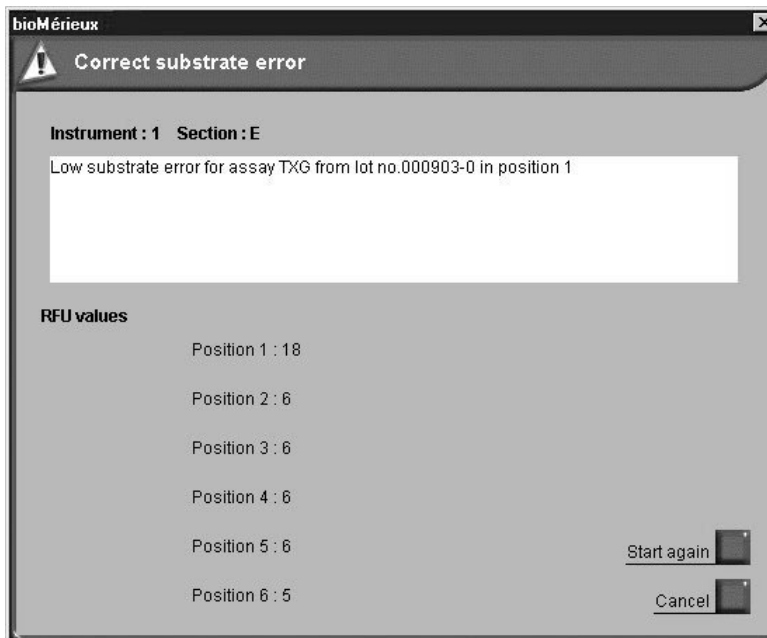
8

In the present case, the substrate value is out of range. The acceptable range varies for each assay. All strips containing a substrate with an out-of-range value must be eliminated. You must run an assay with a new strip.

- Reload the strip in the position in the section indicated.

- Click on "Start again".

Start again

Note: *If you choose to cancel, you must then delete the error.*

Bar code error

ERRCB

- Select the error (the "Description" window gives you the origin of the error).

- Click on the "Error correction" button.

The following window displays:

In the present case, the strip bar code is:

− either incompatible with the assay code entered by the user,

− or unreadable (empty position, strip incorrectly positioned or damaged bar code).

- Manually enter (in upper case characters) the alphanumeric bar code of the strip in the text zone corresponding to the position in which the error has occurred.
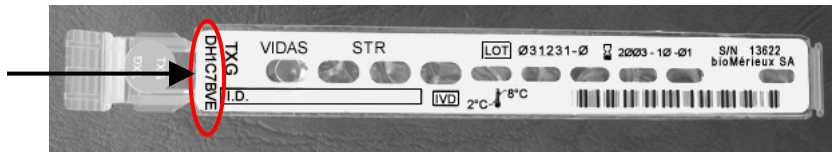
Start again

- Click on "Start again".

A bar code error may also occur if the correct protocol is not activated.

To correct this error,

- Click on "Cancel" to close the bar code error display window.

- Select the bar code error to be corrected.

- Click on the "Delete" icon to delete the error message.

- Activate the correct protocol (see page 8-48).

- Cancel reservation of the concerned sections.

- Delete the concerned assays. For deletion of assays, see Chapter 4.

- Create new assays and run them (see chapter 4).

A bar code error may also occur if the number of assays created in the predefined sections(s) is less or more than the number of reagent strips loaded into the section.

To correct this error,

- select the bar code error,

- click on the delete icon to delete the error message,

- check the predefined sections in the loading plan,

- modify the predefined sections(s) by creating the missing assays or deleting the unnecessary assays,

- reserve the predefined section(s),

- restart the section(s)

or

- remove the unnecessary reagent strip(s) or add the necessary reagent strip(s),

- restart the section(s).

Lot error

- Select the error (the "Description" window gives you the origin of the error).

- Click on the "Delete" icon to delete the error message.

- Retest using reagents from a valid lot.

L o g

The "Log" menu opens the Windows® event viewer which displays the events that occurred during running of *VIDAS PC* (information, warnings and error messages).

In the main menu,

- Click on the navigation tree.
- Select "Journal".
- Then select "Applications".

The following window displays:
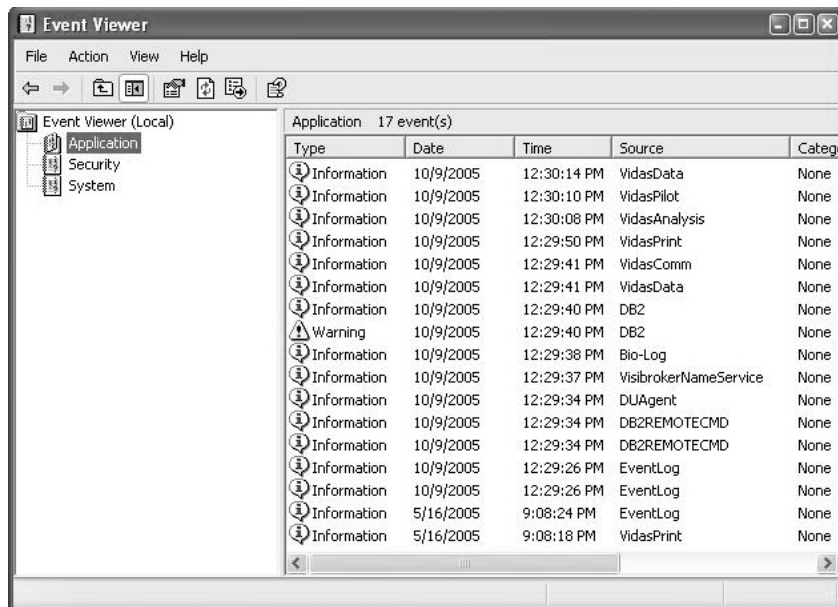
Fig. VIII 14: "Log" menu window

Configuration

CAUTION!   *To access the "Configuration" menu and its submenus, you must have logged on with a user identifier that belongs to the "VIDAS_ADMIN" group. If you have logged on with a user identifier that is a member of the "VIDAS_ROUTINE" group, the "Configuration" menu will not be accessible.*
For further information, please contact your laboratory system administrator.

Modification of configuration parameters should only be carried out by qualified personnel, authorized to do so.
Modification of configuration parameters may lead to problems during use or operation.
Please make sure that these modifications are really necessary before proceeding with them.
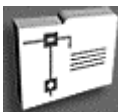
In the main window,

- Click on the navigation tree,

- Select "Configuration".

This menu gives you access to various options and parameters presented in the form of submenus:

8

You can select an option using the corresponding check boxes, the option boxes or by entering the necessary data in the text zones.

Before exiting each submenu, the following window asks you if you want to validate the option or parameter modifications.
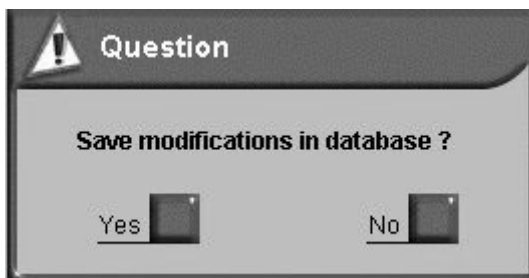
In each submenu, it is possible to access the "Print" function located in the menu bar.

"Routine" submenu
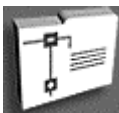
In the main window,

- Click on the navigation tree,

- Select "Configuration".

- Click on the "Routine" submenu.

The following window is displayed.
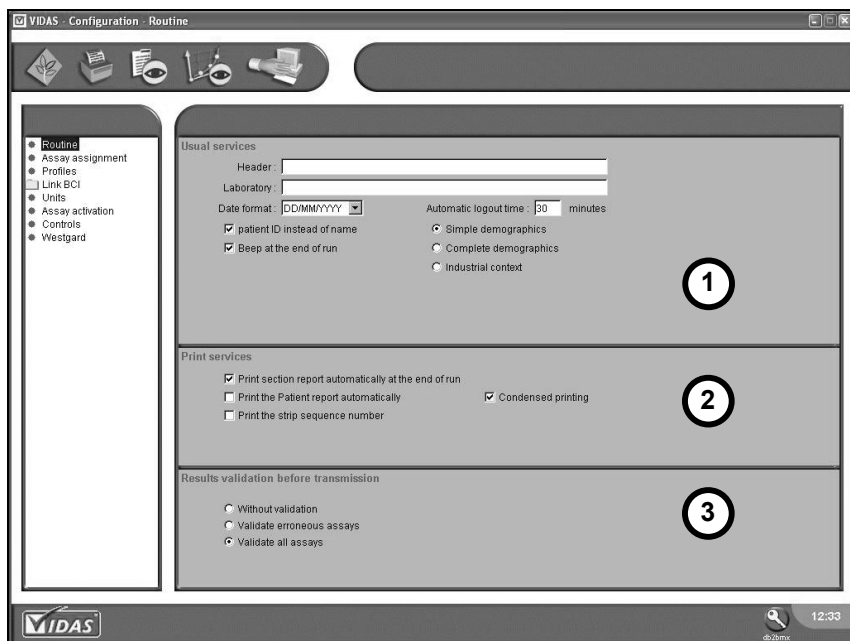
Fig. VIII 15: "Routine" submenu window

1. **Usual services**.

" Laboratory / Header":

- Enter the laboratory's address on two lines. This information will be displayed in the header of the various printed reports.

"**Date format**": the default format is DD/MM/YYYY. It can be modified using the drop-down menu.

"**Automatic disconnection** : the default time is 30 minutes. It can be modified using the numeric keypad (maximum duration: 9999).

"**Simple demographics":** This option enables you to enter basic patient data which are necessary for the entry of the assay request (see page 4-14).

"**Complete demographics":** This option enables you to enter more complete patient data (Patient's name, date of birth, etc.) (see page 4-15).

"**Industrial context":** This option enables you to enter data specific for the industrial environment (see page 4-16).

"**Patient ID instead of name":** This option can only be used if you have selected "Complete demographics". It enables you to report the Patient ID in the loading plan and in the predefined section. Selection or deselection of this option modifies the order of the "Patient ID" and "Name" columns in the "Results" menu and the job list.

"**Beep at the end of run":** A beep will be heard at the end of each run.

2. **Print services**.

"**Print section report automatically at the end of run":** This option enables you to print the complete report of a section as soon as the run is over.

"**Print the patient report automatically":** This option enables you to print a report of all the assays run for a patient at the end of each assay.

"**Print the strip sequence number":** This option enables you to print the strip manufacturing number on section reports.

"**Condensed printing":** This option enables you to print the results in succession, without any page breaks.

3. **Results validation before transmission.**

"**Without validation":** This option enables you to automatically transmit all assay results, even those calculated with an incorrect or expired calibration, to the LIS connected to the *VIDAS*.

"**Validate erroneous assays":** This option enables you to transmit incorrect assay results. The "erroneous" term applies to over-diluted assays, assays calculated with an incorrect or expired calibration and an incorrect control.

"**Validate all assays":** All the assays are transmitted, if initiated by the operator.

"Assay assignment" submenu
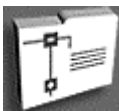
In the main window,

- Click on the navigation tree,
- Select "Configuration".

Then,

- Select the "Assay assignment" submenu.

The following window is displayed.
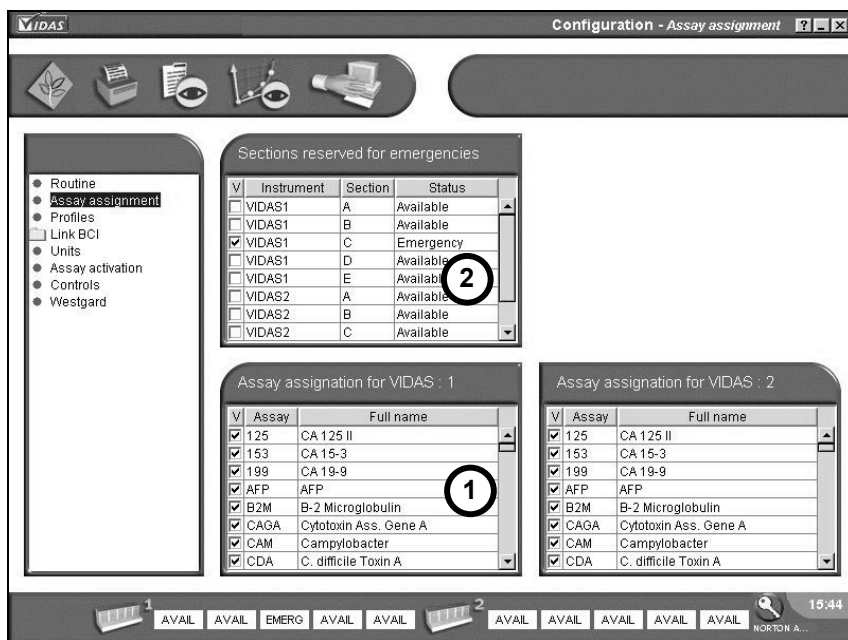
Fig. VIII 16: "Assay assignment" submenu window

1. **Assay assignment**. This zone is divided into two similar list areas for each *VIDAS* module.

   All the assays stored in memory are reported in these list areas. They can be assigned to each *VIDAS* module using the corresponding check boxes.

   By default, all the assays are selected.

2. **Reservation for emergencies**. This zone enables you to reserve sections for emergencies. To do so, you should select the check boxes corresponding to the sections to be reserved for emergencies.

   This operation enables you to use the sections reserved for emergencies in cases of <u>manual reservation</u> of a predefined section. The other reservation modes will not affect the sections reserved for emergencies (see Reserving sections on page 4-22).

Note: *Each **VIDAS** module must be recalibrated with the selected parameters. **VIDAS PC** automatically distributes the assays according to this assignment parameter.*

If an assay is run on a *VIDAS* module to which it has not been assigned, the following window will display:

"Profiles" submenu

A profile of assays is an option enabling several user-defined assays to be grouped together under the same profile number and the same full name (P1, P2, …). You can define these profiles in the "Profiles" submenu and access them in the "Loading" menu just as you do for individual assays.

In the main window,

- Click on the navigation tree,

- Select "Configuration",

- Select the "Profiles" submenu.

The following window displays:

1. **Available assays**. This list zone displays all the assays.

2. **Available profiles**. This list zone displays the available profiles stored in the *VIDAS PC* software. The maximum number of profiles is 10.

3. **Full name of profile**. This text zone enables entry of the name of the selected profile in the "Available profiles" zone.

4. **Assay selection**. This selection zone displays the assays selected from the table of available assays (maximum 10 assays and 5 protocols per profile).
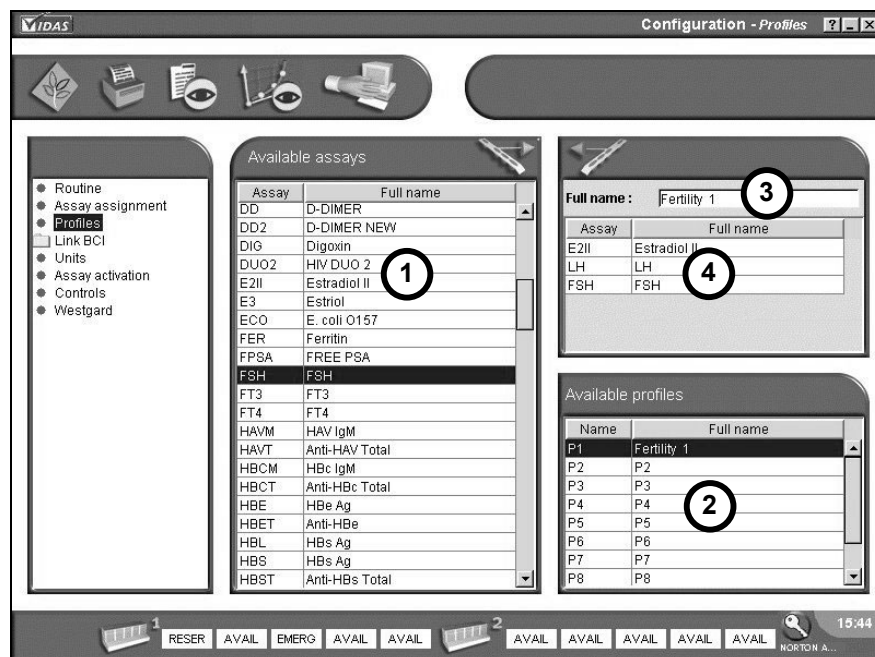
Fig. VIII 17: "Profiles" submenu window

Entering a profile of assays

- In the "Available profiles" zone, select a profile of assays (the selected profile appears in inverse video).

- In the "Full name" zone, enter the name you want to assign to the selected profile.

- In the "Available assays" zone, select an assay to add to the profile (the selected assay appears in inverse video).

- Click on the "Transfer" icon. The selected assay is displayed in the "Selected assays" zone.

- Perform the last two steps again for each assay you want to add to the profile.
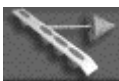
It is also possible to modify an existing profile by adding or deleting assays using the "Add assay" and "Delete assay" icons.

"BCI" submenu

This submenu is described in Chapter 10 "Bidirectional Computer Interface (BCI)".

"Units" submenu

The "Units" submenu enables a dosage unit to be set for each quantitative assay.

Changing the unit of an assay will affect the anteriority of results displayed in the patient data menu.

WARNING!   *Before changing any test units, you must check that the job list and predefined sections are empty.*
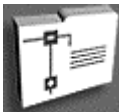
In the main window,

- Click on the navigation tree,

- Select "Configuration",

- Select the "Units" submenu.

The following window appears.
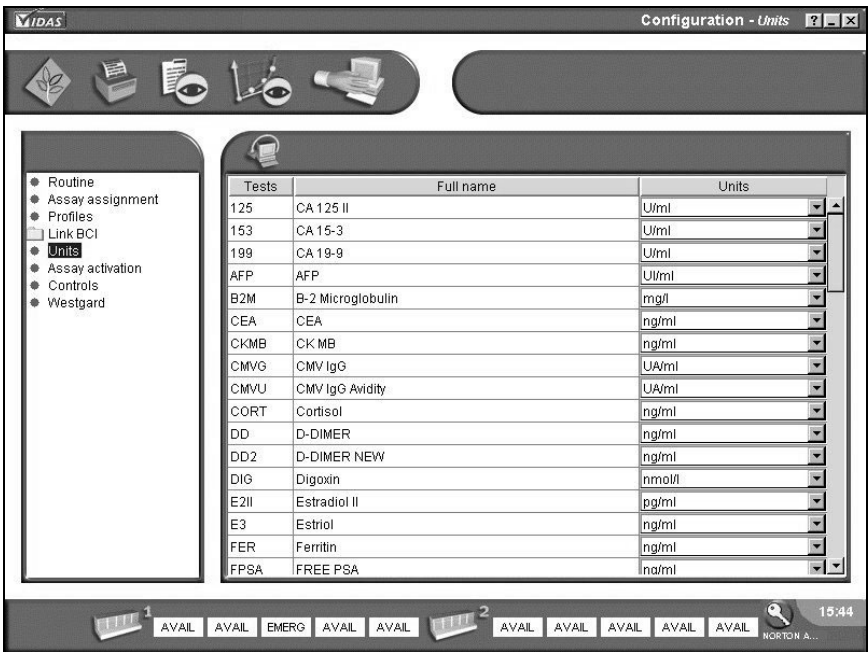
Fig. VIII 18: "Units" submenu window

- For each assay, select a dosage unit from the available units in the list zone,

WARNING!   *If assay results are expressed as a ratio, make sure you use the same unit for all the associated tests.*

or

- click on the "Restore default values" icon to return to the default values of all the bioMérieux® defined assays.

"Assay activation" submenu

The "Assay activation" submenu enables you to validate the protocols used.

In the main window,

- Click on the navigation tree,

- Select "Configuration",

- Select the "Assay activation" submenu.

The following window is displayed.
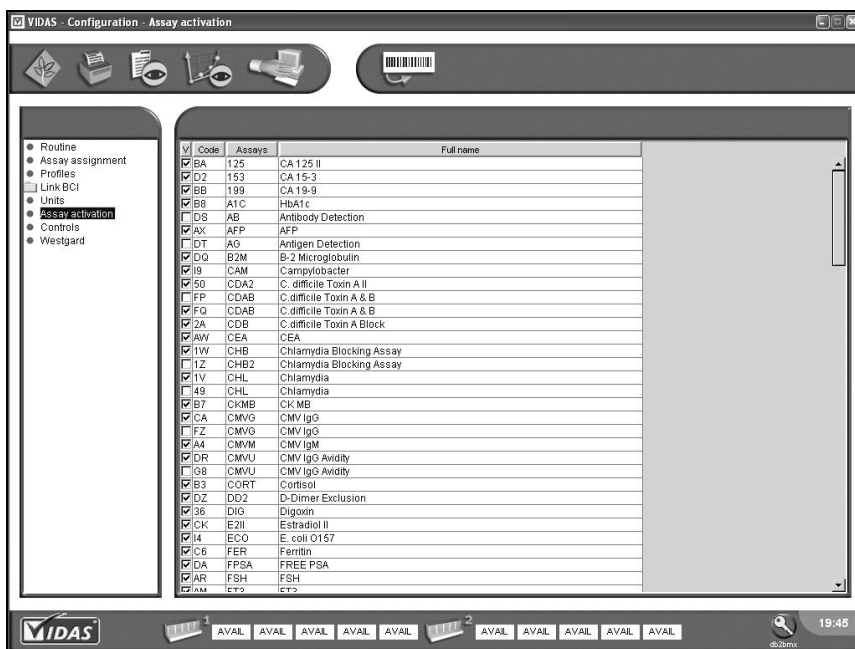
Fig. VIII 19: "Assay activation" submenu

Only one code must be activated for each assay.

All protocol modifications are taken into account at the time of update. For further information, see Chapter 5 "Updating a VIDAS assay".

CAUTION!   ***You should only perform this procedure when informed to do so by bioMérieux®.***

"Controls" submenu

The "Controls" submenu enables external controls to be set up (or user-defined controls) in order to define acceptance ranges which will be used in the Levey Jennings type Quality control menu.
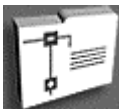
In the main window,

- Click on the navigation tree,

- Select "Configuration",

- Select the "Controls" submenu.

The following window appears.

1. **Assay selection**. This list zone enables you to select a quantitative assay to which controls will be assigned.

2. **Control set-up.** This zone displays six user-defined external controls identified QC1 to QC6.
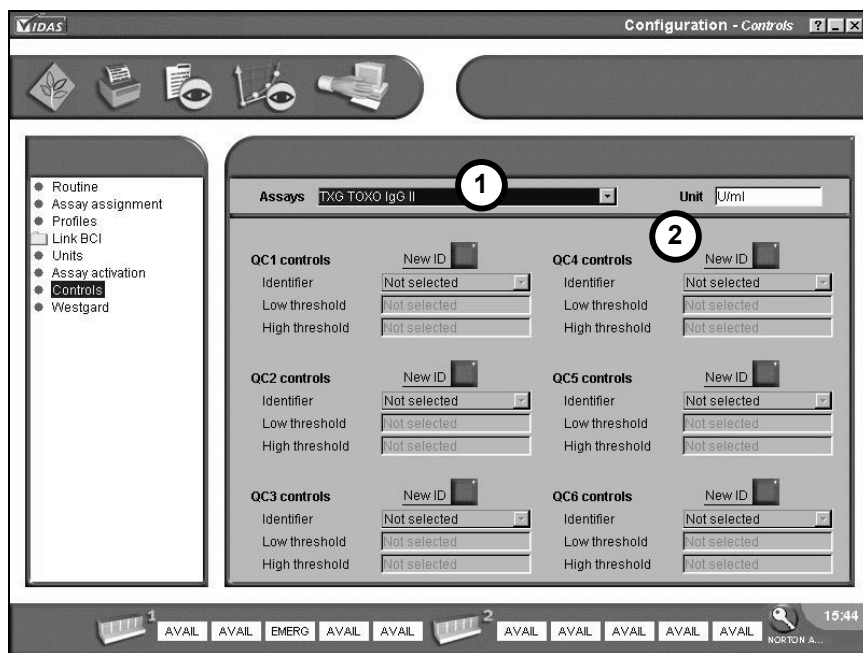
Fig. VIII 20: "Controls" submenu window

Setting up controls

The parameters are, in order of entry:

− <u>The identifier</u>: enter the name of the control in the text zone.

− <u>The low threshold</u>: enter the low threshold in the text zone.

− <u>The high threshold</u>: enter the high threshold in the text zone.

To enter an identifier:

New ID

• Click on "New ID".

• Enter the new identifier (up to 12 characters). The low and high thresholds are now activated.

• Enter the expected values.

If the limits you enter for a new QC do not fit in the assay measure domain, the following warning will be displayed.
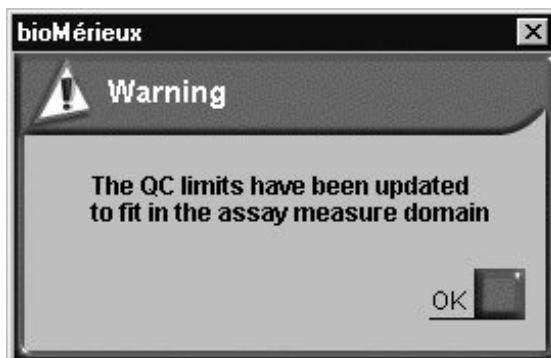
• Click on "OK" to confirm.

If one of the values entered is outside the limits of the assay measure domain it will be replaced by the limit.

Note: *Only quality controls for an identifier displayed in the "Controls" window (current controls), will be used for statistics.*

CAUTION!   **If thresholds are not entered, an error message will appear during the backup and the QC will not be saved.**

The "Westgard" submenu

The "Westgard" submenu enables you to set up the rules for supervising the standard deviations (Westgard) of the control.

In the main window,

- Click on the navigation tree,

- Select "Configuration",

- Select the "Westgard" submenu.

The following window is displayed.
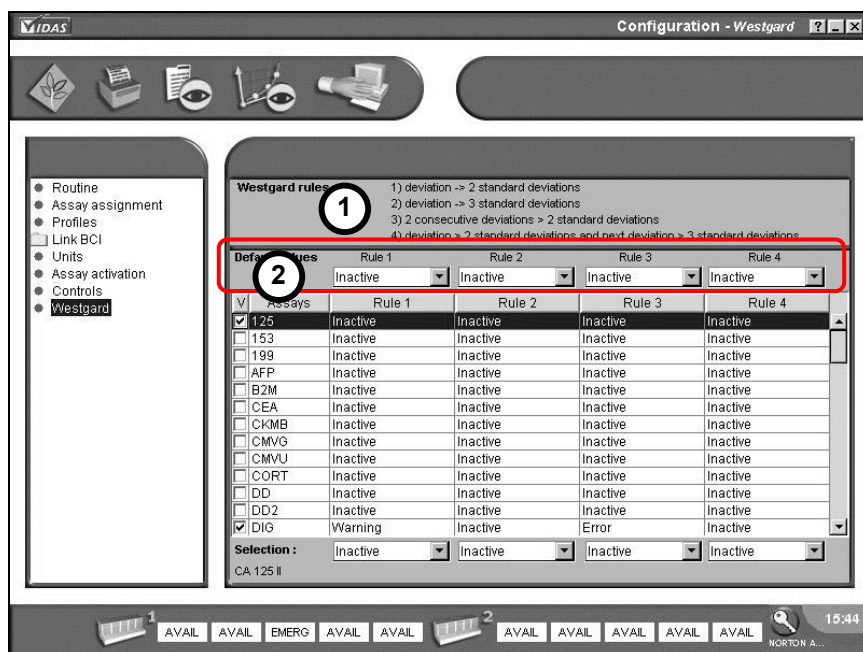
Fig. VIII 21: "Westgard" submenu window

1. **Westgard rules**. This zone describes the Westgard rules. These rules are listed according to their supervision level:

<u>Rule 1</u>**: deviation > 2 standard deviations**

Detection of a deviation beyond 2 standard deviations.

<u>Rule 2</u>**: deviation > 3 standard deviations**

Detection of a deviation beyond 3 standard deviations.

<u>Rule 3</u>**: 2 successive deviations > 2 standard deviations**

Detection of 2 successive deviations beyond 2 standard deviations.

<u>Rule 4</u>**: deviation > 2 standard deviations and following deviation > 3 standard deviations**

Detection of a deviation beyond 2 standard deviations followed by a deviation beyond 3 standard deviations.

2. **Default set-up**. Since the Westgard rules are installed, it is possible to activate the various supervision rules with a defined gravity level.

The following table gives the possible choices of activation of the 4 rules for all the assays.

Gravity level	Rule 1	Rule 2	Rule 3	Rule 4
Inactive	YES	YES	YES	YES
Warning	YES	YES	YES	NO
Error	NO	YES	YES	YES

<u>Inactive rule</u>: no effect on the assay result.

<u>Warning rule</u>: an orange bullet point appears in the Levey Jennings graph. "Warning" appears in the table of results.

<u>Error rule</u>: a red bullet point appears in the Levey Jennings graph. "Error" appears in the table of results.

Specific assay set up

To assign specific rules to an assay:

☑

- Select an assay in the list by clicking on the check box.

- Select the rules for this assay in the specific assay set-up zone which is displayed at the bottom of the screen.

1. **Assay selection**. This table lists all the available assays to which you can assign default or specific rules.

2. **Specific set-up**. The assay appears in inverse video and a specific set-up zone is displayed below the table.
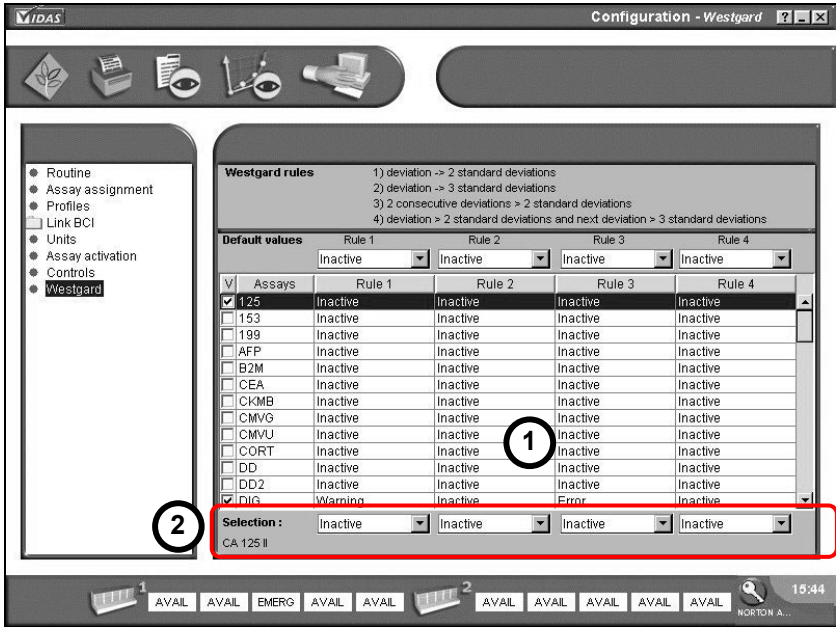
Fig. VIII 22: Specific set-up

Printing
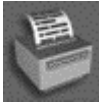
It is possible to print the list of available assays which have been assigned rules.

Maintenance

The "Maintenance" menu is described in Chapter 11 "Maintenance".

"About" dialog box

The "About" menu informs you of the *VIDAS PC* software version.
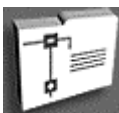
In the main window,

- click on the navigation tree,

- select "About".

The following window displays:
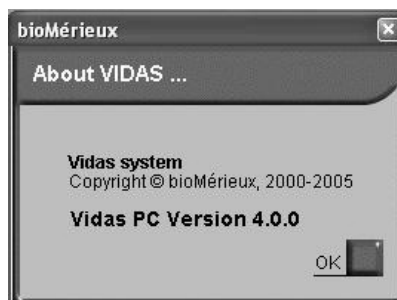
Fig. VIII 23: "About" menu window (example)

9   Backup

Introduction

This chapter deals with the automatic and manual data backup and data restoring after backup.

Depending on your computer, data backup and restoration can be performed using:

−   a CD-RW,

or

−   the backup kit on the bioMerieux USB key.

Programming automatic backup

CAUTION!   *This operation will erase the data currently on your storage medium.*

IMPORTANT!   *In order to program automatic backup or modify the stored backup settings, you must be logged on with a user identifier which gives administration rights over the operating system. For further information, please contact your laboratory system administrator.*

To return to the Windows® desktop without quitting *VIDAS PC*,

- Click on the ▣ button in the top right-hand corner of the *VIDAS PC* screen.

On the Windows desktop,

- Click on the 🏁 **start** button in the bottom left-hand corner of the screen or press one of the Windows keys situated either side of the space bar.
- Select "Settings", "Control Panel", "Scheduled Tasks" and DailyVidasBackup".
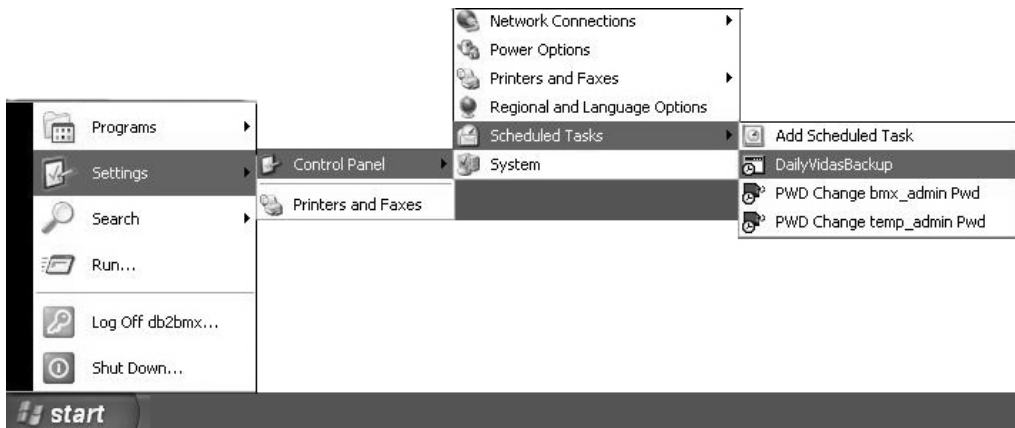
Fig. IX 1: Backup selection

The "DailyVidasBackup" window is displayed.

- Enter the «Schedule» data you want for automatic backup using the "Schedule" and "Settings" tabs (see following Figure).

- Click "OK" to confirm your selection.
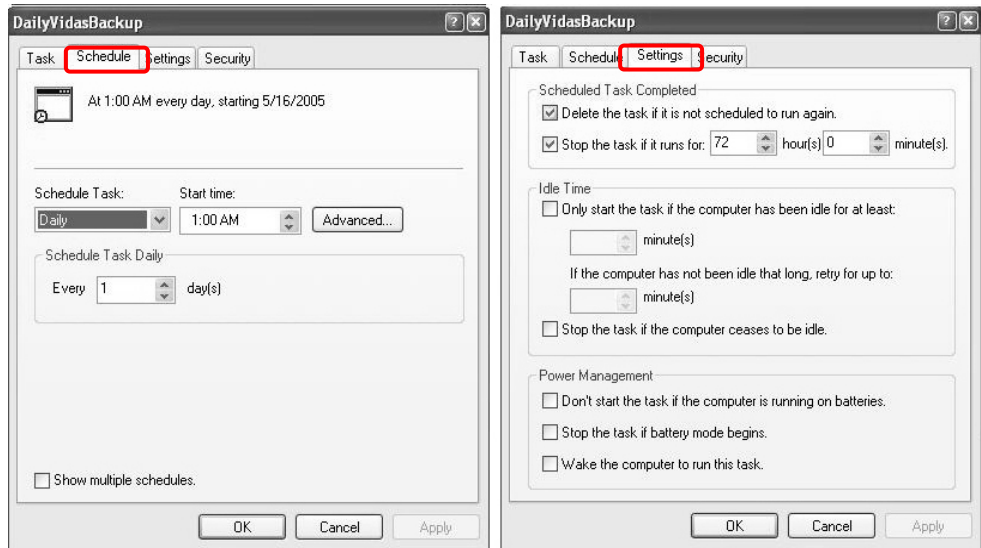
Fig. IX 2: Setting automatic backup parameters

Depending on your selections, backup of your data will start automatically.

If you are using the backup kit on the bioMerieux USB key, the backup will be performed automatically to the USB key.

If you are not using the backup kit on the bioMerieux USB key, then before starting the backup,

- make sure you have a CD-RW that is ready for use (formatted on a PC on which *VIDAS PC* is installed).

- Insert your backup CD-RW in the CD-ROM drive.

- Close the CD-ROM drive.

An "InCD" window may appear.

IMPORTANT!   *Make sure that your data backup CD-RW is in the reader before starting.*

9

When the backup is finished,

- Remove your CD-RW from the CD-ROM drive.

An "InCD" window may appear.

- Store your backup CD-RW in a suitable place.

To return to *VIDAS PC*,

- Click on the ![start] button in the bottom left-hand corner of the screen or press one of the Windows keys situated either side of the space bar.
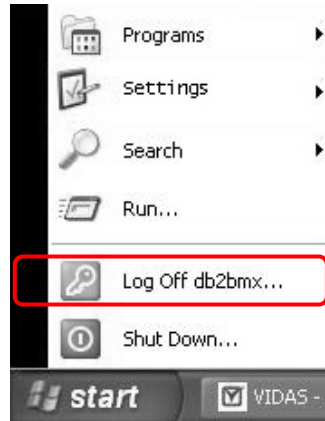
- Select "Log Off …".

The "Lof Off Windows" dialog box is displayed.
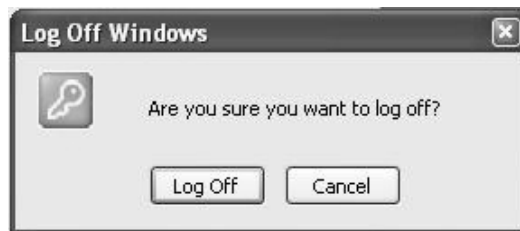
- Select "Log Off".

The session shuts down and a new session opening window is displayed.

- Enter the information required to open a new Windows session, corresponding to the desired user group.

- Follow the *VIDAS PC* starting procedure on page 3-7.

Starting manual backup

CAUTION!   *This operation will erase the data currently on your storage medium.*

IMPORTANT!   *To start manual backup, you must be connected with a user identifier that has all the operating system administration rights. For more complete information, contact your laboratory system administrator.*

If you are using the backup kit on the bioMerieux USB key, the backup will be performed automatically to the USB key.

If you are not using the backup kit on the bioMerieux USB key, then before starting the backup,

- make sure you have a CD-RW that is ready for use (formatted on a PC on which *VIDAS PC* is installed.

- Insert your backup CD-RW in the CD-ROM drive.

- Close the CD-ROM drive.

An "InCD" window may appear.

Note: *A warning message is displayed if the CD used for the backup already contains data.*

Whatever type of backup medium you are using (CD-RW or USB key),

- Start the *VIDAS PC* software.

On the main screen,

- Click on the navigation tree,

- select "Maintenance";

9

The maintenance window is displayed.

- Select "Backup Restore".

- Click on "Backup".
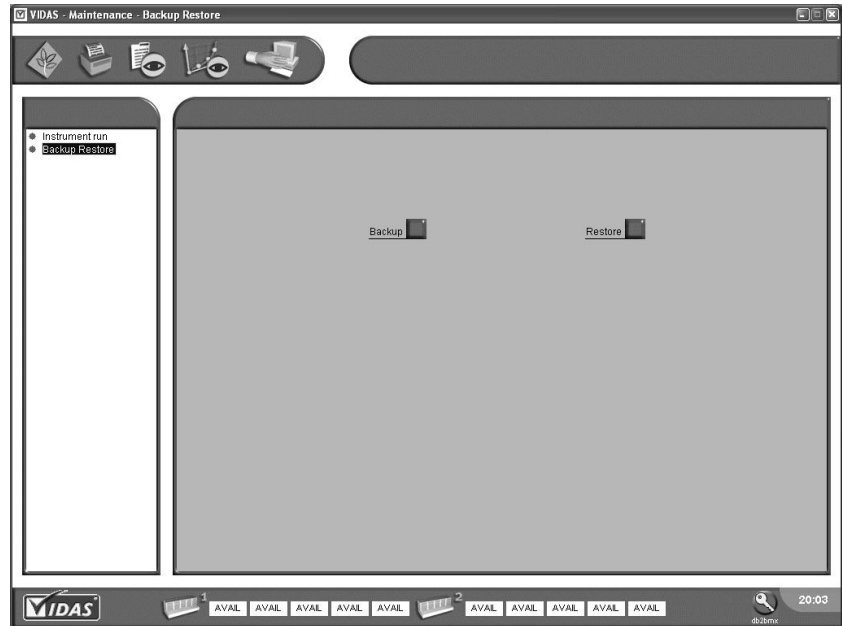
Fig. IX 3: Maintenance menu (backup)

Your data backup will start.

Note: *If **VIDAS PC** is running, the following message will display after a few seconds.*
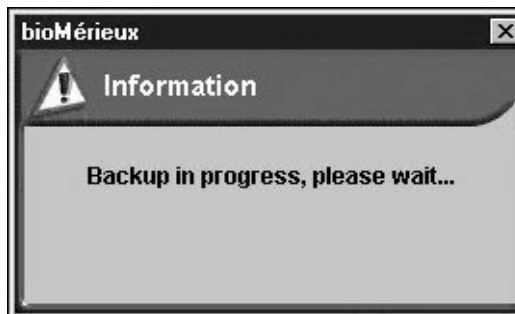
A window displaying different messages on a black background appears and then disappears.

The user is asked to wait for a few minutes.

Note: *The backup time actually depends on the size of the data to be backed up.*

When the backup is finished, if you are not using the backup kit on the bioMerieux USB key,

- Remove your CD-RW from the CD-ROM drive.

An "InCD" window may appear.

- Store your backup CD-RW in a suitable place.

Restoring data

CAUTION! ***The data currently in your database will be erased and replaced by data recorded on your storage medium.***

IMPORTANT! ***To start data restoration, you must be connected with a user identifier that has all the operating system administration rights. For more complete information, contact your laboratory system administrator.***

If you are using the backup kit on the bioMerieux USB key, the restoration will be performed automatically from the USB key.

If you are not using the backup kit on the bioMerieux USB key,

- Insert into the reader the CD-RW containing the data to be restored.

Whatever type of restoration medium you are using (CD-RW or USB key),

- Start the **VIDAS PC** software.

On the main screen,

- Click on the navigation tree,
- select "Maintenance".

9

The maintenance window is displayed.

- Select "Backup Restore".

- Click on "Restore".
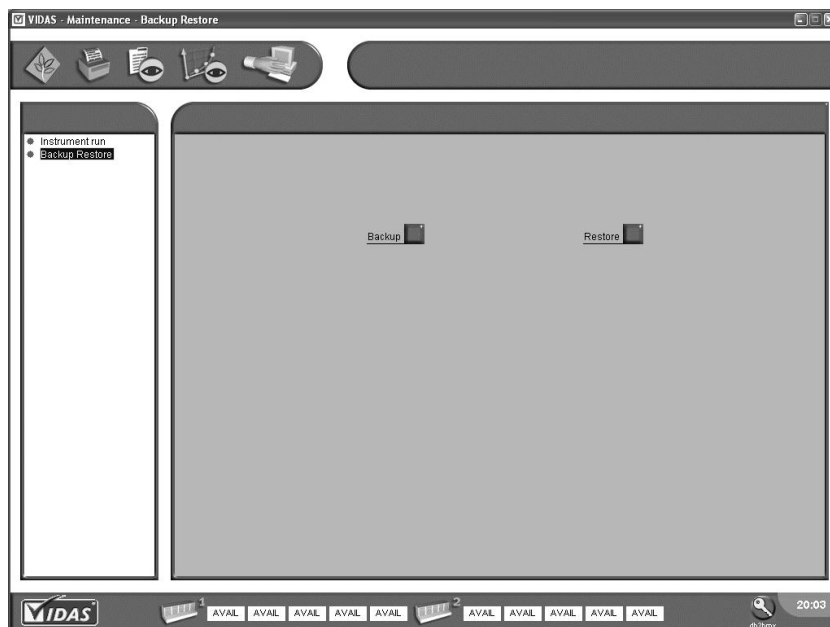
Fig. IX 4: Maintenance Menu (restore)

Restoring of data on your storage medium will start.

If *VIDAS PC* is running, the following message will display.

- Click "OK".

Restoring of data on your storage medium will start.

IMPORTANT!   *Data to be stored must have been saved using the same version of VIDAS PC.*

Restoring data that have been saved with an older version of the VIDAS PC software will have a retroactive effect on the software installed and will require you to update the software.

10 Bidirectional Computer Interface (BCI)

Introduction

This chapter deals with connection of the *VIDAS PC* to the BCI.

IMPORTANT!   *To use BCI NET, refer to the BCI NET User's Manual.*

Introduction

The Bidirectional Computer Interface requires the installation of an additional software program. To perform this connection you must call bioMérieux® SA.

The BCI configuration menus must be set up according to the connection protocol developed with your computer service company.

The technical characteristics of the BCI are available from the bioMérieux Technical Assistance.

CAUTION!   *Configuration and starting of your bidirectional interface (equipment and software required for the bioMérieux computer system, or for your laboratory information system (LIS)) must be performed by qualified personnel, authorized to do so.*
Any modification may lead to incorrect operation.

B C I   C o n f i g u r a t i o n

In the main window,

- Click on the navigation tree,

- Select "Configuration",

CAUTION!   ***To access the "Configuration" menu and its submenus, you must have logged on with a user identifier that belongs to the "VIDAS_ADMIN" group. If you have logged on with a user identifier that is a member of the "VIDAS_ROUTINE" group, the "Configuration" menu will not be accessible.***
For further information, please contact your laboratory system administrator.

This menu gives access to a choice of options and parameters in the form of several submenus. The submenus used by the BCI are:

− "Routine",

− "Link BCI".

10

"Routine" submenu

In the main window,

- Click on the navigation tree,

- Select "Configuration".

- Click on the "Routine" submenu.

The following window displays:
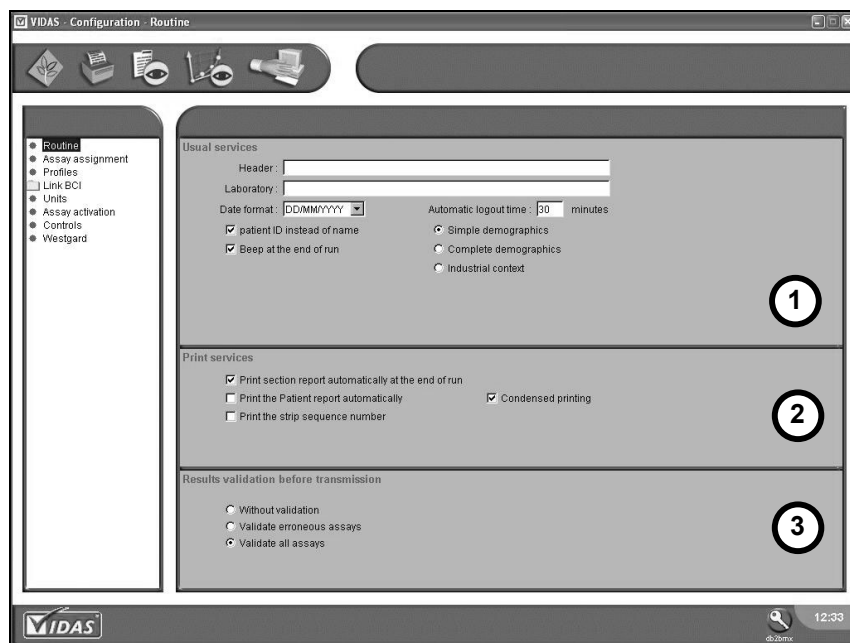
Fig. X 1: "Routine" submenu

1. **Usual services**:

"**Date format**": the default format is DD/MM/YYYY. It can be modified using the drop-down menu.

"**Automatic disconnection**": the default time is 30 minutes. It can be modified using the numeric keypad (maximum duration: 9999).

Patient ID instead of name:

☐   If this box has not been enabled, the Patient's name (Pn) and the Sample identifier (Ci) are present in the loading plan.

☑   If this box has been enabled, the Patient ID (Pi) and the Sample identifier (Ci) are present in the loading plan.

Simple demographics:

Recommended connection: UNIDIRECTIONAL
Only the sample identifier (Ci) is entered, preferably using the bar code reader.

Complete demographics:

Recommended connection: BIDIRECTIONAL.
The requests are transmitted to *VIDAS PC* by the interface.

Industrial context:

Recommended connection: UNI or BIDIRECTIONAL.
The specimen name and sample identifier (Ci) are entered, preferably using the bar code reader for the sample identifier.

CAUTION!   *If you need to change the <u>Patient demographics</u> configuration on VIDAS PC (from <u>Complete demographics</u> option to the <u>Simple Demographics</u> or the <u>Industrial Context</u> option, please contact your computer service company to check the consistency between the two systems, i.e. between the fields transmitted by the LIS and the fields sent back by VIDAS PC.*

2. **Print services**. (refer to page 8-41).

3. **Results validation before transmission.**

Without validation:

The results are automatically transmitted to the mainframe computer.

Validate erroneous assays:

Results with an alarm must be validated before being sent to the mainframe computer.

Validate all assays:

All the results must be validated before being sent to the mainframe computer.

10

"BCI Link" submenu

In the main window,

- Click on the navigation tree,

- Select "Configuration".

Selecting the BCI RS232 link

- Select "Link BCI ".

The BCI links are displayed.

- Select the link you want.

The following window appears:

Fig. X 2: "Link BCI" submenu - "*BCI RS232*" link

1. To set up BCI links:

The "Link name" and "Serial number" fields are used to configure the link.

- Enter the necessary data in the zones of the window.

Link name: Name of link

CAUTION!   *When defining parameters for BCI links, the link names must not include characters with accents.*

The shaded fields "Instrument ID", "Character set", "Case of data", etc. were defined when the *VIDAS PC* software was installed or were kept when the software was updated.

Character set:

- ISO 8859-1

Case of data: Transformation of characters:

- As is = as they are (transmitted characters will be displayed)
- Upper = transmitted characters will all be converted to upper case
- Lower = characters will be in lower case

Date format:

- DD/MM/YY
- DD/MM/YYYY
- MM/DD/YY
- MM/DD/YYYY
- YY/MM/DD
- YYYY/MM/DD

Note: *You must use the "YYYY" format for the year, for uni or bidirectional connection.*

Enable :

☑   Link enabled

☐   Link disabled

Fixed length:

☑   Fields with fixed length = maximum length of field

☐   Fields with variable length

Date separator:

/   Default separator

Time separator:

:   Default separator

Field separator:

| Default separator

10

2. **Selection of fields:**

- Enable the check box to select the fields transmitted or received. Fields with shaded check boxes are obligatory fields which cannot be enabled/disabled.

Note: *The choice of fields depends on the connection protocol developed by the computer company: for further information call bioMérieux®.*

There are 2 possibilities for the shaded check boxes:

The parameter is always enabled (it cannot be disabled).

The parameter is always disabled (it cannot be enabled).

The different fields transmitted or received are shown in the following table:

1. Choice of fields sent to the LIS.

2. Choice of fields received from the LIS.

Fig. X 3: Field selection zone

When *VIDAS PC* transmits results to the LIS, the "expired calibration" (nc) field contains the following mnemonic codes:

Mnemonic	Designation	Condition
lotexp	Lot expired	If lot is expired
calexp	Calibration expired	If calibration is expired
contneff	Control not run	If 1 control (Cx) at least is not present
calinc	Calibration not completed	If calibration is invalid or not present
conthnor	Control out of range	Cx with a footnote
conthwst	Control out of Westgard	QCx with a footnote
valid	Calibration validated	In others cases

To save the modifications,

- Change screens or print.

- The "Save" dialog box is displayed.
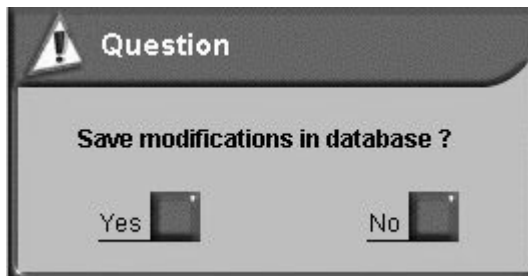
- Click on "Yes" to save the modifications.

Printing of the link configuration.

We recommend that you archive this document.

10

Selecting the *BCI NET* link

- select " BCI Link ".

The list of BCI links appears.

- Select the desired link.

The following window is displayed.

Fig. X 4: " Submenu BCI Link"–*BCI NET* Link

- To set parameters for the BCI link and select the fields, see section Selecting the BCI RS232 link.

BCI RS232 Configuration

- Double click on the icon on the Windows® desktop.

An identification window displays.

- Enter your user name and password.

CAUTION!   *Your user name and password, as well as the user group to which you belong (BCI_ADMIN or BCI_ROUTINE) must have been previously defined by your laboratory system administrator.*

The following window is displayed:
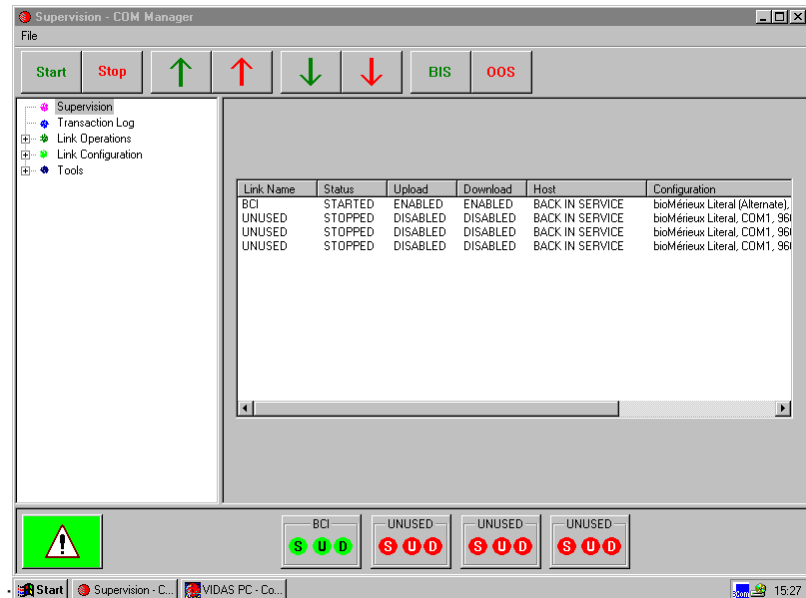
Fig. X 5: "*BCI RS232* Configuration" Menu

To return to the Windows® desktop without quitting *BCI RS232*,

- Click on the ▣ button in the top right-hand corner of the "Supervision - COM Manager" window.

Status of the connection

S: Start/Stop	Green = Connection started.
	Red = Connection halted.
U: Upload	Green = Transmission of results to mainframe computer enabled.
	Red = Transmission of results to mainframe computer disabled.
D: Download	Green = Reception of results from mainframe computer enabled.
	Red = Reception of results from mainframe computer disabled.

Alarm connection

Green = no alarm.

Red = alarm !

- Click on this button to open the "Event viewer" window: for further information call bioMérieux®.

Unused connection

All indicator lights are dark gray.

"Link Operations" submenu

⊞ ✦ Link Operations

This menu gives access to 4 possible links:

⊟ ✦ Link Operations
      ◆ BCI
      ◆ UNUSED
      ◆ UNUSED
      ◆ UNUSED

◆ BCI
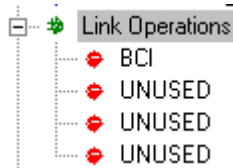
- Select the link you want (e.g. BCI).

The following window is displayed:
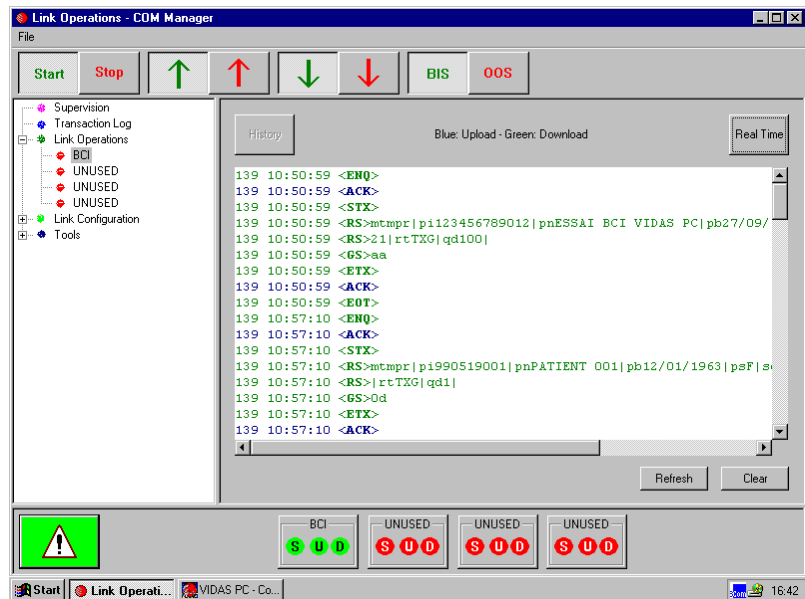
Fig. X 6: BCI-NT Configuration: "Link Operations" submenu

10

Starting/stopping the connection

"Start" button pressed down: connection has started. The corresponding status indicator light "S" is green.

Press "Stop" to halt the connection: the indicator light "S" changes to red.
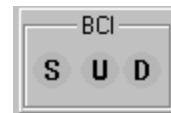
Transmission of results (Upload)

"↑" button (green) pressed down: transmission of results to the mainframe computer is enabled, the corresponding status indicator light "U" is green.

Press "↑" (red) to disable: the status indicator light "U" changes to red.
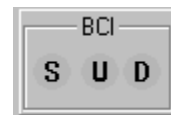
Reception of requests (Download)

"↓" button (green) pressed down: reception of assays from the mainframe computer is enabled, the corresponding status indicator light "D" is green.

Press "↓" (red) to disable: the status indicator light "D" changes to red.
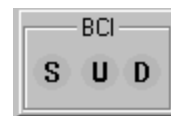
Results on hold (Back in Service/Out of Service)

"BIS" button (green) pressed down: results are uploaded to the mainframe computer.

"OOS" button (red) pressed down: results are not uploaded to the mainframe computer and are held until the BIS button is pressed down.

Note: *Use of the "BIS" and "OOS" functions can be automated by the LIS: refer to the connection protocol developed by your computer service company. For further information contact the bioMérieux® Technical Assistance Service.*

Displaying communications tracking data

Communications tracking data are saved to facilitate after sales service. For further information, call bioMérieux® Technical Assistance.

Green = mainframe computer
Blue = *VIDAS PC*

HH:MM:SS of the transmission

No. of the day in the year
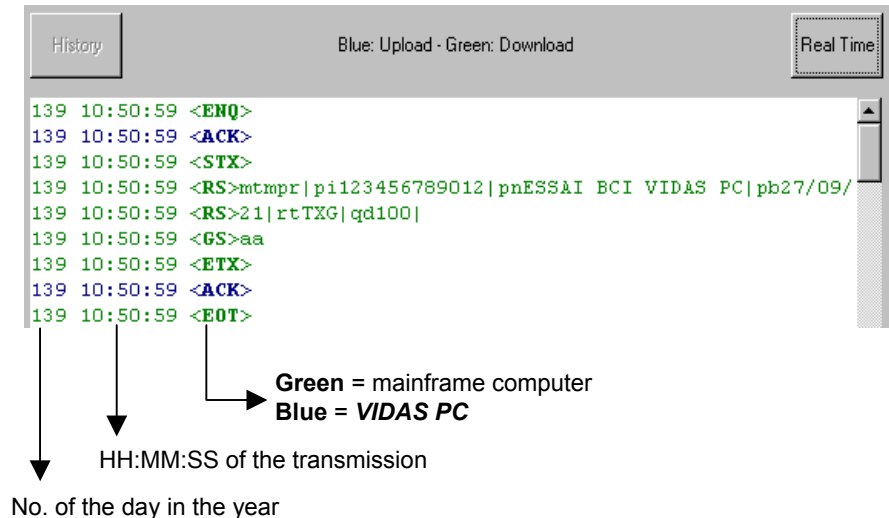
Fig. X 7: Displaying communications tracking data

	Saving of communications tracking data in a file.
	Saving and display of communications tracking data in real time. This mode enables you to test the connection: for further information, call bioMérieux.

Note: *The shaded button indicates the enabled mode.*
                 The "Real time" mode should not be enabled when you quit the window.
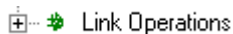
⊞ ✽ Link Operations	• Click on "Link Operations" to return to the main "Link Operations - COM Manager" menu.

10

Displaying uploaded messages

Uploaded messages are saved to facilitate after sales service: for further information call bioMérieux® Technical Assistance.

✿ Transaction Log

- Click on "Transaction Log".

The "Transaction Log" window appears.
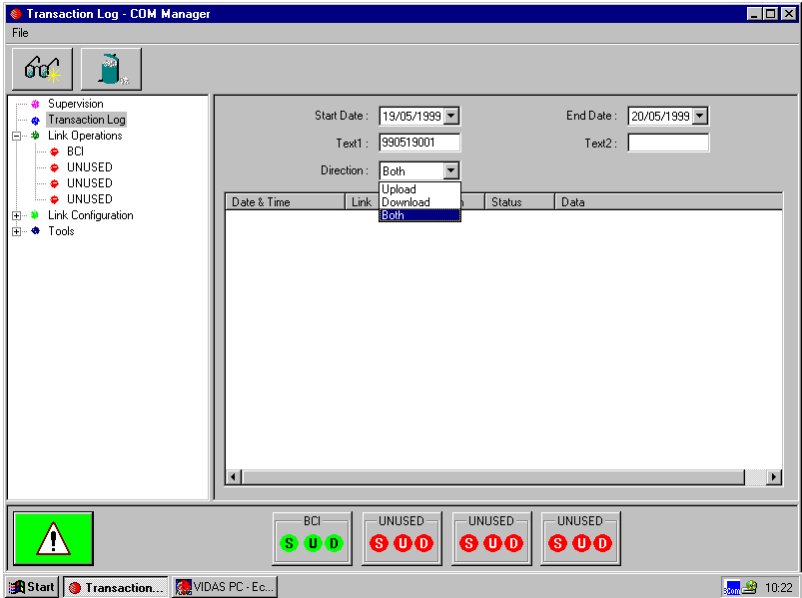
Fig. X 8: Displaying uploaded messages

Searching for uploaded messages

- Enter the following information:

Start Date : [19/05/1999 ▼] − Search start date.

End Date : [20/05/1999 ▼] − Search end date.

Direction : [Both ▼]
[Upload]
[Download]
[Both]
− Direction of messages :
Upload = Results transmitted by *VIDAS PC* to the LIS.
Download = Assays transmitted by the LIS to *VIDAS PC*.
Both = Both together (by default).

Text1 : [990519001] − Text of a message.
Example = sample number.

- Start the search:
The corresponding transmitted messages are displayed.

Start Date : 19/05/1999 ▼			End Date : 20/05/1999 ▼	
Text1 : 990519001			Text2 :	
Direction : Both ▼				

Date & Time	Link	Direction	Status	Data
19/05/1999 10:57:10	BCI	Download	Sent	mtmpr|pi990519001|pnPATIENT 001|pb12/01/
19/05/1999 11:19:33	BCI	Download	Sent	mtmpr|pi990519001|pnPATIENT 001|pb12/01/

Fig. X 9: Search for transmitted messages

Note: *To find out how to utilize transmitted messages, call bioMérieux® Technical Assistance.*

10

Deleting uploaded messages

Select the messages you want.

- Click on the "Date & Time" corresponding to the message you want to delete.

You can select several messages at a time:

- Select the first message, press <Shift> and select the last message to be deleted,

or

- Press <Ctrl> and select in succession the messages you want to delete.

To delete the messages:

- Click on the "Delete" button. The corresponding messages disappear.

Note: *To delete uploaded messages, you need to log on with a user identifier that is a member of the BCI_ADMIN group.*

Printing uploaded messages

To print uploaded messages,

- Click on the "Print" button.

To print one or more messages at a time,

- Select the first message to be printed, press the <Shift> key and select the last message to be printed,

or

- Press <Ctrl> and select the messages one after another.

- Click on the "Print" button.

After each print out, the screen must be refreshed. To do so, you have to perform a new search:

- Click on the "Search" button.

"Link Configuration" submenu

Note: *To access the "Link Configuration" menu, you must log on with a user identifier that is a member of the BCI_ADMIN group.*

🌸 Link Configuration

This menu gives access to 4 possible links:

```
🌸 Link Configuration
  ├─ ● BCI
  ├─ ● UNUSED
  ├─ ● UNUSED
  └─ ● UNUSED
```

● BCI
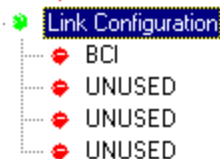
• Select the link you want: e.g. BCI (do not use characters with accents).

The following window displays:
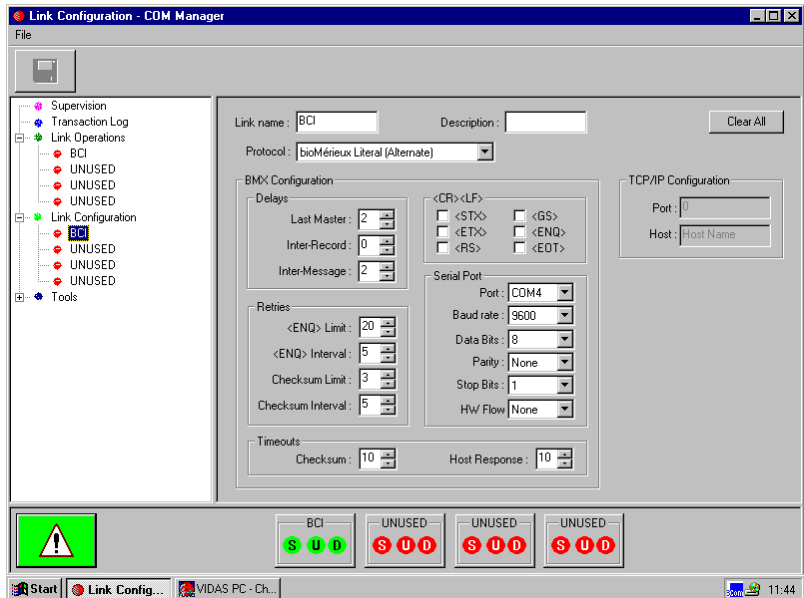
Fig. X 10: "Link Configuration" submenu

Note: *This parameter must be set taking into account the characteristics of the connection protocol developed by your computer company. For further information, call bioMérieux® Technical Assistance.*

● Link Configuration

• Click on "Link Configuration" to return to the main "Link Configuration - COM Manager" menu.

10

"Tools" submenu

Note: *To access the "Open Configuration" and "Save Configuration" options in the "Tools" menu, you must log on with a user identifier that belongs to the BCI_ADMIN group.*
If you log on with a user identifier that is a member of the BCI_ROUTINE group you will only be able to print the configuration.

- Double-click "Tools":

The Tools submenu is displayed:

Open Configuration   Enables you to load connection parameters.

Save Configuration   Enables you to save connection parameters.

Print Configuration   Enables you to print and archive connection parameters.

Unidirectional interface

BCI RS232 parameter setting

- Double click on the **BCI** icon.

- Enter your user name and password.

CAUTION! *Your user name and password, as well as the user group to which you belong (BCI_ADMIN or BCI_ROUTINE) must have been previously defined by your laboratory system administrator.*

- Select a link in the "Link Operations" submenu.
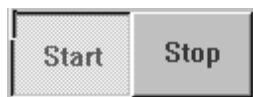
Starting/stopping the connection

"Start" button pressed down, connection has started: the corresponding status indicator light "S" is green.

Transmission of results (Upload)

"↑" button (green) pressed down: transmission of results to the mainframe computer is enabled, the corresponding status indicator light "U" is green.

Reception of requests (Download)

"↓" button (red) pressed down: reception of assays from the mainframe computer is disabled, the corresponding status indicator light "D" is red.

Connection statuses
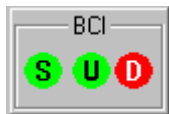
S: Start/Stop
Green = Connection started.
U: Upload
Green = Transmission of results to the mainframe computer is enabled.
D: Download (disabled)
Red = Reception of assays from the mainframe computer is disabled.

10

Setting *VIDAS PC* parameters

In the main window,

- Click on the navigation tree,

- Select "Configuration".

- Select "Routine".

⊙ **Simple demographics**

or,

⊙ **Industrial context**

Recommended connection: UNIDIRECTIONAL.

- Select one of the following validation modes:

⊙ **Without validation**

⊙ **Validate erroneous assays**

Loading
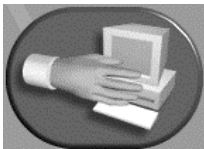
In the main window, or in another window,

- Click on the "Loading" icon,

or,

in the main window,

- Click on the navigation tree and then,

- Select the "Loading" menu.

- Select the assay you want.

- Enter the sample ID (Ci), preferably using the bar code reader.

- Enter the specimen name, for industrial context.

- Enter the dilution factor, if necessary.

In case of a multi-laboratory interface:

- Enter the origin. This will enable you to differentiate the laboratories.

For more information on how to perform assays, see Chapter 4 "Instructions for use".

Automatic transmission of results

Results are sent to the LIS after they have been printed, according to the "**Results validation before transmission**" mode selected.

10

Bidirectional connection

Setting BCI RS232 parameters

- Double click on the *BCI* icon.

- Enter your user name and password.

- Select a link in the "Link Operations" submenu.

Starting/stopping the connection

"Start" button pressed down: connection has started: the corresponding status indicator light **S** is green.

Transmission of results (Upload)

"↑" button (green) pressed down: transmission of results to the mainframe computer is enabled, the corresponding indicator light **U** is green.

Reception of requests (Download)

"↓" button (red) pressed down: reception of assay requests from the mainframe computer is enabled, the corresponding status indicator light **D** is green.

Connection statuses
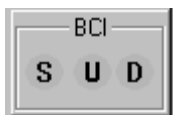
S: Start/Stop
Green = Connection started.

U: Upload
Green = Transmission of results to the mainframe computer is enabled.

D: Download
Green = Reception of assay requests from the mainframe computer is enabled.

Setting *VIDAS PC* parameters

In the main window,

- Click on the navigation tree,
- Select "Configuration".
- Select "Routine".

PATIENT ID instead of name

(select by default)

The Patient's name (or the specimen) (Pn) and the sample identifier (Ci) will be included in the loading plan.

PATIENT ID instead of name

(special connection where the name is transferred to the Ci field).

The patient ID (Pi) and the sample identifier (Ci) are included in the loading plan.

⊙ **Complete demographics**

or,

⊙ **Industrial context**

Recommended connection: BIDIRECTIONAL
requests are transmitted to the *VIDAS PC* by the interface.

Example of download tracking data for the request:

```
140 13:18:54 <ACK>
140 13:18:54 <EOT>
140 13:21:41 <ENQ>
140 13:21:41 <ACK>
140 13:21:41 <STX>
140 13:21:41 <RS>mtmpr|pi990519001|pnPATIENT001|pb12/01/1963|psF|so2|si|ci990519001
140 13:21:41 <RS>|rtHCG|qd1|
140 13:21:41 <GS>ec
140 13:21:41 <ETX>
140 13:21:41 <ACK>
140 13:21:41 <EOT>
```

- Select one of the following validation modes:

⊙ **Without validation**

⊙ **Validate erroneous assays**

10

Loading

In the main window or in another window,

- Click on the "Loading" icon,

or,
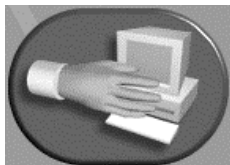
in the main window,

- Click on the navigation tree and then,

- Select the "Loading" menu.

For more information on how to perform assays, see Chapter 4 Instructions for use.

Automatic transmission of results

Results are sent to the mainframe computer after they have been printed, according to the "**Results validation before transmission**" mode selected.

Example of tracking data for an uploaded result:

```
140 15:09:16 <ENQ>
140 15:09:16 <ACK>
140 15:09:16 <STX>
140 15:09:16
<RS>mtrsl|pi990519001|pnPATIENT001|pb12/01/1963|psF|so2|si|ci990519001|rtHCG|rnHCG|
140 15:09:16 <RS>tt15:09|td20/05/1999|ql|qn28,94mUI/ml|y3mUI/ml|qd1:1|ncvalid|
140 15:09:16 <GS>ab
140 15:09:16 <ETX>
140 15:09:16 <ACK>
140 15:09:16 <EOT>
```

Validation / Retransmission of results

"Results" Menu

In the main window, or in another window,

- Click on the "Results" icon,

or,

in the main window,
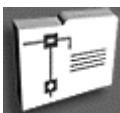
- Click on the navigation tree and then,

- Select the "Results" menu.

Displaying results

Refreshes the day's list of results (if assays have just been completed).

Validation of results

Transmits the selected result(s) to the mainframe computer.

Note: *You can select the assay result to be transmitted by validating the check box at the beginning of each line of results or by selecting the whole line.*

To transmit several assays at the same time,

- Click on the first assay and then on the last assay holding the "Shift" key down. The list to be deleted appears in inverse video.

- Click on the "Validation" icon.

Retransmission of results

Sends the selected result(s) back to the mainframe computer.

10

11 Maintenance

This chapter deals with the maintenance of the patient database.

IMPORTANT! **For information on the VIDAS instrument maintenance, refer to Chapter 6 "Maintenance" in the VIDAS Instrument User's Manual.**

Patient database purge

IMPORTANT!   ***You must close all applications before purging the database.***

Nota :   *The patient database purge procedure can only be performed by the laboratory administrator.*

It is recommended to purge the database at least once a year and before each software update.

The database purge enables the laboratory to select the information they want to keep.

The database can be purged according to the following 3 criteria:

– **Number of runs**: number of runs to be stored in the database.
The default value is 30,000 runs (maximum).

– **Number of patients**: number of patients stored in the database.
The default value is 180,000 patients (maximum).

IMPORTANT!   ***When a patient is deleted, all the results relating to that patient are also deleted.***

– **Lot**: time during which results are archived after the reagent lot has expired.
The default value is 365 days (maximum).

IMPORTANT!   ***When expired lots are removed, all the associated data are purged (calibration, MLE card, patient results).***

WARNING!   ***If you want to store current data, you must perform a data backup.***

To purge,

- Click on the ![start] button in the bottom left-hand corner of the screen or press one of the Windows® key situated either side of the space bar.

- Select "Run".
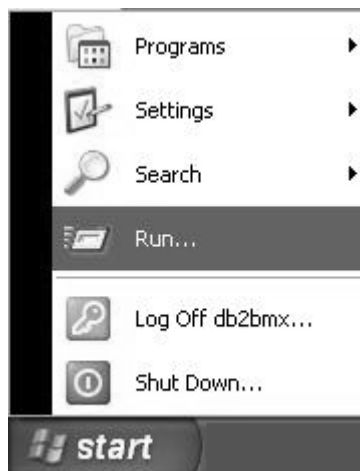
The "Run" window appears in the bottom left-hand corner of the Windows desktop.

- Enter the following command: D:\bmx\system\bin\vidaspurge.bat
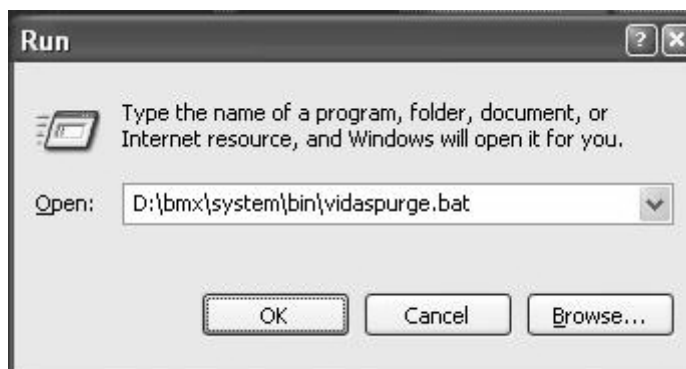
Fig. XI 1: "Run" window

- Click on "OK".

The VidasPurge program opens.
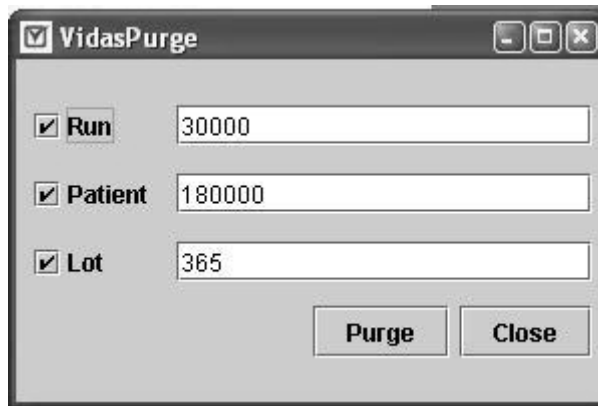
Fig. XI 2: VidasPurge selection window

This selection window enables you to modify default criteria.

To do so,

- deselect the criteria that are not required for the purge.

Note: *At least one criterion must be selected to start the purge. If you deselect all the criteria, the "Purge" will be inactivated (shaded).*

- If necessary, modify the default values for the criteria you have selected.

IMPORTANT!   ***If you enter 0 as a value for one or more criteria, the patient base will be totally purged for the selected criteria.***

- Click on "Purge" to confirm your selection.

The program then identifies the user rights:
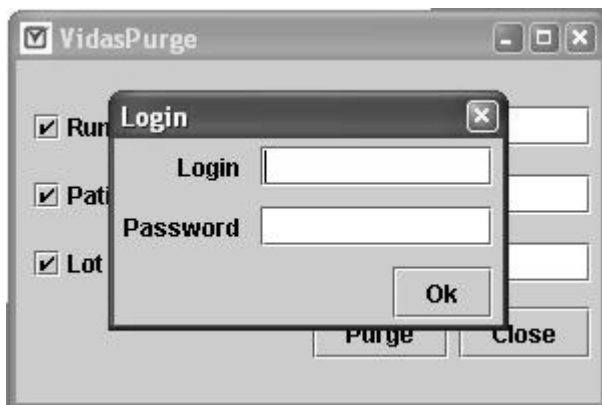
Fig. XI 3: VidasPurge selection window

- Enter the administrator's identifier and password.

- Click on "OK".

IMPORTANT!   *This procedure can only be performed by the administrator. Therefore, if you do not possess the required rights to purge the database, you will not be authorized to continue.*

The following warning message is displayed:

Fig. XI 4: Invalid password

- Click on "OK".

The purge is then aborted.

However, if you have the required rights, you will be authorized to perform the purge.

The purge confirmation window is displayed:
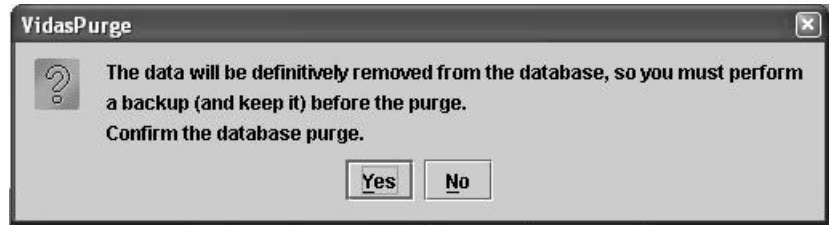
Fig. XI 5: Purge confirmation window

- Click on "Yes" to confirm the database purge,

or

- Click on "No" to cancel the purge.

Note: *To save existing data, check that a backup was previously performed.*

The database purge starts. Its progress is indicated by the progress bar displayed on the screen.

When the patient database purge has finished, the following message appears.

Fig. XI 6: End of VidasPurge

- Click on "OK" to confirm the end of the operation and close the dialog box.

- Click on "Close" to close VidasPurge.

Maintenance "Instrument run"

IMPORTANT! *This menu is for use by bioMérieux® technicians only.*

On the main screen,

- click on the navigation tree,
- select the "Maintenance" menu.

The maintenance window is displayed.

- Select "Instrument run".
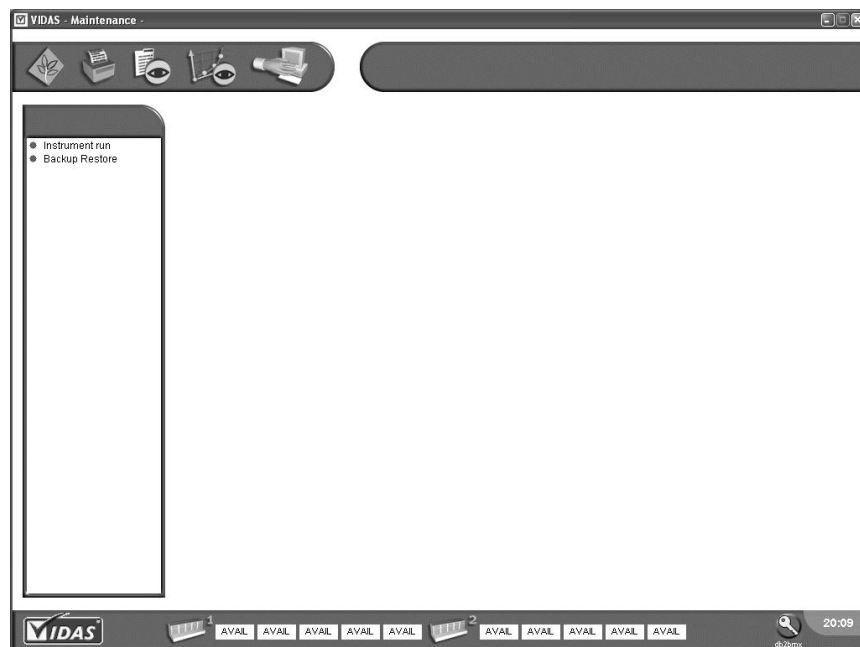
Fig. XI 7: Maintenance Menu

A dialog box is displayed.

Fig. XI 8: Password for the "Instrument run" submenu

12 Troubleshooting

Introduction

Four types of errors may occur when using the software:

− reagent errors,

− instrument errors,

− software errors.

− errors not related to the equipment.

This chapter describes how to manage these four types of errors and what corrective action should be performed.

It also presents the errors and warnings that are printed on the results lists.

Reagent errors

When a reagent error occurs, the following messages are displayed in the section status bar:

− ERRSUB

− ERRCB

− ERRCAL

− ERRLOT

ERRSUB: substrate error

The substrate reading performed on the strip at the start of the assay, is out of range (see page 8-35).

- Check that the reagent storage temperature is 4°C.

- Check the temperature at which the strips are used before starting the assay (see the assay package insert).

- Check the expiration date of the strips.

- Reperform the assay using a new strip.

ERRCB: bar code reading error

If the bar code cannot be read automatically,

- Enter the bar code manually using the instrument menu (see page 8-36).

If the activated protocol of the assay is not the correct one,

- Activate the correct protocol (see page 8-48) and follow the procedure described on page 8-37.

If the number of tests created in a predefined section is more or less than the number of reagent strips loaded in the section(s).

- Follow the procedure on page 8-37.

ERRCAL: standards error

Calibration for this assay is incorrect (see page 8-33).

- Check that entry of master lot data using the MLE card has been performed and that the curve has been stored in memory without an error message.

- Perform recalibration for the assay concerned and check that it is correct.

ERRLOT: lot error

> The lot for this assay has expired (see page 8-37).

- Check the expiration date of the reagents.

- Reperform the assay using reagents from a valid lot.

Instrument errors

> When an instrument error occurs, the message "ERRINST" appears in the section status bar.
>
> Instrument errors are numbered as follows:
>
> − errors 12 to 57 concern a specific section in the analytical module.
>
> An alarm is triggered for each of these errors.
>
> To stop the alarm,

- Correct the cause of the error,

- Delete it from the instrument menu (see page 8-32).

CAUTION! ***Discard the strips and SPR®s of assays which have been halted.***

> − Errors 101 to 163 apply to the analytical module as a whole. These errors <u>require action to be taken</u>.
> Please refer to "List of errors from 101 to 163" on page 12-8 to determine what actions are necessary.

12

List of errors from 12 to 57 and corresponding corrective action

When an error from 12 to 57 occurs, *VIDAS* informs the user as follows:

Error 12 – Tower jam or sensor failure

A mechanical problem has occurred and the tower has jammed, or the sensor has not detected tower movement.

- Reset the section (see page 8-28).

If the problem persists, call bioMérieux® Technical Assistance or your local representative.

Error 13 – Tray jam or sensor failure

A mechanical problem has occurred and the tray has jammed, or the sensor has not detected tray movement.

- Reset the section (see page 8-28).

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 14 – Pipetting jam or sensor failure

A mechanical problem has occurred and the pump has jammed, or the sensor has not detected pump movement.

- Reset the section (see page 8-28).

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 15 – Tower positioning error

Tower positioning error. The motor lost steps.

- Reset the section (see page 8-28).

If the problem persists,

- Wait until all the assays have been completed in all the sections,

and then,

- Turn off the *VIDAS* module and turn it back on again.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 16 – Tray positioning error

Tray positioning error. The motor lost steps.

- Reset the section (see page 8-28).

If the problem persists,

- Wait until all the assays have been completed in all the sections,

and then,

- Turn off the *VIDAS* module and turn it back on again.

If the problem persists, call bioMérieux® Technical Assistance or your local representative.

Error 17 – Pipette positioning error

Pump positioning error. The motor lost steps.

- Reset the section (see page 8-28).

If the problem persists,

- Wait until all the assays have been completed in all the sections,

and then,

- Turn off the *VIDAS* module and turn it back on again.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 18 – Door was opened while assay was in progress

The SPR® block door was opened while an assay was in progress or the section was running.

- Close the SPR block door, the current assay is unusable.

If the error occurs without the SPR block door being open, there is a door detection problem.

Call bioMérieux Technical Assistance.

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Error 50 – High tray temperature

The temperature of the tray is above 38°C.

- Check that the following environmental conditions are respected:
    - the instrument must not be placed in direct sunlight,
    - the instrument must not be placed near a source of heat,
    - room temperature must not exceed 30°C,
    - there must be sufficient space and good circulation of air around the instrument.

Error 51 – Low tray temperature

The temperature of the tray is below 36°C

If the *VIDAS* module has just been turned on, leave it to warm up for 30 minutes, then turn it off and on again.

- Wait 20 minutes before starting assays.

Error 52 – High SPR block temperature

The temperature of the SPR® block is above 38°C.

- Check that the following environmental conditions are respected:
    - the instrument must not be placed in direct sunlight,
    - the instrument must not be placed near a source of heat,
    - room temperature must not exceed 30°C,
    - there must be sufficient space and good circulation of air around the instrument.

Error 53 – Low SPR block temperature

The temperature of the SPR block is below 36°C.

If the *VIDAS* module has just been turned on, leave it to warm up for 30 minutes, then turn it off and on again.

- Wait 20 minutes before starting assays.

Error 54 – Tray temperature higher than the average limit

The temperature of the tray is higher than the average limit by 1°C.

- Check that the following environmental conditions are respected:

    – the instrument must not be placed in direct sunlight,

    – the instrument must not be placed near a source of heat,

    – room temperature must not exceed 30°C,

    – there must be sufficient space and good circulation of air around the instrument.

Error 55 – Tray temperature lower than the average limit

The temperature of the tray is lower than the average limit by 1°C.

If the *VIDAS* module has just been turned on, leave it to warm up for 30 minutes, then turn it off and on again.

- Wait 20 minutes before starting assays.

12

Error 56 – SPR block temperature higher than the average limit

The temperature of the SPR[®] block is higher than the average limit by 0.7°C.

- Check that the following environmental conditions are respected:

    – the instrument must not be placed in direct sunlight,

    – the instrument must not be placed near a source of heat,

    – room temperature must not exceed 30°C,

    – there must be sufficient space and good circulation of air around the instrument.

Error 57 – SPR block temperature lower than the average limit

The temperature of the SPR block is lower than the average limit by 0.7°C.

If the *VIDAS* module has just been turned on, leave it to warm up for 30 minutes, then turn it off and on again.

- Wait 20 minutes before starting assays.

List of errors from 101 to 163

When an error from 101 to 163 occurs (except errors 114, 121, 122, 154), the *VIDAS PC* emits a beep.

The following modifications appear on the status bar:

1. **Analytical module affected by the error**. The icon corresponding to the analytical module affected by the error is circled in red.

2. **Information message**. If you position the cursor on the icon corresponding to the analytical module affected by an error, the message "You have to consult the errors list" will be displayed.

3. **Section with an error (if an assay is running)**. The message "ERRINST" may appear when an assay is running.
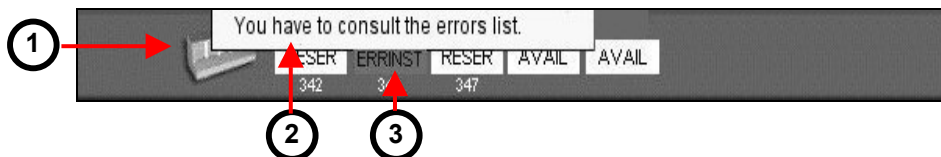
Fig. XII 1: Indication of an error (example)

The beep is deactivated when you view the list of errors in the Instrument menu (available by clicking on the *VIDAS* module icon circled in red, or if necessary, by clicking on the status bar of the section with the error "ERRINST").

1. **Error description**. Click on the line containing "Instrument error" to display the error description.

2. **Error deletion icon**. This icon enables you to delete a previously selected error. The status of the section affected by the error goes back to "RESERV".
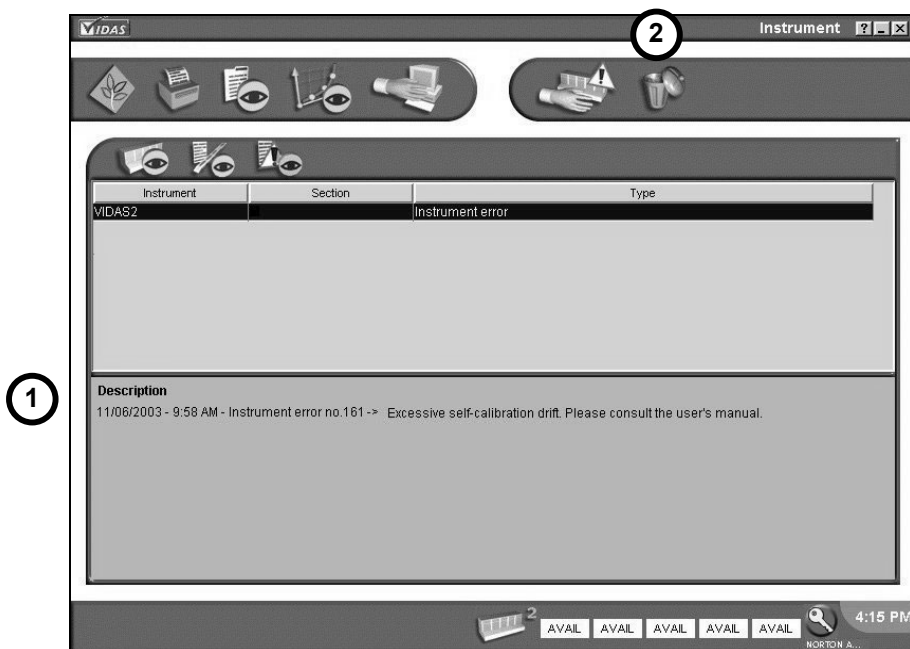
Fig. XII 2: Description of an error (example)

The *VIDAS* icon returns to normal after the instrument error has been corrected or deleted from the list (error deletion icon).

CAUTION!   *Discard the strips and SPR®s of assays which have been halted.*

List of errors from 101 to 163 and corresponding corrective action

When an error from 101 to 163 occurs, *VIDAS* informs the user as follows:

Error 101 to error 102:

Error 101 – Instrument lack of memory

Error 102 – Insufficient memory for protocols

- Restart the analytical module.

If the problem persists, call bioMérieux® Technical Assistance or your local representative.

Error 103 to error 108:

Error 103 – Unknown command received from computer

Error 104 – Invalid VIDASEP parameters

Error 105 – Invalid start section parameters

Error 106 – Invalid retransmit parameters

Error 107 – Invalid reset section parameters

Error 108 – Invalid protocol parameters

- Check that the information entered is correct.

- Restart the analytical module if necessary.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 109 – Section reset error

- Reset the section.

If the problem persists, call bioMérieux® Technical Assistance or your local representative.

Error 110 – Section start error

- Create a new job list.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 111 – Section restart error

- Create a new job list and use new reagents.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 112 – Protocol loading error

- Check that the information entered is correct.
- Reset the section.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 114 – Incubator error

This error is always associated with another error.

- Refer to the associated error to find out what action to take.

Error 115 – Invalid bar code parameters

- Allow the assays in progress to finish then restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 117 – Protocol corrupted

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 119 to error 120:

Error 119 – Invalid reset section parameters

Error 120 – Illegal interpretation parameters

- Check that the information entered is correct.

- Restart the analytical module if necessary.

If the problem persists, call bioMérieux® Technical Assistance or your local representative.

Error 121 to error 122:

Error 121 – Unable to start bar code reading: check doors

Error 122 – Unable to start section

- Look for the reason why the analytical module cannot start (open doors, etc.).

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 123 – Unable to retransmit data to computer

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 124 to error 131:

Error 124 – Optical self test: air reading > 20

Error 125 – Optical self test: extended range hardware failure

Error 126 – Optical self test: air reading > 10

Error 127 – Optical self test failure

Error 128 – Instrument self test failure

Error 129 – Instrument self test failure

Error 130 – Instrument self test failure

Error 131 – Instrument self test failure

- Call bioMérieux Technical Assistance or your local representative.

Error 132 – Invalid SLIPTIME command parameters

- Check that the information entered is correct.

- Restart the analytical module if necessary.

If the problem persists, call bioMérieux® Technical Assistance or your local representative.

Error 133 to error 137:

Error 133 – Protocol reading scheduling error

Error 134 – Protocol reading scheduling error

Error 135 – Protocol reading scheduling error

Error 136 – Tray not detected by scanner head

Error 137 – Protocol reading scheduling error

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

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Error 138 – Invalid SECTEMP command parameters

- Check that the information entered is correct.

- Restart the analytical module if necessary.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 139 – Manual section reset while processing

A section being used has just been reset.

This error does not require user intervention.

Error 141 to error 144:

Error 141 – Section reading status error

Error 142 – Section reading status error

Error 143 – Scanner unable to find home position

Error 144 – Self test: unable to find scanner home position

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 145 – Scanner slow speed warning

- Allow the assays in progress to finish then call bioMérieux® Technical Assistance or your local representative.

Error 146 – Scanner memory capacity warning

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 147 to error 150:

Error 147 – Extended range optics failure

Error 148 – Scanner memory (internal stack) capacity warning

Error 149 – Scanner memory (external stack) capacity warning

Error 150 – Scanner error overflow

- Call bioMérieux Technical Assistance or your local representative.

Error 151 to error 154:

Error 151 – Invalid DELPROTO parameters

Error 152 – Invalid SETVAR parameters

Error 153 – Invalid BCTEXT parameters

Error 154 – Unable to perform bar code reading

- Check that the information entered is correct.
- Restart the analytical module if necessary.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Error 155 to error 159:

Error 155 – Scanner board memory corrupted

Error 156 – Scanner board memory corrupted

Error 157 – Solid standard detected but no value stored

Error 158 – Solid standard not detected but value stored

Error 159 – Solid standard bracket can no longer be detected

- Call bioMérieux Technical Assistance or your local representative.

Error 160 – Self-calibration drift

- Restart the analytical module.

- Call bioMérieux® Technical Assistance or your local representative, unless this error occurs during warm-up of the analytical module.

Error 161 – Excessive self-calibration drift

This error also indicates a problem with the scanner.

- Turn off the analytical module then call bioMérieux Technical Assistance or your local representative.

Error 162 – Instrument too busy to perform calibration

- Do not use the analytical module for 1 hour, or else restart it.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

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Error 163

- Restart the analytical module.

If the problem persists, call bioMérieux Technical Assistance or your local representative.

Software errors

The most common software errors are:

- General error

- Database error

- Communication error

- Internal error

For these types of errors,

- Close the application running.

- Restart the computer.

Note: *If necessary, closing of the application can be forced using the "Task Manager" . To do so,*

- Simultaneously press <CTRL> + <ALT> + <DEL> to open the "Windows® XPe Security" dialog box.

- Click on "Task Manager" .

The "Task Manager" dialog box displays.

- Select the task(s) (applications) to close,

- Click on the "End Task" button.
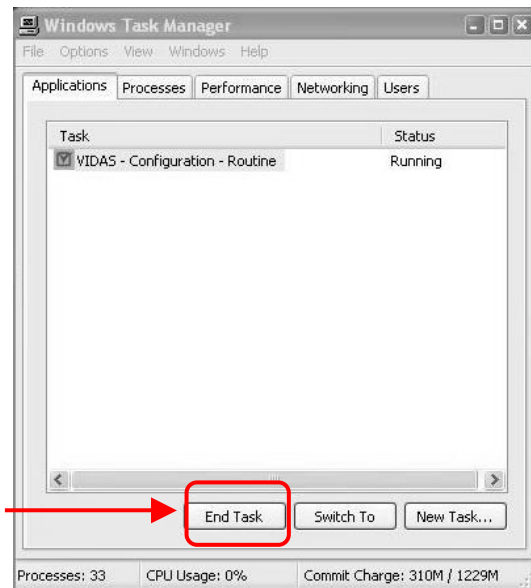
Internal errors

When a software error occurs, the message "ERRINT" appears in the section status bar.

An alarm is triggered for each of these errors. To stop the alarm, delete it in the Instrument menu (see page 8-32).

Assay preparation and loading errors:

This test isn't valid

- Check that the assay name has been entered correctly.

Not enough place in predefined sections

The maximum of 20 predefined sections has been exceeded.

- Run some predefined sections to free some positions.

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Unable to load section {0}: some standards are missing

- Check that you have performed calibration correctly for all the assays in the section.

Unable to load the section, see the loading configuration

The assay loaded in the predefined section has not been assigned to the selected *VIDAS*.

- Go to the Configuration menu: "Assay assignment" submenu.

Unable to load the section, no *VIDAS* connected

- Check the connection between the *VIDAS* module(s) and the computer.

No available section left

All the positions in the analyzer are full.

- Wait until assays have been completed.

Not enough slots available in this section

Not enough slots left in this section for this modification

- Use another section or do not exceed the number of slots in the section.

Impossible to modify assay type, the new protocol isn't compatible with other assays in the section

The assays in a section must have the same protocol or a compatible protocol.

- Check the compatibility of assays and protocols in a section.

Sample ID is required

- Enter the sample ID.

Incorrect Sample

The sample ID can include up to 12 characters. Only alphanumeric characters are accepted.

- Modify the sample ID so that it can be accepted.

No standard for this lot number

- Perform the recalibration for the assay(s).

No calibration for a new lot

- Check the calibration for the lot (MLE card) and the assay (recalibration).

- Enter the MLE card data for the lot and perform a recalibration for the assay.

Unauthorized profiles

- Check profile validity.

No standard or control needed for this test

This assay does not require a standard or a control.

- Run assays without calibration or control.

The dilution value is invalid

- Check the dilution value (between 1 and 999).

Expired lot

The shelf-life of the reagent has expired.

- Use a valid reagent lot.

This test name is incorrect

- Check that the name of the assay to be run is correct.

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"Results" window errors

Incorrect standard

- Perform the correct calibration for the assay.

Expired calibration

The shelf-life of the calibrator has expired.

Can't find calibration

This assay has not been calibrated.

- Perform a calibration for the assay.

Control not run

A control has not been performed for the assay.

- Run the control(s).

Control out of range

The assay controls are out of range.

- Rerun the control(s).

Control out of Westgard

The external control for the assay is out of range.

- Rerun the assay.

Temperature error

A temperature error has occurred during the assay.

The test result is invalid.

- Rerun the assay.

"Configuration" window errors

Assays not compatible for a same profile

- Check compatibility of assays for a same profile.

Too many assays in the profile

The maximum number of assays in a profile is 10.

- Check that the profile does not include more than 10 assays.

Too many assays with incompatible protocols in this profile

The maximum number of protocols in a profile is 5.

- Check that the profile does not include more than 5 different protocols.

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Errors or warnings printed on reports

Symbol	Footnote	Description
*	Indicates final reading is offscale.	The maximal reading capacity of the *VIDAS* has been reached. ➡ Rerun the test after dilution (if possible).
**	Indicates substrate background above accepted limit.	The background fluorescence reading is above its accepted limit. ➡ Rerun the test using new strips and SPR®s.
##	Indicates substrate background below accepted limit.	The background fluorescence reading is below its accepted limit. ➡ Rerun the test using new strips and SPRs.
+	J2 >= J4 and J2-J0 < standard RFV threshold	This applies to a dual calibration curve: the RFV kinetics are incoherent. ➡ Rerun the calibration using new strips and SPR®s.
+1	Standard RFV < calibration threshold of {0}	This applies to a dual calibration curve: the standard S1 is too low. ➡ Rerun the calibration using new strips and SPRs.
+2	Standard RFV >= calibration threshold of {0}	This applies to a dual calibration curve: the standard S2 is too high. ➡ Rerun the calibration using new strips and SPRs.
&x	Incorrect calibration – rerun the standards RFV out of range (value1> - <value2> RFV)	The RFV for a standard is outside the range predetermined by the MLE card. ➡ Repeat calibration using new strips and SPRs.
&&	Standard CV offscale	The CV control is too high. ➡ Vortex the standard and recalibrate using new strips and SPRs.

Symbol	Footnote	Description
$x	Test value is out of range – value should be <= \<value> Test value is out of range – value should be > \<value> Test value is out of range – acceptable value should be in \<value1> - \<value2>	The bioMérieux® control value is out of the limits determined by the MLE card. The results will not be validated. ➡ Rerun the calibration and control(s) and then recalculate the last results with the new calibration.
%x	Dose value out of range – value should be <= \<value> Dose value out of range – value should be > \<value> Dose value out of range – acceptable value should be between \<value1> - \<value2>	This applies to a double calibration curve. The bioMérieux control value is out of the limits determined by the MLE card. The results will not be validated. ➡ Rerun the calibration and control(s) and then recalculate the last results with the new calibration.
$%x	Dose value out of range – value should be <= \<value> Dose value out of range – value should be > \<value> Dose value out of range – acceptable value should be between \<value1> - \<value2>	User external control dose value is outside the range. ➡ Rerun the assay using new strips and SPR®s.
%	Indicates mathematical error	Results have not been calculated: a mathematical error has been detected. ➡ Rerun the assay using new strips and SPRs.
^	Indicates unvalidated results	Results are not validated (validation mode). ➡ Go to the "Results" menu to validate them.
%%	Indicates sample is over-diluted	The sample is overdiluted. ➡ Rerun the assay without dilution or with a different one.
++	Indicates test value above maximum acceptable value	The test value is above the maximum acceptable value ➡ Rerun the assay using new strips and SPRs.
~~	Indicates test value below minimum acceptable value	The test value is below the minimum acceptable value ➡ Rerun the assay using new strips and SPRs.

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Symbol	Footnote	Description
--	Indicates dose value above maximum acceptable value.	The dose value is above the maximum acceptable value. ➡ Rerun the assay using new strips and SPR®s.
$$	Indicates dose value below minimum acceptable value.	The dose value is below the minimum acceptable value. ➡ Rerun the assay using new strips and SPRs.
+	Indicates C1 reference strip is out of range (low).	This applies to dual reagent strips: the value of C1 with the reference strip is outside the range (low). Results will not be validated. ➡ Rerun the assay and controls.
#	Indicates C1 reference strip is out of range (high).	This applies to dual reagent strips: the value of C1 with the reference strip is outside the range (high). Results will not be validated. ➡ Rerun the assay and controls.
!	Indicates reference strip RFV < <value>.	For dual reagent strips: reference strip RFV is below the acceptable low limit. ➡ Rerun the assay.
$	Indicates reference strip RFV > <value>.	For dual reagent strips: reference strip RFV is above the acceptable high limit. ➡ Rerun the assay.
!	Indicates RFV below accepted limit.	Low RFV limit check failed.
#	Indicates RFV above accepted limit.	High RFV limit check failed.

Error not related to the equipment

If a power failure occurs when a system is connected to a UPS, the **VIDAS PC** software and the computer automatically shut down.

13 Glossary

Assay analysis	Interpretation of data using sample assay data, standard assay data and thresholds for data comparison. These calculations can be different for each type of assay and can interpret the assay result.
Assay code	A two-, three-, or four-character designation for an assay used in the *VIDAS*. Assays are entered into the system, for example to create a predefined section using the assay code.
Assay kit	A package containing a set of reagent strips, SPR®s, controls, calibrators, preparation reagents, package insert and MLE card.
Background	The native fluorescence that a sample has without the intended chemical reaction for the assay.
Bar code	A series of lines printed on the label of reagent strips and the MLE card. The encoded information can be read and interpreted by the scanner and used to identify the strip.
BCI	Bidirectional Computer Interface (Bidirectional connection between the laboratory information system and *VIDAS PC*).
Bidirectional	A form of communication between two computers where flow of data works in both directions.
C1, C2, C3	See **Internal kit controls.**
Calibration	The process of adjusting the standard curve of a quantitative assay lot.
Calibrator	A solution containing a known analyte concentration. The RFV obtained from testing a standard is used to interpret the test values of the patient samples and controls.
Central processing unit	The portion of a computer that is responsible for processing software instructions.

Compatible	Assays with the same protocol
Configuration	A group of elements consisting of an instrument, its operating software and the peripheral(s) which can be connected to it.
Connection	Link between the computer and the peripherals or with the central laboratory information system via input and output ports.
Dual reagent strip	A strip consisting of a jointly attached sample reference reagent strip (left) and a sample test reagent strip (right).
Equivocal	An assay result that is neither positive/reactive nor negative/nonreactive; it falls between the high and low threshold values for the test.
External controls	User-defined controls and identified as QC1 to QC6.
Fluorescence	A physical process in which a substance, after exposure to light at a specific wavelength, emits light at another wavelength. This is the process used for analyte detection in the *VIDAS*.
Internal kit controls	Controls included in the reagent kits and identified as C1, C2 and C3.
Interpretation	Translation of an assay result.
L1, L2 … to L10	Linearity point used to perform a linearity control.
LIS	Laboratory Information System.
Master lot data	A set of data supplied by bioMérieux® with each lot of an assay, that supplies quality control ranges and, for quantitative assays, becomes the standard curve for that lot.
Optical scanner	A component of the *VIDAS* module that reads the bar code label and measures the intensity of fluorescence of the assay.

Patient report	A printed report of assay results that groups together the results for a single patient on one report.
Position	A section consists of 6 positions numbered from left to right, from 1 to 6. Each position corresponds to a SPR$^®$ slot in the SPR block.
Predefined section	Compatible tests (maximum 6) grouped under the same number.
Profile codes	This option enables you to group several tests under the same profile or full name.
Protocol	A specific sequence of computer-controlled activities (pipetting, mixing, incubating, reading, etc…) needed to perform an assay.
PTC	Abbreviation for Protocol Test Change.
QC1 to QC6	See **External controls**.
Reagent	Consists of a single or dual reagent strip and a SPR.
Reserved	A predefined reserved section is a list of assays in which the system assigns the reagent strips to specific positions in the *VIDAS* module.
Result	Concentration of assays in a defined unit.
Reagent strip	A polypropylene strip of 10 wells with a foil seal and paper label. The first well (nearest the handle) is for the sample. The next eight wells contain the various reagents required for the immunoassay. The last well of the strip is the optical cuvette containing the substrate.
Reagent strip tray	A temperature-controlled tray with a plastic cover containing six section channels that hold six reagent strips or three dual reagent strips. It is also called the section tray.
RFU	Relative Fluorescence Unit.
RFV	Relative Fluorescence Value.

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S1, S2, S3	See **Calibrator**.
Sample	The patient material being tested.
Section	A microprocessor-controlled assay processing unit in the *VIDAS*, instrument. The *VIDAS* module has five sections, labeled A through E. Each incubator contains a SPR block with channels for six reagent strips or three dual reagent strips.
Sequence number	A number printed on the reagent strip and encoded into the bar code . It can be read by the scanner and printed on the assay report. It uniquely identifies a particular reagent strip.
Solid phase receptacle (SPR®)	A specially designed plastic pipette-shaped device with its inside wall coated with antibody, antigen or other treatments that allow capture of a target analyte. Each SPR has a corresponding *VIDAS* reagent strip.
SPR® block	A temperature-controlled block with receptacles to hold six SPRs. Each has a position for a corresponding reagent strip immediately below it in the section. A tilt-down door provides access to the SPR block.
Strip preparation tray	A tray with 6 positions located under each reagent strip tray. It is used to prepare tests for a specific section as it can hold either 6 individual strips or the boat included in the reagent kit.
Substrate	A substance in the reagent strip, that is broken down enzymatically to create a compound that fluoresces.
Target analyte	A biological element to be assayed (antigens, antibodies …).
Test	Term which refers to the combination of a sample identifier (sample ID or patient ID) and assay code with which the analysis is to be performed.
Test value	Applies to qualitative tests. The result calculated by *VIDAS PC*, using the RFV of the sample and which enables the interpretation of results.
Threshold	A numerical value stored in the computer memory, used to translate the test value to qualitative results such as positive, negative or equivocal.

Unidirectional   A form of communication between computers where the flow of data works in one direction.

Validation   The process of approving an assay result by the user.

VIDAS **Module**   The *VIDAS* reader / analyzer.

Window   Enables information from the *VIDAS PC* software to be displayed.

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