DensiCHEK™ plus

Instrument User Manual

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Liability Disclaimer

bioMérieux, Inc. makes no express or implied warranty regarding this manual, its quality, performance, or appropriate use regarding any type of specific procedure.

Furthermore, this manual may be modified by bioMérieux without notice and without implying any obligation or liability on the part of the company.

Intellectual Property

Warranty

Seller, bioMérieux, Inc., warrants the DensiCHEK™ Plus 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, 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 be not 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 warranted to be new or equivalent to new for the full product warranty period of one year. Disposables and replacement items with a normal expectancy of less than one (1) year, such as batteries and bulbs, are excluded from this warranty.

STANDARD SYMBOLS

The following table presents symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging.

	CE-Marking of Conformity
	Consult Instructions for Use
	Use by
	Manufacturer
	Caution, consult accompanying documents
	In Vitro Diagnostic Medical Device
	Batch code
	Authorized Representative in the European Community
	Catalog number
	Serial Number
	Recyclable
	Separate collection for waste electrical and electronic equipment
	Environmentally friendly use period. Actual number of years may vary by product.

GENERAL WARNINGS

Warnings, Cautions, and Information

This manual uses different types of symbols to alert you to important information. Symbols and their associated information are labeled in text where they occur and set off from surrounding paragraphs, as shown in the following examples.

WARNING

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

CAUTION: Caution is a statement that 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: ***Important relates to content presented in this manual. It is used to reinforce the importance of your understanding or remembering something.***

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

General Warnings

BIOHAZARD WARNING

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 the user of this instrument to establish and follow appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

BIOHAZARD WARNING

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

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 for its appropriate disposal.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in a hazard to the user.

DENSICHEK™ PLUS

Intended Use

The DensiCHEK Plus instrument is intended for use with the VITEK® and VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to microorganism concentrations. DensiCHEK Plus is indicated for use with polystryrene and glass tubes, and the reading range is 0.0 to 4.0 McFarland. The DensiCHEK Plus has applications as an *in vitro* diagnostic medical device.

Introduction

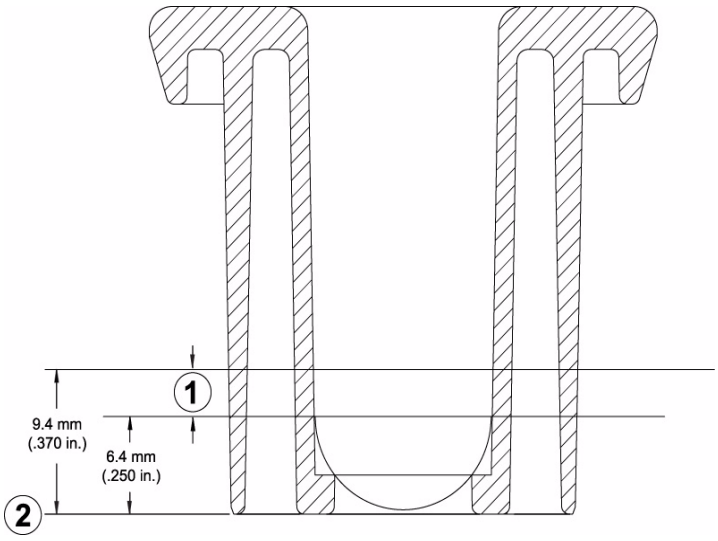
This section provides important information about the DensiCHEK Plus. Please read this manual carefully before attempting to operate this device.

1. Familiarize yourself with the components and functions of the DensiCHEK Plus before operating.
2. The DensiCHEK Plus requires four AAA alkaline (recommended) or four AAA NiMH (Nickel-metal hydride) rechargable batteries. Batteries are not shipped in the DensiCHEK Plus and must be installed prior to use. Refer to Battery Installation on page 3 for the correct procedure.
3. To prolong the life of the DensiCHEK Plus and to ensure accurate results, bioMérieux recommends the following:
   - Press the **Power** key only when ready for testing.
   - The DensiCHEK Plus comes with alkaline batteries that should be good for approximately 90 days (based on usage of device at 300 readings per day). The

Low Battery symbol is displayed with approximately 10% battery life remaining. The Low Battery symbol will flash when measurements are no longer allowed and batteries must be replaced to obtain measurements.

- If using NiMH rechargable batteries, battery life lasts for approximately 30 days (based on usage of device at 300 readings per day). The Low Battery symbol is displayed with approximately 2% battery life remaining. The Low Battery symbol will flash when measurements are no longer allowed and batteries must be replaced to obtain measurements.
- For VITEK® System, use clean 12mm x 75mm glass or polystyrene test tubes that are clear, colorless, and free of scratches.
- For VITEK® 2 Systems use clean 12mm x 75mm polystyrene test tubes that are clear, colorless, and free of scratches. Do not use glass tubes.
- When inserting a test tube or standard, ensure that it is fully seated in the adaptor.
- If the test tube fits tightly, stabilize the DensiCHEK Plus while removing tubes for easier removal.
- Each type of test tube (manufacturer or part number) must be zeroed prior to use (Refer to Zeroing on Saline Filled Test Tube on page 8).
- The DensiCHEK Plus instrument will automatically shut off power when test tubes are not inserted after one minute.
- Do not leave the test tube in the DensiCHEK Plus after completion of a reading.
- Do not use test tubes that contain seams in the optical path of the reading chamber. The position of the optical path is shown in Figure 1.

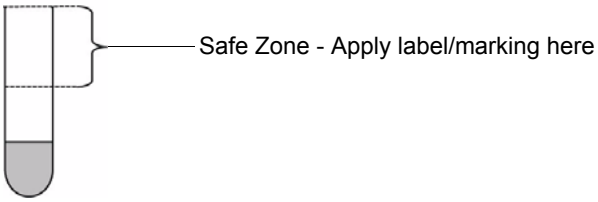
FIGURE 1: Optical Path Area



1 — No Seam allowed in this optical path reading area

2 — Bottom of test tube

IMPORTANT: ***If your laboratory workflow requires application of a sample identification on the organism suspension tube, then the following guidelines must be followed to ensure accurate optical density readings from the DensiCHEK Plus.***



- Apply all labels or markings from the middle of the test tube to the top of the tube (Safe Zone). Do not place any labels or markings from the center to the bottom of the tube as readings occur in this area.

4. The DensiCHEK Plus should always be used on a flat, horizontal surface and operated in an area free of dust.
5. When unpacking the DensiCHEK Plus Kit (21250), verify the following items are included:
   - DensiCHEK Plus Instrument
   - Four AAA batteries
   - Instrument User Manual
   - Product Certificate
6. The packing materials should be retained in case the instrument needs to be returned to bioMérieux.

Battery Installation

The battery compartment is located on the bottom of the instrument and holds four AAA batteries. Use only alkaline or NiMH type batteries.

WARNING

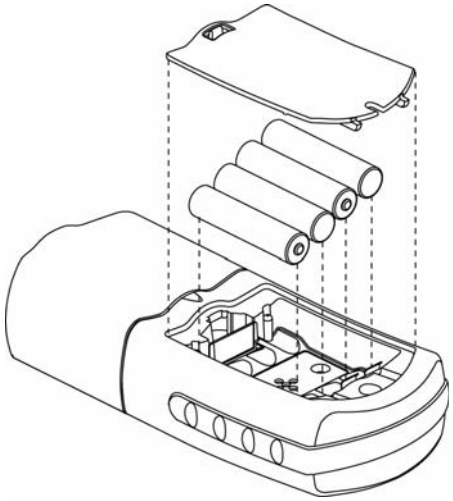
DO NOT use high-energy type AAA batteries, such as lithium or NiCad batteries in the instrument.

Install the batteries as follows (see Figure 2):

1. Remove the battery compartment cover. The polarities are shown in the battery compartment.
2. Place the four batteries provided with the instrument in the battery compartment as indicated and replace the cover.

Note: *When replacing the batteries, it is necessary to respect the correct polarity according to the graphic symbols inside the battery compartment.*

FIGURE 2: Battery Installation



3. Select a clean test tube and visually confirm that it is free from scratches.
4. Fill the test tube with sterile saline and place in the test tube adaptor.

CAUTION: When batteries are installed or replaced, the tube type setting will be set back to instrument default - PLASTIC. Refer to Changing Tube Type Settings on page 6 if you are using glass tubes.

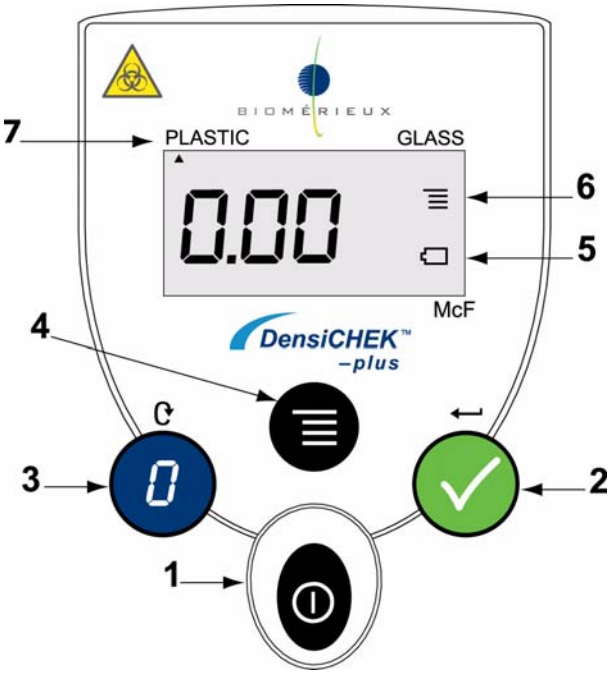
5. Press the **Power** key to turn on the instrument.

Note: *When turning the instrument on, if the power key is held down for one second or more, all segments of the display will turn on. When the power key is released, the firmware version is displayed for two seconds before returning to the measurement screen.*

6. The instrument display will flash a zero. Press the **Zero/Scroll** key. The instrument will show a series of dashes followed by 0.00.
7. The instrument is now ready for use.

Display and Keypad Functions

FIGURE 3: DensiCHEK Plus Display



1 — **Power Key**

2 — **Read/Enter Key**. Allows the user to manually initiate a reading. In menu mode, selects a menu option.

3 — **Zero/ Scroll Key**. In measurement mode, sets the instrument to zero. In menu mode, scrolls through menu options. Also scrolls when entering or editing the time.

4 — **Menu Key**. Enter/Exit the menu mode.

5 — **Battery Low Indicator**. Displayed when 10% battery life remaining for alkaline and 2% for NiMH is remaining. When flashing, the batteries are too low to complete measurements.

6 — **Menu Indicator**. Displayed when in Menu Mode.

7 — **Tube Type Setting**. Indicates one of two tube type settings. The instrument default is set to Plastic. If the left triangle is displayed, the PLASTIC tube setting is being used. If the right triangle is displayed, the GLASS tube setting is being used.

CAUTION: Ensure the tube type setting is set to the tube type in use, either plastic or glass. Failure to set the tube type setting correctly will affect inoculum density and can cause incorrect ID and AST card results.

Setting The Time

1. Press the **Menu** key, then press the **Zero/Scroll** key until the display shows a time in the 00:00 format.

2. Press **Read/Enter**. The digit to be edited will flash.
3. Use the **Zero/Scroll** key to change the entry, then press **Read/Enter** to accept and advance to the next digit. The time is entered in 24-hour format.
4. After setting last digit, press the **Menu** key to exit mode.

Changing Tube Type Settings

IMPORTANT: The factory default setting is PLASTIC.

To change the setting being used, follow the steps below:

1. Press the **Menu** key. SEL and a triangle will be flashing for the current setting.
2. Press the **Read/Enter** key to move the triangle.
3. When the triangle is pointing at the setting to be used, press the **Menu** key.

Recalling Stored Measurements

To access the last 10 stored measurements, follow the steps below:

1. Press the **Menu** key, then press the **Zero/Scroll** key until the display shows rCL.
2. In RCL mode, press **Read/Enter** to recall the stored measurements, beginning with the most recent measurement taken. The instrument stores the measurement number as 01 (most recent) through 10 (oldest), measurement value, and the time the measurement was taken. The **Zero/Scroll** key allows for selection of a specific measurement by number. The **Read/Enter** key scrolls through all stored data points.
3. To exit the RCL mode, press the **Menu** key.

Cleaning

The surface of the DdensiCHEK Plus may be cleaned by using a damp cloth and 10% chlorine bleach solution, 3-25% hydrogen peroxide solution, or commercial quaternary ammonium compounds.

CAUTION: Do not use alcohol to clean the instrument. Use of alcohol may damage the reading lens.

Test Tube Adaptor and Reading Chamber

The test tube adaptor can be removed by lifting it out of the reading chamber. If the contents of a test tube accidentally spills on the DensiCHEK Plus, it may be necessary to remove the test tube adaptor and decontaminate using the following steps:

1. Remove the test tube adaptor from the reading chamber and place the adaptor in a cleaning solution of 10% chlorine bleach solution, 3-25% hydrogen peroxide, or commercial quaternary ammonium compounds.

2. Fully immerse test tube adaptor in plain water.
3. Place the test tube adaptor on a lint free cloth to air dry completely.
4. Use a swab containing one of the above listed cleaning agents to wipe the reading chamber surfaces. Wipe clear circular windows on opposite sides of reading chamber with lens paper or soft dry cloth.
5. Replace the test tube adaptor in the reading chamber and ensure the adaptor is well seated in the reading chamber. Perform instructions described in Instrument Verification on page 7.

Instrument Verification

Verify the DensiCHEK Plus measurement performance using one or more of the McFarland standards (0.5, 2.0 or 3.0) after zeroing the instrument with the 0.0 McF Standard (blank):

- upon receipt and prior to first use
- according to your local regulatory guidelines or at least on a monthly basis

IMPORTANT: ***Before using Standards to verify measurement performance, confirm the GLASS tube setting is displayed. (Refer to Changing Tube Type Settings on page 6).***

1. Select the 0.0 McF Standard and clean the outside surface with a lens tissue.
2. Gently invert the 0.0 McF Standard five to six times to ensure it is homogeneous.

CAUTION: Do not shake the Standard. Air bubbles will affect readings.

3. Ensure the instrument is on and insert the 0.0 McF Standard into the instrument and press the **Zero/Scroll** key. Slowly rotate the standard one full rotation. The instrument will display a series of dashes followed by 0.00.
4. Select the desired Standard (0.5, 2.0 or 3.0) and clean the outside surface with a lens tissue.
5. Gently invert the standard five to six times to ensure it is homogeneous.
6. Insert the Standard into the instrument and rotate slowly one full rotation until a numerical value is displayed.
7. Check that the displayed McFarland value is within the acceptable range.

Table 1: Standard Acceptable Range

Standard	Acceptable Range	
0.5 McF	0.44	0.56
2.0 McF	1.85	2.15
3.0 McF	2.79	3.21

8. Repeat steps 5 – 7 for the remaining Standards as desired.

CAUTION: If any Standards are outside of the acceptable range, repeat the steps in Instrument Verification. If your standard is still out of range, contact bioMérieux Technical Support.

9. If the Standards are within the acceptable range, proceed to Zeroing on Saline Filled Test Tube.

Zeroing on Saline Filled Test Tube

This procedure must be performed whenever a new type of test tube (such as a new manufacturer or part number) is used to ensure proper accuracy.

1. Select a clean test tube and visually confirm that it is free from scratches.
2. Fill the test tube with sterile saline.
3. With the instrument powered off, insert the saline filled test tube into the instrument.
4. Press the **Power** key to turn the instrument on.
5. Ensure the correct tube type setting for plastic or glass is selected.
6. Press the **Zero/Scroll** key and slowly rotate the test tube. Ensure one full rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by 0.00.

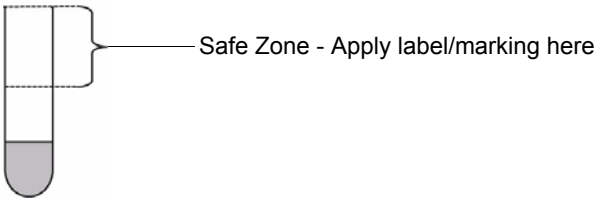
Preparing Inoculum Suspensions

WARNING

POTENTIAL BIOHAZARDOUS MATERIAL! Instrument surfaces and contaminated test kit components are potentially biohazardous. Handle them according to good laboratory practices. Observe universal precautions when you operate the device, and when you perform maintenance or troubleshooting.

CAUTION: Ensure the tube type setting is set to the tube type in use, either plastic or glass. Failure to set the tube type setting correctly will affect inoculum density and can cause incorrect ID and AST card results.

IMPORTANT: ***If your laboratory workflow requires application of a sample identification on the organism suspension tube, then the following guidelines must be followed to ensure accurate optical density readings from the DensiCHEK Plus.***



- Apply all labels or markings from the middle of the test tube to the top of the tube (Safe Zone). Do not place any labels or markings from the center to the bottom of the tube as readings occur in this area.

1. Prepare an inoculum suspension using defined procedures in the appropriate documentation:
   - VITEK® Systems: Refer to the *VITEK® Microbiology Reference Manual*.
   - VITEK® 2 Systems: Refer to the *VITEK® 2 Systems Product Information*.
2. Press the **Power** key to turn the instrument on.
3. Place the well-mixed organism suspension into the instrument and slowly rotate the test tube. Ensure one full rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by a reading.
4. Check that the displayed McFarland value is within the acceptable range for the organism tested.

Table 2: Organism Suspension Range

ACCEPTABLE RANGE	VITEK® CARD	VITEK® 2 CARD
0.50 – 0.63	N/A	GN, AST GN
	GPI, GPS	GP, AST GP
0.90 – 1.10	GNI+, GNS	N/A
1.80 – 2.20	YBC	YST, AST YS
2.70 – 3.30	NHI	NH
	ANI	ANC

Note: *If the instrument flashes 0.00 or 4.00, the suspension is either below 0.0 McF or above 4.0 McF and is not within the acceptable range.*

Note: *If the displayed value is not within an acceptable range, adjust the suspension by adding organism or saline to achieve a suspension that falls within the range.*

CAUTION: When switching test tube manufacturer or type, repeat steps in Zeroing on Saline Filled Test Tube on page 8.

5. Fill bioMérieux cards according to the appropriate documentation:
   - VITEK® Systems: Refer to the *VITEK® Microbiology Reference Manual and the VITEK® Instrument and Accessories Manual*.
   - VITEK® 2 Systems: Refer to the *VITEK® 2 Systems Product Information* and the appropriate Instrument User Manual.

Troubleshooting

The DensiCHEK Plus instrument is designed to require a minimum of maintenance. If the instrument fails instrument verification or error messages are displayed, follow the troubleshooting steps below. For problems of a more complex nature, contact bioMérieux.

Table 3: Troubleshooting Steps

Symptom	Probable Cause	Corrective Action
Test results are inconsistent	Test tubes may be dirty or scratched (inside or outside).	Replace the test tubes as required.
	Test tubes may not be filled to sufficient level.	Adjust liquid level.
	Instrument is not zeroed on type of test tube in use.	Zero on tube type in use. Perform the following procedure, Zeroing on Saline Filled Test Tube on page 8.
	Test tube does not meet criteria as described on page 2.	Confirm test tube meets all criteria or select new tube type.
	Test tube adaptor is not correctly inserted.	Ensure test tube adaptor is fully seated in the reading chamber.
	Test tube not seated in adaptor.	Make sure test tube is seated in adaptor.
Flashing "0"	1) Removal of batteries. 2) Momentary loss of power.	Reseat batteries and follow Battery Installation on page 3.
Error Message on Display E-1	Ambient light is too bright to make an accurate measurement.	Relocate instrument away from bright light sources.
Error Message on Display E-2	Error occurs when the LED (light source) is out of tolerance.	Replace the batteries as described in Battery Installation on page 3. Remove the test tube adaptor and verify the LED flashes (inside the cell holder) when **Read/Enter** is pressed.
Error Message on Display E-9	The instrument is unable to save data.	Contact bioMérieux Technical Support.

Characteristics

Table 4: Physical Characteristics

Portable	
Height	15.5 cm (6.2 in.)
Width	6.1 cm (2.45 in.)
Depth	3.5 cm (1.4 in.)
Weight	0.23 kg (0.5 lb) without batteries

Table 5: Environmental Characteristics

Indoor, laboratory environment for operation	
Altitude	Up to 2,000 meters (6562 ft)
Temperature	Storage: -20 °C to 55 °C (-7.6 °F to 131 °F) Operating: 15 °C to 30 °C (59 °F to 86 °F)
Relative Humidity	Storage: 20% to 85% non-condensing Operating: 20% to 80% non-condensing