VITEK® DensiCHEK

User Manual

048641-01 - en - 2018-08

EN

IVD

CE

Table of Contents

General Information

The content of this document is based on the VITEK® 2 Systems software release 9.01 or higher.

Please discard any previous copies of this document if relevant.

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

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

IMPORTANT: ***VITEK® DensiCHEK® is a new device and this user manual is not referring to previous instrument models, such as the DensiCHEK® Plus.***

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

Screens and equipment are not shown to scale.

IMPORTANT: ***Please read this document carefully before using the system.***

Limited Warranty

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

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

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

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

Intellectual Property

Any other name or trademark is the property of its respective owner.

Compliance Statements

FCC Compliance (Part 15.19(a)(3))

CAUTION: Changes or modifications not expressly approved could void your authority to use this equipment. This device complies with Part 15 of the FCC Rules. Operation to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Per FCC Part 2.925 (f), a radio with the following FCC ID: 2AQJ2-VTK01 and T9JRN4020 is included as an operational function of this product.

Industry Canada (IC) Compliance

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Conformité Industrie Canada (IC)

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. l'appareil ne doit pas produire de brouillage, et
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

FCC and IC Identifiers

The following are applicable to the Pod and the base units:

- Contains FCC ID: T9JRN4020
- Contains IC: 6514A-RN4020

The following are also applicable to the Pod:

- FCC ID: 2AQJ2-VTK01
- IC: 24083-VTK01

1 Introduction to the System

Intended Use and Users

The VITEK® DensiCHEK® instrument measures the optical density of a microorganism suspension in 0.45-0.50% saline.

Related Links

Graphical User Interface
Display Base Screen
FLEXprep Software Interface Screen

Intended Use

The VITEK DensiCHEK instrument is an accessory intended for use with the VITEK 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to the microorganism concentrations. VITEK DensiCHEK is intended for use with polystyrene tubes, and the reading range is 0.00 to 4.00 McFarland. The VITEK DensiCHEK has applications as an *in vitro* diagnostic medical device, or in an industry setting.

Intended Users and Environments

The VITEK DensiCHEK instrument is intended for professional use by laboratory health professionals (ex. Microbiology Laboratory Technologists) in clinical or industry settings. The VITEK® DensiCHEK can be used to prepare suspensions for testing with VITEK 2 automated ID/AST system. Though the reading range may be 0.00 to 4.00 McFarland, the acceptable McFarland ranges vary for specific card types. Refer to the *User Interface* section for more information.

The VITEK DensiCHEK® operates in the same use environments as specified for the VITEK 2 Systems.

The instrument is intended for the following specified users and environments:

- The instrument can be used in a large, medium, and small hospital and in private or industry laboratories for daily processing of a few to several hundred specimens.
- The instrument can help users create a standardized test suspension.
- The instrument can be used by intended users without risk of shock or injury during use.
- The instrument can be used as a portable device on a sample preparation bench.
- The instrument can be used in a biosafety cabinet, if required by standard operating procedures at the customer's laboratory.

Benefits and Limitations of Use

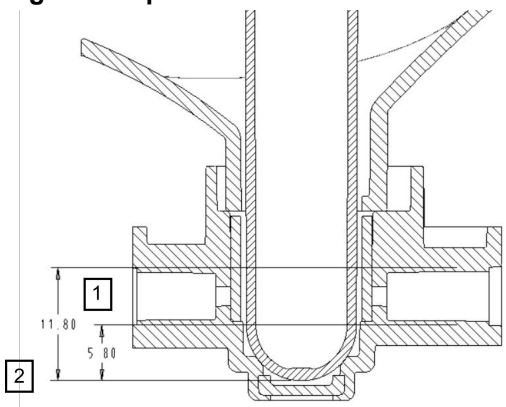
Benefits and limitations of using the VITEK® DensiCHEK® instrument include the following:

- The instrument provides accurate digital readings reported in McFarland units (i.e., estimates the number of organisms in a suspension by measuring the turbidity of the fluid).
- The instrument works with clean 12 mm x 75 mm polystyrene test tubes that are clear, colorless, and free of scratches.
- The instrument is not intended for use with glass test tubes.

- The Pod has a minimum of four hours of continuous battery life before it requires a charge.
- The McFarland References provide a way to verify the performance of the instrument.
- The instrument automatically enters Power Save mode when a test tube is not inserted into the Pod after the configured amount of time.
- The Pod and the base can be cleaned and disinfected.
- The instrument is not intended for use with test tubes that contain seams in the optical path of the Pod.
- The base unit can connect to the VITEK® 2 Systems PC to transmit information via USB if the user has the compatible software.
- The instrument is compatible with VITEK® 2 ID/AST cards and should be used to ensure suspensions are within an acceptable range. Suspensions outside of an appropriate range can compromise card performance.

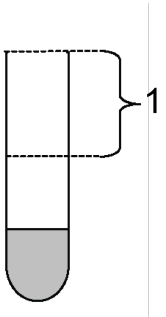
Note: *Any information that refers to VITEK® 2 Systems PCs is limited to use with the VITEK® 2 Systems software that is compatible with the VITEK® DensiCHEK® (ex. 9.01 software or later). If this software is not available to the user, then this information is not applicable.*

Figure 1: Optical Path Area



1. No seams, scratches, or imperfections are allowed in this optical path area
2. Bottom of the test tube

Figure 2: Test Tube Optical Safe Zone



1. Optical Safe Zone - Label and marking applied here

Warning and Safety Messages

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

Statement Types

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

The warning messages in this document mainly refer to:

WARNING

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

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

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

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

General Statements

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

WARNING

⚠ **Equipment is intended for professional use only.**

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

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

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

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

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

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

WARNING

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

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

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

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

WARNING

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

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

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

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

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

WARNING

Decontamination of equipment at the end of its life cycle:

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

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

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

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

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

WARNING

This statement only applies to European countries with regard to the waste electrical and electronic equipment European directive:

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

At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. It is imperative that you contact bioMérieux to assure its appropriate disposal.

WARNING

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

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

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

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

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

WARNING

⚠ **Use of other devices, including those that comply with CISPR emission requirements, could interefere with the instrument's performance.**

Standard Symbols

CE	CE-Marking of Conformity	C SA US	Compliance with US and Canadian Safety Standards certified by CSA
	Compliance with China RoHS Regulation (Chinese Standard SJ/T11364)	c UL us LISTED	UL Listed to US and Canadian Safety Standards
IVD	*In Vitro* Diagnostic Medical Device	LOT	Batch code
EC REP	Authorized Representative in the European Community	REF	Catalogue number
SN	Serial number		Consult Instructions for Use
	Use by date		Manufacturer
	Date of manufacture		This way up
	Do not stack		Caution, consult accompanying documents
Σ	Contains sufficient for <n> tests		Do not reuse


Keep dry

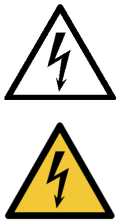

Fragile, handle with care


Keep away from magnetic field


Upper limit of temperature

Sterile

Negative control

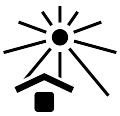

Electric shock warning


Hot surface


Laser beam


High temperature


Potential tip-over/crush hazard


Keep away from light

Humidity limitation


Temperature limitations


Lower limit of temperature

Positive control


Biological risk


Radiation warning


Potential pinch-point warning


Shearing hazard

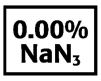

Hazardous magnetic field


Acute toxicity

Corrosives

Irritant

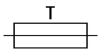
Separate collection for waste electrical and electronic equipment



Sodium azide

Recyclable

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



Fuse

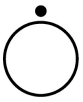
Alternating current

Three-phase alternating current

Protective conductor terminal

Equipotentiality

OFF (supply)



OFF (only for a component of the system equipment)

Ethernet port

For US Only - **Caution:** US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Direct current

Both direct and alternating current

Earth (ground) terminal

Frame or chassis terminal

ON (supply)

ON (only for a component of the system equipment)

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

FCC-Approved Equipment Labels for Part 15 devices

Regulatory Compliance Mark (RCM) for Electrical Quipment Safety System (EESS) from the Electrical Regulatory Authorities Counsil (ERAC) in Australia

2 Safety Information

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

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

System Compliance

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

This instrument complies with:

Base Standard(s): IEC 61010-1:2010 (Third Edition)

Additional Standard(s): IEC 61010-2-101: 2015 (Second Edition)

This is a Class B product.

Instrument Labels

The VITEK® DensiCHEK® instrument has labels on parts of the instrument to provide information and to make the user aware of potential hazards. Be familiar with the location and meaning of the labels on the instrument. There is an instrument label on the bottom of the Pod component and on the bottom of the base component. The labels contain the serial number (SN), voltage information, reference number, and other information specific to the device..

A user interface screen on the Display Base is located on the front of the instrument and provides functions to operate the VITEK® DensiCHEK® instrument. The Pod contains a biohazard symbol to inform the user about biological risks.

The instrument requires McFarland References to verify the instrument performance after receiving it, before its first use, at least on a monthly basis, after cleaning the device, and after relocating the instrument to a new lab environment.. There are four plastic dual-vial test tube McFarland References located inside the plastic container. Each reference is identified by a McFarland value: 0.0 (blank), 0.5, 2.0, and 3.0. The McFarland References have an outer container label that includes the part number of the McFarland Reference (REF), the date of manufacture, and the lot number (LOT).

Figure 3: Biohazard Label on the Pod (Overhead View of the Pod)

On each McFarland Reference, you can view the legal manufacturer (bioMérieux), the product name (VITEK® DensiCHEK®), the LOT number, and the McFarland Reference Value label. An RFID tag is in the bottom of the vial displaying the legal manufacturer, product name, and McFarland Reference Value.

Figure 4: Labels for McFarland Reference Test Tubes - McFarland Value View

Figure 5: Labels for McFarland Reference Test Tubes - LOT Number View

Figure 6: Instrument Label Example- Charging Base

Figure 7: Instrument Label Example- Pod

Figure 8: Instrument Label Example - Display Base

Figure 9: Instrument Label Example - McFarland References

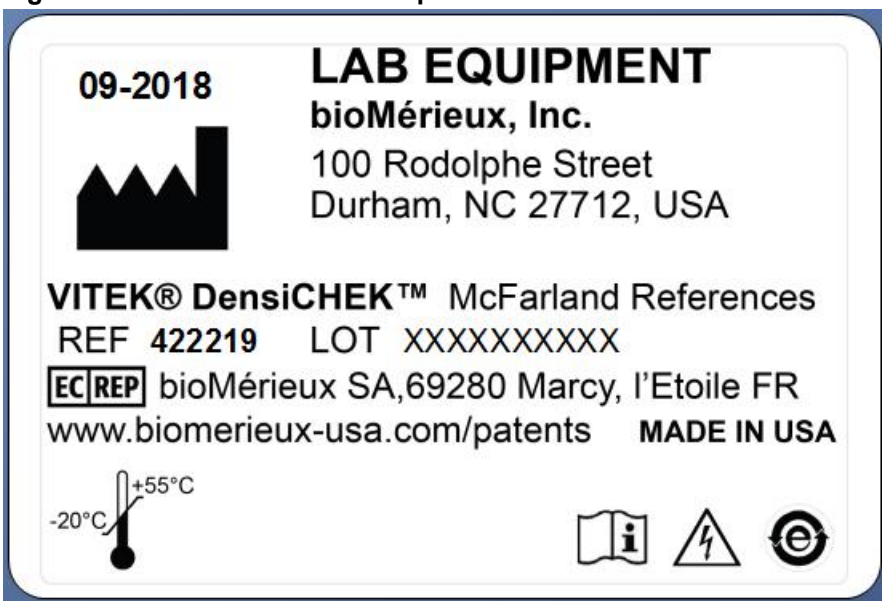
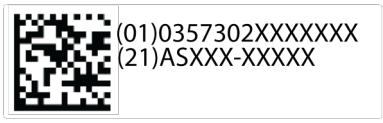


Figure 10: Instrument Label Example - UDI (Intended for the Pod and Base Units)



Safety Precautions

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

WARNING

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

WARNING

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

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

WARNING

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

WARNING

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

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

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

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

WARNING

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

The use of tools not specified by bioMérieux is forbidden.

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

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

WARNING

Handle all materials according to safe microbiological practices in compliance with the installation site's biohazard procedures. Use the personal protective equipment recommended by the facility when handling any of these components, including gloves, safety glasses, and a lab coat.

Ensure that appropriate decontamination is carried out if hazardous materials are spilled on or into the equipment or surrounding areas.

WARNING

⚠ **You must follow the storage and/or transport temperature specifications indicated in this user manual. Failure to do so, may cause the device to malfunction.**

WARNING

⚠ **Other wireless equipment that complies with CISPR8 emission requirements could interfere with the medical device or device system.**

3 System Description and Basic Operations

System Description

The VITEK® DensiCHEK® instrument measures microorganism suspensions for AST and ID testing in support of VITEK® 2 Systems. It measures the McFarland value of a suspension prepared in 0.45-0.50% saline in a polystyrene test tube.

The VITEK® DensiCHEK® instrument contains a base unit with a detachable optical interface, the Pod. With the Pod, the user can visually examine samples with optical readings that are transmitted automatically to the base unit and to the VITEK® 2 software, which allows a user to trace the McFarland values for each specimen prepared.

Note: *The optical readings are sent to the VITEK® 2 software only if the user has the VITEK® 2 software compatible with the VITEK® DensiCHEK® (ex. 9.01 software or later), and has configured it to do so.*

The VITEK® DensiCHEK® instrument has the following features:

- Uses updated optical technologies to determine the turbidity of a suspension, while also continues to support the current McFarland range for VITEK® 2 ID and AST cards and 12 mm x 75 mm test tubes.
- Senses turbidity of suspensions, and provides synergy with the new VITEK® product family.
- Measures across the reading range of 0.20–1.00 McFarland, accurate in the reading range of 0.20 - 1.00 to within +/-0.11 McFarland, when referenced to a calibrated spectrophotometer reading at 635 nm using a reference of *E. coli* (ATCC® 25922).
- Measures across the reading range of 1.01–4.00 McFarland, accurate to within +/-(6.5% +0.06) McFarland, when referenced to a calibrated spectrophotometer reading at 635 nm using a reference of *E. coli* (ATCC® 25922).
- Reads and displays McFarland readings within two seconds of insertion of a tube, without requiring any additions, modifications, or calibration adjustments by the operator (in normal operation).
- Is a handheld, portable accessory for the VITEK® 2 automated ID/AST system.
- Provides an easier way to create a standardized microorganism suspension for improved efficiency in setting up VITEK® 2 ID test cards.
- Contains a rechargeable battery.
- Is available for use 24 hours a day and seven days per week.
- Assists the Laboratory Technologist in easily and accurately preparing a standardized McFarland microorganism suspension.

The instrument is intended for use with pure microorganism cultures. The VITEK® DensiCHEK® instrument is capable of measuring organism suspensions created from the following specimen types:

- Clinical Specimen
- Industry Specimen - Water, air, food samples.

Figure 11: Task Workflow Overview

Reagents

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

List of Components

- VITEK® DensiCHEK® McFarland References Kit
- VITEK® DensiCHEK® Pod (IVD)
- Single USB 2.0 to micro-USB Cable (Included with each Connectivity Base)
- Dual USB 2.0 USB connector to micro-USB Cable, single USB 2.0 to micro-USB Cable, and A/C Power Adapter (Included with each Display Base)

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

List of Accessories

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

- VITEK® DensiCHEK® Display Base
- VITEK® DensiCHEK® Connectivity Base (for the VITEK® 2 software compatible with the DensiCHEK® users)

List of Consumables

- 12 x 75 mm Polystyrene Test Tubes

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

Materials that are required, but not provided with the device include:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks, or swabs
- Appropriate agar medium (See the Culture Requirements Table.)

Optional accessories include:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps

Technical Data and Specifications

The VITEK® DensiCHEK® must be used on a flat, horizontal surface and operated in an area free of dust.

Dimensions

Table 1: VITEK® DensiCHEK® Pod Dimensions

Parameter	Characteristics
Length	76.5 mm
Width	76.5 mm
Height	79.9 mm

Table 2: VITEK® DensiCHEK® Display Base Dimensions

Parameter	Characteristics
Length	121.6 mm
Width	175.0 mm
Height	59.8 mm

Table 3: VITEK® DensiCHEK® McFarland Reference Kit (with Casing) Dimensions

Parameter	Characteristics
Length	120.0 mm
Width	102.0 mm
Height	35.2 mm

Table 4: VITEK® DensiCHEK® Connectivity Base Dimensions

Parameter	Characteristics
Length	95.6 mm
Width	98.0 mm
Height	22.3 mm

Weight

Table 5: VITEK® DensiCHEK® Pod Weight

Parameter	Characteristics
Weight	0.2 lbs/0.09 kg

Table 6: VITEK® DensiCHEK® Display Base Weight

Parameter	Characteristics
Weight	0.6 lbs/0.27 kg

Table 7: VITEK® DensiCHEK® McFarland Reference Kit (with Packaging) Weight

Parameter	Characteristics
Weight	0.21 lbs/0.10 kg

Table 8: VITEK® DensiCHEK® Connectivity Base Weight

Parameter	Characteristics
Weight	0.2 lbs/0.09 kg

Electrical Specifications

Mains Supply

The VITEK® DensiCHEK® Display Base instrument may be powered directly with the customer facility's Mains Supply. The VITEK® DensiCHEK® Display Base or VITEK® DensiCHEK® Connectivity Base instrument may be powered indirectly with the customers USB 2.0 PC.

The USB adapter must follow the specifications identified in the following table:

Specification	Value
Voltage	100-240 VAC
Frequency	50-60 Hz
Current	1A
Power	30 Watts

Note: *The equipment is designed to be connected to building installations which conform to the IEC 60364 standard.*

The USB cable used for the low-voltage connection to the PC must follow the specifications identified in the following table:

Specification	Value
USB 2.0	5 VDC, 0.5A

Radio Specifications

- Blue-tooth 2.4-2.8 GHz (max output 7dBm)
- RFID 200 milliwatts per 2 in - (max output 13.56 MHz)

Environmental Conditions

WARNING

⚠ **You must operate the device within the specified environmental conditions, including the specific ambient laboratory humidity conditions and the specified ambient laboratory lighting conditions. Failing to do so, may cause the device to malfunction.**

The instrument is designed to operate indoors.

The instrument is also intended to be placed on top of a lab bench or a flat, horizontal surface and operated in an area free of dust .

Specification	Value
Pollution degree	2

The device meets the environmental safety requirments defines in clause 1.4 of the standard IEC 61010-1:2010 (Third Addition) and IEC 61010-2-101:2015 (Second Addition)

Environmental Conditions

Table 9: Temperatures for VITEK® DensiCHEK® Instrument and McFarland References

Specification	Value
Operating temperature	15°C to 30°C
Temperature for storage and during shipping	-20°C to 55°C

Humidity

Table 10: Humidity for VITEK® DensiCHEK® Instrument and McFarland References

Specification	Value
Relative humidity	20% to 80% non-condensing
Humidity during storage and transport	20% to 85% non-condensing

Altitude

Specification	Value
Maximum altitude	2000 m

Sound Level

Specification	Value
In Operating Mode	Sound level is lower than 70 dB

Operating Lighting Conditions

Specification	Value
Maximum Ambient Light in In Operating Mode	750 Lux

Computer Specifications

See the *bioMérieux User Management User Manual* for information about accessing, creating, and managing user accounts. Also refer to these user manuals, as well as the *VITEK® 2 FLEXprep™ User Manual*, for information about computer specifications, settings, material properties, performance, and limitations for use.

System Basics

Communication between the Pod and the base unit is via Bluetooth. While off the base, the Pod does not charge and the Pod firmware updates cannot start.

When the Pod is placed on the base unit and paired, firmware updates can be completed and the Pod battery can be charged.

The Pod must be within 10 meters of the base in order for the Bluetooth to function properly. If the Pod is out of Bluetooth range, then the device fails to pair.

The following figures demonstrate the possible configurations for the device.

Figure 12: VITEK® DensiCHEK® System Configurations - Display Base