# VITEK® 2 Compact

## Instrument User Manual


040436-03 - en - 2020-05 -

EN

IVD

CE

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## General Information

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Please discard any previous copies of this document if relevant.

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***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 document carefully before using the instrument.***

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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).

## Patent Information

This product may be protected by one or more patents, see: http://www.biomerieux-usa.com/patents.

# 1 Introduction to the System

## Intended Use and Users

The VITEK® 2 Compact system and this manual are intended for laboratory use by trained, professional, clinical and industrial users. Most material in the manual applies to both sets of users.

The VITEK® 2 System is intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp., and yeast.

The VITEK® 2 System is also intended for the automated identification of most clinically significant anaerobic organisms and *Corynebacterium* species, fermenting and non-fermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.

**Industry Use**

The VITEK® 2 System is intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for veterinary organisms including aerobic Gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp., and yeast.

The VITEK® 2 Systems are intended for the automated identification of most veterinary and environmental organisms including anaerobic organisms, Bacillaceae, *Corynebacterium* species (and related genera), fermenting and non-fermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.

## Benefits and Limitations of Use

The VITEK® 2 System is intended for the automated identification and antimicrobial susceptibility testing of most clinically and/or industry significant organisms (bacteria and yeast) routinely isolated in a microbiology laboratory. The VITEK® 2 System is only intended to be used with the proprietary VITEK® 2 identification (ID) and antimicrobial susceptibility (AST) test cards.

The system benefits the microbiology laboratory, prescribing clinicians, as well as patients due to its unique capability for rapid testing and result reporting. Testing requires a saline suspension of organism be inoculated into a test panel of biochemicals and a test panel of antibiotics. These panels, referred to as "cards", are single-use disposables that are inoculated according to the procedure set out in the *VITEK® 2 Systems Product Information*. The cards are prepared with an organism inoculum from a pure culture according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be performed to ensure that a pure culture was used for testing. The preparation of cards must be performed as described in the *VITEK® 2 Systems Product Information* in order to ensure accurate results. Only those organisms robust enough to grow in the cards will give results.

The Advanced Expert System® software uses the organism ID and antibiotic MICs to determine the best phenotype match, thus providing valuable information to clinicians to help them in patient treatment decisions.

The card performs as intended only when used in conjunction with VITEK® 2 Systems and in accordance with *VITEK® 2 Systems Reagent Package Insert*, *VITEK® 2 Systems Product Information*, *VITEK® 2 Compact Instrument User Manual*, and *VITEK® 2 Systems Software User Manual*.

***Note:*** *Store the card unopened in the original package. Do not use the card if the protective package liner is damaged or if no desiccant is present.*

- *Allow the card to come to room temperature before opening the package liner.*
- *Do not use powdered gloves. Powder may interfere with the optics.*
- *Use of culture media other than the recommended types must be validated by the user for acceptable performance.*

## 21 CFR 11 and HIPAA

The system provides features that enable customers to be compliant with 21 CFR 11 and Health Insurance Portability and Accountability Act (HIPAA) requirements.

When the system is configured to operate in 21 CFR 11 mode, certain functions require login (for example, viewing, editing, and printing test data).

## 21 CFR 11

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When the system is configured to operate in 21 CFR 11 mode, certain functions require login (for example, viewing, editing, and printing test data).

## 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) may be used instead.

The warning messages in this document 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 Warnings

See the *General Safety and Regulatory Information* booklet.

## 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 may be 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 materials 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**

**In order to avoid computer viruses or abnormal functioning of your equipment, never download any software other than those ensuring the protection of your network and those provided or recommended by bioMérieux.**

**It is your responsibility to secure your network and ensure this protection is appropriate and maintained. It is recommended to use all appropriate means (including antivirus software, security patches, firewall) to protect your network from virus intrusion, unauthorized use, alteration, manipulation and disclosure.**

**In an effort to reduce the risk of spreading a virus to bioMérieux equipment, it is recommended that only bioMérieux supplied USB devices are used with bioMérieux equipment. The use of personal USB devices is not recommended. To avoid computer viruses and the potential loss of functionality and/or results, use caution when transferring USB devices between computers. Do not use USB devices intended for bioMérieux equipment in other computers that do not have current antivirus software installed and active.**

**All computer media (CD, DVD, USB key) supplied with this equipment should be stored and stocked in a suitable location.**

**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.

| | | | |
|---|---|---|---|
| CE | CE-Marking of Conformity | C SA US | Compliance with US and Canadian Safety Standards certified by CSA |
| | Compliance with China RoHS Regulation (Chinese Standard SJ/ T11364) | c UL us LISTED | UL Listed to US and Canadian Safety Standards |
| EAC | Eurasian Conformity | | Moroccan Conformity Mark (CMim) |
| IVD | *In Vitro* Diagnostic Medical Device | UK CA | United Kingdom Conformity Assessed |
| LOT | Batch code | | For IVD performance evaluation only |
| EC REP | Authorized Representative in the European Community | REF | Catalogue number |
| SN | 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


Keep dry

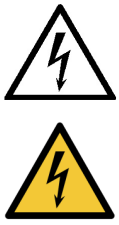

Fragile, handle with care


Keep away from magnetic field


Upper limit of temperature

Sterile

Negative control

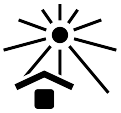

Electric shock warning


Hot surface


Laser beam


High temperature


Do not reuse


Keep away from light

Humidity limitation


Temperature limitations


Lower limit of temperature

Positive control


Biological risk


Radiation warning


Potential pinch-point warning


Shearing hazard


Hazardous magnetic field

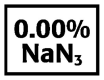
Potential tip-over/crush hazard

Corrosives

Irritant

Separate collection for waste electrical and electronic equipment

Acute toxicity

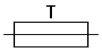



Sodium azide

Recyclable



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




Fuse

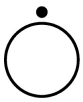
Alternating current


Three-phase alternating current

Protective conductor terminal

Equipotentiality

OFF (supply)



OFF (only for a component of the system equipment)

Ethernet port

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 document 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

The VITEK® 2 System conforms to the relevant European regulations for electrical safety and electromagnetic compatibility (EMC).

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

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

This is a Class A product. This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

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

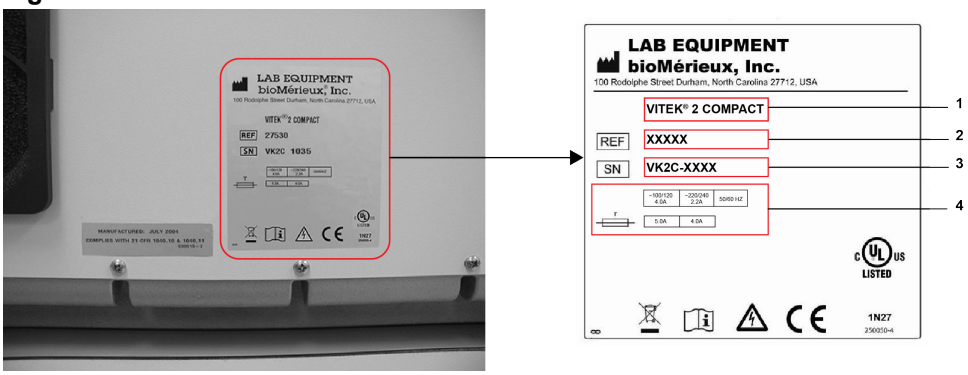
⚠ **CAUTION: Use of this instrument in a dry environment, especially if synthetic materials are present (for example synthetic clothing and carpets) may cause damaging static discharges that may cause erroneous results.**

## Instrument Labels

The VITEK® 2 Compact instrument has multiple labels on various parts of the instrument. Labels may be used to provide information or to make the user aware of potential hazards. It is important to be familiar with the location and meaning of the labels on the instrument. The Instrument Label is located on the rear of the instrument. This label contains the part number of the instrument (REF), the name of the instrument, the serial number (SN), the instrument voltage, and the instrument product identity.

***Note:*** *The XXXXX in the REF and SN fields will be replaced with the appropriate number.*

**Figure 1: Instrument Label**

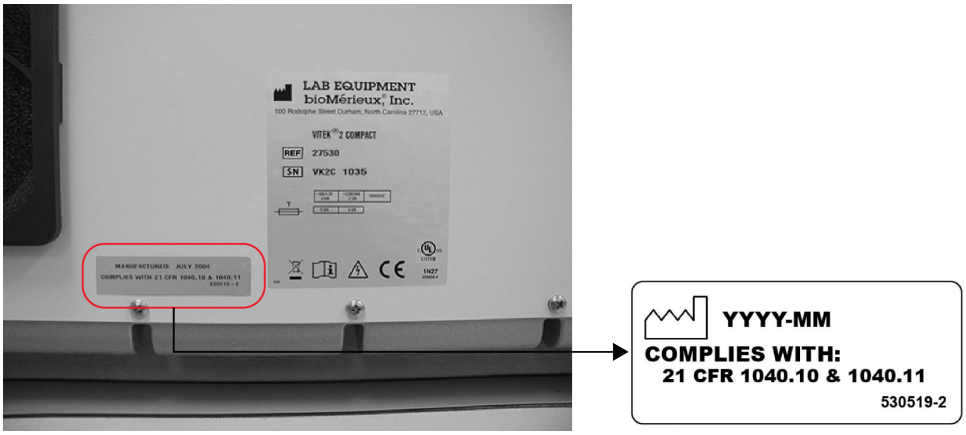



1. Instrument Name
2. Instrument Reference Number/Part Number
3. Instrument Serial Number
4. Instrument Voltage

The instrument contains a Manufactured Month-Year label located on the rear panel of the instrument next to the Instrument Label. This label indicates the year and month the instrument was manufactured and is compliant with 21 CFR 809.10.

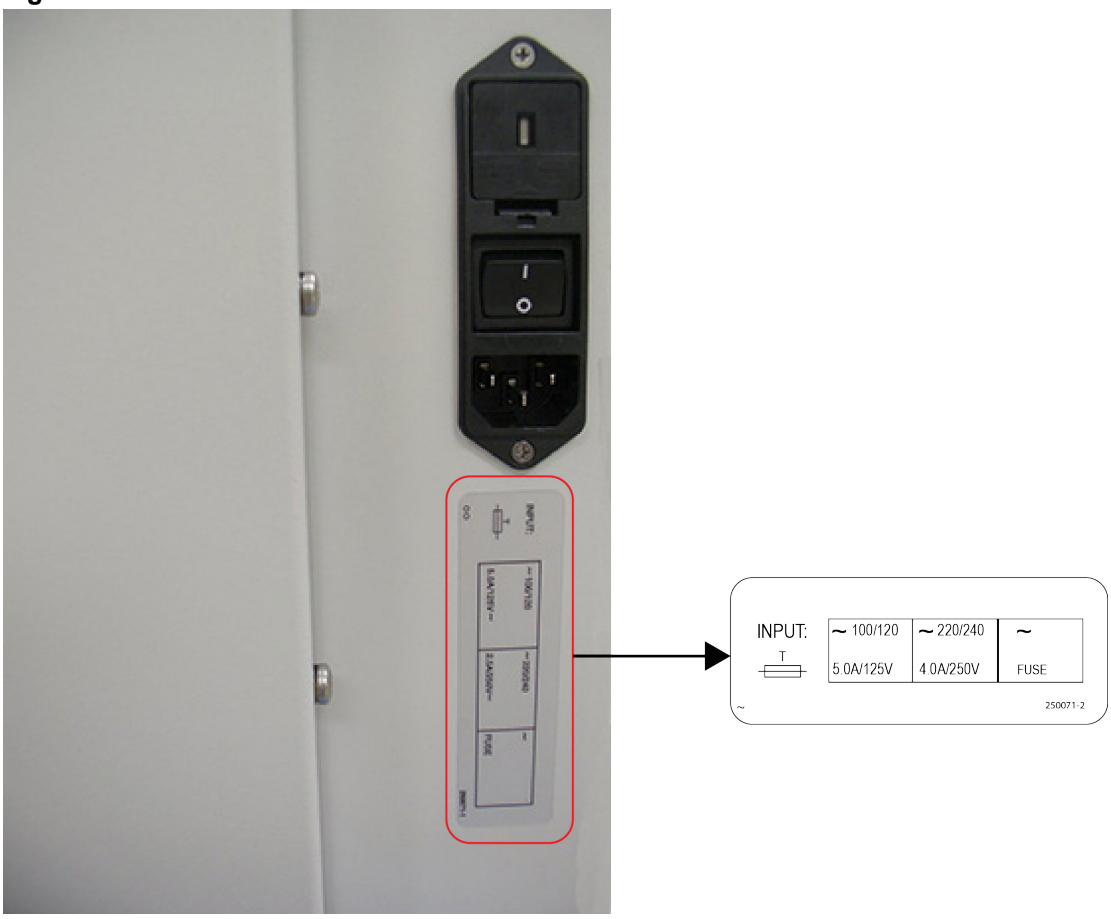
***Note:*** *The picture of the rating plate is provided for information purposes only. The marks of conformity printed on it depend on the current regulations in each country in which the instrument is marketed.*

**Figure 2: Manufactured Month-Year Label**



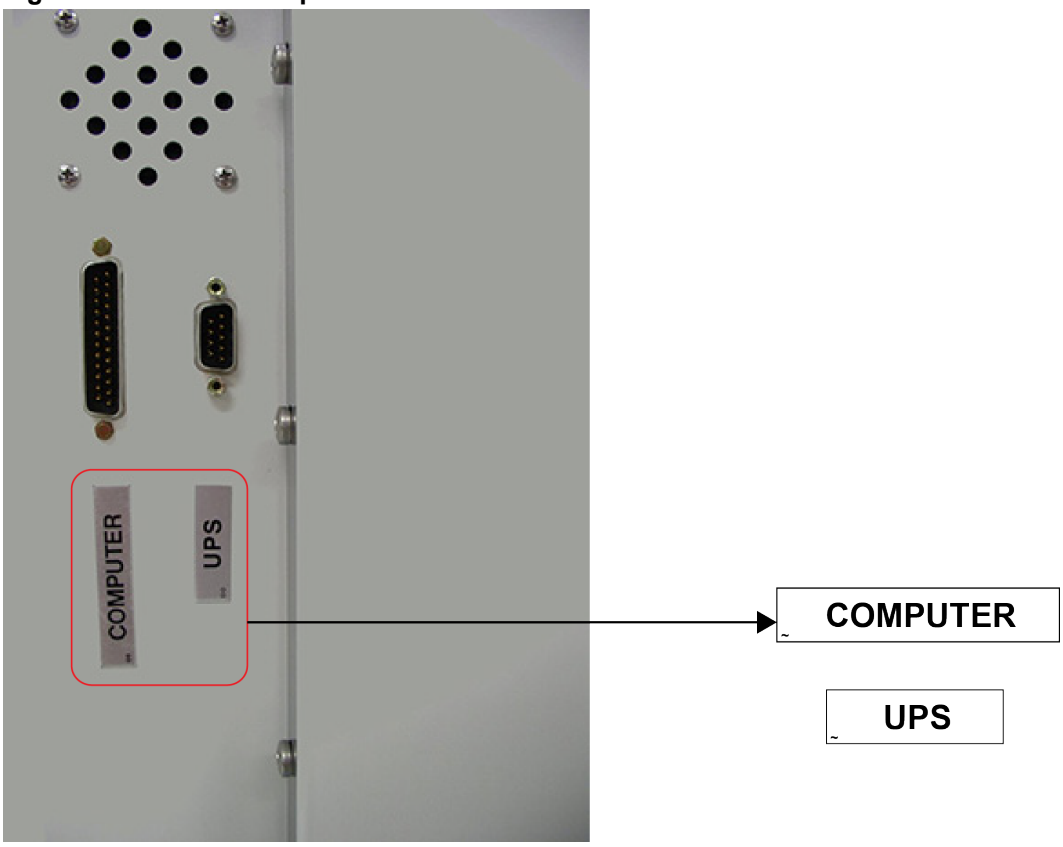

The instrument contains a Fuse label located on the rear panel of the instrument by the AC power switch and cord receptacle. The fuse label indicates the voltage, frequency, current, and fuse rating.

**Figure 3: Fuse Label**




The instrument contains a UPS and Computer label located on the rear panel of the instrument. These labels indicate placement of the UPS and computer communications connector.

**Figure 4: UPS and Computer Label**

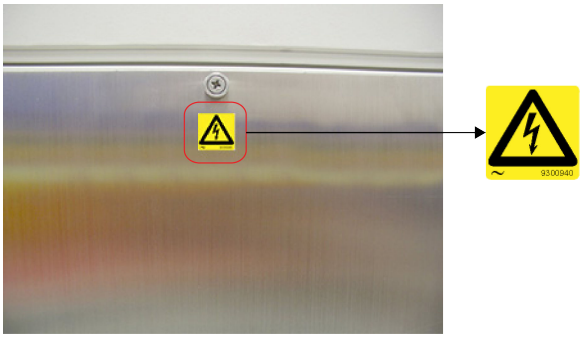



The instrument contains an Electrical Caution label located on the rear panel of the instrument to inform the user of possible shock hazard. The user should not attempt to gain entry into the power supply area.

**WARNING**

**User should not attempt to gain entry into the power supply area at the rear of the instrument. A possible shock hazard could exist.**

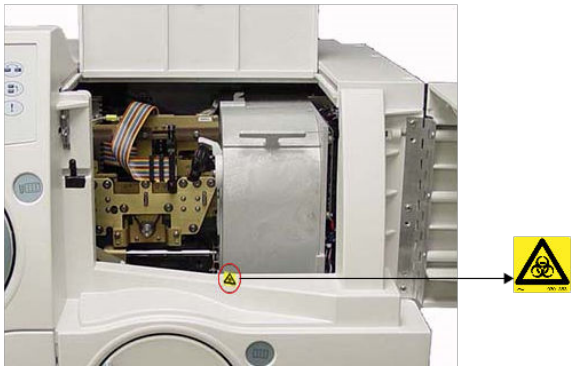
**Figure 5: Electrical Shock Hazard Label**



The instrument contains Biohazard Caution labels inside the Fill Door, Load Door, Waste Collection Door, and Front User Access Door to inform the user about biological risks.

**Figure 6: Biohazard Caution Label - Fill Door, Waste Collection Door, and Load Door**

**Figure 7: Biohazard Caution Label - Front User Access Door**



**WARNING**

**Biohazardous spills can occur inside the VITEK® 2 Compact instrument. All organism suspensions should be considered as potentially infectious.**

## Safety Precautions

Pay particular attention to the following safety precautions. If these safety precautions are ignored, injury to the operator 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 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.**

**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.**

**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.**

**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 computer and its operating system have been carefully configured for optimal system performance. Altering the configuration may severely hamper the usability of the instrument.**

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

**WARNING**

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

**The use of tools not specified by bioMérieux is forbidden.**

**Powder-less gloves, a lab coat and protective glasses or goggles must be worn when performing maintenance operations.**

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

# 3 System Description and Basic Operations

## System Description

The VITEK® 2 Compact is an automated instrument designed for use in low to medium range applications in both Clinical and Industry laboratories. The instrument performs sample well filling and incubation/optical readings. The VITEK® 2 Compact is a two-step automated instrument for:

- Hydrating reagents with sample inoculum
- Pre-processing cards, incubating cards, and continuous reading for growth

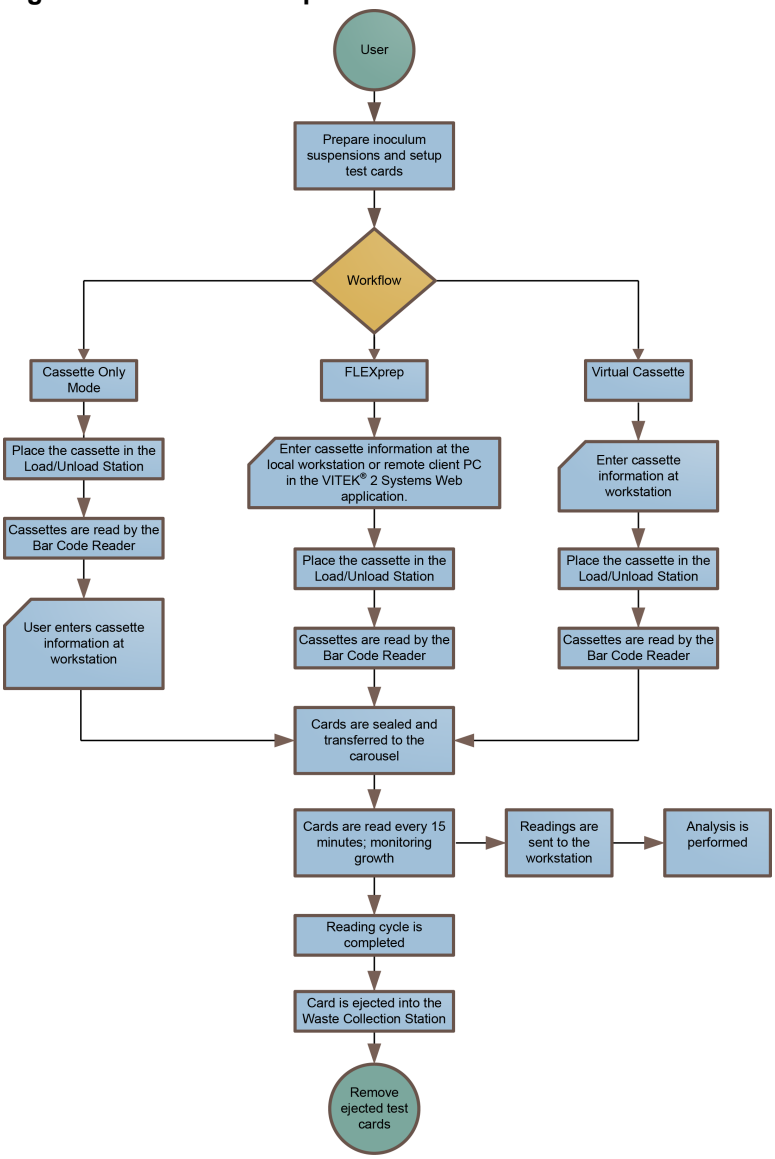
The VITEK® 2 Systems Software receives the instrument optical readings and performs analysis. The instrument then ejects the completed reagent card into the waste area for disposal.

The system includes a VITEK® 2 Compact instrument, a computer (workstation), and a printer. The software provided with the workstation includes analysis and limited data management programs. A bidirectional computer interface (BCI) may transfer results automatically to the user's laboratory information system (LIS).

See the List of Accessories section for additional accessories available for purchase.

A Quality Control System is available to track the quality control results of the test cards. The Advanced Expert System® (Clinical Use) is available to provide online, systematic validation of results and interpretation of resistant phenotypes found during susceptibility testing.

**Figure 8: VITEK® 2 Compact Workflow**




## Reagents

| Product Description |
|---|
| ANC Card (Anaerobic bacteria and coryneform bacteria identification) |
| AST-GN (Gram negative bacterial susceptibility) |
| AST-GP (Gram positive bacterial susceptibility) |
| AST-ST (*Streptococcus* species susceptibility) |
| AST-YS (Yeast susceptibility) |
| BCL Card (*Bacillus* identification) |
| CBC Card (Corynebacteria identification) |
| GN Card (Gram negative bacterial identification) |
| GP Card (Gram positive bacterial identification) |

| Product Description |
|---|
| NH Card (*Neisseria*, *Haemophilus* and other fastidious Gram negative bacteria identification) |
| YST Card (Yeast identification) |

## List of Accessories

| Product Description |
|---|
| VITEK® 2 Compact Cart |
| VITEK® 2 Compact Cart Top Mat |
| Cassettes |
| 145µL, Fixed Volume Pipette |
| 280µL, Fixed Volume Pipette |
| Uninterruptible Power Supply (UPS) |
| DENSICHECK® instrument |
| Printer |
| Power Conditioner |

## List of Consumables

| Product Description |
|---|
| Adjustable Volume Saline Dispenser |
| Saline (0.45%) |
| 0.5-250µL Pipette Tips |
| 100-1000µL Pipette Tips |
| DensiCHEK™ Plus Calibration Verification Standards |

## Technical Data and Specifications

⚠ **CAUTION: The VITEK® 2 Compact instrument is heavy. Use at least two people to move it. When lifting the instrument, it is essential to use only the handhold pockets on all four sides of the grey base pan to prevent severe damage to the instrument and/or personal injury.**

**WARNING**

⚠ **There is a potential for non-laser optical energy emanation from the optics which could result in personal injury or damage to the instrument.**

**Table 1: VITEK® 2 Compact Instrument General Characteristics**

| Parameter | Characteristics |
|---|---|
| Emission wavelengths | 660 nm, 568 nm, 428 nm LED |
| Cassette capacity | 10 cards per cassette |
| Vacuum (Filler) minimum level | 0.89 PSIA ± 0.06 PSIA |
| Incubator temperature | 35.5 °C ± 1 °C average |
| Incubator capacity | 15, 30, or 60 cards per Incubator (depending on configuration) |

## Dimensions

**Table 2: VITEK® 2 Compact Instrument Dimensions**

| Parameter | Characteristics |
|---|---|
| Height | (23.6 in.) |
| Width | 72 cm (28.3 in.) |
| Depth | 68 cm (26.8 in.) |
| Clearance<br>Minimum on left and right side<br>Minimum above | <br>11 cm (4.3 in.)<br>21 cm (8.3 in.) |

## Weight

**Table 3: VITEK® 2 Compact Instrument Weight**

| Parameter | Characteristics |
|---|---|
| Mass | Approximately 75 kg (165 lb) |

## Electrical Specifications

**Table 4: VITEK® 2 Compact Instrument Electrical Specifications**

| Parameter | Characteristics |
|---|---|
| Input voltage | 100/120/220/240 VAC at 50/60 Hz |
| Maximum input current | 4 amps @ 120 VAC or 2.2 amps @ 240 VAC |
| Nominal input current | 2.5 amps @ 120 VAC or 1.25 amps @ 240 VAC |
| Power | 300 watts nominal, 600 watts peak |
| Heat | 1025 BTU/hr (nominal) |
| Power cord | Detachable 3-wire with ground, per IEC 320 |

## Environmental Conditions

⚠ **CAUTION: Indoor usage only.**

⚠ **CAUTION: Do not install in direct sunlight. Strong light shining onto the front of the instrument can cause the optics to read incorrectly.**

***Note:*** *Benchtop should be level within ±3 degrees.*

***Note:*** *Instrument can be placed with its back against the wall, providing nothing is obstructing the instrument's fan air flow.*

**Table 5: VITEK® 2 Compact Instrument Environmental Characteristics**

| Parameter | Characteristics |
|---|---|
| Pollution degree | 2 (in accordance with IEC 664) |
| Overvoltage category | II (per IEC 664) |

*Temperature*

**Table 6: VITEK® Compact Instrument Temperature**

| Parameter | Characteristics |
|---|---|
| Ambient room temperature | 15 °C to 30 °C |
| Shipment and storage temperature | –20 °C to 55 °C |

*Humidity*

**Table 7: VITEK® 2 Compact Instrument Humidity**

| Parameter | Characteristics |
|---|---|
| Relative humidity | 20% to 80% (Non-Condensing) |

*Altitude*

**Table 8: VITEK® 2 Compact Instrument Altitude**

| Parameter | Characteristics |
|---|---|
| Minimum installation | –100 m sea-level |
| Maximum installation | 2000 m sea-level |

*Sound_Level*

**Table 9: VITEK® 2 Compact Instrument Sound Level**

| Parameter | Characteristics |
|---|---|
| Maximum | 55 dBa of continuous audible noise when measured at 1 meter from the instrument. |

## System Basics

The VITEK® 2 Compact instrument is an integrated system, combining the tasks of test card inoculation, incubation, and reading.

The components and functionality of the VITEK® 2 Compact instrument are best described by following a test card through a typical processing cycle. Processing CycleProcessing Cycle summarizes this cycle, and indicates where you can find more details.

**Table 10: Processing Cycle**

| Component | Processing Phase | See also |
|---|---|---|
| Cassettes | Sample preparation | The Cassettes |
| Filler Station | Filling | Filler Station |
| Cassette Load/Unload Station | Sample preparation | Cassette Load/Unload Station |
| Bar Code Reader | Sample preparation | Bar Code Reader |
| Sealer Station | Sealing | Sealer Station |
| Test Card Incubation and Reading | Test card analysis | Test Card Incubation and Reading |
| Card Ejection | Test card transport | Card Ejection |
| Waste Collection Station | Test card transport | Waste Collection Station |
| User Interface System | All process phases | User Interface System |

## Overview of Operation Elements

## Access Doors

**WARNING**

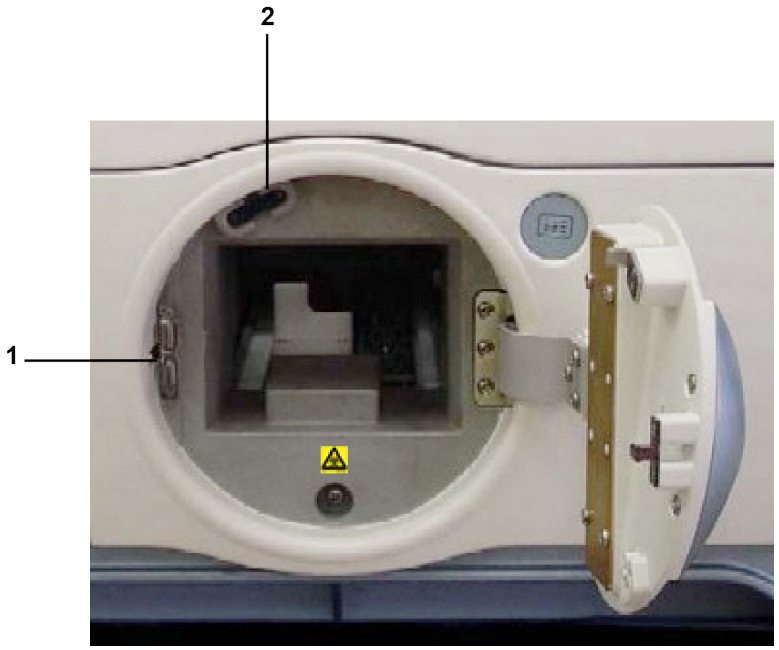
**Due to the nature of the instrument, the potential exists for personal injury or damage to the instrument from electrostatic discharge.**

**Figure 9: Access Doors**


1. Fill Door - Provides access to the Filler Station.
2. Top User Access Door - Opens only when the Front User Access Door is open, and provides access to the optics and carousel. This door lifts from the front (User Access Doors Open Position) and remains in the open position until the operator closes it.
3. Front User Access Door - Provides access to the optics, incubator, and a portion of the test card transport system.
4. Load Door - Provides access to the Cassette Load/Unload Station. A locking mechanism prevents opening of this door during operation.
5. Waste Collection Door - Provides access to the Waste Collection station where ejected test cards are removed from the instrument. The door is held in place magnetically and opens from the right (Fill Door, Load Door, and Waste Collection Door Open).

Locking mechanisms prevent the Load Door and Front User Access Door from opening during operation. The Top User Access Door cannot be opened when the Front User Access Door is locked.

**Figure 10: Access Door Locking Mechanism**




1. Optical Sensor - Senses when the door is opened or closed.
2. Door Latch and Lock - The latch holds the door closed, while the locking mechanism consists of a pin extending from inside the cabinet into the latch, locking the door.

**Figure 11: User Access Doors Open Position**

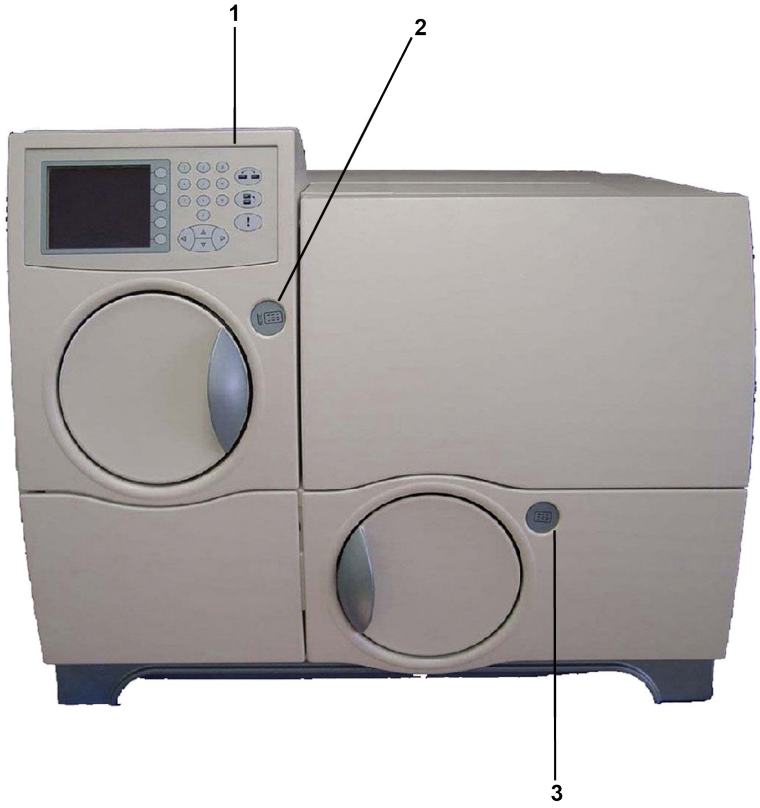

1. Top User Access Door
2. Front User Access Door

**Figure 12: Fill Door, Load Door, and Waste Collection Door Open**


1. Filler Station
2. Cassette Load/Unload Station
3. Waste Collection Bin

## Controls and Displays

**Figure 13: VITEK® 2 Compact Display**

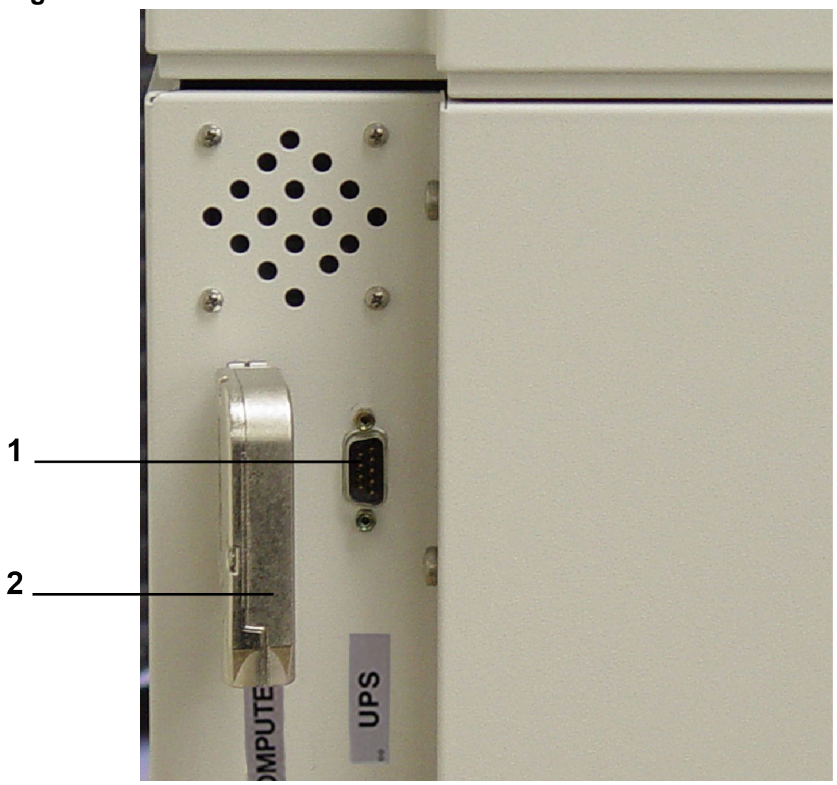



1. User Interface Screen and Keypad - This screen and keypad comprise the instrument User Interface system.
2. Fill Indicator LED - Alerts user of the fill status (see Fill Indicator Status table).
3. Load Indicator LED - Alerts user of the load status (see Load Indicator Status table).

## Exterior Connections

This section illustrates the exterior connections located on the VITEK® 2 Compact instrument.

**Figure 14: UPS and Data Connections**




1. UPS Connection - Located on the left side of the instrument. This cable connector port connects the instrument to an optional uninterruptible power supply (UPS). Through this port, the UPS notifies the instrument of a power failure, so it can begin appropriate procedures.
2. Workstation Connection - This connector port accepts the cable that connects the VITEK® 2 Compact instrument to the workstation computer.

**Figure 15: Power Switch and Power Cord Receptacle**


**1.** AC Power Switch and Cord Receptacle - This switch supplies power to the VITEK® 2 Compact instrument. The cord receptacle accepts the power cord that is connected to the main power supply. This is located on the right side of the instrument.

## The Cassettes

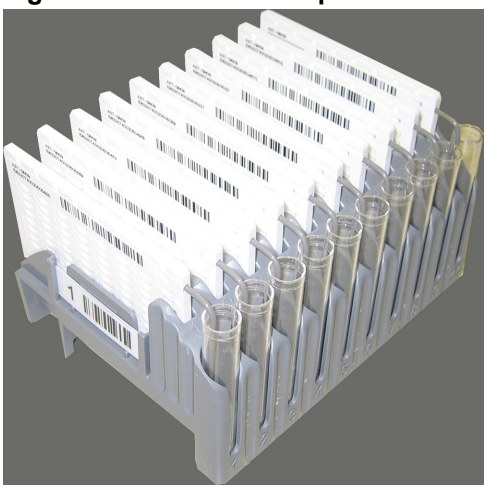
The cassette (Figure 16: VITEK® 2 Compact Cassette) is the main component of the test card transport system. It can hold up to 10 test cards with their inoculum test tubes.

**WARNING**

⚠ **The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for handling infectious agents. Extreme caution should be exercised when handling broken test tubes.**

- Test Card Slots – The top portion of a cassette is divided into 10 test card slots that can hold various combinations of VITEK® 2 Systems /> test cards.
- Test Tube Holders – The cassette has 10 wells that hold test tubes for inoculum.
- Cassette Base – The base of a cassette is custom shaped to fit into the Filler and the Cassette Load/Unload Stations and is designed with a hand grip located on the end of the cassette opposite the bar code.
- Cassette Bar Code ID – Located on the front side of the cassette. This bar code identifies the cassette to the instrument.

**Figure 16: VITEK® 2 Compact Cassette**



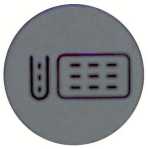
## Filler Station

The station consists of the fill door, fill chamber, and an indicator LED. At the Filler (vacuum) station, all of the test cards in a cassette are inoculated with the suspension contained in their corresponding test tubes.

**Figure 17: Filler Station**

For fill indicator status descriptions, refer to Fill Indicator Status..

**Table 11: Fill Indicator Status**

| Indicator Icon | Indicator Light (LED) | Status |
|---|---|---|
|  | OFF | Filler Idle |
|  | Solid Blue Arrow | Cards are Filling |
| | Blue Blinking Arrow | Filling Cycle Complete with No Errors |

| Indicator Icon | Indicator Light (LED) | Status |
|---|---|---|
|  | X (Red LED) | Filling Error |

***Note:*** *Clean the filler seal periodically. See for details.*

The Filler Station uses a vacuum chamber and pump. When the cassette is placed in this station, the operator initiates the filling cycle by closing the door and pressing the **Start Fill** button. The following occurs:

- The pump evacuates the air from the chamber. This forces the air inside each test card to escape through the transfer tube and bubble up through the suspension. The channels and wells inside of each test card are now at a vacuum.
- After a short period, the instrument slowly releases the vacuum. The increasing air pressure inside the chamber forces the suspension in each test tube through the transfer tube and into the channels and wells of the test card.

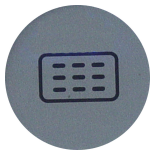
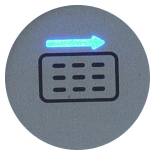
Various temperature and air pressure sensors in the system monitor the inside of the vacuum chamber. VITEK® 2 Compact instrument ensures proper test card fills by monitoring these parameters throughout the entire cycle and controlling the rate at which the vacuum is drawn and released.

## Cassette Load/Unload Station

The station consists of a load door with a locking mechanism and an indicator LED. Cassettes are loaded in the VITEK® 2 Compact instrument for test card processing and removed when test card processing is complete.

**Figure 18: Cassette Load/Unload Door – Load Door**

**Table 12: Load Indicator Status**

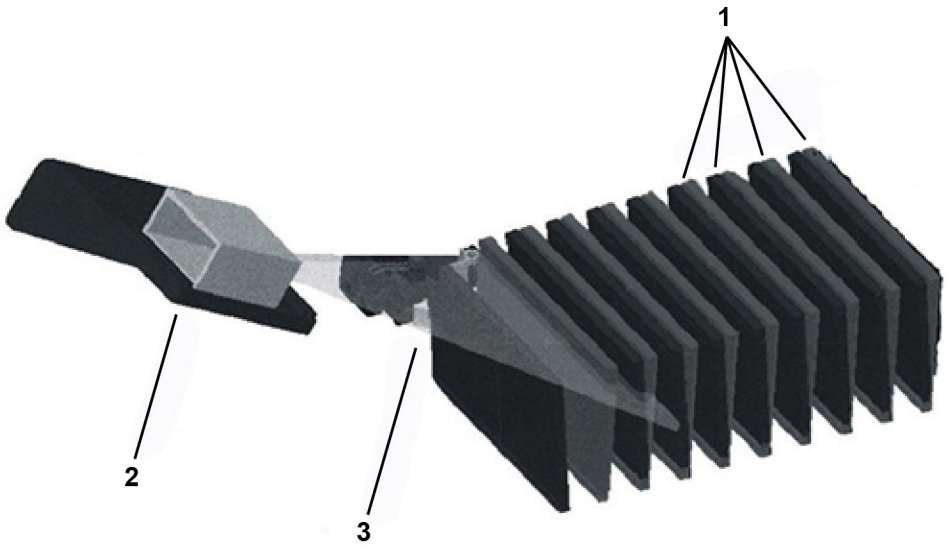
| Indicator Icon | Indicator Light (LED) | Status |
|---|---|---|
|  | Off | Either the loader is idle and the door is locked, or it is ready to load a cassette and the door is unlocked. |
|  | Solid Blue Arrow | Cards are processing in the station and the cassette load door is locked and cannot be opened. |
| | Blue Blinking Arrow | The cassette is ready to be removed from the station. The cassette load door is unlocked. When you remove the cassette and close the door, the indicator LED turns off. |
|  | X (Red LED) | Indicates a processing error. |

**CAUTION: The VITEK® 2 Compact test card transport system stops while the cassette load door is open. Be sure to close the door after loading or unloading a cassette to prevent the test card transport from stopping.**

## Bar Code Reader

After the user loads the cassette into the instrument, the bar code reader scans the information encoded on the bar code label found on each cassette and test card.

**Figure 19: Bar Code Reader**




**1.** Bar Codes
**2.** Bar Code Scanner
**3.** Beam

The following information is linked to the test card bar code:

- Test card type - For example, a Gram-Negative Susceptibility test card.
- Test card expiration date - This date is transferred to the workstation, and appears on the laboratory report.
- Test card lot information and sequence number - The card bar code includes the test card's lot number to provide manufacturing traceability. The sequence number uniquely identifies a test card.

In addition to reading the bar codes on the cards, the reader also scans the bar code located on the cassette itself. This bar code identifies the cassette to the instrument as cassette one through nine.

⚠ **CAUTION: When handling test cards, make sure you do not deface the bar code in any way.**

***Note:*** *The bar code reader inside the instrument has no lasers and is certified to IEC60825-1 LED Safety: Class 1.*

## Sealer Station

⚠ **CAUTION: The sealer station contains a wire that is heated during the sealing operation. Do not attempt to reach into the Load Door or User Access Doors during the sealing operation.**

The Sealer station is located inside the Cassette Load/Unload Station. It completes the sample preparation functions that take place inside the VITEK® 2 Compact instrument. This is accomplished by heat-sealing the transfer tube to seal off the contents of the test card.

A heated wire comes in contact with each transfer tube. The plastic tube melts, causing the remainder of the transfer tube to drop into the test tube. The portion that remains attached to the test card is sealed by the melting plastic. The instrument produces small amounts of fumes during sealing, which is non-toxic.

***Note:*** *The sealer leaves a stub that remains from the transfer tube. The stub may be up to 1.5 mm long and does not affect normal operations.*

## Test Card Incubation and Reading

After test cards are sealed and read by the bar code reader, they are ready for incubation and reading cycles. The test card transport system moves the cassette into position for a mechanism, called the card loader, to place each test card into a slot on a carousel, where it remains throughout the incubation period.

### *Carousel*

The Incubator (Incubator with Cover), with the cover in place, contains a Carousel with a maximum capacity of 15 to 60 test cards depending on the option purchased. During their time in the carousel, the test cards are incubated at an average temperature of 35.5 °C.

***Note:*** *Figure 1 is shown with the optional thermometer (black disc). This thermometer can be independently calibrated to NIST traceable standards and offers a method of checking temperature independent from the internal devices. Instructions for use of this instrument are included in Manual Temperature Check (Optional).*

**Figure 20: Incubator with Cover**

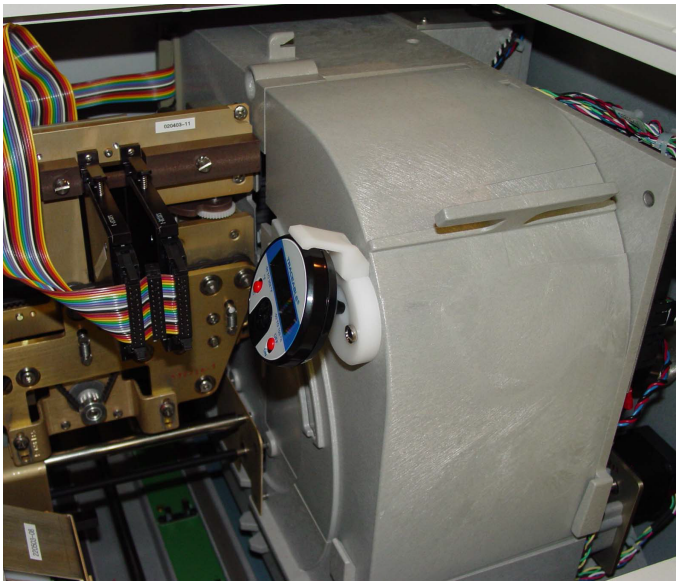
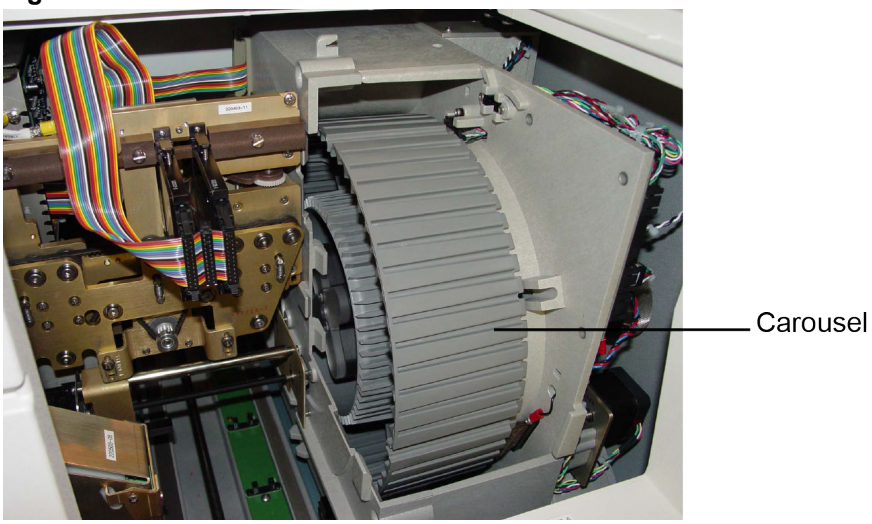


**Figure 21: Incubator without Cover**




As the carousel rotates, each test card moves into the reading position every 15 minutes. The reader head conveys the test card through the optics stations then back to the carousel, where it continues to incubate until its next read cycle. After the reading cycles are completed, the instrument ejects the cards into the waste collection station.

***Note:*** *The carousel is divided into four sections so that it can be easily removed for periodic cleaning. See Cleaning the Carousel.*

## Transmittance Optics

VITEK® 2 Compact instrument performs its identification and susceptibility analyses by continually monitoring the growth and activity of organisms inside the wells of the test cards.

The transmittance optics uses visible light to directly measure organism growth. These optics are based on an initial light reading of a well before significant growth has begun. Light transmittance samplings of the same well every 15 minutes measure organism growth by how much light is prevented from going through the well.

The optics use light emitting diodes (LEDs), which produce light at the appropriate wavelengths, and silicon photodetectors to capture the transmitted light. This system is self-calibrating.

There are two types of transmittance optics assemblies that can be installed on the VITEK® 2 Compact instrument:

- TX1 and TX3 – Pair of separate transmittance optics modules that are hinged on the bottom and held in place by spring-loaded levers (TX1 and TX3 Transmittance Optics).
- Unified Transmittance Optics – A module that is hinged by a magnetic latch (Unified Transmittance Optics).

**Figure 22: TX1 and TX3 Transmittance Optics**

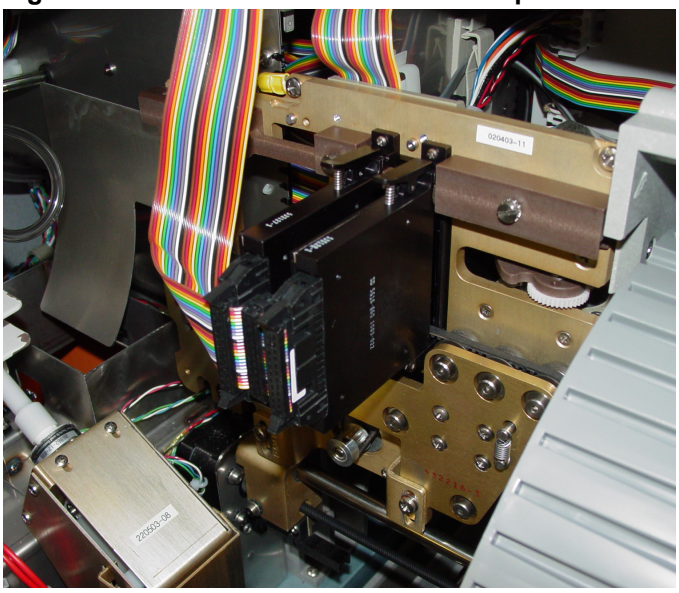
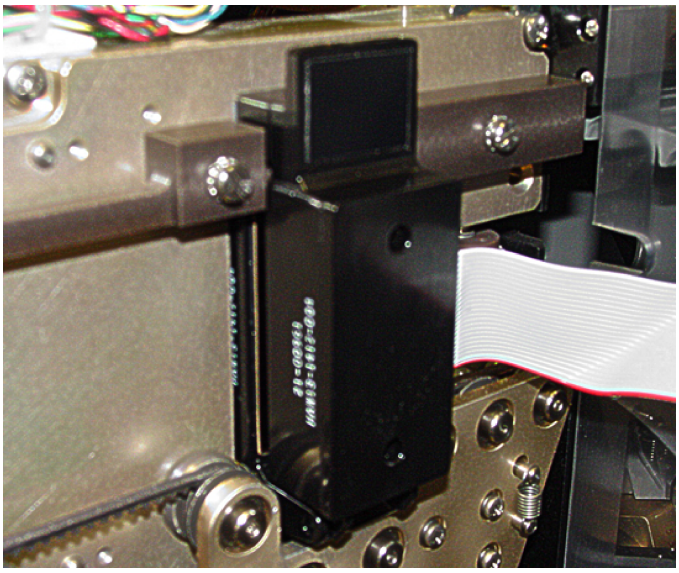


**Figure 23: Unified Transmittance Optics**



***Note:*** *Clean the optics periodically. See Cleaning the Optics (Power Off) for further details.*

## Card Ejection

The card ejection function permanently removes test cards from the carousel after their testing is complete or deleted/terminated by the user. The mechanism that performs this function is the same drive belt system that moves the test cards through the reader. Instead of returning to the carousel, an ejected test card continues on to the waste collection station.

The amount of time that cards are held before being ejected automatically from the carousel is set by an option in the ID and AST Configuration window in the VITEK® 2 Systems software. You can also eject test cards at any time using the manual ejection function. See **Ejecting Cards From The Instrument** in the *VITEK® 2 Systems Software User Manual* for more information.

**CAUTION: Do not reload ejected test cards into the VITEK® 2 Compact instrument. Make sure that all test card processing is complete before ejecting a test card.**

## Waste Collection Station

The card ejector removes test cards that have completed testing from the carousel. These test cards are collected in the Waste Collection bin for removal from the instrument and disposal.

**Figure 24: Waste Collection Station**

The waste collection bin (Waste Collection Station) holds up to 60 test cards. The instrument counts test cards as they fill the bin, and sends a message to the instrument interface screen when the station is full. A sensor in the station detects when the bin is emptied or if the bin is missing.

***IMPORTANT:*** ***Do not remove the waste collection bin without disposing of the cards. The instrument assumes cards are emptied from the waste collection bin when it detects the bin is missing then replaced.***

Access the Waste Collection station by opening the waste collection door on the front of the instrument. Keep the waste collection station door closed except when removing test cards from the station.

Periodically remove the waste collection bin for cleaning. See Cleaning the Waste Collection Bin.

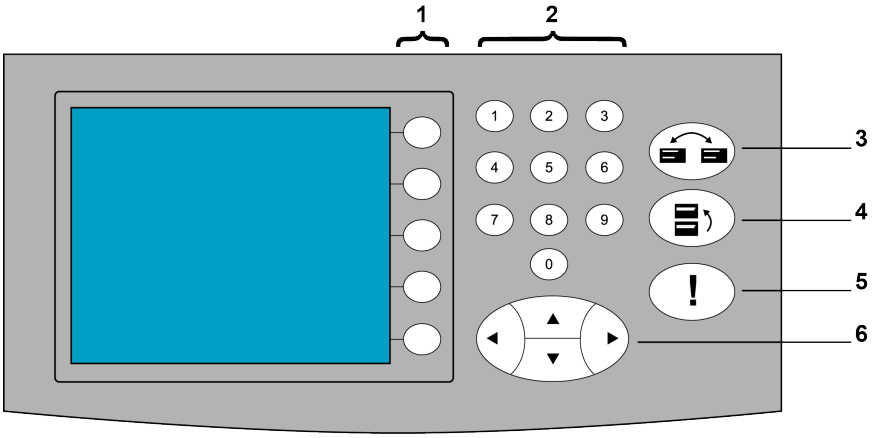
## User Interface System

Throughout the entire processing cycle for test cards, communication between the user and the instrument is essential. The VITEK® 2 Compact User Interface System provides the means of that communication.

## *Keypad and Screen*

A keypad and screen are located on the front of the VITEK® 2 Compact instrument. The system sends messages about the instrument operation, disposables, and errors that are displayed on the screen. Use the keypad to respond to instructions, send commands, and perform other functions (User Interface).

**Figure 25: User Interface**




1. Function Buttons - Select menu options or other specified functions.
2. Numeric Keys - Enter a number onto a screen.
3. Status/Menu Key - Select either the Status screen or Menu screen or to access the Status screen from any screen.
4. Previous Screen Key
   - Exit from a screen or function to its menu
   - Return to a previous screen in a function
   - Go from a sub-menu to its previous menu
   - Go from the Main menu to the Status screen
5. Message Key - Access the Error Message queue. This key is also used to go between the Detailed Error Messages and List of Error Messages screens.
6. Arrow Keys
   - Scroll a screen or menu.
   - Move the cursor on some screens.

***Note:*** *When Arrow keys are active, their icons appear on the display.*

## *Menu System*

All of the functions used on the VITEK® 2 Compact instrument are available through the menu system. The system is composed of a Main menu, five menu options with 20 sub-menus.

**Figure 26: VITEK® 2 Compact Main Menu**

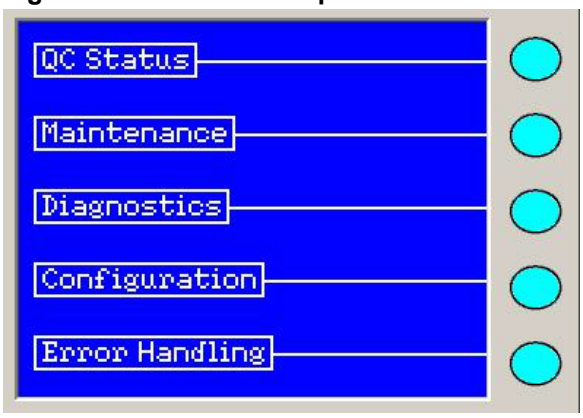
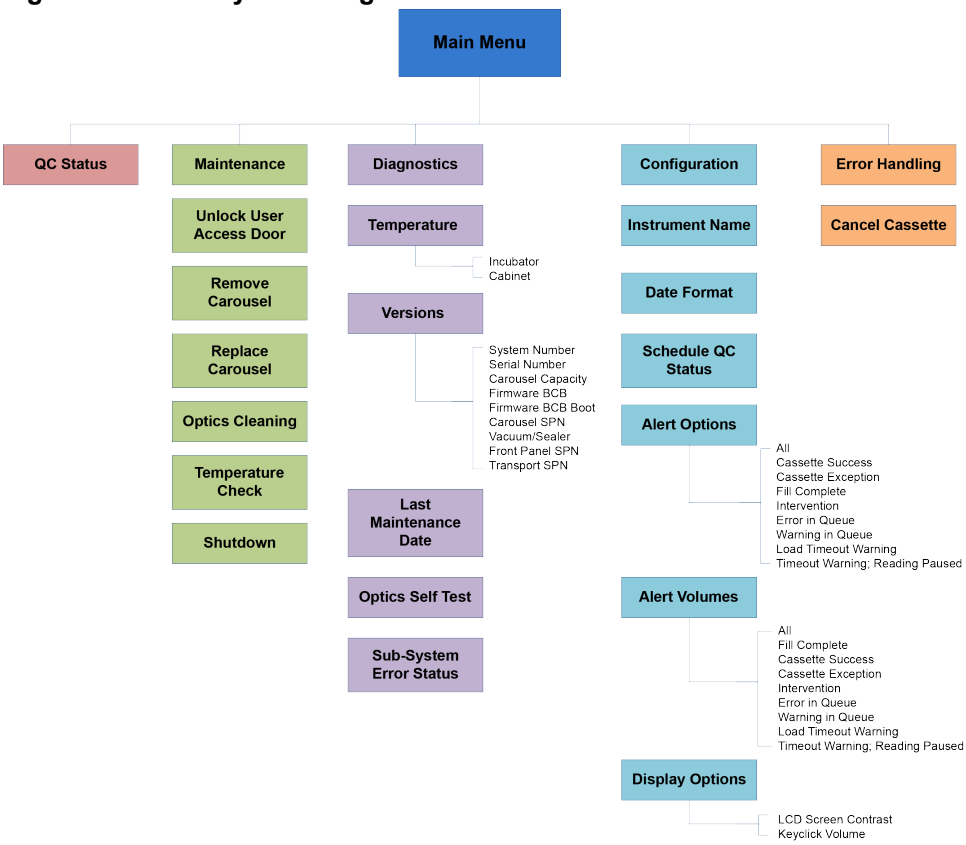



**Figure 27: Menu System Diagram**



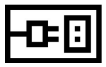

## *General Status*

The General Status portion of the screen uses various icons to display messages that alert the user to these general conditions. Users should become familiar with these indicators to ensure smooth operation of the instrument.

***Note:*** *Some of these indicators or icons are only visible on the screen when the function they represent is active.*

## Information and Warning Indicators

**Table 13: Information and Warning Indicator Icons**

| Icon | Description |
|---|---|
|  | Door Opened Indicator<br>At least one of the following doors is opened:<br>• Top User Access Door<br>• Front User Access Door<br>• Waste Collection Door |
|  | Virtual Cassette<br>This icon displays when the instrument has successfully read the bar codes of the cassette and all of the cards in a Virtual Cassette workflow. |
|  | Cassette Number<br>This icons displays after successful bar code reading and the cassette number is known. |
|  | UPS Status<br>UPS is present, and there is a power failure. |
|  | UPS Battery<br>UPS is present, and the battery is low. |
|  | Waste Collection Bin Not Present<br>The waste collection bin is not present in the instrument. |
|  | Waste Collection Bin Level<br>This icon indicates the level of cards in the waste collection bin. When the waste collection bin is replaced, the icon displays an empty waste collection bin. |
|  | Host Communication Failure<br>This icon indicates that the Host/Workstation Computer is not communicating with the instrument. |
|  | Available Slots<br>This icon indicates the number of available slots in the carousel. The number range is zero to 15, zero to 30, or zero to 60 depending on the instrument model.<br>The **Available Slots** field indicates the number of unoccupied slots in the instrument. You can load one or more cassettes containing up to that number of test cards. If you load more than that number, the instrument will not process some of the test cards unless additional slots become available by the time the test cards reach the carousel. |
|  | Cassette Presence<br>The cassette is present in the Loader Station. |

| Icon | Description |
|---|---|
|  | Carousel Quad Missing<br>At least one quad is missing in the carousel. |
|  | New Error/Warning Indicator<br>The indicator to the left of the Instrument Status displays if there are messages (both errors and warnings) in the Error Message Queue that the user has not viewed. This indicator moves from side to side on the screen. The instrument sounds an alert and/or the screen blinks (depending on the configuration settings), if there is an error or warning in the queue. Press the **Message Key (!)** to view the Error Message Queue. Message Queue Indicator (Warning Mode) displays the message queue indicator's warning icon (bottom left). |
|  | Unauthorized Indicator<br>When the instrument operation is not authorized, due to 21 CFR11, a small unauthorized indicator displays on the upper-right corner of the screen. When the instrument is in this state, several functions and screens are not accessible and a message appears if the user attempts to access them.<br>For more information, refer to the *VITEK® 2 Systems Software User Manual*. |

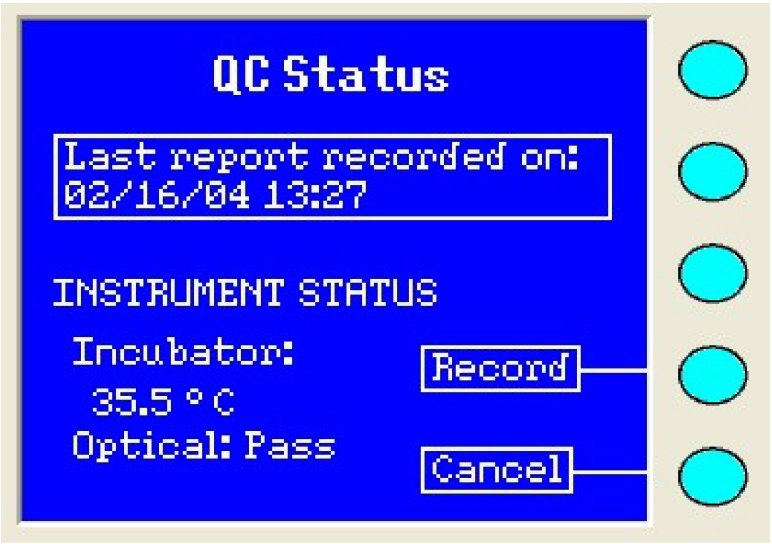
**Figure 28: Message Queue Indicator (Warning Mode)**


## *QC Status*

This function is used to view the current status report of the incubator temperature and the optics (QC Status Screen). This report can be manually sent to the workstation at any time.

From the main menu, select **QC Status**.

**Figure 29: QC Status Screen**




The information shown on the screen is defined as follows:

- Last report recorded on – Displays the date and time that the previous QC Status was recorded.
- Incubator – Displays the current carousel temperature in degrees Celsius.
- Optical – Displays the current status of the transmittance optical systems.
- Record – Press the function button to transmit the displayed information to the workstation PC.
- Cancel – Press this function button to exit from QC Status.

***Note:*** *The **Previous Screen** key or **Status/Menu** key can also be used to exit from QC Status.*

### *Status Screen*

The Status screen is used more often than any other screen in the VITEK® 2 Compact user interface. Since it is basic to the workflow, the Status screen is easy to display and, in many cases, the interface displays it automatically. This section details the various icons and informational messages that you see while operating the instrument.

There are three ways to display the Status screen:

- The Status screen automatically displays at the end of the instrument's power-up initialization process.
- Press the **Status/Menu** or **Previous Screen** key from the Main menu.
- Press the **Status/Menu** from any menu or error message queue screen.

### *Instrument Status Field*

The Instrument Status field appears at the bottom of the Status screen.

**Figure 30: Instrument Status Field**


The white section at the bottom of the screen may contain three types of information:

- New Error/Warning Indicator (**!**) - See New Error/Warning Indicator in Information and Warning Indicator Icons.
- Instrument Status (for example, **OK**).
- Current Time of the day in 24-hour format - This time is based on Host/Workstation Computer time (for example, 10:35).

The Instrument Status field displays the following:

- **OK** - All of the subsystems in the instrument are working normally, and the instrument is ready to accept test cards for processing.
- **Warming** - This status displays after instrument startup or any time the incubation temperature in the reader station has not reached its specified temperature. The instrument can still process cards when the status **Warming** is active.
- **Error** - The instrument is in an error state and needs user intervention or service. Refer to Troubleshooting and Instrument Error Codes when the status **Error** is active.
- **Maintenance** - At least one maintenance item is initiated, such as a carousel section was removed for cleaning. In this case, test card processing cannot resume unless all carousel sections are replaced.
- **Intervention** - The **Intervention** warning displays if there is an error during power-up or card cassette processing that needs the user's immediate attention. Refer to Intervention Screen for details.

## Filler Status

The Filler Status includes a Filler Status indicator on the left and a possible Detailed Message/Action on the right. If there are any warnings or errors related to filling the cards, an Intervention screen appears.

### *Idle*

When the display reads **Filler: Idle**, the instrument is ready to start the fill cycle.

The **Start Fill** function is shown on the upper-right side of the screen. Press the **Start Fill** key to initiate the fill cycle.

**Figure 31: Filler Ready Screen**


*Filling*

The screen displays **Filler: Filling** when the filling process has started. The **Filling-in-progress** indicator displays (Filling-in-progress Indicator) to indicate filling.

**Figure 32: Filling-in-progress Indicator**

This indicator overwrites the **Start Fill** box, and tells the user the cards are filling; it does not show the actual progress or stage of the filling cycle. When the entire bar is filled, it repeats from the beginning until the fill cycle is complete.

⚠ **CAUTION: If the individual cards are exposed to multiple fill cycles. These cards must be discarded as the test results will be inaccurate.**

*Complete*

The **Filler: Complete** indicator shows that the fill cycle is done, and the cassette is ready for transfer into the Loader. This **Filler: Complete** indicator displays regardless of fill success or failure, and the instrument provides an alert to indicate that the fill is complete. This alert can be audible and/or blinking, depending on the custom settings.

*Not Ready*

When the **Filler: Not Ready** indicator displays, the instrument cannot start the filling cycle, because either the Filler is not ready or there is a fault condition in the Filler or in the instrument.

Reasons for a **Not Ready** filler status include:

- Instrument Overall Status is in **Error** state.
- Instrument Overall Status is in **Maintenance** state.
- 21 CFR is enabled and the workstation has timed out and logged out the user. User must login to continue.

**WARNING**

**Biohazardous spills can occur inside the VITEK® 2 Compact instrument. All organism suspensions should be considered as potentially infectious.**

## Loader Status

The Loader Status sub-screen is comprised of two parts: Loader Status on the left and a display area for messages on the immediate right. Based on the workflow, under error-free conditions, the Loader Status proceeds as follows:

**Empty Status** > **Transfer Cassette** > **Bar Code Reading** > **Sealing** > **Loading into Carousel** > **Remove Cassette**

If there are errors during processing of cassette in the Loader an Intervention screen appears. The messages listed below display during normal instrument operation.

### *Empty Status*

When there is no status in the **Loader** field, the loader is not ready for the user to load a cassette, and the loader door is locked.

### *Transfer*

When the **Loader: Transfer** message displays, the filling cycle is complete and the user should transfer the cassette from the Filler Station to the Loader Station. A maximum of 10 minutes is allowed to transfer the cassette. After this time period, the system no longer accepts the cards. This countdown is visible in the upper-right corner of the screen.

**CAUTION: The instrument provides an alert to indicate a Load Timed Out Warning (if less than one minute left). If the time has expired, an intervention message appears to alert the user to discard the test cards.**

### *Reading Bar Code*

When the **Loader: Reading Bar Code** message displays, the cassette is in the loader, and the instrument is processing the cassette and checking the readability of all bar codes.

The instrument provides an alert for **Cassette Success**, if the cassette setup is OK, as well as a unique alert for **Cassette Exception** if the cassette setup has non-correctable errors.

### *Sealing*

The **Loader: Sealing** message indicates that the instrument successfully read the bar codes, and the instrument continues to process the card cassette for sealing.

### *Loading Card*

The **Loader: Loading Card** message means that the sealing is complete, and the instrument is loading cards into the carousel.

### *Remove*

When **Loader: Remove** message displays, the instrument has finished processing the cards in the cassette, and the cassette is ready for the user to remove. However, if there are still cards remaining in the cassette, an error condition has occurred and the user was not able to fix the error.

### *Countdown Timer*

A countdown timer in the upper, right corner of any screen displays in the Start Fill area and indicates the total number of minutes and seconds left for the user to transfer the cassette from the Filler to the Loader. The continuation of this counter is used when any other Intervention Message displays.

## Uninterruptible Power Supply (Optional)

If a power failure occurs, a device called an Uninterruptible Power Supply (UPS) can provide power to the instrument. The UPS is an optional device and is highly recommended. If power is lost, the UPS uses a battery to continue to supply power to the instrument.

The UPS notifies VITEK® 2 Compact of a power failure. The instrument then:

- Initiates a Power Failure error message and displays a Power Fail icon on the main status screen.
- Continues processing test cards in the carousel.
- Continues to support the card transport system's previously filled cassettes, but does not allow you to fill new cassettes.

***IMPORTANT: If the UPS battery fails, the instrument stops processing.***

# 4 System Installation and Configuration

***IMPORTANT:*** ***The initial installation is performed by bioMérieux Service Engineers. Please refer to Technical Data and Specifications for instrument specifications.***

The VITEK® 2 Compact instrument can be configured in a number of different ways to suit your laboratory's workflow and preferences. The configuration options can be set or changed at almost any time using the main menu on the user interface.

Use these following guidelines to set basic operating parameters:

- Read the descriptions contained in this chapter for each option.
- Evaluate the effect that an option would have on your workflow and decide how to set the option.
- Set the options using procedures.
- Operate the system to validate the settings.
- Change any option as required.

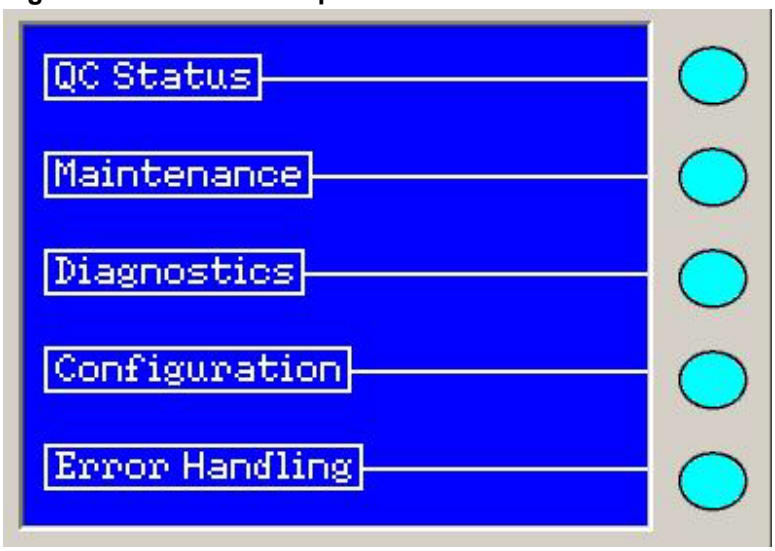
## Configuration

There are six configuration options and 20 sub-menus, all of which can be accessed through the Configuration menu from the VITEK® 2 Compact user interface:

- Instrument Name
- Date Format
- Schedule QC Status
- Alert Options
- Alert Volumes
- Display Options

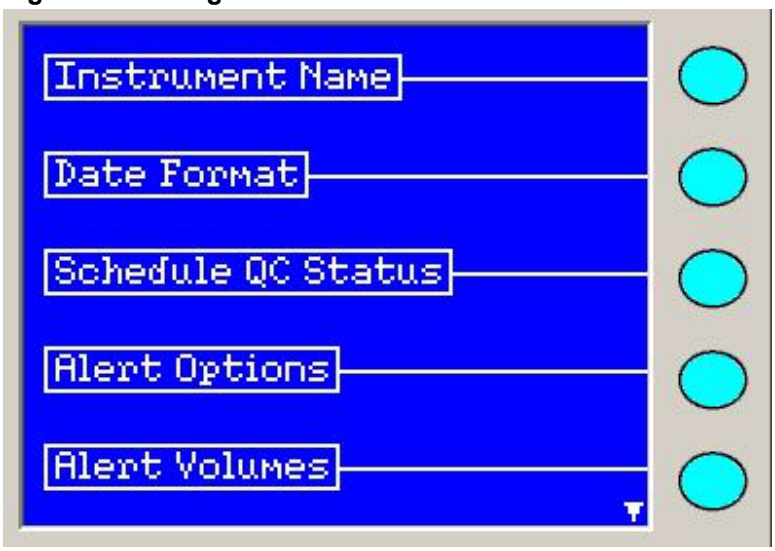
1. Press the **Status/Menu** key to access the Main menu screen.

**Figure 33: VITEK® 2 Compact Main Menu Screen**




2. Select **Configuration**.

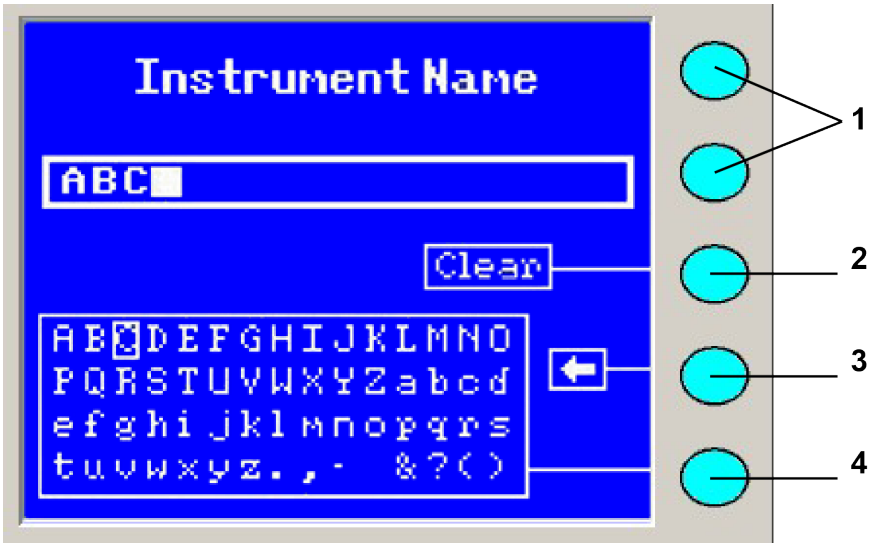
**Figure 34: Configuration Menu Screen**




## Instrument Name

Use the **Instrument Name** option to name a VITEK® 2 Compact instrument. The instrument name is helpful in those laboratories with more than one instrument. The instrument name also displays in the workspace area of the workstation and printed cassette reports.

**Figure 35: Instrument Name Screen**




1. Key is Non-Functional
2. Deletes All Characters
3. Insert Key
4. Backspace Key

The suggested names for VITEK® 2 Compact instruments are Instrument 1, Instrument 2. By assigning each instrument a different name, you can view a list of test cards in the workstation by the instrument in which they are being processed.

### *Setting Instrument Name*

Character sets can include any of the characters shown on the character selection display, plus the 10 digits from the keypad. The maximum number of characters allowed is 20. Leading or trailing spaces are not allowed.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Configuration** > **Instrument Name**.
3. Select **Clear** to ensure that the field is ready to accept new characters.
4. Select a letter using the **Arrow** keys and then press the **Insert** key for the character box. If you make a mistake, press the **Backspace** key.
5. To select a number, use the numeric keypad.

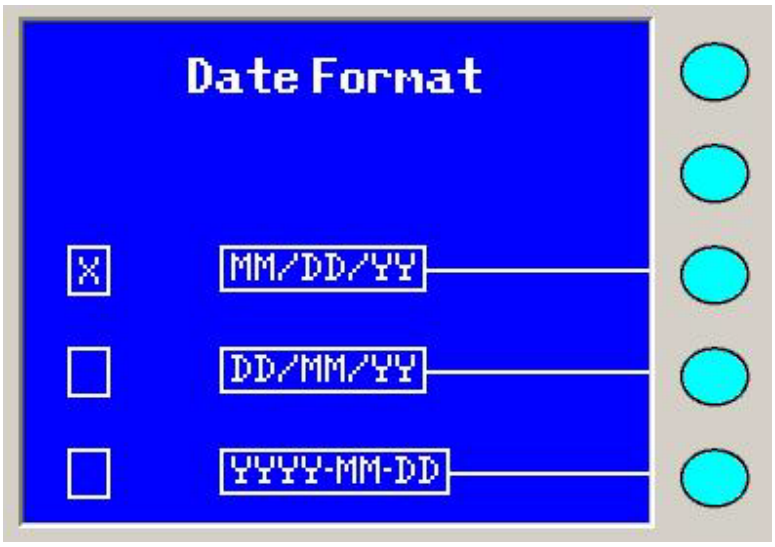
   The instrument automatically saves the Instrument Name when you leave the Instrument Name screen by pressing the **Previous Screen**, **Status/Menu**, or the **Message** key.

## Setting Date Format

Use the date format option to configure how the date appears (for example, MM/DD/YY or YYYY/MM/DD).

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Configuration** > **Date Format**.
3. Press the function key next to the date format you want to use. An **X** appears in the box next to that format.

**Figure 36: Date Format Screen**




4. The instrument automatically saves this format when you exit the screen by pressing the **Previous Screen**, **Status/Menu**, or **Message** key.

## Schedule QC Status

The VITEK® 2 Compact instrument continuously monitors two parameters:

- Carousel Incubator Temperature
- Optics Systems

By using the QC Status, you can manually record a QC Status at any time. See QC Status for further information.

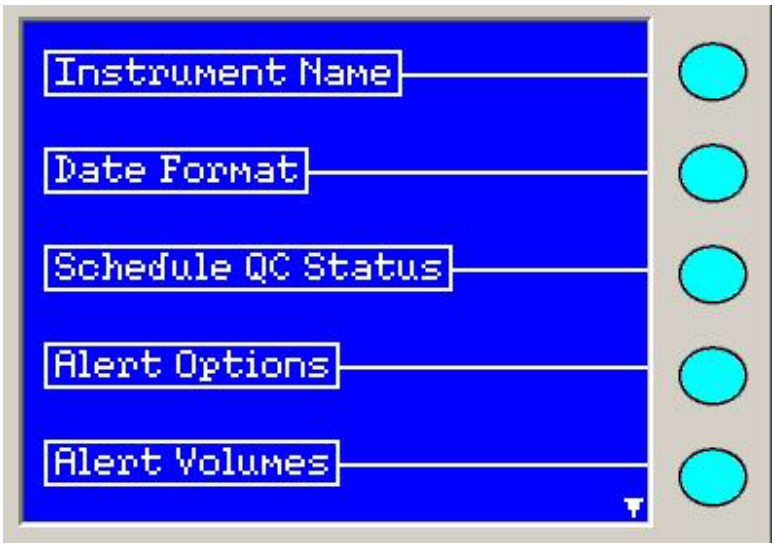
You can also schedule up to three times a day for the system to record a QC Status report.

After the instrument records the QC Status, it sends the information to the workstation, which records the data along with the date and time the data was recorded.

The time fields operate on a 24-hour clock. The times for Schedule A, B, or C are disabled until you schedule the QC Status.

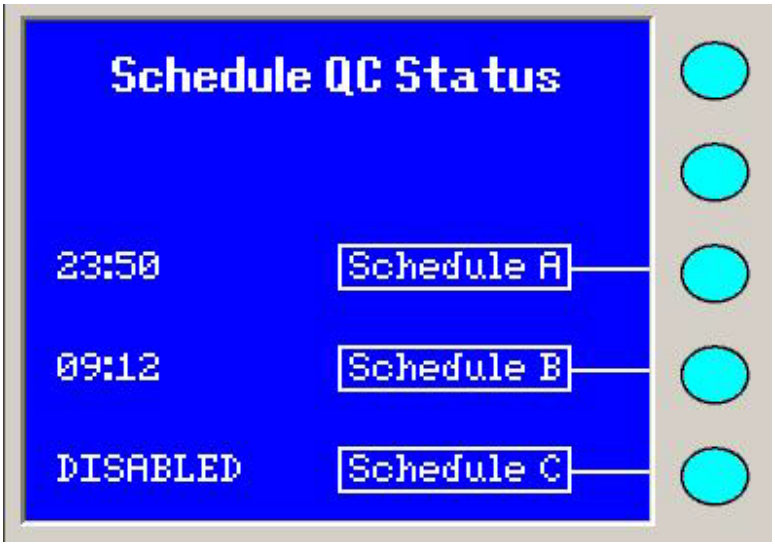
1. Press the **Status/Menu** key access the Main menu screen.
2. Select **Configuration** > **Schedule QC Status**.

**Figure 37: Configuration Menu Screen**



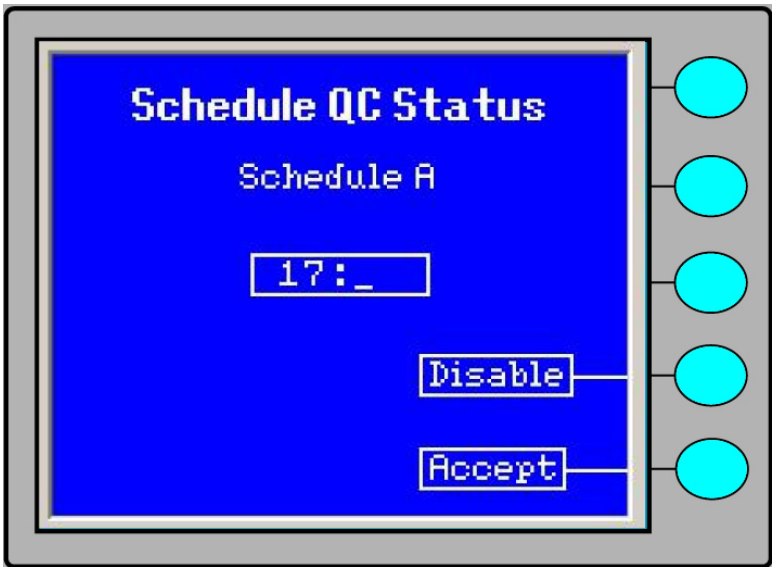

The following screen appears. Schedule QC Status Screen shows Schedule C as disabled.

**Figure 38: Schedule QC Status Screen**




3. By pressing the corresponding function button, you are prompted to enter a time. Once the time is entered, Schedule C is enabled.
4. To set the time for Schedule A, select **Schedule A**.
5. Use the number keypad to set the hour, then the minutes.

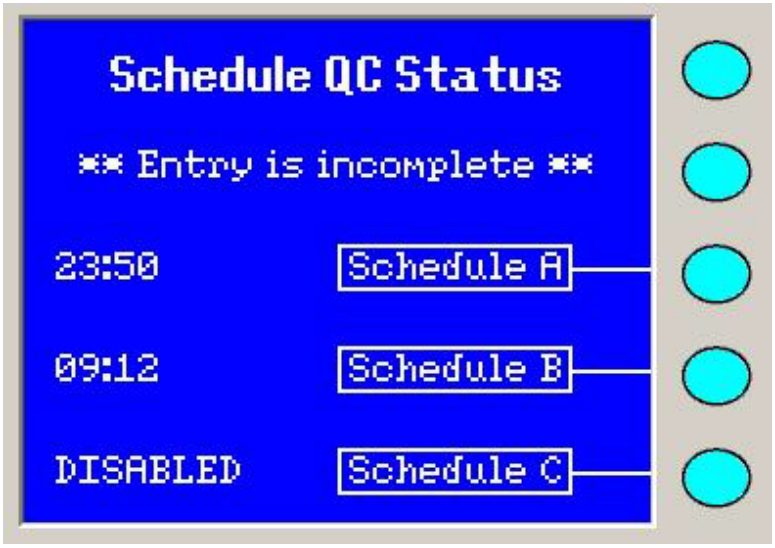
**Figure 39: Set Schedule QC Status Screen**




6. Press **Accept** to save the time and return to the previous screen.
7. To set the time for **Schedule B** and **Schedule C**, repeat Step 4 through Step 6.
   - To disable any schedule, follow Step 4 and Step 5, then select **DISABLE**.
8. To exit the Schedule QC Status screen, press the **Previous Screen** key or **Status/Menu** key.

***Note:*** *If you enter an incomplete schedule (for example, you entered the hour, but not the minute), the system restores the previous schedule, but does not save the new schedule. An error message appears on the first screen (Schedule QC Status Error Screen).*

**Figure 40: Schedule QC Status Error Screen**




The instrument automatically saves the schedule when the user leaves the second screen by pressing the **Previous Screen**, **Status/Menu**, or **Message** key.

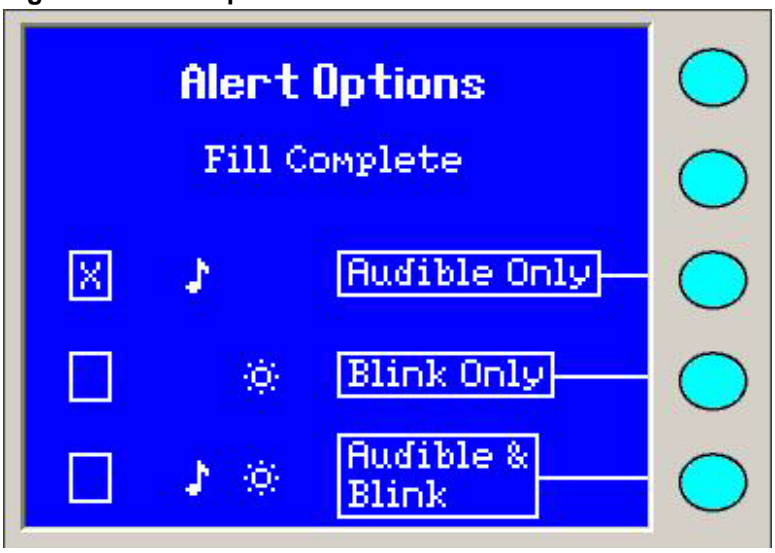
## Alert Options

The instrument gives an audible and/or visual alarm to alert you to an error condition or warning.

**Table 14: Alert Option Icons**

| Icon | Description |
|---|---|
|  | **Audible Only** (Default) |
|  | **Blink Only** |
|  | **Audible and Blink** |

**Figure 41: Alert Options Screen**




***Note:*** *Blink is the blinking of the entire LCD display.*

## *Alert Categories*

You can customize individual alert categories. An intervention, for example, might be set at a high volume, so the user knows attention is required.

Alert categories include:

- **All** – All of the categories use the same alert option or alert volume.
- **Cassette Success** – Cassette setup is okay and accepted by the instrument.
- **Cassette Exception** – Cassette setup has non-correctable errors.
- **Fill Complete** – Filler cycle is complete.
- **Intervention** – Cassette setup has correctable errors or any other intervention that needs immediate intervention.
- **Error in Queue** – New errors are present in the Error Message Queue.
- **Warning in Queue** – New warnings are present in the Error Message Queue.
- **Load Timeout Warning** – Cassette load timeout warning; less than one minute remaining to transfer the cassette from the Filler Station. to the Cassette Load/Unload Station.
- **Timeout Warning: Reading Paused** – Four minutes exceeded. Occurs if reading cycle is paused for more than four minutes, because the User Access Doors were manually unlocked or an optic cleaning is being performed.

Refer to Alert Volumes for further details.

## *Setting Alert Options*

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Configuration** > **Alert Options**.
3. Use the **Up/Down Arrow** keys to view additional categories.

**Figure 42: Main Alert Options Screen**


4. Select a category using the **Function** keys. Three options display on the next screen. The **X** mark indicates the current alert option.
5. The instrument automatically saves this option when you exit the screen by pressing the **Previous Screen**, **Status/Menu**, or **Message** key.

## Alert Volumes

Use the **Function** keys to select a category for volume configuration. The default setting for the alarm volume is at a comfortable level. Use this option to make appropriate adjustments as required.

### *Setting Alert Volumes Screen*

To access the Alert Volumes screen.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Configuration** > **Alert Volumes**.
3. Use the **Up/Down Arrow** keys to view additional categories.

**Figure 43: Main Alert Volumes Screen**


4. Select a category using the **Function** keys.

   Alert Volumes Screen, demonstrates the Alert Volumes — Warning in Queue screen. Use the **Left/Right Arrow** keys to adjust the volume of the audible alarm higher or lower to account for laboratory conditions. Whenever the right or left arrow is pressed, the system sounds the alert at the selected volume.

   If you select the **Blink Only** option for a category, the system displays a warning message (Alert Volumes Screen). However, the user can still set the volume.

**Figure 44: Alert Volumes Screen**


The instrument automatically saves the configuration when you leave this menu screen by pressing **Previous Screen**, **Status/Menu**, or **Message** key.

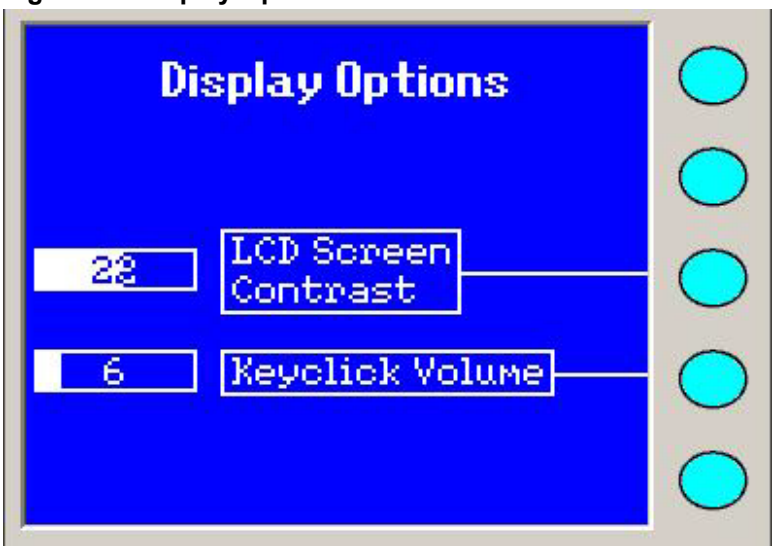
## Display Options

The VITEK® 2 Compact user interface screen uses an LCD display. You can control the amount of background contrast on the display by configuring the Display Options.

### *Setting Screen Contrast*

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Configuration** > **Display Options** > **LCD Screen Contrast**.

**Figure 45: Display Options Screen**




3. Change the range value by pressing the **Left/Right Arrow** keys. The bar graph and the numeric value change, and the actual parameter changes in response to this action.

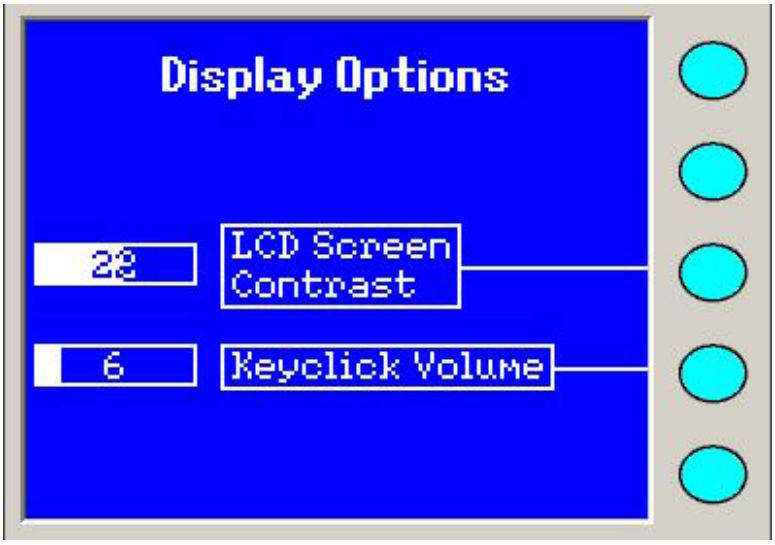
> ⚠ **CAUTION: Do NOT set the screen contrast to either end of its available range. Doing so may make the screen unusable.**

## *Setting Keyclick Volume*

The VITEK® 2 Compact instrument interface uses a touchpad type of keypad. It sounds an audible click when you press each key. You can adjust the volume of the click to account for laboratory conditions.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Configuration** > **Display Options** > **Keyclick Volume**.

**Figure 46: Display Options Screen**




3. Change the range value by pressing the **Left/Right Arrow** keys. The bar graph and the numeric value change, and the actual parameter changes in response to this action.

# 5 Workflow and Instructional Procedures

> ⚠ **CAUTION: Pace yourself of physical movements during periods of high workload to reduce fatigue and the potential for repetitive motion injury.**

There are three methods for processing test cards:

- Virtual Cassette - The user enters the cassette information into the workstation computer prior to loading the cassette into the instrument.
- Setup Tests Post Entry (Cassette Only Mode) - The user loads the cassette into the instrument prior to entering the cassette information into the workstation computer.
- VITEK® 2 FLEXprep - The user enters the cassette information into the VITEK® 2 Systems Web application prior to loading the cassette into the instrument.

***IMPORTANT:*** ***To ensure optimal performance, control the time between filling and introduction into the Cassette Load/Unload Station to begin incubation and reading. The instrument allows 10 minutes for this transfer. After this time the instrument will not accept the cards.***

## Starting the System

1. Make sure the instrument is connected to an appropriate power supply using the power cord supplied with the instrument.
2. Press the AC power switch to the **ON** position (Power Switch and Power Cord Receptacle).

   The instrument goes through an initialization sequence that includes several self-tests.

**Figure 47: Initial Logo Screen**

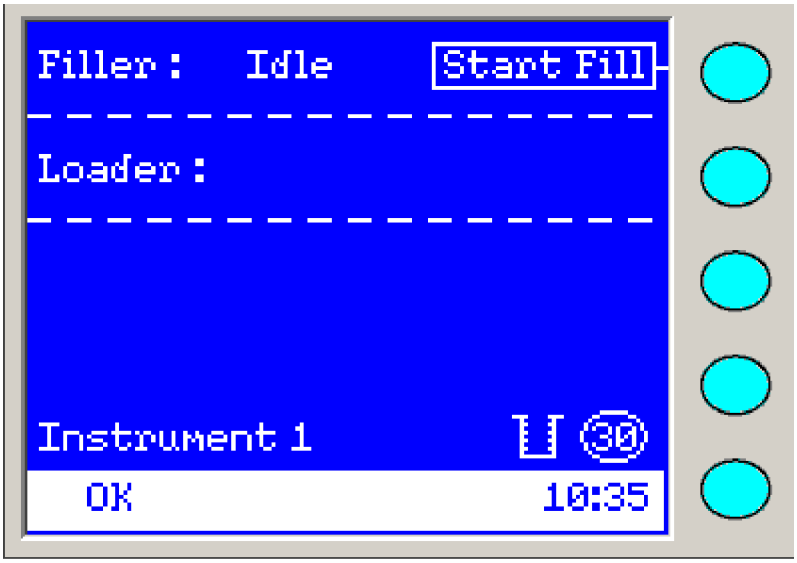

During this time, the instrument is also bringing the carousel/incubator up to the specified temperature for test card incubation. The user interface displays the Initial Logo screen followed by the Initialization screen (Initialization Screen).

**Figure 48: Initialization Screen**


After a few minutes, the Status screen appears. The Status field at the bottom of the screen (Status Screen) should show a status of **Warming** or **OK**. The Warming status means that the carousel temperature is not yet within its specified range. This typically takes 5 to 15 minutes.

The VITEK® 2 Compact instrument is ready to begin processing cards when the Instrument Status field displays **OK**.

**Figure 49: Status Screen**




## Workflow

Setup Tests Post Entry Workflow provides a generalized Setup Tests Post Entry workflow when processing test cards using the VITEK® 2 Compact instrument.

**Table 15: Setup Tests Post Entry Workflow**

| Activity | Reference |
|---|---|
| Make sure that all configuration options are set correctly. | Configuration |

| Activity | Reference |
|---|---|
| Print a cassette worksheet at the workstation. | Refer to **Printing a Blank Cassette Worksheet** in the *VITEK® 2 Systems Software User Manual*. |
| Prepare inoculum suspension and test cards. | Refer to the *VITEK® 2 Systems Product Information*. |
| Fill in the cassette worksheet with the test card and specimen information for the cassette. | Prepare Test Cards and Cassettes.<br>Refer to **Using the Set Up Tests Post Entry Workflow** in the *VITEK® 2 Systems Software User Manual*. |
| Place the test cards and specimen test tubes in their appropriate slots. | Refer to **Configuring and Managing Test Information** in the *VITEK® 2 Systems Software User Manual*. |
| Load the cassette into the Filler Station. | Loading a Cassette |
| Transfer the cassette to the VITEK® 2 Compact cassette loading station. | Loading a Cassette |
| *Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card.* | |
| If the cassette bar code was not read and performed on the user interface screen of VITEK® 2 Compact, access the Manage Cassette view function on the VITEK® 2 Compact workstation. Enter a cassette number. | Prepare Test Cards and Cassettes<br>Refer to Configuring and Managing Test Information in the *VITEK® 2 Systems Software User Manual*. |
| Enter the information from the cassette worksheet into the Setup Tests Post Entry.<br>*Note: Once the cassette is in the loader, a cassette icon appears on the instrument Status screen.* | Refer to **Entering Cassette Worksheet Information** in the *VITEK® 2 Systems Software User Manual*. |

Video Cassette Workflow provides a generalized Virtual Cassette workflow when processing test cards using the VITEK® 2 Compact instrument.

**Table 16: Virtual Cassette Workflow**

| Activity | Reference |
|---|---|
| Make sure that all configuration options are set correctly. | Configuration |
| Prepare inoculum suspension and test cards. | Refer to the *VITEK® 2 Systems Product Information*. |
| Place the test cards and specimen test tubes in their appropriate slots. | Refer to **Configuring and Managing Test Information** in the *VITEK® 2 Systems Software User Manual*. |
| Enter the cassette information into the Maintain Virtual Cassette view on the workstation. | Refer to **Using the Virtual Cassette Workflow** in the *VITEK® 2 Systems Software User Manual*. |
| Load the cassette into the Filler Station. | Loading a Cassette |

| Activity | Reference |
|---|---|
| Transfer the cassette to the VITEK® 2 Compact cassette loading station. | Loading a Cassette |
| *Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card.* | |
| If the cassette bar code was not read and performed on the user interface screen of VITEK® 2 Compact, access the Manage Cassette view function on the VITEK® 2 Compact workstation. Enter a cassette number. | Prepare Test Cards and Cassettes<br>Refer to Configuring and Managing Test Information in the *VITEK® 2 Systems Software User Manual*. |

VITEK® 2 FLEXprep Workflow provides a generalized VITEK® 2 FLEXprep workflow when processing test cards using the VITEK® 2 Compact instrument.

**Table 17: VITEK® 2 FLEXprep Workflow**

| Activity | Reference |
|---|---|
| Make sure that all configuration options are set correctly. | Configuration |
| Prepare inoculum suspension and test cards. | Refer to the *VITEK® 2 Systems Product Information*. |
| Place the test cards and specimen test tubes in their appropriate slots. | Refer to **Configuring and Managing Test Information** in the *VITEK® 2 Systems Software User Manual*. |
| Enter the cassette information into FLEXprep view in the VITEK® 2 Systems Web application and send the cassette. | Refer to **Using the VITEK® 2 FLEXprep Workflow** in the *VITEK® 2 Systems Web User Manual*. |
| Load the cassette into the Filler Station. | Loading a Cassette |
| Transfer the cassette to the VITEK® 2 Compact cassette loading station. | Loading a Cassette |
| *Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card.* | |
| If the cassette bar code was not read and performed on the user interface screen of VITEK® 2 Compact, access the Manage Cassette view function on the VITEK® 2 Compact workstation. Enter a cassette number. | Prepare Test Cards and Cassettes<br>Refer to Configuring and Managing Test Information in the *VITEK® 2 Systems Software User Manual*. |

## Prepare Test Cards and Cassettes

To prepare an inoculum suspension, test cards and cassettes, refer to the *VITEK® 2 Systems Product Information* for complete testing instruction on the particular card type to be tested.

**CAUTION: When carrying the cassette, use the provided hand grip to ensure it is not dropped.**

## Generate Cassette Worksheet

The Cassette Worksheet generated from the *VITEK® 2 Systems Software*, is designed to help you organize a set of test cards and test tube for a cassette when using the Setup Tests Post Entry workflow.

During the first minute after you load a cassette, the instrument reads the bar code on each test card. From this bar code reading, the instrument knows the number of test cards in the cassette, the type of test cards, and the position of each test card. The instrument sends this information, along with the cassette number read during the bar code reading process, to the workstation.

You can view this information in Setup Tests Post Entry, which is part of the workstation software. You can access the view and, using the Cassette Worksheet, fill in the remaining information for the cassette after you load the test cards into the carousel.

For information on using the Setup Tests Post Entry view, refer to the *VITEK® 2 Systems Software User Manual*.

**WARNING**

**Biohazardous spills can occur inside the VITEK® 2 Compact instrument. All organism suspensions, cards, cassettes, test tubes, sample transfer tubes, waste bin, and the user interface panel should be considered as potentially infectious.**

Before you load the cassette into the Filler Station, check the Status screen on the instruments user interface. Refer to the parameters listed in Cassette Preparation Information to ensure the system is ready to start a fill.

**Table 18: Cassette Preparation Information**

| Parameter | Field Value |
|---|---|
| Status | This field should be OK. |
| Available Slots | The value in this field should be greater than or equal to the number of test cards you are loading. |

## Loading a Cassette

**WARNING**

**The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.**

**WARNING**

**All access doors and covers must remain closed when processing cards to avoid exposure to laser light.**

**WARNING**

**The transmittance optics are sensitive to ambient light. Ensure all access doors are closed when cards are processing in the instrument.**

**CAUTION: To avoid possible processing errors, make sure that all the test cards and test tubes are properly seated in the cassette.**

**CAUTION: Be mindful of physical movements around the instrument when the access doors are open. Failure to comply may result in injury to personnel or damage to the instrument.**

To load a cassette into the Filler Station:

1. Open the Fill door and place the cassette into the chamber.

**Figure 50: Fill Door (Open)**

2. Close the Fill door.
3. Press the **Start Fill** button to begin the filling process.
4. After completion of the Fill cycle (Fill Indicator blue arrow blinking), remove the cassette from the Filler Station and close the Fill door.

   The Load door unlocks.

5. Open the Load door and place the cassette into the Cassette Load/Unload Station.

**Figure 51: Load Door (Open)**

6. Close the Load door. The cassette icon appears on the Status screen.

## Monitor Card Processing

After a cassette is loaded, the instrument bar code reader scans the test cards and cassette bar code.

⚠ **CAUTION: Ink placed on disposables may obscure card wells.**

***Note:*** *It is recommended that the user monitor the process until all the cards are scanned by the bar code reader. The process is completed when the instrument sounds the* ***Cassette Success*** *or* ***Cassette Exception*** *alert.*

## Unloading a Cassette

During test card processing, the instrument unloads the test cards from the cassette and places them into the carousel.

When the indicator LED at the Cassette Load/Unload Station is blinking, remove the empty cassette containing the specimen test tubes and the severed transfer tubes from the instrument. This ensures that the instrument can continue to support your laboratory's workflow.

## Unload a Cassette

1. When you are processing test cards, a blinking, blue indicator LED at the Load/Unload Station indicates that an empty cassette is at the station. A red **X** indicator signals an error has occurred and user intervention is necessary.
2. Open the Load door and remove the cassette from the instrument.
3. Close the Load door.

> ⚠ **CAUTION: Leaving the door to the Cassette Load/Unload Station open interferes with the proper processing of the test cards in the VITEK® 2 Compact instrument.**

4. Dispose of the materials in the cassette. You can now use the cassette to process additional test cards.

**WARNING**

⚠ **All of the materials in an empty cassette should be treated as biohazards and disposed of accordingly. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.**

## Removing the Waste Collection Bin and Test Cards

When the instrument ejects a test card, it removes the card from the carousel/incubator to the Card Reader and places it in the Waste Collection station (Waste Collection Station). The bin has a capacity of 60 test cards. However, we recommend that you check and empty the waste bin before it reaches capacity to ensure that VITEK® 2 Compact instrument can continue to support your laboratory's workload.

> ⚠ **CAUTION: Once you remove cards from the Waste Collection station, never reinsert them. This may cause the instrument to jam.**

1. Open the Waste Collection Station door. Note that waste test cards are held in a removable bin.

**Figure 52: Waste Collection Station (Opened)**

2. Remove the Waste Collection Bin from the station by pulling the front edge of the bin toward you.

***Note:*** *The instrument resets the waste count only if the bin is completely removed.*

3. Dispose of the test cards according to good laboratory practices. Consult your local regulations for disposal of CARD ID reagents.

**WARNING**

⚠ **Although VITEK® 2 Compact test cards are sealed, they should be treated as biohazards and disposed of accordingly.**

## Replacing the Waste Collection Bin

1. Slide the Waste Collection Bin back into place.
2. Close the Waste Collection Station door.

***Note:*** *If the waste collection bin is not replaced, the instrument cannot eject cards.*

## Shutting Down the System

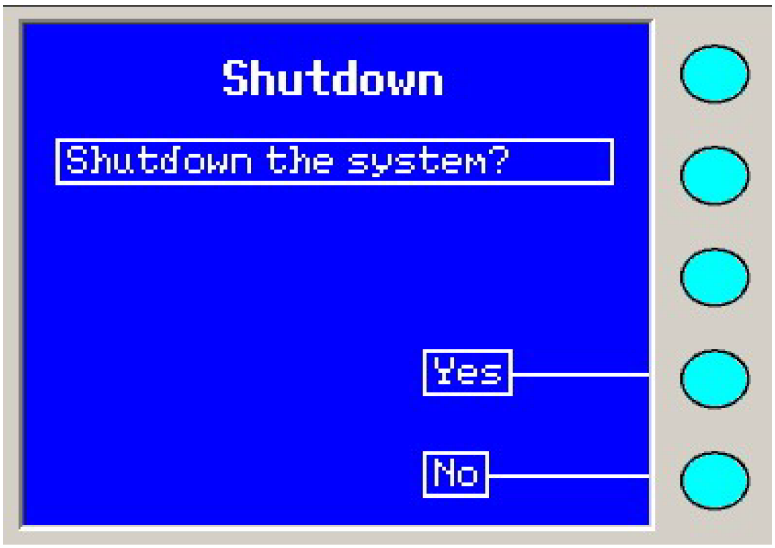
Always use the **Shutdown** function from the user interface to turn off the instrument.

⚠ **CAUTION: There are elevated temperatures and hot surfaces inside the instrument. Shut down the instrument before starting the cleaning or any other procedures inside the instrument.**

***Note:*** *It is recommended all cards finish processing before beginning this procedure.*

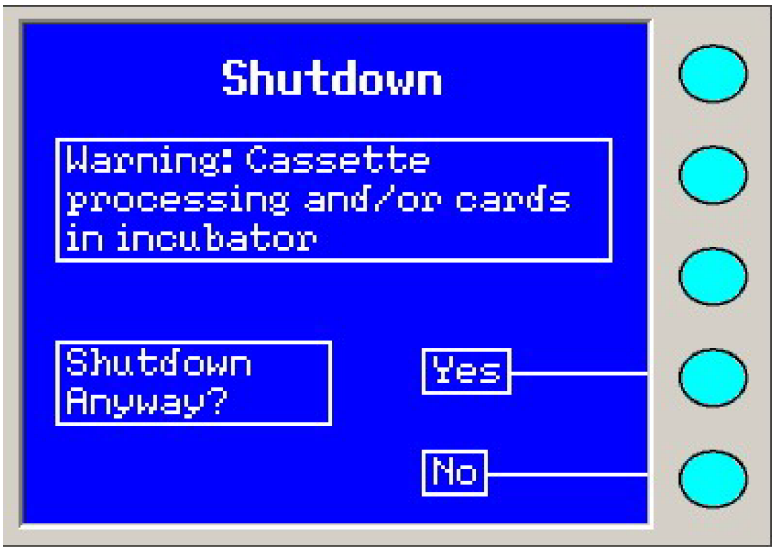
1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Main Menu** > **Maintenance** > **Shutdown**.

**Figure 53: Shutdown System**




If any cards are processing, the instrument displays Confirm Shutdown.

**Figure 54: Confirm Shutdown**




3. Select **Yes** to shut down the instrument.

   The instrument briefly displays the following message while it moves some internal components to their shutdown positions.

**Figure 55: Shutdown in Progress**


When this process is complete, the instrument displays the message **Ready for shutdown**.

**Figure 56: Shutdown Ready**


4. Press the AC power switch to shut the instrument OFF.
5. Remove the AC power cord to prevent any possible electrical hazard.
   It is now safe to access the inside of the instrument.

| WARNING |
| --- |
| ⚠ **Electric shock hazard. Always turn the instrument OFF prior to removing the power cord.** |

# 6 User Maintenance

**CAUTION: Only authorized service technicians should perform any component installation or servicing of the instrument beyond normal operational and routine maintenance tasks. Contact bioMérieux for any additional information or procedural direction.**

**WARNING**

**User should not attempt to gain entry into the power supply area at the rear of the instrument. A possible shock hazard could exist.**

To get servicing contact information, contact bioMérieux or your local distributor (contact information available on www.biomerieux.com).

## Required Tools

- Thermometer  Calibrated to NIST traceable standards (optional)
- 5% bleach solution
- 10% bleach solution (for decontamination)
- Phenolic cleaning solution
- Lint-free lens paper
- Alcohol wipe
- Clean cloths or paper towels
- Plain water

## Calibration and Adjustments

## Instrument Diagnostics

Some error recovery procedures in Error Messages and Recovery Procedures instruct you to perform a diagnostic test on one of the stations in the VITEK® 2 Compact instrument. All of the diagnostic tests for the instrument are located using the following path: **Main Menu** > **Diagnostics**.

Following are the tests found on the Diagnostics menu, and their function:

**Table 19: Diagnostic Tests**

| Diagnostic Test | Function | Possible Results |
|---|---|---|
| Temperature (Checking the Instrument Temperature) | Reads the temperature in the reader carousel incubator and internal cabinet temperature. | Displays the incubator and internal cabinet temperature in degrees Celsius. |

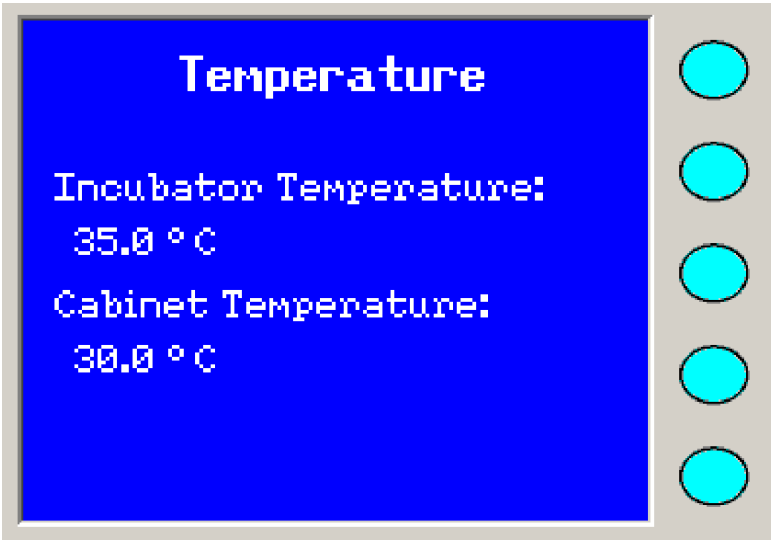
| Diagnostic Test | Function | Possible Results |
|---|---|---|
| Optics (Optics Self Test) | Performs a self-test of the transmittance optics system. | Pass/Fail |

## *Checking the Instrument Temperature*

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Diagnostics** > **Temperature**.

   The screen displays the Incubator temperature and the temperature inside the instrument cabinet (Temperatures).

**Figure 57: Temperatures**

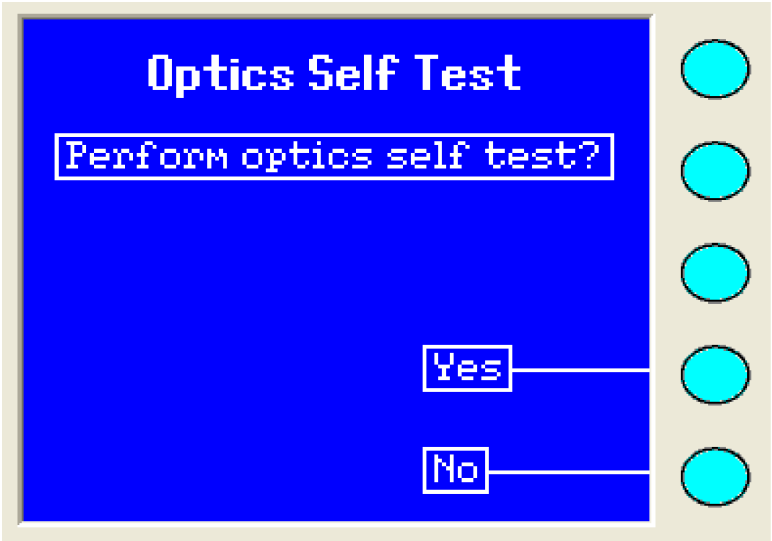



## *Optics Self Test*

Verifying the optics can be performed with or without cards processing.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Diagnostics** > **Optics Self Test**.

**Figure 58: Optics Self Test**




3. Select **Yes** to continue.

4. When the test is complete, select **OK** to exit the screen.
5. If the optical test fails, call bioMérieux Customer Support.

### *Filler Test*

There are times when you may need to run a Filler Test (Instrument Error Codes).

1. Remove any cassette from the Filler Station.
2. Close the Fill Door.
3. Press the Fill Indicator LED (Fill Indicator Status) to begin the filling process.
4. At the completion of a successful fill cycle (the Filler's blue LED blinks), cancel the cassette: **Main Menu** > **Error Handling** > **Cancel Cassette**

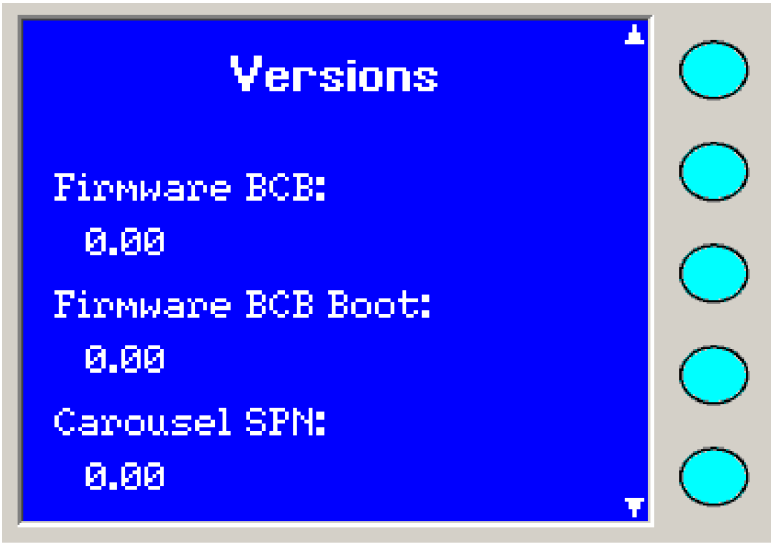
***Note:*** *The cancel cassette function will only be active for ten minutes after which an error will occur. When this error occurs, refer to Instrument Error Codes.*

### *Displaying Version Information*

This function allows you to view the current instrument firmware version for your instrument. Customer Support may ask you to supply this information if you need assistance with any of the recovery procedures.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Diagnostics** > **Versions**.

**Figure 59: Version Information**




3. Use the **Arrow** keys on the keypad to scroll to additional information.

### *Last Maintenance Date*

This function is used to view the last time a field service engineer performed preventive maintenance. The format is the same as that configured for Date Format.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Diagnostics** > **Last Maintenance Date**.

**Figure 60: Last Maintenance Date**


## Manual Temperature Check (Optional)

This procedure should only be performed when:

- More than one hour has passed from the time of power up.
- More than one hour has passed after cards were loaded into the carousel.
- The overall instrument status is **OK**.

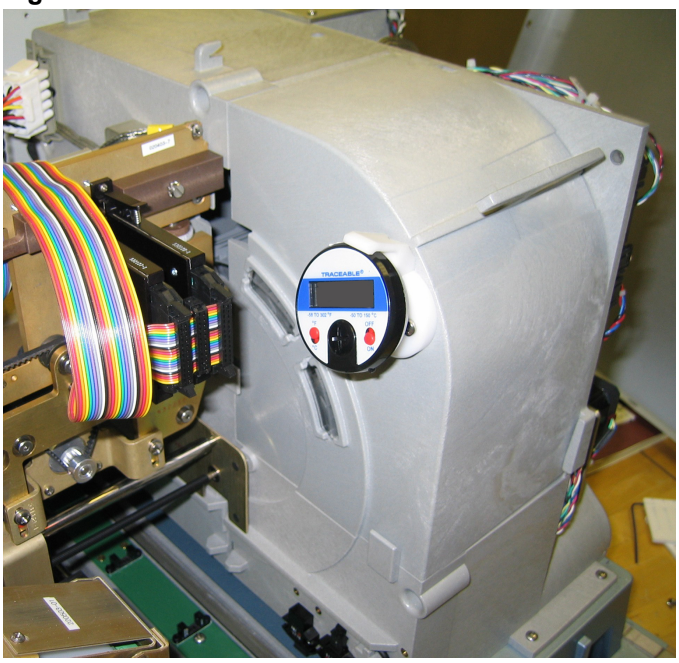
1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Maintenance** > **Temperature Check**.

   A message appears asking the user to check the temperature.

***Note:*** *If the cassette is processing in the Filler Station or in the Cassette Load/Unload Station, the user is not able to check the temperature.*

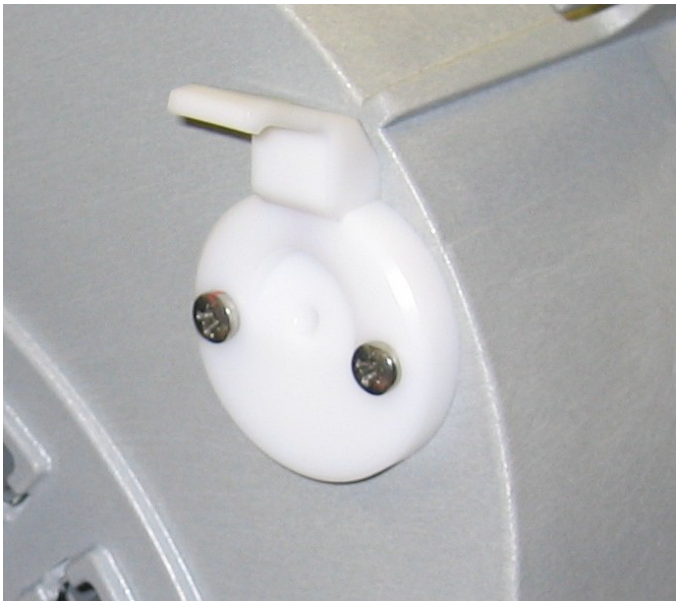
   A warning message appears if the cards are processing in the carousel. The user must confirm pausing card processing.
3. When the Front User Access Door is unlocked, both User Access Doors can be opened to check the temperature.
4. Turn the thermometer on and insert into a small hole in the left side of the incubator cover.

**Figure 61: Incubator with Thermometer**



5. Clip the thermometer into place on the white plastic clip (Thermometer Clip).

**Figure 62: Thermometer Clip**



6. Remove the thermometer by lifting the clip and gently pulling it straight out of the cover. You may also leave the thermometer in place.
7. Check the temperature and close the User Access Doors when done.

***Note:*** *A warning message appears if the process exceeds four minutes.*

## Cleaning Procedures

### Unlock Front User Access Door

This is the first option in the Maintenance menu and is a manual override of the locking system. Use caution when selecting this option. Cards will not process when the User Access Doors are open.

***Note:*** *When cards are incubating and this option is selected, a confirmation screen appears to confirm pausing the card processing.*

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Maintenance** > **Unlock User Access Door**.

   A message appears asking the user to confirm unlocking the User Access Doors.

***Note:*** *If the cassette is processing in the Filler Station or in the Cassette Load/Unload Station the user is not able to unlock the door.*

   A warning message appears if the cards are processing in the carousel. The user must confirm pausing card processing.
3. When the Front User Access Door is unlocked, both User Access Doors can be opened.
4. Close the User Access Doors when you are done.

***Note:*** *A warning message appears if the process exceeds four minutes.*

## Cleaning the Carousel

**WARNING**

⚠ **The carousel should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.**

⚠ **CAUTION: Perform this procedure when the VITEK® 2 Compactinstrument is completely idle (no cards are processing anywhere in the instrument).**

**WARNING**

⚠ **Elevated Temperatures. Do not touch the metallic incubator venting plate (located behind the carousel sections).**

**WARNING**

⚠ **Do not put your hands in the carousel when the carousel is rotating, otherwise an injury could occur.**

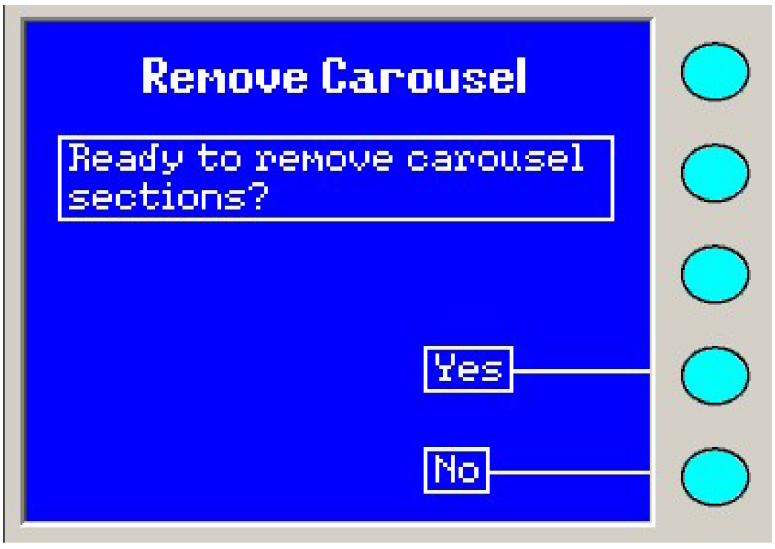
1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Maintenance** > **Remove Carousel**.

**Figure 63: Main Menu**


***Note:*** *If there are cards processing anywhere in the instrument, a screen prompts you to make sure processing is complete and all cards were ejected from the instrument before cleaning.*

If cards are not processing in the incubator, and the carousel sections were not removed, the following screen displays and the Front User Access Door unlocks.

**Figure 64: Carousel Removal Confirmation**



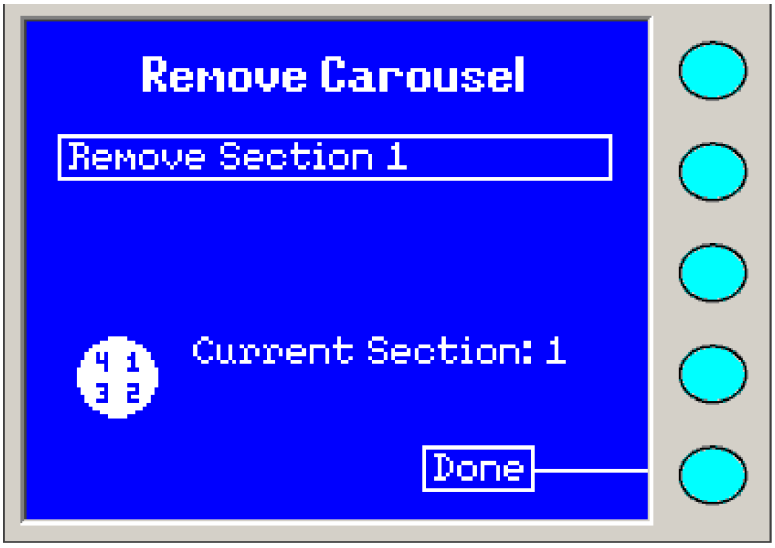

⚠ **CAUTION: Do not open the User Access Doors and remove the cover as soon as Yes is selected. The carousel has moving parts that are rotating into position. Wait until the carousel stops moving.**

***IMPORTANT:*** ***If you press Yes, all sections must be removed. This requires about four minutes. Selecting No is the only opportunity to cancel this operation.***

3. Press **Yes**. The following screens are displayed.

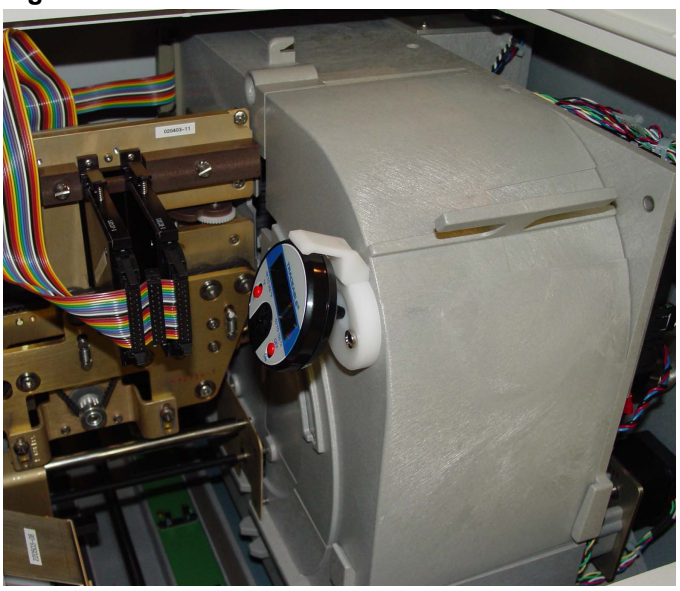
**Figure 65: Preparing for Section Removal**


**Figure 66: Remove Carousel Section**



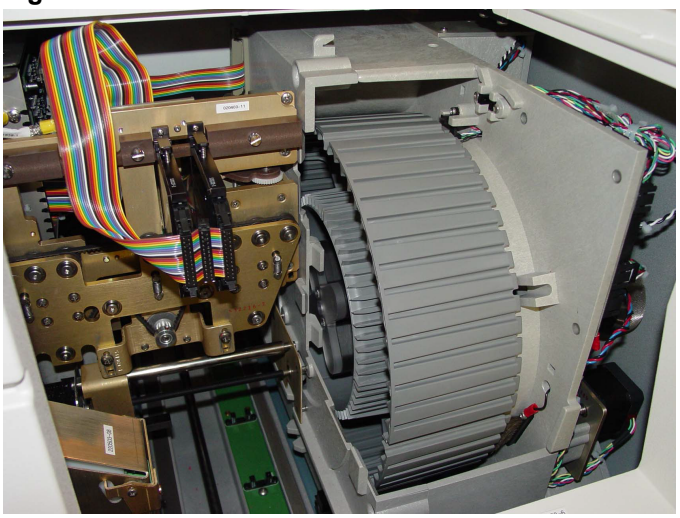

4. When **Remove Section 1** screen is displayed, open the Front User Access Door.
5. Open the Top User Access Door.

**Figure 67: Carousel with Cover**



6. Remove the carousel cover from the carousel by lifting the top of the cover straight up from the instrument.

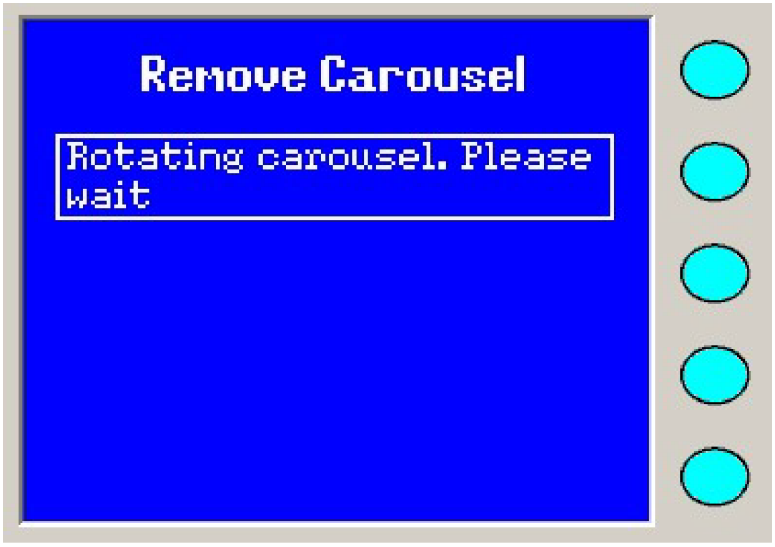
**Figure 68: Carousel without Cover**



***Note:*** *Once the carousel is moved to the correct position, the message on the screen changes (Rotating Carousel).*

7. Grasp a carousel section and tilt it to the left, then toward you.
8. Press **Done** to confirm removal of the carousel section (Rotating Carousel).

**Figure 69: Rotating Carousel**




The carousel turns so you can remove the next section. During this time the message **Preparing for Section Removal** displays again on the screen.

9. Repeat Step 7 and Step 8 until all four carousel sections are removed (Removal Complete).

**Figure 70: Removal Complete**


10. Carefully replace the carousel cover over the carousel and close the User Access Doors.
11. After the four carousel sections are removed, the Maintenance menu appears.
12. Thoroughly clean and dry the four sections of the carousel before replacing them in the VITEK® 2 Compact instrument. The carousel material is designed to withstand any of the following cleaning methods:
    - Automatic dishwasher with standard laboratory detergent
    - 5% bleach solution
    - Phenolic cleaning solution

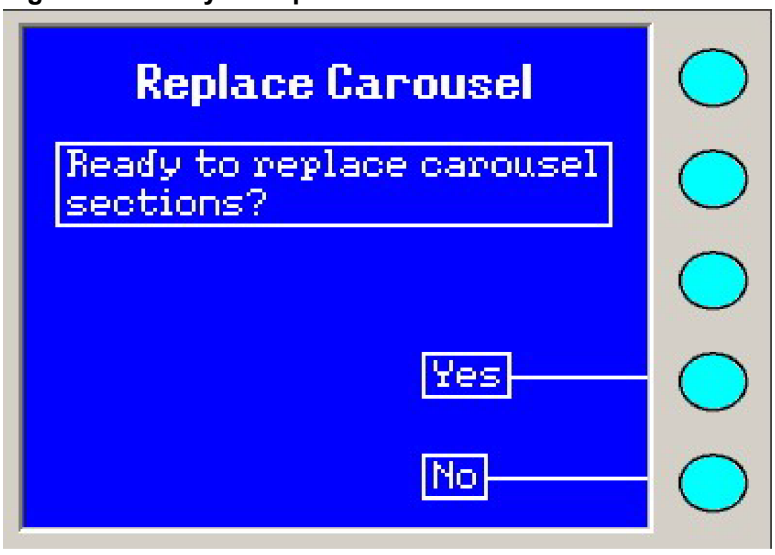
**CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C. Exceeding this temperature causes damage to the carousel sections. Use the top rack of the dishwasher.**

For instructions on replacing the carousel, see Replacing the Carousel.

## Replacing the Carousel

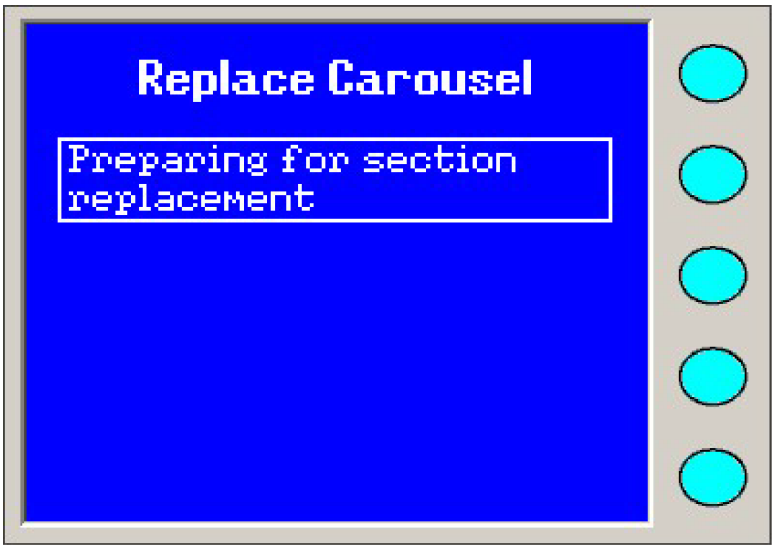
1. Open the Front User Access Door and remove the carousel cover.
2. Press the **Status/Menu** key to access the Main menu screen.
3. Select **Maintenance** > **Replace Carousel**.

**Figure 71: Ready to Replace Carousel**



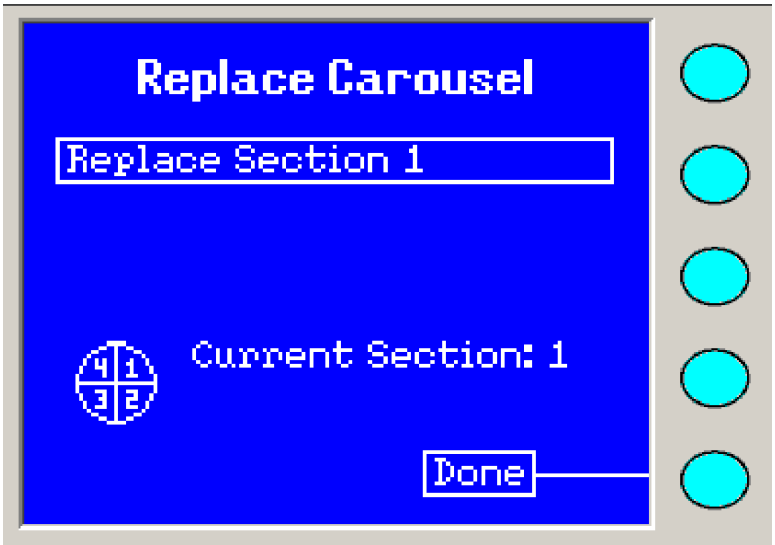

4. Press **Yes** to continue with the carousel replacement.

**Figure 72: Preparing to Replace Carousel**




The carousel rotates until it is in position to replace the section.

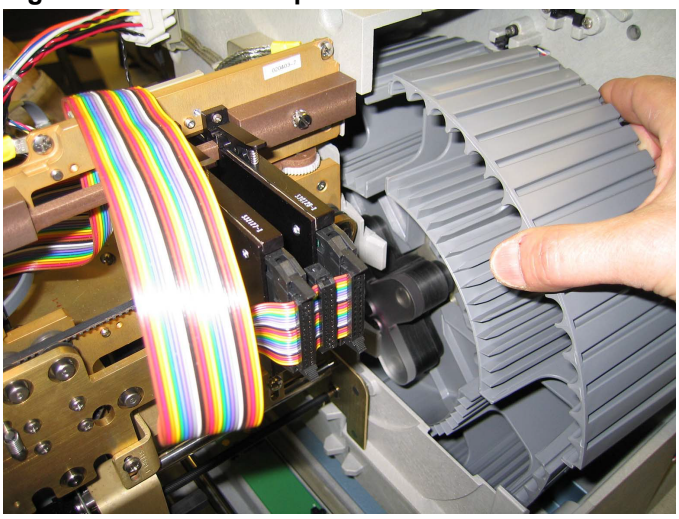
**Figure 73: Ready to Replace Carousel**




> ⚠ **CAUTION: The carousel has moving parts that are rotating into position. Wait until the carousel stops moving.**

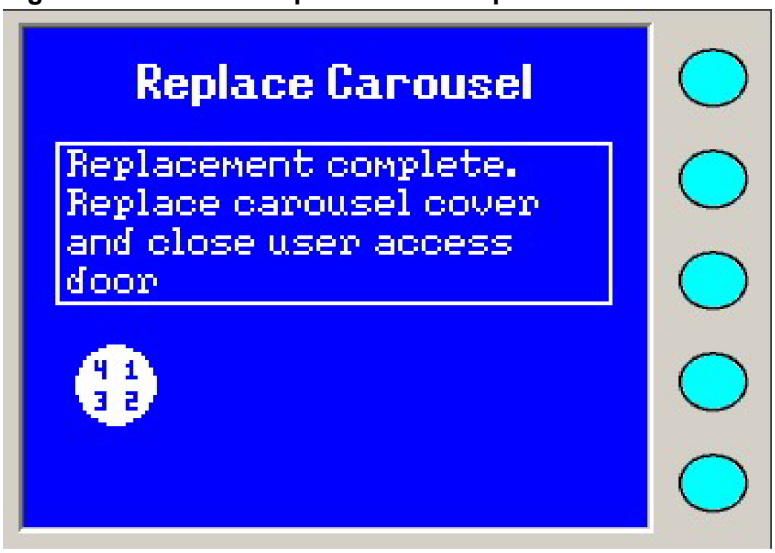
5. Take any one of the carousel sections and orient it (Carousel Replacement). The bottom of the section should touch the base plate and the top portion should tilt slightly toward the left of the instrument. Align the notch to the spring-loaded pin for the correct locking position.

**Figure 74: Carousel Replacement**



6. Slide the section down along the base plate while maintaining the tilted angle.
7. When the section is pushed down all the way, release the top portion, allowing it to rest against the base plate. Two pins on the back of the section should engage the two holes in the base plate and secure the section.
8. Press **Done** when the section is in place.
9. The carousel turns 90 degrees to move the first section out of the way. During this time, **Rotating Carousel: Please Wait** is displayed on the screen.
10. Repeat Step 5 through Step 9 until all four carousel sections are replaced.

**Figure 75: Carousel Replacement Complete**




11. Replace the carousel cover over the carousel. If this is not replaced, a jam condition intervention occurs (Jam Condition Intervention Messages).
12. Lower the Top User Access Door.
13. Close the Front User Access Door, making sure it latches completely.

***Note:*** *The Front User Access Door does not latch unless the Top User Access Door is closed.*

## Cleaning the Cassettes

Clean cassettes monthly, or as conditions require.

⚠ **CAUTION: It is important to remove the bar codes before cleaning the cassettes.**

**WARNING**

⚠ **The cassettes should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.**

The cassette material is designed to withstand any of the following cleaning methods:

- Automatic dishwasher with standard laboratory detergent
- 5% bleach solution
- Phenolic cleaning solution

⚠ **CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C. Exceeding this temperature causes damage to the cassettes. Use the top rack of the dishwasher and remove the bar code insert from the cassette to prevent damage and negative impact on test results.**

1. Thoroughly clean and dry cassettes before using them again.
2. Replace cassette bar code label.

## Cleaning the Optics (With Cards Processing – Power On)

This procedure describes how to clean and verify the optics while test cards are still processing. If the instrument is shut down, you may also clean the optics. See Cleaning the Optics (Power Off).

⚠ **CAUTION: Do not use commercial glass cleaner when cleaning the optics. This may result in calibration failures observed as the optics age. Clean optics using a quality, lint free lens paper that has been slightly moistened with alcohol.**

***Note:*** *There are two types of transmittance optics assemblies that can be configured on the VITEK® 2 Compact instrument. Perform Step 6 and Step 7 if TX1 and TX3 is installed or Step 8 if unified optics are installed.*

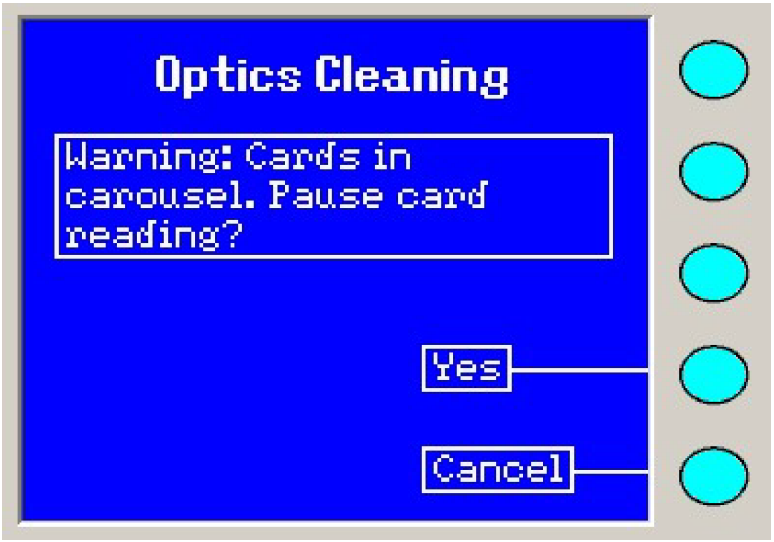
***IMPORTANT:*** ***All steps in this procedure must be completed.***

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Maintenance** > **Optics Cleaning**
   A message appears asking the user to confirm cleaning the optics.

***Note:*** *If the cassette is processing in the Filler Station or in the Cassette Load/Unload Station, the user is not able to unlock the door.*

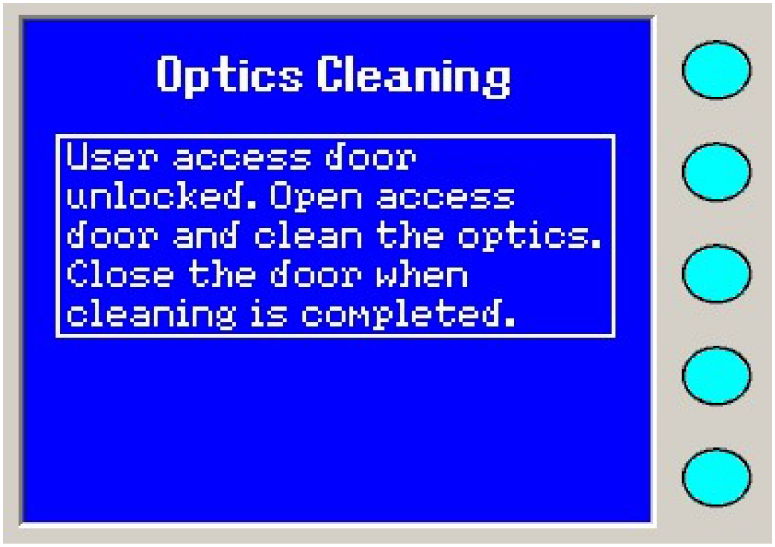
A warning message appears if the cards are processing in the carousel. The user must confirm pausing card processing.

**Figure 76: Optics Cleaning**




3. When the Front User Access Door is unlocked, both User Access Doors can be opened to clean the optics.

**Figure 77: Optics Cleaning Ready**




4. Open the Front User Access Door.
5. Lift the Top User Access Door. This exposes the transmittance optics, as shown in TX1 and TX3 Transmittance Optics Assembly or Unified Optics Assembly.

**Figure 78: TX1 and TX3 Transmittance Optics Assembly**

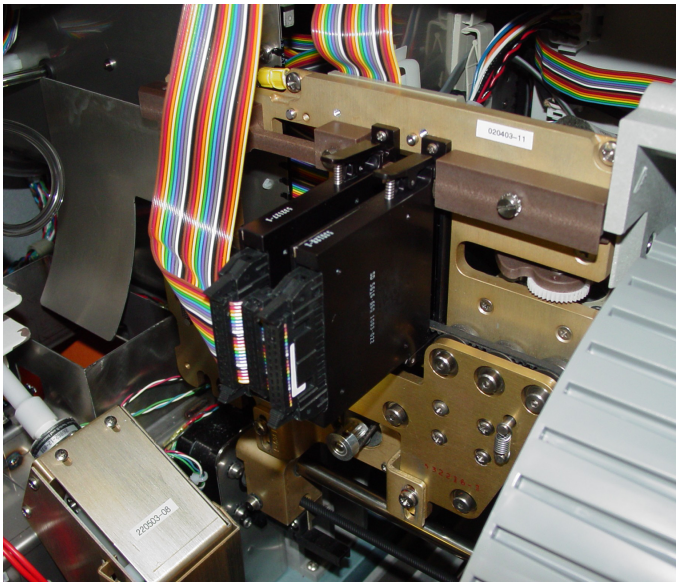
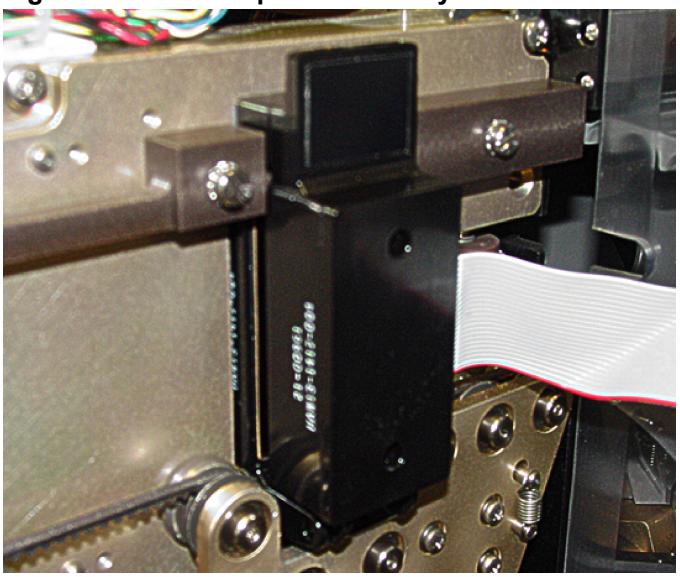
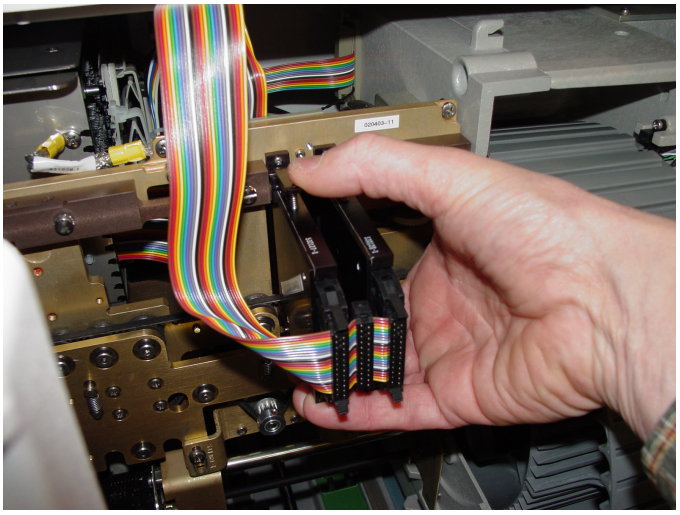


**Figure 79: Unified Optics Assembly**



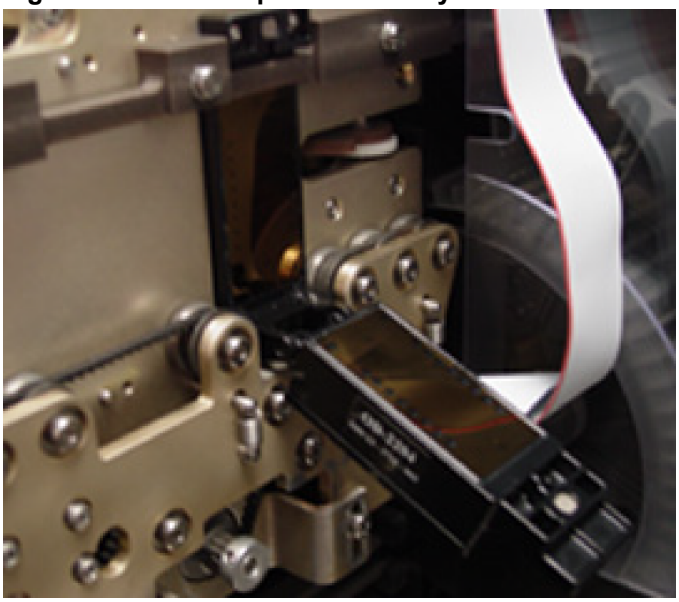
6. Using your right hand, grasp the module units and place your thumb on the levers, as shown in TX1 and TX3 Transmittance Optics Cleaning. Both optics units must be released simultaneously to rotate down for cleaning.

**Figure 80: TX1 and TX3 Transmittance Optics Cleaning**



7. Push down on the levers to release both units and rotate downward.
8. Grasp the tab at the top of the optics assembly and pull the tab forward and gently allow the optics assembly to hinge down.

**Figure 81: Unified Optics Assembly**



9. Inspect the glass on all surfaces for cracks or scratches.

**WARNING**

⚠ **Any apparent crack, scratch, or broken glass should be reported to bioMérieux.**

10. Using a quality, lint-free lens paper that has been slightly moistened with alcohol, clean the glass surfaces. If foreign material remains on either surface, repeat this step using an alcohol wipe. Squeeze out excess alcohol before using, and dry the surface with lens paper. While cleaning the emitter side of the Transmittance Optics, push the reader head plate down and clean the glass as close to the belt as possible. Make sure that you do not leave streaks on the glass.

***Note:*** *If the Roller Plate Assembly is installed, the belt will not be routed close to the emitter side of the Transmittance Optics.*

11. Close each of the optics assemblies until the clamp lever or tab locks in place, as applicable.
12. Close the Top User Access Door and Front User Access Door when you are done.
13. An optics self test is performed automatically, press **OK** when the results are displayed.

***Note:*** *You have four minutes from the time that you press **Yes** to complete the cleaning procedure.*

A warning message appears if the process exceeds four minutes.

## Cleaning the Optics (Power Off)

***Note:*** *bioMérieux recommends that you shut down and power OFF the instrument during this maintenance procedure. Refer to Shutting Down the System before proceeding.*

**CAUTION: Do not use commercial glass cleaner when cleaning the optics. This may result in calibration failures observed as the optics age. Clean optics using a quality, lint free lens paper that has been slightly moistened with alcohol.**

***Note:*** *There are two types of transmittance optics assemblies that can be configured on the VITEK® 2 Compact instrument. Perform Step 3 and Step 4 if TX1 and TX3 is installed or Step 5 if unified optics installed.*

1. Open the Front User Access Door.
2. Lift the Top User Access Door. This exposes the transmittance optics, as shown in TX1 and TX3 Optics Assembly or Unified Transmittance Optics Assembly.

**Figure 82: TX1 and TX3 Optics Assembly**

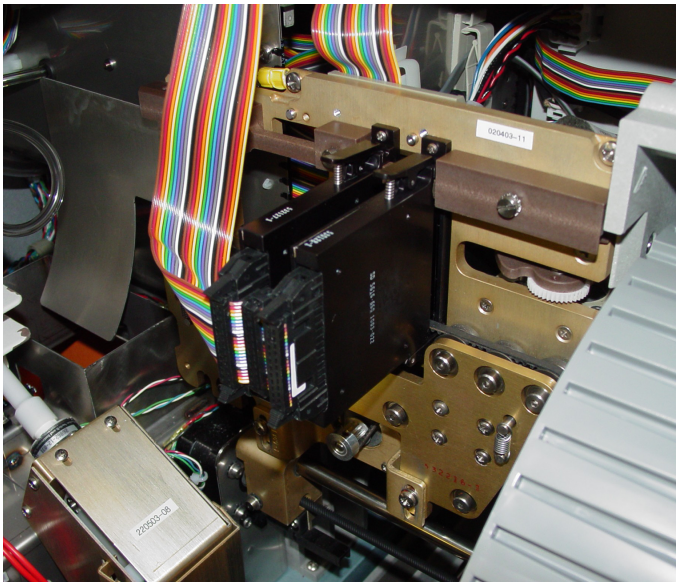
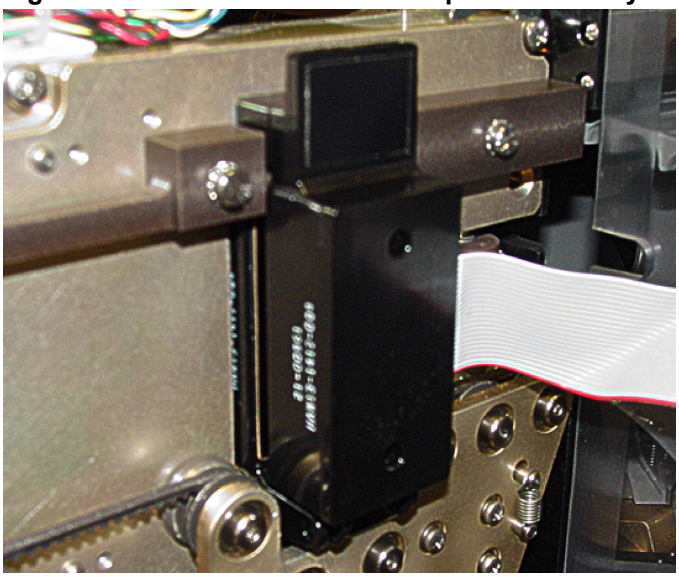
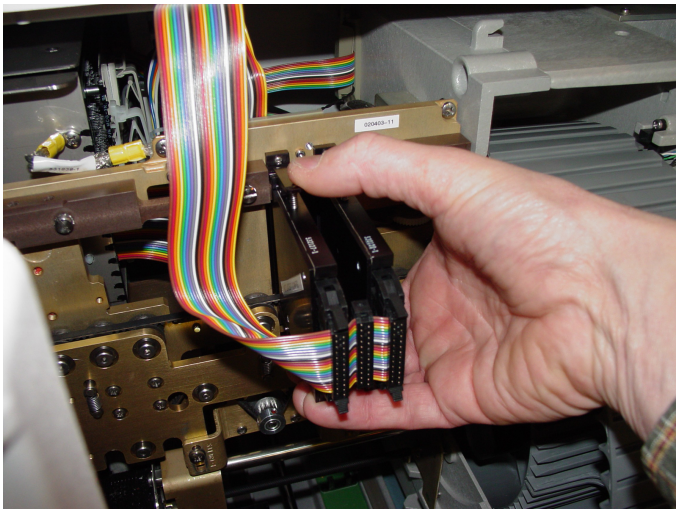


**Figure 83: Unified Transmittance Optics Assembly**



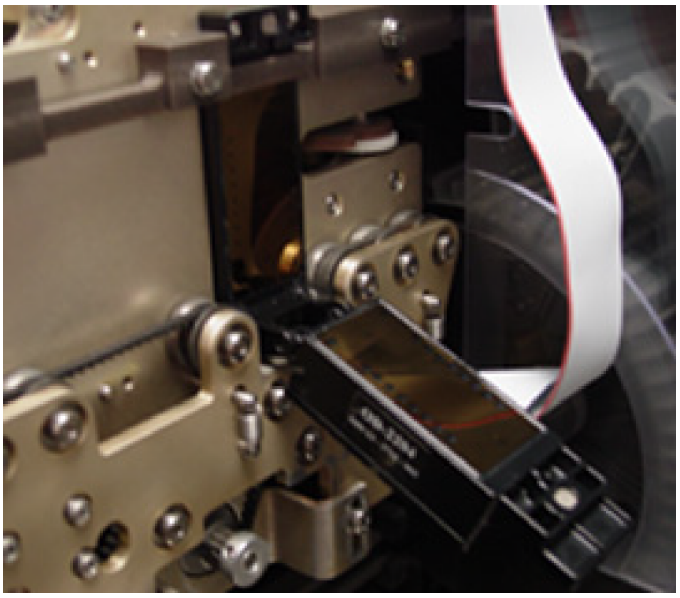
3. Using your right hand, grasp the module units and place your thumb on the levers, as show in Optics Cleaning below. Both optics units must be released simultaneously to rotate down for cleaning.

**Figure 84: Optics Cleaning**



4. Push down on the levers to release both units and rotate downward.
5. Grasp the tab at the top of the optics assembly and pull the tab forward and gently allow the optics assembly to hinge down.

**Figure 85: Unified Transmittance Optics Assembly**



6. Inspect the glass on all surfaces for cracks or scratches.

**WARNING**

**Any apparent crack, scratch, or broken glass should be reported to bioMérieux.**

7. Using a quality, lint-free lens paper that has been slightly moistened with alcohol, clean the glass surfaces. If foreign material remains on either surface, repeat this step using an alcohol wipe. Squeeze out excess alcohol before using, and dry the surface with lens paper. While cleaning the emitter side of the Transmittance Optics, push the reader head plate down and clean the glass as close to the belt as possible. Make sure that you do not leave streaks on the glass.

***Note:*** *If the Roller Plate Assembly is installed, the belt will not be routed close to the emitter side of the Transmittance Optics.*

8. Close each of the optics assemblies until the clamp lever or tab locks in place, as applicable.
9. Close the Top User Access Door.
10. Close the Front User Access Door.

    If you are not performing the remaining cleaning procedures in this section and the instrument is already turned off, refer to Starting the System.

## Cleaning Instrument Exterior and User Access Doors

**WARNING**

⚠ **Biohazardous materials could come in contact with the exterior of the VITEK® 2 Compact instrument. All organism suspensions, cards, cassettes, test tubes, sample transfer tubes, waste bin, and the user interface panel should be considered as potentially infectious.**

***Note:*** *bioMérieux recommends that you shut down and power OFF the instrument during this maintenance procedure. Refer to Shutting Down the System before proceeding.*

The instrument exterior is designed to withstand any of the following cleaning methods:

- 5% bleach
- Phenolic cleaning solution

1. Dampen a cloth with one of these approved solutions and wipe off any dust or dirt from the top, front, and side surfaces of the instrument. Wipe off all User Access Doors.
2. Dampen a separate cloth with plain water and wipe the surface again to remove any disinfectant residue.

**WARNING**

⚠ **Do not liberally apply liquid to the exterior surface of the instrument, display, or keypad. Ingress of liquid could result in loss of instrument function or a shock hazard.**

⚠ **CAUTION: Do not apply cleaning solutions or water to any sensors in the instrument, otherwise a malfunction may occur.**

If you are not performing the remaining cleaning procedures in this section and the instrument is already turned off, refer to Starting the System.

## Cleaning Interior Instrument Components

***Note:*** *bioMérieux recommends that you shut down and power OFF the instrument during this maintenance procedure. Refer to Shutting Down the System before proceeding.*

**WARNING**

**Biohazardous materials could come in contact with the interior of the VITEK® 2 Compact instrument. All organism suspensions, cards, cassettes, test tubes, sample transfer tubes, and waste bin should be considered as potentially infectious.**

**CAUTION: Do not apply cleaning solutions or water to any sensors in the instrument, otherwise a malfunction may occur.**

## *Cleaning the Waste Collection Bin*

1. Open the Waste Collection door and remove the waste collection bin. Empty the bin if any cards are present.
2. Thoroughly clean and dry the bin before replacing it in the VITEK® 2 Compact instrument.

   The bin material is designed to withstand any of the following cleaning methods:

   - Automatic dishwasher with standard laboratory detergent
   - 5% bleach solution
   - Phenolic cleaning solution

   **CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C. Exceeding this temperature causes damage to the cassettes. Use the top rack of the dishwasher.**

3. Replace the waste collection bin in the Waste Collection station and close the Waste Collection door.

   If you are not performing the remaining cleaning procedures in this section and the instrument is already turned off, refer to Starting the System.

## *Cleaning the Filler Station*

The Filler Seal and Filler Station are designed to withstand any of the following cleaning methods.

- 5% bleach solution
- Phenolic cleaning solution

1. Dampen a cloth with one of the approved solutions and wipe off any dust or dirt from the rubber seal on the fill door and its contact surface.

   **CAUTION: Do not apply cleaning solutions or water to any sensors in the instrument, otherwise a malfunction may occur. Instead, use a dry cloth or lens paper.**

2. Using plain water, wipe the same surfaces again to remove any disinfectant residue.
3. Repeat steps 1 and 2 to clean the interior surface of the Filler Station.

If you are not performing the remaining cleaning procedures in this section and the instrument is already turned off, refer to Starting the System.

### *Cleaning the Cassette Load/Unload Station*

***Note:*** *bioMérieux recommends that you shut down and power OFF the instrument during this maintenance procedure. Refer to Shutting Down the System.*

The Cassette Load/Unload Station is designed to withstand any of the following cleaning methods:

- 5% bleach solution
- Phenolic cleaning solution

1. Dampen a cloth with one of these approved solutions and wipe the inside base surface of the instrument, where the cassette is processed.
2. Dampen a separate cloth with plain water and wipe the surface again to remove any disinfectant residue.

**⚠ CAUTION: Do not apply cleaning solution or water to any sensors in the instrument, a loss of instrument function may occur.**

If you are not performing the remaining cleaning procedures in this section and the instrument is already turned off, refer to Starting the System.

## Decontamination Procedures

If decontamination is necessary due to a biological hazard for the following components, follow cleaning procedures using a 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

- Cleaning the Carousel
- Cleaning the Cassettes
- Cleaning Instrument Exterior and User Access Doors
- Cleaning the Waste Collection Bin
- Cleaning the Filler Station
- Cleaning the Cassette Load/Unload Station

## Preventive Maintenance Operations

Preventive maintenance is required to keep the VITEK® 2 Compact instrument components in optimal condition. When performing preventive maintenance in Cleaning Procedures, print and record the information in the Maintenance Check-List.

# A Maintenance Records

**Table 20: Maintenance Schedule**

| Part | Frequency | Procedure |
|---|---|---|
| Carousel | Monthly | Cleaning the Carousel |
| Cassettes | Monthly | Cleaning the Cassettes |
| Transmittance Optics | Weekly | Cleaning the Optics (Power Off) |
| Waste Collection Bin | Monthly | Cleaning the Waste Collection Bin |
| Filler Seal | Monthly | Cleaning the Filler Station |
| Filler Station | Monthly | Cleaning the Filler Station |
| Carousel Temperature | Daily | QC Status |
| Transmittance Optics System Status | Daily | |

## Compact Maintenance Checklist

**YEAR:**

**MONTH:**

| Part Name | Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Frequency | | | | | | | | | | | | | | | | | |
| Carousel | M | | | | | | | | | | | | | | | | |
| Cassettes | M | | | | | | | | | | | | | | | | |
| Transmittance Optics | W | | | | | | | | | | | | | | | | |
| Waste Collection Bin | M | | | | | | | | | | | | | | | | |
| Filler Seal | M | | | | | | | | | | | | | | | | |
| Filler Station | M | | | | | | | | | | | | | | | | |
| Carousel Temperature | D | | | | | | | | | | | | | | | | |
| Transmittance Optics Temperature | D | | | | | | | | | | | | | | | | |
| Frequency TEST | | | | | | | | | | | | | | | | | |
| Frequency | | | | | | | | | | | | | | | | | |
| W = Weekly | | | | | | D = Daily | | | | | | M = Monthly | | | | | |
| Complete with your initials Keep a copy of the preventive maintenance charts. | | | | | | | | | | | | | | | | | |

## Compact Maintenance Checklist

**YEAR:**

**MONTH:**

| Part Name | Day | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Frequency | | | | | | | | | | | | | | | |
| Carousel | M | | | | | | | | | | | | | | | |
| Cassettes | M | | | | | | | | | | | | | | | |
| Transmittance Optics | W | | | | | | | | | | | | | | | |
| Waste Collection Bin | M | | | | | | | | | | | | | | | |
| Filler Seal | M | | | | | | | | | | | | | | | |
| Filler Station | M | | | | | | | | | | | | | | | |
| Carousel Temperature | D | | | | | | | | | | | | | | | |
| Transmittance Optics Temperature | D | | | | | | | | | | | | | | | |
| Frequency | | | | | | | | | | | | | | | | |
| W = Weekly | | | | | | D = Daily | | | | | | M = Monthly | | | | |
| Complete with your initials  Keep a copy of the preventive maintenance charts. | | | | | | | | | | | | | | | | |

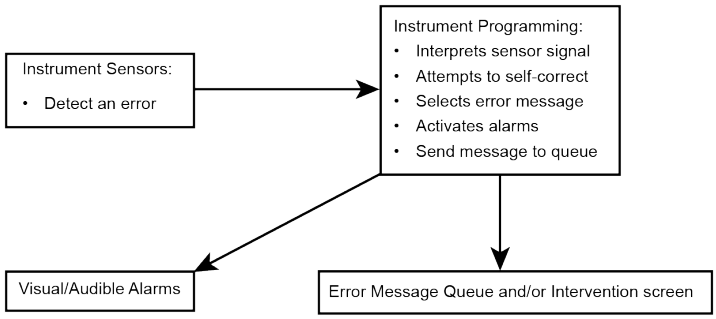
# B Troubleshooting

## Error Messages and Recovery Procedures

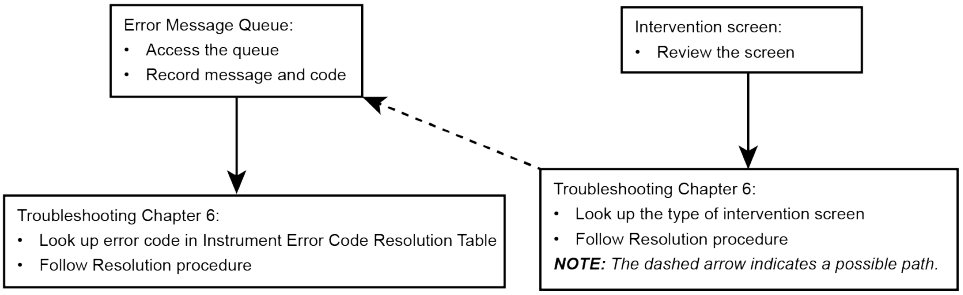
The VITEK® 2 Compact instrument continually monitors itself to ensure that it is operating within specifications. To do this, it uses numerous optical, mechanical, and temperature sensors located within each subsystem.

If a sensor detects a problem, the VITEK® 2 Compact instrument alerts you to the situation, and provides you with the information to resolve the problem. We refer to this process as the Error Handling System below.

**Figure 86: Error Handling Flowchart**
VITEK® 2 Compact Instrument




VITEK® 2 Compact User




There are two major types of error handling:

- Error Message Queue - For general errors or errors associated with the need for an intervention. This is indicated by a blinking/audible alert and the moving (!) on the Status screen.
- Intervention - Errors that need the user's immediate response. This is indicated by an Intervention screen and a visual/audible alert.

The first element of the Error Handling System is the VITEK® 2 Compact instrument. The instrument must first detect the error. In many cases, the instrument attempts to correct the problem by retrying an operation. If that fails, the instrument selects the appropriate error message, activates the error alarms, and places the message in the error message queue.

The second element of the Error Handling System is you, the VITEK® 2 Compact user. You must:

- Respond to the alarm by accessing the error message queue on the instrument interface.

- Read and record all unviewed messages in the queue.
- Locate the error code from the messages, refer to Instrument Error Codes, and follow the information in the Resolution column.
- Contact bioMérieux if the recovery procedure is not successful.

## Error Alarm Notification

The VITEK® 2 Compact instrument has two types of alarm notification to alert you to the presence of an error condition. You can select either the audible or the visible alarm on the instrument, or set both alarms to alert you.

- Audible Alarm - This alarm sounds at the VITEK® 2 Compact instrument. An instrument configuration option allows you to select the alarm (Setting Alert Options). Another instrument configuration option allows you to set the volume of the audible alarm (Setting Alert Volumes Screen).
- Visual Alarm - This alarm uses the screen on the interface display. When the visual alarm is activated, the screen flashes to indicate the presence of an error condition. An instrument configuration option allows you to select the visual alarm (Setting Alert Options).

## Error Message Queue Screens

On the Status screen, a New Error/Warning indicator icon to the left of the Instrument Status signifies that a new warning or error message was generated. To insure proper operation of the instrument when an error occurs, you should review it as soon as possible.

There are two Error Message Queue screens, the first is in a list form and the second is in detail form. You must review the detailed message to clear the New Error/Warning indicator icon.

The queue may contain as many as 250 messages, beginning with the most recent. Number 001 (Error Message Queue (List Form) is the most recent. When a new message is generated, it assumes number 001 and the other messages move down the list.

1. To review a message, press the **Message Key (!)** on the user interface.

**Figure 87: Error Message Queue (List Form)**


The Error Message Queue screen displays a list of error messages.

- An arrow to the left of the message points to the error to be displayed when the **Message Key (!)** is pressed again.
- An asterisk (*) to the far left of a message signifies that it has never been reviewed.

- An exclamation (!) to the immediate left of a message signifies that it is an error instead of a warning.

2. Use the **Arrow Keys** to move the pointer to the desired message. The **Up** and **Down Arrow** keys move the pointer one message at a time. The **Left Arrow** key scrolls to the previous page of messages. The **Right Arrow** key scrolls to the next page of messages.
3. Press the **Message Key (!)** again to display the detailed message.

**Figure 88: Error Message Queue (Detail Form)**


A row of numbers is listed just above a dash line at the bottom of the screen. The numbers pertain to the error:

- The time the error occurred
- The date the error occurred
- The last number is the code for the error:

  Example: 20:13.00.152

  - 20 is the primary code
  - 152 is the detailed part of the code

  Record this row of numbers for use when troubleshooting or contacting bioMérieux Customer Support.

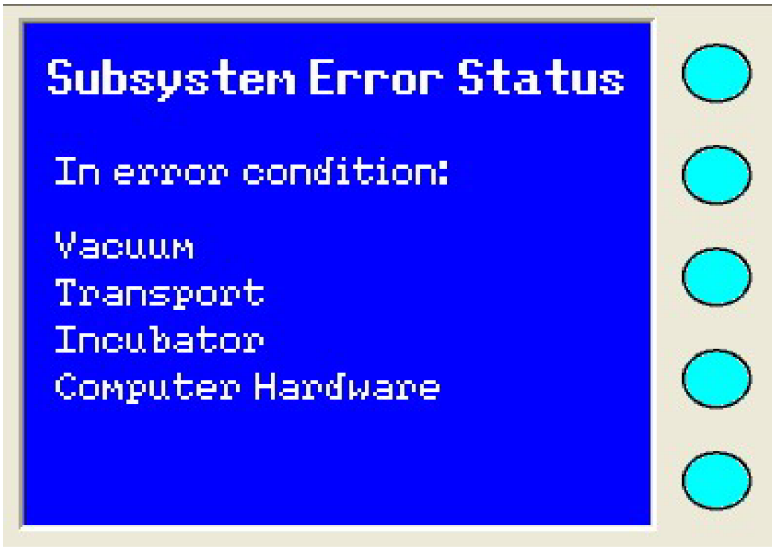
  - You can locate the detailed code number in Instrument Error Codes.
  - Review the Error Message queue for any error message in Instrument Error Codes.

## *Subsystem Error Status*

View the Subsystem Error Status screen when the instrument status is in an error condition. This screen provides additional details about the error.

1. Press the **Status/Menu** key to access the Main menu screen.
2. Select **Menu** > **Diagnostics** > **Subsystem Error Status** > **.**

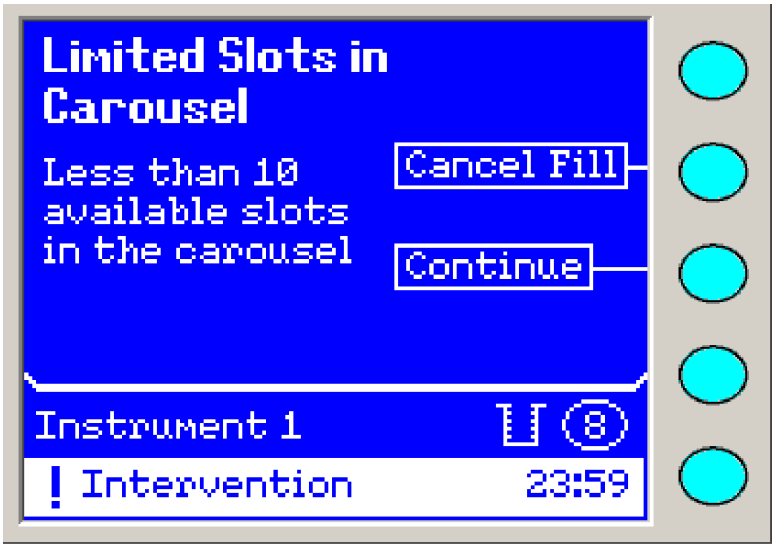
**Figure 89: Subsystem Error Status Screen**




*Intervention Screen*

An Intervention screen is only displayed if there is an error warning during initialization or card cassette processing that needs the user's immediate attention. It contains intervention messages and any other pertinent information. The Intervention screen always requires some type of response by the user.

**Figure 90: Intervention Sample Screen**




*Contents of Intervention Messages*

***Note:*** *Some Intervention screens need a timeout counter. This countdown timer displays on the upper right corner of the Intervention message and indicates the total number of minutes left for the user to intervene.*

The top section of the Intervention screen is comprised of three parts:

- Main Message at the top
- Detailed message/input located on the left
- Two active function buttons located on the right

## Interventions During Filling

The following intervention messages can display after the user presses **Start Fill** on the Main Status screen. These messages do not have a countdown timer, since the timeout is not critical until after a successful fill.

The Fill Intervention screen remains until you intervene.

### *Limited Slots in Carousel*

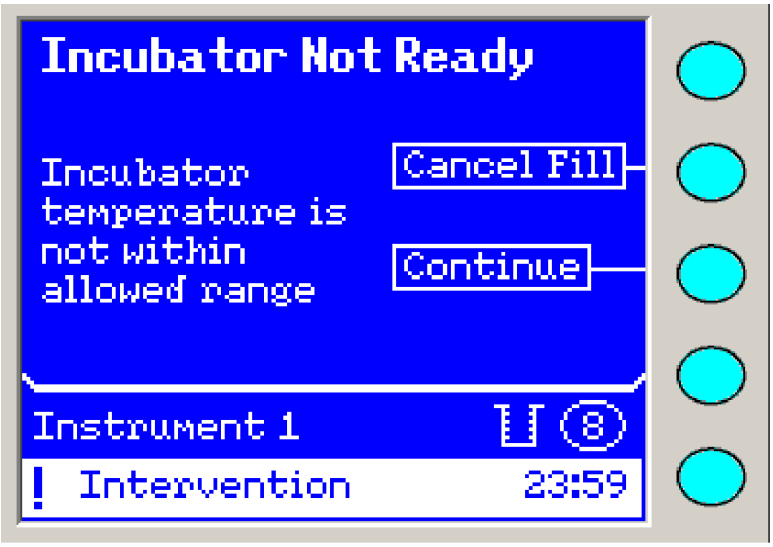
Less than 10 slots are available in the carousel.

1. Select either **Cancel Fill** or **Continue**.

### *Incubator Not Ready*

Incubator temperature is not within the allowed range (for example, instrument status is **Warming**).

**Figure 91: Incubator Not Ready**




Select either **Cancel Fill** or **Continue**.

### *Fill Door Open*

Filling cannot start.

1. Close Fill door.
2. Select **OK**.
3. Press **Start Fill** again.

### *Fill Failure – Discard All Cards*

1. Enter the *Cassette ID* to delete.
2. Select **OK**.
3. Discard all cards in the cassette.
4. Review any recent errors in the Error Message Queue and refer to Instrument Error Codes for further information.

***Note:*** *The **OK** function button will not appear until the user enters a digit.*

## Interventions During Loading

The following intervention message can display after a fill successfully completes, but the user has not successfully loaded the cassette into the Loader. This message does not have a countdown timer since this is a noncorrectable error and the cards terminate.

The Load Intervention screen remains until you intervene.

### *Transfer Failure – Discard All Cards*

The cassette was not moved from the Filler Station to the Cassette Load/Unload Station in the allowed time of 10 minutes.

**Figure 92: Transfer Failure**


1. Enter the *Cassette ID* to delete.
2. Select **OK**.
3. Discard all cards in the cassette.

***Note:*** *The **OK** function button does not appear until the user enters a digit.*

## Interventions During Bar Code Reading

The following intervention messages display when an error is detected during bar code reading. These interventions are time-critical, and a timeout counter displays.

When timed out, if the user has not resolved all of the interventions, the Intervention screen disappears and the cassette continues to process if the load door is closed. The instrument terminates cards with unresolved bar code errors, loads the rest of the cards into the carousel, and logs a message into the Error Message Queue.

If the load door is opened, all cards are terminated and no card is loaded.

### *Cassette Bar Code Unreadable*

1. Using the numeric keypad on the instrument user interface screen, enter *Cassette ID*.
2. Select either **Clear** or **Accept**.

***Note:*** *The **Accept** function key does not appear until the user enters a digit.*

After timeout, if the user has not entered a cassette ID, the cassette is left in the loader, the door is closed, and the card bar codes are readable, then the instrument loads the cards into the carousel, sends a Cassette ID to the workstation computer, and logs a message in the Error Message Queue.

### *Card [X] Bar Code Unreadable (Virtual Cassette Only)*

***Note:*** *[X] is the card slot number.*

1. Enter the last two digits of the bar code using the numeric keypad on the instrument user interface screen: 2 2 2 2 8 8 8 8 3 3 3 3 7 7 7 7 __ __ (example)
2. Select either **Skip** or **Accept**.

***Note:*** *If the **Skip** function is selected, the card(s) specified in the Intervention screen will not load and is terminated. The instrument returns these cards to the Cassette Load/ Unload Station for discard.*

The **Accept** function key appears only after you enter the last two digits correctly. Use the **Left Arrow** key to move back, and the **Right Arrow** key to move to the next digit, if that digit is already entered.

### *Card [X] Bar Code Unreadable (Setup Cards Post Entry)*

***Note:*** *[X] is the card slot number.*

1. Using the numeric keypad on the instrument user interface screen, enter the bar code number: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
2. Select either **Skip** or **Accept**.

***Note:*** *If the Skip function is selected, the card(s) specified in the Intervention screen will not load and is terminated. They return to the Cassette Load/Unload Station and should be discarded.*

The **Accept** function key appears only after you enter all digits correctly. Use the **Left Arrow** key to move back, and the **Right Arrow** key to move to the next digit if that digit is already entered.

### *Card [X] Bar Code Mismatch (Virtual Cassette)*

Bar code Scan: 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4 (example)

VC: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 (example)

1. Remove the cassette from the Cassette Load/Unload Station and locate the card(s) in the position that was previously entered on the workstation/host.
2. Reinstall the cassette in the Cassette Load/Unload Station, and close the door.
3. Select either **Skip** or **Fixed**.

***Note:*** *If the **Skip** function is selected, the card(s) specified in the Intervention screen will not load and is terminated. The instrument returns these cards to the Cassette Load/ Unload Station for discard.*

*Insufficient Slots in Carousel*

1. Remove the cassette from the Cassette Load/Unload Station.
2. Remove [Y] cards from slots:[X][X]. Discard these cards.

***Note:*** *[Y] represents the number of cards and [X] represents the card slot number.*

3. Replace the cassettes.
4. Select **Continue**.

*Error: Cannot Proceed*

1. Ensure that the cassette is placed properly in the Cassette Load/Unload Station.
2. Verify that the door is closed.

*Timed Out*

1. Remove cassette and close the Cassette Load/Unload door.
2. Discard all cards.
3. Select **Continue**.

## Jam Condition Intervention Messages

The instrument detects this kind of jam when cards are processing anywhere in the instrument.

⚠ **CAUTION: When clearing a jam, do not swap carousel sections or individual cards in the carousel. Doing so causes incorrect patient test results to occur.**

1. Select **Yes** when the Unlock user access door screen appears.

**Figure 93: Jam Condition**

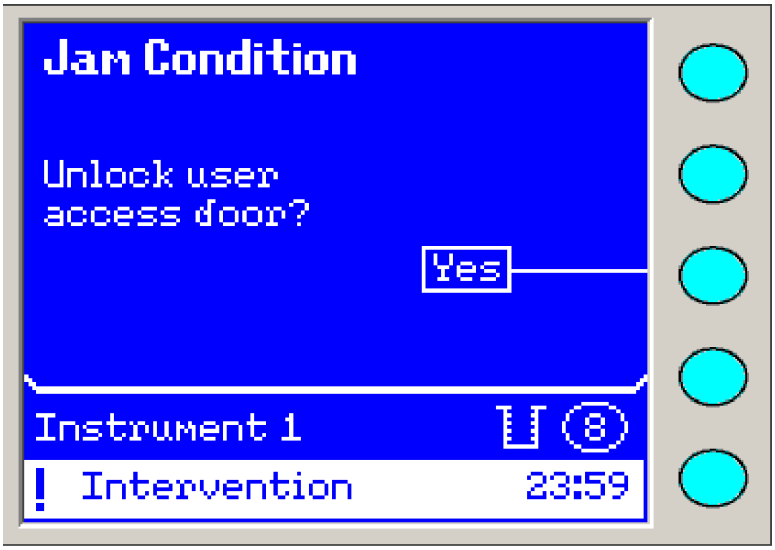
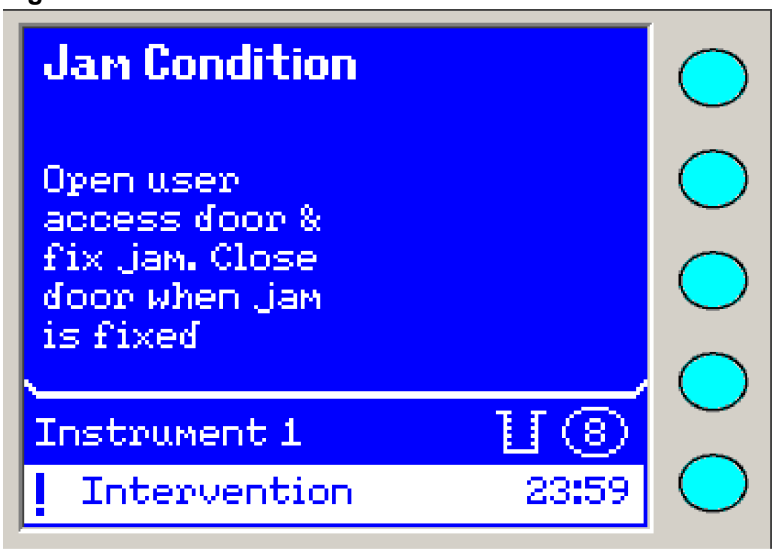


**Figure 94: Jam Condition Fix Intervention**




2. Open User Access Doors.
3. Determine the location of the jam (to determine this, review the Error Message Queue).

**WARNING**

⚠ **Unexpected mechanical movement can occur when the jam is cleared.**

4. Resolve any jam conditions and close the User Access Doors.

## Cycling the Power of the Instrument

Several of the Resolution procedures in Instrument Error Codes, instruct you to cycle the power of the instrument.

1. Perform the Instrument Shutdown procedure in Shutting Down the System.
2. Wait at least 10 seconds.
3. Move the AC power switch to the **ON** position.

## Using the Instrument Error Code Table

The Error Code Table is designed to provide, where possible, the recovery procedure that is most likely to restore the instrument to normal operation. If the described resolution does not prevent recurrences of the error, call bioMérieux for assistance.

1. Locate the detail code from the Error Message Queue screen described in Error Message Queue Screens.
2. Find the **Detail Code** from the first column of the table. Detail codes are listed numerically.
3. Read the corresponding **Detail Code Description**.
4. Read and follow the directions found in the **Resolution** column of the table and address accordingly.
5. If the error reoccurs, or the **Resolution** advises a call to bioMérieux, inform the service representative of the error number found in the lower right portion of the message screen.

## Instrument Error Codes

**Table 21: Instrument Error Code Resolution Table**

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 1 | N/A | <unused> | N/A |
| 2 | 1 Software Failure | Instrument failure | Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 3 | | | |
| 4 | 1 Software Failure | Instrument failure | Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 5 | | | |
| 6 | 1 Software Failure | Instrument failure | Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 7 | | | |
| 8 | 1 Software Failure | Instrument failure | Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 9 | | | |
| 10 | 1 Software Failure | Instrument failure | Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 11 | | | |
| 12 | 12 Software Warning | Instrument Failure | This warning indicates that an internal software resource has fallen below the expected minimum level. The instrument is still functioning normally.<br>Report to bioMérieux. |
| 13 | 1 Software Failure | Bar Code Reader failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 14 | 3 Vacuum/ Loader Failure | Bar Code Reader failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 15 | 8 Autoloader Jam | Autoloader motor failed to home | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 16 | 7 Transport Jam | Transport motor failed to home during initialization | This may be the result of a jam due to foreign material in the mechanism, or it |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 17 | 7 Transport Jam | Transport motor failed to home during loading (after cassette inspection) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 18 | 9 Sealer Jam | Sealer motor failed to home | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 19 | 3 Vacuum/ Loader Failure | Sealer failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 20 | | | |
| 21 | 3 Vacuum/ Loader Failure | Sealer failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 22 | | | |
| 23 | 13 Load Door Open | Load Door open while attempting initialization | Close door and cycle power (Cycling the Power of the Instrument). |
| 24 | 13 Load Door Open | Load Door open while attempting to initiate a cassette load | Close door and cycle power (Cycling the Power of the Instrument). |
| 25 | 3 Vacuum/ Loader Failure | Load Door will not lock | Ensure that the Load Door is fully closed. Check the latching mechanism for foreign materials. |
| 26 | 3 Vacuum/ Loader Failure | Load Door will not lock | Cycle Power (Cycling the Power of the Instrument).<br>Report to bioMérieux. |
| 27 | N/A | <unused> | N/A |
| 28 | 7 Transport Jam | Cassette is not hooked on transport block pins during initialization | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 29 | 7 Transport Jam | Transport motor stalled while counting cards | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | 3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 30 | N/A | <unused> | N/A |
| 31 | 7 Transport Jam | Transport motor stalled while reading card bar code | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 32 | 7 Transport Jam | Transport motor stalled while moving cassette toward load door during bar code retry | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition.<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 33 | 7 Transport Jam | Transport motor stalled while moving cassette toward load door | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | 1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 34 | 7 Transport Jam | Transport motor stalled while sealing | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 35 | 7 Transport Jam | Transport motor stalled while loading cards into carousel | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 36 | 7 Transport Jam | Transport motor stalled while unloading cassette | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | 1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 37 | 8 Autoloader Jam | Autoloader motor stalled while loading cards into carousel | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Message).<br>2. Open user access doors and/or load door.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 38 | 3 Vacuum/ Loader Failure | Vacuum SPN board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 39 | 4 Carousel/ Reader Failure | Carousel SPN board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 40 | 3 Vacuum/ Loader Failure | Transport SPN board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 41 | N/A | <unused> | N/A |
| 42 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 43 | | | |
| 44 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 45 | | | |
| 46 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 47 | | | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 48 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 49 | | | |
| 50 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 51 | | | |
| 52 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 53 | | | |
| 54 | 10 Host Communication Failure | Bad command received | A communications error has occurred. Report to bioMérieux. |
| 55 | | | |
| 56 | | | |
| 57 | 15 Carousel Cover Missing | Carousel cover is missing during pre-initialization check | Ensure that the carousel cover is properly installed. |
| 58 | | Carousel cover missing during carousel initialization | |
| 59 | 15 Carousel Cover Missing | Carousel cover detected missing during move | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 60 | 14 User Access Door Open | User access door is open during initialization | Close door and cycle power (Cycling the Power of the Instrument). |
| 61 | 3 Vacuum/ Loader Failure | User access door will not lock | Ensure that the user access door is fully closed. Check the latching mechanism for foreign materials. |
| 62 | 3 Vacuum/ Loader Failure | User access door will not unlock | Cycle power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 63 | 18 Carousel Section Missing | Quad missing during initialization | Referring to the carousel cleaning section and ensure that all quads are properly installed (Cleaning the Carousel). |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 64 | 6 Carousel Jam | Carousel motor failed to home during initialization | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 65 | 4 Carousel/ Reader Failure | Incubator temperature failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 66 | 5 Reader Jam | Ejector motor failed to home during initialization | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 67 | 5 Reader Jam | Cam motor failed to home during initialization | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 68 | 1 Software Failure | Instrument failure | Call bioMérieux. A power cycle may be required. |
| 69 | 1 Software Failure | Instrument failure | Call bioMérieux. A power cycle may be required. |
| 70 | | | |
| 71 | | | |
| 72 | 17 Card(s) Terminated | All cards unloaded due to incubator temperature fault, carousel position lost or unload via DML | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 73 | 17 Card(s) Terminated | Cards unloaded because their wellmap changed | Call bioMérieux. |
| 74 | 6 Carousel Jam | Carousel motor stalled | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 75 | 4 Carousel/ Reader Failure | Carousel position lost (all cards unloaded) | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required.<br>All cards in the carousel are terminated and an attempt is made to unload them into the waste collection bin. |
| 76 | 37 The card in slot (X) of cassette (X) was rejected because this instrument did not have an appropriate wellmap | Wellmap does not exist for a card during cassette inspection | This card is rejected (and terminated) due to the wellmap not being present.<br>Enter the needed wellmap before attempting to process any further cards of this type. |
| 77 | 17 Card(s) Terminated | Fill-to-load timeout was exceeded (card[s] unloaded) | Card(s) were terminated due to excessive time elapsing between the filling operation and the cassette loading being performed. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 78 | 17 Card(s) Terminated | Could not find the first edge of the card (terminated slot) | A card edge or hole could not be found. The card in this carousel slot is terminated. When instrument processing is idle, perform a carousel cleaning to gain access to the card and make the slot available (Cleaning the Carousel). |
| 79 | 5 Reader Jam | Could not find the first edge of the card (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 80 | 17 Card(s) Terminated | Each optical position mark was not detected in the card while moving out (terminated slot) | A card edge or hole could not be found. The card in this carousel slot was terminated. When instrument processing is idle, perform a carousel cleaning to gain access to the card and make the slot available (Cleaning the Carousel). |
| 81 | 5 Reader Jam | Each optical position mark was not detected in the card while moving out (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 82 | 19 Waste Bucket Full or Waste Door Open | Could not unload card, waste tray is full | Empty the waste bin (Removing the Waste Collection Bin and Test Cards). |
| 83 | 19 Waste Bucket Full or | Could not unload card, waste door is open | Close waste door. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | Waste Door Open | | |
| 84 | 19 Waste Bucket Full or Waste Door Open | Could not unload card, waste bin is not present | Replace the waste bin and close waste door (Replacing the Waste Collection Bin). |
| 85 | 19 Waste Bucket Full or Waste Door Open | Could not unload card, waste chute is clogged | Ensure that the waste bin is empty, present, and that the waste door is closed. Check to be sure there are no cards remaining in the waste chute. |
| 86 | 19 Waste Bucket Full or Waste Door Open | Failed to eject card into waste bin (card was still in read head) | Ensure that the waste bin is empty, present, and that the waste door is closed. Check to be sure there are no cards remaining in the waste chute. |
| 87 | 5 Reader Jam | Failed to place the card back into carousel while verifying the head was clear (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 88 | 5 Reader Jam | Could not find the first edge of the card while reading (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 89 | 17 Card(s) Terminated | Could not find the first edge of the card while reading (terminated slot) | A card edge or hole could not be found. The card in this carousel slot was terminated. When instrument processing is idle, perform a carousel cleaning to |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | gain access to the card and make the slot available (Cleaning the Carousel). |
| 90 | 5 Reader Jam | Each optical position mark (Air) was not detected while reading (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 91 | 17 Card(s) Terminated | Each optical position mark (Air) was not detected while reading (terminated slot) | A card edge or hole could not be found. The card in this carousel slot was terminated. When instrument processing is idle, perform a carousel cleaning to gain access to the card and make the slot available (Cleaning the Carousel). |
| 92 | 5 Reader Jam | Each optical position mark (Plastic) was not detected while reading (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 93 | 17 Card(s) Terminated | Each optical position mark (Plastic) was not detected while reading (terminated slot) | A card edge or hole could not be found. The card in this carousel slot is terminated. When instrument processing is idle, perform a carousel cleaning to gain access to the card and make the slot available (Cleaning the Carousel). |
| 94 | 5 Reader Jam | The last edge of the card was not detected while reading (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | 1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 95 | 17 Card(s) Terminated | The last edge of the card was not detected while reading (terminated slot) | A card edge or hole could not be found. The card in this carousel slot was terminated. When instrument processing is idle, perform a carousel cleaning to gain access to the card and make the slot available (Cleaning the Carousel). |
| 96 | 5 Reader Jam | An additional row was detected while reading (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 97 | 17 Card(s) Terminated | An additional row was detected while reading (terminated slot) | A card edge or hole could not be found. The card in this carousel slot was terminated. When instrument processing is idle, perform a carousel cleaning to gain access to the card and make the slot available (Cleaning the Carousel). |
| 98 | 5 Reader Jam | Cam failure while reading (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | 3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 99 | 5 Reader Jam | Cam failure (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 100 | 5 Reader Jam | Cam failure (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 101 | 5 Reader Jam | Carousel jam after a Cam failure (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | 3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 102 | 5 Reader Jam | Cam failure (JAMMED) | This may be the result of a jam due to foreign material in the mechanism, or it may indicate a mechanical or electrical failure.<br>1. Respond to the Intervention screen for the jam condition (Jam Condition Intervention Messages).<br>2. Open user access doors.<br>3. Examine the affected component for dirt or obstruction (normal jam-clearing actions).<br>4. If this is related to a transport jam, reposition the cassette on the transport block before closing door.<br>5. If the failure reoccurs, call bioMérieux. |
| 103 | 4 Carousel/ Reader Failure | Head Control Board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 104 | 43 Optics problem | Transmittance Optics module TX1 failed calibration | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 105 | 43 Optics problem | Transmittance Optics module TX2 failed calibration | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 106 | 43 Optics problem | Transmittance Optics module TX3 failed calibration | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 107 | 43 Optics problem | Transmittance Optics module TX1 position sensor not functional | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 108 | 43 Optics problem | Transmittance Optics module TX2 position sensor not functional | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 109 | 43 Optics problem | Transmittance Optics module TX3 position sensor not functional | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 110 | 21 Optics Almost Out of Calibration | Transmittance Optics module TX1 nearing calibration limits | The instrument is still functioning normally, however perform optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 111 | 21 Optics Almost Out of Calibration | Transmittance Optics module TX2 nearing calibration limits | The instrument is still functioning normally, however perform optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 112 | 21 Optics Almost Out of Calibration | Transmittance Optics module TX3 nearing calibration limits | The instrument is still functioning normally, however perform optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 113 | 43 Optics problem | Transmittance Optics module TX1 is not available to process this card | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 114 | 43 Optics problem | Transmittance Optics module TX2 is not available to process this card | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 115 | 43 Optics problem | Transmittance Optics module TX3 is not available to process this card | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 116 | 43 Optics problem | Transmittance Optics module TX1 reference readings out of range | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 117 | 43 Optics problem | Transmittance Optics module TX2 reference readings out of range | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 118 | 43 Optics problem | Transmittance Optics module TX3 reference readings out of range | Ensure that the TX optics modules are closed and perform TX optics cleaning (Cleaning the Optics With Cards Processing - Power On). |
| 119 | 11 Internal Data Error | Component Statistics failure | Report to bioMérieux. |
| 120 | | | |
| 121 | | | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 122 | 11 Internal Data Error | Carousel Map memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required.<br>Any tests running in the carousel are lost. Perform a carousel cleaning (Cleaning the Carousel) to manually remove all cards from the carousel. |
| 123 | 11 Internal Data Error | Carousel Map memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required.<br>Any tests running in the carousel are lost. Perform a carousel cleaning (Cleaning the Carousel) to manually remove all cards from the carousel. |
| 124 | 11 Internal Data Error | Carousel Map memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required.<br>Any tests running in the carousel are lost. Perform a carousel cleaning (Cleaning the Carousel) to manually remove all cards from the carousel. |
| 125 | 11 Internal Data Error | Cassette memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required.<br>Any tests running in the carousel are lost. Perform a carousel cleaning (Cleaning the Carousel) to manually remove all cards from the carousel. |
| 126 | 12 Software Warning | Memory failure | Some card reading data may be lost due to a power failure, software crash, or turning off the instrument without first performing the shutdown process.<br>This may prevent results from being obtained for one or more samples. |
| 127 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 128 | | | |
| 129 | 12 Software Warning | Memory failure | Some card reading data may be lost due to loss of communications with the host computer.<br>This may prevent results from being obtained for one or more samples. |
| 130 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 131 | | | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 132 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 133 | | | |
| 134 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 135 | | | |
| 136 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 137 | | | |
| 138 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 139 | 11 Internal Data Error | Memory failure | Report to bioMérieux. The instrument's error code history is lost. |
| 140 | | | |
| 141 | | | |
| 142 | 12 Software Warning | Memory failure | Report to bioMérieux. |
| 143 | 11 Internal Data Error | Memory failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 144 | 12 Software Warning | Memory failure | Report to bioMérieux. |
| 145 | 11 Internal Data Error | WellMap Manager can not add more WellMaps | Report to bioMérieux. |
| 146 | 22 Hardware Failure | SPN board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 147 | N/A | <unused> | N/A |
| 148 | N/A | <unused> | N/A |
| 149 | | | |
| 150 | N/A | <unused> | N/A |
| 151 | | | |
| 152 | 20 Doors opened while processing – Emergency Stop occurred | Emergency Stop – door open while locks engaged | A door was opened while locked. As this could present a hazard to the user, all instrument operations are halted.<br>Ensure doors are closed and then cycle power to the instrument (Cycling the Power of the Instrument).<br>If a cassette was processing in the transport, it tries to recover when power is restored. (Do not remove cassette unless prompted.) |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 153 | 22 Hardware Failure | RTC and CPU Xtal cross-check failure – frequency mismatch | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 154 | 3 Vacuum/ Loader Failure | Cabinet Temperature High | Ensure that the instrument's ambient temperature specifications are not exceeded (Checking the Instrument Temperature).<br>Ensure that the cabinet ventilation fans are not blocked and that all air filters are clean. |
| 155 | 22 Hardware Failure | Power Supply Temperature High | |
| 156 | 24 UPS power failure or battery bad | UPS indicates a power failure has occurred | A power failure has occurred and the instrument is operating on the UPS battery. |
| 157 | 24 UPS power failure or battery bad | UPS Battery has failed | The battery in the UPS may be defective. Call bioMérieux. |
| 158 | 22 Hardware Failure | Cabinet intake fan is rotating too slowly. | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 159 | | Cabinet exhaust fan is rotating too slowly. | |
| 160 | 23 Incubator failure | Incubator heater fan is rotating too slowly. | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 161 | | Incubator circulation fan is rotating too slowly. | |
| 162 | 23 Incubator failure | Incubator temperature is out of specification. | Ensure that the instrument's ambient temperature specifications are not exceeded (Checking the Instrument Temperature).<br>Ensure that the cabinet ventilation fans are not blocked and that all air filters are clean.<br>Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 163 | 25 Filler failure | Fill cycle failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 164 | | | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 165 | 25 Filler failure | Insufficient vacuum level achieved during fill cycle | Enter cassette ID as prompted and discard cards.<br>Ensure that the door seal on the vacuum filler is clean, then perform filler test (Filler Test). |
| 166 | | Incorrect up slope during fill cycle | |
| 167 | | Incorrect down slope during fill cycle | |
| 168 | 25 Filler failure | Fill cycle failure | Enter cassette ID as prompted and discard cards.<br>The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 169 | | | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 170 | 26 The card in slot (X) of cassette (X) will not be loaded because it was not detected after a power failure | The card was removed from the cassette during a power failure and replaced with another card. | Discard the identified card(s). They were not accepted for processing. |
| 171 | | The card was removed from the cassette during a power failure. | |
| 172 | 27 The card in slot (X) of cassette (X) will not be loaded because it could not be scanned after a power failure | The card was no longer readable after a power failure. | Discard the identified card(s).They were not accepted for processing. |
| 173 | 28 The card in slot (X) of cassette (X) will not be loaded because it exceeded the loading timeout | The card was not loaded in the time allowed. (Power Failure) | Discard the identified card(s). They were not accepted for processing. |
| 174 | | | |
| 175 | 29 The card in slot (X) of cassette (X) will not be loaded because it encountered a mechanical error while sealing | The card was being sealed when a mechanical error occurred. (Power Failure) | Discard the identified card(s). They were not accepted for processing. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 176 | N/A | <unused> | N/A |
| 177 | 29 The card in slot (X) of cassette (X) will not be loaded because it encountered a mechanical error while sealing | The card was being sealed when a transport mechanical error occurred. (Alarm) | Discard the identified card(s). They were not accepted for processing. |
| 178 | | The card was being sealed when a transport mechanical error occurred. (jam) | |
| 179 | 30 The card in slot (X) of cassette (X) was rejected because it has expired | The card was rejected because the card is expired. | Discard the identified card(s). They were not accepted for processing. |
| 180 | 31 The card in slot (X) of cassette (X) was rejected because of insufficient carousel capacity | The card was rejected because of insufficient carousel capacity. | |
| 181 | 32 The card in slot (X) of cassette (X) was rejected because it was introduced after the cards in the cassette were sealed | The card was rejected because it was introduced in place of another card during a power failure. | Discard the identified card(s). They were not accepted for processing. |
| 182 | | The card was rejected because it was introduced where no previous card was during a power failure. | |
| 183 | 33 The card in slot (X) of cassette (X) was rejected because this instrument is not configured with the required optics | The card was rejected because the instrument does not have the required optics. | Discard the identified card(s). They were not accepted for processing. |
| 184 | 34 The card in slot (X) of cassette (X) was rejected because a virtual card was | The card was defined and was not detected during processing. | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | defined for that slot and not detected | | |
| 185 | 35 The card in slot (X) of cassette (X) was rejected because the scanned card did not match the virtual card defined for that slot | The card was rejected because it mismatched the definition. | Discard the identified card(s). They were not accepted for processing. |
| 186 | 36 The card in slot (X) of cassette (X) was rejected because the scanned card did not match the virtual card when the cassette timed out | The card was rejected because it mismatched the definition during a timeout. | |
| 187 | 37 The card in slot (X) of cassette (X) was rejected because this instrument did not have an appropriate wellmap | The card was rejected because the instrument did not have a proper wellmap. | Discard the card(s). The “Maintain AST definitions” data entry for this card type should be performed before attempting to process additional cards of this type.<br>For details, see **Maintain AST Card Definitions** in the *VITEK® 2 Systems Software User Manual*. |
| 188 | 40 The card in slot (X) of cassette (X) was not loaded due to a biological timeout | The card was rejected because the cassette load timer timed out. | Discard the identified card(s). They were not accepted for processing. |
| 189 | | The card was rejected because the cassette load timer timed out over a power failure. | Discard the identified card(s). They were not accepted for processing. |
| 190 | 41 The card in slot (X) of cassette (X) was not loaded because it timed out and was unreadable | The card was rejected because the intervention timer timed out and the Bar Code was unreadable. | Discard the identified card(s). They were not accepted for processing. |
| 191 | 42 The card in slot (X) of | The card was rejected (user skipped). | Discard the identified card(s). They were not accepted for processing. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | cassette (X) was rejected | | |
| 192 | 38 Cassette (X) was aborted by the user | The cassette transfer was aborted by the user. | Discard the card(s) in the specified cassette. They were not accepted for processing. |
| 193 | 39 Cassette (X) was terminated due to a fill failure | A filling failure occurred (cassette cancelled) | Discard the card(s) in the specified cassette. They were not accepted for processing. |
| 194 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 195 | 44 Component Stats | N/A | |
| 196 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 197 | 44 Component Stats | N/A | |
| 198 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 199 | 44 Component Stats | N/A | |
| 200 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 201 | 44 Component Stats | N/A | |
| 202 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 203 | 44 Component Stats | N/A | |
| 204 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 205 | 44 Component Stats | N/A | |
| 206 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 207 | 44 Component Stats | N/A | |
| 208 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 209 | 44 Component Stats | N/A | |
| 210 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 211 | 44 Component Stats | N/A | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 212 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 213 | 44 Component Stats | N/A | |
| 214 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 215 | 44 Component Stats | N/A | |
| 216 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 217 | 44 Component Stats | N/A | |
| 218 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 219 | 12 Software Warning | SPN Variable Error | Call bioMérieux. |
| 220 | 1 Software Failure | SPN Variable Error | Call bioMérieux. |
| 221 | 12 Software Warning | SPN Variable Error | Call bioMérieux. |
| 222 | 1 Software Failure | SPN Variable Error | Call bioMérieux. |
| 223 | 12 Software Warning | SPN Variable Error | Call bioMérieux. |
| 224 | 1 Software Failure | SPN Variable Error | Call bioMérieux. |
| 225 | 12 Software Warning | A DML ‘LOGIN’ macro is present | Call bioMérieux. |
| 226 | 1 Software Failure | Memory failure | Cycle Power (Cycling the Power of the Instrument). Report to bioMérieux. |
| 227 | 46 Cassette (X) was not transferred to the loader within the appropriate time | The Cassette was not transferred in the allotted time. (10 Minutes) | Discard the card(s) in the specified cassette. They were not accepted for processing. |
| 228 | 47 The scanned cassette ID did not match the stored cassette ID while verifying an accepted cassette | The scanned cassette ID did not match the scanned ID | This error indicates that after a power failure or clearing of a jam, the cassette ID that was scanned does not match the original ID that was scanned or user-entered.<br>If the bar code of the cards match the originally scanned bar codes, this error is informational only. If they did not match, other errors relating to those cards |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | | rejections are logged. This error code provides information only. |
| 229 | 48 Cassette (X) was filling when power failed and has been discarded | A cassette was filling when a power failure occurred. | Discard the card(s) in the specified cassette. They were not accepted for processing. |
| 230 | 1 Software Failure | Instrument failure | Call bioMérieux. A power cycle may be required. |
| 231 | 28 The card in slot (X) of cassette (X) will not be loaded because it exceeded the loading timeout | The card was not loaded in the time allowed. (power failure). | Discard the card(s) in the specified cassette. They were not accepted for processing. |
| 232 | 1 Software Failure | Reboots halted due to repeating error | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 233 | 22 Hardware Failure | SPN board failure | |
| 234 | 22 Hardware Failure | SPN board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 235 | | Emergency Stop – Front Panel SPN board failure | |
| 236 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 237 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 238 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 239 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 240 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 241 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 242 | 49 A fill was stopped because no vacuum was achieved (Clean the Seal) | A vacuum was not achieved during a fill. | Ensure that the door seal on the vacuum filler is clean and then re-try the filling operation (See Cleaning the Filler Station). |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 243 | 50 Detected a loose read head belt or noisy optical position sensor | Position sensor TX1 tripped during reader head belt test, off condition | Call bioMérieux. |
| 244 | 50 Detected a loose read head belt or noisy optical position sensor | Position sensor TX2 tripped during reader head belt test, off condition | Call bioMérieux. |
| 245 | 50 Detected a loose read head belt or noisy optical position sensor | Position sensor TX3 tripped during reader head belt test, off condition | Call bioMérieux. |
| 246 | 50 Detected a loose read head belt or noisy optical position sensor | Position sensor TX1 tripped during reader head belt test, on condition | Call bioMérieux. |
| 247 | 50 Detected a loose read head belt or noisy optical position sensor | Position sensor TX2 tripped during reader head belt test, on condition | Call bioMérieux. |
| 248 | 50 Detected a loose read head belt or noisy optical position sensor | Position sensor TX3 tripped during reader head belt test, on condition | Call bioMérieux. |
| 249 | 4 Carousel/ Reader Failure | SPN board failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 250 | 3 Vacuum/ Loader Failure | | |
| 251 | | | |
| 252 | 22 Hardware Failure | | |
| 253 | 40 The card in slot (X) of cassette (X) was not loaded due to a biological timeout | The card was rejected because the first read timer timed out. | The cards were not loaded, probably due to a power failure or jam recovery. Discard the card(s) in the specified cassette. They were not accepted for processing. |
| 254 | 40 The card in slot (X) of cassette (X) was not loaded due to a biological timeout | | |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| 255 | 41 The card in slot (X) of cassette (X) was not loaded because it timed out and was unreadable | The card was rejected because the intervention timer timed out and the bar code was unreadable. | Discard the card(s) specified. They were not accepted for processing. |
| 256 | 1 Software Failure | Instrument failure | Call bioMérieux. A power cycle may be required. |
| 257 | 1 Software Failure | Instrument has reset | Report to bioMérieux. |
| 258 | 51 The card in slot (X) of cassette (X) was terminated because the cassette was not present after a power failure | The Cassette was removed over a power failure while it was in process. | Discard the card(s) specified. They were not accepted for processing. |
| 259 | 1 Software Failure | Instrument failure | Call bioMérieux. A power cycle may be required. |
| 260 | 45 BurnIn | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| 261 | | | |
| 262 | 1 Software Failure | Instrument failure | Call bioMérieux. A power cycle may be required. |
| 263 | 40 The card in slot (X) of cassette (X) was not loaded due to a biological timeout | The card was rejected because the first read timer timed out (power failure). | Discard the card(s) specified. They were not accepted for processing. |
| 264 | 40 The card in slot (X) of cassette (X) was not loaded due to a biological timeout | The card was rejected because the cassette load timer timed out (power failure). | Discard the card(s) specified. They were not accepted for processing. |
| 265 | 41 The card in slot (X) of cassette (X) was not loaded because it timed out and was unreadable | The card was rejected because the intervention timer timed out and the Bar Code was unreadable (power failure). | Discard the card(s) specified. They were not accepted for processing. |
| 266 | 42 The card in slot (X) of cassette (X) was rejected | The card was rejected because it has a duplicate in | Discard the card(s) specified. They were not accepted for processing. |

| Detail Code | Primary Code | Detail Code Description | Resolution |
|---|---|---|---|
| | | the cassette or carousel. | |
| 267 | | The card was rejected because the cassette is out of alignment. | |
| 268 | 3 Vacuum/ Loader Failure | Sealer failure | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |
| 269 | | | |
| 270 | 44 Component Stats | N/A | Instrument errors of this type should not occur in normal processing mode. (Factory only.) |
| | | | |
| 272 | 10 Host Communication Failure | No response from the Workstation PC for 1 hour. | Workstation may be turned off or may not be connected. Check the power on the PC and be sure the data cable is secure. |
| 273 | 17 Card(s) Terminated | Card(s) terminated due to missing card in carousel from same cassette | The card(s) were terminated because the instrument detected an inconsistency between cards loaded from the same cassette. |
| 274 | 42 The card in slot (X) of cassette (X) was rejected | A card that was previously loaded was rejected because the cassette processing verification failed. | Discard the identified card(s). They were not accepted for processing. |
| 275 | 42 The card in slot (X) of cassette (X) was rejected | A card that was previously loaded was rejected because the verify cassette set up (power failure or jam) failed. | Discard the identified card(s). They were not accepted for processing. |
| 276 | 22 - Hardware Failure | 1 - wire serial number is unreadable | The instrument is in a fault condition. Call bioMérieux. A field service visit is likely required. |

# C Appendix - Glossary

**Barcode**

- A label affixed to each VITEK® 2 test card. The barcode contains the test card's test type, lot number, and expiration date. The barcode is entered into the system when the Barcode Reader scans the test card’s barcode label.
- An alphanumeric identifier for the configuration of the susceptibility panel located on the package insert. The barcode is entered into the Maintain AST Card Definitions prior to running the AST card.

**Bar Code Reader (Instrument)**

This station reads the bar code label on each cassette and test card after the test cards are loaded into the Cassette Load/Unload Station. It then transfers all of the test card bar code data to the workstation computer.

**Carousel**

The rotating incubator section, which holds up to 60 test cards per incubator.

**Cassette**

The cassette is a card and test tube carrier that holds up to 15 tests. It is used for sample preparation and processing inside the instrument. It can contain a button memory chip that is used to transfer information from the Smart Carrier Station to the VITEK® 2 Workstation computer.

**Filler Station**

The Filler Station inoculates all of the cards in a cassette with the suspension contained in their corresponding test tubes. It uses a vacuum chamber and air pump.

**LED**

Light emitting diode, a light emitting device used in optical displays. See also, Transmittance Optics.

**Sealer Station**

This station seals each test card by cutting and sealing its associated inoculum transfer tube using a hot wire.

**Test Card**

A plastic, disposable card consisting of a set number of wells containing either biochemical substrates (for identification purposes) or antimicrobial concentrations (for susceptibility testing of microbes).

**Transmittance Optics**

A combination of light-emitting diodes (emitters) and photodiodes used to read the growth results in the card wells.

**User Access Doors**

VITEK® 2 Compact has two doors to enable the operator to access the internal systems and stations to perform maintenance and cleaning procedures: Top User Access Door and Front User Access Door.

**VITEK® FLEXprep™**

An application that allows the user to enter cassette definition from a web client PC prior to loading the cards in the instrument.

### Waste Collection Station

Once testing is complete, cards are stacked in a tray for disposal.

### Workstation/Host Computer

The workstation computer is the primary processor used in calculating test results. The workstation can also be used as a means to interface the instrument with a central laboratory information system (LIS) or hospital computer system.

The workstation computer provides the user with the graphical user interface used with the mouse pointing device and workstation monitor, and a text interface for the keyboard. It is also used to configure some options on the system (for example, time of AST card ejection or manually delete/eject cards).

# Revision History

This section contains a summary of changes made to each released revision of this document starting with part number:

040436-03 or 510772-3EN1.

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 |

***Notes:***

- *Minor typographical, grammar, and formatting changes are not included in the revision history.*
- *Not all versions may be available in all languages.*

**Table 22: Revision History**

| Release Date | Reference Number | Change Type | Change Summary |
|---|---|---|---|
| 2020-05 | 040306-03 | Administrative | Updated - **Front Matter**, **Patent Information**, **Warranty**, and **copyright information** |
| | | Technical Change | Updated - **Front matter: Patent information** per Legal department; patent information now available on lab equiptment labels<br>Patent information updated to read: The VITEK® 2 Compact instrument may be covered by one or more of the following U.S. Patent Numbers: http://www.biomerieux-usa.com/patents |
| | | Technical Change | Updated - **System Description and Basic**<br>Added a new sentence to clarify contents that are available for purchase and not inclued with start-up kit. |
| | | Technical Change | Updated - **System Description and Basic**<br>Figure 13: changed callout 3 to refer to Load Indicator Status table. |
| | | Technical Change | Updated - **Table 21: Instrument Error Code**<br>• Removed "(may need cleaning)" from text in rows 104, 107, and 113<br>• Added row 276 (Code 22 Hardware Failure) |
| | | Technical Change | Updated - **Appendix B Troublshooting**<br>Wording change for "Error Message Queue" entry: For general errors or errors associated with the need for an intervention. This is indicated by a blinking/audible alert and the moving (!) on the Status screen. |
| | | Technical Change | Updated - **TX13 callouts to Unified Optics**<br>Throughout the manual, TX13 was replaced with unified optics to be consistent with other documentation. |
| 2015-07 | 510772-5EN1 | Technical change: | Updated - **Section: Intended Use and Users** to specify Clinical and Industry users. |
| | | Technical change: | Updated - **Section: System Description** to include new workflow for FLEXprep using the VITEK® 2 Systems Remote Web Client. |
| | | Technical change: | Updated - **Section: Workflow** to include <tm tmtype="reg">VITEK</tm> 2 FLEXprep Workflow. |
| | | Technical change: | Added - Warning in **Section: Shutting Down the System** to include for elevated temperatures. |

| Release Date | Reference Number | Change Type | Change Summary |
|---|---|---|---|
| | | Technical change: | Added - Warning in **Section: Cleaning the Optics (With Cards Processing – Power On)** and **Section: Cleaning the Optics (Power Off)** regarding user to report any apparent crack, scratch, or broken glass. |
| 2014-05 | 510772-4EN1 | Administrative | Added – **Section: General Information**. |
| | | Administrative | Removed – **Section: Introduction**. This information can be located in **General Information**. |
| | | Administrative | Added – **Section: Intended Use and Users**. This information was previously contained in Intended Audience and Intended Use. |
| | | Administrative | Removed – **Section: Purpose of the VITEK 2 Compact System**. This information can be located in **System Description**. |
| | | Administrative | Removed – **Section: Purpose of this Manual**. |
| | | Administrative | Removed – **Section: Additional Supplies**. |
| | | Administrative | Removed – **Section:Manual Organization**. |
| | | Administrative | Added – **Section: Benefits and Limitation of Use**. |
| | | Administrative | Added – **Section: 21 CFR and HIPPA**. |
| | | Administrative | Added – **Section: Warning and Safety Messages**. |
| | | Administrative | Revised – **Section: General Statements** to **General Warnings**. |
| | | Administrative | Added – **Section: Standard Symbols**. |
| | | Administrative | Removed – **Section: Instrument Overview**. |
| | | Administrative | Removed – **Section: Installation Recommendations**. This information can be located in **System Installation and Configuration**. |
| | | Administrative | Removed – **Section: External Instrument Components**. This information can be located in **Overview of Operation Elements**. |
| | | Administrative | Removed – **Section: Turning on the VITEK 2 Compact Instrument**. This information can be located in **Workflow and Instructional Procedures**. |
| | | Administrative | Removed – **Section: Internal Processing**. This information can be located in **System Basics** and **Overview of Operation Elements**. |
| | | Administrative | Added – **Section: Safety Information** that includes the following topics: System |

| Release Date | Reference Number | Change Type | Change Summary |
|---|---|---|---|
| | | | Compliance, Instrument Labels, and Safety Precautions. |
| | | Administrative | Added – **Section: System Description and Basic Operations** that includes the following topics: System Description, Reagents, List of Accessories, List of Consumables, Technical Data and Specifications, System Basics, and Overview of Operation Elements. |
| | | Technical Change | Updated – **Figure 27** to add Cassette Success and Cassette Exception. |
| | | Technical Change | Removed – Sealer stub length parameter and characteristics from **Table 1**. |
| | | Technical Change | Updated – **Section: Test Card Incubation and Reading** to add "maximum" to indicate the capacity of test cards in the carousel. |
| | | Administrative | Removed – **Section: Configuration**. This information can be located in **System Installation and Configuration**. |
| | | Administrative | Added – **Section: System Installation and Configuration** that includes the following topic of **Configuration**. |
| | | Technical Change | Updated – **Section: System Installation and Configuration > Configuration** to indicate there are 20 sub-menus. |
| | | Administrative | Removed – **Section: Processing Cards**. This information can be located in **System Description and Basic Operations** and **Workflow and Instructional Procedures**. |
| | | Administrative | Added – **Section: Workflow and Instructions Procedures** that includes the following topics: Starting the System, Workflow, Prepare Test Cards and Cassettes, Generate Cassette Worksheet, Loading a Cassette, Monitor Card Processing, Unloading a Cassette, Removing the Waste Collection Bin and Test Cards, Replacing the Waste Collection Bin, and Shutting Down the System. |
| | | Technical Change | Moved – Caution statement in **Section: Workflow and Instructions Procedures > Generate Cassette Worksheet** to **Section: Workflow and Instructions Procedures > Monitor Card Processing**. |
| | | Technical Change | Updated – **Table 15: Workflow** to separate Virtual Cassette and Setup Tests Post Entry activities. |
| | | Administrative | Removed – **Section: Instrument Maintenance**. This information can be located in **Calibration and Adjustments** and **Cleaning Procedures**. |

| Release Date | Reference Number | Change Type | Change Summary |
|---|---|---|---|
| | | Administrative | Added – **Section: User Maintenance** that includes the following topics of: Required Tools, Calibration and Adjustments, Cleaning Procedures, Decontamination Procedures, and Preventive Maintenance Operations. |
| | | Technical Change | Added – Caution statement of moving parts in **Section: User Maintenance > Cleaning Procedures > Replacing the Carousel**. |
| | | Technical Change | Added – Internal cabinet temperature to **Table 17: Diagnostic Tests**. |
| | | Technical Change | Removed – Automatic Dishwasher with standard laboratory detergent in **Section: User Maintenance > Required Tools**. |
| | | Technical Change | Updated – **Section: Manual Temperature Check** to instruct user to turn the thermometer on before inserting into incubator cover. |
| | | Technical Change | Technical Change – **Section: Cleaning the Optics (With Cards Processing – Power On) and Cleaning the Optics (Power Off)**. Additional information when cleaning transmittance optics to push reader head plate down and clean close to the glass. |
| | | Technical Change | Updated – **Section: Cleaning the Optics (With Cards Processing – Power On) and Cleaning the Optics (Power Off)** to add TX13 information. |
| | | Technical Change | Updated – **Section: Cleaning the Optics (Power Off)** to remove commercial glass cleaner and replace with alcohol. |
| | | Administrative | Removed – **Section: Diagnostics and Troubleshooting**. This information can be located in Troubleshooting. |
| | | Administrative | Removed – **Section: Hardware Specifications**. This information can be located in Technical Data and Specifications. |
| | | Administrative | Removed – **Section: Maintenance Log**. This information can be located in Maintenance Records. |
| | | Administrative | Added – **Section: Maintenance Records** that includes the topic of Maintenance Check-List. |
| | | Technical Change | Update – **Section: Maintenance Records** to change frequency of Transmittance Optics to weekly. |
| | | Administrative | Removed – **Section: Instrument Error Code User Response Table**. This information can be located in Troubleshooting. |
| | | Administrative | Added – **Section: Troubleshooting** that includes the following topics of: Error |

| Release Date | Reference Number | Change Type | Change Summary |
|---|---|---|---|
| | | | Messages and Recovery Procedures, Cycling the Power of the Instrument, and Using the Instrument Error Code Table. |
| | | Technical Change | Updated – **Table 19: Instrument Error Code Resolution Table** to add Error Code 273, 274, and 275. |
| 2013-11 | 510772-3EN1 | Requirement | Added – Intended Use section in **Section: Introduction**. |
| | | | Added – **Section: General Warnings**. |
| | | | Added – Note to check the saline level in the tubes after filling in **Section: Processing Cards > Processing Test Cards > The Workflow**. |
| | | Administrative | Removed – **List of Figures**, **List of Tables**, **Index**, and **Notes**. |
| | | | Removed – The following sections in Chapter 1 > Introduction: **Organization**, **Finding Topics**, and **Typographic and Usage Conventions**. |
| | | | Removed – **Standard Symbols**. |
| | | | Removed – **Chapter Contents** in each chapter. |

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