

# VITEK® 2 User's Manual 510731-4



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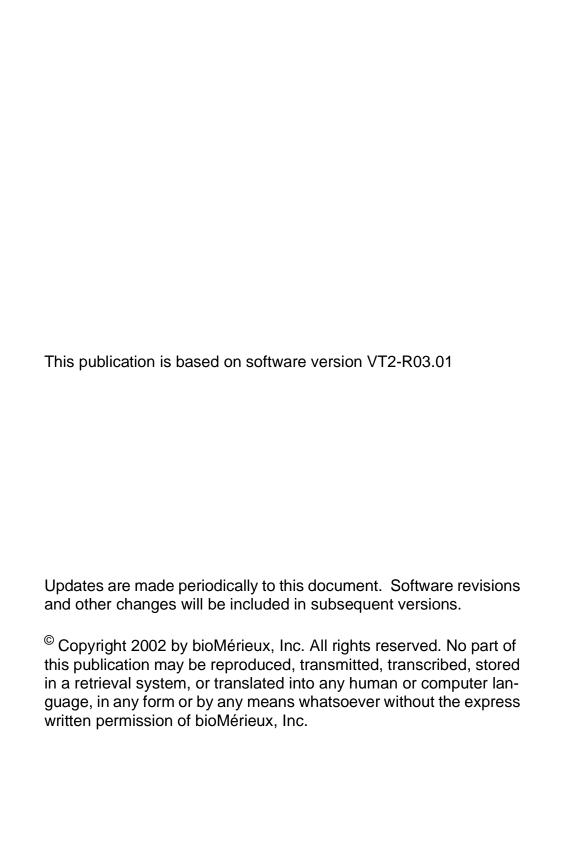
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#### WARRANTY

Seller, bioMérieux, Inc., warrants the VITEK ® 2 instrument (the "instrument") to the original purchaser for a period of one (1) year after date of installation against defects in material and workmanship and defects arising from failure to conform to specifications applicable on the date of installation. Seller further agrees to correct, either by repair, or, at its election, by replacement, any such defect found on examination to have occurred, under normal use and service, during such one (1) year period, provided Seller is promptly notified in writing upon discovery of such defect.

Seller shall not be liable under this Warranty for any defect arising from abuse of the system, failure to operate and maintain the system in accordance with the documentation included with the Instrument, including repair service, alteration or modification of the system by any person other than service personnel of bioMérieux, Inc., or Seller; or use of modified, changed, or previously used disposables.

THE WARRANTY OF SELLER SET FORTH ABOVE AND THE OBLIGATIONS AND LIABILITIES OF SELLER THEREUNDER ARE EXCLUSIVE AND IN LIEU OF ALL OTHER REMEDIES OR WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE SYSTEM DELIVERED HEREUNDER (INCLUDING WITHOUT LIMITATION ANY OBLIGATION OF SELLER WITH RESPECT TO MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND CONSEQUENTIAL DAMAGES, AND WHETHER OR NOT OCCASIONED BY SELLER'S NEGLIGENCE).

This Warranty shall not be extended or altered except by written instrument signed by Seller.

All of the product elements in the Seller's Instrument and the total instrument are warrented to be new or equivalent to new for the full product warranty period of one year. Disposables and replacement items with a normal life expectancy of less than one (1) year, such as batteries and bulbs, are excluded from this warranty.

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Glossary

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# **General Warnings**

**IMPORTANT:** The user is advised to read and understand

all instructions in this manual to be able to derive the best performance from VITEK 2.

**IMPORTANT:** 

The configuration that you have purchased is adapted to the legislation and standards of the different countries it will be sent to. For this reason, it may differ from the one presented in this document. However, this will have no effect on the performance of your VITEK 2. For further information on peripherals (computer, printer, monitor, etc.) please refer to the relevant manufacturers' instruction manufacturers' instruc-

tion manuals.

**IMPORTANT:** 

If the system does not respond properly to keyboard inputs after an inadvertent electrostatic discharge or electrical fast transient, simply recycle power using the power switch and resume normal operations.

### **CAUTION:**

This product carries the CE label to comply with the limits pursuant to European directives.

The equipment has been tested and found to comply with the limits pursuant to the rules and standards indicated in the certificate sent with the product. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential, commercial, or "light industrial" environment.

The equipment generates, uses, and can radiate radio frequency energy and if not installed in accordance with the instruction manual, may cause harmful interference to radio communications. We recommend that you observe the different warnings inscribed on the instrument itself and indicated in the documentation supplied. Changes to the equipment not expressly approved by bioMérieux SA could void the user's authority to operate the equipment.

The user will be required to repair damage at their own expense.

### **CAUTION:**

bioMérieux SA is in no case liable for any damage that may arise from failure to comply with technical specifications in this manual, from the handling of organism suspensions by unqualified personnel, or from any operation conducted on the equipment not in compliance with these mandatory standards.

### **DANGER:**

This instrument may be involved with hazardous organism suspensions. This user manual does not purport to address all of the safety problems associated with its use. It is the responsibility of whoever uses this instrument to establish and follow appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

#### **DANGER:**

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material

### **Laser Caution Statement**

The label below is found:

- VITEK 2 On the front access door
  - On the inside panel behind the front access door
  - **S**behind the waste collection door
- VITEK 2 XL on the left front access door
  - **⊃**above the center front sliding door
  - Dehind the right side waste collection door

CAUTION
Laser light when open.
DO NOT STARE INTO BEAM.
00 530520-1

## **Caution Statement:**

Caution-use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

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

Pages 4-6, 4-17, 8-41, and 8-49

# **Warning Messages**

The following warnings are used throughout the manual for safety reasons:

- CAUTION. Used when a particular action may affect the outcome of a test.
- DANGER. Used when a particular action may result in personal injury, damage to the instrument, or create a biohazard.

#### **CAUTION Statements**

All access doors should remain closed when processing cards. Page 4-6

The VITEK 2 test card transport system stops while the cassette load door is open. Be sure to close the door after loading or unloading a cassette.

Page 4-14

Do not move or remove a boat from the instrument unless you are using the programmed function for this purpose. Doing so can cause an instrument jam. (See the procedure for removing boats on page 7-39.)

Page 4-14

When handling VITEK 2 test cards, make sure you do not deface the bar code in any way.

Page 4-16

The Button Memory chip must be removed from the cassette before cleaning the cassette.

Page 4-17

Ejected test cards must not be reinserted into VITEK 2. Make sure that all test card processing has been completed before ejecting a test card.

Page 4-27

Do not disable both the audible and visual alarms on the instrument unless it is located very near to the workstation. Doing so makes it more difficult to know that an error condition exists. Page 5-15

The disposable monitors should be used as an approximate indicator. Care should be used to prevent running out of either disposable during test card processing.

Page 6-9

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

Page 6-34

Leaving the door to the Cassette Unload station open will interfere with the proper processing of the test cards in the VITEK 2 instrument.

Page 6-56

Use aseptic technique when installing an accessory kit. Page 7-6 and 7-14

To prevent possible contamination of the saline, use aseptic technique when handling the saline dispenser tube. Page 7-9

To avoid contaminating new pipette tips, do not touch the inside of the pipette container.

Page 7-16

The exposed ends (**6**) of the pipette tips are the ones that come in contact with your specimens. Appropriate precautions to prevent contamination during this procedure are advised.

Page 7-18

Dishwasher temperatures during the washing and drying cycles must not exceed 85° C (185° F). Exceeding this temperature will cause damage to the carousel sections. Use the top rack of the dishwasher.

Page 7-28, 7-35, 7-42, 7-49 and 7-58

If you select Yes to continue, the cards being processed will be TERMINATED.

Page 7-47

Do not wear powdered latex gloves while cleaning the fluorescence optics. The gloves that contain a powder can interfere with the optics.

Page 7-50

To prevent damage to the metal contacts on the SCS base unit, make sure that you wipe them GENTLY in an up and down motion, rather than side to side.

Page 7-61

Do not disable both the audible and the visual alarms. Doing so eliminates all indicators of an error condition, which could result in the termination of tests in progress.

Page 8-5

Do not wear powdered latex gloves while cleaning the fluorescence optics. The gloves that contain a powder can interfere with the optics.

Page 8-43

The VITEK 2 instrument is heavy. Use at least two people to move it. Lift handles are provided at each end of the instrument. Page -1

# **Danger Statements**

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.

Page 4-10

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

Page 4-14

The sealer station contains a wire that is heated during the sealing operation. Do not reach into the instrument during the sealing operation.

Page 4-23

Biohazardous spills can occur inside the VITEK 2 instrument if the Dilution Mode option is not properly set. This is especially true if pre-diluted samples are used with the mode set to Automatic.

Page 5-12

Biohazardous spills can occur inside the VITEK 2 instrument if the Dilution Mode option is not properly set, especially if prediluted samples are used with the mode set to Automatic. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Page 6-7 and 6-43

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.

Page 6-31 and 6-44

Do not attempt to load a cassette if a boat is not at the station. Damage to the cassette and the VITEK 2 instrument is possible. Page 6-33 and 6-46

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.

Page 6-56

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

Page 6-58

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.

Page 7-21

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.

Page 7-34

Exposing the button memory to the recommended cassette cleaning procedures can cause irreparable damage to the unit. Page 7-34

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

Page 7-39

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Page 7-46 and 7-56

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. Page 7-46

The base pan should not be cleaned unless the drip pan is properly installed. See 7-56 for instructions on cleaning the drip pan. Page 7-54

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Page 7-56

The contents of the drip pan may include biohazardous materials. Take appropriate precautions.

Page 7-57

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.

Page 8-18

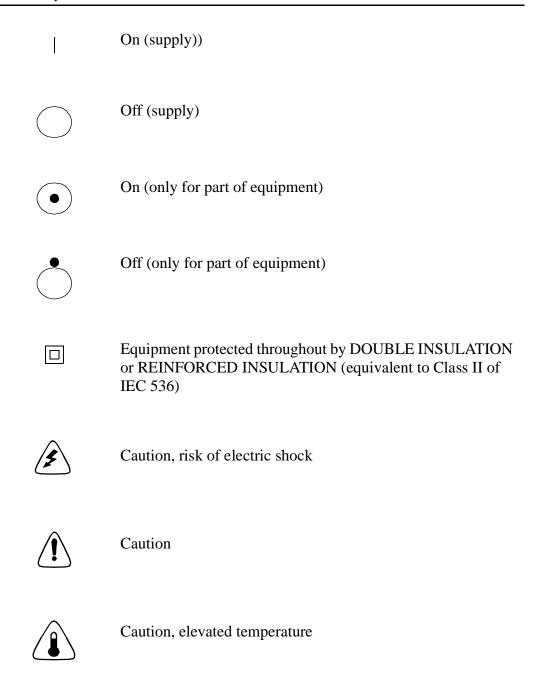
The instrument contains an ultraviolet light source. Make sure that the fluorescence optics unit is closed before resuming instrument operation.

Page 8-43

# **Standard Symbols**

The symbols used in the VITEK 2 system are shown below:

	Direct current
$\sim$	Alternating current
$\overline{}$	Both direct and alternating current
3~	Three-phase alternating current
<u>_</u>	Earth (ground) terminal
	Protective Conductor terminal
<del> </del>	Frame or chassis terminal
	Equipotentiality





Caution, biological agents

Refer to the publications below for instructions on handling biohazardous materials.

National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue - Approved Guideline, 1997.

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, *Biosafety in Microbiological and Biomedical Laboratories*, 1988.

**Smart Carrier Station Temperature Label** 



Indicates a maximum ambient temperature of 30°C. The newer Smart Carrier Stations, beginning with Serial Number SCSA 3000, have a Maximum Temperature Label affixed to the Smart Carrier Station.

# 1. How To Use This Manual

# Organization

The manual is separated into four basic parts:

- Part 1, which includes Chapters 2 and 3, covers the Smart Carrier Station. Chapter 2 describes the hardware and Chapter 3 provides the procedures you use to configure this station for your laboratory work flow.
- Part 2, which includes Chapters 4 and 5, covers the VITEK 2 Instrument. Chapter 4 describes the hardware and Chapter 5 shows you how to configure the instrument's user interface.
- Part 3, including only Chapter 6, is the primary part of the manual. It describes all of the procedures you need to follow to process VITEK 2 test cards. The chapter contains two subparts, one each to describe test card processing with, and without, a Smart Carrier Station.
- Part 4, consisting of Chapters 7 and 8, provides troubleshooting and maintenance procedures for the VITEK 2 instrument.

# Printed vs. Online Documentation

The documentation for the VITEK 2 system consists of both this printed manual and online help. The division between the two types of documentation is distinct and straightforward. This printed manual covers the VITEK 2 instrument and the Smart Carrier Station, including both the hardware and the programmed user interfaces.

The online help documentation, which is found in the user interface of the computer workstation, covers only the programmed user interface that you see at the workstation. This division allows for the possibility that the computer workstation may be in a different location than the VITEK 2 instrument and Smart Carrier Station.

# **How to Find Topics and Procedures**

There are four devices in the manual to help you find a topic or procedure.

- General Table of Contents. This table is located in the front of the manual and includes the entire document. You can use this table to locate major headings throughout the manual. The table also includes a list of figures.
- Chapter Table of Contents. Each of the succeeding chapters begin with their own tables of contents. They contain the same information as the general table for the manual, but have the advantage of addressing only what is in that chapter.
- Page Headers. Each page in the manual has a header, which can serve as a visual aid to help you find a topic. The inside portion of the header, the side closest to the binding, always shows the chapter title. The outside portion of the header shows the title of the current section.
- Index. Found at the end of the manual, the index is the most useful device for finding individual topics throughout the manual.

# **Typographic Conventions**

The following typographic conventions are used throughout the manual:

• Names of Keys. The names of keys, either on the VITEK 2 instrument keypad, or the Smart Carrier keyboard, are shown in capital letters, bold and italic.

Example: Press the *UP* or *DOWN ARROW* keys.

• **Action objects.** In a procedural step, the object of the action you take is highlighted in bold italics.

Example: Open the *Cassette Load station* by sliding the station door up.

• **References.** References to other sections in the manual are shown in italics.

Example: See the section *Monitoring Test Card Processing* on page 6-47.

- Notes. A NOTE contains information of special interest.
- Cautions. A CAUTION statement is used when a particular action may affect the outcome of a test.
- **Danger.** A DANGER statement is used when a particular action may result in personal injury, damage to the instrument, or create a biohazard.

## 2. The Smart Carrier Station

### Introduction

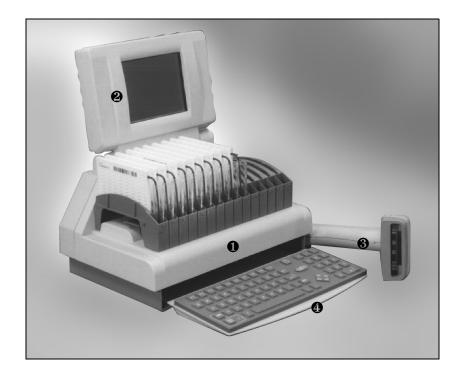
Use this chapter to familiarize yourself with the Smart Carrier hardware. In the following section, "What is the Smart Carrier Station?," there is an overview of the entire unit, including a section on the advantages of using the Smart Carrier Station. In the sections that follow, we provide more detailed descriptions of particular parts of the station.

#### Where to Find It

- What is the Smart Carrier Station? 2-2
- The SCS Base Unit 2-4
- The SCS Screen 2-5
- The SCS Bar Code Scanner 2-5
- The SCS Keyboard 2-5
- Starting the Smart Carrier Station 2-7

## What is the Smart Carrier Station?

The Smart Carrier Station (SCS) is a small computer dedicated to collecting information about test cards and specimens, and for transferring that information to the VITEK 2 instrument. The SCS, shown in the figure below, has four main components:



Component of the SCS	See also page
• The SCS Base Unit. The base of the SCS contains the computer. There are connection ports on the back of the base for the keyboard and the bar code scanner. The top of the base is specifically shaped to accept a cassette. Metal contacts on the base connect the unit's computer to a button memory chip on the cassette. This memory chip stores the information you entered to be transferred to the VITEK 2 instrument.	2-4
<b>②</b> The SCS Screen. The display for the SCS is a black and white liquid crystal display (LCD). You use the display to view and confirm the information you are entering for the test cards and specimens. The display can be tilted to allow viewing at various angles, or tilted down when the SCS is not in use.	2-5
<b>The SCS Bar Code Scanner.</b> The SCS is equipped with a bar code scanner. The scanner facilitates data entry by substituting one bar code scan for several keystrokes. The scanner can be hand-held or used while mounted in its holder.	2-5
● The SCS Keyboard. The keyboard for the SCS has a standard set of alphanumeric keys, plus several specially designed keys for SCS functions. The SCS keyboard is smaller than a standard size keyboard so that it can be stored under the Base Unit.	2-5

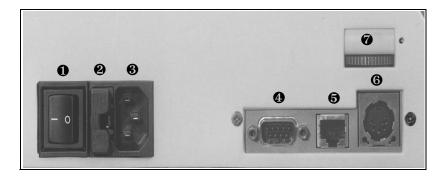
Table 2-1: Components of the Smart Carrier Station

### The SCS Base Unit

The base unit for the Smart Carrier Station (SCS) contains the electronic components that make its data entry and storage functions possible. The back panel of the base unit is where the power switch and cable connectors are found.

The base unit is actually a small computer. It has a processing unit, memory, and a software program. The program in this computer, however, is limited to the task of entering and storing data for a cassette.

The back panel of the base unit, shown in the figure below, contains the on/off switch, the power cord receptacle, and the connector ports for various cables:



- On/Off Switch
- 2 Fuse Holder
- **3** AC Power Receptacle
- 9-pin Service/Update Cable Connector
- **6** RJ45 Receptacle for the Bar Code Scanner
- **6** Circular Connector for the SCS Keyboard
- Contrast adjustment wheel for screen contrast

#### The SCS Screen

The Smart Carrier Station (SCS) includes an LCD screen for viewing the data that is being entered. This flat, black and white display has a compact size so that it requires minimum bench top space.

## The SCS Bar Code Scanner

The Smart Carrier Station (SCS) is equipped with a hand-held bar code scanner that can greatly facilitate data entry. Without the bar code scanner, you would have to key in the information for each test card placed in a cassette. With the bar code scanner, you scan a bar code for most data fields. The data appears automatically on the display, saving you many keystrokes. The scanner comes with an optional holder so that the scanner can be positioned for the most efficient work flow.

## The SCS Keyboard

The Smart Carrier Station (SCS) keyboard has a standard set of alphabetic and numeric keys. It also has several keys that are uniquely designed for use on the SCS.





This is the **HELP** key. You use it to display the context-sensitive help screens and data field option boxes.

This key has two functions. When you press the arrow on the left, the display changes to the **PRE-VIOUS SLOT.** When you press the arrow on the right, the display changes to the **NEXT SLOT.** 



This is the **SHIFT** key. Use it to type upper case letters as you would on any keyboard.



This is the **SHIFT LOCK** key. When you press it the light next to it goes on and the keypad stays in the upper case mode. Press the Shift Lock key again to cancel upper case mode.

For detailed descriptions of all the functions of the SCS keyboard, see the table on page 6-19.

## **Starting the Smart Carrier Station**

Use this procedure to begin using the Smart Carrier Station (SCS). The unit should be located on a bench top with room next to it for test cards and specimens. Use the following figure of the back of the SCS to locate and identify the various parts referred to in the procedure.



- 1. Tilt the **SCS** screen so that you can see the display.
- 2. Connect the **power cord** to the back of the SCS (**1**) and the other end to an AC power outlet.
- 3. Connect the **SCS keyboard** to its receptacle (**②**) on the back of the base unit.
- 4. Connect the **bar code scanner** to its receptacle (**③**) on the back of the base unit.

5. Push the **power switch** (**1**) to turn the unit on.

The computer takes a few moments to go through its startup routine.

6. If nothing appears on the display, use the **contrast adjustment wheel** (**⑤**) to adjust the display once it has become active.

The following screen appears when the SCS is ready to use:

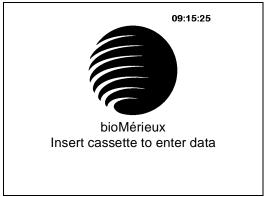


Figure 2-1: Initial SCS Screen

**NOTE:** If you have not yet assigned a Station Name on the Configuration screen, the Configuration screen appears rather than the one above. For information on configuring the Station Name, see the instructions on page 3-5.

# 3. Configuring the Smart Carrier Station

## Introduction

Configuration options allow you to operate the Smart Carrier Station in a number of different ways. This chapter explains not only how to set these options, but how each option affects the data stored in the button memory of a cassette.

#### Where To Find It

- Configuration Overview 3-2
  - When Should Configuration Options be Set? 3-3
  - How do You Access the Configuration Screens? 3-4
- Why and How to Set the Options 3-4
  - AST Dilution Mode 3-4
  - Station Name 3-5
  - Key Click 3-6
  - Language 3-7
  - Time and Date 3-8
  - Firmware Update Options 3-9
  - Cassette Erase 3-10

# **Configuration Overview**

There are nine configuration options on the SCS:

Configuration Screen Name	Option	Find a Description on
SCS Configuration	AST Dilution Mode	3-4
	Station Name	3-5
	Key Click	3-6
	Language	3-7
	Time and Date	3-8
Firmware Update Options	Update all SCS files	3-9
	Update Specific file	3-9
DensiChek Configuration	DensiChek Connector	For future use
Cassette Erase Configuration	Erase Cassette	3-10

Table 3-1: SCS Configuration Options

The options are divided among three screens:

- Station Configuration. Includes the AST Dilution Mode, SCS Name, Key Click, Language, and Time and Date options.
- **Firmware Update.** Includes options for uploading new software for the SCS.
- **DensiChek.** Contains the option for enabling a power connection for the DensiChek. For future use.
- Cassette Erase Configuration. Contains the option for automatically erasing data in the button memory of the cassette.

**NOTE:** The Smart Carrier Firmware Status screen has no options to set. It only displays the current version of the Smart Carrier Station firmware.

## When Should Configuration Options be Set?

SCS configuration options should be set **before** a cassette is inserted and information is entered for the test cards. In fact, the Station Configuration screen is the first screen displayed on an SCS for which a Station Name has not been defined.

**NOTE:** One exception to this is the Program Updates option. You do not need to use that screen until you receive instructions from bioMérieux to do so.

## How do You Access the Configuration Screens?

The Station Configuration screen is accessed by pressing the *F4* key.

You then press the **PREVIOUS** 

**SLOT** keys to switch to the other screens.

or NE

NEXT

## Why and How to Set the Options

#### **AST Dilution Mode**

An AST, or Antimicrobial Susceptibility Test, uses an inoculum that is specifically diluted according to the type of test card being used. These inocula can be prepared manually by the technologist, or prepared automatically by VITEK 2 at the Dispenser/Pipettor station.

The AST Dilution mode setting is transferred to the VITEK 2 instrument via the button memory on the cassette. If you set the AST Dilution Mode to automatic, every AST in a cassette has its inoculum diluted by VITEK 2. If the AST Dilution Mode is set to pre-diluted, VITEK 2 assumes that the AST dilutions have already been performed.

#### How to Set this Option

- 1. Press the *F4* key to access the Configuration screen.
- 2. Press **1** to set the dilution mode to Automatic, or **2** to set the dilution mode to Pre-diluted (manual).
- Press the F2 key to exit the SCS Configuration screen or the NEXT or PREVIOUS SCREEN keys to access other configuration screens.

#### **Station Name**

A Smart Carrier Station is given a name to identify the cards that were processed on that station. This is especially useful in laboratories with multiple Smart Carrier stations.

The station name consists of one to three alphanumeric characters. A SCS name could reflect something about the use of the station. If, for example, a particular individual is assigned to an SCS, that individual's initials can be used for the SCS name.

The station's name is stored in the cassette's button memory. The name is transferred to the VITEK 2 instrument and is then sent to the computer. The station name becomes a part of each test card's address that appears on the card directory.

#### How to Set this Option

- 1. Press the *F4* key to access the Configuration screen.
- Press the **DOWN ARROW** key to move the cursor to the Station Name field.
- In the Station Name field, type up to three characters and press ENTER.
- Press the F2 key to exit the SCS Configuration screen or the NEXT or PREVIOUS SCREEN keys to access other configuration screens.

## **Key Click**

The SCS custom keyboard does not have an audible click when you press a key. This option enables an audible "click" from the instrument every time you press a key.

#### HOW TO ENABLE THIS OPTION

- 1. Press the *F4* key to access the Configuration screen.
- 2. Press the **DOWN ARROW** key to move the cursor to the Enable Key Click field.
- 3. In the Key Click field, press 1 to turn the key click off, 2 to turn the key click on.
- 4. Press the **F2** key to exit the SCS Configuration screen or the **NEXT** or **PREVIOUS SCREEN** keys to access other configuration screens.

## Language

The SCS interface is programmed in six languages:

English

• French

• Italian

German

• Spanish

Japanese

By setting this configuration option, you can work on the SCS in the language of your choice.

### How to SET THIS OPTION

- 1. Press the *F4* key to access the Configuration screen.
- 2. Press the **DOWN ARROW** key to move the cursor to the Language Choice field.
- 3. In the Language field, press the *HELP* key to display an option box with the available languages.
- 4. Press the **UP** or **DOWN ARROW** keys to select a language, and then press ENTER.
- 5. Press the **F2** key to exit the SCS Configuration screen or the **NEXT** or **PREVIOUS SCREEN** keys to access other configuration screens.

#### **Time and Date**

The SCS tracks the time of day and the calendar date.

#### How to Set these Options

- 1. Press the *F4* key to access the Configuration screen.
- Press the **DOWN ARROW** key to move the cursor to the Time field.
- 3. In the Hour field, enter the *current hour*, using a 24-hour format (i.e. 9 p.m. = 2100).
- 4. Press the **ENTER** key to accept the new value.
- 5. Enter the *current* minutes.
- 6. Press the **ENTER** key to accept the new value.
- 7. Enter the *current day*.
- 8. Press the **ENTER** key to accept the new value.
- 9. Enter the *current month*.

- 10. Press the **ENTER** key to accept the new value.
- 11. Enter the current, four-digit year.
- 12. Press the **ENTER** key to accept the new value.
- Press the F2 key to exit the SCS Configuration screen or the NEXT or PREVIOUS SCREEN keys to access other configuration screens.

## **Firmware Update Options**

The SCS firmware can be updated to enhance its functions. These updates are performed by connecting the SCS to the workstation using a cable. Since you may need to update only a portion of the SCS firmware, the Program Updates options allow you to select the firmware you need.

#### How to Use this Option

You receive periodic program updates, along with installation instructions for these updates, from bioMérieux. Once you perform an update, all the necessary SCS files are included in the workstation.

**NOTE:** Make sure the SCS is connected to the workstation.

- 1. Press the *F4* key to access the Configuration screen.
- 2. Press the **NEXT** or **PREVIOUS SCREEN** key until the Firmware Update Options screen displays.

- 3. Press the **DOWN ARROW** key to move the cursor to the option specified in the update instructions.
- 4. Press the **ENTER** key to select the option. The following message appears:

Press F1 to start selected function any other key to cancel

- 5. Press the *F1* key.
- 6. (Update Specific File only). Enter the **file name** specified in the update instructions. The following message appears:

Press F1 to start transfer

7. Press the **F1** key to begin the update.

### **Cassette Erase**

The Cassette Erase function gives you the option of automatically erasing data in the button memory of cassettes that have been processed by the VITEK 2.

HOW TO SET THIS OPTION

- 1. Press the *F4* key to access the Configuration screen.
- Press the **NEXT** or **PREVIOUS SCREEN** key to access the Cassette Erase screen.

There are two settings available, Automatic and Verify First. Select Automatic to automatically erase cassettes that have been processed. Select Verify First to display and review data before it is erased.

3. Press **1** and **2** to toggle between Automatic and Verify First.

**NOTE:** If you select Verify First, when you place a cassette that has been processed by the instrument on the Smart Carrier Station, the following message displays:

Cassette has been processed.

Press *F1* to erase, any other key to display processed information.

4. Press **F2** to exit the screen.

## 4. The VITEK 2 Instrument

## Introduction

This chapter describes the hardware systems in the VITEK 2 instrument. The section *External Components of the VITEK 2 Instrument* points out the controls and connections found on the instrument's exterior, and the doors by which you gain access to its interior. The section *What Happens Inside VITEK 2* describes the work stations and components in the instrument.

#### Where to Find It

- External Components of the VITEK 2 Instrument 4-3
  - Controls and Connections 4-5
  - Access Doors 4-6
- Turning on the VITEK 2 Instrument 4-8
  - Start-up Procedure 4-8
- What Happens Inside VITEK 2 4-9
  - Test Card Processing Cycle 4-9
  - The Smart Carrier Station (SCS) 4-10
  - The Cassettes 4-10
  - Cassette Load and Unload Station 4-13
  - The Boats 4-15
  - VITEK 2 Bar Code Reader 4-16
  - The Button Memory Reader 4-17
  - VITEK 2 Dispenser/Pipettor Station 4-18
  - The Filler Station 4-22

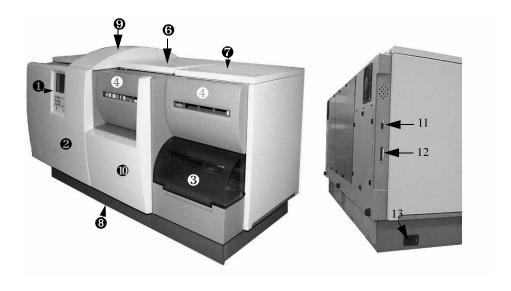
- The Sealer Station 4-23
- Test Card Incubation and Reading 4-23
- Card Ejection 4-26
- The Waste Collection Station 4-28
- The User Interface System 4-29
  - Keypad and Screen 4-30

# **External Components of the VITEK 2 Instrument**

The picture on the following page contains a front and a left side view of the VITEK 2 and VITEK 2 XL instrument. Use the diagram to locate and familiarize yourself with the external controls and the access doors to the interior of the instrument.



VITEK 2 60 Instrument



VITEK2 XL Instrument

#### **Controls and Connections**

- User Interface Screen and Keypad. This screen and keypad comprise the User Interface system. See page 4-29 for detailed information.
- **2** Front access door. Provides access to the diluter, pipette tip container, and a portion of the test card transport system. The door opens from the right side.
- **3** Cassette Load/Unload door. Provides access to the Cassette Load/Unload station. The door slides up to open. A locking mechanism prevents opening of this door at inappropriate times.
- **4 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 lowers from the top.

#### **Access Doors**

#### **CAUTION:**

All access doors should remain closed when processing cards.



See Laser Caution statement on page xviii.



**NOTE:** The top right access door cannot be opened unless the Waste Collection door (4) is opened first.

**6 Top-right access door.** Provides access to the optics and the carousel. The door lifts from the front and stays in the open position.

**NOTE:** This door is secured by two screws, and requires a flathead screwdriver to open.

- **Top access door Section A.** VITEK 2 XL only. Provides access to the optics and carousel for Section A.
- **Top access door Section B.** VITEK 2 XL only. Provides access to the optics and carousel for Section B.
- **8 Bottom access door.** Provides access to the drip pan. The door is held in place magnetically and must be pulled down to open.
- **9** Saline access door. Provides access to the sterile saline bag. The door lifts from the front and stays in the open position.

- 11 **UPS connection.** This cable connector port connects VITEK 2 to an **uninterruptable power supply (UPS).** The connection allows the UPS to notify the VITEK 2 of a power loss so that the VITEK 2 can start appropriate procedures.
- 12 **Workstation connection.** This connector port accepts the cable that connects the VITEK 2 instrument to the workstation computer.
- 13 **AC power switch and cord receptacle.** This switch supplies power to the VITEK 2 instrument. The cord receptacle accepts the power cord that is connected to the electricity source.

## **Turning on the VITEK 2 Instrument**

**NOTE:** Refer to the environmental and electrical specifications for the VITEK 2 instrument in the Appendix before starting the instrument.

## **Start-up Procedure**

- Make sure VITEK 2 has been connected to an appropriate power supply using the power cord supplied with the instrument.
- 2. Press the *AC power switch* to the ON position. (See item 13 in the figure on page 4-4.)

The instrument goes through an initialization sequence that includes several self tests. During this time, VITEK 2 is also bringing the carousel area up to its specified temperature for test card incubation.

After a few minutes, the VITEK 2 Status Screen appears. The Status field at the top of the 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 can take several minutes.

VITEK 2 is ready to begin processing cards when the Status field shows **OK**. (For more information about the Status Screen, see page 6-3.)

## What Happens Inside VITEK 2

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

## **Test Card Processing Cycle**

The parts and functions of the VITEK 2 instrument can best be described by following a test card through the phases of a typical processing cycle. The following table summarizes this cycle, and shows you where you can find more details about a particular component of the VITEK 2 instrument.

Component	<b>Processing Phase</b>	See also page
Cassettes	Test card transport	4-10
Cassette Load and Unload Station	Test card transport	4-13
Boats	Test card transport	4-15
Bar Code Reader	Sample preparation	4-16
Button Memory Reader	Sample preparation	4-17
Dispenser/Pipettor Station	Sample preparation	4-18
Filler Station	Sample preparation	4-22
Sealer Station	Sample preparation	4-23
Test Card Incubation and Reading	Test card analysis	4-23
Card Ejection	Test card transport	4-26
Waste Collection Station	Test card transport	4-28
User Interface System	All process phases	4-29

## The Smart Carrier Station (SCS)

The SCS is not a part of the VITEK 2 instrument, but it is the station where the entire process begins. For complete details on the SCS, see Chapter 2, *The Smart Carrier Station*.

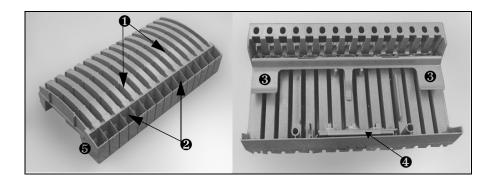
#### The Cassettes

#### **DANGER:**



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.

The cassette is the main component of the test card transport system. It can hold up to 15 test cards with their inoculum test tubes. In systems utilizing the Smart Carrier Station, the button memory chip on the cassette is used to store and transport data from the Smart Carrier Station to VITEK 2.



- Test Card Slots. The top portion of a cassette is divided into 15 test card slots that can hold various combinations of VITEK 2 test cards.
- **2 Test Tube Holders.** The front portion of a cassette has 15 wells into which you place test tubes for inoculum.
- **Test Tube Release.** Test tubes are held securely in the cassette by a retaining bar. A release lever is provided for easy disposal of used test tubes.
- **9 Button Memory.** For systems utilizing a Smart Carrier Station, each cassette is fitted with a special memory chip, called the button memory. When a cassette is on a Smart Carrier Station, the button memory stores the information that you enter for each test card. This information is read by a station in VITEK 2, which marks the memory chip as being read, allowing the cassette to be reused.

- **6** Cassette Base. The base of a cassette is specially shaped to
  - Fit snugly onto the base unit of the Smart Carrier Station.
    When properly fitted on the base unit, the contacts for the
    button memory are touching the contacts that protrude
    from the base unit.
  - Fit into a boat. The shape of the cassette base matches the well on the top of a boat. This ensures that the two units move as one through VITEK 2. The shape also ensures that the cassette can only be put into a boat in the proper orientation.

## **Cassette Load and Unload Station**

You load and unload cassettes from VITEK 2 using this station. As seen in the picture, the station consists of the cassette load door and a green indicator light. The door has a locking mechanism.



If the Indicator Light is	Then
On	The cassette load door is unlocked. You may open the door to load cassettes.
Off	The cassette load door is locked and cannot be opened.
Blinking	A boat with an empty cassette has arrived at the station. The cassette load door is unlocked. You should open the door and remove the cassette. When the door is closed again, the blinking stops.

#### **CAUTION:**



The VITEK 2 test card transport system stops while the cassette load door is open. Be sure to close the door after loading or unloading a cassette.

#### **DANGER:**



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

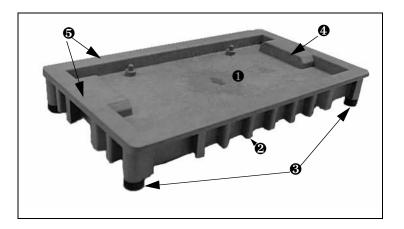
#### **CAUTION:**



Do not move or remove a boat from the instrument unless you are using the programmed function for this purpose. Doing so can cause an instrument jam. (See the procedure for removing boats on page 7-39.)

#### The Boats

VITEK 2 contains four plastic trays called boats. They are called boats because they carry a cassette through the various processing stations inside VITEK 2.



A Boat, shown in the figure above, has particular features that support its three major functions:

### **Test Card Transport**

- The top surface of a boat forms a specially shaped well into which a cassette is placed. The shape of the well conforms to the base of a cassette, providing it with a secure platform on which to ride. The two pins in the well ensure that the cassette can be placed into the boat only in the proper orientation. An arrow is molded into the surface of the well to show the proper orientation of the boat when placed in the instrument.
- The base of each boat is notched in several places.

  These areas are used by the VITEK 2 test card transport mechanisms that move the boats through the module.
- **8** Each boat stands on four low-friction feet, providing a surface on which the boat can easily move.

- **Spill prevention.** The well in the top of the boat catches any spills from the cassette.
- **Test Card filling.** Above the cassette well, there is a flat surface that extends around the perimeter of the boat. This surface becomes the base of the vacuum chamber when the boat reaches the Filler station.

#### VITEK 2 Bar Code Reader

After a cassette has been loaded onto a boat, the test card transport system moves the boat past the bar code reader station. This station reads the information encoded on the bar code label found on each VITEK 2 test card. The following information is included in the bar code:

- **Test Card type.** For example, a Gram Negative Susceptibility test card.
- Investigational Use Only (IUO) flag. This tells VITEK 2 if an experimental test card is being processed.
- **Test Card expiration date.** This date is transferred to the workstation, which prints it on the laboratory report.
- Test Card lot information and a sequence number. This includes the test card's lot number to provide manufacturing traceability. The sequence number uniquely identifies a test card.

## **CAUTION:**



When handling VITEK 2 test cards, make sure you do not deface the bar code in any way.

#### **CAUTION:**

See Laser Caution statement on page xviii.



### The Button Memory Reader

The Button Memory Reader is a device that VITEK 2 uses to read the test card information stored by the Smart Carrier Station in the memory chip on a cassette. VITEK 2 uses this test card information in two ways:

- The test card type entered at the SCS is compared to the test card type that VITEK 2 reads with its own bar code reader. This ensures that no changes were made in the position of any test card in the cassette.
- The accession ID, test card type, and the other fields entered at the SCS are sent to the computer. This information allows the software to link the test card results from VITEK 2 to patient demographic data and any previous test results.

After the information is extracted from the button memory, VITEK 2 marks its contents as having been read. When the cassette is put on the SCS again, a button memory marked as read is erased so that the cassette can be used again.

### **CAUTION:**



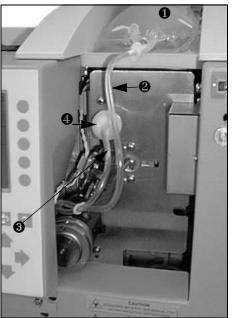
The Button Memory chip must be removed from the cassette before cleaning the cassette.

### **VITEK 2 Dispenser/Pipettor Station**

This station automatically prepares the organism dilution used for AST (Antimicrobial Susceptibility Testing) cards. VITEK 2 provides a significant time savings by ensuring that mated ID and AST cards are processed from the same sample.

#### THE DISPENSER

The dispenser system, shown in the following figure, delivers 2.5 ml of sterile saline into the test tube of each AST card in a cassette.



**Sterile Saline.** The top of VITEK 2 has a compartment designed to hold a one-liter bag of sterile saline (**1**). This is enough saline to process about 330 AST cards.

**Dispenser Assembly.** The dispenser assembly consists of a plastic dispensing chamber and two sections of plastic tubing. One section of tubing (2) leads from the dispensing chamber and is attached to the sterile saline bag. The other section of tubing (3) also leads from the dispensing chamber but is attached to an air pump. It is fitted with a filter (4) to prevent any particulate contamination.

**Electromechanical Components (not shown).** The electromechanical components control how the system works:

- 1. When an AST card is detected, a valve opens to allow saline to travel from its bag to the dispensing chamber.
- 2. An optical sensor detects when the chamber is full (2.5 ml) and closes the valve.
- 3. The dispensing chamber rotates into position over the AST card's test tube.
- 4. The air pump is activated, forcing the saline into the tube at a controlled rate that minimizes splashing.

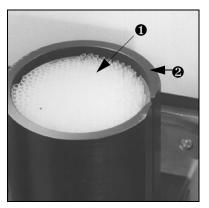
#### THE PIPETTOR

The pipettor station transfers a preset volume of an organism suspension from its test tube into the test tube of its mated AST card.

• Disposable Pipette Tips.

To prevent contamination,

VITEK 2 uses single-use,
disposable pipette tips.



- **2** Container. The container holds up to 350 pipette tips. It has an internal mechanism that ensures proper delivery of each pipette tip to the displacement pump.
- **Obsplacement Pump (not shown).** The displacement pump withdraws a specified volume of inoculum for dilution in the inoculum tube of an AST card.

**NOTE:** The displacement pump is not normally visible as it is located directly behind the interface screen and keypad.

#### HOW THE DISPLACEMENT PUMP WORKS

The displacement pump is part of a larger assembly that performs the pipetting and transfer of the suspension when VITEK 2 is in the Automatic dilution mode. Here is how it works:

- 1. The container drops a pipette tip into position.
- 2. The displacement pump assembly extends a hollow metal tube into the container, attaches a pipette tip to the tube, and withdraws the pipette tip from the container. The instrument checks to make sure that a pipette tip is attached.
- 3. The pump assembly rotates so that the pipette tip is over the ID suspension test tube. The pipette tip is then lowered into the suspension. The instrument checks to make sure there is fluid in the ID test tube.
- 4. The pump draws the preprogrammed amount of suspension and withdraws the pipette tip from the test tube.
- 5. The cassette moves so that the susceptibility test tube is now under the pipette tip.
- 6. The pipette tip is lowered into the test tube and the pump dispenses the suspension into the tube where it mixes with the saline from the Dispenser.
- 7. The pipette tip is removed from its attachment and left in the sample tube for disposal.

#### The Filler Station

At the Filler station, all of the test cards in a cassette are inoculated with the suspension contained in their corresponding test tubes.

#### How Does FILLING WORK?

The Filler station uses a vacuum chamber and pump. When the boat carrying a cassette reaches this station, the top of the vacuum chamber is lowered onto the boat. The boat, therefore serves as the base of the vacuum chamber. The following steps occur:

- 1. The pump evacuates the air from the chamber. This forces the air inside each test card to escape via the transfer tube and bubble up through the suspension. The channels and wells inside of each test card are now at a vacuum.
- 2. After a short period, the vacuum is slowly released. 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 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.

**NOTE:** The seal on the vacuum chamber should be cleaned periodically. See the maintenance schedules and procedures in chapter 7 of this manual.

#### The Sealer Station

#### **DANGER:**



The sealer station contains a wire that is heated during the sealing operation. Do not reach into the instrument during the sealing operation.

The Sealer station completes the functions inside VITEK 2 that prepare the test cards for incubation and reading. This is accomplished by heat-sealing the transfer tube that delivered inoculum to the test card from its test tube. This seals off the contents of the test card.

As the boat and cassette move through this station, a heated wire comes in contact with each transfer tube. The plastic tube melts, causing most of it to separate from the test card and drop into the test tube. The portion that remains in the test card is sealed by the melting plastic.

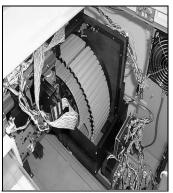
**NOTE:** The stub left from the transfer tube may be up to 1/10 inch (0.25 cm) long.

### **Test Card Incubation and Reading**

Once test cards are sealed, they are ready to be incubated and read. The test card transport system moves the boat and 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 reading cycle.

#### THE CAROUSEL

The Carousel, pictured here, has a capacity of 60 test cards. During their time in the carousel, the test cards are incubated at an average temperature of 35.5°C.



As the carousel rotates, each test card moves into the reading position every 15 minutes. A mechanical device called the reader head, shown at the left, conveys the test card through the optics stations.

After the reading cycle, the test card returns to its slot in the carousel, where it continues to be incubated until its next read cycle.

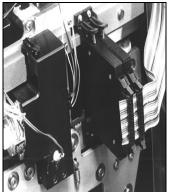
**NOTE:** The carousel is divided into four sections so that it can be easily removed for periodic cleaning. See *Cleaning the Carousel* on page 7-21.

#### THE OPTICS

VITEK 2 performs its identification and susceptibility analyses by continually monitoring the growth and activity of organisms inside the wells of the test cards. Two different optics systems perform ths function:

#### FLUORESCENCE OPTICS

The fluorescence optics indirectly detect the growth and activity of organisms using a chemical by-product of their growth rather than the organisms themselves. This chemical, called a fluorophore, absorbs light at a wavelength of 365 nm and immediately re-emits the light at a different wavelength of 445 nm.

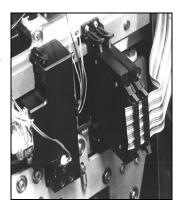


A xenon flash tube and optical filters are used to create the specific wavelength of light and a fluorescence detector captures light re-emitted by the fluorophore. The biochemical system in these wells is designed to produce this substance in direct proportion to the growth and activity of the organisms. The amount of re-emitted light produced, therefore provides an excellent growth activity indicator. The fluorescence optics are self-checking using an internal reference.

**NOTE:** The optics should be cleaned periodically. See *Cleaning the Optics (Normal Maintenance)* on page 7-50.

#### TRANSMITTANCE OPTICS

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

**NOTE:** The optics should be cleaned periodically. See *Cleaning the Optics (Normal Maintenance)* on page 7-50.

### **Card Ejection**

The card ejection function permanently removes test cards from the carousel after their testing is completed. 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 System Configuration window at the workstation computer. Cards can also be ejected at any time using a manual ejection function.

### **CAUTION:**



Ejected test cards must not be reinserted into VITEK 2. Make sure that all test card processing has been completed before ejecting a test card.

#### The Waste Collection Station

The card ejector removes test cards that have completed testing from the reader. These test cards are collected in a tray at the Waste Collection station for removal from VITEK 2 and disposal. The station, shown here, holds up to 60 test cards. The instrument counts test cards as they fill the tray, and sends a mes-



sage to the VITEK 2 interface screen when the station is full. A sensor in the station detects when the tray has been emptied or if the tray is missing.

Access the Waste Collection station by opening the waste collection door on the front of VITEK 2.

#### **NOTES:**

- Keep the waste collection station door closed except when test cards are being removed from the station.
- Empty the waste collection tray after loading a new cassette into the instrument.
- Periodically remove the waste collection tray for cleaning.
   See Cleaning the Test Card Collection Tray on page 7-49.

# The User Interface System

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

### **Keypad and Screen**

A keypad and screen are located on the front of VITEK 2. VITEK 2 uses the screen to send you messages about its operation, on-board disposables, and possible problems. You use the keypad to respond to VITEK 2 instructions, send commands to VITEK 2, and to perform other functions. Use the diagram below to identify the components of the keypad and screen:

Option Buttons. Use these buttons to select menu options or other specified functions.



Error/Message Key.
Press this key at any time to access the error/message queue.



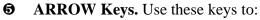
9 Previous Screen Key.

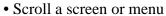
Use this key to:

- 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



**4** Undo Key. Use it to cancel the last action performed.





• Move the cursor on some screen

**NOTE:** When ARROW keys are active, their icons appear on the display.



**6 ENTER Key.** Use this key to complete data entries, or when instructed to do so on a screen.

**NUMERIC Keys.** Use these keys to enter a number onto a screen.

# 5. Configuring the VITEK 2 Instrument

### Introduction

Configuration options allow you to operate the VITEK 2 instrument in a number of different ways. This chapter explains not only how to set these options, but how each option affects the operation of the instrument, and therefore your laboratory work flow. Some affect only the physical interface and can be changed to suit your preferences. For example, you can adjust the contrast on the interface screen. Other options affect how VITEK 2 processes test cards. Therefore, careful consideration should be given to setting or changing these options.

#### Where to Find It

- Configuration Overview 5-3
  - What are the Configuration Options? 5-3
  - When Should Configuration Options be Set? 5-4
- How Configuration Options Affect VITEK 2 5-5
  - Cassette Names 5-5
  - Instrument Name 5-7
  - Schedule Instrument OC Status 5-8
  - Cassette Mode 5-10
  - Dilution Mode 5-11
  - Bar Code Reader 5-12
  - Audible Alarm Enable 5-13
  - Audible Alarm Volume 5-14
  - Visual Alarm Enable 5-15
  - Keyclick Volume 5-16
  - Screen Contrast 5-17

- How to Set VITEK 2 Configuration Options 5-18
  - Where to Find Configuration Options 5-19
  - How to Define Character Sets 5-20
  - How to Set Time for the QC Status 5-22
  - How to Use Option Boxes 5-24
  - How to Set a Range Value 5-25

## **Configuration Overview**

### What are the Configuration Options?

There are 11 configuration options in the VITEK 2 user interface. They can be divided into two groups, depending on whether or not the option affects how the instrument operates. The group that does affect instrument operation is composed of the following options:

Option	Find a Description on
Cassette Names	5-5
Instrument Name	5-7
Schedule QC Status	5-8
Cassette Mode	5-10
Dilution Mode	5-11
Bar Code Reader	5-12

Table 5-1: Configuration Options that Affect Instrument Operation

The group of options that only affect the physical parameters of the user interface is composed of the following options:

Option	Find a Description on Page
Audible Alarm Enable	5-13
Audible Alarm Volume	5-14
Visual Alarm Enable	5-15
Keyclick Volume	5-16
Screen Contrast	5-17

Table 5-2: Configuration Options that Affect Only Physical Parameters

### When Should Configuration Options be Set?

Configuration options can be set or changed at almost any time. However, you should follow this simple work flow to ensure that you set your options correctly.

1. Read the descriptions contained in this chapter for each option.

Evaluate the effect that an option would have on your work flow and decide how the option should be set. This is especially important for the options in Table 5-1.

2. Set the options according to the choices made in step 1.

Use the procedures in this chapter for instructions on how to set an option.

3. Operate the system to validate the settings.

During this time evaluate the physical parameter settings for the options in Table 5-2.

4. Change any option as required.

# **How Configuration Options Affect VITEK 2**

#### **Cassette Names**

The Cassette Names option allows you to define up to ten, three-character VITEK 2 users. When a cassette is processed, the Cassette Name becomes part of what is called the **cassette address.** When viewing test card directories on the VITEK 2 workstation, the cassette address can be used to filter the directory view so that only those test cards processed by a particular user are seen. Cassette names can represent the technologists who process test cards, sections of the laboratory from which test cards originate, or any identification scheme that you want to use.

#### WHY USE THIS OPTION?

The Cassette Names option is designed for work flows in which a Smart Carrier Station (SCS) is not used. A **Cassette Name** that you define replaces the **cassette name** that would be read from the cassette's button memory. You should use this option if you do not have an SCS, or if you have a work flow that does not require the use of an SCS.

**NOTE:** If the VITEK 2 instrument is in Smart Carrier mode, the Cassette Names option cannot be accessed. If you attempt to use the option, the screen displays the message:

This option is used with cassette only mode

#### How to Set this Option

The procedure for setting this option is *How to Define Character Sets* on page 5-20.

#### **Instrument Name**

The Instrument Name option allows you to name a VITEK 2 instrument module. The name can contain up to 20 printable characters, including spaces. The instrument name can be helpful in those laboratories with more than one VITEK 2 instrument to segregate, for example, specimen types or technologists. The instrument name also displays on the Directory window at the VITEK 2 workstation.

#### WHY USE THIS OPTION?

The VITEK 2 instrument names default to "Instrument 1," "Instrument 2," etc. You should use this option if you have **more than one** instrument module. By assigning each instrument module a different name, you can view test card directories by the instrument in which they are being processed.

#### How to Set this Option

The procedure for setting this option is *How to Define Character Sets* on page 5-20.

#### Schedule Instrument QC Status

The QC Status is a report of the current incubator temperature and the status of the optics systems. The report is sent to the VITEK 2 workstation where it is recorded with the date and time the report was taken.

The configuration option allows you to schedule up to three times of day when a QC report is taken and recorded at the workstation.

The Instrument Quality Control Status includes two parameters:

- Carousel Incubator Temperature
- Optics Systems

The instrument continuously monitors these parameters so that their status can be determined at any time. The user interface provides a function, called Display Instrument QC Status, to access this information.

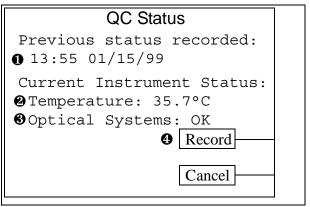


Figure 5-1: The Instrument QC Status Screen

- This field displays the time and date that the previous QC status was recorded. The field is blank if this function has never been used before.
- **2 Temperature**. For the VITEK 2, this field displays the current carousel temperature in degrees Celsius. For the VITEK 2 XL, the temperatures for carousel A and B are displayed.
- **Optical Systems.** This field displays the status of the fluorescence and transmittance optical systems.
- **Q** Record. Press this option button to transmit the QC status information to the workstation. During the transfer the message Recording QC Report appears on the screen.

#### WHY USE THIS OPTION?

The instrument user interface contains a function with which you can manually record a QC Status. You can set this option if you want the report recorded automatically. For example, you can have the report recorded at the same time every day.

#### How to Set this Option

The procedure for setting this option is *How to Set Time for the QC Status* on page 5-22.

#### **Cassette Mode**

The Cassette Mode option tells the VITEK 2 instrument whether or not you use a Smart Carrier Station (SCS), and is critical to instrument operation. The option enables or disables the instrument's Button Memory Reader, a device that reads information stored in the button memory.

#### WHY USE THIS OPTION?

The Cassette Mode option defaults to **Smart Carrier**, meaning that an SCS is being used. Use this option to change the mode to **Cassette Only** if your laboratory does not have an SCS.

#### How to Set this Option

The procedure for setting this configuration option is *How to Use Option Boxes* on page 5-24.

#### **Dilution Mode**

The Dilution Mode option can be set to either **Automatic** or **Pre-diluted**. In the Automatic mode, the Dispenser/Pipettor station in the VITEK 2 instrument automatically prepares the inoculum for AST cards that have matching ID cards. In the Pre-diluted mode, the Dispenser/Pipettor station is disabled.

#### WHY USE THIS OPTION?

If you use a Smart Carrier Station (SCS), the operation of the Dispenser/Pipettor station is determined by the information in the cassette's button memory.

**NOTE:** If the VITEK 2 instrument is in Smart Carrier mode, the Dilution Mode option cannot be accessed. If you attempt to use the option, the screen displays the message.

This option is used with cassette only mode

However, if you are not using an SCS, this option must be set as follows:

- To Automatic if you want VITEK 2 to prepare your AST card inocula.
- To **Pre-diluted** if you prepare AST card inocula manually.

**NOTE:** If the instrument is in Cassette Only mode, you can use the Cassette Setup function (Main Menu) to process individual cassettes in the dilution mode opposite to the configuration setting.

#### **DANGER:**



Biohazardous spills can occur inside the VITEK 2 instrument if the Dilution Mode option is not properly set. This is especially true if pre-diluted samples are used with the mode set to Automatic.

#### How to Set this Option

The procedure for setting this configuration option is *How to Use Option Boxes* on page 5-24.

#### Bar Code Reader

The VITEK 2 instrument has a bar code station that reads the bar code labels on the test cards. If the reader becomes misaligned, or if some other error occurs in the station, you could get repeated error messages about bad bar codes.

#### WHY USE THIS OPTION?

Use this option to **disable** the bar code reader if there is a problem with the station. Do **NOT** use this option unless you think there is a problem in the bar code reader station.

#### How to SET THIS OPTION

The procedure for setting this configuration option is *How to Use Option Boxes* on page 5-24.

#### **Audible Alarm Enable**

The instrument sounds an audible alarm to alert you to an error condition. The alarm stops temporarily when you press any key on the instrument keypad, sounding again if you do not access the message queue.

#### WHY USE THIS OPTION?

The Audible Alarm Enable option defaults to **Enabled.** The option to disable the alarm is provided for the case where the instrument is located very near the workstation. Since the workstation also sounds an alarm, disabling the instrument's alarm eliminates this redundancy.

#### How to SET THIS OPTION

The procedure for setting this configuration option is *How to Use Option Boxes* on page 5-24.

#### **Audible Alarm Volume**

The volume of the audible alarm can be adjusted higher or lower to account for laboratory conditions.

#### WHY USE THIS OPTION?

The default setting for the alarm volume is at the midpoint of its range. Use this option to make the appropriate adjustments as required. The option includes a test function so that you can hear the alarm while changing it.

#### How to Set this Option

The procedure for setting this configuration option is *How to Set a Range Value* on page 5-25.

#### Visual Alarm Enable

The instrument causes the interface screen display to blink to alert you to an error condition. The blinking terminates when you press any key on the instrument keypad.

WHY USE THIS OPTION?

Since the VITEK 2 instrument and workstation each have an audible alarm, the visible alarm may be unnecessary. If so, use this option to **Disable** the alarm.

#### **CAUTION:**



Do not disable both the audible and visual alarms on the instrument unless it is located very near to the workstation. Doing so makes it more difficult to know that an error condition exists.

How to Set this Option

The procedure for setting this configuration option is *How to Use Option Boxes* on page 5-24.

### **Keyclick Volume**

The VITEK 2 instrument interface uses a "touch pad" type of keypad. It sounds an audible click when you press each key. The volume of the click can be adjusted to account for laboratory conditions.

#### WHY USE THIS OPTION?

The default setting for the keyclick volume is at the midpoint of its range. Use this option to make the appropriate adjustments.

#### How to Set this Option

The procedure for setting this configuration option is *How to Set a Range Value* on page 5-25.

#### **Screen Contrast**

The VITEK 2 user interface screen uses an LCD display. This option controls the amount of background contrast on the display.

WHY USE THIS OPTION?

Viewing of an LCD screen can be enhanced by changing the contrast under certain lighting conditions. Use this option to change the screen if conditions require it.

How to Set this Option

The procedure for setting this configuration option is *How to Set a Range Value* on page 5-25.

# **How to Set VITEK 2 Configuration Options**

There are eleven configuration options, but only four different procedures for setting them, depending on the interface used. The four interfaces used and the applicable configuration options are shown in the following table:

Type of Interface	Application Configuration Option	Find the procedure on page
Character set	Cassette Names     Instrument Name	5-20
Set time	Schedule QC Status	5-22
Option box	<ul> <li>Cassette Mode</li> <li>Dilution Mode</li> <li>Bar Code Reader</li> <li>Audible Alarm</li> <li>Visible Alarm</li> </ul>	5-24
Set range value	Audible Alarm Volume     Keyclick Volume     Screen Contrast	5-25

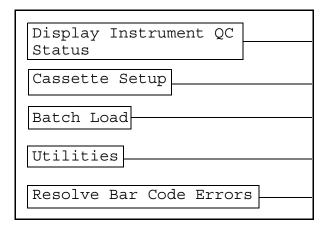
Table 5-3: Types of Interfaces for Configuration Options

### Where to Find the Configuration Options

All of the configuration options for VITEK 2 are on the Configuration Menu. You access this menu using the path:

VITEK 2 Main Menu ⇒ Utilities ⇒ Configuration

The VITEK 2 Main Menu looks like this:



#### **How to Define Character Sets**

Use this procedure for the **Cassette Names** and **Instrument Name** configuration options. Character sets can include any of the characters provided on the character selection, plus the 10 digits from the keypad.

 Select the Cassette Names or Instrument Name configuration options using the path:

Main Menu ⇒ Utilities ⇒ Configuration

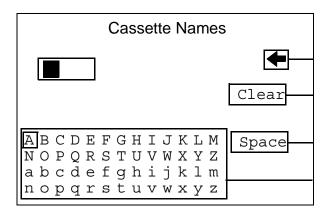
For the **Cassette Names** option, the following screen appears:

Cassette Names		
0:	5 <b>:</b>	
1:	6:	
2:	7:	
3:	8:	
4:	9:	
0:		
Enter the	user number	
to add or modify		

**NOTE:** This screen does not appear for the **Instrument Name** option.

2. Press a *number key* to select one of the ten cassette name positions, and then press <ENTER>.

The character selection screen appears:



**NOTE:** This screen is similar for both the **Cassette Names** and **Instrument Name** options.

3. Select a letter using the *ARROW keys* and then press the option button for the character box. If you make a mistake, press the backspace option button.

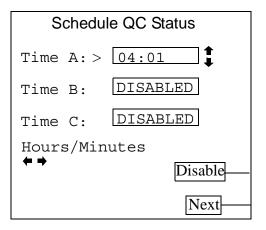
#### How to Set Time for the QC Status

The function allows you to set up to three times during the day at which an instrument QC report is sent to the workstation.

Access the Schedule QC Status function using the path:

Main Menu ⇒ Utilities ⇒ Configuration

The following screen appears:



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

**NOTE:** The *LEFT* or *RIGHT ARROW* keys beneath Hours/ Minutes allow you to toggle between Hours and Minutes when setting the time.

To set the Hour for Time A:

- 1. Press the *LEFT ARROW* key until 'Hours' displays.
- 2. Use the **UP** or **DOWN ARROW** keys to set the Hour.

To set the Minutes for Time A:

- Press the *LEFT ARROW* key until 'Minutes' displays.
- 4. Use the **UP** or **DOWN ARROW** keys to set the minutes.
- 5. To schedule another QC Status report, select Time B by pressing the *NEXT* button.
- 6. To exit the function press the *ENTER* option button.

## **How to Use Option Boxes**

This procedure applies to the following configuration options:

- Cassette Mode
- Dilution Mode
- Bar Code Reader
- Audible Alarm Enable
- Visual Alarm Enable
- 1. Access one of the above configuration options using the following path:

Main Menu ⇒ Utilities ⇒ Configuration

A screen similar to the following appears:

### Cassette Mode

✓ Smart Carrier ★

Cassette Only **₹** 

To change the current setting, press the *UP* or *DOWN ARROW* keys.

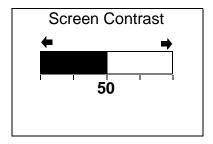
## How to Set a Range Value

This procedure applies to the following configuration options:

- Audible Alarm Volume
- Keyclick Volume
- Screen Contrast
- 1. Access one of the above configuration options using the following path:

 $Main\ Menu \Rightarrow Utilities \Rightarrow Configuration$ 

Below is an example of a range value screen.



1. Press the **DOWN ARROW** to view the configuration options.

A range bar appears:



2. Change the range value by pressing the **LEFT** or **RIGHT ARROW** keys.

The bar graph and the numeric value change, and the actual parameter change in response to this action.

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

**NOTE:** For the Audible Alarm Volume parameter, a test button is provided to sound the alarm.

# 6. Processing VITEK 2 Test Cards

## Introduction

This chapter contains the procedures you need to process VITEK 2 test cards. The chapter begins with three introductory sections that provide reference information about the VITEK 2 Status screen, the VITEK 2 Menu system, and the Smart Carrier Station interface.

The next two sections contain suggested work flows and the procedures for working either with or without a Smart Carrier Station. The final section deals with unloading test cards from the instrument.

#### Where to Find It

- Introduction 6-1
  - About the VITEK 2 Status Screen 6-3
  - About the VITEK 2 Menu System 6-10
- About the Smart Carrier Station 6-13
  - Advantages of Using the SCS 6-13
  - Data Fields 6-16
  - Using the Slot Indicator 6-19
  - SCS Functions 6-19
  - Option Boxes 6-22
  - About the Bar Code Scanner 6-24

- Processing Test Cards Using the Smart Carrier Station 6-25
  - Configuration Options to Consider 6-25
  - The Work Flow 6-26
  - How to Enter Data With the SCS 6-28
  - Loading a Cassette 6-31
- Processing Test Cards in Cassette Only Mode 6-36
  - Configuration Options to Consider 6-36
  - The Work Flow 6-37
  - Cassette Preparation 6-39
  - Loading a Cassette 6-44
  - How to Enter Data for a Cassette 6-48
- Batch Loads (in Smart Carrier or Cassette Only Mode) 6-50
  - How to Select Batch Loading 6-50
  - To Begin a Batch Load 6-51
- Unloading the Cassette and Removing Waste 6-54
  - How to Unload a Cassette 6-55
  - How to Remove Ejected Test Cards 6-57

## About the VITEK 2 Status Screen

You use the Status screen more often than any other screen in the VITEK 2 user interface. Since it is so basic to the work flow, the Status screen is very easy to display and in many cases, the interface displays it automatically.

#### HOW TO DISPLAY IT

There are three ways to display the Status screen:

- Automatically displays at the end of the instrument's power up initialization process.
- Automatically displays from the Main Menu whenever that menu is left unattended for more than one minute.
- Displays from the Main Menu by pressing the PREVIOUS SCREEN key.

### INSTRUMENT STATUS FIELD

The Status field appears at the top of the VITEK 2 Status screen.

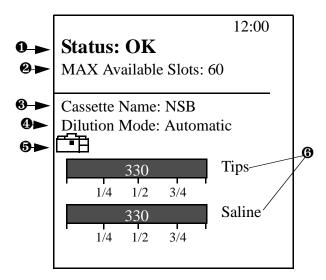


Figure 6-1: The VITEK 2 Status Screen in Cassette Only Mode

The Instrument Status field (**1**) displays one of the following:

- OK. This status means that all of the subsystems in the instrument are working normally, and that the instrument is ready to accept test cards for processing.
- Warming. This status is seen after the instrument is turned on. It means that the incubation temperature in the reader station has not reached its specified temperature. Test cards cannot be processed until this status changes to "OK."

- **Messages.** This status indicates that there is an error message in the error/message queue that has not been viewed. Press the Message key (?) to view the error/message queue.
- Errors. This status appears <u>after</u> the error/message queue is accessed if the error condition has not been resolved. This status can be cleared only by resolving the condition that generated the original message.
- Cleaning. This status indicates that either all four boats, or at least one carousel section, have been removed for cleaning. Test card processing cannot resume unless all carousel sections, or at least one boat, are replaced.

#### KNOWING HOW MANY TEST CARDS YOU CAN LOAD

The MAX Available Slots field (②) 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, some of the test cards will not be processed unless additional slots become available by the time the test cards reach the carousel.

The number you see in the **MAX Available Slots** field depends on the VITEK 2 instrument you have and the optical configuration of the instrument.

Instrument/Max Available	Optical Configuration
VITEK 2 MAX Available Slots: 60	1 fluorescence optic
	1set of transmittance optics
VITEK 2 XL MAX Available Slots: 120 Available ID Slots: 60	• 1 fluorescence optic (Section A)
	• 2 sets of transmittance optics (Sections A & B)
VITEK 2 XL MAX Available Slots: 120	2 sets of fluorescence optics Sections A & B
	• 2 sets of transmittance optics Sections A & B

Table 6-1: MAX Available Slots

## THE CASSETTE NAME FIELD

When the instrument is in **Cassette Only mode** (3), this field displays the name of the most recently used cassette. That cassette name is applied to all cassettes unless you elect to change it. When the instrument is in **Smart Carrier mode**, the field displays the name "SCS."

#### THE DILUTION MODE INDICATOR

This field (4) displays only when the instrument is in **Cassette Only mode.** The field then tells you whether the instrument is set to the **Automatic** or **Pre-Diluted** dilution mode. This field should be checked before loading a cassette.

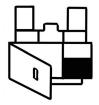
## **DANGER:**



Biohazardous spills can occur inside the VITEK 2 instrument if the Dilution Mode option is not properly set, especially if pre-diluted samples are used with the mode set to Automatic. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

## STATUS SCREEN ICONS

The area on the Status screen just above the disposables graphs is reserved for the Status screen (**6**) icons.



 VITEK 2 Instrument Icon. This icon represents the VITEK 2 instrument. It shows when one of the access doors is open. These include the front access door on the front of the instrument, and the top access door.



• VITEK 2 XL Instrument Icon. This icon represents the VITEK 2 XL instrument. It shows when one of the access doors is open. These include the Section A top access door, Section B top access door, and the center front sliding door.

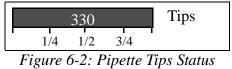


• Cassette Icon. An icon graphic of a cassette appears while a cassette is processing through the Bar Code Reader and Button Memory Reader stations. Its presence reminds you to stay near the instrument to ensure that the cassette does not experience any load errors.

HOW TO MONITOR PIPETTE TIPS AND SALINE

The VITEK 2 instrument uses pipette tips and saline (**6**) for automatic dilution of susceptibility inocula.

For each disposable the Status screen displays a bar graph and number similar to the one shown in Figure 6-2:



As the disposables are used, the bar graphs begin to decrease. The graphs are marked to show levels of 1/4, 1/2, and 3/4 capacity. The number associated with the graph decreases at the same time. When the number goes under 40, the value changes to "LOW."

**NOTE:** For pipette tips, the number refers to the number of available tips. For saline, the number refers to the available number of aliquots.

## **CAUTION:**



The disposable monitors should be used as an approximate indicator. Care should be used to prevent running out of either disposable during test card processing.

## **About the VITEK 2 Menu System**

All of the functions used on the VITEK 2 instrument are available through the menu system. The system is composed of a Main Menu and a set of five submenus.

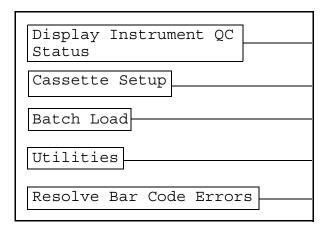


Figure 6-3: VITEK 2 Main Menu

In Figure 6-4 on page 6-11, the menu structure is shown with all of the function options added. The bold lines in this figure show the menus and the pathways between them.

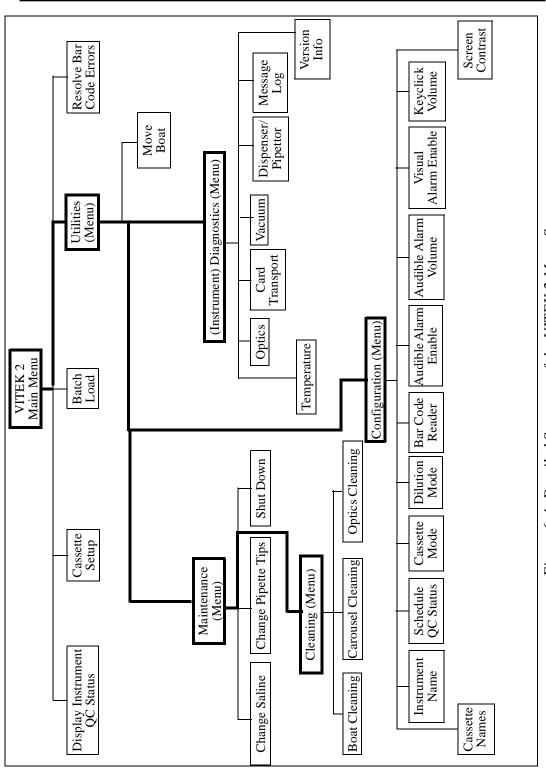


Figure 6-4: Detailed Structure of the VITEK 2 Menu System

This manual describes the pathway to a specific function by naming each menu to access, with the menus separated by arrows. For example, the pathway to the Change Saline function on the Maintenance menu would be shown as follows:

Main Menu  $\Rightarrow$  Utilities  $\Rightarrow$  Maintenance

#### KEYS YOU USE MOST OFTEN

There are several keys on the keypad that are used often when using the VITEK 2 menu system.

- **Option Buttons.** There are five round buttons located along the right side of the user interface screen. When a menu or function option appears on the screen, you press the corresponding option button to access that menu or function.
- **Previous Screen Key.** This key has three actions, depending on what displays on the screen.



Figure 6-5: The Previous Screen Key

- If a function displays on the screen, pressing the PRE-VIOUS SCREEN key returns the display to the menu from which the function was selected.

- If a menu displays on the screen, pressing the PREVI-OUS SCREEN key returns the display to the previous menu.
- If the Main menu displays on the screen, pressing the PREVIOUS SCREEN key returns the display to the Status screen.

## **About the Smart Carrier Station**

## **Advantages of Using the Smart Carrier Station**

The Smart Carrier System is a labor-saving device that provides several advantages for your laboratory work flow:

• Bar Code Scanner. The bar code scanner allows you to utilize the bar codes that are printed on the test cards and the SCS Job Aid card. The Test Card Type, Organism, Ancillary Test, and Modifier fields can be entered without having to use the keyboard. If your laboratory uses bar codes for accession number of specimens, these can also be entered using the scanner.

- Cassette. The cassette helps you organize your work. Each cassette has 15 slots for test cards and 15 corresponding wells for specimen test tubes. Information entry using the SCS bar code scanner or keyboard is organized by slot, which allows you to create a simple work flow. For example, using the bar code scanner, you could
  - scan the accession ID, place specimen test tube in its well
  - scan the test card, place it in the corresponding slot
  - scan the Job Aid card for optional fields such as organism, ancillary tests, or modifiers.
- Matching ID and AST Cards. When the SCS computer sees an AST card, it looks at the card in the previous slot. (For gram negative AST cards, the previous **two** slots are included.) If it finds an ID card with the same accession number in that slot, it declares a match. A matched ID/AST card set provides two advantages:
  - In Automatic Dilution mode, the inoculum for the AST card is created automatically in the VITEK 2 instrument.
  - The organism identification called by the ID card is automatically applied to its matching AST card. (Two gram negative AST cards can be matched to a gram negative ID card; only one gram positive AST card can be matched to a gram positive ID card.)

- SCS Station Name. In larger laboratories, using multiple Smart Carriers provides an automatic identification system for the test cards. Each SCS is given a three-character name. That name is applied to every test card that is processed through the station. When you look up a test card on the VITEK 2 directory, the source of any test card is instantly known. Smart Carriers can be named for the technologists using them, for a laboratory location, or for the types of specimens processed through them.
- **Safety.** The cassette portion of the SCS provides a safe and convenient method of transporting multiple test cards from the workbench to VITEK 2. Once a sample is placed in the cassette, the technologist never has to touch it again.
- Security. The SCS provides an extra measure of security for your test card/specimen information. After a cassette is placed in VITEK 2, a bar code reader in the instrument reads the bar code on the test card, and compares that information with the information it read from the cassette. Any discrepancies in test card type or position in the cassette are reported to the user so that corrective action can be taken.

## **Data Fields**

There is one data entry screen with six fields. The fields are repeated for each of the available 15 slots in the cassette.

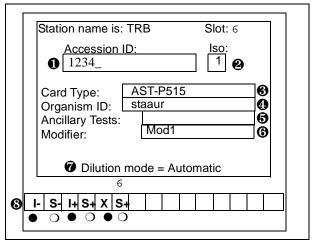


Figure 6-6: Fields of the Data Entry Screen

Field	Description
• Accession ID	This field identifies the specimen. It can contain up to 20 alphanumeric characters. This is a <b>required</b> field, meaning it must be filled before other fields can be entered.
2 Isolate Number	This field defaults to a value of 1 and is normally skipped during data entry. To replace the default, move the cursor to this field using the UP arrow key.
Test Card Type	This field is used to identify the type of test card that is to be placed in the cassette slot.
4 Organism ID	This field is used for identifying an organism in an AST card.

Table 6-2: Smart Carrier Station Data Fields

Field	Description
6 Ancillary Tests	This field holds the results of off-line tests performed for some test cards.
<b>6</b> Modifier	This field is used for organism modifiers. Six generic entries, mod1 to mod6, are preloaded. When this data reaches the workstation computer, the generic entry is converted to one of the first six corresponding entries in the Organism Modifier table of the bioLIAISON database.
ODilution Mode	The current dilution mode setting always displays on the Data Entry screen.  NOTE: Check the setting before starting a new cassette. (See callout (**) in Figure 6-6 on page 6-16.)

Table 6-2: Smart Carrier Station Data Fields

Description
The slot indicator is the set of boxes at the bottom of the Data Entry screen (see callout (3) in Figure 6-6 on page 6-16). The information in the slot indicator is read as follows:
A number corresponding to the currently displayed slot appears over the appropriate box.
The row of boxes is filled in as data is entered. These boxes are empty unless the user has entered data previously.
A box in the row is filled automatically when the user enters data into the Card Type field. Indicators are  I+ = gram positive ID  I- = gram negative ID  IA = anaerobe ID  IY = yeast ID  S+ = gram positive susceptibility  S- = gram negative susceptibility  X = Indicates the position of the inoculum tube for a susceptibility test without a preceding mated ID when in automatic dilution mode. This slot must not contain a card.

Table 6-2: Smart Carrier Station Data Fields

## **Using the Slot Indicator**

A filled-in circle (●) appears under a box when the SCS
determines the test card in the slot requires an organism suspension. A completely open circle (○) appears under a box
when the test card in the slot requires an empty tube. Empty
tubes are used for AST cards when the SCS is set to Automatic dilution mode.

## **SCS Functions**

The following table summarizes the functions that can be performed while entering data, and the use of the special function keys.

Use these keys	То	Do this:
<b>②</b>	Display context-sensitive help screens and data field option boxes:	Press the ? key.
\$ \$ \$	Move between fields:	Press the <i>UP/DOWN</i> or <i>LEFT/RIGHT ARROW</i> keys.
\$ \$ \$	Access the Isolate Number field:	Press the <i>LEFT</i> or <i>UP ARROW</i> keys to move to the Isolate # field.

Table 6-3: Summary of SCS Functions

Use these keys	То	Do this:
\$ <b>~</b> \$	Display an adjacent slot:	Press the <b>NEXT</b> or <b>PREVIOUS SLOT</b> key.
	Copy data to the current slot.	Information must have been entered in a previous slot.
<b>€ 1 1 1 1 1 1 1 1 1 1</b>		2. Press the <i>F1</i> key to copy the appropriate data from the previous slot.
F2	Exit a screen:	Press the <b>F2</b> key.
F3	Display the Summary screen:	Press the <i>F3</i> key to display the first summary screen.
		2. Press the <b>NEXT</b> or <b>PREVIOUS SLOT</b> key to display the second summary screen.
F4	Display the Configuration screen:	Press the <b>F4</b> key.
F5	Display data for a non-adjacent slot:	Press the <i>F5</i> key. A popup prompt appears.
		Enter the <b>slot number</b> you want to display.
F6	Display the Flex Panel Entry screen:	Press the <b>F6</b> key.
F8	Erase the data in the current field.	Press the <b>F8</b> key.

Table 6-3: Summary of SCS Functions

Use these keys	То		Do this:
F9	Erase the data for a slot.	1.	Press the <b>F9</b> key. A confirmation window appears.
	NOTE: This function also erases data in any successive linked slots.	2.	Press the <b>F1</b> key to erase the data.
F10	Erase all the data in the button memory chip.	1.	Press the <b>F10</b> key. A confirmation window appears.
	Cmp.	2.	Press the <i>F1</i> key to erase the button memory chip.

Table 6-3: Summary of SCS Functions

**NOTE:** The F7 key is currently unassigned.

## **Option Boxes**

The Organism ID, Ancillary Test, and Modifier fields are restricted, that is, they accept only certain data. When entering data manually via the keyboard, option boxes provide access to the acceptable data entries.

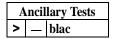
#### ORGANISM ID

This field has two option boxes, depending on the AST card type you enter in the Card Type field. For example:

Positive	Negative
Organism ID	Organism ID
> staaur	> esccol
staneg	promir
entspp	provul
strpre	pseaer

## **ANCILLARY TESTS**

The contents of the option boxes for this field depend on the type of card you enter in the Card Type field. For example, the option box for a gram positive card would be similar to the following:



### **MODIFIER**

The option box for the Modifier field contains six default entries, "mod 1" to "mod 6." When this data reaches the workstation computer, the entry is matched to one of the first six entries in the Organism Modifier table of the bioLIAISON database.

Select Modifier
Mod1
Mod2
Mod3
Mod4
Mod5
Mod6

#### HOW TO ENTER DATA USING AN OPTION BOX

- Use the UP or DOWN ARROW key to move the cursor into the correct field.
- 2. Press the **HELP** (?) key to access the option box for the field.
- Use the *UP* or *DOWN ARROW* key to move the selection pointer (>) to the correct data entry.
- 4. (Ancillary Test only). Press the + or key to enter a positive or negative result, respectively.
- 5. Press the **ENTER** key to return to the data screen.

## **About the Bar Code Scanner**

• The bar code scanner reduces the time required for data input. If your laboratory uses bar codes to identify patient specimens, these can be scanned to enter the accession ID.

The required bar codes for the Organism, Ancillary Test, and Modifier fields have been printed on the SCS Job Aid Card.

 Bar code labels on every test card allow you to scan in the entry for the Card Type Field. Additional information from this bar code is also stored in the button memory of the cassette. This information helps VITEK 2 properly identify and process each test.

## **Processing Test Cards Using the Smart Carrier Station**

**NOTE:** If your system does not have a Smart Carrier Station, refer to the section *Processing Test Cards in Cassette Only Mode* on page 6-36.

## **Configuration Options to Consider**

Before using the SCS, make sure that the following options are properly set:

- On the Smart Carrier Station. All of the configuration options on the SCS should be set. The most important of these is the Dilution Mode option. Make sure that it corresponds to how susceptibility inocula are processed for this cassette. See *AST Dilution Mode* on page 3-4.
- On the VITEK 2 Instrument. The most important configuration option for using the SCS is the Cassette Mode option. This option must be set to Smart Carrier.

### The Work Flow

The following table provides a general work flow for using the Smart Carrier Station (SCS). This work flow assumes that you have

- selected the VITEK 2 test cards to process
- decided whether to prepare susceptibility suspensions manually or automatically using VITEK 2

**NOTE:** If you choose to prepare suspensions manually, suspension preparation instructions can be found in the appropriate *Online Product Information* in the online help system at the workstation.

prepared the inocula and have all material positioned by the SCS

Activity	For more information see
A. Make sure that all configuration options are set cor-	• Configuration Options to Consider on page 6-25.
rectly.	• Fields of the Data Entry Screen on page 6-16.
B. Insert a cassette to display the Data Entry screen.	Step 1 on page 6-28.

Activity	For more information see
C. Select a slot in the cassette for the first test card and specimen.	<ul> <li>Using the Slot Indicator on page 6-19</li> <li>SCS Functions on page 6-19</li> </ul>
NOTE: The SCS automatically starts with slot 1 and fills the cassette sequentially. Slot selection is therefore an optional activity.	
D. Enter the information for the first test card and specimen:	• How to Enter Data With the SCS on page 6-28.
• Using the SCS bar code scanner, or	• SCS Functions on page 6-19.
• Using the SCS keyboard	• Option Boxes on page 6-22.
E. Place the first test card and specimen test tube in their appropriate slots.	N/A
F. Continue activities C, D, and E for the remainder of the cassette.	N/A

## How to Enter Data With the SCS

The Data Entry screen is used to store information about specimens and their test cards. You enter the information by positioning the cursor in a data field for a particular test card slot. By default, the cursor is always in the Accession ID field for slot 1 when the screen is first accessed. All fields are empty unless previous data was entered for that slot.

## 1. Access the **Data Entry** screen.

The SCS displays the Data Entry screen (see Figure 6-6 on page 6-16) automatically whenever a cassette is firmly seated on the SCS base unit.

#### Select the correct slot.

- Make sure that the data entry screen is displaying the correct slot (1 - 15). Use the NEXT SLOT or PREVI-OUS SLOT keys.
- Make sure also that the cursor (blinking bar) is in the correct field. Use the *UP* or *DOWN ARROW* keys.

## 3. Enter the data:

Field	Using the bar code scanner	Using the keyboard	
<b>Accession ID</b>	Scan the bar code	Type the ID into the Acces-	
	label on the speci- men.	sion ID field.	
Card Type	Scan the bar code label on the card.	Type the 18-digit code from the bar code label on the test card.	
	<b>NOTE:</b> The SCS does not allow you to enter expired cards.		
Organism ID (AST card)	Scan an organism ID from the SCS job aid card.	Place the cursor in the Organism ID field and press the <i>Help</i> key. Select an organism from the option box.	
Ancillary Test	Scan a test from the SCS job aid card.	Place the cursor in the Ancillary Test field and press the <i>Help</i> key. Select a test from the option box.	
Modifier	Scan a modifier from the SCS job aid card.	Place the cursor in the Modifier field and press the <i>Help</i> key. Select a modifier from the option box.	

**NOTE:** If you need to change any of the data you have entered, you must do so **before** you remove the cassette from the SCS.

### **CORRECT POSITIONING OF AST CARDS**

If you pre-dilute the inocula for the susceptibility tests, you can place the test cards into any slots in the cassette, in any order you choose. However, when VITEK 2 is performing the dilution (Automatic dilution mode), you must follow these rules:

- The AST card must be placed in a slot immediately following the slot containing the inoculum test tube.
- A gram negative inoculum can be used for either one or two susceptibility tests. When diluting the inocula for two tests, the test cards must occupy the two slots **immediately following** the slot containing the inoculum test tube.

These rules apply whether or not an ID card is used.

## Loading a Cassette

### **DANGER:**



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.

After the information for a cassette has been entered at the SCS, the cassette is ready to be loaded into the VITEK 2 instrument. **Before** you load the cassette, however, you should always check the Status screen. Look at the following parameters to make sure it is okay to load the cassette:

Parameter	What to Look For	
Status	This field should read "OK."	
Available Slots	The value in this field should be greater than or equal to the number of test cards you are loading.	
Tips and Saline	The level of both disposables should be greater than or equal to the number of test cards you are loading.	
	<b>NOTE:</b> This parameter may be ignored if you are operating in the Pre-diluted mode.	
Cassette Mode	This field should read SCS (Smart Carrier Station)	

### USING THE CASSETTE LOAD STATION

The Cassette Load station is composed of the cassette load door and a green indicator light. The indicator light tells you the status of the load station, as follows:

If the Indicator Light is	It Means that
On	The cassette load door is unlocked. You may open the door to load cassettes.
Off	The cassette load door is locked and cannot be opened.
Blinking	A boat with an empty cassette has arrived at the station. You should open the cassette load door and remove the cassette. When the door is closed again, the blinking stops.

Table 6-4: Interpreting the Cassette Load Station Indicator Light

Before you attempt to load a cassette, make sure the indicator light is on or is blinking.

### How to Load a Cassette

1. Open the *Cassette Load station* by lifting the cassette load door up. There should be an empty boat at the station, or one with a cas-



**DANGER:** 



Do not attempt to load a cassette if a boat is not at the station. Damage to the cassette and the VITEK 2 instrument is possible.

2. Place the *cassette* in the boat so that the specimen test tubes face the front of the instrument.

sette that contains waste.

**NOTE:** The boat is shaped such that it will only accept a cassette in the proper orientation.



### **CAUTION:**



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

Close the cassette load door.

The cassette icon appears on the Status screen.

 Monitor the instrument until the cassette icon disappears and the boat moves forward to process cards.

### MONITORING CARD PROCESSING

After a cassette is loaded, the test cards in it are scanned by the bar code reader in VITEK 2. This information is sent to the workstation so that you can see a listing of the test cards in the Directory window. Additional information is provided once the test cards reach the Card Incubator and Reader station and are read for the first time.

**NOTE:** The VITEK 2 instrument should be attended during the first minute after a cassette is loaded and the boat moves forward to process cards. This period is denoted by the presence of the cassette icon on the VITEK 2 Status screen. See also the section *Cassette Load Processing Errors* on page 8-15.

### ABOUT THE CASSETTE ADDRESS

The cassette address, which appears in the VITEK 2 Directory screen at the workstation, provides a means to identify each test card in the VITEK 2 instrument. The following figure illustrates two examples:

RMT-03 Apr 03 08:35:40 URN-11 Mar 29 13:45:01

Figure 6-7: The Cassette Address

A cassette address has three basic parts. Using the first example from Figure 6-7, the following table shows what each of these parts mean, and how they are derived.

The Cassette Address Section	For example	Is taken from
The cassette name.	RMT	The three-character cassette name that is entered on the Configuration screen of the Smart Carrier Station.
The slot position (1 - 15) of the test card in the cassette.	03	The actual test card position as read by the VITEK 2 bar code reader.
Date/time stamp.	Apr 03 08:35:40	The date and time the test card was read by the VITEK 2 bar code reader.

The cassette name portion of the address can represent various laboratory parameters, such as a technologist's initials, a specimen source, or a work shift.

# **Processing Test Cards in Cassette Only Mode**

**NOTE:** If your system has a Smart Carrier Station, refer to the section *Processing Test Cards Using the Smart Carrier Station* on page 6-25.

## **Configuration Options to Consider**

On the VITEK 2 instrument, set the

- Cassette Mode option to Cassette Only.
- **Dilution Mode** option to Automatic or Pre-Diluted, as appropriate.

**NOTE:** The procedure for these options appears on page 5-24.

### The Work Flow

The following table provides a generalized work flow for working without a Smart Carrier Station (SCS). This work flow assumes that you have

- selected the VITEK 2 test cards to process.
- decided whether to prepare susceptibility suspensions manually or automatically using VITEK 2.

**NOTE:** If you choose to prepare suspensions manually, suspension preparation instructions can be found in the appropriate *Online Product Information* in the online help system at the workstation.

Activity	For more information see
A. Make sure that all configuration options are set correctly.	Configuration Options to Consider on page 6-36.
B. Print a cassette worksheet at the workstation.	VITEK 2 Online Help System. See the topic <i>Entering Cassette Information</i> .
C. Fill in the cassette worksheet with the test card and specimen information for the cassette.	How to Use the Cassette Worksheet on page 6-39.
D. Place the test cards and specimen test tubes in their appropriate slots.	Correct Positioning of Susceptibility Test Cards on page 6-41.
E. Access the Cassette Setup function on the VITEK 2 instrument. Select or enter a cassette name, and, if necessary, change the dilution mode.	How to Use the Cassette Setup Function on page 6-42.
F. Load the cassette onto the VITEK 2 instrument.	Loading a Cassette on page 6-44.
G. Enter the information from the cassette worksheet into the Cassette Edit window.	Monitoring Test Card Processing on page 6-47.
<b>NOTE:</b> During the first minute of processing, a cassette icon appears on the VITEK 2 Status screen. Wait until the boat moves forward to process cards before accessing the Cassette Edit window.	

# **Cassette Preparation**

Follow these procedures to set up the test cards and specimens for a cassette.

### How to Generate a Cassette Worksheet

You generate Cassette worksheets at the VITEK 2 workstation. For information, please refer to this topic on the VITEK 2 Online Help System.

### How to Use the Cassette Worksheet

The Cassette Worksheet, shown in Figure 6-8, is designed to help you organize a set of test cards and specimens for a cassette.

Date: 2/12/99		bioMérieux		Page: 1
WSVT2-R2.02	Cassette Report			
	• Cassette ID:			_
	2 Tes	sts:		
_	<b>6</b> Instrume	ent:		
<b>4</b> Test Type				
<u>Test Type</u>		_		Ancillary Tests
1 6				
2				
3				
4				
5				
6				
7				
0				
10				
11				
12				
13				

Figure 6-8: The Cassette Worksheet

Cassette ID Fill in the cassette name here.
 Tests Fill in the number of test cards being placed in the cassette.
 Instrument Name Fill in the name of the VITEK 2 instrument into which you placed the cassette.

Use these fields to fill in the applicable information about the test cards and specimens.
 Slot Numbers
 The worksheet is preprinted with the fifteen slot numbers.

### CORRECT POSITIONING OF SUSCEPTIBILITY TEST CARDS

If you pre-dilute the inocula for the susceptibility tests, you can place the test cards into any slots in the cassette, in any order you choose. However, when VITEK 2 is performing the dilution (Automatic dilution mode), you must follow these rules:

- The AST card must be placed in a slot immediately following the slot containing the inoculum test tube.
- A gram negative inoculum can be used for either one or two susceptibility tests. When diluting the inocula for two tests, the test cards must occupy the two slots **immediately fol**lowing the slot containing the inoculum test tube.

These rules apply whether or not an ID card is used.

### How to Use the Cassette Setup Function

Use the cassette setup function to define the cassette name to the instrument, and, if necessary, to change the Dilution Mode setting for a cassette.

 Access the *Cassette Setup* function on the Main Menu.

**NOTE:** If the VITEK 2 instrument is in Smart Carrier mode, the Cassette Setup function cannot be accessed. If you attempt to use the option, the screen displays the message

This option is used with Cassette Only mode

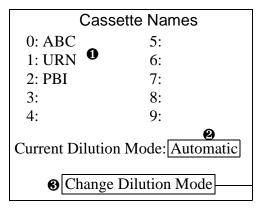


Figure 6-9: Cassette Setup Screen

The screen has places for up to ten cassette names. You do not enter these names on this screen. That is done in the Cassette Names function on the Configuration menu.

 Select one of the *cassette names* (1) from the list shown by pressing its corresponding number on the keypad.

The selected name is highlighted.

**NOTE:** If you need to add a new cassette name, refer to the section *Cassette Names* on page 5-5.

3. If necessary, press the **Change Dilution Mode** option button (③) to change the current dilution mode (②).

### **DANGER:**



Biohazardous spills can occur inside the VITEK 2 instrument if the Dilution Mode option is not properly set, especially if pre-diluted samples are used with the mode set to Automatic. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

4. Press the **ENTER** key to accept the information as shown on the screen.

# **Loading a Cassette**

### **DANGER:**



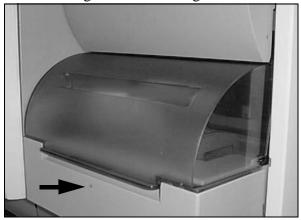
The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

**Before** you load a cassette you should always check the Status screen. Look at the following parameters to make sure it is okay to load the cassette:

Parameter	What to Look For	
Status	This field should read "OK."	
MAX Available Slots	The value in this field should be greater than or equal to the number of test cards you are loading.	
Available ID Slots (VITEK 2 XL only)	The value in this field should be greater than or equal to the number of identification test cards you are loading.	
Tips and Saline	The level of both disposables should be greater than or equal to the number of test cards you are loading.	
	<b>NOTE:</b> This parameter may be ignored if you are operating in the manual dilution mode.	
Cassette Name	The name of the previously used cassette is shown, and will be applied to this cassette unless you change it.	
Dilution Mode	Make sure that the mode displayed matches the way in which you are processing the test cards.	

### USING THE CASSETTE LOAD STATION

The Cassette Load station shown below is composed of the cassette load door and a green indicator light.



The indicator light, shown in the figure above, tells you the status of the load station, as follows:

If the Indicator Light is	It Means that
On	The cassette load door is unlocked. You may open the door to load cassettes.
Off	The cassette load door is locked and cannot be opened.
Blinking	A boat with an empty cassette has arrived at the station. You should open the cassette load door and remove the cassette. When the door is closed again, the blinking stops.

Before you attempt to load a cassette, make sure the indicator light is **On** or **Blinking.** 

### How to Load a Cassette

Open the Cassette
Load station by lifting the cassette load
door up. There
should be an empty
boat at the station, or
one with a cassette
that contains waste.



### **DANGER:**



Do not attempt to load a cassette if a boat is not at the station. Damage to the cassette and the VITEK 2 instrument is possible.

2. Place the *cassette* in the boat so that the specimen test tubes are towards the front of the instrument.



**NOTE:** The boat is shaped such that it will only accept a cassette in the proper orientation.

3. Close the cassette load door.

The cassette icon appears on the Status screen.

4. Monitor the instrument until the cassette icon disappears and the boat moves forward to process cards.

# MONITORING TEST CARD PROCESSING

After a cassette is loaded, the test cards in it are scanned by the bar code reader in VITEK 2. This information is sent to the workstation so that you can see a listing of the test cards in the Directory window. Additional information is provided once the test cards reach the Card Incubator and Reader station and are read for the first time.

### How to Enter Data for a Cassette

During the first minute after you load a cassette, the bar code on each test card is read. 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. This information, along with the cassette name you selected in the Cassette Setup function, is sent to the workstation.

The information can be viewed in the Cassette Edit window, which is part of the VITEK 2 workstation software. You can access that window and, using the Cassette Worksheet, fill in the remaining information for the cassette once the test cards have been loaded into the carousel.

For information on using the Cassette Edit window, please refer to this topic on the Online Help System.

### ABOUT THE CASSETTE ADDRESS

The cassette address, which appears in the VITEK 2 Directory window at the workstation, provides a means to identify each test card in the VITEK 2 instrument. The following figure illustrates two examples:

RMT-03 Apr 03 08:35:40 URN-11 Mar 29 13:45:01

Figure 6-10: The Cassette Address

A cassette address has three basic parts. Using the first example from Figure 6-10, the following table shows what each of these parts mean, and how they are derived.

The Cassette Address Section	For example	Is taken from
The cassette name.	RMT	The three-character cassette name that is entered in the Cassette Names function.
The slot position (1 - 15) of the test card in the cassette.	03	The actual test card position in the cassette as read by the VITEK 2 bar code reader.
Date/time stamp.	Apr 03 08:35:40	The date and time the test card was read by the VITEK 2 bar code reader.

The cassette name portion of the address can represent various laboratory parameters, such as a technologist's initials, a specimen source, or a work shift.

# **Batch Loads (Smart Carrier or Cassette Only Mode)**

# **How to Select Batch Loading**

Batches of three or four cassettes can be loaded in rapid succession using the Batch Load function.

### BEFORE YOU BEGIN

Because a batch load requires most or all of VITEK 2's resources, you should do the following before initiating a batch load:

- 1. Batch loading requires at least three cassettes, so check your work load to make sure that you are processing enough test cards.
- 2. Check the Status screen to make sure that
  - the number of available slots equals or exceeds the number of test cards that you are loading
  - the quantities of tips and saline is sufficient for the number of test cards that you are loading

# To Begin a Batch Load

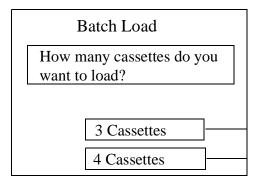
This process begins with the preparation of the cassettes. Refer to one of the following two procedures:

- The procedure for cassette preparation in Smart Carrier mode begins on page 6-25.
- The procedure for cassette preparation in **Cassette Only** mode begin on page 6-39.

**NOTE:** You must prepare all three or four of the cassettes to be included in the batch load before proceeding.

- 1. Bring the **cassettes** to the VITEK 2 instrument.
- Access the Batch Load function on the Main Menu.

The VITEK 2 instrument checks to ensure that at least three boats are available, and that there are no test cards currently in the card transport system. It then displays the following screen:



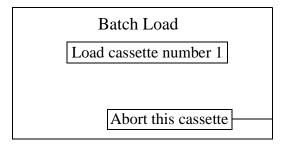
**NOTE:** This screen does not appear if there are only three boats in the instrument. In that case, a batch load of three cassettes is assumed.

**NOTE:** If less than three boats are available, or if the card transport system is unavailable, the following message appears:

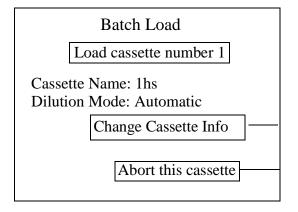
The card transport system is not available for batch load. Load a single boat or try again later.

3. Press the *option button* that corresponds to the number of cassettes that you want to load.

The following screen displays for Smart Carrier Mode:



**NOTE:** The following screen displays for Cassette Only Mode:



Open the *door* to the load station, place the *cassette* in the boat, and close the *door*.

The instrument moves the boat away from the load station, moves the next boat into the station, and redisplays the screen shown in the previous step.

5. Repeat Step 4 as required for the other cassettes.

# **Unloading the Cassette and Removing Waste**

This section describes two procedures that you need to perform on a regular basis. One is to remove empty cassettes from the instrument, which should be done whenever the light at the Cassette Load station is blinking. The other is to remove ejected test cards, which should be done routinely whenever a new cassette is loaded. Performing these activities ensures that VITEK 2 can continue to support your laboratory's work load.

### How to Unload a Cassette

During test card processing, test cards are unloaded from the cassette and placed into the carousel at the Card Reader and Incubator station. This means that when the boat and cassette return to the unload station, only the specimen test tubes and the severed transfer tubes remain in the cassette. The cassette must be removed so that the boat is available to accept another cassette.

 When you are processing test cards, look for the green indicator light at the unload station to be blinking.

This indicates that an empty cassette is at the station.

For more information about the indicator light, see the section *Using the Cassette Load Station* on page 6-32 or on page 6-45.

2. Open the *cassette unload door* and remove the *cassette* from the boat.

**NOTE:** The boat itself should **not** be removed.

Close the cassette unload door.

### **CAUTION:**



Leaving the door to the Cassette Unload station open will interfere with the proper processing of the test cards in the VITEK 2 instrument.

 Dispose of the materials in the cassette. The cassette can now be used to process additional test cards.

### **DANGER:**



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.

## **How to Remove Ejected Test Cards**

When a test card is ejected, it is removed from the carousel in the Card Reader and Incubator station, and placed in the Waste Collection station (see Figure 6-11). This station has a capacity of 60 test cards, equivalent to the capacity of the carousel. However, we do recommend that you check and empty the waste station every time you load a new cassette

**NOTE**: Once cards have been removed from the Waste Collection station, never reinsert them. This will cause the instrument to jam.

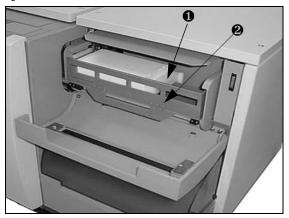


Figure 6-11: The Waste Collection Station

### REMOVING THE WASTE COLLECTION TRAY

- Open the waste collection station door. Note that waste test cards are held in a removable tray.
- Place the index finger of one hand on the sliding retainer bar (●) to prevent it from snapping back.

- 3. Remove the **waste collection tray** (②) from the station by lifting the front edge of the tray slightly and then pulling it toward you.
- 4. When the tray is clear of the station, allow the **slid-ing retainer bar** to slowly slide back into place.
- 5. Dispose of the *test cards* in the tray.

**NOTE:** Once cards have been removed from the Waste Collection station, never reinsert them. This will cause the instrument to jam.

### **DANGER:**

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



### REPLACING THE WASTE COLLECTION TRAY

- 6. Slide the *tray* onto its shelf, lifting the front edge to clear the retaining brackets.
- 7. Close the waste collection door.

**NOTE:** If the waste collection tray is not replaced, the instrument cannot eject cards and eventually stops processing.

# 7. Maintaining the VITEK 2 Instrument

# Introduction

This chapter includes the procedures required to maintain the VITEK 2 instrument. Maintenance includes monitoring and changing the disposables, cleaning the boats and the carousel, and general maintenance and cleaning.

**NOTE:** The Maintenance Log provided at the end of this chapter lists recommended maintenance procedures and their frequency. Please make one copy for your use and keep the original with this manual.

### Where to Find It

- Maintaining the VITEK 2 Disposables 7-3
  - Monitoring the Disposables 7-3
  - The Dispenser/Pipettor Accessory Kit 7-5
  - How to Install an Accessory Kit, Part A: Saline and Tubing 7-6
  - How to Install an Accessory Kit, Part B: Pipette Tips 7-14
- Cleaning the Carousel 7-21
- How to Remove the Carousel for Cleaning 7-21
- How to Clean the Carousel 7-28
- How to Replace the Carousel After Cleaning 7-29

- Cleaning the Cassettes 7-34
  - How to Clean the Cassettes 7-34
- Cleaning the Boats 7-39
  - How to Remove Boats for Cleaning 7-39
  - How to Clean the Boats 7-42
  - How to Replace Boats after Cleaning 7-42
- Cleaning the Inside of the VITEK 2 Instrument 7-46
  - Shutting Down the VITEK 2 Instrument 7-46
  - Cleaning the Test Card Collection Tray 7-49
  - Cleaning the Optics (Normal Maintenance) 7-50
  - Cleaning the Base Pan, Vacuum Seal and Vacuum Chamber 7-53
- Cleaning the Drip Pan 7-56
  - Removing the Drip Pan 7-57
  - How to Clean the Drip Pan 7-58
  - Replacing the Drip Pan 7-58
  - Turning the Instrument On 7-59
- Cleaning the Smart Carrier Station 7-60
  - How to Clean the Smart Carrier Station (SCS) 7-60
- VITEK 2 Maintenance Log
- VITEK 2 XL Maintenance Log

# **Maintaining the VITEK 2 Disposables**

Chapter 6, Processing VITEK 2 Test Cards, introduced the Status screen and how to incorporate it into your work flow. A specific part of that screen is devoted to the maintenance of the VITEK 2 disposables

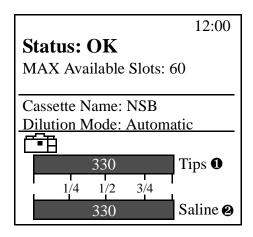


Figure 7-1: The VITEK 2 Status Screen

# **Monitoring the Disposables**

Note the two bar graphs at the bottom of the screen. Graph (①) displays the current level of pipette tips that remain in the instrument. Graph (②) displays the level of saline that remains in the instrument.

### INTERPRETING THE GRAPHS

As the two disposables are used, the shaded portion of the graphs moves to the left. At the same time, the value inside the graph decreases correspondingly. The graphs are marked to show full (330), three-quarter (248), one-half (165), and one-quarter (83) capacity. If the level of either disposable drops below 40, the value changes to "LOW."

What do these numbers mean and how should you use them? The graphs and their values refer specifically to the **number of antimicrobial susceptibility tests** (**AST**) that can be processed. This means that the graphs and values are important only when you are processing ASTs in the **Automatic Dilution** mode, that is, when the VITEK 2 instrument is performing the dilution of the AST inoculums. For example, when one of the graphs is at one-half capacity, it means that enough of that disposable remains to process approximately 160 ASTs.

### USING THE GRAPHS

The best way to use the graphs is to periodically compare the levels of the graphs to the number of ASTs you anticipate during a period. If the disposables level is lower than the anticipated work load, install an accessory kit before you begin (see following sections). In this way, your work flow will not be interrupted during test card processing. When comparing the disposables level to your work load, it is important to remember that the graphs are **APPROXIMATIONS** of the actual level of disposables.

#### EXPIRATION OF DISPOSABLES

VITEK 2 is programmed to measure the amount of time that the disposables have been in the instrument. When the specified time limit is exceeded, VITEK 2 displays an error message telling you that a disposable has expired.

## The Dispenser/Pipettor Accessory Kit

If the disposables have reached a low level, or if they have expired, you need to install a Dispenser/Pipettor Accessory Kit. The kit consists of a container of pipette tips and a saline dispenser tube with its associated tubing. The following two sections in this chapter describe how to install an accessory kit.

# How to Install an Accessory Kit, Part A: Saline and Tubing

**NOTE:** If the card transport system is processing cassettes through the card transport station, the following message appears:

Card transport system is busy. Please try later.

**CAUTION:** 

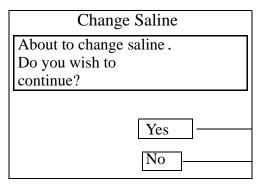
Use aseptic technique when installing an accessory kit.



1. Access the *Change Saline* function using the path:

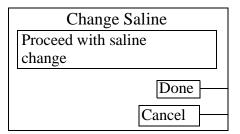
 $\mbox{Main Menu} \Rightarrow \mbox{Utilities} \Rightarrow \mbox{Maintenance} \Rightarrow \mbox{Change} \\ \mbox{Saline}$ 

The following prompt appears:

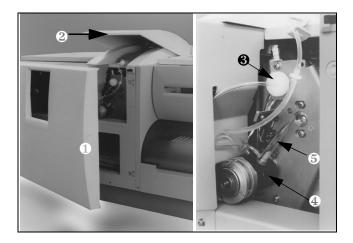


2. Press the **Yes** option button to continue with the saline change.

After you proceed the instrument displays the next prompt, to which you should respond **after** the saline change is completed:



3. Open the *front access door* (**1**) (see left figure below) to expose the dispenser station, then lift the *saline access door* (**2**) to expose the saline bag.



- 4. Pull on the *filter disk* (❸) (see right figure above) to remove it from its connector.
- 5. While pushing the *Dispenser Release button* (♠), carefully pull the *saline tube* (♠) out of its housing.

6. The entire assembly is now disconnected. Since they are **Single Use Only** items, you must discard the **saline tube**, its **tubing**, and the **saline bag**.

**NOTE:** Since the saline dispenser tube does not come in contact with any specimen, it is not considered a biohazard. Use normal laboratory precautions when disposing of this assembly.

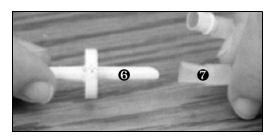
## **CAUTION:**



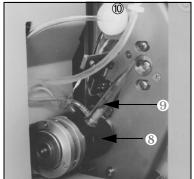
To prevent possible contamination of the saline, use aseptic technique when handling the saline dispenser tube.

- 7. Remove a new bag of 0.45% **sterile saline** from its protective pouch.
- 8. Remove a new *tubing assembly* from its container.

- 9. Remove the covers from the large port of the saline bag and from the bag spike of the tubing assembly.
- 10. Insert the **bag spike** (**⑤**) from the tubing assembly into the port (**⑥**) of the saline bag.



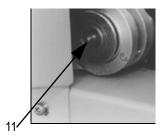
- 11. Place the new bag of saline on its shelf on the top of the instrument.
- While pushing the release button (3) (see figure at right), insert the saline dispenser tube (3) into its housing. After the tube is fully inserted, release the button.



NOTE: Make sure that the saline dispenser tube is firmly seated in the housing and that the tubing flows smoothly without any kinks or twisting.

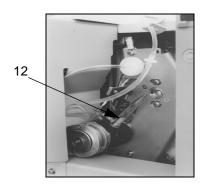
13. Grasp the *filter disk* (①) and firmly push it onto the connector located above the saline dispenser tube. Avoid excessive pressure, however, as it could cause the filter to break.

14. Press the round plate (11) to allow saline to flow into the saline dispenser tube. Do not allow the saline level to fill above the top inlet port. (12)

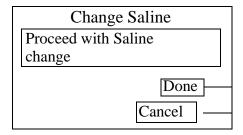


- 15. Release the plate.
- 16. Close both the *front*access door and the

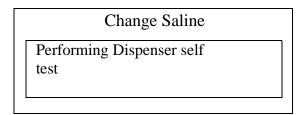
  saline access door to
  the instrument.



#### 17. Press the **Done** option button.



The following message appears:



The self test checks for proper installation of the saline dispenser tube. It is recommended that you wait for the test to complete (about 20 seconds) before leaving the instrument.

If the test is successful, the Maintenance Menu displays.

If the test fails, the message 'Saline Dispenser Tube installation error' displays. There is a problem with the saline dispenser tube installation. Inspect the tube installation and correct it as needed.

Press *Continue* to return to the Change Saline screen. At the Change Saline screen, press *Cancel* to return to the Maintenance Menu or *Done* to repeat the test.

18. Perform the Dispenser/Pipettor diagnostic test, described on page 8-36, to ensure that the dispenser station is functioning properly.

# How to Install an Accessory Kit, Part B: Pipette Tips

**NOTE:** If the card transport system is processing cassettes through the card transport station, the following message appears:

Card transport system is busy. Please try later.

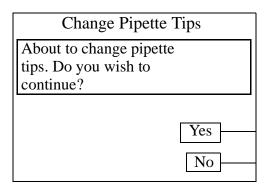
#### **CAUTION:**

Use aseptic technique when installing an accessory kit.



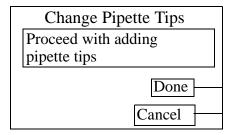
1. Access the *Change Pipette Tips* function using the path:

 $\mbox{Main Menu} \Rightarrow \mbox{Utilities} \Rightarrow \mbox{Maintenance} \Rightarrow \mbox{Change} \\ \mbox{Pipette Tips} \\$ 



2. Press the **Yes** option button to continue with the pipette tip change.

The following message appears:



3. Open the *front access door* (**1**) of VITEK 2 to expose the Pipettor station.



4. Open the Pipette Tip access door.

5. Rotate the *pipette tip container* (2) 90° in a counterclockwise direction.



- 6. Remove the *pipette container* from its base using a pulling motion.
- 7. Discard any *pipette tips* that remain in the container.

# **CAUTION:**



To avoid contaminating new pipette tips, do not touch the inside of the pipette container.

**NOTE:** Discarding the remaining tips is required in order for VITEK 2 to maintain an accurate count of them. This action also minimizes the risk of contamination.

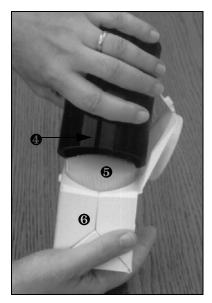
8. Open a *pipette tip replacement pack* and hold it in one hand (see figure on following page).

#### **CAUTION:**



The exposed ends (**⑤**) of the pipette tips are the ones that come in contact with your specimens. Appropriate precautions to prevent contamination during this procedure are advised.

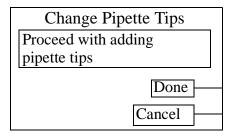
- Hold the empty pipette container (1) in your other hand with its open end down and lower it over the exposed ends of the pipette tips.
- 10. Invert the *container* and *pack* (**6**) so that the pipette tips fall into the container from the pack.
- Replace the *pipette tip* container on its base, making sure that it is firmly seated.



There is a key pin on the side of the container that must mate with a slot on the container base.

**NOTE:** If the container is not seated correctly, you will not be able to rotate it back into position.

- 12. Rotate the *container* 90° in a clockwise direction, making sure that it is fully seated in the down position.
- 13. Close both access doors.
- 14. Press the *Done* option button.



The following message appears:

Change Pipette Tips
Performing Pipettor Self
test

The pipettor self test only checks the electric motors in the pipettor station. If the motors pass the test, no further message is displayed, and you are done with the installation. If a problem is found, the message "Pipette Tip installation error" appears, and you will need to call bioMérieux for assistance.

15. Perform the Dispenser/Pipettor diagnostic test, described on page 8-36, to ensure that the pipettor station is functioning properly.

# **Cleaning the Carousel**

The four sections of a carousel should be removed and cleaned monthly, or as conditions require.

# How to Remove the Carousel for Cleaning

#### **DANGER:**



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.

**NOTE:** This procedure must be performed when the VITEK 2 instrument is completely idle (no cards are processing anywhere in the instrument).

Access the *Carousel Cleaning* function using the path:

Main Menu  $\Rightarrow$  Utilities  $\Rightarrow$  Maintenance  $\Rightarrow$  Cleaning  $\Rightarrow$  Carousel Cleaning

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

If you have a VITEK 2 XL, the screen below displays allowing you to select a Reader.

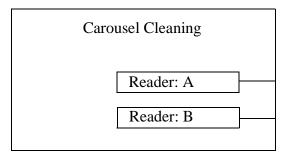
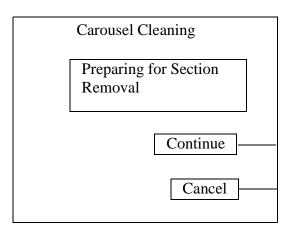


Figure 7-2: VITEK 2 XL Carousel Cleaning Screen

If cards are not processing in the selected incubator, and the carousel sections have not been removed, the following screen displays:

**NOTE:** When the *Continue* button is pressed, you are required to remove all of the sections. This will require about four minutes. The *Cancel* button provided here is the only opportunity to cancel this operation.



#### 2. Press Continue.

The following screen displays:

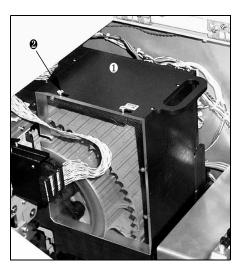
Carousel Cleaning

Remove the incubator access cover now

- 3. Open the *Waste Collection door* for the carousel being cleaned.
- 4. Open the *top access door* for the carousel being cleaned.

**NOTE:** The remaining steps may be easier if you also remove the *Waste Collection tray*.

5. Remove the *incubator access*cover (1) from the carousel by holding the retaining pin (2) on the top of the cover to the right while pulling the cover slightly forward and to the right, out of the instrument.

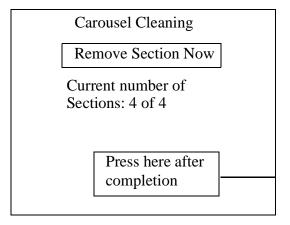


When you remove

the cover, the message on the screen changes to this next message while it moves the carousel into position:

Carousel Cleaning

Preparing for Section Removal When the carousel is in position, the following screen displays:



 The carousel is removed in four sections. Grasp the first carousel section and *pull it slightly forward* (toward the front of the instrument). You should then be able to *pull the section up and to the right*, as shown in Figure 7-3.

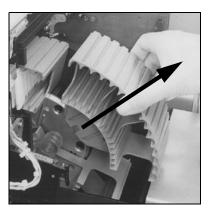
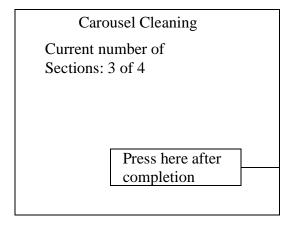


Figure 7-3: Removing a Carousel Section

7. Press the **Press here after completion** option button to indicate removal of the carousel section.

The following screen displays:



The carousel turns 90° so that the next section can be removed. During this time the message "Preparing for Section Removal" displays again on the screen.

8. Repeat this procedure, starting at step 6, until all four carousel sections have been removed.

9. Press the **Press here after completion** option button.

The following screen displays:

**Carousel Cleaning** 

Replace the incubator access cover now

10. Hold the retaining pin on the top of the cover to the right and carefully replace the incubator access cover over the carousel. Release the retaining pin when the cover is in place.

Once you have replaced the incubator access cover, the Cleaning menu appears.

For instructions on replacing the carousel, see *How to Replace the Carousel After Cleaning* on page 7-29.

## How to Clean the Carousel

The four sections of the carousel should be thoroughly cleaned and dried before they are replaced in the VITEK 2 instrument. The carousel material is designed to withstand any of the following cleaning methods:

• Automatic dishwasher with standard laboratory detergent

#### **CAUTION:**



Dishwasher temperatures during the washing and drying cycles must not exceed  $85^{\circ}$  C ( $185^{\circ}$  F). Exceeding this temperature will cause damage to the carousel sections. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

**NOTE:** To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

# **How to Replace the Carousel After Cleaning**

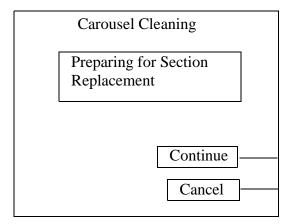
After the four carousel sections have been removed, the Cleaning menu displays.

1. Access the *Carousel Cleaning* function using the path:

Cleaning ⇒ Carousel Cleaning

The screen below displays.

**NOTE:** If the power has cycled, the screen below displays automatically.



# 2. Press **Continue** to continue with the carousel replacement.

The following screen displays:

Carousel Cleaning

Remove the incubator access cover now

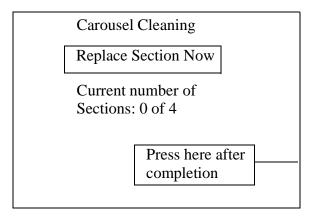
#### 3. Remove the incubator access cover.

When the access cover has been removed, the following screen displays:

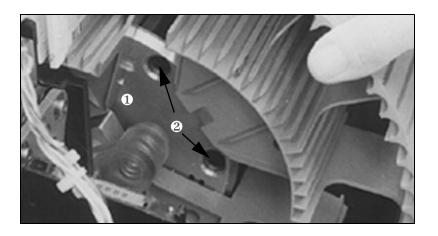
**Carousel Cleaning** 

Preparing for section replacement

When the carousel is in position, the following screen displays:



4. Take any one of the *carousel sections* and orient it as shown in the following figure. The bottom of the section should be touching the base plate (●), and the top portion should be tilted slightly toward the front of the instrument.



7

- 5. Slide the section down along the base plate while maintaining the tilted angle.
- When the section has been pushed down all the way, release the top portion, allowing it to rest against the base plate.

When you perform step 6, two pins on the back of the section should engage the two holes (2) in the base plate and secure the section.

7. Press the **Press here after completion** option button to indicate that the section is in place.

The carousel turns 90° to move the first section out of the way. During this time the message "Preparing for Section Replacement" displays on the screen.

8. Repeat this procedure, starting at step 4, until all four carousel sections have been replaced.

The screen displays the following message:

Carousel Cleaning

Replace the incubator access cover now

- 9. Hold the *retaining pin* on the top of the cover to the right and carefully replace the *incubator access cover* over the carousel. Release the retaining pin when the cover is in place.
- 10. Lower the *top access door* for the carousel being cleaned.

**NOTE:** Replace the *Waste Collection Tray* if it was removed earlier.

11. Close the Waste Collection door.

# **Cleaning the Cassettes**

Cassettes should be cleaned monthly, or as conditions require.

#### **How to Clean the Cassettes**

#### **DANGER:**



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.

If they are so equipped, you must first remove the button memory module from the cassette. If not, proceed to Step 5.

### **DANGER:**



Exposing the button memory to the recommended cassette cleaning procedures can cause irreparable damage to the unit.

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

Automatic dishwasher with standard laboratory detergent

## **CAUTION:**



Dishwasher temperatures during the washing and drying cycles must not exceed  $85^{\circ}$  C ( $185^{\circ}$  F). Exceeding this temperature will cause damage to the cassettes. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

**NOTE:** To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

- 1. Turn an *empty cassette* over so that its underside is facing you, as shown in the figure below.
- 2. Apply a slight inward pressure to the *plastic tab* (**①**) that extends from the memory module (**②**).
- 3. At the same time, pull the **button memory module** away from the cassette.

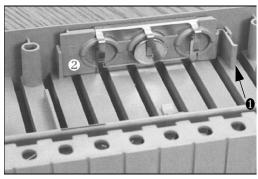
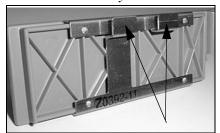


Figure 7-4: Removing the Button Memory Module

 Clean the metal contacts (see figure at right) on the module with an alcohol wipe.



**NOTE:** When cleaning multiple cassettes, it is **not** necessary to match a button memory module to a particular cassette. The units are completely interchangeable.

5. The cassettes should be thoroughly cleaned and dried before they are used again.

#### REPLACING THE BUTTON MEMORY MODULE

- 6. Turn the *cassette* over and hold it in your right hand.
- 7. Hold the memory module by the extended tab (1) in your right hand so that the two metal contacts (2) will line up with the two holes in the side of the cassette (3).

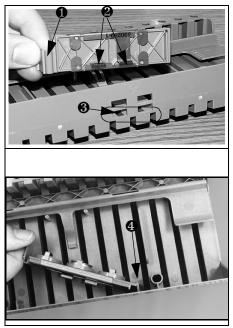


Figure 7-5: Replacing the Button Memory Module

8. Place the other end of the module against the holding bracket (4) and push the module towards the side of the cassette.

The module should snap into place.

# **Cleaning the Boats**

**NOTE:** The procedures in this section should be performed monthly, or as conditions require.

**NOTE:** Do not replace the boats if you are going to clean the inside of the instrument using the procedures that begin on page 7-46.

## **How to Remove Boats for Cleaning**

#### **DANGER:**



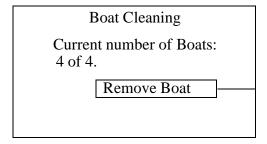
The boats should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

**NOTE:** This procedure should be performed while the instrument is idle. If you are performing this procedure to remove only a particular boat, the system can continue to process with as few as one boat.

1. Access the **Boat Cleaning** function using the path:

Main Menu ⇒ Utilities ⇒ Maintenance ⇒ Cleaning ⇒ Boat Cleaning

The following screen appears:



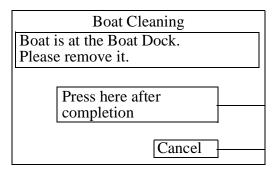
2. Press the **Remove Boat** option button. If there are boats in the card transport system, and it is not idle, the instrument displays the message

Card transport system is busy. Please try later.

If the system is idle, the instrument moves a boat to the boat dock while displaying this message:

Boat Cleaning
Moving Boat to Boat Dock

When the boat is ready for removal, the following screen appears:



 Open the front access door (see figure at right).

A boat will be positioned below the Dispenser/Pipettor station.



**NOTE:** A boat may be positioned at the Cassette Load Station, but it must **NOT** be removed from that position.

4. Remove the boat from below the Dispenser/Pipettor station and press the *Press here after completion* option button (see step 2 on page 7-40).

The first screen reappears with the boat count at "3 of 4."

- 5. Repeat this procedure, starting at step 2, until all 4 boats have been removed.
- 6. Press the Previous Screen key



#### How to Clean the Boats

The four boats should be thoroughly cleaned and dried before they are replaced in the VITEK 2 instrument. The boat material is designed to withstand any of the following cleaning methods.

Automatic dishwasher with standard laboratory detergent

#### **CAUTION:**



Dishwasher temperatures during the washing and drying cycles must not exceed  $85^{\circ}$  C ( $185^{\circ}$  F). Exceeding this temperature will cause damage to the boats. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

**NOTE:** To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

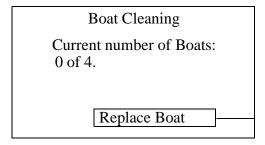
## **How to Replace Boats after Cleaning**

**NOTE:** If you are performing monthly maintenance on the entire instrument, do not replace the boats until after you clean the base pan. Refer to the procedure on page 7-53.

1. Access the **Boat Cleaning** function using the path:

 $\mbox{Main Menu} \Rightarrow \mbox{Utilities} \Rightarrow \mbox{Maintenance} \Rightarrow \mbox{Cleaning} \Rightarrow \mbox{Boat Cleaning}$ 

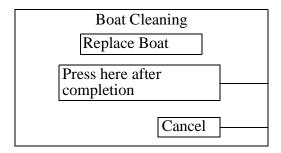
The following prompts appear:



 Press the *Replace Boat* option button. If there are boats in the card transport system, and it is not idle, the instrument displays the message

Card transport system is busy. Please try later.

3. If the system is idle, the instrument prepares for the boat replacement, and then displays this prompt:

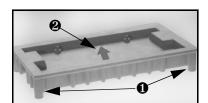


4. Open the *front access door* and replace the *boat* below the Pipettor station.

**NOTE:** Boats must **NOT** be replaced at the Cassette Load/ Unload Station.

**NOTE:** Make sure that

- the front legs (**①**) of the boat are positioned in the channel of the base pan.
- the boat is oriented with the arrow (2) pointing toward the back.



5. Press the **option button** shown below after replacing the boat.

Press here after completion

The first screen reappears with the boat count at "1 of 4."

- 6. Repeat this procedure, starting at step 2, until all four boats have been replaced.
- 7. Press the **Previous Screen key** when the display shows 'Current number of Boats: 4 of 4'.

### Cleaning the Inside of the VITEK 2 Instrument

### **DANGER:**



All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

**NOTE:** The procedures in this section should be performed monthly, or as conditions require.

### **Shutting Down the VITEK 2 Instrument**

### **DANGER:**



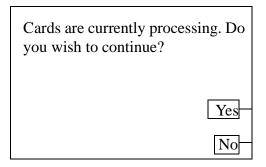
There are elevated temperatures and hot surfaces inside the instrument. Shut down the instrument before starting the cleaning or any other procedures inside the instrument.

**NOTE:** Finish processing all cards before beginning this procedure.

1. Access the **Shut Down** function using the path:

Main Menu ⇒ Utilities ⇒ Maintenance ⇒ Shut Down

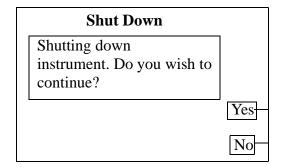
If any cards are processing the instrument displays this screen:



**CAUTION:** 

If you select Yes to continue, the cards being processed will be TERMINATED.

The instrument displays the following prompt:



Press the **Yes** option button to shut down the instrument.

The instrument briefly displays the message

Shutting Down Instrument

while it moves some internal components to their shutdown positions. When this process is complete, the instrument displays the message

Shut down has completed. Turn power off when ready

- 3. Press the *AC power switch* to shut the instrument off.
- 4. Remove the *AC power cord* to prevent any possible electrical hazard.

It is now safe to access the inside of the instrument.

### **Cleaning the Test Card Collection Tray**

- Open the Waste Collection door and remove the test card collection tray.
- 2. Thoroughly clean and dry the tray before replacing it in the VITEK 2 instrument.

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

Automatic dishwasher with standard laboratory detergent

### **CAUTION:**



Dishwasher temperatures during the washing and drying cycles must not exceed  $85^{\circ}$  C ( $185^{\circ}$  F). Exceeding this temperature will cause damage to the cassettes. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

**NOTE:** To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

3. Replace the *test card collection tray* in the Waste Collection station.

### **Cleaning the Optics (Normal Maintenance)**

**NOTE:** Perform procedure *Shutting Down the VITEK 2 Instrument* on page 7-46 before proceeding with this procedure.

### **DANGER:**



The instrument contains an ultraviolet light source. Make sure that the fluorescence optics unit is closed before resuming instrument operation.

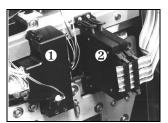
### **CAUTION:**



Do not wear powdered latex gloves while cleaning the fluorescence optics. The gloves that contain a powder can interfere with the optics.

- 1. Open the Waste Collection door.
- 2. Lift the top access door.

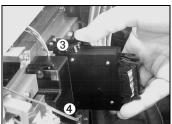
This exposes both the fluorescence (1) and the transmittance (2) optics, shown in the figure to the right.



Both optics consist of units that are hinged on the bottom and held in place by spring-loaded levers. The transmittance optics consists of two of these units while the fluorescence optics have only one.

**NOTE:** The remainder of this cleaning procedure is the same for both optics.

3. Using your right hand, grasp the *optics unit* and place your thumb on the lever (3) (see figure at right).



- 4. Push down on the *lever* to release the unit and allow it to rotate on its hinges (4).
- 5. Inspect the *glass* on both surfaces for cracks or scratches.

**NOTE:** Any apparent crack or scratch should be reported to bioMérieux.

6. Using a quality, lint free lens paper that has been slightly moistened with a commercial glass cleaner, 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. Make sure that you do not leave streaks on the glass.

- 7. Rotate the *unit* back into place while pushing down slightly on the lever until it is secured.
- 8. Replace the empty *test card collection tray* in the Waste Collection station.
- 9. Close the top access door.
- 10. Close the Waste Collection door.

**NOTES:** After cleaning the optics, perform the *Optical Diagnostic Test* on page 8-48.

If you are not performing the remaining cleaning procedures in this section, skip to the procedure *Turning* the *Instrument On* on page 7-59.

### Cleaning the Base Pan, Vacuum Seal and Vacuum Chamber

**NOTE:** Perform the instrument shutdown procedure on page 7-46 before proceeding with this procedure.

**NOTE:** If the boats have not already been removed, perform the procedure to remove them. (See page 7-39.)

### **DANGER:**



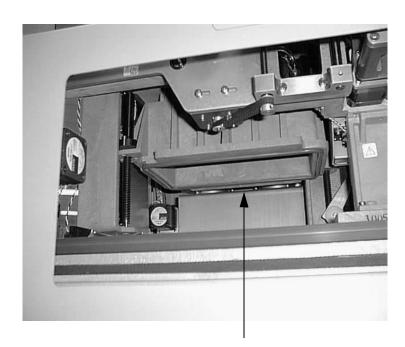
The base pan should not be cleaned unless the drip pan is properly installed. See 7-56 for instructions on cleaning the drip pan.

The base pan, vacuum seal, and vacuum chamber are designed to withstand any of the following cleaning methods.

- 10% bleach solution
- Phenolic cleaning solution

**NOTE:** Remove all boats (see procedure on page 7-39) and shut down the instrument (see procedure on page 7-46) before performing this procedure.

The base pan is the surface on which the boats move. The vacuum seal is the bottom surface of the vacuum chamber where the chamber makes contact with a boat (see arrow in figure below).



 Using a solution of disinfectant and warm water, wipe off any dust or dirt from the surface of the base pan.

Particular attention should be paid to the area beneath the Dispenser/Pipettor station, where drips or spills may have occurred.

**NOTE:** To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

- 2. Using plain water, wipe the same **surfaces** again to remove any disinfectant residue.
- 3. Repeat steps 1 and 2 to clean the *vacuum seal* and the *interior surface of the vacuum chamber*.

**NOTE:** The remaining cleaning procedures in this section do not require that the instrument be shut down. You can now turn the instrument back on using the procedure on page 7-59.

### **Cleaning the Drip Pan**

### **DANGER:**



All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

**NOTE:** This procedure should be performed monthly, or as conditions require.

VITEK 2 has a small container, called the drip pan, located underneath the Dispenser/Pipettor station. The pan is designed to catch any spills that occur at this station.

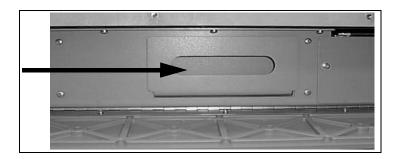
**NOTE:** This procedure should be performed **after** you clean the base pan. See "Cleaning the Base Pan, Vacuum Seal and Vacuum Chamber" on page 53.

### Removing the Drip Pan

Lower the **bottom access door** located in the bottom, front portion of the instrument.

The plate is held magnetically and should swing down on its hinges when you pull on it at both ends.

2. Grasp the handle of the drip pan (see figure below) and carefully pull it from the instrument.



### **DANGER:**

The contents of the drip pan may include biohazardous materials. Take appropriate precautions.

### How to Clean the Drip Pan

The drip pan should be thoroughly cleaned and dried before it is replaced in the VITEK 2 instrument. The pan material is designed to withstand any of the following cleaning methods:

Automatic dishwasher with standard laboratory detergent

### **CAUTION:**



Dishwasher temperatures during the washing and drying cycles must not exceed  $85^{\circ}$  C ( $185^{\circ}$  F). Exceeding this temperature will cause damage to the drip pan. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

**NOTE:** To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

### Replacing the Drip Pan

- 1. Holding the *pan* by its handle, push it into the space provided for it under the front of the instrument.
- 2. Close the **bottom access door** by pushing it up.

The door is held in place magnetically.

### **Turning the Instrument On**

1. Move the AC power switch to the **ON** position.

The system goes through the initialization process. When the Status Screen appears it will display a status of **Cleaning**, indicating that all four boats have been removed.

2. Perform the **boat replacement procedure** that begins on page 7-42.

After all four boats have been replaced, the Status Screen should display a status of **OK**.

**NOTE:** If the instrument was shut down for a long period of time, the status may be **Warming.** Wait until the status is **OK** before resuming test card processing.

### **Cleaning the Smart Carrier Station**

### **DANGER:**



All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Maintaining the VITEK 2 Instrument

**NOTE:** This procedure should be performed monthly, or as conditions require.

### **How to Clean the Smart Carrier Station (SCS)**

The SCS base unit, keypad, display, and bar code scanner (**except** the glass lens) are designed to withstand any of the following cleaning methods:

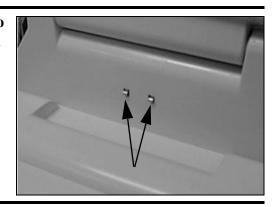
- 10% bleach solution
- Phenolic cleaning solution
- 1. Remove the *cassette* if one is on the SCS base unit.
- 2. Push the **AC power switch** on the SCS to the **off** position.

- 3. Remove the SCS **AC power cord** from its outlet.
- Clean all surfaces of the SCS base unit, keypad, display, and bar code scanner, except the glass lens of the scanner.

### **CAUTION:**



To prevent damage to the metal contacts on the SCS base unit, make sure that you wipe them GENTLY in an up and down motion, rather than side to side.



- Wipe the glass lens of the bar code scanner using a quality, lint free lens paper that has been moistened with a commercial glass cleaner. If foreign material remains on the surface, repeat this step using an alcohol wipe.
- 6. Allow all parts to dry thoroughly before reconnecting the power card and switching the power on.

The VITEK 2 and VITEK 2 XL Maintenance Logs on the following pages lists recommended maintenance procedures and their frequency. Make one copy for your use and keep the original in this manual.

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Month

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Change Pipette Tips A/R															
Clean Boats *															
Clean Carousel *															
Clean Cassettes *															
Clean Optics *															
Clean Waste Tray *															
Clean Base Pan *															
Clean Vacuum Seal *															
Clean Vacuum Chamber *															
Clean Drip Pan *															
Check Instrument QC Status Report for the															
Carousel Temperature **															
Optics Systems **															
Clean Smart Carrier *															
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\* = Monthly

\*\* = Daily

# **VITEK 2 Maintenance Log**

Year

Month

Day of Month:	Change Saline A/R	Change Pipette Tips A/R	Clean Boats *	<u>Clean</u> Carousel *	<u>Clean</u> Cassettes *	Clean Optics *	<u>Clean</u> Waste Tray	<u>Clean</u> Base Pan *	<u>Clean</u> Vacuum Seal *	<u>Clean</u> Vacuum Chamber *	<u>Clean</u> Drip Pan	<u>Check</u> Instrument QC Status Report for the	Carousel Temperature **	Optics Systems **	Clean Smart Carrier *
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Year

Month

Day of Month:	1	7	e	4	N	9	7	8	6	10	11	12	13	14	15
Change Saline A/R															
Change Pipette Tips A/R															
Clean Boats *															
Clean Carousel A & B *															
Clean Cassettes *															
Clean Optics A & B *															
Clean Waste Tray A & B *															
Clean Base Pan *															
Clean Vacuum Seal *															
<u>Clean</u> Vacuum Chamber *															
<u>Clean</u> Drip Pan *															
<u>Check</u> Instrument QC Status Report for the															
Carousel Temp. A & B **															
Optics Systems A & B **															
<u>Clean</u> Smart Carrier *															
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\* = Monthly

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# **VITEK 2 XL Maintenance Log**

Year

Month

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26 27															
24 25															
23 2															
21 22															
20															
18 19															
17															
Day of Month:	Change Saline A/R	Change Pipette Tips A/R	Clean Boats *	Clean Carousel A & B *	<u>Clean</u> Cassettes *	Clean Optics A & B *	Clean Waste Tray A & B *	<u>Clean</u> Base Pan *	Clean Vacuum Seal *	<u>Clean</u> Vacuum Chamber *	<u>Clean</u> Drip Pan	<u>Check</u> Instrument QC Status Report for the	Carousel Temp. A & B **	Optics Systems A & B **	*

\* = Monthly

\*\* = Daily

## 8. Troubleshooting the VITEK 2 Instrument

### Introduction

This chapter helps you to resolve any problems that may occur while operating the VITEK 2 instrument. The first section, The Error Handling System, explains how the instrument reacts to an error, and how you, the user, should respond. The second section, Cassette Load Errors, covers a specific set of errors that are the ones most likely to occur in normal operation. Other sections cover the Bar Code Reader, and instrument diagnostics and quality control status.

### **Error Messages and Recovery Procedures**

This section contains a listing of all the possible error messages that could occur on the VITEK 2 instrument. This is the first place you should go to if an error occurs and you need to find out what to do.

### Where to Find It

- The Error Handling System 8-3
  - The Error Alarms 8-5
  - Types of Errors 8-6
  - The Status Screen in an Error Condition 8-7
  - Reviewing an Instrument Halted Screen 8-12
  - Reviewing a Status Screen with Messages 8-13
  - Reviewing a Status Screen with Errors 8-14

- Cassette Load Processing Errors 8-15
  - Why Do They Occur? 8-16
  - Work Flow Considerations 8-17
  - Bar Code Read Failure 8-17
  - SCS and Bar Code Reader Conflict 8-21
  - Inoculum Errors 8-24
  - Card Capacity Errors 8-26
  - Disposables Errors 8-29
- Working Without the VITEK 2 Bar Code Reader 8-30
  - How to Enter Bar Codes Manually 8-31
- Instrument Diagnostics 8-33
  - Instrument Diagnostics Menu 8-33
  - Diagnostic Tests 8-34
- Cleaning and Verifying the Optics with Cards Processing 8-43
  - Optical Diagnostic Test 8-48
- Boat Transport Positions 8-50
- Power Failures 8-52
- Displaying Version Information 8-54
- How to Use the Error Message and Recovery Table 8-55
  - How to Restart the Instrument 8-56

### **The Error Handling System**

The VITEK 2 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 instrument is programmed to alert you to the situation, and to provide you with the information you need to resolve the problem. We refer to this process as the Error Handling System. Figure 8-1 illustrates these elements.

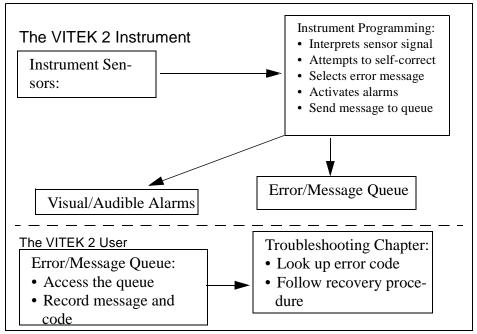


Figure 8-1: The VITEK 2 Error Handling System

The first element of the Error Handling System is the VITEK 2 instrument. First it must detect the error. In many cases, the instrument will attempt 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 user. First, you must

- respond to the alarm by accessing the error/message queue on the instrument interface.
- read and record all messages in the queue.
- look up the error code from the message in this chapter and follow the recovery procedure.

### The Error Alarms

VITEK 2 has two alarms to alert you to the presence of an error condition. The dual alarms are provided in case the VITEK 2 instrument and the workstation are in different locations. When they are in close proximity, the audible alarm on the instrument can be disabled as a configuration option.

Audible alarm.

This alarm sounds both at the VITEK 2 instrument, and at the workstation. Another instrument configuration option allows you to set the volume of the audible alarm.

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 disable the visual alarm.

### **CAUTION:**



Do not disable both the audible and the visual alarms. Doing so eliminates all indicators of an error condition, which could result in the termination of tests in progress.

### **Types of Errors**

There are three basic types of errors:

- those that cause the Reader or Card Transport system to halt
- those that do not cause the Reader or Card Transport system to halt
- errors that occur when you load a new cassette

**NOTE:** All errors/messages are logged in the Error Log whether or not they are resolved. The log is cleared when the instrument is turned off.

### The Status Screen in an Error Condition

Depending on the type of error, you will see one or more types of screens.

- **Instrument Halted Screen** Indicates an error has caused the Reader or Card Transport system to halt.
- Status screen with a status of Messages Indicates there are error messages that need to be reviewed. These are minor errors that do not cause the Reader or Card Transport to halt.

There are two ways you can handle a Status screen with a status of Messages.

- Review the message and resolve the condition as indicated in Table 8-2.
- Review the message and decide not to resolve the condition.

**NOTE:** If the first error recovery procedure directs you to contact bioMerieux, do so immediately.

• Status screen with a status of Error Indicates a message has been reviewed but not resolved, or the recovery procedure was not successful. This status can only be cleared by resolving the condition that caused the original error.

### INSTRUMENT HALTED SCREEN

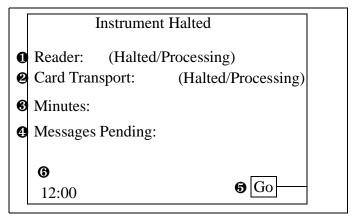


Figure 8-2: Instrument Halted Status Screen

- Reader. This field indicates whether the Reader station is still processing, or has been halted due to the error.
- **2 Card Transport.** This field indicates whether the card transport system is still processing, or has been halted due to the error.
- **18 Minutes.** This field indicates how many minutes the error condition has existed.
- **Messages Pending.** This field indicates how many messages are currently in the error/message queue.
  - **NOTE:** You can access the error/message queue by pressing the Error/Message key.
- **6 Go.** Press the **Go** option button to resume processing after you have corrected the problem.
- **6** 12:00. Time error occurred.

### STATUS SCREEN WITH A STATUS OF MESSAGES

This status indicates that there is an error message in the error/message queue that has not been viewed. Notice that the Status field (①) has changed to "Messages," indicating that there are error messages in the error/message queue.

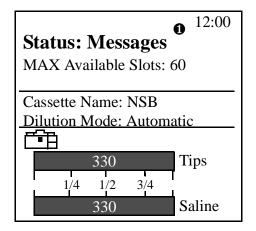
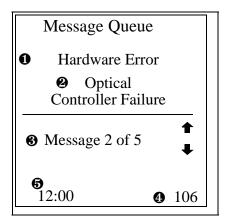


Figure 8-3: The VITEK 2 Status Screen

Press the Error/Message key (?) to view the error/message queue.

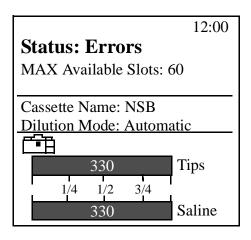
If there is more than one message or error, press the *Down Arrow* to review and address each message.



- **1 Hardware Error.** The first line in the error/message queue gives you the **Primary Error Code**. For examples of other Primary Error Codes, see Table 8-2.
- **Optical Controller Failure.** The second line of the error/message queue tells you the **Secondary Error Code**. For examples of other Secondary Error Codes, see Table 8-2.
- **Message 2 of 5.** The third line in the error/message queue is the **message counter.** The counter tells you how many messages are in the queue.
- **106.** The last line of the queue is the **error code.** This code contains information for a bioMérieux service representative, should you need to call for assistance.
- **6** 12:00. Time the error occurred.

### STATUS SCREEN WITH A STATUS OF ERRORS

This status appears <u>after</u> the error/message queue is accessed if the error condition has not been resolved or the recovery procedure was not successful. This status can be cleared only by resolving the condition that generated the original message.



Review the error/message queue for any error messages the VITEK 2 instrument has generated. Resolve the problem as indicated in Table 8-2.

### **Reviewing an Instrument Halted Screen**

Press the *Error/Message* key to view the error/message queue.

**NOTE:** If there is more than one message, use the *DOWN ARROW* to review and address each message.

- 2. Look up the **Primary Error Code** and then the **Secondary Error Code** in the section *How to Use Error Message and Recovery Table* on page 8-55 in this chapter. If an error recovery procedure is given, follow its directions, then continue with Step 3.
- 3. Press the **PREVIOUS SCREEN** key to exit the error/message queue and return to the Halted screen.
- 4. Press **GO** to resume processing.

**NOTE:** If the recovery procedure was successful, the Status screen appears with a Status of *OK*. If the Instrument Halted screen reappears, record the error code number and call bioMérieux.

### **Reviewing a Status Screen with Messages**

Press the *Error/Message* key to view the error/message queue.

**NOTE:** If there is more than one message, use the *DOWN ARROW* to review and address each message.

- Look up the Primary Error Code and then the Secondary Error Code in Table 8-2. If an error recovery procedure is given, follow its directions, then continue with Step 3.
- 3. Press the **PREVIOUS SCREEN** key to exit the error/message queue and return to the Status screen.

**NOTE:** If the recovery procedure was successful, the Status screen appears with a Status of *OK*. If a problem still exists, either the word 'Errors' will be displayed in the status field or the word 'Messages' if a new message has been generated.

**NOTE:** If a problem recurs, contact bioMérieux.

### **Reviewing a Status Screen with Errors**

When the status of 'Messages' has changed to 'Errors' this indicates one of two conditions:

The message was reviewed but not resolved

Follow Steps 1 through 3 in the procedure for *Reviewing a Status Screen with Messages*.

**NOTE:** If the recovery procedure was successful, the Status screen appears with a Status of *OK*. If the Instrument Halted screen reappears, record the error code number and call bioMérieux.

The recovery procedure was not successful, call bioMérieux

# **Cassette Load Processing Errors**

Cassette load processing errors are a special set of errors that occur immediately following the loading of a cassette. You should be familiar with this type of error because:

- They are often caused by problems that can be resolved quickly, thereby preventing any interruption in your work flow.
- They occur at predictable times.

### Why Do They Occur?

During the first minute of processing, a cassette passes through the Bar Code and Button Memory stations. During this time the button memory of a smart cassette and the bar codes on all test cards are read. From this information VITEK 2 can detect the following errors:

- The bar code reader was unable to read one or more bar codes on the test cards.
- An inconsistency was found between the information read from the button memory on the cassette and the bar codes on the test cards. For example, the button memory told VITEK 2 that a gram negative susceptibility card is in slot 4 of the cassette. The bar code reader, however, found that slot to be empty.
- The bar code reader detected a susceptibility card for which there is no inoculum (Automatic dilution mode only).
- The number of test cards in the cassette exceeds the number of available slots currently in the reader carousel.
- There is an insufficient quantity of pipette tips or saline to process the number of cards being loaded.

#### **Work Flow Considerations**

For any type of load error, the VITEK 2 instrument backs the cassette out to the Load station so that you can resolve the error. If the cassette loading door is not opened within 10 minutes, the instrument assumes that no corrective action will be taken. The errors are ignored and the cassette is restarted. Any test card in the cassette that has a load error will not be processed. The cards remain in the cassette when the cassette returns to be unloaded.

Whenever you load a cassette, the cassette icon appears on the Status screen. You should wait until the icon disappears before leaving the instrument.

#### **Bar Code Read Failure**

As a cassette passes through the Bar Code Reader station, the bar code on each test card is read. If the bar code reader is unable to read any of the bar codes:

- The cassette is backed out to the Cassette Load station.
- The error alarm is activated.

#### How to Resolve a Bar Code Read Error

 Press the Question Mark key to display the Error queue.

For a bar code error, you see the following message:

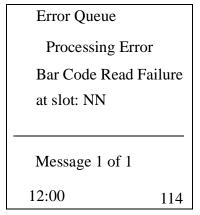


Figure 8-4: Bar Code Error Message

2. Open the door to the *Cassette Load station* and remove the cassette. The door should remain open while resolving the bar code error.

### **DANGER:**



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.

- 3. Remove the *card* from the slot indicated in the message.
- 4. Press the **PREVIOUS SCREEN key** twice to exit the error queue to the Main Menu.
- Access the *Resolve Bar Code Errors* option on the Main Menu.

The following screen appears:

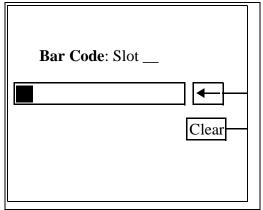


Figure 8-5: Screen for Resolving Bar Code Errors

6. Using the numeric keypad, enter the *bar code* from the bar code label. Press the *ENTER* key.

**NOTE:** The bar code you enter may be longer than the space provided on the screen. When this occurs, the first portion of the bar code scrolls off the display and the symbol ">" appears.

### VITEK 2 checks your entry for:

- A valid bar code number.
- A card type match based on the bar code entered compared with the information read from the button memory on the cassette (smart carrier only). See the following section for more information.

If there is another bad bar code, the screen in Step 5 reappears with the new slot number. Repeat Step 6. After the last bar code is entered, the display returns to the main menu.

Place the *cassette* back into the Cassette Load station and close the door.

This restarts the processing cycle for this cassette.

#### SCS and Bar Code Reader Conflict

This type of error only occurs when VITEK 2 is operating in Smart Carrier mode. That is because the error is based on a comparison of the information read from the bar codes with that read from the cassette memory. The card type is part of the information read on the bar code. Therefore, a card type error occurs if a test card type that is different from the one expected according to the cassette memory. If the instrument detects a card type error:

- The cassette is backed out to the Cassette Load station.
- The error alarm is activated.

HOW TO RESOLVE A SCS AND BAR CODE READER CONFLICT

 Press the *Error/Message* key to display the error/ message queue.

For a card type error you see the following screen:

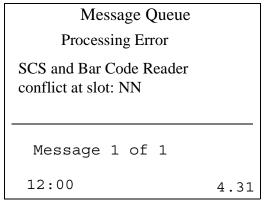


Figure 8-6: Card Type Error Message

2. Open the *Cassette Load station door* and remove the cassette and place it on the SCS.

### **DANGER:**



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.

- 3. Press the *F3* key to display the Summary screen.
- 4. Check the positions and the types of test cards against the data displayed on the screen.
- 5. Move the test cards and their dilution tubes, as necessary, to match the data on the screen.
- Place the *cassette* back into the Cassette Load station and close the door.

This restarts the processing cycle for the cassette.

#### **Inoculum Errors**

When VITEK 2 is operating in the Automatic dilution mode, every susceptibility test card must be provided with an inoculum source. The inoculum must be placed in the slot<sup>1</sup> that immediately precedes the susceptibility card. It can be placed next to an empty slot, or a slot containing a matching<sup>2</sup> identification card. During the bar code read, the instrument checks for one of these two conditions. If the instrument detects an inoculum error:

- The cassette is backed out to the Cassette Load station.
- The error alarm is activated.

<sup>1.</sup> For gram negative test cards, the inoculum can be followed by one or two susceptibility cards.

<sup>2.</sup> A matching identification card is one having the same accession ID and test type (gram +/gram -) as the susceptibility card.

#### How to Resolve an Inoculum Error

Press the *Error/Message* key to display the message queue.

For an inoculum source error you see the following screen<sup>1</sup>:

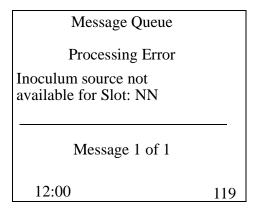


Figure 8-7: Inoculum Source Error Message

Open the Cassette Load door and remove the cassette.

#### **DANGER:**



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.

<sup>1.</sup> Another inoculum error message is "Grouping Error at Slot: NN

- 3. Place the *inoculum source* next to the appropriate slot.
- Place the *cassette* back into the Cassette Load station and close the door.

This restarts the processing cycle for the cassette.

# **Card Capacity Errors**

As the bar codes on the test cards are read, the cards are counted. The count is compared to the number of empty slots currently available in the reader carousel. If the number of cards exceeds the number of available slots:

- The cassette is backed out to the Cassette Load station.
- The error alarm is activated.

### HOW TO RESOLVE A CARD CAPACITY ERROR

 Press the *Error/Message* key to display the error/ message queue.

For a card capacity error you see the following screen:

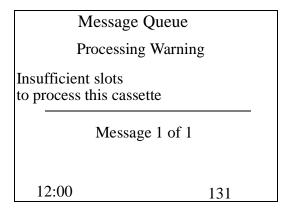


Figure 8-8: Card Capacity Warning Message

Open the Cassette Load door and remove the cassette.

You can remove a number of test cards from the cassette to resolve this type of error. However, there is another option available because it takes several minutes for a cassette to reach the Reader station. During this time, additional carousel slots can be made available by ejecting cards whose tests have finalized. Continue the procedure as follows:

- Consult the *card directory* at the workstation. Count the *number of cards* whose tests have finalized and that can be ejected.
- 4. Eject those *cards* using the workstation software.
- 5. If there are still too many test cards in the current cassette, and remove the needed number of cards.
- Place the cassette back into the Cassette Load/ Unload Station and close the *door*.

This restarts the processing cycle for the cassette.

**NOTE:** If the instrument's card capacity is exceeded, the extra test cards are **not** processed, and will be unusable.

### **Disposables Errors**

When a cassette begins processing, VITEK 2 calculates the quantity of disposables that will be needed. If the calculated value exceeds the current level of a disposable:

- The cassette is backed out to the Cassette Load station.
- The error alarm is activated.

#### How to Resolve a Disposables Error

 Press the *Error/Message* key to display one of the following messages:

Tip Level Low or Saline Level Low

- Open the Cassette Load door and remove the cassette.
- 3. Perform the procedure in Chapter 7 to install a new VITEK 2 accessory kit and saline bag.
- 4. Place the *cassette* back into the Cassette Load Station and close the door.

# Working Without the VITEK 2 Bar Code Reader

A good reading of the test card bar code is required by the system to know the card type and how to process it. The primary method of entering these bar codes is the Bar Code Reader station in the VITEK 2 instrument. There are also two backup methods:

- The bar code scanner on a Smart Carrier Station, which is then transferred to VITEK 2 via the smart cassette.
- Manually on the VITEK 2 interface keypad.

If the Bar Code Reader station fails, one of the two backup methods could be used.

# **How to Enter Bar Codes Manually**

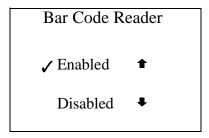
Failure of the Bar Code Reader station on the VITEK 2 instrument would result in a bar code read error for every card processed. This can be avoided by disabling the station, and then entering bar codes via the Smart Carrier Station, or manually on the VITEK 2 keypad.

TO DISABLE THE BAR CODE READER

1. Access the **Bar Code Reader** configuration option using the path:

Main Menu ⇒ Utilities ⇒ Configuration

The Bar Code Reader screen appears:

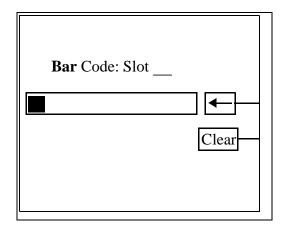


Press the **DOWN ARROW** key to disable the bar code reader.

#### TO ENTER BAR CODES MANUALLY

 Access the Resolve Bar Code Errors option on the Main Menu.

The following screen appears:



 Using the numeric keypad, enter the *bar code* from the bar code label. Press the *ENTER* key to accept the entry. Repeat this step for each test card in the cassette.

**NOTE:** The bar code you enter may be longer than the space provided on the screen. When this occurs, the first portion of the bar code scrolls off the display and the symbol ">" appears.

**NOTE:** Press the *ENTER* key to bypass empty slots.

5. Press the **Done** key when all the cards have been entered for the Cassette.

# **Instrument Diagnostics**

Some of the error recovery procedures in this chapter ask you to perform a diagnostic test on one of the stations in the VITEK 2 instrument. This section tells you how to access and use those tests.

### **Instrument Diagnostics Menu**

All of the diagnostic tests for the instrument are located on the Diagnostics Menu, which can be accessed using the following path:

Main Menu ⇒ Utilities ⇒ Diagnostics

# **Diagnostic Tests**

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

Diagnostic Test	Function	Possible Results
Temperature	Reads the temperature in the reader carousel.	Displays the carousel temperature in degrees Celsius. Also displays the word "LOW" or "HIGH" if the temperature is out of specification.
Optics	Performs a self-test of the transmittance and fluorescence optics systems.	Pass/Fail
Card Transport	Performs a self-test of the Card Transport system.	Pass/Fail
Vacuum	Performs a vacuum test of the Filler station.	Pass/Fail
Dispenser/Pipet- tor	Performs a saline dispensing and a simulated organism suspension transfer.	Pass/Fail
Error/Message Log	Stores all errors/messages occurring since the power was last turned on. When you power off the VITEK 2 all messages and errors are deleted from this log.	NA

**NOTE:** Some of the diagnostic test functions contain a confirmation screen. These are included for the diagnostic tests that take several minutes to run. The confirmation window asks if you want to continue.

CHECKING THE INSTRUMENT TEMPERATURE

Access the **Temperature Diagnostics** using the path:

Main Menu ⇒ Utilities ⇒ Diagnostics ⇒ Temperature

If you have a VITEK 2 XL, the screen below displays:

Temperature

Incubator A: 35.5° C

Incubator B: 35.5° C

Inside: 28.0° C

If you have a VITEK 2, the screen below displays:

Temperature

Incubator: 35.5° C

Inside: 28.0° C

The screen displays the Incubator temperature and the temperature inside the instrument.

THE DISPENSER/PIPETTOR DIAGNOSTIC TEST

**NOTE:** The transport system must be idle to perform this test.

This test is designed to be performed:

- after installing an Accessory Kit to confirm correct operation of the dispenser/pipettor station.
- during the error recovery procedure for a dispenser or pipettor failure.
- 1. Prepare a *cassette* with the following items:

•two test tubes containing 3.0 ml saline, placed in test tube slots 1 and 3.

•three blank test tubes, placed into test tube slots 2, 4 and 5.

**NOTE:** This cassette does **NOT** require the use of the Smart Carrier Station.

2. Access the *Dispenser/Pipettor diagnostic test* using the path:

 $\mbox{Main Menu} \Rightarrow \mbox{Utilities} \Rightarrow \mbox{Diagnostics} \Rightarrow \mbox{Dispenser/Pipettor}$ 

The following message displays:

About to perform dispenser pipettor test. Do you wish to continue?

3. Press the **Yes** option button.

A message on the display will instruct you to load the cassette that you prepared in step 1.

- 4. Open the **Cassette Load door**, load the **cassette** and close the **Cassette Load door**.
- While the instrument is performing this test, open the front door of the instrument and visually check the saline dispenser for any of the abnormal conditions listed below.
- Look for repeated back and forth movement while the saline dispenser is in the upright position. The saline dispenser tube should move smoothly up and down when filling each AST tube.

- Look for saline remaining in the saline dispenser tube when it returns to the upright position.
- Look for a saline stream and/or drops released from the saline dispenser tube when it is filling with saline
- Look for a saline stream and/or drops released from the saline dispenser tube as it returns to the upright position.
- Look for lower volumes of saline in one test tube compared to another.
- Observe the instrument user interface screen for Pipettor error 21 or any Dispenser errors.

**NOTE:** Ensure there is no sunlight shining directly on the saline dispenser.

You can continue to use Automatic Dilution Mode if none of the abnormal conditions are observed.

If you see any of the above abnormal conditions or instrument errors continue to occur, please discontinue using Automatic Dilution Mode and contact bioMérieux immediately. You can configure the instrument to use the Predilution Mode as described in Chapter 5 of this manual.

### DISPENSER/PIPETTOR VOLUMETRIC TEST

This test is not required by bioMérieux as part of the recommended routine maintenance procedures. This test has been provided for those laboratories who are required to verify the accuracy of the volumes dispensed by the Pipettor/Dispenser by regulatory/licensing agencies.

**NOTE:** The transport system must be idle to perform this test.

- 1. Prepare a *test cassette* with the following items:
- *two test tubes containing 3.0 ml saline*, placed in test tube slots 1 and 3.
- *three blank test tubes*, placed into test tube slots 2, 4 and 5.

**NOTE:** This cassette does **NOT** require the use of the Smart Carrier Station.

- 2. Record the **weights** of the test tubes placed in test tube slots 1, 3 and 5 using Table 8-1.
- Record the *weight* of the tube in slot 1 in the Pipettor Low Volume section. Test tube 1 - Before test (B)
- Record the *weight* of the tube in slot 3 in the Pipettor High Volume section. Test tube 3 Before test (B)
- Record the *weight* of the tube in slot 5 in the Diluter section. Test tube 5 Before test (B)

Use this table to record the weights of your test tubes. Make one copy for your use and keep the original in this manual.

Pipettor Low Volume	Results	Date Tested	Performed By
Test tube 1 - Before test (B)			
Test tube 1 - After test (A)			
Weight of 1 (B) - 1(A)			
Acceptable range .095 gm to .105 gm.			
Pipettor High Volume			
Test tube 3 - Before test (B)			
Test tube 3 - After test (A)			
Weight of 3 (B) - 3 (A) Acceptable range .285 gm to .315 gm			
Diluter			
Test tube 5 - Before test (B)			
Test tube 5 - After test (A)			
Weight of 5 (A) - 5 (B) Acceptable range 2.33 gm to 2.63 gm			

Table 8-1: Dispenser/Pipettor Volumetric Test

3. Access the *Dispenser/Pipettor diagnostic test* using the path:

Main Menu ⇒ Utilities ⇒ Diagnostics ⇒ Dispenser/Pipettor

The following message displays:

About to perform dispenser pipettor test. Do you wish to continue?

4. Press the Yes option button.

A message on the display will instruct you to load the cassette that you prepared in step 1.

- 5. Open the cassette load door, load the *test cassette* and close the cassette load door.
- 6. Allow the cassette to process and return to the cassette load/unload door. Remove the cassette.
- 7. Record the **weights** of the test tubes placed in test tube slots 1, 3 and 5 using Table 8-1.
- Record the *weight* of the tube in slot 1 in the Pipettor Low Volume section. Test tube 1 After test (A)
- Record the *weight* of the tube in slot 3 in the Pipettor High Volume section. Test tube 3 After test (A)
- Record the *weight* of the tube in slot 5 in the Diluter section. Test tube 5 After test (A)

- 8. Determine if the Dispenser/Pipettor is performing to specification by performing the following calculations using Table 8-1:
- In the Pipettor Low Volume section, subtract the *weight* of tube 1(A) from the *weight* of 1(B). The acceptable value must be between .095 gm to .105 gm.
- In the Pipettor HighVolume section, subtract the *weight* of tube 3(A) from the *weight* of tube 3(B). The acceptable value must be between .285 gm to .315 gm.
- In the Diluter section, subtract the *weight* of tube 5(B) from the *weight* of tube 5(A). The acceptable value must be 2.33 gm to 2.63 gm.

**NOTE:** If the values recorded in the tables are not within the recommended range, call bioMérieux for assistance.

# Cleaning and Verifying the Optics with Cards Processing

This procedure allows you to clean and verify the optics while test cards are still processing. Use the Optics Cleaning procedure in Chapter 7 if the instrument is shut down.

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

### **DANGER:**



The instrument contains an ultraviolet light source. Make sure that the fluorescence optics unit is closed before resuming instrument operation.

### **CAUTION:**



Do not wear powdered latex gloves while cleaning the fluorescence optics. The gloves that contain a powder can interfere with the optics.

### **CAUTION:**

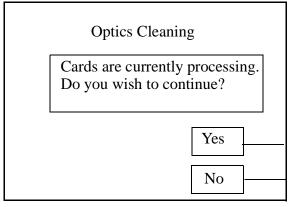
See Laser Caution statement on page xviii.



1. Access the **Optics Cleaning** function using the path:

 $\begin{array}{l} \text{Main Menu} \Rightarrow \text{Utilities} \Rightarrow \text{Maintenance} \Rightarrow \text{Cleaning} \\ \Rightarrow \text{Optics Cleaning} \end{array}$ 

If cards are processing, the following screen appears:

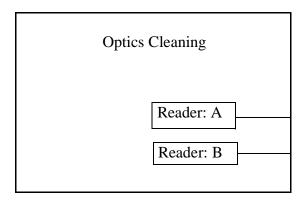


2. Press the **Yes option button** to continue.

The screen briefly displays the message

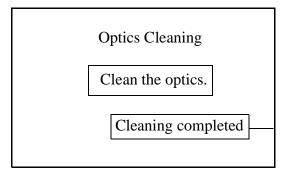
Preparing for Optics Cleaning

**NOTE:** If you have a VITEK 2 XL, a screen appears allowing you to select a Reader.



You have five (5) minutes from the time that you press the **Yes** option button to complete the cleaning procedure. Test card processing automatically resumes after that time.

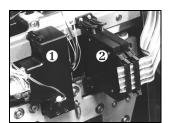
It then displays the following screen:



3. Open the **Waste Collection station door** and remove the **test card collection tray**. Dispose of any test cards in the tray.

# 4. Lift the *top access door* of the instrument.

This exposes both the fluorescence (①) and the transmittance (②) optics, shown in the figure to the right.

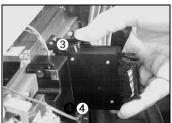


This provides easier access to the optics and an opportunity to clean this component also.

Both optics consist of units that are hinged on the bottom and held in place by spring-loaded levers. The transmittance optics consists of two of these units while the fluorescence optics have only one.

**NOTE:** The remainder of this cleaning procedure is the same for both optics. Remember that for the transmittance optics, you do each step for **both** units at the same time.

 Using your right hand, grasp the optics unit and place your thumb on the lever (3) (see figure at right).



6. Push down on the *lever* to release the unit and allow it to rotate on its hinges (4).

Inspect the *glass* on both surfaces for cracks or scratches.

**NOTE:** Any apparent crack or scratch should be reported to bioMérieux.

8. Using a quality, lint free lens paper that has been slightly moistened with a commercial glass cleaner, 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. Make sure that you do not leave streaks on the glass.

- 9. Rotate the *unit* back into place while pushing down slightly on the lever until it is secured.
- 10. Replace the empty *test card collection tray* in the Waste Collection station.
- 11. Close the *top access door*, then close the *Waste Collection station door*.

12. Press the *Cleaning completed option button* that was displayed in the screen in step 2.

**NOTES:** If step 12 is not completed within the five minutes allowed, test card processing resumes automatically. If the optics are still open, the instrument generates an error condition.

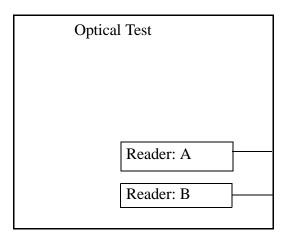
After cleaning the optics, perform the Optical Diagnostic Test.

# **Optical Diagnostic Test**

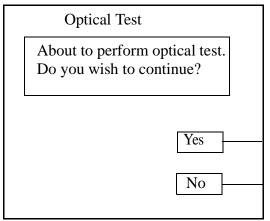
1. Access the Optical Diagnostic Test using the path:

Main Menu ⇒ Utilities ⇒ Diagnostics ⇒Optics

**NOTE:** If you have a VITEK 2 XL, the following screen appears allowing you to select a Reader.



The following screen appears for either the VITEK 2 or VITEK 2 XL



- 2. Press Yes to continue.
- 3. If the optical test failed, call bioMérieux.
- 4. Once the test is complete, press **PREVIOUS SCREEN** to exit the window.

### **Boat Transport Positions**

The diagram below shows the six boat transport positions. It is important to know the boat positions inside the instrument to aid in the troubleshooting of jams involving the card transport system.

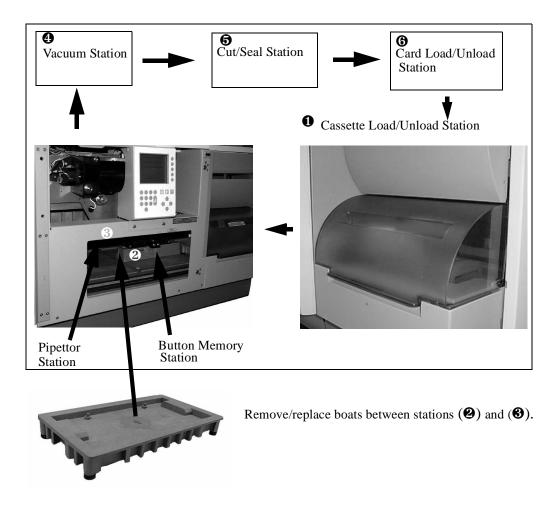


Figure 8-9: Boat Transport Positions

8

• Cassette Load/Unload station.

**NOTE:** Boats must not be removed or replaced at this station.

- **② ③** This is the area you see when you open the front access door.
  - **2** Button Memory Station
  - **3** Pipettor Station

Boats must only be removed and replaced from between stations (2) and (3).

When a boat is replaced, center it on the opening between the two guide rails (see arrow in the picture).

- **4** Vacuum Station.
- **6** Cut/Seal Station.
- **6** Card Load/Unload Station.

**NOTE:** Always remove and replace boats using the procedures on page 7-39 and page 7-42, respectively.

**CAUTION:** 

See Laser Caution statement on page xviii.



### **Power Failures**

What happens in the VITEK 2 instrument if there is a power failure? The instrument is supported by a device called an Uninterruptible Power Supply (UPS). If power is lost, the UPS uses a battery to continue to supply power to the instrument.

The UPS notifies VITEK 2 of a power failure. The following events then take place in which the instrument:

- Initiates a Power Failure error message.
- Begins a 20 minute timer
- Continues processing test cards in the carousel.
- Continues to support the card transport system, but does
   NOT allow new cassettes to be loaded.

8

If power is restored within the 20 minute period, normal operation is resumed. If the power failure continues after the 20 minute period has expired, VITEK 2 shuts down the card transport system but continues to process cards in the carousel. Carousel processing continues as long as the battery in the UPS supplies power. If the backup battery in the UPS begins to fail before the 20 minute period expires, VITEK 2 terminates the timer and shuts down the card transport system. Test cards, however, continue to process as long as any battery power is available.

## 8

## **Displaying Version Information**

Allows you to view the current instrument firmware for the VITEK 2. You may be requested to supply this information to bioMérieux if you need assistance with any of the recovery procedures in Table 8-2.

Access the *Version Information* function using the path:

Main Menu ⇒ Utilities ⇒ Diagnostics ⇒ Version Info

A screen displays similar to the one below.

BCB:02.26.09: Apr 20 1999

T04.03 Mar 18 1998 BOOT

01.61 18-11-1997:Left

01.61 18-11-1997:Right

01.61 18-11-1997:Dil

01.61 18-11-1997:Pip

01.58 23-10-1997: VacSeal

01.61 18-11-1997:Read A

01.61 18-11-1997:Caro A

### **How to Use Error Message and Recovery Table**

Table 8-2 in this section contains all of the messages that can be displayed in the error/message queue.

The Error Message and Recovery table is designed to provide you, where possible, with the recovery procedure that is most likely to restore the instrument to normal operation. If the described procedure does not prevent recurrences of the error, call bioMérieux for assistance.

- 1. Find the *Primary Error Code* from the error message in the first column of the table. Primary error codes are listed alphabetically.
- 2. Find the **Secondary Error Code** from the error message in the second column of the table.
- Read and follow the directions in the Recovery Procedure found in the third column and address accordingly.
- 4. If the error reoccurs or the recovery procedure advises a call to bioMérieux, inform the service representative of the error number found in the lower right portion of the message queue.

#### How to restart the instrument

Several of the recovery procedures in the table instruct you to restart the instrument. To do this:

- 1. Perform the instrument shutdown procedure on page 7-46.
- 2. Wait at least 10 seconds.
- 3. Move the AC power switch to the **ON** position.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Hardware Error	• FLASH Memory Failure	Call bioMérieux for assistance.
	• Incubator Tem- perature Control- ler Failure	Call bioMérieux for assistance.
	• Internal Instru- ment Tempera- ture Controller Failure	Call bioMérieux for assistance.
	• Internal Clock	Call bioMérieux for assistance.
	• Internal Data Failure	Call bioMérieux for assistance.
	• Optical Control- ler Failure	Call bioMérieux for assistance.
	• Serial Number Failure	Call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Host Communication	• Communication Failure	1. Ensure that the cable between VITEK 2 to the workstation is connected securely.
		2. Confirm that the workstation is operating.
		3. If the error continues, call bioMérieux for assistance.
		NOTE: If this error occurs while a software update is being performed, or during the automatic data backup, no action is required.
	• Card data has been lost	Call bioMérieux for assistance.
Initializa-	• Dispenser Failure	Call bioMérieux for assistance.
tion Error	• Incubator Tem- perature Control- ler Failure	Call bioMérieux for assistance.
	• Motor/Sensor Failure	Call bioMérieux for assistance.
	• Pipettor Failure	Call bioMérieux for assistance.
	• Power Fail Recovery Failure	Call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Initializa- tion Error (Cont.)	• Transport Failure	Call bioMérieux for assistance.
Instrument Error	Restart System	Call bioMérieux for assistance.
	• Call bioMérieux	Call bioMérieux for assistance.
Optical Error	• Fluorescence Calibration Failure	1. See Cleaning and Verifying the Optics with Cards Processing on page 8-43.
	• Fluorescence Process Failure	2. Call bioMérieux if the problem recurs.
	• Transmittance Calibration Fail-	1. See Cleaning and Verifying the Optics with Cards Processing on page 8-43.
	• Transmittance Process Failure	2. Call bioMérieux if the problem recurs.
Optical Error	• Fluorescence Requires Liquid	The instrument self diagnostics has determined that it is time to recalibrate the fluorescence optics.
(Cont.)	Canoranon	Call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing	• An optical system	1. Unload cassette from the instrument.
101101	for card type in slot:	2. See Cleaning and Verifying the Optics with Cards Processing on page 8-43 to clean and test the optics.
		3. Reload cassette into the instrument.
		4. If problem persists, call bioMérieux.
	• Bar Code read failure at Slot:	Follow the procedure for bar code read failure on page 8-17.
	• Card has expired at Slot:	Replace the expired test card.
	• Card Sealer Fail- ure	Call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error (Cont.)	• Card Transport System Failure	1. Open the front access door and the cassette load/unload door to check for any jams or obstructions throughout the transport system. Things to look for are:
		• pipette tips that have fallen onto the base pan
		• test cards that are not seated properly in the cassette
		<ul> <li>boats that are not seated properly in their track</li> </ul>
		2. Close both doors and press the <b>GO</b> option button on the Halt screen.
		<b>NOTE:</b> If the Halt screen is not displayed, press the <i>Previous Screen</i> key until it is.
		3. Call bioMérieux if the problem recurs.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error	• Carousel Jam	1. Open the waste collection door and top-right access door.
(Cont.)		2. Remove the incubator access cover.
		<ol> <li>Make sure that there is no card jammed between the reader head and the carousel. If there is, push the card into the carousel.</li> </ol>
		<ol> <li>Make sure that there is no card jammed between the card loader and the carousel. If there is, push the card back into the cassette.</li> </ol>
		5. Replace the incubator access cover.
		6. Close the top-right access and waste collection doors. (Refer to Step 9 of the procedures on page 7-52.)
		7. Press the <b>GO</b> option button on the Halt screen.
		<b>NOTE:</b> If the Halt screen is not displayed, press the <i>PREVIOUS SCREEN</i> key until it is.
		8. Call bioMérieux if the problem recurs.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing	• Cassette button	1. Unload the cassette from the instrument.
(Cont.)	memory tanure	2. Confirm that the instrument is in Smart Carrier Mode. If the mode setting is correct, position the cassette back on the SCS and verify that it can read the cassette.
		3. If SCS cannot read the cassette, clean the contacts on the button memory and place the cassette on the SCS. (See Step 4 in the procedures on page 7-36) If still not successful, replace the button memory on the cassette and re-enter the data on the Smart Carrier Station.
		4. If the SCS reads the cassette properly, squeeze out an alcohol wipe and then wipe the button memory contacts inside the VITEK 2 instrument. Re-insert the casette into the instrument.
		5. If the problem recurs, call bioMérieux.
		NOTE: If the instrument is in casssette only mode and this setting is correct, reload the cassette immediately and the cassette will process, ignoring information stored on the button memory.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing	• Dispenser Failure	1. Open the front access door and check for:
(Cont.)		• proper installation of the accessory kit. (See Accessory Kit installation procedure on page 7-6.)
		• a sufficient quantity of saline in the bag.
		• tangles or pinches in the saline tubing
		2. If needed, install a new accessory kit.
		3. Perform the Dispenser/Pipettor diagnostic test. (See the procedure on page 8-36.)
		4. If the problem continues, call bioMérieux.
		5. If the problem recurs, call bioMérieux.

Table 8-2: Error Message and Recovery Table

Processing General Failure 1. Press the tus screen (Cont.)  2. If the Statution tray. (Second Page 8-43) 3. If the Halt secons conduct the calculation of the proced the proced the proced the proced	Secondary Error Code
	1. Press the <b>PREVIOUS SCREEN</b> key until either the Status screen or the Halt screen is displayed.
3. If the Halt and top-rig access covaccess covaccess covacces and top-rig access covacces and top-rig access and top-rig access and the proced the proced	2. If the Status screen is displayed, empty the waste collection tray. (See page 6-57.) Also follow the procedure on Page 8-43 to clean and test the optics.
4. Make sure reader hea into the ca into the ca into the ca card loade back into the target into the card loade back into the access and the procedule.	3. If the Halt screen is displayed, open the waste collection and top-right access door and remove the incubator access cover.
5. Make sure card loade back into the gross and the procedule.	4. Make sure that there is no card jammed between the reader head and the carousel. If there is push the card into the carousel.
6. Replace that access and the proced	5. Make sure that there is no card jammed between the card loader and the carousel. If there is, push the card back into the cassette.
	6. Replace the incubator access cover. Close the top right access and waste collection doors.( Refer to step 10 of the procedure on page 7-33.)
7. Press the	7. Press the <b>GO</b> option on the Halt screen.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error		8. Call bioMérieux if the problem recurs.
(Cont.)		NOTE: If any cards terminate and remain in the carousel, wait for all cards to complete and then perform carousel cleaning. (See the procedure on How to Remove the Carousel for Cleaning on page 7-21 and the procedure How to Replace the Carousel After Cleaning on page 7-29)
	• Grouping Error at Slot:	The instrument has found a mated pair in which the test types do not match. Mated pairs require gram negative ID and AST cards. As and AST cards, or a gram positive ID and AST cards. Remove the cassette from the instrument and replace the appropriate test card.
	• Inoculum source not available for Slot:	Refer to the procedure for correcting inoculum errors on page 8-24.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error	• Load Failure	1. If the instrument has <b>not</b> displayed the Halt screen, go to Step 5.
(Cont.)		2. If the instrument is displaying the Halt screen, open the top-right access door and remove the incubator access cover. (Follow steps 4 and 5 of the procedure on page 7-23 and 7-24.)
		3. Check for a test card jam in the card loader (the mechanism near the bottom of the carousel that pushes test cards from the cassette into the carousel). Push any test cards that you find back into the carousel.
		4. Press the GO option button on the Halt screen.
		NOTE: If test cards remain in the carousel, you can allow them to finish processing. You should not, however, load new cards into the instrument until after you have completed this recovery procedure.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error (Cont.)		5. After all test cards have finished processing, remove the four carousel sections and remove any test cards that are found. (See the procedure <i>How to Remove the Carousel for Cleaning</i> on page 7-21, and the procedure <i>How to Replace the Carousel After Cleaning</i> on page 7-29.)
		NOTE: You cannot reprocess test cards after a Load Failure. Any test cards found in the carousel in step 5 must be discarded.
		<b>NOTE:</b> If the cards terminated immediately after loading, check for obstructions throughout the transport system and perform the Transport Test on page 8-23.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error	Pipettor Failure	1. Open the front access door and check for the presence of pipette tips in the container
(COIII.)		2. If needed, install a new accessory kit. (See the procedure for adding pipette tips on page 7-14.)
		3. Check for the presence of pipette tips that may have fallen onto the base pan, and remove them.
		4. Perform the Dispenser/Pipettor diagnostic test. (See the procedure on page 8-36.)
		5. If the problem continues, call bioMérieux.
	• Process Jam	Refer to the Recovery Procedures for any messages that have approximately the same date/time stamp.
	Reader Error     Occurred	Refer to Procedure on General Failure
	• SCS and Bar Code Reader con- flict at Slot:	Follow the procedure for SCS and Bar Code Reader Conflict on page 8-22.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing	• SCS information	1. Remove the cassette from VITEK 2.
(Cont.)	nas enors at siot:	2. Put the cassette on the SCS.
		3. Press the <b>F10</b> key to erase the data in the button memory.
		4. Re-enter the data for the cassette.
	• SCS memory contains old	1. Make sure that the VITEK 2 instrument is in the correct cassette mode. (See procedure on page 5-10.)
	iniorination that has previously been processed	<ol><li>If the problem still continues, call bioMérieux for assistance.</li></ol>
	• Unknown Card Type at Slot:	1. Make sure that the test card has been entered in the Flex Panel Entry screen at the workstation computer.
		2. Try processing the test card again.
		3. If the problem recurs, call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error	• Unload Failure	Open the Waste Collection station door and check for jams.
(Cont.)		2. Empty the waste collection tray (See page 6-57).
		3. Open the top-right access door and remove the incubator access cover. (Follow steps 4 and 5 of the procedure on page 7-23 and 7-24.)
		4. Make sure that there is no card jammed between the reader head and the carousel. If there is, push the card into the carousel.
		5. Make sure that there is no card jammed between the card loader and the carousel. If there is, push the card back into the cassette.
		6. Replace the incubator access cover. (Follow step 9 of the procedure on page 7-33.)
		7. If the problem recurs, call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Error (Cont.)	• Vacuum System Failure	1. After all test cards have finished processing, clean the seal on the vacuum chamber and all surfaces of the boat. (See page 7-53.)
		2. Perform the vacuum test on the Instrument Diagnostics menu. (See page 8-34.)
Processing Warning	• Cannot unload cards, waste tray is full	Empty the test card waste collection tray. (See the procedure on page 6-54.)
	• Cannot unload cards, waste tray is not available	Reinstall the test card waste collection tray. (See the procedure on page 7-49.)
	• Cannot unload cards, waste tray is not functional	Open the Waste Collection station door and check for jams.
		2. Empty the waste collection tray. (See page 6-56)
		3. Call bioMérieux for assistance if the problem recurs.
	Cassette Loading door is open	Close the Cassette Load door. If the error recurs, call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Warning (Cont.)	• Saline has been in use longer than the recommended time	The saline has been in the instrument longer than the specified time. Replace the saline bag. (See procedure on page 7-6.)
	• Saline Level Low	Replace the saline bag. (See procedure on page 7-6.)
	• Incubator cover is off.	Open the top-right access door and replace or reseat the incubator cover.
	• Incubator Temperature HIGH	Ensure that the ambient room temperature is below 30° C. Wait 15 minutes and recheck. If the incubator temperature has not returned to normal, call bioMérieux for assistance.
		NOTE: Test cards that are still processing in the carousel will be terminated after this error occurs. A laboratory report will be printed with the message "CARD TERMINATED: Insufficient incubation time for analysis." For AST cards, any antibiotics that were finalized prior to the error will be reported.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Warning (Cont.)	• Incubator Temperature LOW	Ensure that the ambient room temperature is above 20° C. Wait 15 minutes and recheck. If the incubator temperature has not returned to normal, call bioMérieux for assistance.
		NOTE: Test cards that are still processing in the carousel will be terminated after this error occurs. A laboratory report will be printed with the message "CARD TER-MINATED: Insufficient incubation time for analysis." For AST cards, any antibiotics that were finalized prior to the error will be reported.
	• Internal Instru- ment Tempera- ture is HIGH	Ensure that the ambient room temperature is below 30° C. Wait 15 minutes and recheck. If the instrument temperature has not returned to normal, call bioMérieux for assistance.
	• Insufficient slots to process this cassette	Refer to procedures for Card Capacity Errors on page 8-26.
		NOTE: You should check the Status screen before loading a cassette to make sure you have a sufficient number of slots available.

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Warning (Cont.)	• Power Fail. System will park until power is restored	Normal processing will resume when power is restored. See page 8-52 for description of how instrument handles power failures.
	• Tip Level Low	See Disposables Error procedure on page 8-29

Table 8-2: Error Message and Recovery Table

Primary Error Code	Secondary Error Code	Recovery Procedure
Processing Warning (Cont.)	• Tips have been in use longer than the recommended time	The pipette tips have been in the instrument longer than the specified time. Install a new Accessory Kit. (See procedure on page 7-14.)
	• The fluorescence is approaching calibration limits	1. After cards complete and eject, clean the optics (See page 7-50)
		2. Perform diagnostics test on the optics (See page 8-34)
	• The Uninterrupt- ible Power Sup- ply has a Low Battery	Call bioMérieux for assistance if this error occurs when there is <b>not</b> a power failure. (This would be a normal error during a power failure.)
		See page 8-52 for description of how instrument handles power failures.
	• Waste tray cannot hold the number	Empty the test card waste collection tray. (See procedure on page 6-57.)
	of cards currently in the Carousel	

# **Appendix: Hardware Specifications**

### **VITEK 2 Instrument**

### **Dimensions**

Dimension	VITEK 2	VITEK 2 XL
Height	67 cm (26.3 in.)	67 cm (26.3 in.)
Width	100 cm (39.4 in.)	140 cm (55.1 in.)
Depth	71 cm (27.7 in.)	71 cm (27.7 in.)

#### Mass

	VITEK 2	VITEK 2 XL
Mass	Approximately 110 kg (240 lb)	Approximately 145 kg (320 lb)

### **CAUTION:**



The VITEK 2 instrument is heavy. Use at least two people to move it. Lift handles are provided at each end of the instrument.

#### **Environment**

**NOTE:** The specifications below apply to both the VITEK 2 and the VITEK 2 XL.

Indoor usage

Do not install in direct sunlight

Benchtop should be level within 2°

Minimum of 5 cm (2 in) clearance on all sides for adequate ventilation; 50 cm (20 in) above

Minimum installation altitude: -100m

Maximum installation altitude: 2000m

Ambient room temperature: 20°C to 30°C

Shipment and storage temperature: -20°C to +50°C

Relative humidity: 40% to 80% non-condensing

Pollution degree 2 in accordance with IEC 664

Overvoltage Category II per IEC 664

### **Electrical Characteristics**

Electrical Characteristics	VITEK 2 VITEK 2 XL	
Input voltage	200/240 VAC at 50/60 Hz	200/240 VAC at 50/60 Hz
	100/120 VAC at 50/60 Hz	100/120 VAC at 50/60 Hz
Maximum input current	4 amps @ 120 VAC or 2 amps @ 240 VAC	5 amps @ 120VAC or 2.8 amps @ 240 VAC
Nominal input current	1.5 amps @ 120 VAC or 0.75 amps @ 240 VAC	2.75 amps @ 120 VAC or 1.75 amps @ 240 VAC
Power	150 watts nominal, 471 watts peak	200 watts nominal, 569 watts peak
Heat	512 BTU/HR (nominal)	682 BTU/HR (nominal)
Power cord	Detachable 3-wire with ground, per IEC 227 or IEC 245	Detachable 3-wire with ground, per IEC 227 or IEC 245

### **Optical Characteristics**

**NOTE:** The specifications below apply to both the VITEK 2 and the VITEK 2 XL.

TRANSMITTANCE OPTICS

Emission wavelengths: 660 nm, 590 nm, 568 nm, 430 nm LED

Percent transmission range: 30% to  $100\% \pm 10\%$ 

FLUORESCENCE OPTICS

Emission wavelength: 365 nm Detection wavelength: 445 nm

Calibration: 3,800 RFU  $\pm$  5% with 5  $\mu$ M 4-MU in CHES @ pH

9.6

Accuracy and stability: ± 10% over 6 months

Lamp life: 30 million flashes minimum

#### **General Characteristics**

**NOTE:** The specifications below apply to both the VITEK 2 and the VITEK 2 XL.

#### CASSETTE

Capacity, cassettes: 4 cassettes maximum Capacity, cards: 15 cards per cassette

#### DISPENSER

Dispensing volume: 2.33 - 2.63 ml Capacity: 1000 ml, user replaceable

#### **PIPETTOR**

Dispensing volume:  $60 \mu l$  to  $300 \mu l \pm 5\%$  or  $\pm 5 \mu l$ , whichever

is greater

Pipettor drum capacity: 330 pipette tips minimum, user replace-

able

VACUUM (FILLER)

Minimum level: .89 PSIA  $\pm$  0.06 PSIA

**SEALER** 

Mechanical: stub length .025 mm to 2.5 mm

INCUBATOR

Temperature:  $35.5^{\circ}C \pm 1^{\circ}C$  average Capacity: 60 cards per Incubator

### **Smart Carrier Station**

### **Dimensions**

**NOTE:** The specifications for the Smart Carrier Station apply

to both the VITEK 2 and the VITEK 2 XL.

Width: 27.15 cm (10.7 inches)

Height: 28.26 cm (11.1 inches)

Depth: 17.78 cm (7 inches)

#### Mass

Approximately 2.6 kg (5.85 lbs.)

#### **Environment**

Indoor Usage

Do not install in direct sunlight

Relative Humidity: 40% to 80% non-condensing

Ambient room temperature: 15° C to 30° C

Shipment and Storage temperature: -20° C to +50° C

Pollution Degree 2 in accordance with IEC 664

Over voltage Category II per IEC 664

#### **Electrical Characteristics**

Input Power: 100/120 VAC, 50/60 Hz

200/240 VAC, 50/60 Hz

Fused input current: 2 amp - T (GDC-2)

Nominal input current: .2 amps @ 120 VAC

.1 amps @ 240 VAC

Power: 10 watts nominal

Heat: 34 BTU/HR (nominal)

Power Cord: Detachable 3 wire/g, per IEC 227 or IEC 245

## **Glossary**

#### **Access doors VITEK 2**

VITEK 2 has six doors to enable the operator to access the internal systems and stations to replenish supplies and perform maintenance and cleaning procedures: top access door, saline access door, front access door, bottom access door, cassette load (and unload) door, and waste collection access door.

#### Access doors VITEK 2 XL

VITEK 2 XL has nine doors to enable the operator to access the internal systems and stations to replenish supplies and perform maintenance and cleaning procedures: top access door section A, top access door section B, saline access door, front access door, front center sliding door, bottom access door, cassette load (and unload) door, and 2 waste collection access doors.

#### Accession ID

The Accession ID is a unique identifier that associates a patient culture to a test card in the VITEK 2 system. The Accession ID, which can contain up to 20 alphanumeric characters, is followed by a dash and a single-digit isolate number.

### **Accessory kit**

Supplied by bioMérieux, the accessory kit contains the tubing, disk filter, and shot tube for the Dispenser station, and a container of pipette tubes.

### **Aliquot**

A calculated unit of saline (see *dispenser/pipettor*) used with the organism culture to inoculate into the test card.

### **Antimicrobial Susceptibility Testing (AST)**

Testing the susceptibility of certain bacteria to known antibiotic concentrations. VITEK 2 helps the diagnostician determine the best medical treatment for the patient's specific strain of microorganism tested.

### **Analytical system**

Located in a portion of the instrument called the Reader/Incubator station, it consists of the carousel, and two optics systems. The transmittance optics system indirectly measures organism growth as a function of decreasing light transmittance. The fluorescence optics system directly measures organism growth or enzymatic activity by direct measurement of a biochemical product.

#### **Automatic Dilution Mode**

One of two possible settings for the Dilution Mode configuration on the VITEK 2 instrument. In Automatic Dilution mode, AST suspensions are diluted by VITEK 2. In Pre-diluted mode, the user prepares AST suspensions prior to loading test cards on the instrument.

#### Bar code

An alphanumeric interface identifier label affixed to each VITEK 2 test card. The bar code contains the card's test type, lot number, and expiration date, which is entered either by the SCS subsystem by bar code wanding, or when the test card's bar code label is read by the bar code reader inside of the VITEK 2 instrument.

#### **Boat**

The tray-like device that carries the cassette around the instrument. It forms the bottom of the vacuum chamber and helps to capture any spills. It is removable for cleaning.

### **Button memory**

A Button Memory is a microchip located in a clip underneath the Cassette that stores test card information that is entered at the Smart Carrier Station. During the entry cycle of processing, the data is transferred to the workstation computer by the button memory reader.

### **Button memory reader**

A magnetic data storage device that reads the button memory and sends data entered at the Smart Carrier Station to the VITEK 2 workstation computer.

### **Card transport system**

Moves the test cards among the stations within the VITEK 2 instrument. It consists of the cassette tray, boat, cassette loading and unloading station, electromechanical arms, card ejectors, and the waste collector station.

#### 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.

#### **CPU**

Central Processing Unit, the electronics of the personal computers and workstations.

### **Dispenser**

Dispenses 2.5 ml of 0.45% saline into an empty susceptibility card test tube. This system includes a saline dispensing system, 1,000 ml bag of sterile saline and a "fixed volume" saline dispenser tube.

### **Dispenser/Pipettor**

Transfers and mixes the appropriate inoculum volume predetermined by the test card bar code (60 uL to 300uL - see *aliquot*) to adjacent susceptibility tubes. The system includes a container for pipette tips, a displacement pump, and various tip mechanisms.

### **Disposables**

VITEK 2 disposables are pipette tips, sterile saline, test cards, and inoculum tubes.

Disposable supplies are biohazardous after use and must be discarded according to local laws regarding biohazardous material. They should not be recycled or disposed of with normal trash, etc.

#### Filler station

This station inoculates all of the cards in a cassette with the suspension contained in their corresponding test tubes. It utilizes a vacuum chamber and air pump.

### Fluorescence optics

The optical detection system designed for use with fluorescence substrates (nominal excitation @365 nm and emission @445 nm).

#### Incubator

The incubator contains a heater and a circulating fan used to incubate the cards during test. The temperature is monitored and controlled through the use of two remote precision thermistors monitored by a microprocessor holding the card at an average temperature of 35.5° C.

#### Instrument Bar code reader

This station reads the bar code label on each VITEK 2 test card within the first minute after the test cards are read, and transfers all of the test card bar code data to the VITEK 2 Workstation computer.

#### Job Aid Card

A laminated card containing frequently used functions that can be used as a quick reference tool. There is one Job Aid Card for the Smart Carrier Station, and another for the VITEK 2 Instrument.

#### **LED**

Light emitting diode, a light emitting device used in optical displays (and such consumer products as microwave ovens and digital clocks). Also see *transmittance optics*.

### **Pre-diluted Mode**

One of two possible settings for the Dilution Mode configuration on the VITEK 2 instrument. In Pre-diluted mode, the user prepares AST suspensions prior to loading test cards on the instrument. See *Automatic Dilution Mode*.

### **Saline Dispenser Tube**

A "fixed volume" chamber used to measure and dispense 2.5 ml of saline into a susceptibility tube.

### Sample preparation stations

This multi-function VITEK 2 system consists of several stations: Bar Code Reader, Button Memory Reader, Dispenser/Pipettor, Filler, and Sealer.

#### **SCS Base Unit**

See Smart Carrier Station.

#### Sealer station

This station, a part of the Sample Preparation System, seals each test card by cutting and sealing its associated inoculum transfer tube with a hot wire.

### **Smart Carrier Station (SCS)**

A laptop computer-like device used to aid in setting up the test and for entering test information. It consists of the base unit (computer), the display (black and white LCD, 40 characters wide by 12 lines high), bar code scanner, and the keyboard (slides under base unit).

The system is optional, and offers many productivity and security features for the user. It has user-configurable modes for automatic dilution for matching ID and AST Test cards.

#### **Test card**

A 3-1/2 by 2-1/4 inch (76.2 by 49.45 mm) cassette card with 64 growth wells for biological testing in the VITEK 2 system. Each well contains an air-dried suspension of a biochemical or drug used to identify and suggest treatment for microbial infections in patients.

### **Transmittance optics**

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

### **User interface (UIF)**

The portion of the VITEK 2 system in which the user and the system's software interact. The system has three user interfaces:

- Workstation computer, consisting of a monitor, keyboard, and mouse.
- VITEK 2 instrument, consisting of a keypad and screen.
- Smart Carrier Station, consisting of a keyboard and screen.

### Waste collection station

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

### **Workstation 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 VITEK 2 system with a central laboratory or hospital computer system.

The workstation computer provides the user with the graphical interface used with the mouse pointing device and workstation monitor, and a text interface for the keyboard.

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