MINI Vidas

User Manual

Industry Use - US version

EN

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BIOMÉRIEUX INDUSTRY

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General Information

The content of this manual is based on the Software release **5.6**.

Please discard any previous copies of this manual if relevant.

This manual may contain information or references relating to certain bioMérieux products, software or services which are not available in the country of release; this shall not mean that bioMérieux intends to market such products, software or services in such country.

To request copies of publications or for any technical request / assistance, contact bioMérieux or your local distributor (contact information available on www.biomerieux.com).

Note: *The screens and figures shown are intended as illustrations only and must not be interpreted as actual representations of data, results or equipment.*
Screens and equipment are not shown to scale.

IMPORTANT: Please read this manual carefully before using the mini VIDAS® analyzer.

Limited Warranty

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMerieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

Customer acknowledges and agrees that use of the System for testing of sample types or for indications other than those described in the IFU is done solely at the Customer’s own risk. Customer acknowledges and agrees that it is Customer’s sole and exclusive responsibility to validate the System for any such intended use, and to determine whether the System is suitable for that intended use. The performance of any validation studies and the subsequent use of the System based on Customer’s validation studies shall be the Customer’s sole risk and responsibility.

Product warranty details can be obtained from bioMérieux or your local distributor (contact information available on www.biomerieux.com).

Intellectual Property

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1 Introduction to the System

Intended Use and Users

The ***mini VIDAS®*** **Industry** system is an immunodiagnostic system intended to be used by trained and qualified laboratory professionals, for veterinary and industrial applications.
The ***mini VIDAS®*** **Industry** system is intended to execute an immunoassay protocol and to release results according to the package insert of the ***VIDAS®*** assay kits.

Note: *When referring to the* ***mini VIDAS®*** *analyzer or system in this user manual, it refers to the* ***mini VIDAS®*** **Industry** *analyzer or system.*

Note: *Some information in this user manual may only apply to* ***mini VIDAS®*** *for a clinical application. Information specific for clinical use will mention "for clinical use only" and will not be taken into account for* ***mini VIDAS®*** *Industry.*

Benefits and Limitations of Use

The ***mini VIDAS®*** analyzer has a built-in system for detecting and reporting errors. Its unique design enables it to operate around the clock and daily start-up is completed in a few seconds.

The ***mini VIDAS®*** analyzer is a completely self-contained system that includes:

- an analytical module (12 test positions i.e. two 6-test sections) and,
- data processing equipment (monitor, keypad, printer).

The ***mini VIDAS®*** analyzer enables different analytes to be used simultaneously according to their compatibility.
The number of tests/ hour depends on the kit (eg: up to 36 tests/ hour with ***VIDAS®*** PCT).

It is used with ***VIDAS®*** assay kits covering numerous immunoassay* fields (non exhaustive list):

- hepatitis,
- AIDS,
- serology testing,
- bacterial and viral antigen detection,
- fertility/pregnancy monitoring,
- thyroid hormones,
- allergies,
- tumor markers,
- endocrinology,
- anemia,
- cardiovascular diseases,
- therapeutic drug monitoring,
- immuno-hemostasis,
- **industrial microbiology**.

** The availability of certain* ***VIDAS®*** *tests may be restricted in some countries, depending on registration release dates. Please contact your local bioMérieux representative for further information.*

Warning and Safety Messages

The user documentation uses several types of statements to alert you to important information. Important information is labeled in text and identified using symbols.

Statement Types

The statement types are Warning, Caution, Important, and Note. The following examples define each statement type. The general caution symbol is used in these examples, but other symbols (see Standard Symbols on page 1-6) may be used instead.

The warning messages in this manual mainly refer to:

WARNING

A Warning statement alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION: A Caution statement alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. Where applicable, a Caution statement may include a precaution that should be taken to avoid the hazard.

IMPORTANT: An Important statement relates to content presented in the user documentation. It is used to reinforce the user's understanding of selected information.

Note: *A Note statement supplies additional information about a topic.*

General Statements

This section provides important statements that apply to all products. Equipment meets the requirements and standards stated in the certificate supplied with it.

WARNING

Equipment is intended for professional use only.

Laboratory personnel should be qualified and adhere to the principles of good laboratory practice.

All the user documents supplied must be read prior to use of the equipment.

Under no circumstance should the user dismantle equipment due to the risk of touching dangerous parts, including parts that are infectious or connected to a source of electric power.

Do not obstruct the equipment and hardware ventilation apertures, and leave sufficient clearance around the equipment for the circulation of air.

All biological and industry samples should be considered as potentially infectious. Suitable individual protective equipment is required when handling chemical or biological substances.

bioMérieux is in no case liable for the harmful consequences of incorrect use or improper handling of these substances.

WARNING

Electromagnetic Compatibility (EMC):
The EMC class of the equipment is indicated on the certificate supplied with it.

If equipment is a class A product, it may cause radio interference in a domestic environment, in which case the user will be required to correct the interference at his own expense.

Do not use this device near strong sources of electromagnetic radiation (for example, intentionally unprotected radio-electric sources), which could interfere with the operation of the equipment.

It is recommended to evaluate the electromagnetic environment before starting the device.

WARNING

Only modify the software configuration parameters you are authorized to modify and which are described in the user documentation.

WARNING

Decontamination of equipment at the end of its life cycle:
The following instructions must be followed by all users in countries where local legislation imposes the treatment and recycling of equipment at the end of its life cycle.

As a general rule, and as a precautionary measure, any part of the equipment (including sub-assemblies, components and materials) considered to be potentially infectious, must be decontaminated, whenever possible, or removed if decontamination is impossible or presents a risk.

Any part considered to be potentially infectious, which is not decontaminated, must be removed from the instrument before following the normal channels for elimination of infectious products, in accordance with local regulations.

The decontamination instructions in the user documentation correspond to the parts of the equipment that are potentially infectious according to their intended use. These operations must be performed before the equipment is transferred to a third party.

However, bioMérieux cannot exclude that other parts of the equipment have not been contaminated in other circumstances, in particular as the result of spillage of infectious substances. In this case, the user is solely responsible for decontaminating these parts or removing them before they follow the normal channels for elimination of infectious products.

WARNING

This statement only applies to European countries 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. It is imperative that you contact bioMérieux to assure its appropriate disposal.

IMPORTANT: Electrical or other connections should only be made using the accessories supplied with the equipment.

IMPORTANT: It is important to follow all the restrictions on use, particularly concerning temperature, storage, installation and voltage, which are indicated on the product label or in the user documentation.

IMPORTANT: The accuracy of results obtained with this equipment depends on the maintenance operations described in the user documentation (user maintenance and/or periodic preventive maintenance performed by bioMérieux).

IMPORTANT: The user should be aware that if the maintenance operations are not performed, are only partially performed, or are not performed as described in the user documentation, bioMérieux is in no case liable for any false test results obtained.

IMPORTANT: It is recommended to keep the original packaging materials in case the equipment needs to be moved. Any damage directly or indirectly resulting from the transport of the equipment without adequate containers will not be covered by the warranty.

Standard Symbols

The following table defines symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging. When surrounded by a triangle on a yellow background, the symbol highlights an immediate warning and is positioned on the instrument itself.

	Compliance with US and Canadian Safety Standards certified by CSA		Batch code
	Authorized Representative in the European Community		Catalog number
	Serial number		Consult Instructions for Use
	Use by date		Manufacturer
	Date of manufacture		This way up
	Do not stack		Caution, consult accompanying documents
	Contains sufficient for <*n*> tests		Do not reuse
	Keep dry		Keep away from light
	Fragile, handle with care		Humidity limitation
	Keep away from magnetic field		Temperature limitations

Upper limit of temperature

Lower limit of temperature

Sterile

Positive control

Negative control

Biological risk

Electric shock warning

Radiation warning

Hot surface

Potential pinch-point warning

Laser beam

Shearing hazard

High temperature

Hazardous magnetic field

Potential tip-over/crush hazard

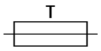
Acute toxicity

Corrosives

Sodium azide


Irritant


Separate collection for waste electrical and electronic equipment



Fuse


Alternating current

Three-phase alternating current


Protective conductor terminal


Equipotentiality

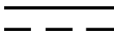

OFF (supply)


OFF (only for a component of the system equipment)


Ethernet port


Recyclable

Environmentally friendly use period. Actual number of years may vary by product. This symbol is typically orange in color.


Direct current


Both direct and alternating current


Earth (ground) terminal


Frame or chassis terminal

ON (supply)


ON (only for a component of the system equipment)


Equipment protected throughout by double insulation or reinforced insulation (Equivalent to Class II of IEC 536)

2 Safety Information

It is essential that the warnings, cautions and safety requirements contained in this manual are read and understood by the user before operating the system.

Warning symbols have been placed on the system to draw your attention to areas of potential hazards.

System Compliance

This instrument complies with the emissions and immunity requirements of IEC 61326.

This is a Class A product. The instrument was designed and tested against CISPR 11, class A.
In a domestic environment this product may cause radio interference, in which case the user may be required to take adequate measures.

- bioMérieux recommends the evaluation of the electromagnetic environment before operating the instrument.

CAUTION: Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.

- Laser Class 1

  The Instrument is a Class 1 LED/Laser product in accordance with the requirements of:

  - 21CFR1040.10 and 1040.11 except for deviations pursuant to Laser Notice No 50, dated July 26,2001
  - IEC 60825-1: 1993+Amendments
  - EN 60825-1:1994+Amendments
  - IEC 60825-1: 2007
  - EN 60825-1:2007

  Class 1 devices are not considered to be hazardous when used for their intended purpose.

CAUTION: Use of controls, adjustments or performance of procedure other than those specified in the user's manual may result in hazardous LED/laser light exposure.

Instrument Labels

The following photos of the analyzer illustrate the positions of the safety warning labels.

SPR® Block

The label is applied above the SPR® slots inside each SPR® block.

This label reads:
WARNING - DO NOT APPLY PRESSURE IN ORDER TO SEAT SPRS.
INADVERTENT EJECTION OF SPR MAY RESULT.

Figure 2-1: SPR® Block Label

Figure 2-2: Position of the label

Reagent Strip Tray

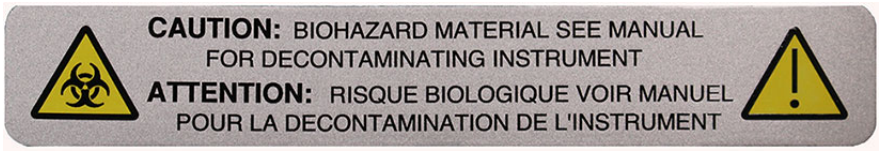
When you pull out the reagent strip tray, the biological risk label appears.

Figure 2-3: Reagent strip tray label (Biohazard)

Figure 2-4: Position of label

Strip Section

The label is applied inside the transparent part of the each section door. In addition to the biological risk, the label directs the user to read the user manual in French and English.



This label reads:
CAUTION: BIOHAZARD MATERIAL. SEE MANUAL
FOR DECONTAMINATING INSTRUMENT

Figure 2-5: Strip section label

Figure 2-6: Position of label

Rear Panel

The label is positioned on the rear panel of the ***mini VIDAS®*** analyzer.

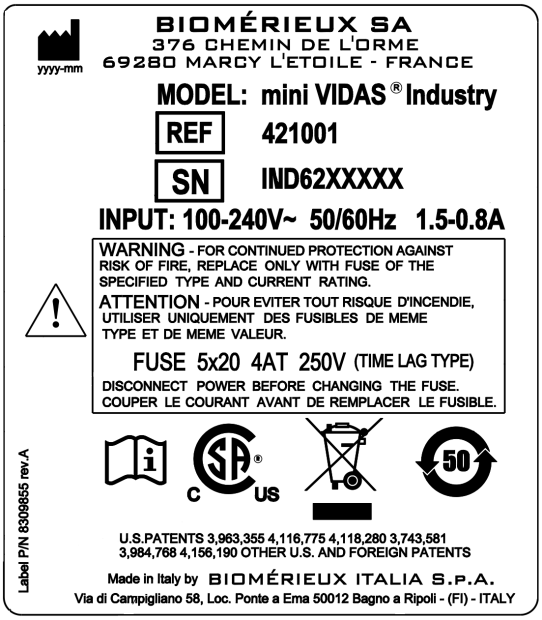


Figure 2-7: Label (rating plate)

This label reads:
WARNING - FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH FUSE OF THE SPECIFIED TYPE AND CURRENT RATING.
FUSE 5x20 4AT 250V (TIME LAG TYPE)
DISCONNECT POWER BEFORE CHANGING THE FUSE.

Safety Precautions

Pay particular attention to the following safety precautions. If these safety precautions are ignored, injury or damage to the instrument may occur. Each individual precaution is important.

WARNING

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

WARNING

All biological and industry samples and quality control (QC) products incubated in this system, as well as all waste in the waste containers, should be treated as potentially biohazardous materials. All materials and mechanical components associated with the waste systems should be handled according to safe microbiological practices in compliance with the installation site's biohazard procedures. Use the personal protective equipment recommended by the facility when handling any of these components, including gloves, safety glasses, and a lab coat.

The system must be decontaminated before its covers are removed by service personnel. Ensure that appropriate decontamination is carried out if hazardous materials are spilled on or into the equipment or surrounding areas.

WARNING

Treat waste material, including consumable items, and any components coming into contact with waste material as having the potential hazards of the samples used.

All service personnel should be familiar with the Material Safety Data Sheet (MSDS) for all materials used in the procedures relating to this instrument, and the correct procedures for handling these materials.

WARNING

Even when power is removed from the instrument, the potential exists for electricity to be generated if components, such as assemblies that are mounted on belts, are moved too quickly. Components should be moved slowly to prevent the buildup of electricity. Failure to comply may result in injury to personnel or damage to the instrument.

WARNING

Do not replace detachable main supply cords by inadequately rated cords. Only use main supply cords provided by the manufacturer.

Do not replace electric cables. If cables do not have the same technical specificities, there is a risk of electrical shock.

Nothing should be placed on top of the connection cables, whether temporarily, permanently or intermittently. Cables should not be laid across passage-ways.

Computer cables must not intersect or be placed too close to cables for connection of the power supply.

Cables should not be allowed to form loops or knots, or be rolled up near or on other electrical equipment.

WARNING

Electronic equipment can be the source of electrical shocks. Installation, service, and repair should only be performed by authorized and qualified bioMérieux personnel.

WARNING

All power switches should be off when connecting or disconnecting cables to power outlets to reduce the risk of electrical shock.

WARNING

bioMérieux recommends connecting this instrument to a main power outlet that is protected with a ground fault circuit interrupter to reduce the risk of electrical shock.

The electrical supply to which the system is connected must conform to current standards:

- **diameter of cables,**
- **grounding,**
- **connector calibration and type etc.**

The electrical power supply must be direct, individual, calibrated, and compatible with the technical specifications of the product or configuration.

WARNING

No other equipment likely to interfere with the proper functioning of the system should be connected on the same circuit.

Extension sockets and serially connected adapters should not be used.

If the power supply is not sufficient to guarantee proper functioning of the product, an independent protective device, adapted to the product's technical characteristics should be used.

Do not use power sockets controlled by wall-mounted switches or timers. Accidental power cuts may destroy information in both the analytical module and the computer memories.

No electrical equipment likely to cause interference (equipment not bearing the CE mark …) should be operated in the immediate vicinity of the system.

The safety connection should not be interrupted by an extension cord without a protection conductor.

Before connecting or disconnecting the connecting cables, check that the power supply cords of the CPU and all the units connected to it are themselves disconnected.

When adding units to the system or removing them, disconnect the power cables to these units before connecting or disconnecting the connecting cables.

Never connect the *mini VIDAS*® analyzer to the same power supply as devices which generate high current surges (centrifuges) or which, due to frequent start-ups, generate interferences if they are ill-protected (freezers, water baths etc.).

WARNING

As with any mechanical system, certain precautions must be taken when operating the instrument. The instrument has a protective cover intended to prevent the operator from coming into contact with any moving parts and aerosols. When servicing the instrument, take special care, as there are moving parts that can cause injury.

WARNING

Cleaning and disinfecting solutions have corrosive properties. Always wear protective (chemical resistant) gloves and safety glasses when handling cleaning and disinfecting solutions.

WARNING

Hot surfaces can cause injury.

WARNING

After replacement or recalibration of the scanner head of the *mini VIDAS*® analyzer, reperform a calibration for each assay used.

CAUTION: Any liquid spilled on the system may result in system malfunctioning. If liquid is spilled on the system, wipe it up immediately using decontamination wipes.

CAUTION: The ***mini VIDAS***® analyzer has been carefully configured for optimal system performance. Altering the configuration may severely hamper the usability of the instrument.

IMPORTANT: For optimum operation of the instrument, the SPR® block and tray doors must be kept closed.

Note: *Before performing electrical safety or other compliance testing on the instrument, contact your local bioMérieux representative.*

WARNING

The user must only perform the maintenance operations described in this user manual and rigorously follow each of the steps.

The use of tools not specified by bioMérieux is forbidden.

Powderless gloves, a lab coat and safety glasses or goggles must be worn when performing maintenance operations.

Always use personal protective equipment, including powderless gloves, a lab coat and safety glasses or goggles when handling reagents.

Precautions For Use Of Reagents

General Precautions

CAUTION: Carefully read the reagent kit package insert before using the reagents.

Store the reagent kits according to the kit label instructions.

ONLY use bioMérieux reagents to perform the analyses. The use of any other reagents is the sole responsibility of the user.

Do not mix reagents from different lots.

Do not use reagents after the expiration date.

Use powderless gloves.

Preparing the Analyses

CAUTION: Sample preparation steps, which may vary from assay to assay, are covered in the package insert for each assay.

ONLY remove the required number of tests from the reagent kit.

Reagents should be at room temperature before use (refer to the package insert in the reagent kits).

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

Carefully mix the standard/calibrator, controls and samples before pipetting into the strip.

Do not use visibly deteriorated strips (damaged foil or plastic) or if reagents are leaking, as this could affect the accuracy of test results.

Do not re-use a SPR®.

Avoid touching the SPR® dots.

Check that each SPR® has a color-coded dot that is clean and undamaged.

Check that each SPR® dot on top has a hole.
Reject SPR®s with no hole in the center of the dot.

Precautions for Samples

CAUTION: The sample must not contain any solid matter that could clog the tip of the SPR®.

Always put the correct sample into the assigned strip.

At the End of the Run

CAUTION: If a SPR® does not have its color-coded dot:

- Reject the result corresponding to the defective SPR®.
- Check that the dot is not adhered to the SPR® block or the SPR® seal and if it has, remove it.
- Repeat the assay for the defective SPR®.
- Contact bioMérieux Technical Assistance or your local bioMérieux representative.

3 System Description and Basic Operations

mini VIDAS® analyzer Description

Figure 3-1: ***mini VIDAS***® analyzer

1 — Operating status light
2 — SPR® block
3 — Strips section
4 — Strip preparation tray
5 — Keypad and screen
6 — Thermal printer
7 — External bar code reader

Note: *Previous versions of the* ***mini VIDAS***® *analyzer may not have a strip preparation tray.*

CAUTION: Never use material other than that specified by bioMérieux.

Screen and Keypad

Figure 3-2: ***mini VIDAS®*** screen and keypad

1 — Liquid crystal display screen

2 — Selection keys
Used to select one of up to five options that can appear on the display screen. The options are displayed on the screen opposite the keys used to select them.

3 — Arrow keys
Used to move the cursor on certain screens.
The up and down keys are also used to page the display screen.

4 — Number keys
Used to input numbers and to make input selections.

5 — Function keys

Function key	Description
	Undoes a keypad input. Deletes the last action and returns to the previous operation.
	Returns the user to the previous screen during a procedure or returns to a particular menu or corrects a selection error.
	Help key: • Press it once to display information about a screen, error, or flashing screen. • Press it twice to access the Help Mode Screen.

Internal Printer

The ***mini VIDAS®*** analyzer includes an internally mounted thermal printer.

The printer is located on the top of the instrument, directly above the keypad and screen.

Rear Panel Components

Figure 3-3: ***mini VIDAS®*** rear panel

1 — Memory card slot
This slot is for the ***mini VIDAS®*** software update cards.

2 — Diagnostic port
Used by bioMérieux Field Service Engineers to troubleshoot the ***mini VIDAS®*** analyzer.
Also used external bar code reader.

3 — Computer port
Used to connect the ***mini VIDAS®*** analyzer to a computer.
Assay results are then sent to that computer via this connection.

4 — Printer port
Used to connect the ***mini VIDAS®*** analyzer to a matrix parallel printer.

5 — Power inlet module with ON/OFF switch, mains connector and replaceable fuses.

Bar Code Readers

There are two types of bar code readers:

1. A hand-held bar code reader is included in the ***mini VIDAS®*** configuration. It is used to:
   - read the bar codes of certain reagents before they are used.
   - enter the sample ID and read the master lot data.

2. A bar code reader inside the instrument identifies the reagent strips.

Memory Cards

Memory cards store the ***mini VIDAS®*** software.

bioMérieux sends a program update memory card for software updates.

This card should be returned to bioMérieux after your instrument has been upgraded.

CAUTION: When using memory cards:

- Keep them away from humidity, extreme temperatures, direct sunlight, and strong magnetic fields.
- Do not bend them.
- Handle them with care.

Technical Data and Specifications

Technical data and specifications are given for the latest version of the ***mini VIDAS®*** analyzer (analyzer with transparent blue section covers).
For previous versions of the ***mini VIDAS®*** analyzer, see Appendix E, Appendix - Technical Data and Specifications (previous versions of mini VIDAS® analyzers).

Dimensions

	Instrument + Packaging	Instrument
Height (cm)	59	45
Width (cm)	80	57.5
Depth (cm)	66	55

Weight

	Instrument + Packaging	Instrument
Weight (kg)	47	40

Physical Space Requirements

	Value
Height (cm)	65
Width (cm)	120
Depth (cm)	90

The instrument must be placed on a flat surface tilted no more than 5°.

Electrical Specifications

The instrument includes an internal bar code reader with a 660 nm LED whose radiation is Class 1 according to IEC 60825-1.

Specification	Value
Voltage	100 - 240 VAC 3 - 1.2 A
Consumption	100 - 240 VAC 1.5 – 0.8 A
Frequency	50 - 60 Hz
Power	150
Fuse Current	External: 4.0 AT
Approximate Emission of Heat	512 Btu / hr 150 W
Power Switch	Location: back of instrument Type: bipolar (phase + neutral) Max. leakage of current: < 1mA

Caution:

The user must comply with the technical specifications and standards in this manual to ensure user safety as well as the proper functioning of the instrument.

bioMérieux is in no case liable for any damage that may arise from failure to comply with these specifications or any operation conducted on the equipment not in compliance with these mandatory standards.

Moreover, the warranty for this equipment is expressly subject to use of the ***mini VIDAS®*** analyzer in compliance with the procedures and specifications herein.

Environmental Conditions

Specification	Value
Type of Installation	For indoor use only
Installation category	II
Pollution degree	2

The ***mini VIDAS®*** analyzer is compliant with the environmental safety requirements in IEC 61010-1, section 1.4.

Temperature

Specification	Value
Operating temperature	15°C to 30°C (room temperature)
Storage temperature	-10°C to 50°C

Note: *The average heat emission is approximately 512 BTU - 150 W.*

Humidity

Specification	Value
Relative humidity	10% to 80% RH non-condensing
Humidity during storage and transport (non-condensing within the storage and transport temperature range)	up to 90%

Altitude

Specification	Value
Maximum altitude	2,500 m

Sound Level

Specification	Value
During an analysis	< 59 dBA

Technical features

Capacity

- 12 test positions (2 sections with 6 positions in each section).
- Up to 30 tests/hour depending on the type of assay used (see test duration in the package insert for each ***VIDAS®*** assay).

Motors

- Automatic control by stepper motors.

Pumping

- 2 pumps; one for each section
- Mixing, diluting, and transferring of liquids

Temperature control

Absolute Accuracy

- SPR®: 36°C – 38°C
- Tray: 35°C – 38°C

Relative Accuracy

- SPR®: ± 0.7°C between the 2 sections
- Tray: ± 1°C between the 2 sections

Thermal resistance

- Process: thermal resistance
- Automatic Control: by thermal probe

Optics

Specification	Value
Detector	Photodiode fluorimeter
Detection range	40 to 40 000 nmol of 4MU (4-Methyl Umbelliferone)
Automatic checking	Automatically checks the optic system every 12 hours against a reference standard (named "solid standard"); automatic calibration if the difference with the solid standard is $\geq$ 0.6 %

Optional Hardware

- External printer (optional)

Note: *See Appendix - Installing external hardware.*

- Unidirectional interface (optional)

Note: *See Appendix - Computer interface information*

Accessories for Industry Use

- ***VIDAS®* Heat and Go** or water bath (95-100°C)

These accessories are necessary for the sample preparation procedures recommended in the package insert.

Figure 3-4: ***VIDAS®*** Heat and Go instrument

Contact bioMérieux or your local bioMérieux representative to purchase the ***VIDAS®* Heat and Go** instrument.

Refer to the ***VIDAS®* Heat and Go** user's manual for further instructions.

Assay Kit Specifications

VIDAS® SPR®

Specification	Value
Length	76 mm
Material	Plastic polymer
Work volume	5 to 350 µl

VIDAS® Single Reagent Strip

External dimensions	Value
Length	157 mm
Width	18 mm
Depth	15 mm

Well	Capacity
Sample Well	960 µl
Reagent Well	960 µl
Substrate Well	530 µl

The strip is sealed by a foil to ensure that no evaporation will occur that may compromise the reagents.

The substrate well is made of a plastic that complies with the appropriate optical qualities.

Reagents

VIDAS®Assay Kit

Each ***VIDAS***®assay kit contains everything required to carry out a specific assay:

- Single or dual reagent strips,
- SPR®s (Solid Phase Receptacle)
- Standard/calibrator(s)
- Controls
- Diluent (depending on the kit),
- a Master Lot Entry (MLE) bar code printed on the box label

Note: *Some assay kits may also include a Master Lot Entry (MLE) card.*

- a package insert (included in the kit or downloadable from a server) with the protocol to be loaded if necessary
- A closing clip for the bag of SPR®s (in certain kits)

Single Reagent Strip

The ***VIDAS***® single reagent strip is made of polypropylene and contains ten wells.

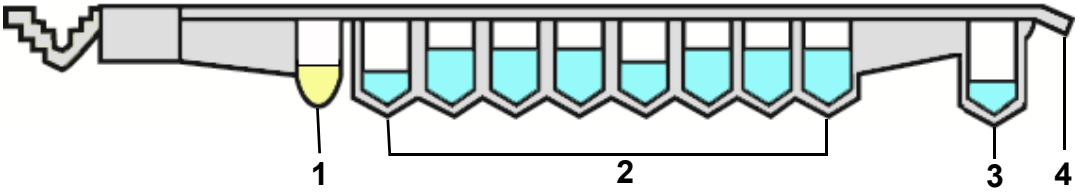


Figure 3-5: Single reagent strip

1 — First well, where the sample is placed
2 — Eight reagent wells (conjugate, diluent, wash buffer)
3 — the last well is the optical cuvette in which the fluorescence of the substrate is measured.
4 — Tab ensures that the strip is correctly positioned in its channel guides.

Single Reagent Strip for Immuno-Concentration (for Industry Use Only)

These strips are used to concentrate a targeted antigen. No result interpretation is done.

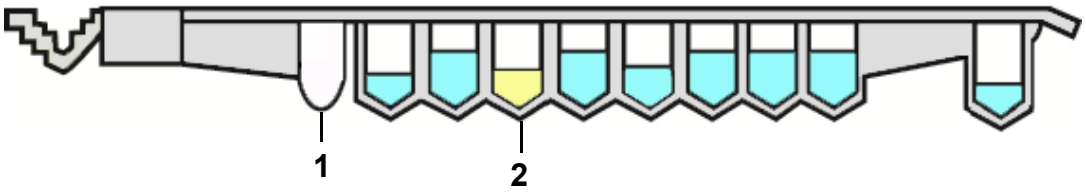


Figure 3-6: Single reagent strip for immuno-concentration

1 — Well where the immunoconcentrated targeted antigen is released at the end of the run
2 — Well where sample is dispensed

Dual Reagent Strip (for Clinic Use Only)

Some assays require the use of a dual reagent strip, consisting of two strips side by side. The dual reagent strip is used to compensate for sample variability.

The sample is divided between the two sample wells on the two reagent strips. One strip serves as the reference strip and the other as the sample test strip.

The sample test strip contains a reagent which is not included in the sample reference strip.

A comparison of the measurements from the two strips determines the test result.

Dual strips fit in the reagent strip tray exactly like single strips, but they require two channels.

Reagent Strip Label

Each ***VIDAS***® reagent strip has a label, a colored dot and the assay code (2 or 4 letters/digits).

The color-coded dot corresponds to a matching dot on the test's companion SPR®. The bar code identifies:

- the assay code
- the manufacturing lot number
- the sequence number
- the assay kit expiration date

The figure below represents a typical label:

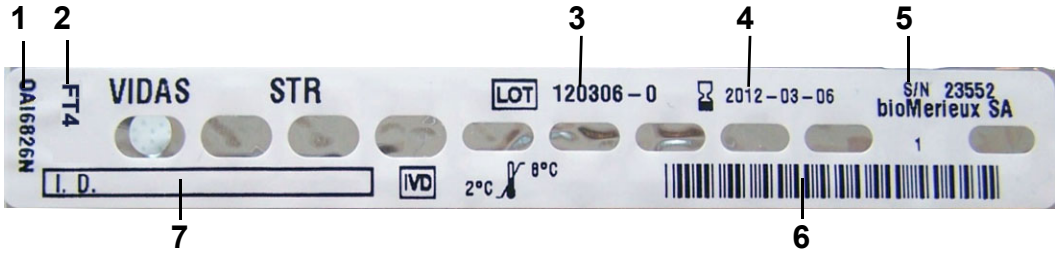


Figure 3-7: Reagent strip label

1 — Alphanumeric bar code.
The first two characters of the alphanumeric code indicate the unique assay code (UAC). If the system is unable to read this code, the alphanumeric form of the bar code is used to enter the bar code.

2 — Assay code
The assay code is based on three or four characters which represent the name of the assay to be performed.
Examples:
RBG = RUB IgG (Immunoassay)
153 = CA 15-3
All references to an assay in the software and on printed reports use the assay code.

3 — Lot number
The lot number is used by the ***mini VIDAS***® analyzer to code the expiration date of the reagent lot.

4 — Expiration date
This corresponds to the expiration date of the reagent lot.
When the bar code reader reads this date, the ***mini VIDAS***® analyzer compares it to the date stored in its memory to ensure that the lot has not passed its expiration date.

5 — Sequence number
Within a single batch, each reagent tray carries a different number corresponding to the order of manufacture.

6 — Bar code
Read by the internal bar code reader.

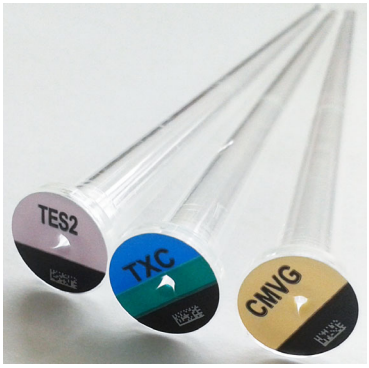
7 — ID
Optional: A blank space is provided to write the sample ID (if required).

SPR®

The SPR® is a plastic (polystyrene) device capable of capturing soluble proteins, viruses and bacteria. It is sealed with a color-coded, barcoded dot perforated in the center. Each SPR® is disposable.

It eliminates cross-contamination between reagent and instrument and reduces maintenance to a minimum since there is no tubing, syringe or sampling needle involved.

Each SPR® for a specific assay is identified by a color-coded dot on which a bar code and a letter and/or digit code representing the assay name are printed.



VIDAS® clinical assays

VIDAS® industry assays

Figure 3-8: Solid phase receptacle (SPR®)

The SPR® is the solid phase base for the immunological reaction. Its interior walls are coated with antibody or antigen that captures a target analyte.
The target analyte from the sample binds to the SPR®s interior coating (antibody, antigen, etc.). It is then bound by an enzyme-conjugated antibody or antigen, forming a «sandwich». The immobilized enzyme catalyzes the hydrolysis of the substrate into a fluorescent end product.

The SPR® is used to pipette samples and reagents and perform the following operations:

- sampling
- incubation
- mixing
- washing

The beveled tip of the SPR® enables it to pierce the protective seal that covers the wells in a reagent strip. The reagent strip tray then moves in and out to allow liquids to be transferred from one well to another.

Standards / Calibrators and Controls

The standards/calibrators, which are used to calibrate the ***mini VIDAS®*** analyzer to each lot, are available in the reagent kit at one or more concentrations levels depending on the test. They can be either ready to use or lyophilized (follow the instructions in the reagent package insert).

Figure 3-9: Vial (control and/or standard/calibrator)

System Basics

The ***mini VIDAS®*** analyzer is a compact, multiparametric, automated immunoanalyzer.

After the samples have been dispensed, the ***mini VIDAS®*** analyzer automatically performs the different stages of analysis, including report printing.

The software processes the reagents using the strips bar codes and can send the results to a Laboratory Information System (uni-directional interface). The bar code labels on the sample tubes can be read using an external bar code reader.

Analysis Protocols

The analysis protocol determines a specific sequence of operations required to perform an analysis. It defines the volume of sample to be aspirated, and the sequence of fluid manipulations and fluorescence readings. It also manages the mechanical and sensor functions of the pipettor during sample pipetting.

Principle of a *VIDAS®* Assay

The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and predispensed in the sealed reagent strips. All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR® several times.
Unbound components are eliminated during the washing steps. During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR®. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm.
The intensity of the fluorescence depends on the concentration of alkaline phosphatase present on the SPR® that transforms the substrate.

At the end of the assay, results are automatically calculated by the instrument. For some tests, two detection steps are performed successively.

For antigen detection, the SPR® is generally coated on the interior with capture antibody or sometimes with a derivative of the analyte.
For antibody detection, the SPR® is coated with a capture antigen or antibody directed to the antigen.
Depending on the test, the conjugate can be a derivative of the analyte or an antibody labeled with alkaline phosphatase.
For more details, refer to the assay package inserts.

Analysis Methods

The ***mini VIDAS***® analyzer uses several different methods to calculate results. Three basic categories of analysis methods are:

Calculation method	Description
Test sample to Standard	A comparison of the Relative Fluorescence Value (RFV) of the test sample to that of a standard. This method is used in Single Reagent Strip qualitative and most semi-quantitative assays.
Test sample to Reference	A comparison of the RFV of the test sample to that of a reference. This method is used in Dual Reagent Strip qualitative assays.
Curve Fitting Equations	The RFV of a test sample is mathematically placed on a Calibration Curve. This method is used for all quantitative and some semi-quantitative assays.

Qualitative Assays (Single Reagent Strips)

Two analysis methods are used for single reagent strip qualitative assays: the P/S method and the P-S method.

In these methods, the “P” stands for the RFV of the test sample and the “S” stands for the RFV of a standard.

Assay Calibration

Single reagent strip assays are calibrated using one or two standards/calibrators supplied with the assay kit. Calibration using the standard(s)/calibrator(s) provided in the kit should be run the first time the assay kit lot is used, after the master lot data have been entered.

If replicate standards are run, their values are averaged. The calibration obtained can be used for a programmed period of days.

After that, the software automatically expires the calibration, requiring that you run another one from the same lot.

P/S Method

For assays that use the P/S method, the test value is calculated from the ratio of the sample RFV to that of the standard RFV.

- RFV (tested sample) = 2158
- RFV (standard) = 2177
- Test value (VT) = 2158/2177 = 0.99

P-S Method

For assays that use the P-S method, the test value is calculated from the difference between the sample RFV and the standard RFV.

- RFV (tested sample) = 1774
- RFV (standard) = 1689
- Test value (VT) = 1774 - 1689 = 85

Assay Result

In both the P/S and P-S methods, the result of the assay is determined by comparing the test value to a set of preprogrammed thresholds.

Depending on the assay and the test value result compared to the thresholds, the result can be either positive, equivocal or negative.

For every assay type, there is a high and low threshold value. The assay result is interpreted from the test value as follows:

If the test value is:	the result is:
≥ high threshold	Positive
< high threshold and ≥ low threshold	Equivocal
< low threshold	Negative

Note: *For some qualitative assays (e.g. TOXO Competition, anti-HBc total), the result of the test value will be negative if the test value is to the high threshold.*

Qualitative Assays (Dual Reagent Strips)

Two analysis methods are used for dual reagent strip qualitative assays: the P/N method and the P-N method.

In these methods, the “P” stands for the RFV of the test sample and the “N” stands for the RFV of a reference.

Assay Calibration

Dual reagent strip assays do not require separate calibration standards. Instead, the reference strip serves the same purpose.

P/N Method

For assays that use the P/N method, the test value is calculated from the ratio of the sample RFV to that of the reference RFV.

- RFV (tested sample) = 2158
- RFV (reference) = 2177
- Test value (VT) = 2158/2177 = 0.99

P-N Method

For assays that use the P-N method, the test value is calculated from the difference between the sample RFV and the reference RFV.

- RFV (tested sample) = 1774
- RFV (reference) = 1689
- Test value (VT) = 1774 - 1689 = 85

Assay Result

In both the P/N and P-N methods, the result of the assay is determined by comparing the test value to a set of preprogrammed thresholds.

Depending on the assay and the test value result compared to the thresholds, the result can be either positive or negative.

If the test value is:	the result is:
≥ high threshold	Positive
< high threshold and ≥ low threshold	Equivocal
< low threshold	Negative

Note: *For some qualitative assays (e.g. TOXO Competition, anti-HBc total), the result of the test value will be negative if the test value is to the high threshold.*

Quantitative Assays

Quantitative ***VIDAS®*** assays use a calibration curve to determine analyte concentrations in test samples.

Note: *Although standards/calibrators can be run after analyses have completed, it is recommended that they be run either before or with analyses from the same assay kit lot. If an assay has two standards/calibrators, both must be run at the same time.*

Principles Of Calibration / Recalibration

The reagents are calibrated according to two different modes, depending on whether the assays are quantitative or qualitative.

Assay	Description
Quantitative	Calibration is performed at the factory for each new reagent lot and is entered into the instrument using a bar code provided with each reagent kit. This creates a «Master Curve» that is stored in memory. It can be readjusted by running a standard/calibrator. Readjustment of the curve must be validated by testing the control(s) in the kit. Recalibration should be performed every 14 days or 28 days depending on reagents.
Qualitative	The result is interpreted by comparing the «Test Value» to one or two threshold values entered into the ***mini VIDAS®*** software.

Calibration

Theoretical Principle for Quantitative Assays

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/calibrators.

Well-defined reference solutions (standards) are used to make this determination. This calibration curve is established with at least 5 standards/calibrators. It is valid between zero and the standard/calibrator with the highest titer.

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

1. 4 logistic parameters or Rodbard model

$$RFV = \frac{a_1 - a_4}{1 + (c / a_3)^{a2}} + a_4$$

2. Polynomial

$$\ln(c) = a_1 + a_2\,RFV + a_3\,RFV^2 + a_4\,RFV^3$$

3. Semi-log

$$RFV = a_1 + a_2 \ln(c)$$

c represents the concentration.

a_1, a_2, a_3, a_4 are the mathematical parameters of the model. They are recalculated for each calibration.

Principle Applied to the *mini VIDAS*® analyzer

For the ***mini VIDAS***® analyzer, calibration is performed during the production of each new lot of SPR®s and reagents. The number of standards/calibrators varies between 5 and 11 depending on the biological assay. Each lot is associated with a particular mathematical model.

To determine the master curve, the standards/calibrators are tested in seven different runs on the same ***mini VIDAS***® analyzer. The mean curve of these seven runs becomes the master curve.

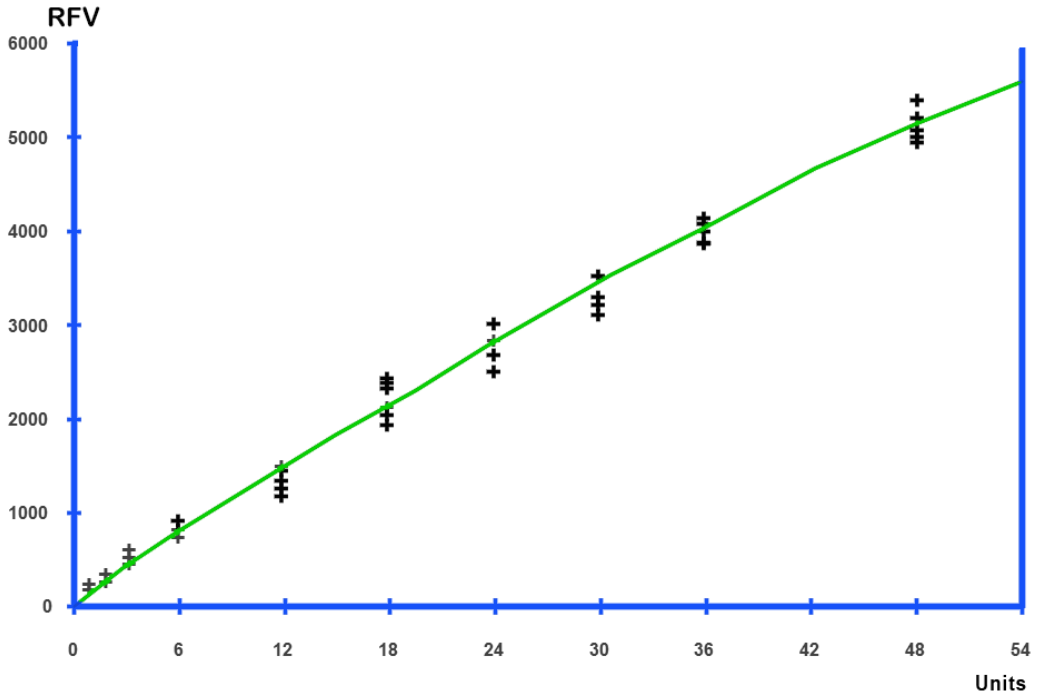


Figure 3-10: Master curve (example)

The master curve is specific for a certain manufacturing lot and biological parameter.

Recalibration

Theoretical Principle

Recalibration consists of establishing a calibration curve from a reference curve and a standard/calibrator. 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 ***mini VIDAS***® modules and any possible alteration of the reagent kit.

This readjustment is called recalibration. It may affect the master curve defined at the factory as well as the calibrator's RFV.

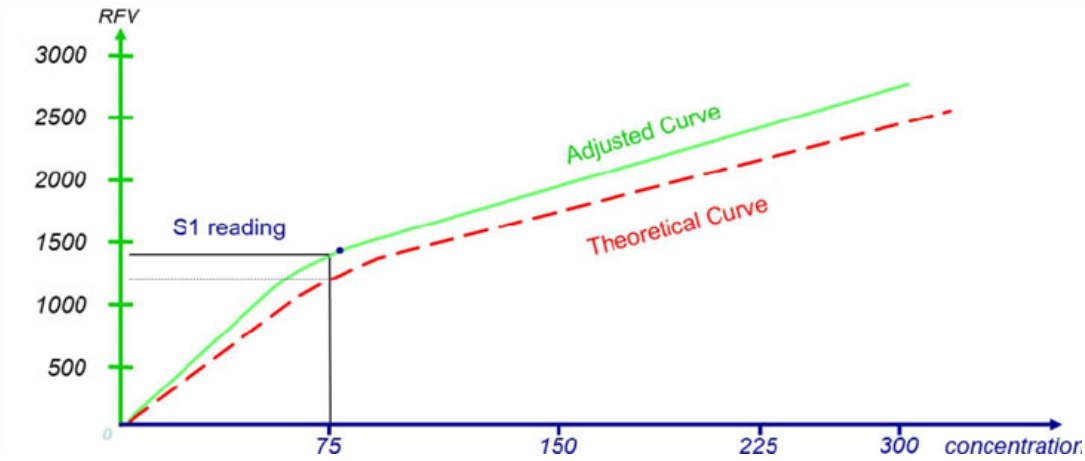


Figure 3-11: Master curve (example)

Principle of Use

Upon receipt of a new lot of reagents, the user must enter the master curve (master lot data) using the Master Lot Data (bar code) provided with the kit. The standard/calibrator should then be run to readjust the curve. The controls are tested in the same run to check the recalibration.

Recalibration is valid for 14 days or 28 days depending on reagents, after which, the software requests another calibration.

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 for a given assay.

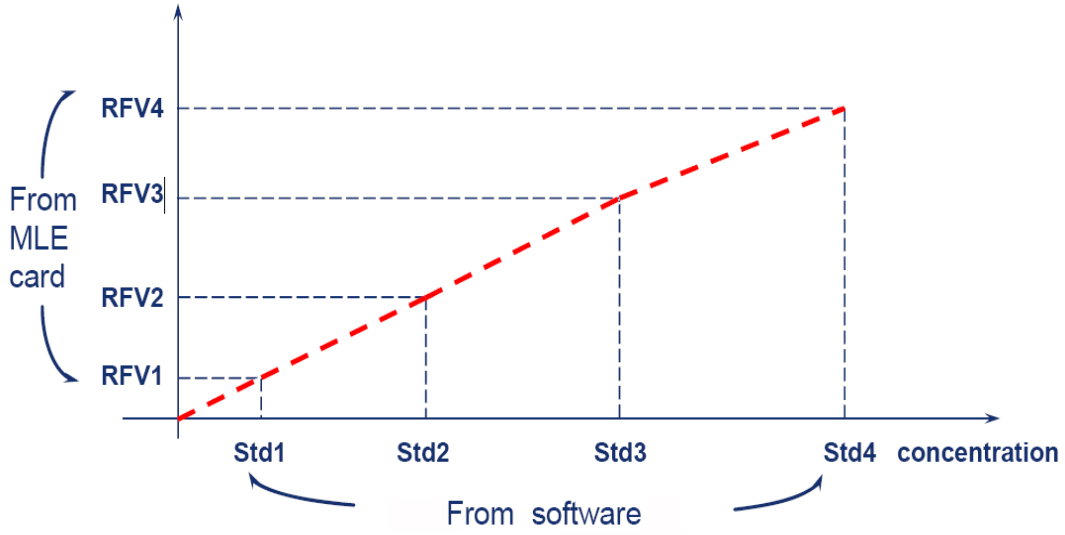


Figure 3-12: Master curves

Establishing the Master Curve

Each kit includes the master curve in the form of:

- an MLE bar code printed on the reagent kit label,
- an MLE card provided in the reagent kit (for certain assays).

The bar code contains the following information:

- 4 RFV levels, corresponding to 4 standards defined in the software. The master curve is restored using 4 points. The levels of concentration of these 4 standards are known to the ***mini VIDAS®*** software and are specific for each assay.

  The ***mini VIDAS®*** software replots the total curve using the 4 pairs of concentrations and RFVs (master lot data).

The remaining information includes:

- the assay code,
- the kit lot number (SPR®s and reagents). It is used to link the master curve data to the strip lot number,
- mathematical model used to establish the master curve (7: Rodbard, 8: Polynomial, 9: Semilog),
- the dose value for the standard (recalibrator) which is essential for calculating the correction factor. This value may vary slightly from one lot to another,
- range values for the controls in the kit,
- range values for the standard's RFV,
- maximum variation coefficient of the standard's RFV duplicates or triplicates.

All these data are specific to an assay and a given lot.

The standard/calibrator must be identified by S1 or S2 (e.g. HBET) or S1 and S2 (e.g.TSH3).

Calibration should be performed each time a new lot is opened (after master lot data have been entered), and every 14 or 28 days, depending on the reagent.

If the values obtained are not within the acceptable range, an error message appears on the result sheet.

The control(s) should be tested in single.

Overview of Operation Elements

Strip and SPR® Sections

The ***mini VIDAS***® analyzer contains two compartments called “sections”. Each section (labeled A and B) can process six single, or three dual, reagent strips for a maximum capacity of twelve single or six dual tests.

These sections operate independently or linked, allowing a variety of assays to be run on the ***mini VIDAS***® analyzer at the same time. On each section, a plastic cover can be lifted to access the reagent strip tray.

Figure 3-13: Strip section

The reagent strip tray consists of six channels into which you can slide a reagent strip. Each of the six channels constitutes a position in the section.

Up to six reagent strips can be inserted per section for a total combined capacity of up to 12 tests. The tray is pulled into the instrument during processing.

WARNING

The reagent strip trays are movable parts. Use caution to avoid pinch injuries.

The SPR® block has six slots used to hold the Solid Phase Receptacles (SPR®). The six positions of the block correspond to the six positions of the reagent strip tray.

During processing, the SPR® block and SPR®s form a pipetting device that is used throughout the assay.

Figure 3-14: SPR® Block

A small light above the SPR® block door indicates the operating status of each section.

When the section is running a test, the light is on; when the light is off, the section is idle.

A flashing light indicates that the tests in that section are completed, and that the reagent strips and SPR®s should be removed.

Strip Preparation Tray

A retractable strip preparation tray is located under each reagent strip tray.

Note: *Previous versions of the **mini VIDAS®** analyzer may not have a strip preparation tray.*

Figure 3-15: Strip preparation tray

The ***mini VIDAS®*** preparation tray can be used to bring the reagents to room temperature.

Caution:

Never dispense samples into the reagent strips when they are on the strip preparation tray.

The strip preparation tray should only be used for reagent strips. Do not place samples on it.

Microprocessor

In addition to the central processing unit, each ***mini VIDAS***® section contains its own microprocessor. This unit is responsible for storing and operating the assay protocols.

A protocol is a series of commands including all necessary operations for an analysis to be run. The microprocessor enables the ***mini VIDAS***® analyzer to perform a fully automated analysis.

Incubator

The assays used in the ***mini VIDAS***® analyzer require temperature control.

Two systems control temperature, one in the reagent strip tray and the other in the SPR® block.

Note: *For more information on temperature monitoring, see* *Displaying and Printing Instrument Temperatures on page B-18.*

Detection System

The ***mini VIDAS***® detection system consists of an optical fluorimetric scanner. It is mounted on a mechanical device which enables it to be used on all the sections.

The system detects any chemical changes occurring in the optical cuvette at the end of each reagent strip.

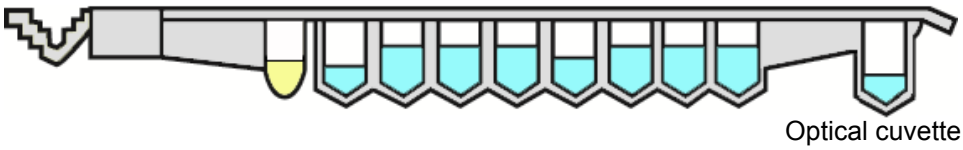


Figure 3-16: Optical cuvette on a reagent strip

Central Processing Unit

The central processing unit controls all aspects of the operations, including data analysis, and verification of the mechanical and optical systems.

Software Basics

Menu Structure

The Main Menu is the entry point into the ***mini VIDAS***® software. It also serves as the pathway to the other ***mini VIDAS***® menus.

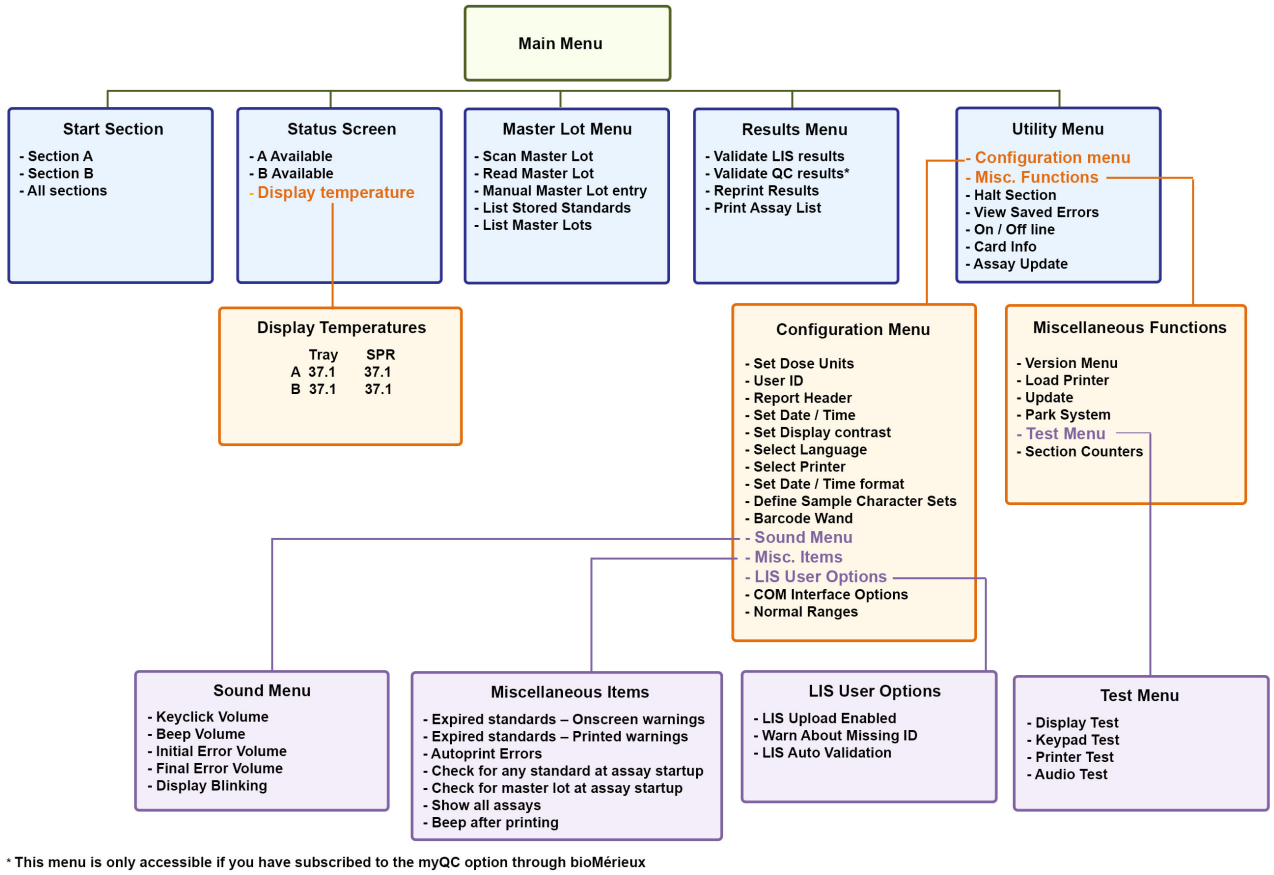


Figure 3-17: ***mini VIDAS***® menu structure

A menu accessed from another menu is called a submenu.

Each submenu contains a particular group of programs that are related.

The **Configuration Menu**, for example, contains all the programs that set the configuration of the ***mini VIDAS***®.

Selecting a Menu Option

Five selection keys on the right of the screen enable you to select options in ***mini VIDAS®*** menus.

Since not all displays use all five selection keys, the boxed selections and lines indicate the active keys.

The active selection keys are noted by the marker «●—» and the enclosed box with a line extending to a selection key.

The following figure shows the status screen for the two ***mini VIDAS®*** sections, A and B.

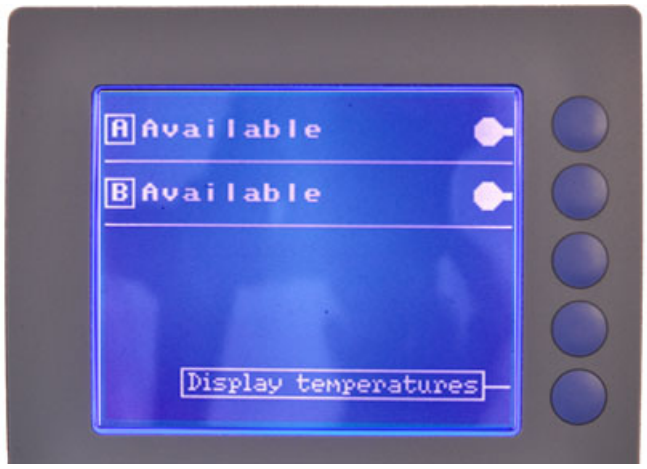


Figure 3-18: Showing active selection keys

The Status Screen

The **Status Screen** display is used to indicate the current status of the two ***mini VIDAS***® sections and to assign assays to them.

It is also used to display the temperature of each section's tray and SPR® block.

The First Status Screen

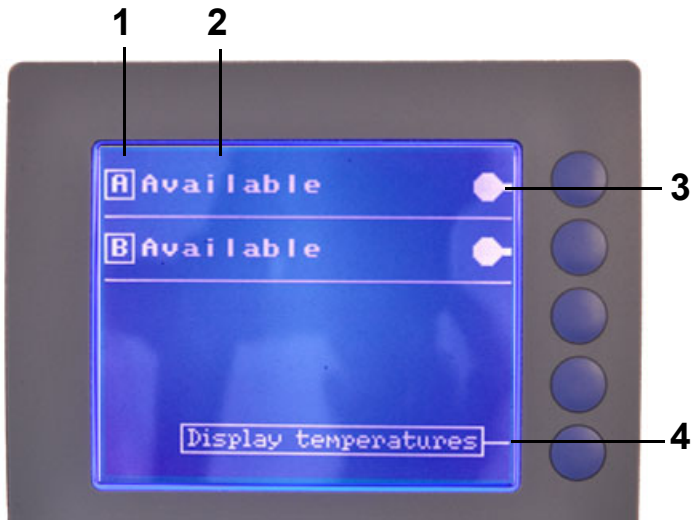


Figure 3-19: First status screen

1 — Section labels
2 — Section status (see Table 3-1, Section Status for the different statuses)
3 — The «●—» marker: indicates that a selection key is active and that a section can be selected.
4 — **Display temperatures**: if you select this key, a screen is displayed showing the internal temperature of each reagent strip tray and SPR®block.

Table 3-1: Section Status

Section Status	Description
`Available`	The section is available to be assigned and run tests
`Barcode`	The ***mini VIDAS***® analyzer is in the process of reading the bar codes of the reagent strips in the section.
`Error`	Indicates a temperature control or hardware problem in the section.
`Offline`	The section has been taken offline.
`Resetting`	The section is in the process of a hardware reset and is not available. This status normally lasts for less than one minute.
`Run`	The section is running tests. When a section is running, the following information appears on the screen: • Assay code of the assay in the section (it is not displayed if several tests are running in the same section). • The estimated time of the day that the run is expected to finish.

Section Status	Description
`Starting`	The section has completed the preprocessing steps and is preparing to run tests.
`Unload`	The section is waiting for the SPR®s to be removed. This occurs at the completion of a run, and is accompanied by the blinking of the operating status light located over the SPR® block door.
`Start error`	There is an error related to the preprocessing of a reagent strip. See Start Errors in Appendix - Troubleshooting.

The Second Status Screen

The second status screen is accessed by selecting one of the two sections on the first screen.

The purpose of the second status screen is to display the tests you have assigned to each position within the section.

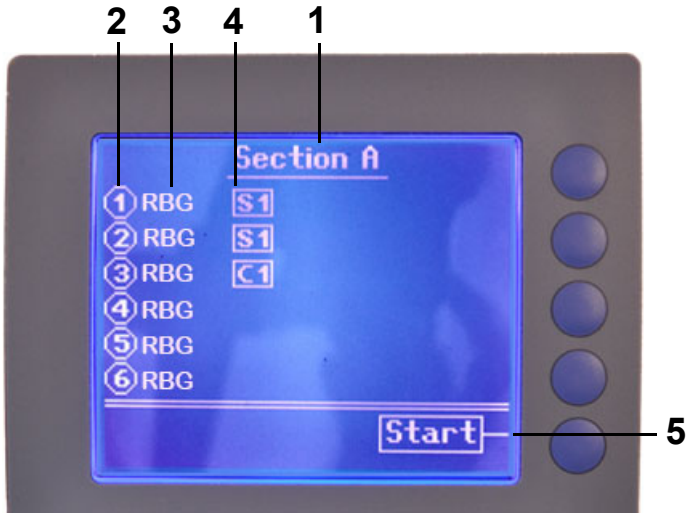


Figure 3-20: Second status screen (six positions assigned)

1 — Screen label: this label shows you are looking at the status of section A.
2 — Position numbers: these numbers identify the six positions in the section.
3 — Assay code: these codes appear as tests are assigned to the section or after the strip's bar code has been read.
4 — Standards/calibrators, control: If a position is assigned to a standard/calibrator or a control, this type of designator appears.
5 — **Start**: a selection option to start processing. In other circumstances, this selection may have another function.
the **halt** function appears while the section is processing. Use it to stop the processing.

The Third Status Screen

The third status screen is accessed by selecting **Display temperatures** from the first status screen. See Displaying and Printing Instrument Temperatures on page B-18.

Online Help

You can display information on the menu or program you are using by accessing the online help function.

Pressing ? on the keypad activates this function.

If you press ? a second time, the following screen appears:

Figure 3-21: Help mode screen

1 — Print Screen: creates a printout of the screen from which you accessed the help function.
2 — System Status: displays the current date/time and the instrument status.
3 — Information: displays the first help screen.
4 — Assay compatibility list: displays a list of the ***mini VIDAS***® assay codes classified according to compatibility.
Compatible assays are assays with the same protocol = assays which can be run simultaneously in the same section.

Viewing Error Messages

The ? key also functions to display error messages.

Screen Paging

Using the Arrow Keys

As some of the ***mini VIDAS®*** displays are too long for one screen, you can page the screen display using the <↑> and <↓> arrow keys.

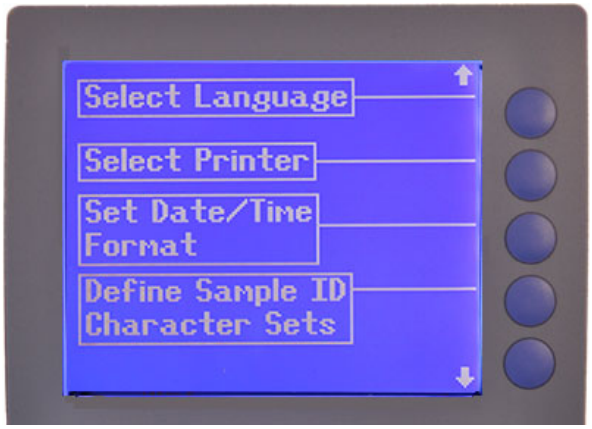


Figure 3-22: Screen paging

Paging Bar

Some ***mini VIDAS®*** screens have a paging bar.
It is used for displays that require several screens. As you page down to the last page, the solid bar moves down the slot.

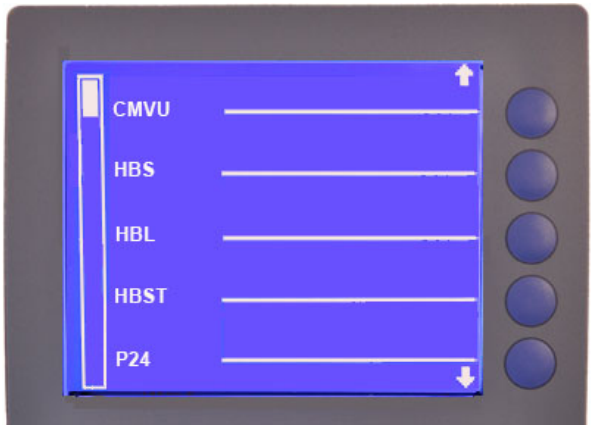


Figure 3-23: Paging bar

4 System Installation and Configuration

WARNING

The *mini VIDAS*® analyzer must be installed by bioMérieux Technical Assistance or your local bioMérieux representative.

WARNING

The *mini VIDAS*® analyzer weighs 40 kg. Before moving any of the equipment, it is imperative that you contact bioMérieux Technical Assistance or your local bioMérieux representative.

Users are trained during installation of the ***mini VIDAS***® analyzer so that they are able to derive the best performance from it.

Unpacking

Caution: The different components of the ***mini VIDAS***® analyzer must be unpacked by bioMérieux or by your local bioMérieux representative.

Caution: Keep the packaging materials to ensure protection of the equipment if ever it needs to be moved.

Caution: The ***mini VIDAS***® analyzer must only be moved by bioMérieux or by your local bioMérieux representative as fragile components have to be secured prior to transport.

Caution:
Any damage directly or indirectly resulting from the transport of an instrument without adequate containers will not be covered by the warranty or maintenance contract.

Storage Conditions

IMPORTANT: ***It is recommended to keep the original packaging materials in case the equipment needs to be stored for any period of time.***

IMPORTANT: ***All the equipment, disposables, reagents, etc., must be stored at the temperatures and in the conditions described in their respective documentation.***

Note: *The storage temperatures and conditions for the* ***mini VIDAS®*** *analyzer are indicated in* *Environmental Conditions on page 3-6**.*

Choosing A Location

WARNING

Avoid exposing the *mini VIDAS®* analyzer to direct sunlight, excessive heat, humidity or dust.

Leave sufficient space around the *mini VIDAS®* analyzer to allow airflow that is essential to proper operation of the thermostat. At a minimum, the instrument requires 10 cm on each side and at the rear of the instrument.

Do not obstruct the *mini VIDAS®* analyzer ventilation apertures.

Electrical connections

Refer to Safety Information in Chapter 2 for safety precautions concerning electrical connections.

Checking Installation

After the ***mini VIDAS®*** analyzer has been installed, bioMérieux or your local bioMérieux representative will perform a test to check that the system is operating correctly.

Connecting an external bar code reader

Caution: Always shut down the ***mini VIDAS®*** analyzer before connecting an external bar code reader.

See Appendix - Installing external hardware for further information on how to connect the bar code reader.

Starting the System

The ***mini VIDAS***® analyzer may be on 24 hours a day:

- to avoid incorrect auto-calibration,
- to enable the temperature of electrical components to remain stable

1. Make sure the ***mini VIDAS***® analyzer is connected to a power outlet.

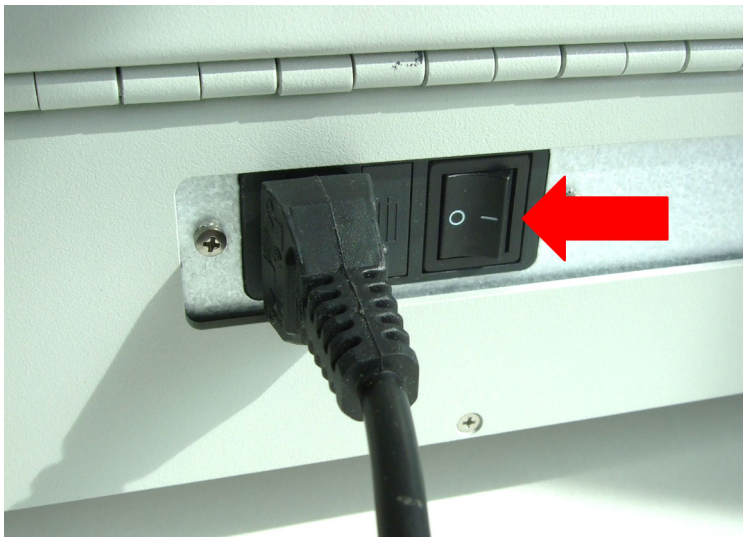


Figure 4-1: Power switch

2. Turn the ***mini VIDAS***® analyzer power switch to **ON**.
   The power switch is located on the back of the instrument.

CAUTION: The power switch must be easily accessible.

3. Let the ***mini VIDAS***® analyzer warm up **for 45 minutes**.
4. Turn the power switch to OFF.
5. Wait 1 minute and turn it ON again.

The ***mini VIDAS***® Main Menu appears.

Note: *If the room temperature is too low when the **mini VIDAS**® analyzer is turned on, error 160 will appear after the initialization phase or when the instrument is restarted (see Instrument Errors on page B-7).*

Shutting Down the System

Introduction

When the ***mini VIDAS®*** analyzer is shut down the following data are stored:

- the ***mini VIDAS®*** software application,
- Protocols,
- Configuration,
- Results of the last two calibrations per assay,
- Master Lot Data.

The following data are erased:

- Assay results (except calibration results),
- Error messages.

Procedure

1. Make sure that no analyses are in progress.
2. Make sure that all results have been printed and/or transmitted to the LIS.
3. Turn the ***mini VIDAS®*** analyzer power switch to OFF.
4. Disconnect the power cord from the power outlet.

Configuring the *mini VIDAS®* analyzer

Caution: Configuration parameters should only be modified by trained and qualified personnel.

Any modification to configuration parameters may lead to problems when the system is used or cause it to operate in an unexpected manner.

Make sure that modifications are necessary and justified.

Selecting a Language

Menus, messages and other information displayed on the ***mini VIDAS®*** screen can be displayed in two different languages, one of which is English. The display language is selected at the time of installation.

Proceed as follows to select one of the installed languages.

1. Select **Configuration menu** in the **Main Menu**.
2. Select **Select Language**.

   A list of languages appears.

Note: *If the language you want to install is not in the list, contact bioMérieux or your local bioMérieux representative.*

3. Select the language you want to use.

   If no other language is selected at the time of installation, **only English will be installed**.

   The following message appears:

   ```
   Please wait...
   ```

The screen returns to the **Configuration Menu**.

Setting Dose Units

This option is used to set the standard units applicable to results for the quantitative ***VIDAS®*** assays.

Caution: After selecting a new unit for an assay, the results for assays run after this change are automatically calculated with this new unit.
Therefore, always pay particular attention to the units displayed on the results reports.

1. Make sure that no assays are running.
2. Select **Set Dose Units** in the **Configuration Menu**.

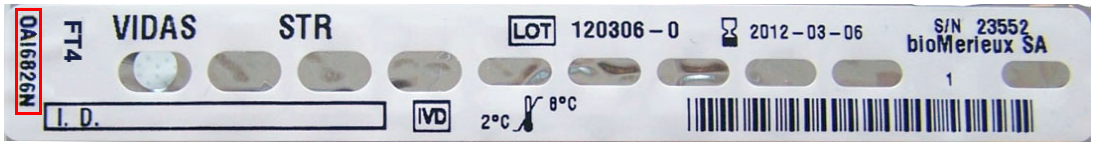
   A list of assays appears.

Note: *If the **Show all assays** function is not activated, only assays for which the Master Lot data have been read will be displayed. See* *Show All Assays on page 4-22**.*

3. Select an assay for which you want to set the dose units.

If an assay has several versions, a second screen is displayed allowing you to select the assay version you want. This version is represented by the two characters preceding the abbreviated assay code (AL or OA in the following example).

On the reagent strip label, the assay version is indicated by the first two characters in the alphanumeric code printed vertically (OA in the following example).



4. Select the assay version for which you want to set the dose units.

Note: *The dose unit currently set is indicated by an arrow.*

5. Select the dose unit desired for this assay.

   The **Configuration Menu** appears.

6. Select another assay to set the dose units.
7. Repeat the same procedure.
8. Press  to return to the **Configuration Menu**.

Setting User IDs

This option is used to enter user IDs (up to nine). These IDs will appear automatically on all reports.
If you do not set a user ID, the user field is left blank on the reports.

1. Select **User ID** in the **Configuration Menu**.

2. Press the **<Number Key>** for the user you want to define.

3. Press the arrow keys to highlight the appropriate character in the character box.
4. Press the **Selection** key to select the character.

   The character appears in the cursor box.
5. Repeat steps 3 and 4 to create an ID.

Note: *IDs can contain up to 10 characters.*

6. To delete characters, use:
   - [**Clr**] to clear the cursor box.
   - [←] to delete one character in front of the cursor.
7. Press  to return to the **Set User ID** screen.

8. Repeat this procedure to enter another user,

   or

   Press  to return to the **Configuration Menu**.

Setting the Report Header

This option is used to define a line of up to 32 characters. This line appears in the header information of the assay report.

1. Select **Report Header** in the **Configuration Menu**.

Note: *The space next to the "Z" character can be used to create a space in your header.*

2. Press the arrow keys to highlight the appropriate character in the character box.
3. Press the **Selection** key to select the character.

   The character appears in the cursor box.
4. Repeat steps 2 and 3 to create a report header.

Note: *Report headers can contain up to 32 characters.*

5. To delete characters, use:
   - [**Clr**] to clear the cursor box.
   - [←] to delete one character in front of the cursor.

Note: *The display shows a maximum of 14 characters. If the report header created is longer, the symbol "<" will appear first followed by the last 14 characters.*

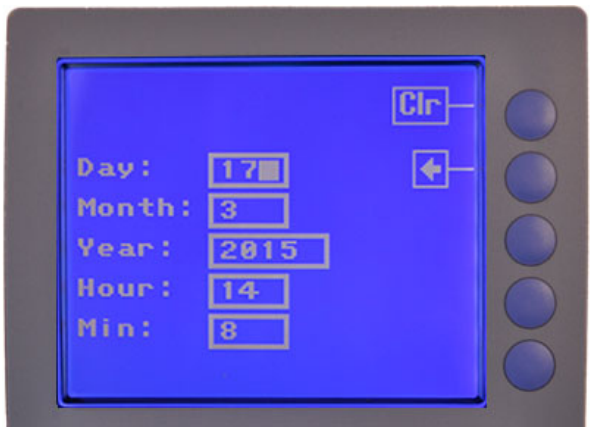
6. Press  to return to the **Configuration Menu**.

Setting the Date and Time

This option is used to set the date and time for the ***mini VIDAS®*** analyzer.
These values appear on the assay report and all other places in the software where the date or time of day is used.

Caution: Incorrect setting of the date and time can lead to incorrect running of programs and loss of data.

1. Select **Set Date/Time** in the **Configuration Menu**.



2. Set the date and time using the following functions:
   - Numeric keypad to fill in the numerical value for a day, month, year, hour or minute.
   - [**Clr**] to clear the cursor box.
   - [←] to delete one character in front of the cursor.

Note: *Use*  *to validate the numerical values.*

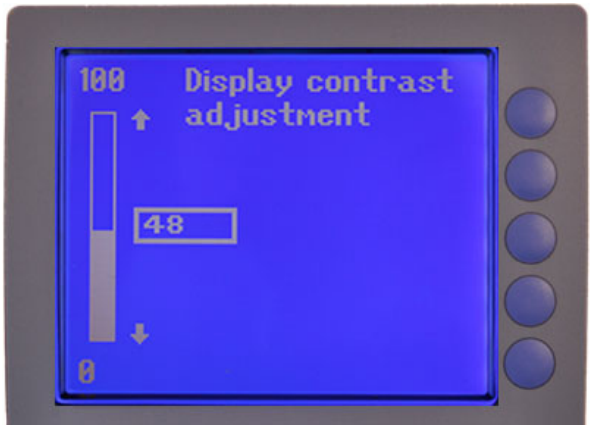
3. Press  to return to the **Configuration Menu**.

Setting Display Contrast

The liquid crystal display of the ***mini VIDAS®*** analyzer has a contrast adjustment to allow for proper viewing in different room lighting conditions.

Caution: Too much contrast could reduce the life span of your monitor.
It is recommended that you use your ***mini VIDAS®*** analyzer for several days with the original setting before modifying the contrast.

1. Select **Set Display Contrast** in the **Configuration Menu**.



2. Press the <↑> or <↓> key to adjust the contrast.

   The contrast bar and relative contrast level (number in the box) increase or decrease.

   The actual display contrast also changes as you make the adjustments.

3. Press  to go back to the default setting

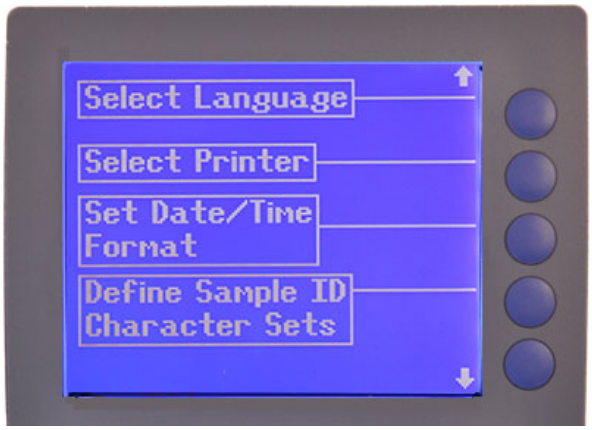
   or

   Press  to return to the **Configuration Menu**.

Selecting the Printer

This option lets you select the internal thermal printer or an external matrix parallel printer.

1. Select **Select Printer** in the **Configuration Menu**.



The following selections appear:

- **Internal Printer**
- **External Printer**

Note: *A ☒ symbol indicates the current setting.*

2. Select the printer you want to use.

IMPORTANT: Before selecting an external printer, see Appendix - Installing external hardware for external printer installation instructions.

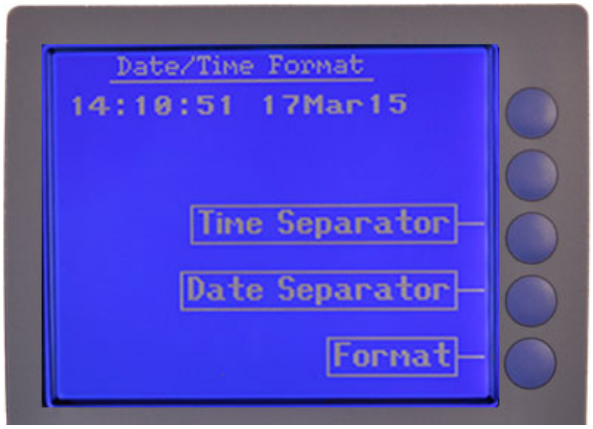
3. Press  to return to the **Configuration Menu**.

Setting the Date/time Format

To set the format of the date and time used on the reports:

1. Select **Set Date/Time** in the **Configuration Menu**.

   The **Date/Time format** screen appears:



2. Select **Time Separator**.
3. Select one of the time separators:
   - **[:] (colon)**
   - **[.] (period)**
   - **[,] (comma)**

   The display automatically returns to the **Date/Time format** screen.
4. Select **Date Separator**.
5. Select one of the date separator:
   - **[/] (slash)**
   - **[-] (dash)**
   - **[.] (period)**

   The display automatically returns to the **Date/Time format** screen.
6. Select **Format**.
7. Select one of the date/time formats:
   - **[HH.MM ddmmm]**
   - **[HH.MM ddmmmyy]**
   - **[HH.MM yy.mm.dd]**
   - **[HH.MM.SS ddmmmyy]**
   - **[HH.MM mm.dd.yy]**

Note: *The date and time separators used in this display are based on your previous selections.*

   The display automatically returns to the **Date/Time format** screen.

8. Press  to return to the **Configuration Menu**.

Defining the Sample ID Character Sets

This option enables you to define two separate ID sets with three characters.

Use one or both of these sets to input repetitive characters for sample IDs.

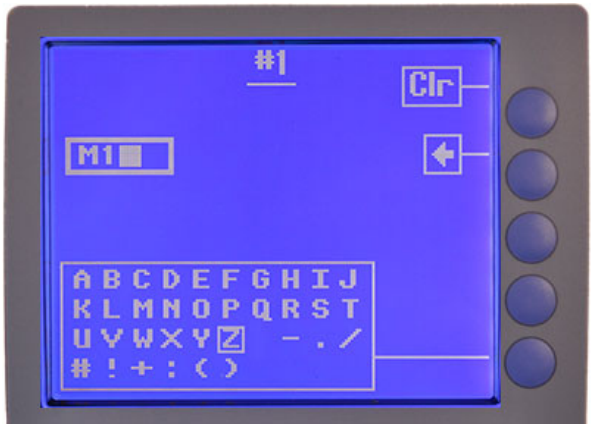
1. Select **Define Sample ID Character Sets** in the **Configuration Menu**.

   The following selections appear:

   - **Sample ID Set 1**
   - **Sample ID Set 2**

2. Select one of the two character sets to define.

   The following screen appears.



Note: *The space next to the "Z" character can be used to create a space in your ID set.*

3. To highlight the appropriate character in the character box, press the arrow keys.
4. Press the **Selection** key to select the character.

   It then appears in the cursor box.

5. Repeat this procedure to add up to three additional characters to the ID.
6. To delete characters, use:

   - [**Clr**] to clear the cursor box.
   - [←] to delete one character in front of the cursor.

7. Press  two times to exit to the **Configuration Menu**.

   or

   Press  once and repeat the whole procedure if you want do define the other ID character set.

Changing the Keyclick Volume

When you press any key on the keypad, there is an audible tone that confirms the keystroke.

1. Select **Sound Menu** in the **Configuration Menu**.
2. Select **Keyclick Volume** in the **Sound Menu**.

3. Press the arrow keys to adjust the keyclick menu.

   The volume bar and relative volume level (number in the box) increase or decrease.

4. Press  to go back to the default setting.

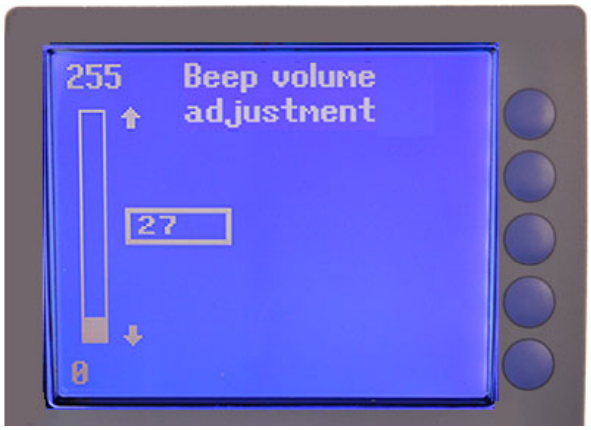
   or

   Press  to return to the **Sound menu**.

Changing the Beep Volume

The beep is the tone you hear when you press a key that is inactive (it should not be pressed on the particular screen you are viewing).

1. Select **Sound Menu** in the **Configuration Menu**.
2. Select **Beep Volume** in the **Sound Menu**.



3. Press the arrow keys to adjust the beep volume.

   The volume bar and relative volume level (number in the box) increase or decrease.

4. Press  to go back to the default setting.

   or

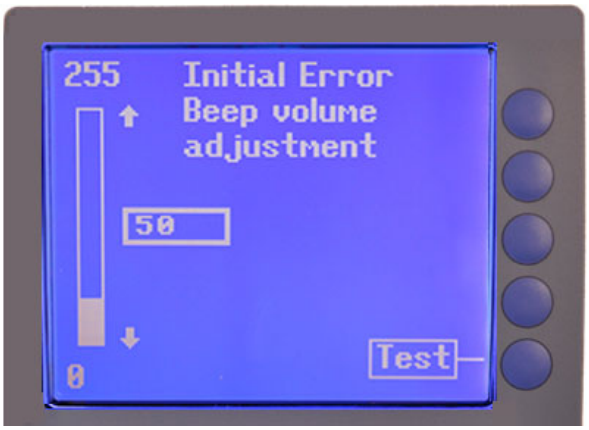
   Press  to return to the **Sound menu**.

Error Beeps

When an error occurs, the ***mini VIDAS®*** analyzer begins to beep. The beep grows louder over a 5 minute period.

You can set the initial and final volume of this error beep.

1. Select **Sound Menu** in the **Configuration Menu**.
2. Select **Initial Error Volume** in the **Sound Menu**.



3. Press the arrow keys to adjust the initial error beep volume.

   The volume bar and relative volume level (number in the box) increase or decrease.

4. Press  to go back to the default setting.

   or

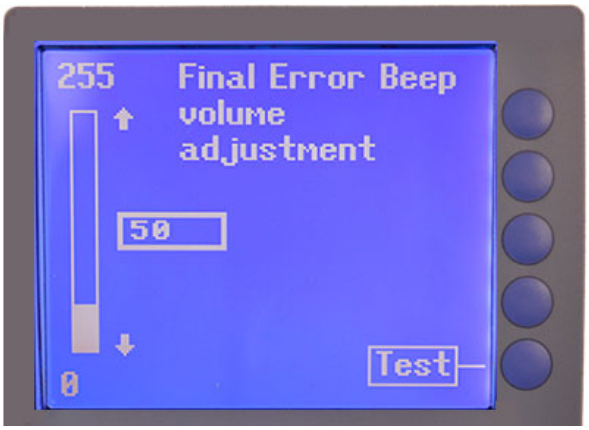
   Select **Test** to hear the tone at the adjusted volume.

   or

   Press  to return to the **Sound menu**.

Setting the Final Error Volume

1. Select **Sound Menu** in the **Configuration Menu**.
2. Select **Final Error Volume** in the **Sound Menu**.



3. Press the arrow keys to adjust the final error beep volume.

   The volume bar and relative volume level (number in the box) increase or decrease.

4. Press  to go back to the default setting.

   or

   Select **Test** to hear the tone at the adjusted volume.

   or

   Press  to return to the **Sound menu**.

Enabling Display Blinking

A blinking display is associated with the error beep since it only occurs when an error happens.

When enabled, it causes the display to blink when an error occurs.

1. Select **Sound Menu** in the **Configuration Menu**.
2. Select **Display Blinking** in the **Sound Menu**.

Note: *The current condition of this function is shown with an arrow "→" in the selection box.*

3. Select the appropriate key.

   The display returns to the **Sound Menu**.

Miscellaneous Items

This option is used to configure various warnings concerning Master Lot data and standards.

Note: *In the default configuration, all of the miscellaneous options are enabled except the two for:*
- Expired Standard Printed Warnings,
- Autoprint Errors.

1. Select **Misc. Items** in the **Configuration Menu**.
2. Press the <↑> and <↓> keys to access the option you want to use.

Note: *A ☒ symbol indicates an enabled option. Each option is independent. This is why more than one option can be selected. The ☒ symbol is removed when you disable a selected option.*

Onscreen Warnings for Expired Standards

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Expired Standard - Onscreen warnings**.

   The ***mini VIDAS®*** analyzer automatically checks for expired calibrations. This procedure is performed every 24 hours or when the instrument is started up.
   If there are any expired calibrations, an error message is displayed.

Note: *See Appendix - Troubleshooting for more information on error messages.*

Printed warnings for Expired Standards

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Expired Standard - Printed warnings**.

   The ***mini VIDAS®*** analyzer automatically checks for expired calibrations. This procedure is performed every 24 hours or when the instrument is started up.
   If there are any expired calibrations, an error message is displayed and printed (printing can be configured).

Note: *See Appendix - Troubleshooting for more information on error messages.*

Autoprint Errors

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Autoprint Errors**.

   The ***mini VIDAS®*** analyzer will generate a printout when an error occurs. You will still need to view the error on screen to stop the blinking and beeping.

If you do not select this option, messages are printed only after the user acknowledges the error.

Note: *See Appendix - Troubleshooting for more information on error messages.*

Check for Any Standard at Assay Startup

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Check for ANY Standard at assay startup**.

   The ***mini VIDAS®*** analyzer generates a startup error if there are no standard, current or expired for the selected assay. If an expired standard exists, the assay will start.

Note: *See Appendix - Troubleshooting for more information on error messages.*

Check for Current Standard at Assay Startup

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Check for Current Standard at assay startup**.

   The ***mini VIDAS®*** analyzer generates a startup error if there are no current standards for the selected assay.

Note: *See Appendix - Troubleshooting for more information on error messages.*

Check for Master Lot at Assay Startup

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Check for Master Lot at assay startup**.

   The ***mini VIDAS®*** analyzer generates a startup error if there is no Master Lot data for the selected assay.

Note: *See Appendix - Troubleshooting for more information on error messages.*

Show All Assays

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Show all assays**.

   The ***mini VIDAS®*** analyzer will include all of the assays it is capable of running when it displays an assay selection list.
3. Deselect **Show all assays** to display only the assays for which Master Lot data have been entered.

Note: *A change to this option does not take effect until the **mini VIDAS®** analyzer is restarted.*

Beep After Printing

1. Select **Misc. Items** in the **Configuration Menu**.
2. Select **Beep After Printing**.

   The ***mini VIDAS®*** analyzer will beep discontinuously for a few seconds each time it generates a printout.
3. Press  to return to the **Configuration menu**.

LIS User Options

This option is used if your ***mini VIDAS®*** analyzer is connected to a Laboratory Information System (LIS).

Before results can be sent to the LIS, the LIS upload function must be enabled.

This option is also used to validate results before they are transmitted to the LIS.

Caution: Your unidirectional connection must be configured and brought into service by trained and qualified personnel.
Any modification may lead to problems when the connection is used or cause it to operate in an unexpected manner.

Enable LIS Upload

1. Select **LIS User Options** in the **Configuration Menu**.
2. Select **LIS Upload Enabled**.

   This selection will activate the Laboratory Information System (LIS) upload feature.

Note: *A ☒ symbol indicates a selected option. The ☒ symbol is removed when you disable a selected option.*

Warn About Missing IDs

1. Select **LIS User Options** in the **Configuration Menu**.
2. Select **Warn About Missing IDs**.

   Assays are checked at assay startup.

If an assay does not have an ID, a warning message is generated.

The assay will continue if you acknowledge the message. You can then add an ID to the assay.

If this option is not selected, no ID warning messages are generated.

IMPORTANT: If you select «LIS upload Enabled», it is recommended that you also select «Warn About Missing IDs» since any results without IDs will not be transmitted to the LIS.

LIS Auto Validation

1. Select **LIS User Options** in the **Configuration Menu**.
2. Select **LIS auto validation**.

   Results will be automatically uploaded to your LIS.
3. Press  twice to return to the **Main menu**.

Creating Normal Ranges for Assays

You can create up to 8 lines of free text for any ***mini VIDAS®*** assay.

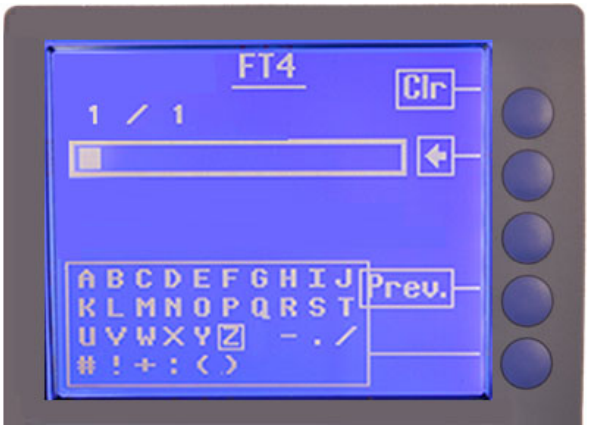
These lines, each with up to 36 characters, are printed at the bottom of each report for the particular assay type.

1. Select **Normal Ranges** in the **Configuration** Menu.

   A list of assays displays.

Note: *The assays that actually appear may be limited by the* **Show All Assays** *configuration option.*

2. Press the arrow keys to find an assay.
3. Select the assay with the normal ranges you want to create.



Note: *The [1 / 1] in the upper left portion of the display tells you that this screen is for Line #1 of 1 total lines.*

These numbers change as you access the screens for other lines.

4. Press the arrow keys to highlight the appropriate character in the character box.

Note: *The space next to the "Z" character can be used to create a space in your text.*

5. Press the **Selection** key to select the character for the character box.

   The selected character then appears in the cursor box.

6. Repeat steps 4 and 5 to select other characters.

   Use these functions as needed:

   - [**Clr**] to clear the cursor box.
   - [←] to delete one character in front of the cursor.
   - [**Prev.**] to switch to the screen for the previous line of text.

7. Press  to switch to the screen for the next line of text,
8. Repeat steps 4 to 7 to enter up to eight lines of text.
9. Press  to return to the **Configuration menu**.

Installing Paper in the Internal Printer

Note: *The paper for this printer is coated on only one side. If the printer does not print after the paper is installed, reorient the roll to expose the other side.*

1. Select **Utility Menu** on the **Main Menu**.
2. Select **Misc. Functions**.

3. Select **Load Printer**.

   The following message appears:

   `Load paper now (Press any key to quit)`

4. Lift the printer door.

Note: *The printer door is on the top of the instrument above the keypad.*

5. Retrieve the paper spindle from its slots and put it through the core of the paper roll.

Note: *If you have just unpacked the **mini VIDAS®** analyzer, there may be a piece of tape holding the spindle. Remove and discard this tape.*

6. Return the loaded spindle to the vertical slots in the print roll housing.

   The paper engagement lever is in the LOWER end of its slot.

7. Push the edge of the paper under the paper feed roller.

   A sensor that detects the presence of the paper activates the paper roller.

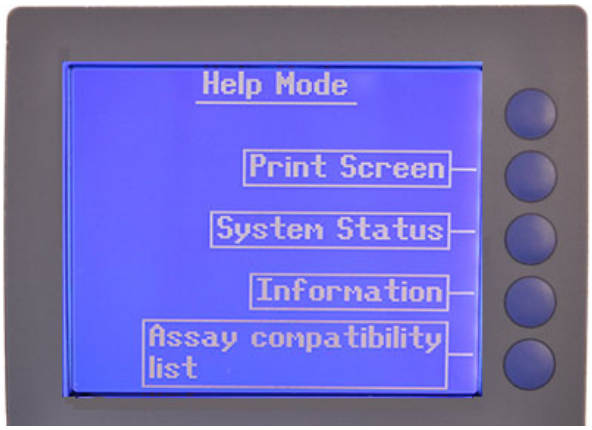
8. Push the edge of the paper under the paper feed roller.
9. Allow the roller to feed the paper.
   It stops automatically after a few seconds.
10. Slide the paper engagement lever to the UPPER end of its slot.

IMPORTANT: The paper must be fed enough so that the leading edge extends under the plastic paper guide and out of the printer compartment so that it is exposed when you close the printer door. If necessary, select* Load Printer *again to feed more paper.

11. Hold the leading edge of the paper in one hand.
12. With the other hand, close the printer door.

Print Screen

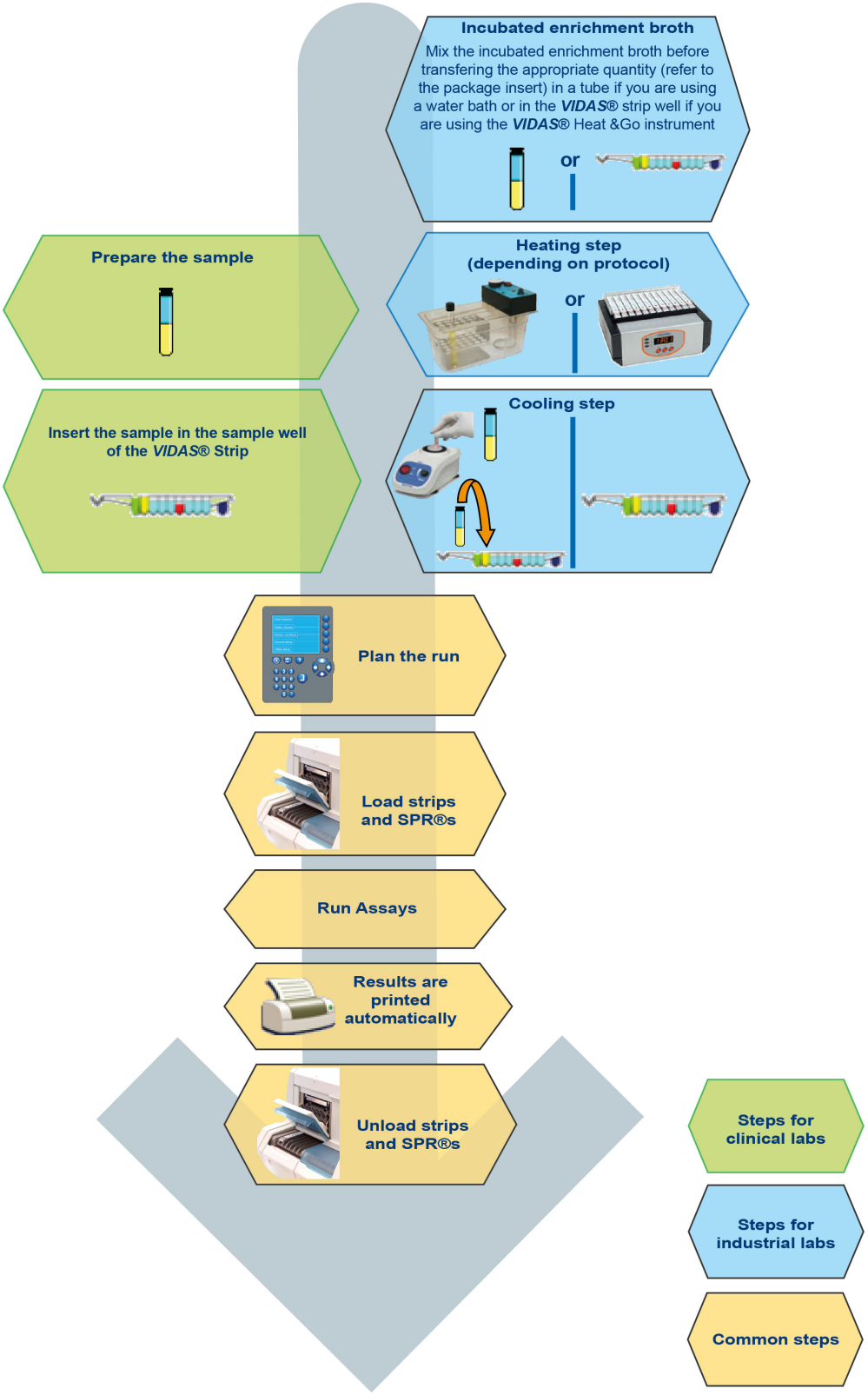
1. Display the page you want to print.
2. Press the ? key twice.



3. Select **Print Screen** to start printing.
4. Press the key to go back to the previous screen.

5 Workflow and Instructional Procedures

Routine Workflow



Planning a Run

Managing the Job List

The laboratory job list is a list of all assay requests entered and queued pending receipt of the results.

Assays may be performed on different instruments, so each ***mini VIDAS®*** analyzer has its own job list.

The assay requests have to be created directly on the ***mini VIDAS®*** analyzer.

You need to manage tube prioritization and allocation of the assays to be run depending on the samples to be analyzed.

Defining the Type of Run Required

Your workload and procedural requirements will determine the type of run you use.

There are two ways to run a test with the ***mini VIDAS®*** analyzer:

- «Load and Go» mode:
  Start the test and then define its routine information.
  The information that the ***mini VIDAS®*** analyzer requires is taken from the labels on the reagent strips during the initial steps of the run.
  The Sample ID, standard(s)/calibrator(s) or control(s), dilution factor can be entered after the run has been started.
- «Defined» mode:
  Enter routine information before running the test.
  In addition to the assay type, Sample ID, standard(s)/calibrator(s) or control(s), dilution factor can be entered prior to starting a defined run.

Checking Assay Compatibility

The ***mini VIDAS®*** analyzer allows you to run different assays in the two sections at the same time as long as these assays have the same protocol.

1. Press  twice from any screen.

   A help screen appears.

2. Select **Assay compatibility list**.

   The assays listed in the same column are compatible with one another. If an assay is not on this list, it is not compatible with any other assay.

Defining the Standards/calibrators and Controls to be used

CAUTION: To obtain a result, it is important to use a valid standard/calibrator.

Standards/calibrators

All single strip reagent assays require that a standard/calibrator assay result be stored in the ***mini VIDAS®*** analyzer.

A standard/calibrator must be included in a run when:

- you are running an assay kit lot for the first time,
- the previous standard/calibrator for the lot you are using was run over 14 or 28 days ago (depending on assays) and has therefore expired.

Controls

For qualitative assays, Positive and Negative Controls are provided in all ***VIDAS®*** assay kits.

For quantitative assays, controls with targeted value are provided in all ***VIDAS®*** assay kits.

Controls should be tested routinely according to your laboratory's regulatory guidelines.

Always refer to the reagent package insert for more information.

Running Assays

Before running assays, carefully read the precautions described in Precautions For Use Of Reagents on page 2-11.

Entering Master Lot Data

Before each new lot of reagents is used, specifications (or factory master data) must be entered into the ***mini VIDAS***® analyzer using the Master Lot Entry (MLE) data.
The master lot data only needs to be entered once for each lot.

Master Lot data can be entered into the ***mini VIDAS***® analyzer automatically using:

- the Master Lot Entry (MLE) data printed on the reagent kit label.
  This bar code can only be read using the hand-held bar code reader connected to the instrument
- the Master Lot Entry (MLE) card provided in the ***VIDAS***® assay kit (for certain assays).

Note: *The **mini VIDAS**® analyzer uses a check code to verify the Master Lot data entered manually and by the bar code reader.*

Scanning Master Lot Data on the Reagent Kit Label

Before reading the bar code, check that:

- The bar code reader has been installed and configured.
  If not, see Appendix - Installing external hardware.
- The reagent kit label is in good condition.
  To be readable the bar code must be complete, free of stains or tears.
  If the label is stained or torn, contact bioMérieux or your local bioMérieux representative.

1. Select **Master Lot Menu** in the **Main Menu**.
2. Select **Scan Master Lot**.

   The **Master Lot** screen appears:

3. Using the bar code reader, scan the bar code printed on the reagent kit label.

Note: *Older bar code readers may require that you slowly scan the bar code on the kit label from top to bottom or bottom to top until the code has been read completely.*

A message is displayed that reading is in progress.
The reader beeps when the reading is finished.

If the bar code is read correctly, the display returns to the **Master Lot Menu**.
Entering the Master Lot Data is now complete and a report showing the main characteristics of the lot is automatically printed.

In case of problem when reading the Master Lot Entry (MLE) bar code,

- if the kit does not contains the Master Lot Entry (MLE) card, contact bioMérieux or your local bioMérieux representative.
- if the kit contains the Master Lot Entry (MLE) card, perform the manual data entry procedure (see Manually Entering Master Lot Data Using the Master Lot Entry (MLE) card. on page 5-7).

Automatically Entering Master Lot Data Using the Master Lot Entry (MLE) card

IMPORTANT: Some VIDAS® reagent kits no longer include the Master Lot Entry (MLE) Card. Refer to Scanning Master Lot Data on the Reagent Kit Label.

The Master Lot Entry (MLE) card is placed into a specially designed holder and then inserted into a section of the ***mini VIDAS®*** analyzer.

Note: *The data are presented in two forms: machine-readable bar codes and alphanumerics. This allows for manual data entry or correction if the machine cannot read all of the bar codes.*

1. Select **Master Lot Menu** in the **Main Menu**.
2. Select **Read Master Lot**.

   The list of available sections appears.
3. Place the Master Lot Entry (MLE) card in the reagent strip tray of the section you will use.

Note: *The status of the selected section must be* "**Available**"*.*

4. Select the appropriate section.

   The ***mini VIDAS®*** analyzer reads the bar coded data from the card and the screen returns to the **Master Lot** Menu.

Entering the Master Lot Data is now complete and a report showing the main characteristics of the lot is automatically printed.

If the instrument is unable to read all the data on the card, the ***mini VIDAS®*** analyzer beeps and an error message is generated.

1. Make sure the Master Lot Entry (MLE) Card is properly oriented in the tray and perform this procedure again.

If the instrument again fails to read the data, perform the manual data entry procedure (see Manually Entering Master Lot Data Using the Master Lot Entry (MLE) card. on page 5-7).

Manually Entering Master Lot Data Using the Master Lot Entry (MLE) card.

CAUTION: There is a risk of error when entering the Master Lot Data manually. Make sure that you enter the lines in exactly the same order as they appear on the Master Lot Entry (MLE) card.

IMPORTANT: Some VIDAS® reagent kits no longer include the Master Lot Entry (MLE) Card. Refer to Scanning Master Lot Data on the Reagent Kit Label

There are two reasons for manually entering Master Lot data:

- when you want to correct bar codes read incorrectly by the ***mini VIDAS®*** analyzer (see Correcting Bar codes Manually on page 5-7),
- when you want to enter the information manually (see Entering Bar codes Manually on page 5-10).

Note: *Data can be read using the bar code reader. However, new models of bar code readers cannot read bar codes printed on the Master Lot Entry (MLE) card.*

Correcting Bar codes Manually

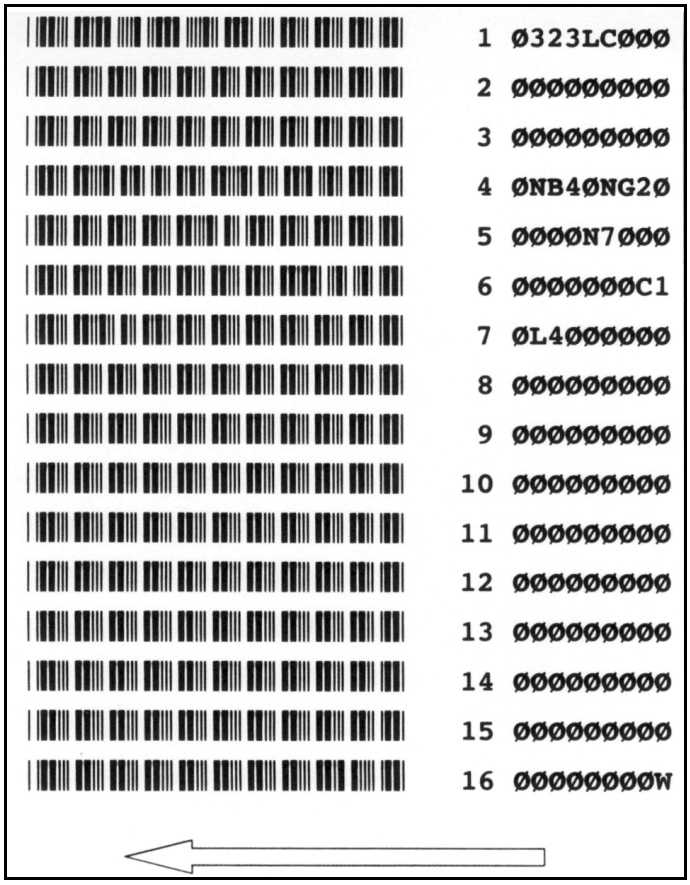
1. Select **Master Lot Menu** in the **Main Menu**.
2. Select **Manual Master Lot Entry**.

   The following screen appears:

Note: *The numbers "**1/16**" on the screen indicate that there is a total of 16 bar codes on the Master Lot data card, and, in the example shown, bar code # 1 is bad.*

3. Select **<Clr>** to clear the bar code window of the message «**BAD**».
4. Find the appropriate bar code on the Master Lot Data card.

The figure below shows a portion of a sample card with the 16 machine-readable bar codes and matching alphanumeric strings.



5. Enter the correct bar code by typing the characters of the bar code manually.
6. Press the arrow keys to highlight the appropriate character in the character box.
7. Select the character.

   The character appears in the cursor box.
8. Press a **<Number Key>** to place a number in the cursor box.
9. Continue this for all nine characters in the bar code.
10. Use these functions as needed:
    - **[Clr]** to clear the cursor box.
    - **[←]** to delete one character in front of the cursor.
    - **[Prev.]** to go back to the previous bar code.
      (do not mistake this key for the key on the keypad).

Note: *"O" and "I" are letters.*
"Ø" and "1" are the digits zero and one.

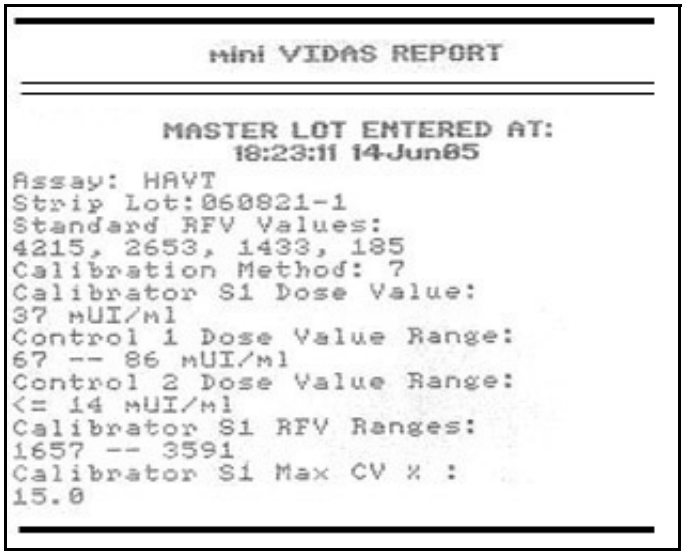
11. Press when the bar code entry is complete.

    The ***mini VIDAS®*** analyzer checks the bar code.

If the bar code was entered correctly and there are no other errors, the display exits to the **Master Lot Menu**.

Entry of this Master Lot Data is complete.

The Master Lot Data report showing the main characteristics of the assays is printed automatically.



If you entered the bar code incorrectly, or if other bar codes need to be corrected, the following prompt appears:

MLE Card data bad.
Edit again?

12. Select **Yes** to continue the entry process.

    The manual bar code entry screen appears again.

    The digits, indicating the bar code number from 1 to 16, are displayed.

13. Repeat this procedure to correct other bar code(s) if necessary.

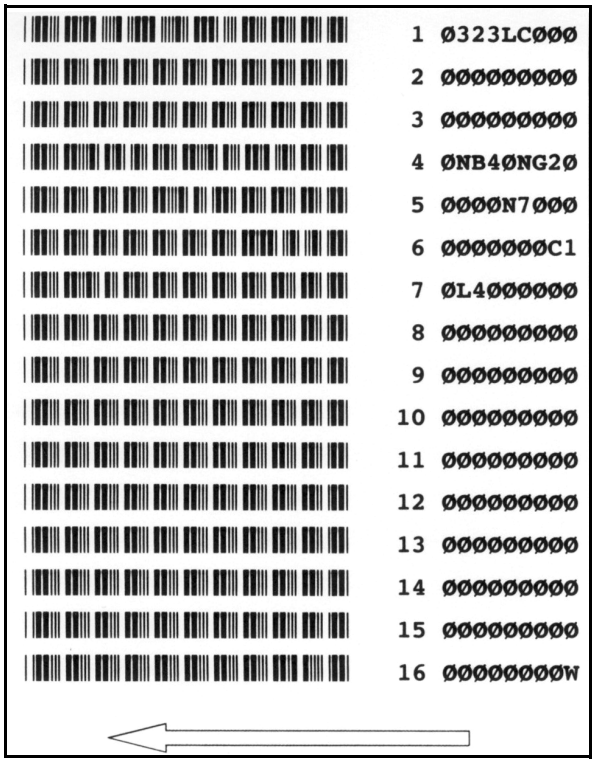
Entering Bar codes Manually

1. Select **Master Lot Menu** in the **Main Menu**.
2. Select **Manual Master Lot Entry**.

   The following screen appears:

Note: *The numbers "**1/16**" on the screen indicate that there is a total of 16 bar codes on the Master Lot data card, and, in the example shown, you are entering bar code # 1.*

The figure below shows a portion of a sample card with the 16 machine-readable bar codes and matching alphanumeric strings.



3. Enter the first bar code on the Master Lot Entry (MLE) card by typing the characters of the bar code manually.
4. Press the arrow keys to highlight the appropriate character in the character box.

5. Select the character.

   The character appears in the cursor box.

6. Press a **<Number Key>** to place a number in the cursor box.
7. Continue this for all nine characters in the bar code.
8. Use these functions as needed:
   - **`[Clr]`** to clear the cursor box.
   - **`[←]`** to delete one character in front of the cursor.
   - **`[Prev.]`** to go back to the previous bar code.
     (do not mistake this key for the  key on the keypad).

Note: *"O" and "I" are letters.*
"Ø" and "1" are the digits zero and one.

9. Press  .
10. Enter the second bar code on the Master Lot Entry (MLE) card.
11. Press  .
12. Repeat this procedure for the following bar codes.
13. Press  after having entered the last bar code (entry zone 16/16).

    The ***mini VIDAS***® analyzer checks the bar codes.

The Master Lot Data report is printed automatically.

Running Assays in «Load and Go» Mode.

CAUTION: When calibration is performed, the standard/calibrator and/or controls must be identified. In this case, only «Defined» mode will be used.

CAUTION: When different assays use the same strip (eg.: ***VIDAS®*** LYG and ***VIDAS®*** LYGS), the assay must be selected prior to the run. If no assay is selected, a start error occurs and the run is stopped.

1. Check that a calibration has been run for this assay.
2. Make sure that the appropriate samples have been inoculated into the assigned strips.

CAUTION: It is very important to respect the required volume indicated in the assay package insert.

Loading Reagent Strips and SPR®s

CAUTION: Strips and SPR®s should not be loaded in advance but just before the test is performed as preincubation in the sections can affect results.
However, certain tests require preincubation, so the strips need to be incubated in the instrument (refer to the reagent package insert).

1. Lift the cover of the reagent strip section.
2. Hold the strip by its handle and insert it into a test position.
3. Slide the strip into the section channel.

CAUTION: Make sure the strip is firmly placed by sliding it all the way until you feel the strip lock into the section channel.

4. Open the SPR® block door.

5. Place the SPR® in the SPR® block position directly over the reagent strip.

CAUTION: When placing the SPR® in the SPR® block position, do not apply pressure to the block position as this may cause the SPR® to be ejected.

Check the position of SPR®s and reagent strips. The SPR® color-coded dot must match the dot on the reagent strip.

It is very important that all the SPR®s for the assay you want to run are properly placed in the SPR® block and that the dot on top has a hole.

The ***mini VIDAS®*** analyzer cannot detect the type of SPR® used nor the absence or presence of an SPR®.

6. Repeat this procedure for other strips and SPR®s to be loaded.
7. Close the SPR® block door and the reagent strip tray cover.

Starting A «Load and Go» Run

1. Select **Start Section** on the **Main Menu**.
2. Select the section(s) you want to run.

Note: *If two or more user IDs have been defined, the following screen appears.*
If only one user ID was defined, that ID appears on the assay report.
If no user IDs were defined, no ID is included on the assay report.
See Setting User IDs on page 4-8 for more information.

3. Press the **<Number Key>** for the user ID assigned to this section.

   The following message appears:

```
Starting Section
Please wait...
```

The status of the started section now displays «**Barcode**».

4. Press  to return to the **Main Menu**.

Note: *The Sample ID, standard(s)/calibrator(s) or control(s), dilution factor can be entered after the run has been started.*

5. After the assays are completed, remove the SPR®s and strips from the ***mini VIDAS®*** analyzer.
6. Dispose of the used SPR®s and strips into an appropriate receptacle.

Running Assays in «Defined» mode

1. Make sure that the appropriate samples have been inoculated into the assigned strips.

IMPORTANT: It is very important to respect the required volume indicated in the assay package insert.

Assigning Assays to a Position

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

Note: *A section must have an "**Available**" status in order for you to proceed.*

3. Press the **<Number Key>** for the position where you want to place a reagent strip.

Note: *Dual reagent strips MUST be placed in positions 1 & 2, 3 & 4, or 5 & 6. Placing one in positions 2 & 3, for example, causes an error.*

4. Select **Assay**.

5. Select **Select Assay**.

   An assay code list appears.

Note: *The assays that actually appear may be limited by the* **Show All Assays** *configuration option. See* *Show All Assays on page 4-22**.*

Note: *If an assay has already been selected for the section, the assay code list only includes the assays compatible with the previously selected assay and with the other assays that have the same name.*

6. Scroll the list using the arrow keys to select the assay code.

   The **Position** screen appears with the assay code now included.

Assigning Standards/calibrators for Assays with one standard/calibrator

Always refer to the reagent package insert for more information on the standard(s)/ calibrator(s) to be run for an assay.

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

Note: *A section must have an "**Available**" status in order for you to proceed.*

The **Section** screen appears displaying the six positions in the section.

3. Press the **<Number Key>** for the position where you want to place a reagent strip.

4. Select **S** on the **Position** screen.

   The following prompt appears:

   ```
   Enter standard number (1-4)
   ```

5. Select «**1**» or «**2**» on the numerical keypad (depending on the kit: eg for HBET).

   S1 or S2 is created automatically and appears on the screen.

6. Press  .
7. Repeat steps 4 to 6 if the standard/calibrator must be run in duplicate (S1 S1) or in triplicate (S1 S1 S1).

Assigning Standards/calibrators for Assays with two standards/calibrators (S1 and S2)

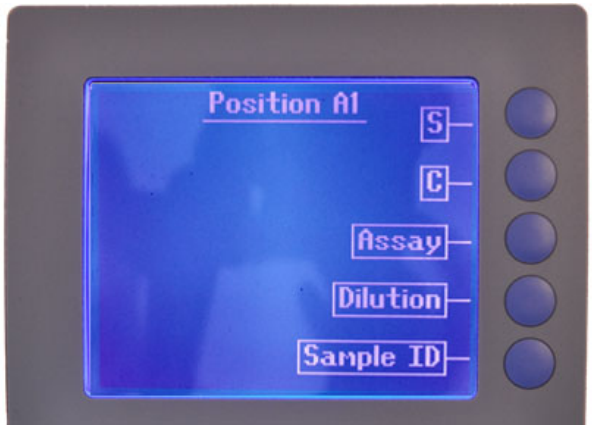
Always refer to the reagent package insert for more information on the standard/calibrator to be run for an assay.

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

Note: *A section must have an "**Available**" status in order for you to proceed.*

The **Section** screen appears displaying the six positions in the section:.

3. Press the **<Number Key>** for the position where you want to place a reagent strip.



4. Select **S** on the **Position** screen.

   The following prompt appears:

   ```
   Enter standard number (1-4)
   ```

5. Select «**1**» on the numerical keypad.

   S1 is created automatically and appears on the screen.

6. Press  .
7. Repeat steps 4 to 6 if S1 must be run in duplicate or in triplicate.
8. Select **S** on the **Position** screen.
9. Select «**2**» on the numerical keypad.

   S2 is created automatically and appears on the screen.

10. Press  .
11. Repeat the steps 8 to 10 if S2 must be run in duplicate or in triplicate

Note: *Multiple standards/calibrators with the same ID number are considered to be replicates by the **mini VIDAS®** analyzer.*

The number of replicates to be performed for each standard/calibrator is indicated in the reagent package insert.

Assigning Controls to a Position

Always refer to the reagent package insert for more information on controls.

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

Note: *A section must have an "**Available**" status in order for you to proceed.*

The **Section** screen appears displaying the six positions in the section.

3. Press the **<Number Key>** for the position where you want to place a reagent strip.

4. Select **C** on the **Position** screen.

Note: *If your **mini VIDAS®** analyzer has been configured to run internal quality controls and to send them to a web application for statistical processing, the **Position** screen will display **Controls** instead of **C**. In that case, select **Controls**, then select **C** to enter controls.*

The following prompt appears:

```
Enter Control number (1-4)
```

5. Press the **<Number Key>** for the ID number for the control.

Assigning Sample IDs to a Position using a Bar code Reader

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

Note: *A section must have an "**Available**" status in order for you to proceed.*

The **Section** screen appears displaying the six positions in the section.

3. Press the **<Number Key>** for the position where you want to place a reagent strip.

4. Select **Sample ID**.

5. Scan the sample bar code label with the bar code reader.

The sample ID now appears on the screen.

6. Repeat the whole procedure to enter other sample IDs.
7. After identification of the last sample, press  until the work list for the section is displayed on the screen

Assigning Sample IDs to a Position Manually

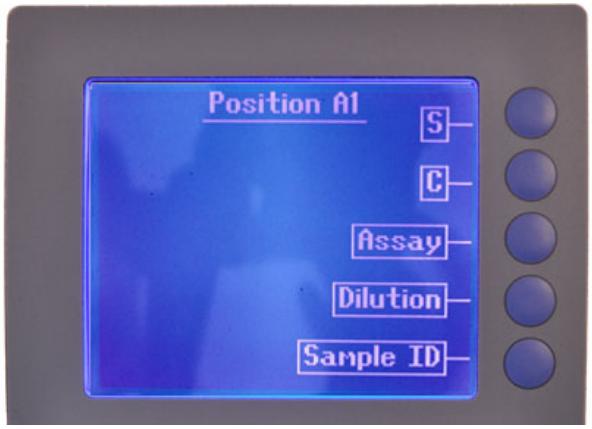
Note: *Sample IDs may contain a maximum of 12 alphanumeric characters.*

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

   The **Section** screen appear.

Note: *A section must have an "**Available**" status in order for you to proceed.*

3. Press the **<Number Key>** for the position where you want to place a reagent strip.



4. Select **Sample ID**.

5. Press the arrow keys to highlight the appropriate character in the character box.
6. Select the character.

   The character appears in the cursor box.
7. Press a **<Number Key>** to place a number in the cursor box.
8. Select one of the two sample ID character sets if you want to place one of these in the cursor box.

Note: *See Defining the Sample ID Character Sets on page 4-14 fore more information.*

9. Repeat these steps until the sample ID for the test is complete.

10. Press  to validate the sample ID and to go to the next position if other sample IDs must be entered.
11. Repeat the whole procedure to enter other sample IDs.
12. After identification of the last sample, press  until the work list for the section is displayed on the screen.

Defining the Same Assay Type for the next position

If the **Assay Type** has been selected,

1. Press  to copy the same assay type for the next position.

Erasing Inputs for a Position or a Section

1. Select **Status Screen** from the **Main Menu**.
2. Select a section.

Note: *A section must have an "**Available**" status in order for you to proceed.*

The **Section** screen appear.

3. Press the **<Number Key>** for the position where you want to place a reagent strip.
4. Select **Assay** in the **Position** screen.

5. Select **Clear**.

6. Select **Clear this position's setup only** or **Clear entire section's setup**.

Loading Reagent Strips and SPR®s

CAUTION: Strips and SPR®s should not be loaded in advance but just before the test is performed as preincubation in the sections can affect results.
However, certain tests require preincubation, so the strips need to be incubated in the instrument (refer to the reagent package insert).

1. Lift the cover of the reagent strip section.
2. Hold the strip by its handle and insert it into a test position.
3. Slide the strip into the section channel.

CAUTION: Make sure the strip is firmly placed by sliding it all the way until you feel the strip lock into the section channel.

4. Open the SPR® block door.
5. Place the SPR® in the SPR® block position directly over the reagent strip.

CAUTION: When placing the SPR® in the SPR® block position, do not apply pressure to the block position as this may cause the SPR to be ejected.

Check the position of SPR®s and reagent strips. The SPR® color-coded dot must match the dot on the reagent strip.

It is very important that all the SPR®s for the assay you want to run are properly placed in the SPR® block and that the dot on top has a hole.

The ***mini VIDAS®* analyzer** cannot detect the type of SPR® used nor the absence or presence of an SPR®.

6. Repeat these steps for other strips and SPR®s to be loaded.
7. Close the SPR® block door and the reagent strip tray cover.

Starting a «Defined» Run

Note: *Sections can be started individually or together.*
The only difference is in defining the user ID. Sections started together will use the same user ID; those started individually can use different user IDs.

Starting Sections Individually

1. Select **Start** in the concerned section screen.

Note: *If two or more user IDs have been defined, the following screen appears.*
If only one user ID was defined, it appears on the assay report.
If no user IDs were defined, no ID appears on the assay report.
See Setting User IDs on page 4-8 for more information.

2. Press the **<Number Key>** for the user ID assigned to this section.

The following message appears:

```
Starting Section
Please wait...
```

The status of the section displays «**Barcode**».

3. Press  to return to the **Main Menu**.

Starting Sections Together

1. Select **Start Section** on the **Main Menu**.
2. Select **All Sections**.

Note: *If two or more user IDs have been defined, the following screen appears.*
If only one user ID was defined, it appears on the assay report.
If no user IDs were defined, no ID appears on the assay report.
See Setting User IDs on page 4-8 for more information.

3. Press the **<Number Key>** for the user ID assigned to this section.

The following message appears:

```
Starting Section
Please wait...
```

The status of the sections displays «**Barcode**».

4. Press  to return to the **Main Menu**.

Unloading Reagent Strips and SPR®s

1. After the assays are completed, remove the SPR®s and reagent strips from the ***mini VIDAS®*** analyzer.
2. Dispose of the used SPR®s and reagent strips into an appropriate receptacle.

IMPORTANT: When unloading the Reagent strips and SPR®s, carefully read the precautions described in Precautions For Use Of Reagents on page 2-11, section «At the End of the Run».

Assigning a Dilution Factor

Note: *Standards/calibrators, controls and qualitative assays should not be diluted.*

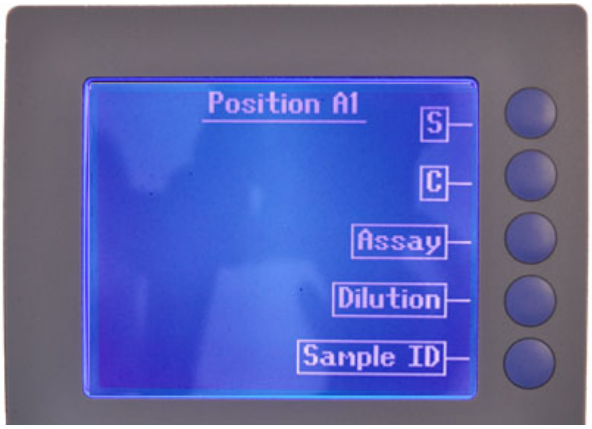
Use this feature to assign a dilution factor to an individual test.

Report printouts indicate when a dilution factor is being used. On this screen, a number will appear in a box next to the section if a dilution factor is used.

A dilution factor can be assigned or changed at any time before the completion of a run.

IMPORTANT: You should perform sample dilution manually using the dilution factor memorized by the mini VIDAS® analyzer.

1. Select **Status Screen** on the **Main Menu**.
2. Select a section.
3. Press the **<Number Key>** for the position to which you want to assign a dilution factor.

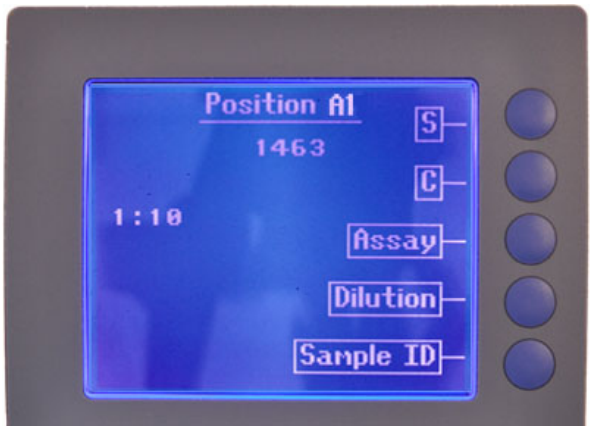


Note: *If the position contains an assay that should not be diluted, the **Dilution** option does not appear on the **Position** screen.*
If you attempt to dilute a standard/calibrator or a control, that designation is removed and the test becomes a normal assay.

4. Select **Dilution**.

5. Enter a dilution factor between 1 and 999.
6. Press  .

   The **Position** screen appears with the new dilution factor displayed.



7. Press  to return to the **Section** screen.
8. Repeat this procedure to assign dilution factors to additional positions in the section.
9. Press  to return to the **Main Menu**.

Running Internal Quality Controls (for Clinic Use Only)

The ***mini VIDAS***® analyzer allows you to run internal quality controls and to send them to a web application where the results will undergo intra- and inter-laboratory statistical processing.

IMPORTANT: Since this function is optional, certain menus will not be displayed if you have not subscribed to this service through bioMérieux.

Only a bioMérieux representative can configure the mini VIDAS® software to run and send internal quality controls.

Internal quality controls can only be performed on quantitative assays.

1. Select **Status screen** from the **Main Menu**.
2. Select a section.
   The selected section screen appears.
3. Select a position.
   The **Position** screen appears.
4. Select the assay for which you want to run an internal quality control.

5. Select **Controls**.

6. Select **QC**.

7. Press the **<Number Key>** for the level of the internal quality control.

8. Enter the lot number of the internal quality control you want to run.

Note: *If an internal quality control with the same level has already been performed for this assay, the software will display the lot number of the last internal quality control that was run for that level.*

9. Press  .
10. Repeat this procedure to define another internal quality control.
11. When all the positions in a section are defined, press the  key to return to the **Section** screen.
12. Start the section.

Note: *To transfer internal quality controls results, refer to* *Validating Internal Quality Controls Transfers (for Clinic Use Only) on page 6-11*.

Viewing Stored Standards/calibrators

Use this procedure to view the standards/calibrators for a particular assay lot.

1. Select **Master Lot Menu** in the **Main Menu**.
2. Select **List Stored Stds**.

   An assay code list appears.
3. Select the assay code.
4. Press  to view additional standards/calibrators (if any) for this assay type.

   A screen appears displaying information on the stored standard/calibrator for the selected assay.
5. Select **Delete** to delete the stored standard/calibrator shown.

   The following prompt appears:

   ```
   Standard will be deleted.
   Are you certain?
   ```
6. Select **Yes** to delete the stored standard/calibrator.
7. Press  to return to the **Master Lot Menu**.

Viewing Master Lot Data

Use this procedure to display the master lot data entered.

1. Select **Master Lot Menu** in the **Main Menu**.
2. Select **List Master Lots**.

   A list of assays appears for which master lot data exists.
3. Select an assay code to display master lot data.

   A screen appears displaying information on the stored master lot data for the selected assay.

Note: *If there is more than one lot that has master lot data, a lot selection screen appears first.*

4. Press any key to return to the Assay Code List.
5. Repeat this procedure to select another assay code for which you want to display Master Lot data.

   or

   Press  to return to the **Main Menu**.

Stopping a Section

CAUTION: You must discard the strips and SPR®s that are in a section that has been stopped.

Use this procedure to stop processing one or more sections.

Note: *The stop option is also available on the first status screen, accessed via the* ***Status Screen*** *selection in the* **Main Menu**. *This stop option is only available while a section is running.*

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Halt Section**.
3. Select one of the sections to stop.

   The following selections appear:

   Halt (clear setup)
   Halt (retain setup)

4. Select the **Halt (clear setup)** option to stop the section and erase the tests defined in the positions. Use this option when the tests will not be run again.

   or

   Select the **Halt (retain setup)** option to stop the section and retain the tests defined in the positions. Use this option when the tests will be run again.

   The **Utility Menu** appears again.

5. Press  twice to return to the **Main Menu**.

6 Results and Reports

The Assay Reports

When the run for a section is completed, the ***mini VIDAS®*** analyzer automatically prints an assay report.

The report is printed on the internal printer or on the optional external printer, depending on how printers are configured.

All assay reports are similar, but not identical. Slight differences occur, depending on the assay type.

Report Header

The figure below shows a sample of a report header that contains information common to all reports.

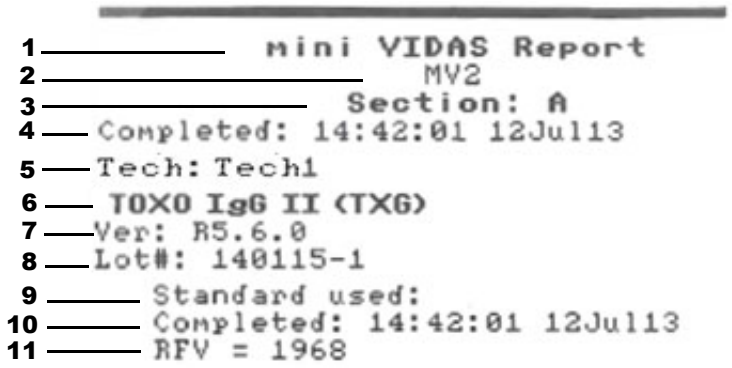


Figure 6-1: Example of a result report header

1 — The report title
2 — The custom report header you can enter in the appropriate configuration option.
3 — The identity of the section, A or B.
4 — Date and time the assay completed.
5 — Technologist ID, from the appropriate configuration option.
6 — Name (and code) of the assay.
7 — Version of the mini VIDAS software (Ver).
8 — Assay kit lot number.
9 — Information on the standard/calibrator used.
10 — Date and time the standard/calibrator was run.
11 — Mean RFV of the standard/calibrator.

Note: *Information concerning the standard/calibrator (lines 9, 10 and 11) do not appear on reports for dual reagent strip Assays.*

Qualitative Assays Results

Results are compared to the threshold provided by the Master Lot data and adjusted by standards during calibration.

The result is either:

- Negative
- Positive
- Equivocal

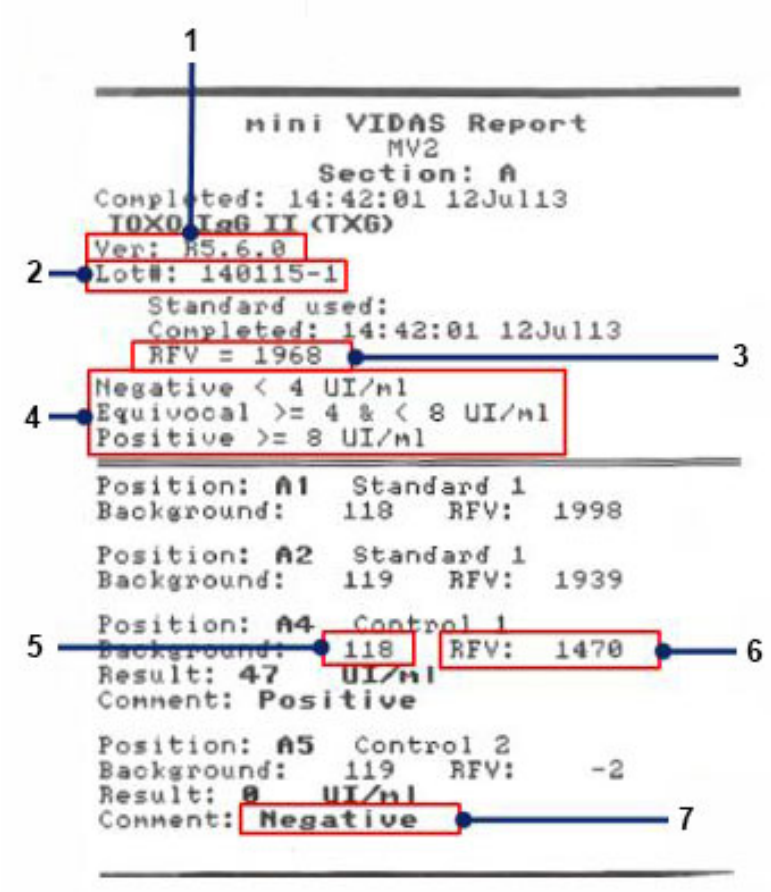
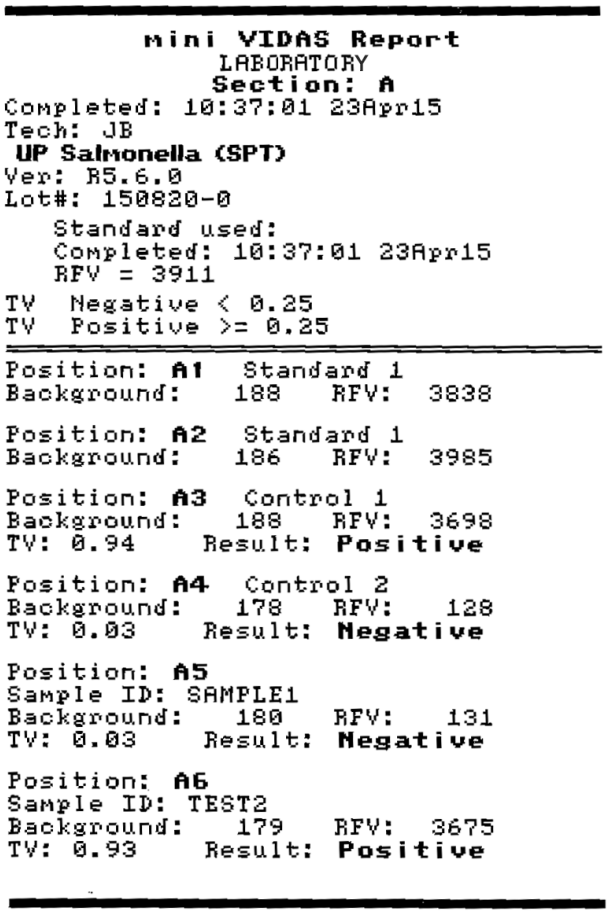


Figure 6-2: Example of a qualitative result report

1 — Software and protocol version
2 — Reagent lot number
3 — Mean of S1 Relative Fluorescence Value
4 — Cut off
5 — Initial strip's Relative Fluorescence Value
6 — Final Relative Fluorescence Value
7 — Interpretation



```
        mini VIDAS Report
             LABORATORY
            Section: A
Completed: 10:37:01 23Apr15
Tech: JB
 UP Salmonella (SPT)
Ver: R5.6.0
Lot#: 150820-0
   Standard used:
   Completed: 10:37:01 23Apr15
   RFV = 3911
TV  Negative < 0.25
TV  Positive >= 0.25
Position: A1  Standard 1
Background:   188   RFV:  3838

Position: A2  Standard 1
Background:   186   RFV:  3985

Position: A3  Control 1
Background:   188   RFV:  3698
TV: 0.94    Result: Positive

Position: A4  Control 2
Background:   178   RFV:   128
TV: 0.03    Result: Negative

Position: A5
Sample ID: SAMPLE1
Background:   180   RFV:   131
TV: 0.03    Result: Negative

Position: A6
Sample ID: TEST2
Background:   179   RFV:  3675
TV: 0.93    Result: Positive
```

Figure 6-3: Example of a qualitative result report

Note: *For dual reagent strip, «Reference» is reported next to the position of the test strip.*

Quantitative Assays Results

Results are compared to the master curve provided by Master Lot data and adjusted by standards/calibrators during calibration.

The result is a concentration given in the chosen unit.

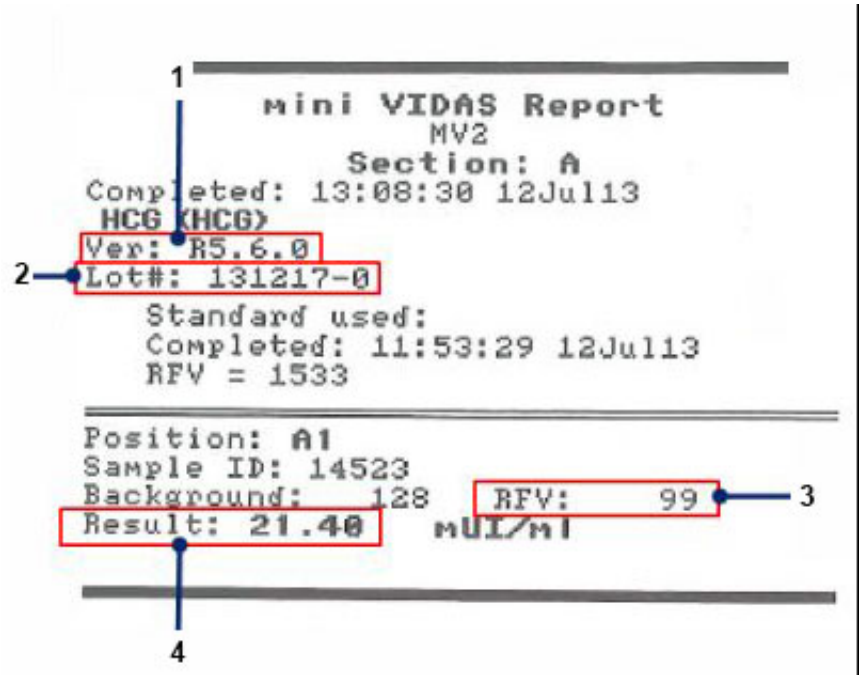


Figure 6-4: Example of a quantitative result report

1 — Software and protocol version
2 — Reagent lot number
3 — Relative Fluorescence Value
4 — Result concentration

Assay Report Errors

The ***mini VIDAS***® assay report is designed to display error messages whenever a result does not conform to the internal requirements that are programmed for each assay.

On the report, any values found to be outside control ranges are noted.

An error message is then printed at the bottom of the report.

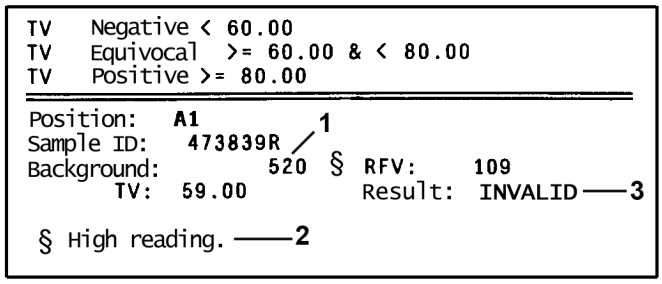


Figure 6-5: Assay report error (example)

1 — Noted value.
Note the "§" symbol next to the value. Different symbols are used for different error messages.

2 — Note and error message.
In this case, the error message is: «High reading»

3 — The test result has been flagged as «INVALID» due to the type of the error.

Note: *See Appendix - Troubleshooting for a listing of the error messages.*

Reprinting an Assay Report

Note: *Only those tests stored in the **mini VIDAS®** analyzer memory are available for reprinting. If the**mini VIDAS®** analyzer is turned off, stored results are no longer available.*

The***mini VIDAS®*** analyzer can store up to 48 results.
For example, all 48 results can be from one section, or they can be divided between the two sections in any combination. The total, however, cannot exceed 48 (6 results x 8 sections).

The storage system works on a «First In, First Out» basis. This means that the results of the last eight sections are the ones that are stored.

When the results of the ninth section are stored, the first results of the first section to be stored are deleted.

Reprinting an Assay Report without Editing Data

1. Select **Results Menu** in the **Main Menu**.
2. Select **Reprint Results**.

3. Select one or more sections to reprint.

Note: *The ☒ symbol appears in the box for the selected section(s).*

4. Press  to print your selection.
   The following prompt appears:

   `Edit the data before reprinting?`

5. Select **No** to reprint the selected section without viewing the assays run before reprinting results.

   The display returns to the **Results Menu**.
   After a few seconds, the results print out.

Editing Data before Reprinting an Assay Report

1. Select **Results Menu** in the **Main Menu**.
2. Select **Reprint Results**.

3. Select one or more sections to reprint.

Note: *The ☒ symbol appears in the box for the selected section(s).*

4. Press to print your selection.

   The following prompt appears:

   `Edit the data before reprinting?`

5. Select **Yes** to view one or more positions in a section before reprinting results.

6. Press a digit, 1 to 6, on the keypad to recalculate the results of this section using a more recent standard.

The following prompt appears:

```
Replace the Standard currently used by this report for this
assay with the most recent stored Standard?
```

7. Select **Yes** to replace the standard/calibrator currently used.

Note: *If you select **No**, the report will print with the standard/calibrator currently used. The screen will then return to the next section for editing.*

The following message appears:

```
Retrieving most recent Standard
Please wait....
```

The screen returns to the **Section** screen for further editing.

Note: *After recalculation, you cannot retrieve the original standard/calibrator.*

8. Press  to edit the next section.

When all sections have been printed, the screen returns to the **Results Menu**.

9. Press  to return to the **Main Menu**.

Validating LIS Results

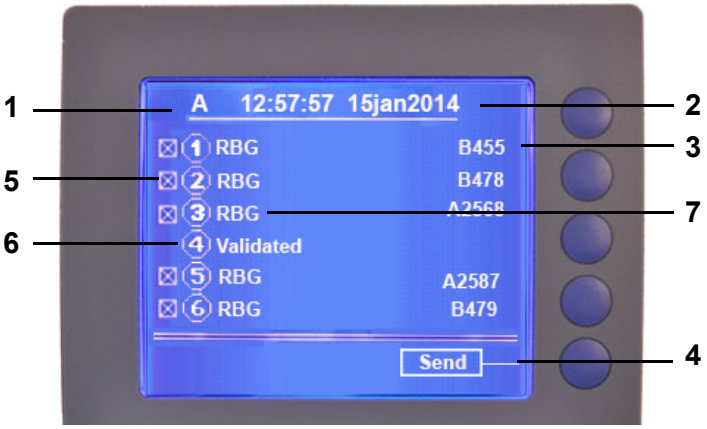
The ***mini VIDAS***® software has a unidirectional interface which allows results to be uploaded to the Laboratory Information System (LIS).

You can access results to be uploaded when the option «**LIS auto validation**» is not activated.

CAUTION: Notes associated with the results are not uploaded to the LIS. They only appear at the bottom of result reports.

Note: *There cannot be more than 8 sections in the LIS validation queue.*
If this queue is full, a warning message will appear when you start additional assays.
The message will warn you that the assay you are about to start will not be placed in the LIS validation queue unless you validate some assay results. However, the results will still be printed.

1. Select **Results Menu** in the **Main Menu**.
2. Select **Validate LIS results**.



1 — Section number
2 — Date / time the results were completed
3 — Sample identifier
4 — Send
A selection option to upload results to the LIS queue.
5 — Check boxes
- When a result is invalid, it is shown on the screen but does not include a check box.
- When the box is checked, the position is validated for LIS upload.
The position will not be validated when there is an expired reagent kit lot, expired calibration standard or a result based on calibration with a single standard.

6 — Position numbers
7 — Assay code
Assay being run in a position.

3. Press the **<Number Key>** for the position to be validated.
4. Select **Send** to upload the results to the LIS.

The screen will display the other results that need to be validated.

5. Repeat this procedure to upload other results to the LIS.

When all the validated results have been uploaded, the screen returns to the **Results Menu**.

Canceling Uploads of Results to the LIS

1. Select **Results Menu** in the **Main Menu**.
2. Select **Validate LIS results**.
3. Press the **<Number Key>** for the position number with the box checked.

   The ☒ will be removed indicating that the test result will not be uploaded to the LIS.

Deleting the Remaining Non-validated LIS Upload Data

1. Select **Results Menu** in the **Main Menu**.
2. Select **Validate LIS results**.
3. Press  .

   The following message appears:

   ```
   Delete the remaining non-validated LIS upload data ?
   Are you certain ?
   ```

4. Select **Yes**.

   The screen returns to the **Results Menu**.
5. Select **No** to cancel deletion.

   The screen will display the other results that need to be validated.

Stopping Validation

1. Select **Results Menu** in the **Main Menu**.
2. Select **Validate LIS results**.
3. Press the **<Number>** key that corresponds to the position to be validated.
4. Press  .

   The following message appears:

   ```
   Validation aborted.
   Current Section's results NOT validated.
   ```

The screen returns to the **Results Menu**.

5. Press  to return to the **Main Menu**.

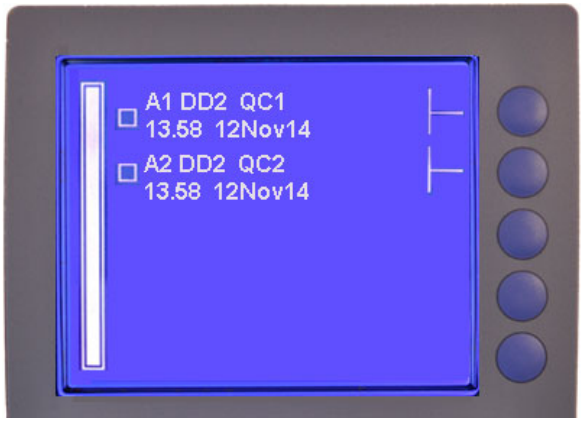
Note: *A result can only be uploaded once (unless the section results are reprinted).*

CAUTION: If you turn OFF the***mini VIDAS®*** **analyzer**, the memory will refresh and results will be lost.

Validating Internal Quality Controls Transfers (for Clinic Use Only)

Internal quality controls can be sent to a Web application where statistical processing will be performed on the results.
See Running Internal Quality Controls (for Clinic Use Only) on page 5-28 for further details.

1. Select **Results Menu** in the **Main Menu**.
2. Select **Validate QC results**.
3. The following screen appears (if the «internal quality controls» function is activated).



4. Select more internal quality controls results to be transferred to the Web based application.

   The ☒ symbol will appear in the box for each selected result.

5. Press  .

To delete the remaining non-transferred results of internal quality controls,

1. Select more internal quality controls results to be deleted.

   The ☒ symbol will appear in the box for each selected result.

2. Press  .
3. Select **Delete**,

   or

   Select **Cancel**.

Note: *If you select **Delete**, a message will display asking you to confirm the deletion. The screen will return to the **Main Menu**. If you select **Cancel**, you will cancel the request and return to the **Results** menu.*

Note: *A result can only be uploaded once (unless the section results are reprinted).*
If results are reprinted, they can also be recalculated.
See Reprinting an Assay Report on page 6-6.

Printing the *mini VIDAS®* Assay List

Use this procedure to print a list of the ***mini VIDAS®*** assays that have Master Lot Data loaded on your ***mini VIDAS®*** analyzer.

The assay list includes the complete name of each assay and its assay code.

Assays in the list are grouped by compatible protocols.

1. Select **Results Menu** in the **Main Menu**.
2. Select **Print Assay List**.

   The following message appears for a moment:

   ```
   Constructing assay list printout.
   Please wait
   ```

   The assay list then begins to print and the display returns to the **Results Menu**.

A portion of an assay list printout appears below.

mini Vidas Assay List

CMVG	(CA)	CMV IgG
TXG	(DH)	TOXO IgG II
TXGA	(DN)	Toxo IgG Avidity
HBST	(G9)	Anti-HBs Total Quick
P24	(DM)	HIV P24 II
FSH	(AR)	FSH
T3	(AN)	T3
ST	(BH)	STALLERGY
HBE	(D6)	HBe Ag
HBET	(AG)	Anti-HBe
HIV4	(DF)	HIV DUO
TES	(DJ)	Testosterone

Figure 6-6: A sample of the assay list printout.

7 Miscellaneous Operations

Taking a Section Off line

An off-line section is not available for running assays. The operating temperature remains the same whether a section is off-line or on-line.

Note: *Use the same procedure to place an off-line section on-line. The section will be available for use immediately after it has been put back on-line.*

1. Select **Utility Menu** in the **Main Menu**.
2. Select **On/Off line**.
3. Select one of the sections to place off-line.

   The display returns to the previous menu.

Note: *You can confirm the off-line status of a section by selecting* **Status Screen** *on the main menu. The first screen shows the status of each section.*

4. Press  to return to the **Utility Menu**.

Changing Factory Settings

CAUTION: Configuration parameters should only be modified by trained and qualified personnel.

Any modification to configuration parameters may lead to problems when the system is used or cause it to operate in an unexpected manner.

Make sure that modifications are necessary and justified.

The factory settings control various physical parameters that affect the keypad and display screen.

All of the factory-set parameters are found on the **Configuration Menu**.

This section contains the procedures needed to change these parameters from the values set by bioMérieux.

Note: *We suggest that you use the* ***mini VIDAS®*** *analyzer for several days before changing any of the settings. Later, if you find that you need to change the settings, you can make the necessary adjustments.*

Testing the *mini VIDAS®* analyzer

There are a number of simple tests that the ***mini VIDAS®*** analyzer can perform.

These tests provide a quick and easy way to verify the display, the keypad, the printer, and the audio output are working properly.

It is not necessary to perform any of these tests on a routine basis.

All of the hardware tests are found on the **Test Menu**.

Testing the Display

The ***mini VIDAS®*** display screen is composed of several hundred individual points called pixels.

The display test darkens all the pixels on the display. It begins with the first vertical column on the left side of the screen, quickly moving towards the right, column by column.

The failure of any pixel to darken can easily be seen.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Functions**.
3. Select **Test Menu**.
4. Select **Display Test**.

   The screen clears initially, and then begins to darken, from left to right, as described above.
5. When the entire screen has darkened, inspect it for pixels that have failed to darken. They appear as “holes” in an otherwise dark screen.
6. Press  to return to the **Test Menu**.

Decrease in the Intensity of Display

The ***mini VIDAS®*** analyzer is equipped with a backlight system which improves the display’s luminosity.

If the intensity decreases considerably or becomes irregular, call bioMérieuxTechnical Assistance or your local bioMérieux representative.

Note: *The intensity of the display does not affect the **mini VIDAS®** analyzer's ability to perform operations.*

Testing the Keypad

This test ensures that every key on the keypad is connected to the ***mini VIDAS®*** analyzer.

The test requires that you press every key on the keypad.

The ***mini VIDAS®*** analyzer responds with a symbol for each key on the display.

The only exception to this pattern is the  key, which activates the help screen.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Functions**.
3. Select **Test Menu**.
4. Select **Keypad Test**.

   The screen clears except for the title:

   ```
   Keypad Test
   ```

5. Press each key on the keypad.

   When you are done, the display should be similar to the **Keypad Test** screen.

Note: *The last key pressed ends the test and returns the display to the **Test Menu**. You will not see that key's symbol on the screen.*

After the last key is pressed, the following message confirms a passed test:

```
Keypad okay
Press any key to continue
```

Note: *If you do not receive this message, contact bioMérieux or your local bioMérieux representative.*

Testing the Printer

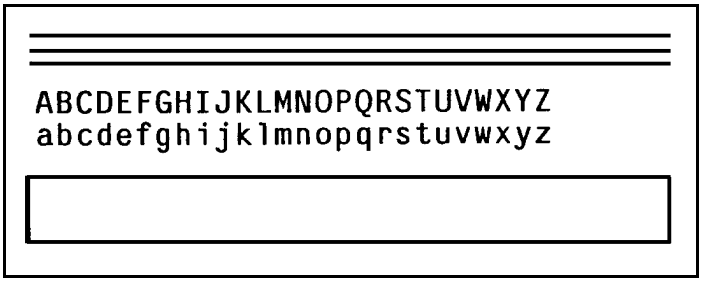
Testing the printer is a matter of sending a string of known characters and ensuring that those characters are printed.

There are two printer tests: one for an internal and one for an external printer.

Before beginning, make sure that the***mini VIDAS®*** analyzer is connected to the external printer and that the cord is properly plugged in.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Functions**.
3. Select **Test Menu**.
4. Select **Printer Test**.

   The printer should immediately begin to print the following test pattern.



Note: *If the printer does not print the test pattern, the printer is not properly connected.*

Testing the audio output

This procedure tests the audio output for the instrument's alarms.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Functions**.
3. Select **Test Menu**.
4. Select **Audio Test**.

   The ***mini VIDAS®*** analyzer should respond with the beep tone.

Note: *The display does not change during this test.*

Updating an Assay

When you update an assay, you can use the complete range of ***VIDAS®*** reagents by updating the ***VIDAS®*** assay protocols.

IMPORTANT: This function enables you to transfer assay data to the mini VIDAS® analyzer when a new assay is used or when an existing assay is updated.

IMPORTANT: The update is stored in the mini VIDAS® analyzer for further use of the assays.

CAUTION: If your ***mini VIDAS®*** analyzer is connected to an LIS, please contact your computer service company to check that the new assay version is consistent with your LIS.

Preliminary Instructions

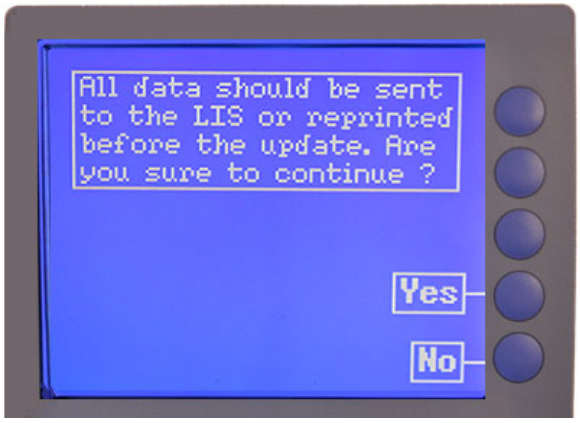
Before performing the update, make sure that:

- no assays are running,
- no reagents (strips and SPR®s) remain in the strip sections and SPR® blocks,
- printing is not in progress,
- results have been printed or sent to the LIS, if applicable (see Reprinting an Assay Report and Validating LIS Results for further information).
- the bar code reader provided for this update has been installed and configured.
  If not, see Appendix - Installing external hardware .
- the PTC bar codes on the reagent kit package insert must be in good conditions.
  To be readable the bar code must be complete, free of stains or tears.
  If the bar codes are stained or torn, contact bioMérieux or your local bioMérieux representative.

Note: *If PTC bar codes have to be printed (after downloading them from the bioMérieux technical library), do not change their size and contrast. Changing size and contrast can affect the quality of the printed bar code and subsequently, the ability of the bar code to be read by the bar code reader.*

Reading Assay Update Card Bar codes

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Assay Update**.



3. Select **No** if the data has to be sent to the LIS or reprinted.
   Follow the instructions for sending or printing data before the update (see Reprinting an Assay Report and Validating LIS Results for further information).

or

Select **Yes**.

The following message appears:

Please wait...

The assay update card bar code screen is displayed:

1 — Assay Update: describes the status of the current reading.
2 — Reading instructions: follow these instructions as they appear during the update procedure.

To read a bar code:

4. Take the page in the package insert that includes the bar codes (back of the package insert) or the printed bar codes (downloaded from the technical library).

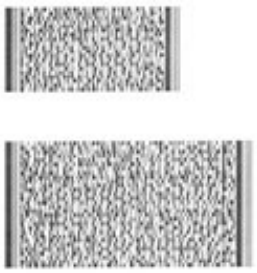


Figure 7-1: Example of a bar code

5. Read the first bar code using the bar code reader.

Note: *Older bar code readers may require that you slowly scan the bar code from top to bottom or bottom to top until the code has been read completely.*

The reader beeps when the reading is finished.

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

The following message is displayed on the screen:

Please wait…

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

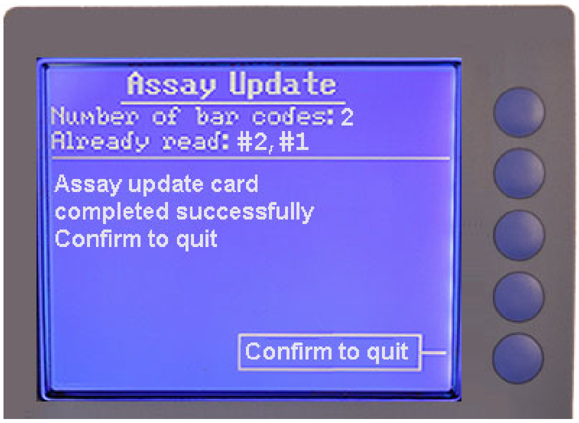
The reading screen is updated.

1 — Total number of bar codes to be read.
2 — Number of the code already read.
The codes may not necessarily be read in numerical order.

7. Read the second bar code using the bar code reader.
8. Wait for a few moments to allow transfer of the data.
9. If necessary, repeat the reading and waiting steps until all the codes required to update the protocol have been read.

Note: *The number of bar codes to be read for the update depends on the protocol.*

When reading is complete, a summary of the update status is displayed on the screen.



10. Select **Confirm to quit** to validate the update.

    The following message appears:

    `Please wait...`

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

    The **Utility Menu** is displayed. The update is complete.

12. Press  to return to the **Main Menu**.

    An assay update report is printed.

Assay Update Report
Completed : 10:59 12-12-19

Short assay name : HAC5
Unique assay code : 20
Full name :
HEMOGLOBIN A1C
Assay version : 0
Update card version : 1
Units :
1. nmol/l (1.00)
2. ng/ml (0.65)
3. ug/l (0.65)
4. ug/100ml (0.07)
Verify default units for this assay
Low detection limit : 2.50
High detection limit : 60.00

Warning : Please keep this report.
Inform your LIS Administrator
about the reported data

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 bar code reading fails, a warning message is displayed.

1. Solve the problems described in the message.
2. Repeat the bar code reading.

Displaying the *mini VIDAS*® Software Version

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Function**.
3. Select **Version Menu**.
4. Select **Show Software Version**.

   The software version screen displays.
5. Press any key on the keypad to return to the Version Menu.
6. Press  to return to the **Main Menu**.

Printing the *mini VIDAS*® Software Version

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Function**.
3. Select **Version Menu**.
4. Select **Print Software Version**.

   The Software version begins to print and the display returns to the Version Menu.
5. Press  to return to the **Main Menu**.

Displaying the Assay Version

Use this procedure to display the Assay version for the selected assay.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Function**.
3. Select **Version Menu**.
4. Select **Show Assay Version**.

   An assay selection list appears:
5. Select an assay.

Note: *An intermediate screen appears for assays that have more than one version; the version used is represented in the first two characters of the strip's bar code.*

6. Press any key to return to the assay selection list.
7. Repeat this procedure to display additional assays.

   or

   Press  to return to the **Main Menu**.

Section Counters

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Function**.
3. Select **Section Counters**.
4. Select a section.

   A screen appears showing the 2 counters.

1 — [C1]: The number of job lists run in this section since the ***mini VIDAS***® analyzer was installed.

2 — [C2]: The number of job lists run in this section since the last reset performed by a bioMérieux representative.

3 — Date of the last reset.

IMPORTANT: Only bioMérieux personnel or a qualified person trained by bioMérieux can perform the reset operation.

Printing the Assay Version

Use this procedure to print the list of assays and their respective versions.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Function**.
3. Select **Version Menu**.
4. Select **Print Assay Version**.

   The following message appears:

   ```
   Preparing report
   Please wait...
   ```

The assay list then begins to print and the display returns to the **Version Menu**.

5. Press  to return to the **Main Menu**.

Updating the *mini VIDAS®* Software

Updates are sent to you by bioMérieux on memory cards. An update procedure will also be provided if the ***mini VIDAS®*** software needs to be updated by the customer.

IMPORTANT: The update process saves all database contents, including previous protocols data loaded with updated PTC features. Valid calibrations and controls are not impacted by the update.

Before performing the update, 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,
- results have been printed or sent to the LIS, if applicable (see Reprinting an Assay Report and Validating LIS Results for further information).
- the bar code reader provided for this update has been installed and configured. If not, see Appendix - Installing external hardware .

To update the ***mini VIDAS®*** software:

1. Shut down the ***mini VIDAS®*** analyzer (see “Shutting Down the System” on page 4-4).
2. Place the memory card in the slot on the back of the instrument, in the direction indicated by the arrow, with the label towards the outside.

Figure 7-2: ***mini VIDAS®*** analyzer back panel

Note: *The memory card is placed in the slot with the end containing the two rows of connector holes inserted first.*

3. Apply gentle pressure on the center of the card to place it.

Note: *The eject button, located below the slot, pops up when the card is properly seated. The card itself is keyed so that it can be placed properly.*

4. Switch on the ***mini VIDAS®*** analyzer (see “Starting the System” on page 4-3).
5. Follow the instructions of the update procedure provided with the memory card.

Verifying the Memory Card Data

Use this procedure to verify the data on the memory card that is installed in the memory card slot on the back of the ***mini VIDAS®*** analyzer.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Card Info.**

   The following message appears:

   ```
   Scanning card
   Please wait...
   ```

   After the ***mini VIDAS®*** analyzer reads the card, a screen containing the card data appears.
3. Press any key to return to the **Utility Menu**.

Parking the*mini VIDAS®* analyzer

CAUTION: Follow this procedure very carefully to avoid causing any damage to the extremely fragile electrical components and the optical parts of the instrument.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **Misc. Functions**.
3. Select **Park system**.

   The following message appears:

   ```
   Parking disables the instrument.
   Are you certain?
   ```

   The prompt is accompanied by `[Yes]` and `[No]` selections.
4. Select **Yes** to park the***mini VIDAS®*** analyzer.

Note: *From this point, the parking process cannot be interrupted.*

The following occurs:

- The scan head moves inside the instrument. It is being placed in its parked position.
- Other parts of the ***mini VIDAS®*** analyzer are placed in their parked positions.
- The two reagent strip trays are retracted into the instrument.

When the ***mini VIDAS®*** analyzer is fully parked, the status lights on each section blink.

5. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4).

8 Maintenance

Maintenance of the ***mini VIDAS***® analyzer comprises:

- the preventive maintenance operations performed by bioMérieux technicians or a qualified person trained by bioMérieux,
- the routine maintenance operations which should be performed by the user.

Preventive Maintenance

IMPORTANT: Optimum performance of the mini VIDAS® analyzer (within the limits of bioMérieux specifications) depends on the preventive maintenance being performed by bioMérieux technicians or a qualified person trained by bioMérieux only, as part of a maintenance contract.

For servicing information, contact bioMérieux or your local distributor (contact information available on www.biomerieux.com).

User Maintenance

Required Tools

The basic equipment and products required are:

- Disposable powderless gloves (latex-type)
- Dacron® swabs (Part no. 30531)
- Cleaning & disinfection wipes
- Laboratory cleaning and disinfection solution
- Quality Control ***VIDAS***® (QCV) pipette mechanism test (Part no. 30706).
- ***VIDAS***® Lens Cleaner (Part no. 93567)

WARNING

Cleaning and disinfection solution and wipes should be provided by your local suppliers.
The cleaning and disinfection solution can be identical to the one used in the wipes (same active principle).

Solutions concentrations must be LOWER than or EQUAL to:

- **70% for ethanol**
- **70% for isopropanol**
- **0.05 M for NaOH**

Cleaning and Disinfection Procedures

Cleaning and disinfection involve:

- Routine cleaning which should be performed on a periodic basis.
- Cleaning of accidental spills (accidental contamination), which should be dealt with immediately.

CAUTION: Turn the ***mini VIDAS®*** analyzer power switch to OFF and then disconnect the power cord (see Starting the System on page 4-3).

This operation must be performed once all assays are completed.

Use powderless disposable gloves.

Do not allow disinfectant solution to spill into the instrument.

CAUTION: It is the responsibility of the user to clean and disinfect the ***mini VIDAS®*** analyzer.

The instrument must always be thoroughly cleaned and disinfected before servicing by a bioMérieux Service Engineer.

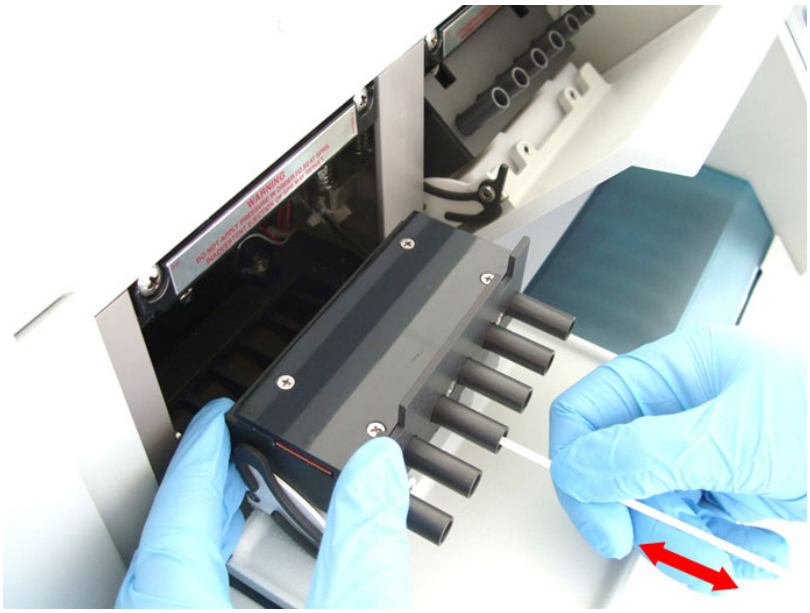
Complete decontamination of the instrument involves all cleaning tasks described in the Maintenance Schedule.

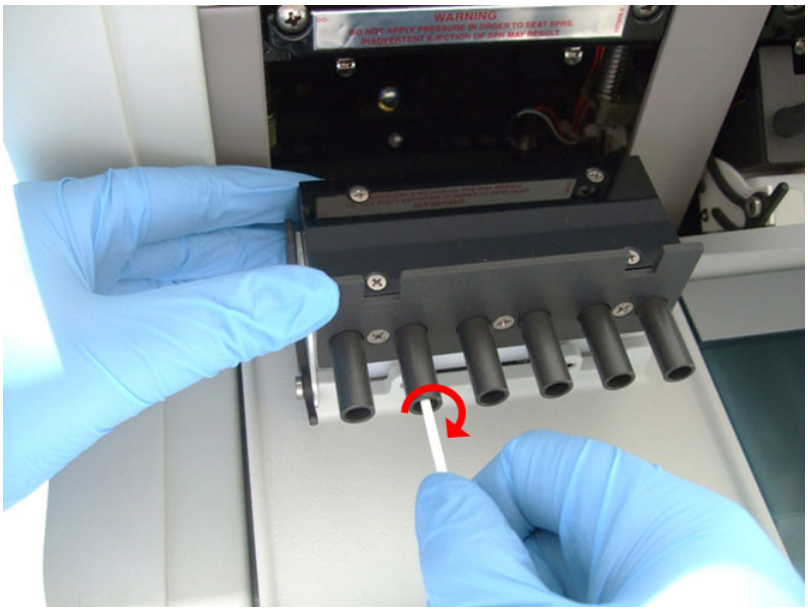
Cleaning the SPR® block (Monthly)

1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4).

2. Open the SPR® block door slightly.
3. Tilt the safety latch located on the left side and then fully open the SPR® block door.

Note: *Previous versions of the* ***mini VIDAS®*** *analyzer have no safety latch. For these versions, you can directly open the* SPR® *block door*





4. Using a Dacron® swab moistened with a laboratory cleaning and disinfection solution, carefully clean the interior of each SPR® liner of the first SPR® block.
5. Continue the operation by using a new Dacron® swab moistened with the cleaning and disinfection solution for each SPR® block.

Note: *Laboratory cleaning and disinfection solution can be identical to the one used in the wipes (same active principle).*

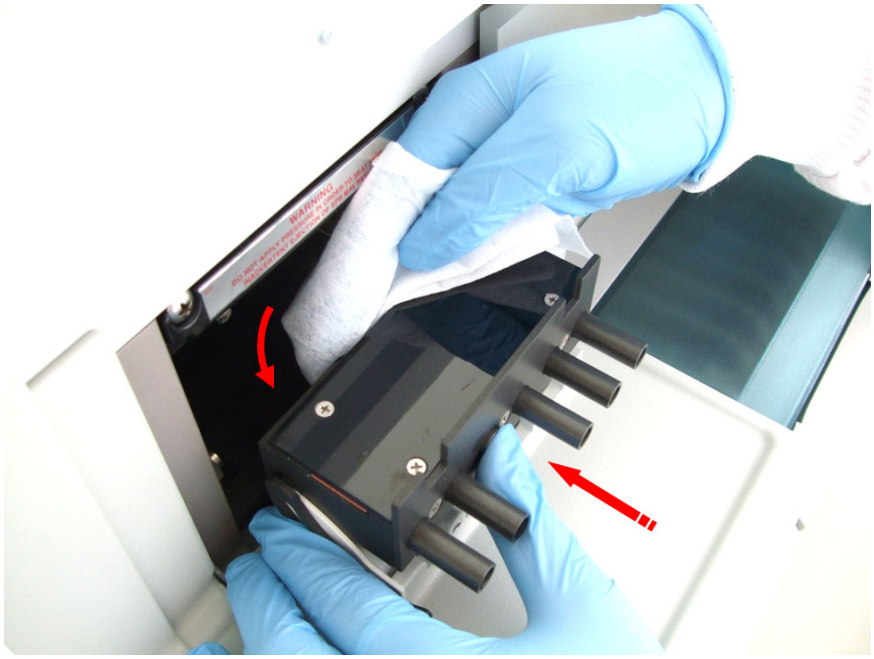
IMPORTANT: The presence of fibers from the Dacron® swab inside the SPR® liners may interfere with the performance of the mini VIDAS® analyzer.
When cleaning the SPR® liners, replace any swab if it becomes fluffy.

6. Clean all surfaces of the SPR® block by using the cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

CAUTION: Do not clean the seals situated above the SPR® block as they only require cleaning when preventive maintenance is performed by the bioMérieux Field Service Engineer.

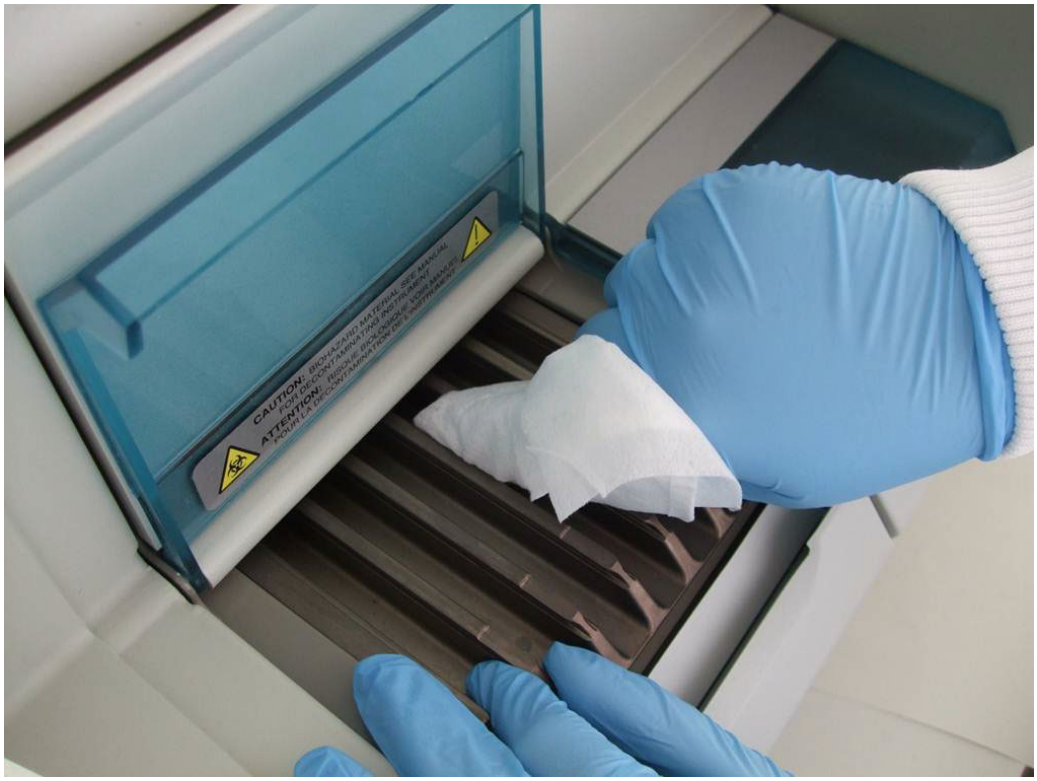
In the event of accidental spills or contamination, it is imperative that you contact bioMérieux or your bioMérieux representative.
Handling of the seals may affect the performance of your instrument.



7. Press each SPR® liner until you are able to clean its rear end.
8. Repeat this procedure for each SPR® liner of each block.
9. If no other maintenance tasks have to be performed, start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).

Cleaning the Reagent Strip Trays (Every 6 Months or if Needed)

1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4.).
2. Open the section tray dust cover (Plexiglas).



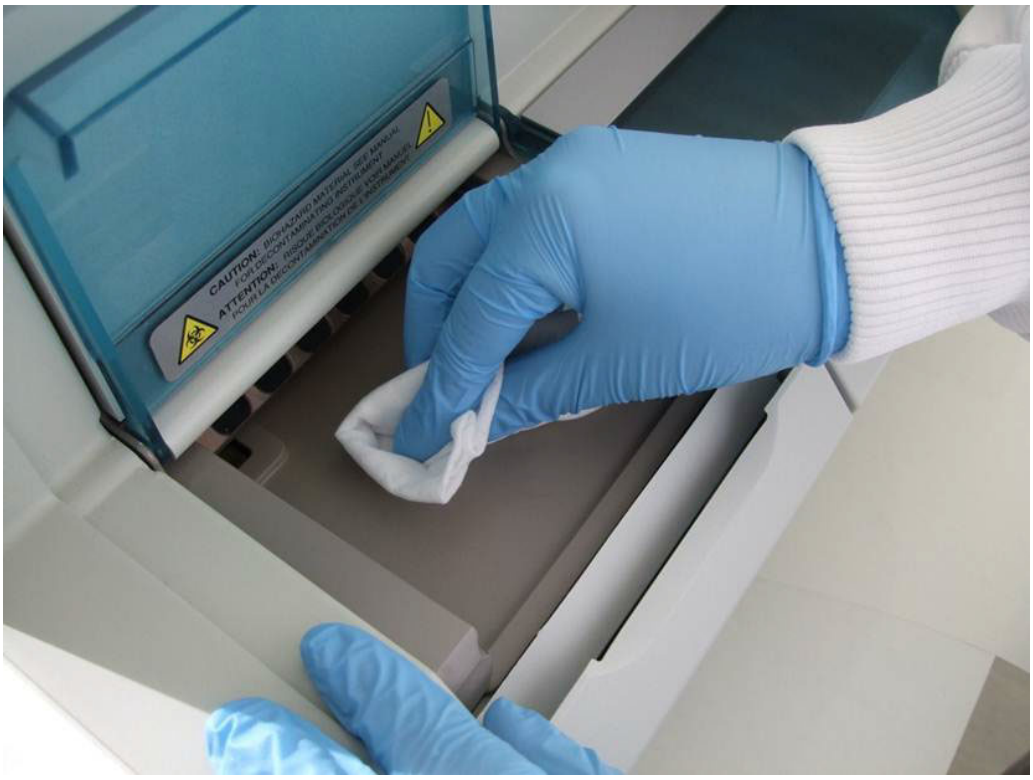
3. Clean the strip slots with the cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

4. If no other maintenance tasks have to be performed, start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).

Cleaning the Plastic Trays (Every 6 Months or if Needed)

1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4.).
2. Open the section tray dust cover (Plexiglas).
3. Move the strip tray in order to have access to the plastic tray.



4. Clean the plastic tray with cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

5. If no other maintenance tasks have to be performed, start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).

   The strip tray will move back into place automatically.

Cleaning the Strip Preparation Trays (Every 6 Months or if Needed)

Note: *Previous versions of the **mini VIDAS®** analyzer may not have a strip preparation tray.*

1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4.).
2. Open the strip preparation bay.

3. Clean the strip preparation tray with cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

4. If no other maintenance tasks have to be performed, start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).

Cleaning the Outer Covers of the Instrument (Every 6 Months or if Needed)

1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4.).
2. Wipe all surfaces with cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

3. If no other maintenance tasks have to be performed, start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).

Cleaning the Screen and Keypad (Every 6 Months or if Needed)

1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4.).
2. Wipe the screen and the keypad with cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

3. If no other maintenance tasks have to be performed, start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).

Cleaning the Bar Code Reader (Every 6 Months or if Needed)

1. Wipe the bar code reader (except the window) with cleaning and disinfection wipes.

Note: *Wipe all surfaces thoroughly with the wipe, ensure complete wetting and allow to take effect.*

2. Clean the reader window with a soft cloth.

Cleaning Optical Lenses (Monthly)

It is recommended to perform the following procedure to ensure the cleanliness of the scanner and prevent optical self-test errors and self-calibration drifts.

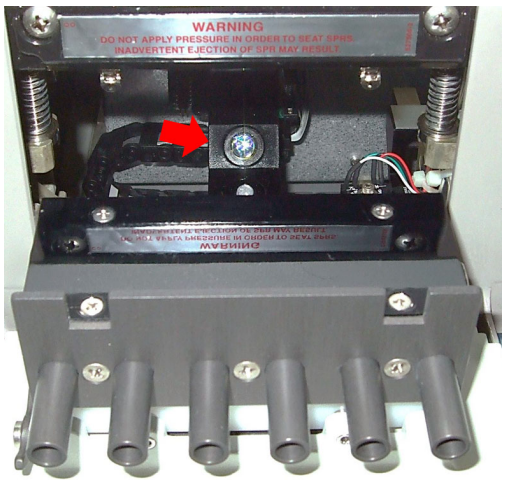
IMPORTANT: The VIDAS® Lens Cleaner is intended for cleaning the optical lenses of the mini VIDAS® analyzers.

- ***Turn the power switch to OFF before cleaning the optical lenses.***
- ***Before each use: Take the VIDAS® Lens Cleaner out of its package and squeeze the rubber ball hard two or three times in order to remove any moisture inside.***
- ***During cleaning: Avoid touching the lenses with the extremity of the tool as it could damage them.***
- ***After each use: Put the VIDAS® Lens Cleaner back into its package and store it in a dry place.***
- ***In case of accidental spills on the VIDAS® Lens Cleaner, clean the tool with a dry clean cloth.***
- ***If any substance is accidentally introduced inside the VIDAS® Lens Cleaner, replace the tool.***

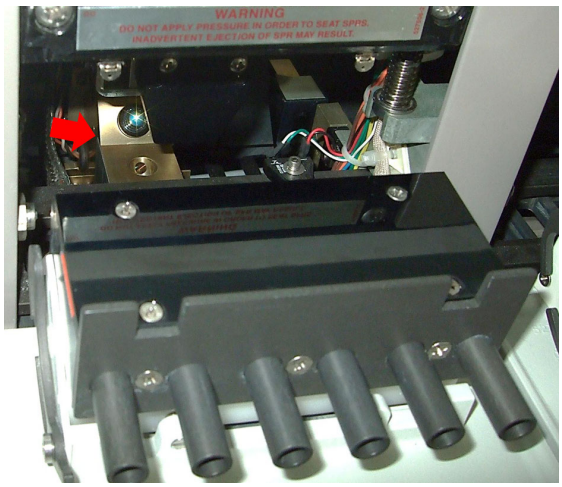
1. Open the SPR® block doors of sections A and B.

   The Scanner head should be visible (see figures below) either in section A or section B.

There are two scanner head models (see Figure 8-1).



Model A

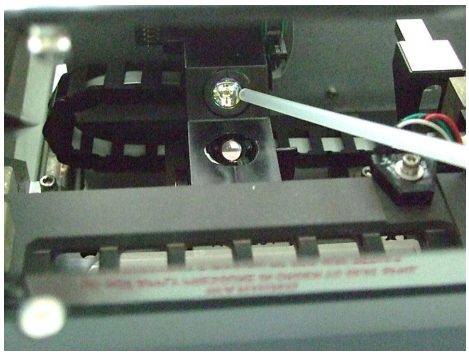


Model B

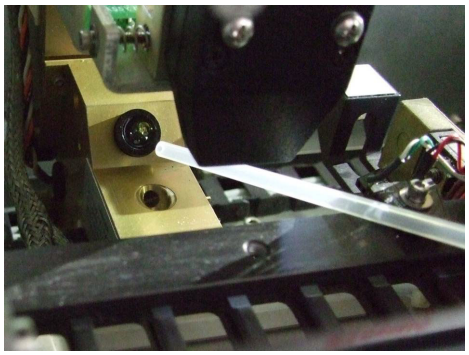
Figure 8-1: Scanner models

2. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4.).

3. Position the ***VIDAS***® Lens Cleaner above the lens.
4. Clean the upper lens *(tilted surface)*: squeeze the rubber ball hard ten times.



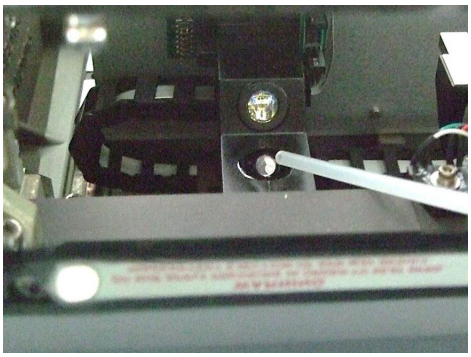
Model A



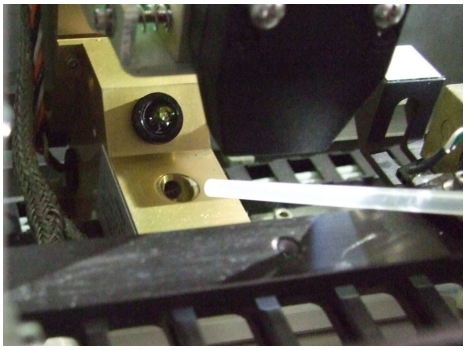
Model B

Figure 8-2: Cleaning the upper lens

5. Clean the lower lens (*horizontal surface*) by squeezing the rubber ball ten times.



Model A



Model B

Figure 8-3: Cleaning the lower lens.

6. Close the SPR® block doors.
7. Start the ***mini VIDAS***® analyzer (see Starting the System on page 4-3).

Checking the Pipetting System (Monthly)

CAUTION: Quality Control ***VIDAS***® (QCV) must be run on all the ***mini VIDAS***® analyzer positions at least once a month or anytime that a pipetting problem is suspected.

The Quality Control ***VIDAS***® (QCV) allows to check pipette mechanisms of the section pumps. Follow the instructions in the ***VIDAS***® QCV package insert.

To analyze the results, refer to the «Results interpretation» section in the ***VIDAS***® QCV package insert.

Calibration and Adjustments

Optical System

The ***mini VIDAS®*** analyzer optical system measures the concentration of the reaction product developed during an assay with a single channel fluorometer.

This optical system uses a dual beam excitation system to compensate for variations in the lamp output.

The optical system can be moved across the instrument to read the desired test position. The reagent then produces a fluorescence signal proportional to its concentration.

Manual Optics Calibration

Instrument calibration is provided using a standard calibration solution in a ***VIDAS®*** strip prepared by bioMérieux. These calibration strips are checked by QC/QA and values are assigned to the strip [approximately a 3,200 RFU reading with an 8,000 nM solution of 4-methylumbelliferone (4-MU) in a buffer.

Instrument calibration should be checked every 12 months by bioMérieux Technical Assistance.

Self Diagnostics

Internal self diagnostics of the optics include computations that monitor the CVs of the readings and will issue warning messages if wide ranges of data within the readings of a cuvette is detected.

The computer also periodically takes readings on the surrounding environment and issues a message if the air readings fall out of expected bounds.

Self-calibration

To further verify the performance of the optical system, the ***mini VIDAS®*** analyzer also uses the optical reference to detect instrument problems before they have an opportunity to impact the results of an assay.

The ***mini VIDAS®*** analyzer incorporates a fluorescent europium material embedded in an optically transparent polymer as a fluorescence optical reference.

This reference allows the ***mini VIDAS®*** analyzer to monitor the condition of the entire optical system for changes that could result in optical drift.

The long life reference material is placed in a standard ***VIDAS®*** cuvette mounted internal to the instrument and placed between bays A and B.

The optical system periodically measures the reference and the results are closely monitored by the ***mini VIDAS®*** analyzer to insure there is minimal optical drift between calibrations.

The instrument is calibrated at the appropriate service intervals by the service technician using a standardized solution of 4 MU in a buffer. Once the instrument is properly calibrated, the technician instructs the ***mini VIDAS®*** analyzer to measure the built-in reference standard.

The value of this reading is stored by the ***mini VIDAS®*** analyzer and becomes a reference point for future calibration checks.The internal reference is recalibrated every time the instrument is recalibrated.

In normal operation, the ***mini VIDAS®*** analyzer periodically measures the reference during an idle period and compares the result to the one stored when the instrument was calibrated.

- If the result is outside of the internal adjustment range, the ***mini VIDAS®*** analyzer automaticaily readjusts the optical system to bring the result back within the expected range.
  Moderate drift in the optical system is detected and reported in an error message (error 160).
  Unless the error occurs while your analytical module is warming up, clean the optical lenses (see Cleaning Optical Lenses (Monthly) on page 8-11).
  If the problem persists, contact bioMérieux or your local bioMérieux representative.
- If calibration from one reference check to the next is more than ± 3%, a warning message is issued to alert the operator to the calibration adjustment and to contact bioMérieux or your local bioMérieux representative.
  Significant optical drift since the last calibration is detected and reported as an instrument error.

Pipetting System

The ***mini VIDAS***® analyzer handles reagents via two six-pipettor channels (1 per section), which carry out all reagent transfers, dilution and washing by means of the SPR®s.

The pipettors can accommodate liquid volumes. The entire module can move up and down, allowing the SPR®s to access wells in the reagent strip. The six pipettor channels are physically independent, but mechanically linked to act in unison.

Fluids move in and out of each SPR® channel by using an air displacement piston.

Pipetting volume and the speed at which fluids are moved into or out of the SPR® are microprocessor controlled and programmable via protocol commands. A linear stepper motor is used to product the precise linear motion required by the module.

Calibration and self diagnostics

The volume accuracy of the fluid displacement is controlled by precision machining of the critical geometries in the pipettor at the time of manufacture. Field calibration of the pipettor assembly is not required. Manufacturing verification of pump accuracy is done prior to shipment.

When running an assay, optical sensors and the microprocessor monitor the linear motion in the pipetting system. If a deviation in the expected linear displacement occurs, the assay is automatically stopped and an error message is issued via the computer to the operator.

Field checks of the pipettor accuracy may be accomplished by using bioMérieux controls. SeeChecking the Pipetting System (Monthly) on page 8-12.

Temperature Validation

The temperature of each tray and SPR® block in the ***mini VIDAS***® analyzer is independently controlled and monitored.

Each tray and SPR® block contains a highly accurate and stable temperature sensing device called a thermistor. The thermistors used in the ***mini VIDAS***® analyzer are 0.2°C accurate.

Self diagnostics

The software controlling the instrument runs an algorithm which measures the temperature at each thermistor every 60 seconds.

This algorithm checks these temperatures and verifies the temperature across all SPR® blocks within an instrument as well as the temperature across all trays within the instrument.

In addition to these consistency measurements, an absolute measurement comparison is made to insure that the temperature at any thermistor is also within specified range.

If any of these checks fails, the instrument will report an error to the user and the assay being run on this section will be aborted. No other assays can be run until the condition is resolved.

Master Curve Establishment and Calibration

Establishing the master curve (performed at the manufacturer)

The master curve is established at the time of manufacture for each lot of reagents. It establishes the mathematical relationship of RFV versus concentration and is provided with each kit.

Well defined reference solutions (standards) are used to make this determination.

Each assay is associated with a particular mathematical model based on the fundamental properties of that assay.

To determine the master curve, the standards/calibrators are tested in seven different runs on the same ***mini VIDAS®*** analyzer.

The mean curve of these seven runs becomes the master curve. Four points from the master curve, which uniquely and completely specify the curve, become the master curve data. These data are specific for a certain manufacturing lot and are encoded in bar codes (Master Lot Data) provided with each kit.

Establishing the Calibration Curve (performed by the customer)

The customer defines a curve specific to a particular ***mini VIDAS®*** analyzer by recalibrating the master curve using the standard/calibrator provided in the kit.

Each laboratory must establish its own Calibration Curve.

This function is called recalibration and is based on the mathematical master curve data and the test results of one or two standards/calibrators tested in duplicate or triplicate by the customer.

Recalibration serves to control for minor variations in assay signal from one ***mini VIDAS®*** analyzer to another and is therefore specific for each instrument.

On receipt of a new lot of reagents, the customer must enter the master curve data. It may be entered by a bar code scanner or manual entry of the codes. The customer runs the standard(s)/calibrator(s) in duplicate or triplicate to define the instrument-specific calibration curve.

The calibration curve is valid for an extended period of time specified for each assay (14 or 28 days, depending on the type of assay). After this time, the software requires another calibration.

This recalibration over time accommodates minor variations in assay signal throughout the shelf-life of the kit.

The calibration curve is valid for analyte concentrations between zero and the standard/ calibrator (from the master curve data) with the highest concentration.

If the RFV is higher or lower (depending on the type of assay) than the signal of this highest standard/calibrator, the message "greater than the concentration of (assay dependent standard)" is given.

A Appendix - Maintenance Records

Maintenance Schedule

Part	Frequency	Procedure
SPR® block	Monthly	Cleaning the SPR® block (Monthly)
Reagent strip tray	Every 6 months or if needed	Cleaning the Strip Preparation Trays (Every 6 Months or if Needed)
Plastic tray (underneath the reagent strip tray)	Every 6 months or if needed	Cleaning the Plastic Trays (Every 6 Months or if Needed)
Strip preparation tray	Every 6 months or if needed	Cleaning the Strip Preparation Trays (Every 6 Months or if Needed)
Outer covers	Every 6 months or if needed	Cleaning the Outer Covers of the Instrument (Every 6 Months or if Needed)
Screen and keypad	Every 6 months or if needed	Cleaning the Screen and Keypad (Every 6 Months or if Needed)
Bar code reader	Every 6 months or if needed	Cleaning the Bar Code Reader (Every 6 Months or if Needed)
Optical lenses	Monthly	Cleaning Optical Lenses (Monthly)
Pipetting device	Monthly	Checking the Pipetting System (Monthly)

Maintenance Check-List

YEAR:

	Month	1	2	3	4	5	6	7	8	9	10	11	12
	Frequency												
	M												
	6M/N												
	6M/N												
	6M/N												
	6M/N												

	Month	1	2	3	4	5	6	7	8	9	10	11	12
	**6M/N**												
	**6M/N**												
Cleaning Optical lenses (using ***VIDAS***® Lens Cleaner)	**M**												
Checking the Pipetting System (using ***VIDAS***® QCV)	**M**												

Frequency **M** = Monthly **6M** = Every 6 months **N** = if needed

Complete with your initials  Keep the preventive maintenance charts.

B Appendix - Troubleshooting

Indication Of Errors

The ***mini VIDAS***® analyzer has several ways to indicate errors: an alarm (a beep) and an optional visual cue (the display blinks).
Both can be configured.

- Error beep.
  You can set the volume of the beep the ***mini VIDAS***® analyzer emits when there is an error. There are configuration options to set an initial volume and a final volume.
  The initial volume is the volume used when the beep begins.
  The volume then increases until you respond, or until it reaches the final volume.
  Both volumes can be set to the same level so that there is no increase in loudness.
- Blinking display.
  There is a configuration option in which you can enable or disable a display blink to accompany the error beep.

See System Installation and Configuration in Chapter 4 for procedures to set these configuration options.

Displaying Errors

When the ***mini VIDAS***® analyzer alerts you to the presence of an error condition,

1. Press ? to respond.

   This stops the beeping and blinking display.

   Whatever was being displayed when you pressed ? is replaced by an error message screen.

The format of the message screen depends on the type of error.

There are two basic types of error message screens.

- Start error message screen: a start error occurs during the initial processing of a run of reagent strips.
- Other type of error message screens: it consists of an error code number and the error message itself.

Error Messages and Recovery Procedures

This section lists the possible error messages and general problems that could occur when using the system.

Start Errors

A start error can occur when you start a section during the verification phase.

The ***mini VIDAS***® analyzer reads the bar code on the label of each reagent strip and performs an optical check of the substrate. If one of these checks fails, a start error message will appear.

Depending on the selections you made in the **Configuration Menu**:

- The ***mini VIDAS***® analyzer beeps.
- The display blinks.
- The error message is printed.

Start errors cause the ***mini VIDAS***® analyzer to stop the run in the section containing the error. The other section is not affected by any of this action.

1. Press ? to display the error message screen.

   An error screen appears.

The screen displays the status of each position in the section that has the error.

2. Solve the anomalies if needed (See the Problem Resolution table on page B-3).
3. Press ☰ from the error message screen.

   The following selections are displayed:

   Restart
   Cancel

4. Select **Cancel** to abort the run.

or

5. Select **Restart** to restart the run.

Note: *If you select* **Cancel**, *the* ***mini VIDAS®*** *analyzer returns to the state it was in before the run was started.*
Any data you entered about the assays are retained.
If you select **Cancel**, *the run resets and begins with another bar code reading and substrate check.*

Table B-1: Problem Resolution

Error Message / Problem	Cause	Resolution
`Bad Barcode`	The ***mini VIDAS®*** analyzer was unable to read the bar code on the reagent strip.	1. Enter the strip bar code manually. See Manually Entering Bar codes on page B-5.
`Expired lot`	The ***VIDAS®*** reagent lot has expired. If you run the assay, a message will appear on your result sheet indicating that the assay was performed using an expired lot.	1. Use a new reagent kit.
`Incompatible`	The assay in this position is not compatible with other assays in the section. This type of error should only occur in a Load and Go run. In a defined run, the ***mini VIDAS®*** analyzer would detect incompatible assays before they were run.	1. Run the reagent strip in the other section or in a different run. 2. Check for assay compatibility (see Checking Assay Compatibility on page 5-2).
`Misaligned`	A dual reagent strip has been placed in the wrong positions. This type of error should only occur in a Load and Go run. In a defined run, the ***mini VIDAS®*** analyzer would detect a misaligned dual reagent strip.	1. Move the strip so that it occupies an acceptable pair of positions: 1 & 2, 3 & 4, 5 & 6.
`Sub.(XX)`	The initial substrate fluorescence reading is not acceptable. `XX` corresponds to the fluorescence value read.	1. Make sure the optical cuvette on the reagent strip is clean. 2. Change the reagent strip and start again.
`Wrong type`	The type of assay specified for this position is different to the one found by the ***mini VIDAS®*** analyzer. This type of error should only occur in a defined run.	1. Put the reagent strips in their proper positions or correct the test entries.
`No strip`	An assay was specified for this position but no reagent strip was found. This type of error should only occur in a defined run.	1. Place a reagent strip in the appropriate position or delete the entry for that position.

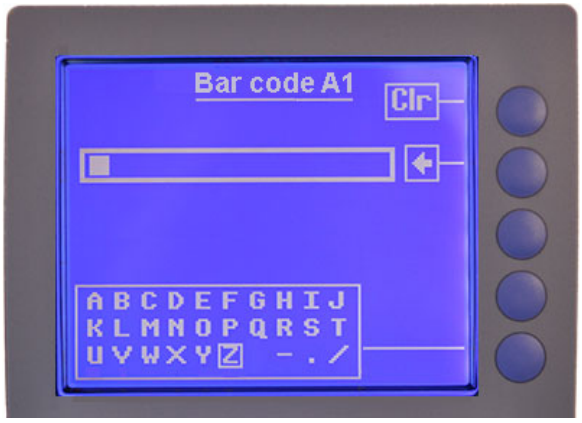
Table B-1: Problem Resolution

Error Message / Problem	Cause	Resolution
Unknown Assay	There is no protocol stored in the ***mini VIDAS®*** analyzer for the assay type. This type of error should only occur in a Load and Go run.	1. Stop and update the PTC of the assay of the corresponding position.
Not Empty	The position is supposed to be empty, yet a test is detected.	1. Remove the reagent strip.
Missing ID	The sample ID, required for configuration of the LIS, is missing.	1. Stop and return to the section status screen to enter an ID for the position.
Wrong Control Wrong Std	The number of the control or standard has been entered for a parameter whereas it does not exist in the PTC base.	1. Stop and return to the section status to check controls or standards/calibrators for the position.
No Standard	There is no calibration in the ***mini VIDAS®*** analyzer and no standards/ calibrators in the job list.	1. Stop and return to the section status screen to enter standards/calibrators for the position.
Old Standard	The calibration for this assay lot has expired.	1. Stop and return to the section status screen to run a new calibration for the position.
No Master Lot	The Master Lot Data were not entered.	1. Stop and enter the Master Lot Data for the assay of the corresponding position.
Select Assay	This type of error should only occur in a Load and Go run when the same strip can be used for different assays (eg.: ***VIDAS®*** LYG and ***VIDAS®***LYGS).	1. Stop and return to the section status screen to select the assay you want to run.

Manually Entering Bar codes

This procedure begins from the error message screen display.

1. Press the **<Number Key>** for the position containing the bar code error.



2. Remove the reagent strip from the section and find the eight-digit alphanumeric bar code, located next to the assay code.
3. Manually enter the bar code as follows:
   a. Press the appropriate **<Number Key>** to enter a digit.
   b. For a letter, press the arrow keys to highlight the appropriate character in the character box.
   c. Select the [character box].

      It appears in the cursor box.

Note: *"O" and "I" are letters.*
"Ø" and "1" are the digits zero and one.

When the bar code entry has been completed,

4. Press  .

   The ***mini VIDAS***® analyzer checks the bar code you entered.

   - If the bar code is valid, the display returns to the Error message screen.
   - If the bar code is not valid, the following message appears:

     ```
     Warning: Barcode still invalid
     Press any key to continue
     ```

5. Press any key on the keypad.

   The display returns to the error message screen.

6. Start the procedure from the start if you want to reenter the bar code.

   or

   Press  .

   If you press  , the following selections appear:

   Restart
   Cancel

7. Select **Cancel** to abort the run.

   or

   Select **Restart** to restart the run.

Note: *If you select* **Cancel**, *the* ***mini VIDAS®*** *analyzer returns to the state it was in before the run was started.*
Any data you entered about the assays are retained.
If you select **Restart**, *the run resets and begins with another bar code reading and substrate check.*

Other Error Messages

When the ***mini VIDAS***® analyzer detects a System error, an error message screen is displayed.

System errors cause the ***mini VIDAS***® analyzer to halt the run in the section containing the error. The other section is not affected by any of this action.

These error alert cues continue until you respond to the error condition by pressing the <?> key.

This action causes the ***mini VIDAS***® analyzer to display an error message screen. The text on the screen is similar to the following:

```
Errorcode: 73
Time: 14:53:20 14/09/15
MLE Card data bad
```

Instrument Errors

Instrument errors can occur for a broad range of error conditions.

An error message display consists of three lines: the error code, the time, and the error message. For example:

- **Errorcode: 73**
  This line contains a number that corresponds to the specific error. Make note of this number in case you need to contact the bioMérieux Technical Assistance.
  The ***mini VIDAS***® analyzer maintains a log of the last ten error messages produced by the *mini VIDAS*. They are saved unless THE ***mini VIDAS***® analyzer power is shut off.
  You can access stored error messages via the View Saved Errors function.
- **Time: 14:53:20 14/09/15**
  This line contains the time and date that the error message was produced.
- **MLE Card data bad**
  This line contains the actual error message text. These messages are detailed in the Error Messages section.

Error Messages

Listed below are all of the error messages programmed into the ***mini VIDAS®*** analyzer.

- If error messages other than the ones below appear, call bioMérieux Technical Assistance or your local bioMérieux representative.
- In some cases, there are suggestions for corrective action. Where no corrective action is possible, or if the corrective actions fail, the final action is to call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
`Warning - LIS Validation Queue Full`	The validation queue is a temporary storage area for results waiting to be validated. This message appears if the results of 8 sections are already stored in the validation queue and a 9th section is run.	1. Use the results validation procedure to remove results from this queue (see Validating LIS Results on page 6-9).
`Warning LIS upload queue full`	This message indicates a possible problem in the ***mini VIDAS®*** analyzer to LIS interface.	1. Call bioMérieux Technical Assistance or your local bioMérieux representative to report this message.
`Some scanner errors lost due to overflow`	This message may occur after repeated scanner errors.	1. Call bioMérieux Technical Assistance or your local bioMérieux representative to report this message.
`Some section errors lost due to overflow`	This message may occur after repeated scanner errors.	1. Call bioMérieux Technical Assistance or your local bioMérieux representative to report this message.
`Optics autocalibration data corrupt - instrument may be out of calibration`		1. Call bioMérieux Technical Assistance or your local bioMérieux representative to report this message.
`Configuration data not found`	This error would occur during the power-on startup sequence. Note that any previously entered configuration options are lost, and the options have returned to their default states.	1. Enter one or two configuration changes. 2. Repeat the power up start sequence. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
`MLE Card data bad`	The instrument failed to read a Master Lot Entry (MLE) card (for assays using a MLE card).	1. Inspect the card for proper placement in the reagent strip tray, debris, or smudges. 2. Replace or reinsert, as necessary. 3. Retry the read operation, or enter the data manually. 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
Assay data load failed	The ***mini VIDAS***® analyzer cannot read the protocol memory card.	1. Make sure the protocol memory card is in the memory card slot. 2. Reinsert the memory card to ensure proper contact. 3. Retry the last operation. 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Normal Range save failed		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
Normal Range load failed		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
Assay startup error	This error would appear during the preprocessing steps of a run.	1. Perform the procedure to halt the section. 2. Retry an assay in the same section. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Section reset failed		1. Check the section for physical obstructions or any jams. 2. Perform the halt operation on the section. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Standard save failed		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
Assay failed	The assays in a section have failed to process correctly.	1. Retry an assay in the same section. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Assay processing error	The assays in a section have failed to process correctly	1. Retry an assay in the same section. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Communications error		1. Retry the operation that created the error. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Section communications error		1. Halt the Section with the error. Retry an assay in the same section. 2. If the error recurs, place the Section offline and call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
`Unknown section error`		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
`Unknown software error`		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
`Unknown scanner error`		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
`External printer error`	The external printer has sent an error signal to the ***mini VIDAS***® analyzer	1. Consult your printer manual.
`Internal printer error`		1. Retry a print operation. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
`Cannot begin bar code read - check door`		1. Check to see that the door to the SPR® block is completely closed and restart the assay. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
`Cannot begin assay - check door`		1. Check to see that the door to the SPR® block is completely closed and restart the assay. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
`Unable to initialize Section`	This error would occur during the power-on startup sequence.	1. Shut down the ***mini VIDAS***® analyzer (see Shutting Down the System on page 4-4.) 2. Check the instrument for physical obstructions or other possible jams. 3. Start the ***mini VIDAS***® analyzer again (see Starting the System on page 4-3). 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
`External printer offline`	The external printer has sent an offline signal to the ***mini VIDAS***® analyzer.	1. Press the online button on the printer, or consult your printer manual.
`Instrument has been too busy for autocalibration to occur`		1. Allow the ***mini VIDAS***® analyzer to sit idle (not performing assays) for at least two hours. 2. Continue normal operations. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
New LIS Results have been discarded due to full queues	This message appears after other messages warning you that the LIS result validation or upload queues are full.	1. Use the results validation procedure to remove results from this queue (see Validating LIS Results on page 6-9).
Boot EPROM obsolete	This error would appear during the power-on startup sequence	1. Shut down the ***mini VIDAS®*** analyzer and then restart it (see Shutting Down the System on page 4-4 and Starting the System on page 4-3). 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Scanner board memory almost full		1. Call bioMérieux Technical Assistance or your local bioMérieux representative to report this message.
Scan head motor movement becoming restricted		1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4). 2. Check for any physical obstructions that could cause a jam. 3. Call bioMérieux Technical Assistance or your local bioMérieux representative to report this message
Scanner Board failure		1. Shut down the ***mini VIDAS®*** analyzer and then restart it (see Shutting Down the System on page 4-4 and Starting the System on page 4-3). 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Temperature monitoring failed		1. Allow any assays that are running to complete. 2. Shut down the ***mini VIDAS®*** analyzer and then restart it (see Shutting Down the System on page 4-4 and Starting the System on page 4-3). 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Section hardware failure		1. Shut down the ***mini VIDAS®*** analyzer and then restart it (see Shutting Down the System on page 4-4 and Starting the System on page 4-3). 2. If the error recurs, halt the section, place it offline, and then call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
Scan head motor failure		1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4). 2. Check for any physical obstructions that could cause a jam. 3. Start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3). 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Software failure		1. Call bioMérieux Technical Assistance or your local bioMérieux representative.
Tray mechanism failure		1. Check the reagent strip tray area for any physical obstructions that could cause a jam. 2. Also check the tray to see that it is on its track. This is especially important after decontaminating the instrument. 3. Run a TP6 assay. 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Pump mechanism failure		1. Check the area inside the SPR® block for any physical obstructions that could cause a jam. 2. Run a TP4 assay. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Tower mechanism failure		1. Check the area inside the SPR® block for any physical obstructions that could cause a jam. 2. Run a TP5 assay. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Hardware failure		1. Shut down the ***mini VIDAS®*** analyzer and then restart it (see Shutting Down the System on page 4-4 and Starting the System on page 4-3). 2. Retry another assay. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
Optical hardware failure (or excessive auto-calibration drift)		1. Shut down the ***mini VIDAS®*** analyzer (see Shutting Down the System on page 4-4). 2. Clean the optical lenses (see Cleaning Optical Lenses (Monthly) on page 8-11). 3. Start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3). 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
No Master Lots available	The ***mini VIDAS®*** analyzer cannot read the protocol memory card.	1. Make sure the protocol memory card is in the memory card slot. 2. Reinsert the memory card to ensure proper contact. 3. Retry the last operation. 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
External printer paper empty	The external printer has sent a signal to the ***mini VIDAS®*** analyzer indicating it is out of paper	1. Reload the printer with paper. 2. If the printer still has paper, check the cable connections between the printer and the ***mini VIDAS®*** analyzer. 3. Consult your printer manual if necessary.
Internal printer paper empty		1. Install another roll of paper in the thermal printer. 2. Attempt another print operation. 3. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Restoring saved master lot information		1. Try to reenter the Master Lot data. 2. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
SPR temperature out of allowed range		1. Check the temperature of the SPR® block. 2. If the temperature is low, make sure all doors on the ***mini VIDAS®*** analyzer are closed. 3. Allow time for the temperature to equilibrate. 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.

Table B-2: Problem Resolution

Error Message / Problem	Cause	Resolution
Tray temperature out of allowed range		1. Check the temperature of the reagent strip tray. 2. If the temperature is low, make sure all doors on the ***mini VIDAS®*** analyzer are closed. 3. Allow time for the temperature to equilibrate. 4. If the error recurs, call bioMérieux Technical Assistance or your local bioMérieux representative.
Unable to complete LIS upload of results	The ***mini VIDAS®*** analyzer was unable to transfer its results.	1. Check all cable connections between the ***mini VIDAS®*** analyzer and the LIS computer. 2. Make sure that your LIS computer is ready to receive data.

Problems that May Occur with the Bar code Reader

The reader does not emit a beam of light

1. Check that the cable is securely connected (see the installation procedure in Appendix - Installing external hardware).
2. Check that the trigger is working.

After verification, if the reader does not function properly:

1. Repeat the bar code reader installation procedure.

If the problem persists, call bioMérieux Technical Assistance or your local bioMérieux representative.

Reader fails to read bar codes

The bar codes are unreadable:

IMPORTANT: To be readable, bar codes must be complete, unstained, and untorn.

1. If the configuration sheet provided with the reader is missing or unreadable, call bioMérieux Technical Assistance or your local bioMérieux representative.

The reader window is not clean:

1. Check that the reader window is clean and if necessary clean it using a soft cloth.
2. Repeat the reading.

The reading distance is incorrect:

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

Note: *A beep indicates that reading has been performed.*

Assay Report Errors

Errors related directly to results on an assay report are not displayed on an error screen.

Rather, the assay report itself is used to report these errors.

The assay report uses a set of symbols to mark the part of the report that contains the error. A footnote then appears at the bottom of the report, referencing the same symbol. The footnote includes the error message.

Correcting Assay Report Errors

In all cases, the test should be repeated.

If the error recurs and you suspect a problem in the ***mini VIDAS***® analyzer, call bioMérieux Technical Assistance.

Assay Report Error Symbols

The symbols in Table B-3 are used on assay reports to indicate error messages.

Table B-3: Assay Report Error Symbols

Symbol	Message	Cause
&	Low reading.	A fluorescence reading for the reagent strip is below a preset limit.
§	High reading.	A fluorescence reading for the reagent strip is above a preset limit.
¥	Offscale reading.	A fluorescence reading for the reagent strip is outside the operating range of the detector.
#	Low RFV.	An RFV for the reagent strip is below a preset limit.
!	High RFV.	An RFV for the reagent strip is above a preset limit.
{	No reading.	Call bioMérieux Technical Assistance.
¬	Math Error.	The ***mini VIDAS***® analyzer encountered a calculation error, e.g., a divide by zero.
@	High Test Value.	A test value calculated for the reagent strip is above a preset limit.
¤	Low Test Value.	A test value calculated for the reagent strip is below a preset limit.
¢	Sample Over-Diluted.	
~	Low control.»	A high control is giving a low response.
¶	High control.	A low control is giving a high response.
$	Std. CV exceeded.	The coefficient of variation (CV) for the standard result is greater than a preset limit.
£	Invalid std.	The result for the standard is invalid and cannot be used to calculate the result for the test samples.
]	Please refer to the package insert	

Error Messages on Assay Reports

If a standard is out-of-range or missing (when an assay is started), the following error message is printed at the bottom of the assay report:

```
Insufficient standard run or Standard value out of range
```

The test result should not be taken into account, and it is recommended to repeat calibration for the test.

Printer Errors

If the internal printer is out of paper or does not respond, the ***mini VIDAS®*** analyzer will keep retrying for 30 seconds and begin beeping.

1. Press  to display the error message screen.

   The error message refers to the internal printer.

2. Replace the printer paper if the error indicates that the printer is out of paper.

   The following selections are displayed:

   Retry Printing

   Abort Printing

3. Select **Retry Printing** to try to print the job at this time,

   or

   Select **Abort Printing** to stop printing at this time.

The ***mini VIDAS®*** analyzer will try to print this job again if:

- the printer is told to print something else,
- you use the **Select Printer** function on the configuration menu.

Viewing Saved Errors

The ***mini VIDAS***® analyzer stores the last ten error messages it creates.

These messages remain in the ***mini VIDAS***® analyzer unless the power is turned off.

Use the following procedure to access the stored error messages.

1. Select **Utility Menu** in the **Main Menu**.
2. Select **View Saved Errors** in the **Utility Menu**.

   The screen displays an error message similar to the following:

```
Errorcode: 73 (Saved)
Time: 14:53 09/14/Ø2
MLE Card data bad
```

Note: *The first message shown is the newest message stored in the message file.*

3. Press  to display the next message.

   or

   Press  to return to the **Utility Menu**.

Displaying and Printing Instrument Temperatures

1. Select **Status Screen** in the **Main Menu**.
2. Select **Display temperatures**.

   The **Temperatures** screen appears displaying the temperature readings for the reagent strip tray and the SPR® block of both sections.
3. Press  twice to return to the **Main Menu**,

   or
4. Select **Print** if you want to print a copy of the temperature readings.

   The temperature report begins to print and the screen returns to the **Main Menu**.
5. *Wait until the result sheet finishes printing (if one is in progress) before printing the temperature report.*

C Appendix - Installing external hardware

External printer

Equipment Required

- Compatible printer.
  For information on the recommended type of printer, contact bioMérieux or your local bioMérieux representative.
- PC compatible printer cable with a DB 25-pin connector on one end and a 36-pin Centronix connector on the other end.
- Small, flathead screwdriver.

Before Installation

1. Make sure that the ***mini VIDAS***® analyzer has been configured for an external printer.
2. If not, refer to Selecting the Printer on page 4-12.

Installation

1. Shut down the ***mini VIDAS***® analyzer (see Shutting Down the System on page 4-4.).
2. Set the printer near the ***mini VIDAS***® analyzer within reach of the printer cable and an appropriate electrical outlet.
3. Locate the Printer Port on the rear of the ***mini VIDAS***® analyzer.

Figure C-1: location of printer port

4. Insert the DB 25-pin connector of the cable into the printer port.
   Make sure it is oriented correctly.
5. With the screwdriver, tighten the connector to the port.
6. Insert the 36-pin Centronix connector of the cable into the port on the printer.
   Make sure it is oriented correctly.
7. Load the printer with paper per the manufacturer's instructions.
8. Turn the printer on.
9. Start the ***mini VIDAS®*** analyzer (see Starting the System on page 4-3).
10. Test the external printer (see Testing the Printer on page 7-4).

Possible Error Message

If the message "**External printer error**" appears:

1. Check that the printer is turned on,.
2. Make sure there is a enough paper.

Installing the Bar code Reader

Equipment Required

The reader is supplied in a kit containing:

- 1 bar code reader,
- 1 cable,
- 1 configuration sheet.

Note: *The kit must include the above mentioned components. If any are missing, contact bioMérieux or your local bioMérieux representative.*

Installation

1. Connect the cable to the bar code reader.
2. Make sure that the ***mini VIDAS®*** analyzer has been configured to use the correct bar code reader.
3. Select **Barcode Wand** in the **Configuration Menu**.

   The following selections appear:

   - **None** (the default setting)
   - **Barcode Wand**

Note: *A ☒ symbol indicates the current setting.*

4. Select **Barcode Wand**.

5. Press  to return to the **Configuration Menu**.
6. Shut down the ***mini VIDAS***® analyzer (see Shutting Down the System on page 4-4.)

Caution: Always shut down the ***mini VIDAS***® analyzer before connecting the external bar code reader.

7. Locate the diagnostic port on the rear of the ***mini VIDAS***® analyzer.

Figure C-2: Location of diagnostic port

8. Connect the bar code reader cable to the diagnostic port.

   The port and connector are shaped such that the cable can be successfully inserted in only one orientation.
9. Start the ***mini VIDAS***® analyzer (see Starting the System on page 4-3).

   The bar code wand is now ready to use.

If the ***mini VIDAS***® analyzer was already equipped with a bar code reader, the old reader's configurations will be replaced by the default configuration of the new bar code reader.

The bar code reader you have received has already been configured by bioMérieux and takes into account most of the existing types of bar codes.

If the reader does not retain its configuration,

1. Scan the bar codes on the configuration sheet provided with the bar code reader kit. If the configuration sheet is missing, contact bioMérieux or your local bioMérieux representative.

D Appendix - Computer interface information

Introduction

The ***mini VIDAS***® analyzer is a standalone instrument that does not use a separate computer.

It contains everything to support a unidirectional computer interface.

This interface only allows the ***mini VIDAS***® results to be transmitted (i.e., uploaded) to the Laboratory Information System (LIS) or other host computer system.

Note: *The pn and pi fields (patient name and patient identification) are not transmitted as part of the upload on a* ***mini VIDAS***® *analyzer as this information does not exist in the* ***mini VIDAS***®*application.*

The ***mini VIDAS***® fields that are transmitted include:

- mtrsl message type
- pi patient ID
- pn patient name
- si specimen separator
- ci sample ID
- rt short assay name
- rn long assay name
- ql qualitative result
- qn quantitative result
- tt test completion time
- td test completion date
- qd dilution (optional)

The following results are not uploaded:

- Strips without a sample ID
- QCV, OPT, LEAK.
- Any raw result analysis type assays
- Controls
- Standards/Calibrators.

The «Ready-to-send» queue can hold up to 48 sample results.

As ***mini VIDAS***® results are not permanently stored in the instrument, uploads should be performed on a routine basis.

If attempts to upload results are unsuccessful, once the retry interval and number of retries have elapsed, an error will be logged.

1. To view this log, select ? on the keypad or view saved errors from the **Utility Menu** selection.

Configuration Information

CAUTION: Your unidirectional connection must be configured and brought into service by trained and qualified personnel. Any modification may lead to problems when the connection is used or cause it to operate in an unexpected manner.

1. Select **Configuration Menu** in the **Main Menu**.
2. Select **LIS Interface Options**.

Table D-1: LIS Interface Options

Option			
Communication settings	**Minim.**	**Maxim.**	**Default**
• Baud rate	• 300	• 38400	• 1200
• Parity (None, Odd, Even, Low, High)			• None
• Character Size	• 7	• 8	• 8
Timeouts & Limits	**Minim.**	**Maxim.**	**Default**
• Timeout	• 2	• 99	• 3
• Checksum Retry Limit	• 0	• 99	• 3
• Checksum Error Retry Interval	• 0	• 99	• 10
• <ENQ> Retry Limit	• 0	• 99	• 3
• <ENQ> Retry Interval	• 0	• 99	• 10
• InterRecord Delay	• 0	• 99	• 0
• InterMessage Delay	• 0	• 99	• 2
Data Format			
• Misc. Format	*Alternate Protocol* • STX : <CR><LF> • ETX : <CR><LF> • RS : <CR><LF> • GS : <CR><LF> • ENQ : <CR><LF> • EOT : <CR><LF> • Send Dilution		
			Default
• Time Separator	• . : / - ,		• :
• Date Separator	• . : / - ,		• /
• Field Terminator	• ! @ # $ % ^ & * ( ) - = + < > / ? [ ] \ | { }		• |
Send Text Message	Used to send text message patern		

Example of a *mini VIDAS*® Upload

```
mtrsl|pi|pn|si|ci218421|rtRBG|rn RUB IgG|
tt 15:16|td 10/10/03|qlNegative|qn 10 UI/ml|
qd 1|
```

E Appendix - Technical Data and Specifications (previous versions of *mini VIDAS®* analyzers)

Technical data and specifications are given for previous versions of the ***mini VIDAS®*** analyzer (analyzer without transparent blue section covers).

Dimensions

	Instrument packed	**Instrument unpacked**
Height (cm)	57	44
Width (cm)	68	54
Depth (cm)	68	53

Weight

	Instrument packed	**Instrument unpacked**
Weight (kg)	46	37

Physical Space Requirements

	Value
Height (cm)	65
Width (cm)	120
Depth (cm)	90

The instrument must be placed on a flat surface tilted no more than 5°.

Electrical Specifications

The instrument includes an internal bar code reader with a 660 nm LED whose radiation is Class 1 according to IEC 60825-1. This class does not present a risk.

Specification	Value
Voltage	100 - 240 VAC 200 - 240 VAC The voltage (100 - 240 VAC or 200 - 240 VAC) is selected using the power unit at the back of the instrument)
Consumption	1.5 A at 100 - 120 VAC 0.8 A at 200 - 240 VAC
Frequency	50 - 60 Hz
Power	180 Watts (maximum) 75 Watts (minimum)
Fuse Current	External (power input module): 1.5 AT at 100 - 120 VAC 1.6 AT at 200 - 240 VAC
Approximate Emission of Heat	250 Btu / hr 75 W
Power Switch	Location: back of instrument Type: bipolar (phase + neutral) Max. leakage of current: < 1mA

Caution:

The user must comply with the technical specifications and standards in this manual to ensure user safety as well as the proper functioning of the instrument.

bioMérieux is in no case liable for any damage that may arise from failure to comply with these specifications or any operation conducted on the equipment not in compliance with these mandatory standards.

Moreover, the warranty for this equipment is expressly subject to use of the ***mini VIDAS®*** analyzer in compliance with the procedures and specifications herein.

Environmental Conditions

Specification	Value
Type of Installation	For indoor use only
Installation category	II
Pollution degree	2

The ***mini VIDAS®*** analyzer meets the environmental safety requirements defined in clause 1.4 of the standard IEC 61010-1.

Temperature

Specification	Value
Operating temperature	15°C to 30°C (room temperature)
Storage temperature	-10°C to 40°C

Note: *The average heat emission is approximately 512 BTU - 150 W.*

Humidity

Specification	Value
Relative humidity	10% to 80% RH non-condensing
Humidity during storage and transport (non-condensing within the storage and transport temperature range)	up to 90%

Altitude

Specification	Value
Maximum altitude	2,000 m

Sound Level

Specification	Value
During an analysis	< 59 dBA

Technical features

Capacity

- 12 test positions (2 sections with 6 positions in each section).
- Up to 30 tests/hour depending on the type of assay used (see test duration in the package insert for each ***VIDAS***® assay).

Motors

- Automatic control by stepper motors.

Pumping

- 2 pumps; one for each section
- Mixing, diluting, and transferring of liquids

Temperature control

Absolute Accuracy

- SPR®: 36°C – 38°C
- Tray: 35°C – 38°C

Relative Accuracy

- SPR®: ± 0.7°C between the 2 sections
- Tray: ± 1°C between the 2 sections

Thermal resistance

- Process: thermal resistance
- Automatic Control: by thermal probe

Optics

Specification	Value
Detector	Photodiode fluorimeter
Detection range	40 to 40 000 nmol of 4MU (4-Methyl Umbelliferone)
Automatic checking	Automatic checking every 12 hours of the optic system against a reference standard (named "solid standard"); automatic calibration if the difference with the solid standard is ≥ 0.6 %

Assay Kit Specifications

VIDAS® SPR®

Specification	Value
Length	76 mm
Material	Plastic polymer
Work volume	5 to 350 µl

VIDAS® Single Reagent Strip

External dimensions	Value
Length	157 mm
Width	18 mm
Depth	15 mm

Well	Capacity
Sample Well	960 µl
Reagent Well	960 µl
Substrate Well	530 µl

The strip is sealed by a foil to ensure that no evaporation will occur that may compromise the reagents.

The substrate well is made of a plastic that meets with the appropriate optical qualities.

F Appendix - Glossary

Assay

A complete test procedure using immunological methods and fluorescent chemistry to detect or quantify an analyte.

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 ***mini VIDAS®*** analyzer. Assays are defined in the ***mini VIDAS®*** analyzer, for example, using the assay code.

Assay Compatibility

The property that two or more assay types have when they utilize the same protocol in the ***mini VIDAS®*** analyzer.

Assay kit

A package containing a set of reagent strips, SPR®s, and a package insert along with any necessary controls, standards, and sample treatment reagents.

Background

The native fluorescence that a substrate has without the intended chemical reaction for the assay.

Bar code

A series of lines printed on the label of a reagent strip. The encoded information can be read and interpreted by the scanner and used to identify the strip.

Calibration

The process of adjusting the standard curve of a quantitative assay lot or storing the calibrator's RFV for a qualitative assay.

Calibration curve

A set of data, supplied by bioMérieux with each lot of a quantitative assay, that becomes the standard curve for that lot.

Cuvette

The last of the 10 wells of the reagent strip. It is made of optically clear plastic that permits the scanner to take an accurate fluorometric reading of the substrate.

Defined run

An assay run in which assay types, sample IDs, standards, and controls are defined on the ***mini VIDAS®*** analyzer prior to the start of the run.

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 analysis result that is neither positive/reactive nor negative/nonreactive; it falls between the high and low threshold values for the test.

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 ***mini VIDAS®*** analyzer.

Fluorescent units

A numerical value that represents the intensity of fluorescence detected by the optical scanner.

Load and Go run

An assay run in which reagent strips are placed into the ***mini VIDAS®*** analyzer and run without any prior definition on the ***mini VIDAS®*** analyzer.

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.

Master Lot Entry (MLE) card

It is used to enter master lot data into the ***mini VIDAS®*** analyzer. Some reagent kits no longer contain a MLE card. The master lot data is printed under the form of a bar code on the reagent kit label.

Optical cuvette

The last of the ten wells of the reagent strip. It is made of optically clear plastic that permits the scanner to take an accurate fluorometric reading of the substrate.

Optical scanner

A component of the ***mini VIDAS®*** analyzer that reads the bar code label and measures the intensity of fluorescence of the assay.

Port

A cable connection site on the back of the ***mini VIDAS®*** analyzer.

Position

The reagent strip and SPR® slots in the ***mini VIDAS®*** analyzer where a reagent strip/SPR® pair can be placed.

Protocol

A specific sequence of computer-controlled activities (pipetting, mixing, incubating, reading, etc.) needed to perform an assay. Only assays with identical Protocols can be run in the same section.

Reagent strip

A polypropylene strip consisting of 10 wells with a foil seal and paper label.
One well of the strip is for the sample.
The other eight wells contain the various reagents required for the immunoassay. The last well of the strip is the optical cuvette that contains the substrate.

Reagent strip compartment

A temperature-controlled tray with a plastic cover containing six section channels that hold six reagent strips or three dual reagent strips.

Reagent strip tray

The temperature-controlled tray within the reagent strip compartment. Also called section tray.

Reference strip

The reagent strip in a dual strip pair that is used to measure the background reading for the sample.

Relative Fluorescence Value (RFV)

The difference between the final and the initial (background) fluorescent readings of a reagent strip.

Replicates

The multiple samples of a standard that are run, and of which an average value is calculated.

Result

Interpretation of a quantitative or qualitative test.

Sample

The material being tested.

Scanner

A unit in the ***mini VIDAS®*** analyzer that contains the fluorescent detector and the bar code reader.

Section

A microprocessor-controlled assay processing unit in the ***mini VIDAS®*** analyzer. Each analyzer has two sections. Each section contains an SPR® block with six corresponding reagent strip channels. An SPR® position and its corresponding reagent strip channel make one test position.

Section channel

A groove in a section tray that holds a reagent strip. Channels are designated one through six. Each has a corresponding SPR® position in the SPR® compartment.

Section tray

A temperature-controlled plate with six channels to hold six Single reagent strips or three dual reagent strips. Also called reagent strip tray.

Single reagent strip

See 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 SPR®s. 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.

Standard/Calibrator

A solution containing a known analyte concentration. The RFV obtained from testing a Standard is used to calculate concentrations and to interpret samples or controls.

Stored Standard

The test result of a standard, stored as data in the ***mini VIDAS®*** analyzer, and used to calculate results for test samples over a period of time.

Strip preparation tray

Note: *Previous versions of the **mini VIDAS®** analyzer may not have a 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.

Test

That portion of an assay kit used to process a specimen, control, or standard; consists of a paired reagent strip and SPR®.

Test value

The result calculated using the Relative Fluorescent Value (RFV) of the sample and the Relative Fluorescent Value of the reference or of the standard, depending upon whether it is a dual or Single reagent strip, respectively.

Threshold

A numerical value stored in the ***mini VIDAS®*** analyzer memory.

It is used to translate the test value to qualitative results such as «Positive», «Negative», «Equivocal».

Unique Assay Code (UAC)

The Unique Assay Code corresponds to 2 characters encoding the link between all information needed for the biological assay.

VIDAS® Lens Cleaner

A tool for cleaning the ***mini VIDAS®*** analyzer optical lenses in order to avoid optical drift.

Revision History

This section contains a summary of changes made to each released revision of this manual starting with part number 161150-849 - A.

Change type categories:

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note:
- *Minor typographical, grammar, and formatting changes are not included in the revision history.*
- *Not all versions may be available in all languages.*

Release Date	Part Number	Change Type	Change Summary
2016/10	161150-849 - A	N/A	First publication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