Figure 37: AC/DC Adapter - Back View

Related Links

Graphical User Interface
Display Base Screen
FLEXprep Software Interface Screen

Figure 38: Connectivity Base with Cable (Single USB 2.0 to micro-USB)

Charging the Pod

1. Ensure the base is plugged into a power source. (See above: Connecting the Device.)

Note: *To use the instrument, the base unit must have power applied.*

2. Place the Pod on the base unit.

   The Pod charges while placed on the base unit.The status of the Pod battery life can be viewed on the Display Base or the FlexPREP software.

Note: *The Pod will continue to charge, even if the display of the Display Base is asleep.*

Pairing a Pod with a Base

1. Ensure the base unit is plugged into a power source.

   A blinking red light on the Pod indicates that the Pod is not synced to the base unit.
2. Place the Pod on the base unit.

Note: *No illumination of the light indicates that the Pod is not charged.*

Note: *If the Pod was previously paired with a base, once the Pod is within range of the base unit, the Pod LED stops flashing red and turns the solid pairing color that was previously configured.*

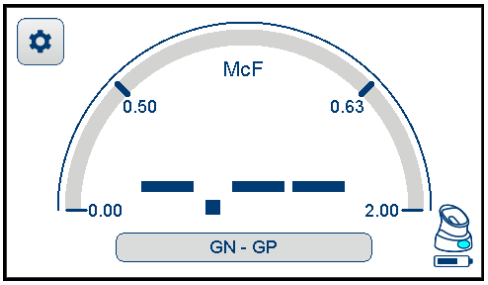
A solid colored light on the Pod matching that of the base indicates that the Pod is synced to the corresponding base unit.

Configuring the Display Base Settings

Customize your Display Base screen to select LED colors, adjust brightness, and more.

1. Place the Pod on the Display base unit.

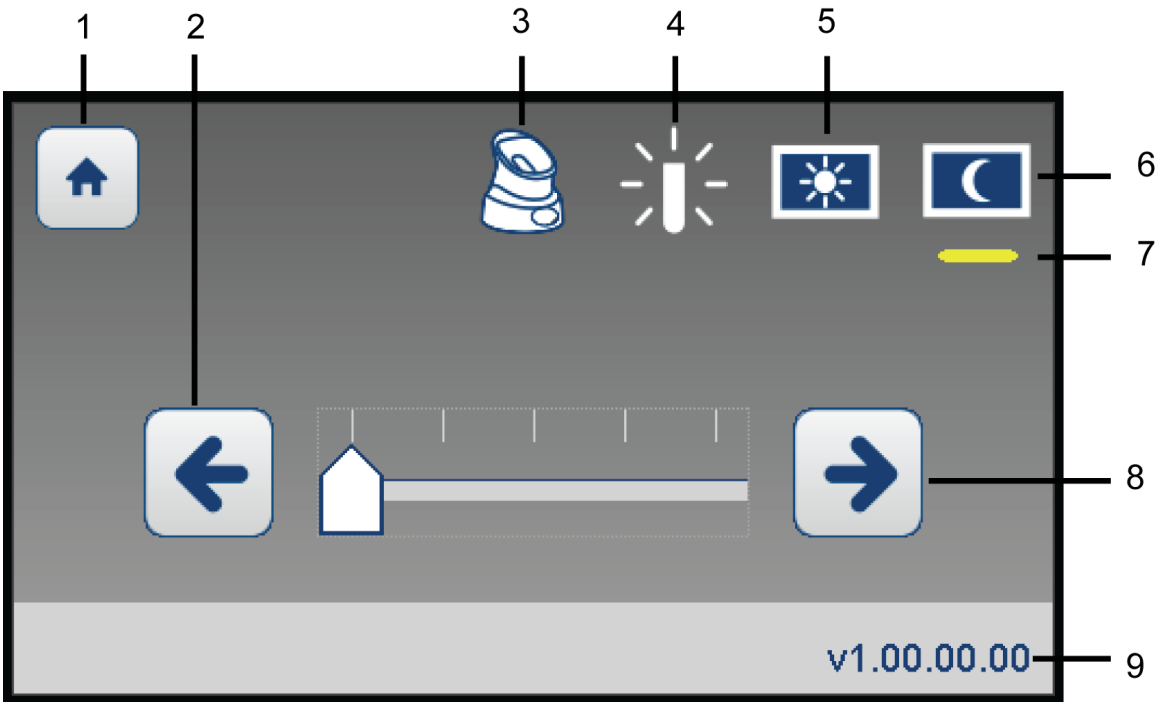
Figure 39: Display Base - McFarland Screen - No tube is inserted



A solid colored light on the Pod matching that of the base unit indicates that the Pod is synced to the base unit. The Display Base lights up and shows dashes for the **McFarland** value.

2. Tap the **Configuration** button  .

Figure 40: Configuration Screen



1. **Home** button
2. **Left (Decrease) Arrow** button
3. **Pod Pairing Color** button
4. **Tube Light Intensity** button
5. **Display Brightness** button
6. **Base Sleep Time** button
7. **Selection Indicator**
8. **Right (Increase) Arrow** button
9. Firmware Version

The **Configuration** screen appears.

3. Tap the **Pod Pairing Color** button, and tap the **Left Arrow** or **Right Arrow** buttons to change the pairing LED color (ex. cyan, blue, pink, white, green, or yellow LED light options).
4. Tap the **Tube Light Intensity** button, and tap the **Left Arrow** button to decrease the LED brightness, or click the **Right Arrow** button to increase the LED brightness.
5. Tap the **Display Brightness** button, and tap the **Left Arrow** button to decrease the LCD screen brightness, or click the **Right Arrow** button to increase the LCD screen brightness.
6. Tap the **Base Sleep Time (min)** button, and tap the **Left Arrow** button to decrease the amount of time before Power Save mode automatically turns on, or click the **Right Arrow** button to increase the amount of time before Power Save mode automatically turns on.

Note: *In the **Base Sleep Time** configuration screen, the zero setting (far left) disables the Power Save mode, so the base screen never turns off. The incremental marks represent 5, 10, 20 and 30 minutes from left to right, which is the amount of time that must occur before the base unit enters Power Save mode.*

7. Tap the **Home** button to return to the McFarland Reading screen.

Note: *A Pod sitting on the Display Base will continue to charge even when the Display Base is asleep.*

Configure FLEXprep™ with the Instrument

To use the FLEXprep™ software with the VITEK® DensiCHEK® instrument, you must complete the following configuration tasks:

1. Downloading and Installing the DensiCHEK® Communication Bridge
2. Configuring the DensiCHEK® Certificates in FLEXprep™
3.

These tasks must be completed in the order written before using the FLEXprep™ program with your VITEK® DensiCHEK® instrument.

Note: *These configurations must be completed for every VITEK® 2 System PC and remote PC accessing FLEXprep™*

Related Links

Graphical User Interface
Display Base Screen
FLEXprep Software Interface Screen
Downloading and Installing the DensiCHEK Communication Bridge
Configuring the DensiCHEK Certificates in FLEXprep
Downloading and Installing the DensiCHEK Communication Bridge

Optional: You can customize your VITEK® DensiCHEK® Connectivity Base settings through FLEXprep™ by performing the Configuring the Connectivity Base Settings procedure.

Downloading and Installing the DensiCHEK® Communication Bridge

1. Ensure the instrument is connected to a VITEK® 2 PC or a remote PC that's accessing FLEXprep™, and the PC desktop is displayed.
2. Click the **VITEK 2 System** (legacy) icon on the Desktop.
3. Log in to the system software.

   Administrator or Supervisor level login access is required. Refer to the VITEK 2 Systems Software User Manual or the VITEK 2 Systems Web Software User Manual for information about accessing, creating and managing user accounts.
4. When the VITEK® 2 home screen appears, click the **Configuration View** icon, and then click **General Configuration**.

   The **System** screen appears.
5. Click the **Unlock** icon at the top-middle of your screen, and then click **Yes** to continue.
6. Click the **Settings** tab, and then under the **Miscellaneous** section, select the **Enable McFarland** checkbox.

   Refer to *VITEK® 2 System User Manuals* for more user information regarding the additional setting options.

Note: *Once Enable McFarland is saved, it is configured for all users. You cannot configure this setting differently for each user from the VITEK 2 System application. However, you will configure user settings in FLEXprep, as described in the following steps.*

7. Click **Save**.Click the Lock icon and then Quit or Close the VITEK 2 Systems application.

8. For the VITEK® 2 PC, access FLEXprep™ on the desktop, and then double-click the **FLEXprep** icon. For a remote PC, access FLEXprep™ by launching the Firefox® browser. Refer to the FLEXprep™ User Manual for configuration of FLEXprep™ from a remote PC.

Note: *If Firefox browser states "Your connection is not secure", refer to the VITEK 2 Systems Web Software User Manual for instructions about adding Exceptions.*

The FLEXprep™ program launches in a Firefox browser window.

9. At the **bioMérieux Single Sign-On** screen, log in with the appropriate lab credentials.

Note: *See the VITEK® 2 Systems Software User Manual or the VITEK® 2 Systems Web Software User Manual and the bioMérieux User Management User Manual for information about accessing, creating, and managing user accounts.*

To reconfigure your FLEXprep™ settings or certificates, refer to the VITEK® 2 FLEXprep™ User Manual.

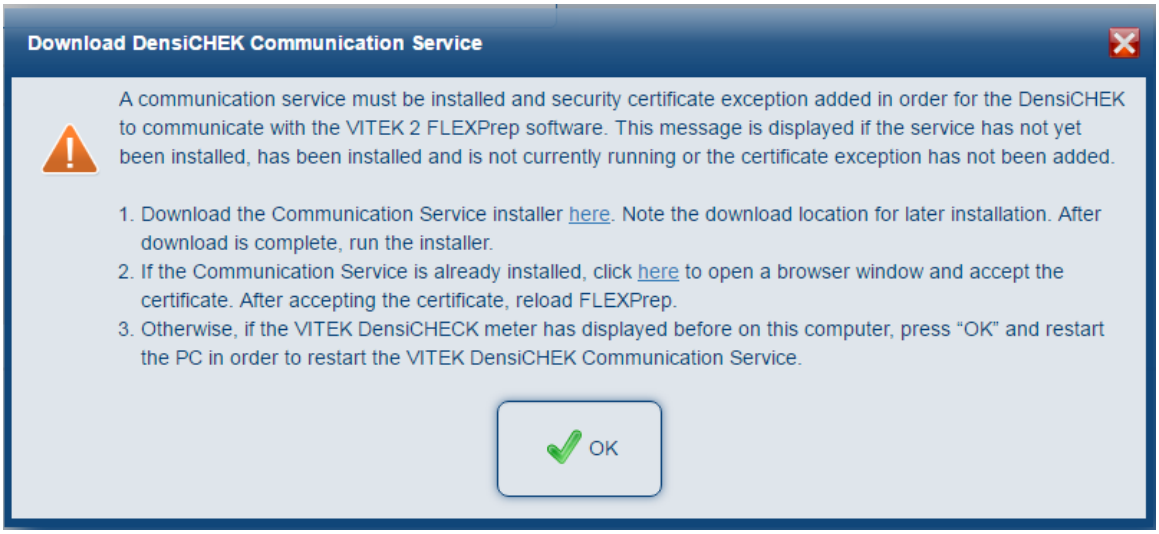
The FLEXprep™ home screen appears with the **Sample Preparation** and **Configuration** options.

10. Click **Configuration**, and for the **Display McFarland**, and the **Use VITEK DensiCHEK** options, select **Yes**.

Note: *This configuration must be completed for each VITEK® 2 System user. Once it is configured, it is only configured for that particular user.*

11. Shortly thereafter, the Download DensiCHEK Communication Service window appears to alert you that installation of the Communication service is needed.

Figure 41: Download DensiCHEK Communication Service Window



12. Remove all USB memory devices, CDs, and DVDs.
13. After reading the Communication Service Window instructions, follow step 1 by clicking the **link here**. The **Opening install-dce-bridge.exe** window appears.
14. Click **Save File**.
15. When the File Explorer appears ensure that **Downloads** folder is selected, and then click **Save**. The file will download into the **Downloads** folder. The download may take several minutes to finish.
16. Navigate to the **Downloads** folder, locate the **install-dce-bridge.exe** file, and then double-click it to execute the file installation.

Note: *This Language selection is only for the text display of the InstallAnywhere wizard. Language options: English, French, German,Italian, Portuguese, Spanish.*

17. If the **Open Executable File?** warning appears, click **OK**.
18. If the **User Account Control** warning appears, click **Yes**. (This may appear as a flashing shield in the Windows task bar which you must first click.)
19. Select your corresponding language from the dropdown and click **OK**.
20. The **DensiCHEK Bridge 1.0** install wizard launches. When the "Congratulations! DensiCHEKBridge has been successfully installed" message appears, keep all the default settings "Yes, restart my system", and click **Done**.
21. If the computer does not restart automatically, from the desktop restart the computer to complete the install.

Configuring the DensiCHEK® Certificates in FLEXprep™

Note: *This configuration must be completed for every VITEK® 2 System PC and remote PC accessing FLEXprep™. Once it is configured, it is configured for all users. You cannot configure these settings differently for each user.*

Note: *Administrator or Supervisor level login access is required. Refer to the VITEK 2 Systems Software User Manual or the VITEK 2 Systems Web Software User Manual for information about accessing, creating and managing user accounts.*

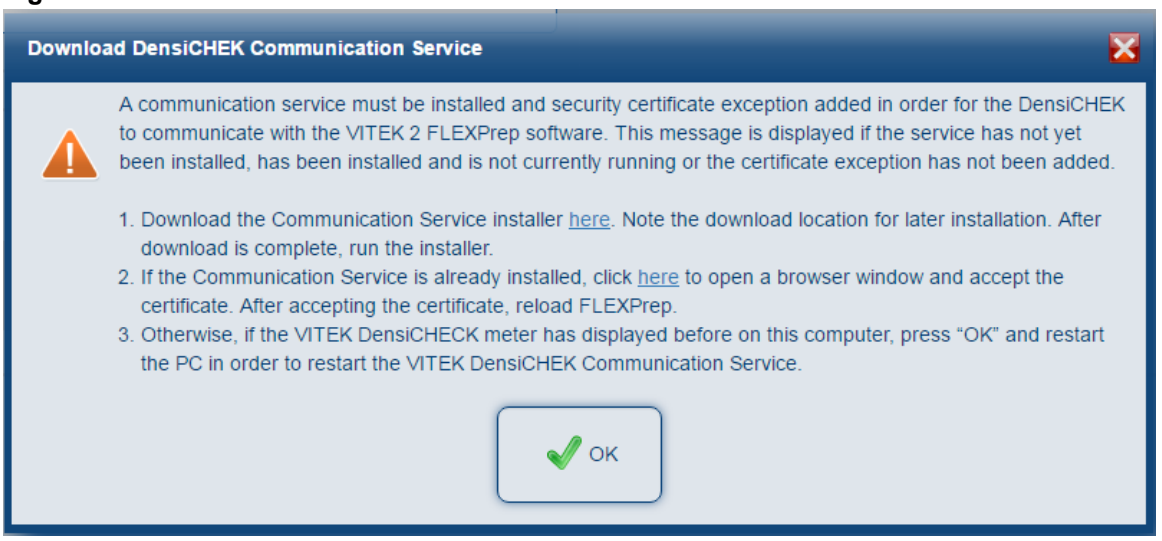
1. For the VITEK® 2 PC, access FLEXprep™ on the desktop, and then double-click the **FLEXprep** icon. For a remote PC, access FLEXprep™ by launching the Firefox® browser. Refer to the *FLEXprep™ User Manual* for configuration of FLEXprep™ from a remote PC.

   The FLEXprep™ program launches in a Firefox browser window.
2. At the **bioMérieux Single Sign-On** screen, log in with the appropriate lab credentials.

Note: *See the VITEK® 2 Systems Software User Manual or the VITEK® 2 Systems Web Software User Manual and the bioMérieux User Management User Manual for information about accessing, creating, and managing user accounts.*

To reconfigure your FLEXprep™ settings or certificates, refer to the VITEK® 2 FLEXprep™ User Manual.

Figure 42: Download DensiCHEK Communication Service Window



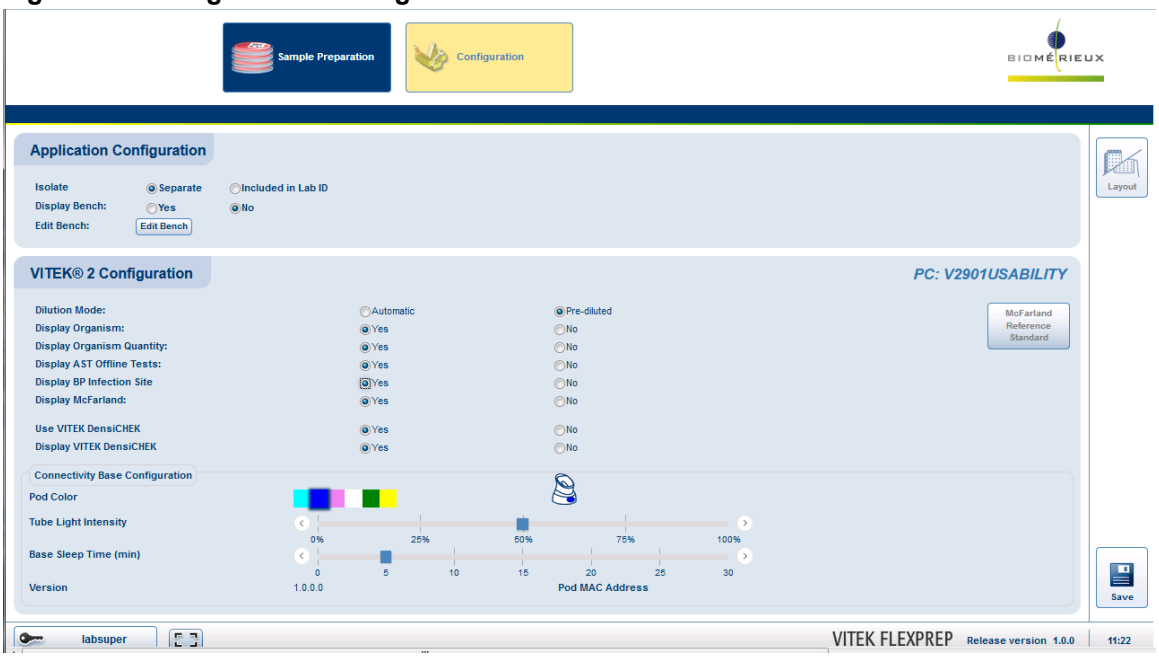
3. After reading the instructions, follow step 2 by clicking **Click Here**.
   Certificates have to be configured to use the VITEK® DensiCHEK® with FLEXprep™.
   A tab appears that states, Your connection is not secure, indicating that certificates have not been accepted yet.
4. Click **Advanced**.
   Information appears about security certificates.
5. Click **Add Exception**.
   The **Add Security Exception** window appears.
6. Keep the default settings and click **Confirm Security Exception**.
   The screen is refreshed, and the version is displayed in the top-left corner.
7. Close the current tab.
   The FLEXprep™ screen reappears.
8. In the **Download DensiCHEK Communication Service** window, click **OK**.
9. Close and re-open FLEXprep™ to refresh the settings.
10. Re-login to FLEXprep.
11. Click the **Save** button, and click **OK**.

Configuring the Connectivity Base Settings

You can customize your VITEK® DensiCHEK® Connectivity Base settings through FLEXprep™.

With the compatible VITEK® 2 software, you can customize your screen to select your LED colors, adjust your brightness, and more on the VITEK® 2 Systems PC by launching the VITEK® FLEXprep™ program.

Figure 43: Configuration Settings



Note: *This configuration must be completed for every VITEK® 2 System PC and remote PC accessing FLEXprep™. Once it is configured, it is configured for all users. You cannot configure these settings differently for each user.*

1. Ensure the instrument is connected to a VITEK® 2 PC or a remote PC that's accessing FLEXprep™, and the PC desktop is displayed.
2. Place the Pod on the base unit.

   A solid colored light matching that of the base unit indicates that the Pod is synced to the base unit.
3. For the VITEK® 2 PC, access FLEXprep™ on the desktop, and then double-click the **FLEXprep** icon.

   The FLEXprep™ program launches in a Firefox browser window.
4. At the **bioMérieux Single Sign-On** screen, log in with the appropriate lab credentials.

Note: *See the VITEK® 2 Systems Software User Manual or the VITEK® 2 Systems Web Software User Manual and the bioMérieux User Management User Manual for information about accessing, creating, and managing user accounts.*

To reconfigure your FLEXprep™ settings or certificates, refer to the VITEK® 2 FLEXprep™ User Manual.

The FLEXprep™ home screen appears with the **Sample Preparation** and **Configuration** options.

5. Click **Configuration**, and navigate to the **Connectivity Base Configuration** section.

   The **Connectivity Base Configuration** settings only appear if the VITEK® DensiCHEK® Communication Bridge is set up in FLEXprep™ and if a Connectivity Base is connected to the VITEK® 2 PC.
6. For the **Pod Color**, select a color to change the pairing LED color (ex. cyan, blue, pink, white, green, or yellow LED light options).

   A solid colored light matching that of the base unit indicates that the Pod is synced to the base unit.

7. For the **Tube Light Intensity**, click the left/right arrow to decrease/increase the LED brightness or click the scale to adjust it from 0-100% brightness.
8. For the **Base Sleep Time (min)**, click the left/right arrow to decrease/increase the amount of time or click the scale to adjust it from 0-30 minutes before the Power Save mode automatically turns on.

Note: *In the **Base Sleep Time** configuration screen, the zero setting (far left) disables the Power Save mode, so the base power never turns off. For the 5-30 minute values, the value indicates the amount of inactivity time in minutes that must occur before the base unit and the Pod enters Power Save mode.*

9. Click **Save**.

   The **Confirmation** message appears.
10. Click **OK** to save the settings.

IMPORTANT: ***The contents of your VITEK® 2 cassette is discarded upon saving the configuration if the cassette has not been sent to the VITEK® 2 server.***

The settings have been updated and the pairing color changes.

User Management

See the *VITEK® 2 Systems Software User Manual* or the *VITEK® 2 Systems Web Software User Manual* and the *bioMérieux User Management User Manual* for information about accessing, creating, and managing user accounts. Refer to these documents for a list of all possible user groups and rights.

5 Workflow and Instructional Procedures

Starting the System

The base unit must be plugged in, and the Pod must be charged by placing it on the base. Before use, the device is in Power Save mode. The device turns on once a tube is inserted into the Pod when the display screen is tapped, or when the Pod is removed and re-seated onto the base unit.

Note: *In the **Base Sleep Time** configuration screen, the zero setting (far left) disables the Power Save mode, so the base power never turns off. For the 5-30 minute values, the value indicates the amount of inactivity time in minutes that must occur before the base unit and the Pod enters Power Save mode.*

For instructions to start the VITEK® 2 software and PC compatible with the device, refer to the VITEK® 2 User Manuals.

Shutting Down the System

After the configured amount of time, the instrument enters Power Save mode. The amount of time before entering the Power Save mode can be chosen by the user on the **Configuration** screen. The default amount of time is five minutes. The device turns on again once a tube is inserted into the instrument, or once the base screen is touched. A base unit also turns off if it is unplugged. When the Display Base enters Power Save mode, the display screen turns off and the Pod pairing light blinks.

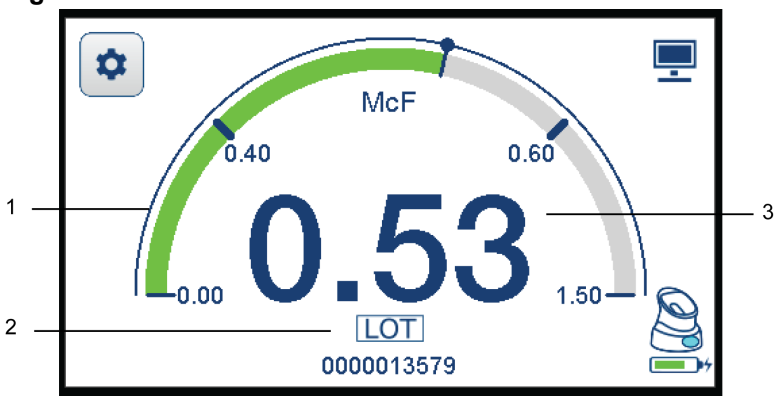
Note: *In the **Base Sleep Time** configuration screen, the zero setting (far left) disables the Power Save mode, so the base power never turns off. For the 5-30 minute values, the value indicates the amount of inactivity time in minutes that must occur before the base unit and the Pod enters Power Save mode.*

When the Connectivity Base enters Power Save mode, the base pairing light blinks and the Pod pairing light blinks. However, if the Pod is on the Connectivity Base when the device enters Power Save mode, the base light remains on, without blinking.

Understand McFarland Reference Ranges

The McFarland References are labeled with values to indicate a target range. When a McFarland Reference is inserted, a screen similar to the following appears:

Figure 44: McFarland Reference Screen



1. McFarland Range Meter
2. LOT Number (Received from RFID tag)
3. McFarland Reference Value

The screen is different from the normal **McFarland** screen, because a LOT number appears.

The McFarland Reference value is recorded in the RFID tag. The McFarland meter appears green when the device is reading within the acceptable ranges. Additionally, the McFarland Status light on the Pod indicates the status of the McFarland Reference--red indicates a failing value and green indicates a passing value.

This must be confirmed in order for users to determine that the McFarland References and the device are working properly.

Table 13: Values for McFarland References

McFarland Reference	Acceptable Range	Explanation
0.0 McF	N/A	This McFarland Reference must be used before inserting a 0.5, 2.0, or 3.0 McFarland Reference. It is specific to the McFarland Reference set and must not be used with a different set. After completing the McFarland Reference checks, you must perform the Zeroing Saline-Filled Test Tubes procedure using one of your test tubes with saline.
0.5 McF	0.39 - 0.61 McF	This value represents the McFarland value for GP/GN cards. The value is not intended to be exact.
2.0 McF	1.81 - 2.19 McF	This value represents the McFarland value for YST/BCL cards. The value is not intended to be exact.
3.0 McF	2.74 - 3.26 McF	This value represents the McFarland value for CBC/NH/ANC cards. The value is not intended to be exact.

IMPORTANT: ***The RFID tag within each of the McFarland References sends the McFarland Reference value to the instrument. Use the McFarland meter on the screen to determine whether the device is reading within the acceptable ranges.***

Performing McFarland Reference Checks

If you are using the VITEK® 2 software compatible with VITEK® DensiCHEK®, follow the *Logging in to the VITEK® 2 FLEXprep™ Software* procedure before performing these steps.

Users are expected to perform a McFarland Reference check prior to the first use of the device, at least once a month, after cleaning the device, and after relocating the instrument to a new lab environment. The user never calibrates the device. It is calibrated at the manufacturing site during assembly. The user must perform McFarland Reference checks to confirm that the device performance is within the acceptable range.

Before use, the device is in Power Save mode. The device turns on once a tube is inserted.

Use the device to perform the McFarland Reference checks and record the McFarland values that appear on the meter.

WARNING

⚠ **If you insert a McFarland Reference tube and any of the following issues occur, then the McFarland Reference or device may be malfunctioning:**

- **A McFarland range or McFarland value fails to appear on the screen.**
- **A LOT number fails to appear on the screen.**
- **The tube does not illuminate (if configured to do so).**
- **The McFarland Reference tube is out of range.**

Failure to resolve a malfunctioning McFarland Reference or device may lead to incorrect McFarland results. Contact your bioMérieux representative for more information.

WARNING

⚠ **Failure to perform regular McFarland Reference checks could cause incorrect McFarland readings when creating suspensions. Users must run a McFarland Reference check once a month to confirm that the device is reading within the acceptable ranges.**

WARNING

⚠ **If a McFarland Reference tube or a saline-filled test tube with specimen is smeared, has debris on it, is scratched, or is damaged, do not use it. Using a dirty or damaged McFarland Reference or test tube can cause incorrect results.**

WARNING

If the McFarland References are free of damage, scratches, and debris, and the reading is red, then thedevice or the McFarland Reference is not functioning properly. If the issue persists, contact a local bioMérieux representative for assistance.

CAUTION: When performing a McFarland Reference check, if the McFarland reading appears outside an acceptable range for multiple McFarland References, there may be an issue with your device. Contact a local bioMérieux representative for assistance.

CAUTION: If the McFarland Reference tube is inserted incorrectly, then the McFarland Reference value does not appear on the screen.

1. Ensure the test tubes are free of damage, scratches, and debris before use.
2. *Optional:* If interfaced with the FLEXprep™ software, navigate to the **Configuration** screen within FLEXprep before inserting the 0.0 McFarland Reference.
3. Insert the 0.0 McFarland Reference into the instrument so that the tube with the McFarland Reference value faces you and is in the front tube location of the Pod.

   The device illuminates the tube and measures the McFarland Reference. Either a McFarland value or X.XX in red appears on the screen, along with the LOT number of the McFarland Reference .
4. Press and hold the button on the back of the Pod until the Tube Light flashes and the two second reading period begins. The lower McFarland value appears as **0.00** on the screen.

   The McFarland Reference is zeroed.
5. Insert the next McFarland Reference into the instrument.

Note: *The 0.0 McFarland Reference (blank) must be checked first. You do not have to insert the other McFarland References (0.5, 2.0, and 3.0) in a particular order.*

   The instrument illuminates the tube and measures the McFarland Reference, during the two second reading period. The corresponding McFarland value and status of the McFarland Reference appears on the screen.The McFarland Status light on the Pod also indicates the status of the McFarland Reference--red indicates a failing value and green indicates a passing value. The LOT number appears on the screen, which indicates it is a McFarland Reference and not a sample tube.
6. When the screen displays the McFarland value, confirm that the value displays with a green colored meter gauge. If the meter gauge displays as the color red, the McFarland Check has failed. Clean the McFarland Reference tube and try again. If the problem persists, try another McFarland Reference set or contact a local bioMerieux representative for assistance.

   A McFarland value appears on the meter.

   This value can be manually recorded for your record.
7. Remove the McFarland Reference.

The McFarland meter disappears when the tube is removed.

8. Repeat steps 5-7 for each McFarland Reference (0.5, 2.0, 3.0).

The McFarland Reference check is complete. You can begin preparing suspensions.

Related Links

Logging in to the VITEK 2 FLEXprep Software
Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)
Maintenance Schedule
Preventive Maintenance Operations

Zeroing Saline-Filled Test Tube

This procedure must be performed after a McFarland Reference check and as needed to ensure that the results are accurate. Plastic tubes must be used with this device. If a glass tube is used instead, the results can be inaccurate. Perform this zeroing procedure for each of the following events:

- After receiving a new shipment of test tubes.
- After performing a McFarland Reference check.
- As a part of routine monthly maintenance.
- After relocating the instrument to a new lab environment.

⚠ **CAUTION: Do not use an empty tube, a tube with an inoculated suspension, or a glass tube to zero an instrument. The user must use a clean 12 mm x 75 mm polystyrene test tube, filled with saline to zero the instrument.**

IMPORTANT: ***When moving the instrument from a stored location that is outside of the specified operating temperature, you must allow the device temperature to stabilize before performing the zeroing procedure and before measuring suspensions.***

IMPORTANT: ***To ensure your device is configured correctly, always zero the instrument before measuring and recording McFarland values.***

WARNING

⚠ **Zeroing an instrument with an empty tube can cause incorrect values to display when the inoculated suspension is inserted into the device.**

1. *Optional:* If interfaced with the FLEXprep™ software, navigate to the **Sample Preparation** screen within FLEXprep and go to the Quick McFarland Entry or the new cassette screen.Place the Pod on the base unit, or if the Pod is charged, hold the Pod while zeroing, if preferred.
2. Insert a saline-filled tube free of damage, scratches,or smudges into the front tube location of the Pod and press it all the way down. Rotate the tube one full rotation

during the 2 second reading period, indicated by the dots on the screen. A numerical value is displayed.

3. If a value of 0.00 is not displayed, press and hold the button on the back of the Pod for approximately three seconds. The Tube Light will flash and the two second reading period begins. Rotate the tube one full rotation, **0.00** will appear on the screen.

   The test tube is zeroed, and you can begin preparing suspensions.

Related Links

Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)

Prepare Suspensions

When preparing a test tube to measure the McFarland value of a cultured isolate, you must select the correct range type for microorganisms. The selected range must correspond to the card type you are using.

Table 14: Display Screens and Corresponding Ranges

Display Screen	Displayed Reading Ranges	Performance Ranges
GN - GP	0.00 - 2.00	0.50 - 0.63
YST- BCL	0.00 - 4.00	1.80 - 2.20
CBC - NH - ANC	0.00 - 4.00	2.70 - 3.30
N/A	0.00 - 4.00	N/A

WARNING

⚠ **The correct card type must be selected for a suspension in order for the correct McFarland range to be used to evaluate the suspension. Failure to do so can lead to incorrect evaluations of suspensions.**

WARNING

⚠ **Using a tube that is under-filled with saline can cause incorrect McFarland value readings for inoculated suspensions. If you identify an under-filled saline tube, do not use it.**

⚠ **CAUTION: The device is not intended for use with glass tubes. If you identify a tube as glass, do not use it.**

WARNING

⚠ **Clumps in a suspension must be properly mixed before an accurate McFarland value can be recorded. Clumps or contaminants in a suspension can cause incorrect McFarland value readings. For accurate readings, ensure the suspension is properly mixed.**

WARNING

If saline or organism spills or drips on the Pod, clean the device with the specified cleaning agent.
Failure to clean spills or drips on the Pod can cause incorrect McFarland value readings for inoculated suspensions.

WARNING

After any cleaning, perform a McFarland Reference check prior to using the VITEK DensiCHEK device again. Failure to do so can lead to inaccurate readings.

WARNING

Spilling liquid in the device can cause malfunctioning. Do not dispense saline into the test tube while it is in the Pod. In the event of an accidental spill, immediately clean and dry the device, and then perform a McFarland Reference check to confirm proper operation before continuing use.

Related Links

Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)

Standalone Workflow (Display Base only)

Standalone workflows refer to using the VITEK® DensiCHEK® instrument with a Display Base not connected to the VITEK® 2 software. A Display Base is required to use the VITEK® DensiCHEK® with Standalone workflows.

Related Links

Graphical User Interface
Display Base Screen
FLEXprep Software Interface Screen

Preparing Suspensions for ID and AST Cards (Standalone)

Ensure the Pod is paired with the base by verifying that the Pod and base both have the same solid color pairing light. Zero the Pod at the beginning of each session by inserting a saline tube free of damage, scratches,or smudges to the front tube location. Press the button on the Pod for approximately three seconds. The Tube Light will flash and and the two second reading period will begin, indicated by the dots on the screen. Rotate the tube one full rotation, and **0.00** will display.

WARNING

Failure to follow these instructions to prepare suspensions or to use test tubes may cause incorrect results or the device to malfunction.

WARNING

If a VITEK® DensiCHEK® device is not available, not charged, or not ready for use, measure the turbidity of the inoculation with a comparable backup VITEK® device. Failing to do so, may cause delayed results.

WARNING

Repeatedly inserting and removing a test tube during suspension creation can cause scratches which may lead to incorrect results.

WARNING

Only sample tubes provided by the manufacturer and specified in the user instructions should be used.

1. Press the **Card Type** button on the Display Base screen, until the desired card type appears (ex. **CBC - NH - ANC**).

   The card type options are as follows:

   - GP - GN
   - BCL - YST
   - ANC - CBC - NH
   - N/A (Miscellaneous)

   Figure 45: Card Type Button on the Display Base (ANC - CBC - NH)

2. Ensure the test tubes are free of damage, scratches, and debris before use.
3. Do one of the following:
   - Select a tube and fill it with the appropriate volume of saline.
   - Select a pre-filled saline tube.
4. Add a microorganism to the saline-filled tube and manually mix the suspension in the tube with a swab or loop until a homogenous solution is achieved.
5. Insert a saline-filled tube into the front tube location of the Pod and press it all the way down. Then rotate the tube a full turn. The instrument illuminates the saline-filled tube, measures the McFarland value, and updates the meter.

   If desired, perform the zeroing procedure for a saline filled tube.
6. Ensure the screen shows the correct card type option when the tube is inserted into the Pod.

Note: *The defaultMcFarland range for the device is GP-GN. This card type appears when the device is first plugged into a power source or if the unit lost power and then resumes. Thereafter, the device will display the last selected McFarland range when a test tube is inserted.*

IMPORTANT: ***If the correct card type is not selected, then an acceptable McFarland range will not appear on the meter. The correct card type must be selected in order for the appropriate McFarland meter to appear.***

7. **WARNING**

   ⚠ **Ensure that the sample test tube is rotated.**

   With the tube in the Pod, add a microorganism to the saline-filled tube and manually mix the suspension in the tube with a swab or loop until the McFarland reading is within the performance range.

IMPORTANT: ***If the #.## screen appears,either the the swab is blocking the lens, a clump of specimen is blocking the lens, or the suspension is too heavy. (See Appendix B Troubleshooting for more information.)***

   A green light on the Pod and meter indicates that the suspension is within the selected card type performance range.A red light indicates that the suspension is above the selected card type performance range. A yellow light indicates that the suspension is below the selected card type performance range.

8. If the McFarland goes over range, perform one of the following solutions:
   - Discard the tube and repeat the previous steps to create a new suspension.
   - Dilute the over-inoculated sample with saline.
   - Remove the sample tube from the Pod before adding saline to the suspension.
9. Once an acceptable McFarland value appears on the screen, manually record the McFarland value for your record (standalone mode) or click the button on the back of the Pod to transfer the McFarland value to FLEXPrep (Connectivity mode). Note: The cursor must be focused in the McFarland field in order for the value to populate in FLEXPrep. Ensure the value is sent to the interfaced PC and appears in the McFarland field on the screen.
10. The saved McFarland value appears above the main number on the screen.
11. Remove the suspension for ID and AST testing. The McFarland meter on the FLEXPrep screen disappears when the tube is removed.
12. Perform this procedure with additional sample specimen tubes.

Connectivity Workflow (Connectivity Base or Display Base)

The connectivity workflow refers to using the VITEK® DensiCHEK® instrument with the compatible VITEK® 2 Systems software (ex. 9.01 or later).

IMPORTANT: ***Do not connect two base units to the same PC at the same time.***

Related Links

Graphical User Interface
Display Base Screen
FLEXprep Software Interface Screen

Shutting Down the System

The Pod cannot be turned off. Battery power is depleted over time when it has not been charged on the base.

For instructions to shut down the VITEK® 2 software and PC compatible with the device, refer to the *VITEK® 2 User Manuals*.

Note: *The base unit can only be turned off by unplugging it from its power source. The Pod will turn off when the battery is depleted.*

Logging in to the VITEK® 2 FLEXprep™ Software

If you are using the VITEK® 2 software compatible with VITEK® DensiCHEK®, follow this procedure before performing the McFarland Reference checks.

1. Ensure the section **Configure FLEXprep with the Instrument** has been performed.
2. For the VITEK® 2 PC, access FLEXprep™ on the desktop, and then double-click the **FLEXprep** icon.For a remote PC, access FLEXprep by launching the Firefox browser. Refer to the FLEXprep User Manual for configuration of FLEXprep from a remote PC.

   The FLEXprep™ program launches in a Firefox browser window.
3. At the **bioMérieux Single Sign-On** screen, log in with the appropriate lab credentials.

Note: *See the VITEK® 2 Systems Software User Manual or the VITEK® 2 Systems Web Software User Manual and the bioMérieux User Management User Manual for information about accessing, creating, and managing user accounts.*

To reconfigure your FLEXprep™ settings or certificates, refer to the VITEK® 2 FLEXprep™ User Manual.

The FLEXprep™ home screen appears with the **Sample Preparation** and **Configuration** options.

Navigating the FLEXprep™ Software

Refer to the **System Description and Basic Operations** > **System Basics** > **User Interface** section in Chapter 3 of this user manual for screen captures of the FLEXprep™ interface.

Note: *To manually type in the McFarland values during any workflow, navigate to the **Configuration** screen, and set the **Use VITEK DensiCHEK** option to **No** and then **Save** the setting. Follow the VITEK® 2 FLEXPrep User Manual to enter the McFarland values manually.*

1. Follow the *Logging in to the VITEK® 2 FLEXprep™ Software* procedure.
2. On the first **Sample Preparation** screen, enter data in the following fields:
   - **Lab ID**
   - **Isolate**
   - *Optional:* **Bench ID**

Note: *In FLEXprep™, click **Configuration**, and then for the **Display Bench** option, click **Yes** and then **Save** the setting. Refer to the VITEK® 2 Web Software User Manual for more information about configuring your Bench settings.*

- **[VITEK 2] PC**
- **Cassette ID**

Note: *If you are using a VITEK® 2 Compact instrument, enter a valid number (1-9) or scan the barcode on the cassette in the **Cassette ID** field. If you are using a VITEK® 2 instrument, the data for the **Cassette ID** field must be manually entered each time.*

3. Press **Enter**.

   The second **Sample Preparation** screen appears with additional fields.

4. With your card, perform one of the following tasks depending on your preferred method:

Option	Description
Using FLEXprep™, perform one of the following tasks:	Click the Card Type field, and then scan the barcode on the card. OR Manually enter the barcode numbers in the Card Type field.
Using your VITEK® DensiCHEK® Display Base, perform the following task:	◦ Press the **Card Type** button on the bottom of the Display Base so that the appropriate card type category appears.

IMPORTANT: ***When the instrument is connected to the FLEXprep™ PC, the user can scan the card barcode and the instrument automatically adjusts to the correct McFarland range for that particular card.***

5. Click **Add Card**.
6. Enter data in rest of the fields for the same isolate specimen.

Note: *There can be up to two AST cards per isolate, but only one ID card per isolate.*

7. When an isolate is completed, click **Validate** (after a maximum of two AST cards and one ID card).
8. Perform steps 4-7 for any remaining AST and ID cards.

Note: *If you entered card data in the first and second **Sample Preparation** screens, clicked **Validate**, and then closed the browser to restart FLEXprep™, when FLEXprep™ is opened again, it returns to the second **Sample Preparation** screen with the validated card data present.*

*You can continue where you left off or click **New Cassette** to return to the first **Sample Preparation** screen.*

Note: *If you click **New Cassette** before clicking **Send Cassette**, the data entered for the current cassette is erased and not saved. Clicking **New Cassette** also clears your Bench settings. Always click **Send Cassette** in order to save the data entered for each cassette.*

9. Use the **>/<** arrows to move to the previous or next card.

Note: *To delete a card, navigate to the necessary card, and click **Delete Card**.*

The highlighted card in the **Abbreviated Summary** view shifts to reflect your card selection.

10. Click **Summary** on the right to view all the data for the cassette.
11. Click **Back** to return to the second **Sample Preparation** screen.

12. When the cassette is completed, click **Send Cassette**.

Note: *If you click **New Cassette** before clicking **Send Cassette**, the data entered for the current cassette is erased and not saved. Clicking **New Cassette** also clears your Bench settings. Always click **Send Cassette** in order to save the data entered for each cassette.*

After clicking **Send Cassette**, the cassette is closed, and the data goes to the VITEK® 2 server. The cassette can be loaded in the corresponding VITEK® 2 instrument. The first **Sample Preparation** screen appears and your Bench settings still appear.

13. *Optional:* Click **New Cassette**.

    The screen refreshes and the first **Sample Preparation** screen appears. The previous cassette data and the Bench settings are cleared. From here, you can enter a **Cassette ID**, and begin the task from Step 1 again.

14. Click the **PC: [VITEK]** text to visit the **Work List** screen to view results, to view isolates, or to define cards.

    Refer to the *VITEK® 2 Web Software User Manual* for more information.

Note: *The **[VITEK]** text changes depending on what the user has named their PC.*

A new tab opens with the **Work List** screen in the VITEK® 2 Systems Web application.

Related Links

Logging in to the VITEK 2 FLEXprep Software
Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)

Preparing Suspensions for ID and AST Cards (Connectivity)

Ensure the Pod is paired with the base by verifying that the Pod and base both have the same solid color pairing light. Zero the Pod at the beginning of each session by inserting a saline tube free of damage, scratches,or smudges to the front tube location. Press the button on the Pod for approximately three seconds. The Tube Light will flash and **0.00** will display.

Prepare a primary suspension for use with a VITEK® 2 ID test or a VITEK® 2 AST test.

Use the instrument to prepare suspensions and record the McFarland values for the cards that appear in FLEXprep™ program on the VITEK® 2 PC. The card type options are as follows:

- GP - GN
- YST - BCL
- CBC - NH - ANC
- N/A (Miscellaneous)

WARNING

⚠ **Failure to follow these instructions to prepare suspensions or to use test tubes may cause incorrect results or the device to malfunction.**

WARNING

If a VITEK® DensiCHEK® device is not available, not charged, or not ready for use, measure the turbidity of the inoculation with a comparable backup VITEK® device. Failing to do so, may cause delayed results.

WARNING

Repeatedly inserting and removing a test tube during suspension creation can cause scratches which may lead to incorrect results.

Note: *To manually type in the McFarland values during any workflow, navigate to the **Configuration** screen, and set the **Use VITEK DensiCHEK** option to **No** and then **Save** the setting. Follow the VITEK® 2 FLEXPrep User Manual to enter the McFarland values manually.*

1. Ensure the test tubes are free of damage, scratches, and debris before use.
2. Follow the *Logging in to the VITEK® 2 FLEXprep™ Software* procedure.
3. On the first **Sample Preparation** screen, enter data in the following fields:
   - **Lab ID**
   - **Isolate**
   - *Optional:* **Bench ID**

Note: *In FLEXprep™, click **Configuration**, and then for the **Display Bench** option, click **Yes** and then **Save** the setting. Refer to the VITEK® 2 Web Software User Manual for more information about configuring your Bench settings.*

   - **[VITEK 2] PC**
   - **Cassette ID**

Note: *If you are using a VITEK® 2 Compact instrument, enter a valid number (1-9) or scan the barcode on the cassette in the **Cassette ID** field. If you are using a VITEK® 2 instrument, the data for the **Cassette ID** field must be manually entered each time.*

4. Press **Enter**.
   The second **Sample Preparation** screen appears with additional fields.
5. With your card, perform one of the following tasks depending on your preferred method:

Option	Description
Using FLEXprep™, perform one of the following tasks:	◦ Click the **Card Type** field, and then scan the barcode on the card. OR ◦ Manually enter the barcode numbers in the **Card Type** field. OR ◦ Insert a tube, and when **DensiCHEK Gauge** appears in FLEXprep™, click the correct card type, and then scan the barcode on the card.

Option	Description
Using your VITEK® DensiCHEK® Display Base, perform the following task:	◦ Press the **Card Type** button on the bottom of the Display Base so that the appropriate card type category appears.

IMPORTANT: ***When the instrument is connected to the FLEXprep™ PC, the user can scan the card barcode and the instrument automatically adjusts to the correct McFarland range for that particular card.***

6. When the correct card type and range appears (ex. GN/GP: 0.50 to 0.63), continue to the next step.

   The **Card Type** field populates with the card information.
7. Do one of the following:
   - Select a tube and fill it with the appropriate volume of saline.
   - Select a pre-filled saline tube.
8. Insert a saline-filled tube into the front tube location of the Pod and press it all the way down.

IMPORTANT: ***If the #.## screen appears,either the the swab is blocking the lens, a clump of specimen is blocking the lens, or the suspension is too heavy. (See Appendix B Troubleshooting for more information.)If a McFarland value is not displayed, refer to Appendix B Troubleshooting.***

   The instrument illuminates the saline filled tube and continually measures the McFarland value, and updates the display.
9. Ensure the screen shows the correct card type option when the tube is inserted into the Pod.

Note: *The defaultMcFarland range for the device is GP-GN. This card type appears when the device is first plugged into a power source or if the unit lost power and then resumes. Thereafter, the device will display the last selected McFarland range when a test tube is inserted.*

IMPORTANT: ***If the correct card type is not selected, then an acceptable McFarland range will not appear on the meter. The correct card type must be selected in order for the appropriate McFarland meter to appear.***

10. Add a microorganism to the saline-filled tube and manually mix the suspension in the tube with a swab or loop. Insert the tube in the Pod.

    A green light on the Pod and on the meter indicates that the suspension is within the selected card type performance range. A red light indicates that the suspension is above the selected card type performance range.A yellow light indicates that the suspension is below the selected card type performance range.
11. If the McFarland goes over range, perform one of the following solutions:
    - Discard the tube and repeat the previous steps to create a new suspension.
    - Dilute the over-inoculated sample with saline.
12. Once an acceptable McFarland value appears on the screen, press the button on the back of the Pod to freeze the value and send it to the FLEXprep software.

    The saved McFarland value appears above the main number on the screen.
13. Ensure the value is sent to the interfaced PC and appears in the **McFarland** field on the screen.

14. Remove the suspension for ID and AST testing. The McFarland meter disappears when the tube is removed.
15. *Optional:* Click **Add Card** to add a new card accession to the Lab ID.
16. After the values are captured in the **McFarland** field, click **Validate** to save the value.
17. Repeat all of the previous steps for the remaining suspensions, and then click **Send Cassette**.

Related Links

Logging in to the VITEK 2 FLEXprep Software
Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)

Entering Multiple McFarland Values at Once

Using the VITEK® 2 Logging in to the VITEK® 2 FLEXprep™ Software User Manual, access **Quick McFarland Entry** feature.

Note: *To manually type in the McFarland values during any workflow, navigate to the **Configuration** screen, and set the **Use VITEK DensiCHEK** option to **No** and then **Save** the setting. Follow the VITEK® 2 FLEXPrep User Manual to enter the McFarland values manually.*

Enter Multiple McFarland values at once in Connectivity mode as follows:

1. Click the **Lab ID** field next to **1**.
   The cursor appears in the field.
2. Scan a plate, or type the Lab ID in the **Lab ID** field.
   Depending on the barcode used, the **Isolate** field may automatically populate. The cursor automatically jumps to the next line.
3. Scan the rest of the plates, or enter the **Lab ID** and **Isolate** for the rest of the plates.
   Depending on the barcode used, the **Isolate** field may automatically populate. The cursor automatically jumps to the next line.
4. If needed, manually enter the isolate number for the plates in the **Isolate** field.
5. If needed, manually enter the rest of the isolate numbers for the other plates.
6. Click the row for *Isolate 1*, and prepare the appropriate suspension for the card type and insert the tube into the Pod and rotate the tube one full turn. Adjust the suspension and remeasure as necessary. Refer to section for Preparing Suspensions for ID and AST Cards.

Note: *In the **DensiCHEK Gauge**, you can minimize or expand the window as needed by clicking the appropriate buttons. If the **DensiCHEK Gauge** is closed, it appears again when a tube is inserted.*

Note: *The **DensiCHEK Gauge** appears on the FLEXPrep™ screen when you insert a tube into the Pod. Clicking the **Card Type** button on the **DensiCHEK Gauge** changes the performance range for the McFarland meter.*

7. Press the button on the Pod to capture the value.
   The **McFarland** field populates with the McFarland value and the next row is automatically highlighted for the next isolate. The cursor does not appear in the **McFarland** field because it cannot be manually typed unless configured to do so.
8. Click the row for each of the isolates, and prepare suspension for each isolate and press the button on the Pod to capture each McFarland value in the McFarland field.

9. To correct or edit a McFarland value, select the appropriate row, insert the suspension tube into the Pod, rotate the tube during the 2 second reading period, and press the button on the Pod to save a new value.
10. When all the data is added to the **Quick McFarland Entry** window, remove the tube from the Pod, and click **OK** to save.
11. Enter an appropriate ID in the **Cassette ID** field, and press **Enter**.

    The second **Sample Preparation** screen appears. The **McFarland Entries** option is active.
12. Click **McFarland Entries** on the right.

    The **McFarland Entries** window appears with the data you entered previously, but it is not editable.
13. Close the window and on the second **Sample Preparation** screen, enter an ID in the **Lab ID** field.

    Once the **Lab ID** is entered, the system pulls the appropriate McFarland values from the **Quick McFarland Entry** window and populates the **McFarland** field.
14. Finish defining the cassette in FLEXprep™, and then click **Send Cassette**.

Note: *Data entered in the **Quick McFarland Entry** window is specific to each PC. When defining a cassette in FLEXprep™, the McFarland values auto populate in the McFarland field when defining a cassette in FLEXPrep. The McFarland values will only auto populate if the data was captured in Quick McFarland Entry on the same PC. These values expire in one hour from time McFarland values are saved in Quick McFarland Entry and will no longer auto populate into the McFarland field when defining cassettes in FLEXPrep.*

Note: *Data from the **Quick McFarland Entry** window is not transferable when using the **Load and Go** workflow in the VITEK® 2 Systems Web software (Cassette view).*

Related Links

Logging in to the VITEK 2 FLEXprep Software
Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)

Preparing a QC Suspension in Quality Control Mode

Preparing suspensions without Quality Control mode on is intended for patient samples. Turn on Quality Control mode to perform a Quality Control workflow according to your lab requirements.

1. Follow the *Logging in to the VITEK® 2 FLEXprep™ Software* procedure.
2. On the first **Sample Preparation** screen, enter data in the following fields:
   - *Optional:* **Bench ID**

Note: *In FLEXprep™, click **Configuration**, and then for the **Display Bench** option, click **Yes** and then **Save** the setting. Refer to the VITEK® 2 Web Software User Manual for more information about configuring your Bench settings.*

   - **[VITEK 2] PC**
   - **Cassette ID**

Note: *If you are using a VITEK® 2 Compact instrument, enter a valid number (1-9) or scan the barcode on the cassette in the **Cassette ID** field. If you are using a VITEK® 2 instrument, the data for the **Cassette ID** field must be manually entered each time.*

3. Press **Enter**.

   The second **Sample Preparation** screen appears with additional fields.
4. When the second **Sample Preparation** screen appears, click **QC**.

   The QC (Quality Control) mode is turned on and the QC fields appear.
5. Enter the necessary QC data and refer to the *VITEK® 2 Software User Manual* or the *VITEK® 2 Web Software User Manual* to use and understand the various available options in FLEXprep™.

Related Links

Logging in to the VITEK 2 FLEXprep Software

Navigating Through Card Entries

After entering the data for multiple cards in FLEXprep™, follow these steps to navigate through the card data.

Note: *To manually type in the McFarland values during any workflow, navigate to the **Configuration** screen, and set the **Use VITEK DensiCHEK** option to **No** and then **Save** the setting. Follow the VITEK® 2 FLEXPrep User Manual to enter the McFarland values manually.*

1. Follow the *Logging in to the VITEK® 2 FLEXprep™ Software* procedure.
2. Enter your **Lab ID**, **Isolate**, and **Cassette ID** information to view the card summary information for the cassette you created with previously mentioned procedures, such as the *Entering Multiple McFarland Values at Once* or *Preparing Suspensions for ID and AST Cards* procedures.
3. Ensure that more than one card and the related data is entered in FLEXprep™.
4. Use the **>/<** arrows to move to the previous or next card.

Note: *To delete a card, navigate to the necessary card, and click **Delete Card**.*

The highlighted card in the **Abbreviated Summary** view shifts to reflect your card selection.

Related Links

Logging in to the VITEK 2 FLEXprep Software
Preparing Suspensions for ID and AST Cards (Connectivity)
Preparing Suspensions for ID and AST Cards (Standalone)

Updating Firmware

Users may be contacted by a bioMérieux representative with additional instructions and information.

1. Place the Pod on the base unit.

   The Pod charges while placed on the base unit.
2. Ensure there is no tube in the Pod.
3. Using the provided USB cord, connect the instrument to the VITEK® 2 Systems PC.

   The instrument communicates with the VITEK® 2 Systems PC and determines that a firmware update is available.
4. Wait for the firmware update to complete.

The instrument receives the firmware update from the VITEK® 2 Systems PC and performs the update. The Display Base screen visually indicate that the Pod's firmware is updating. Once the update completes, the instrument resumes normal operation.

Related Links

Logging in to the VITEK 2 FLEXprep Software

6 User Maintenance

For service information, contact bioMérieux or your local distributor (contact information available on www.biomerieux.com).

Required Tools

- Household cleaner (not ammonia-based)
- Paper towels
- Soft, dry cloth
- Neutral, non-abrasive detergent as defined in the Approved Cleaning Agents section.
- Cloth or facial tissue
- Water or suitable glass cleaner

Calibration and Adjustments

The device is calibrated at the manufacturing site during assembly. The calibration is confirmed with McFarland References, as described in Chapter 5, Performing McFarland Reference Checks.

For information or for assistance, contact bioMérieux or your local distributor (contact information available on www.biomerieux.com).

Preventive Maintenance Operations

Perform McFarland Reference checks regularly. If issues arise that are not documented in this user manual, then contact your bioMérieux representative for assistance.

Perform McFarland Reference checks if the follow events occur:

- After receiving a new shipment.
- As a part of routine monthly maintenance.
- After cleaning the device.
- After relocating the instrument to a new lab environment.

Related Links

Maintenance Schedule
Preventive Maintenance Operations

Cleaning Procedures

Approved Cleaning Agents

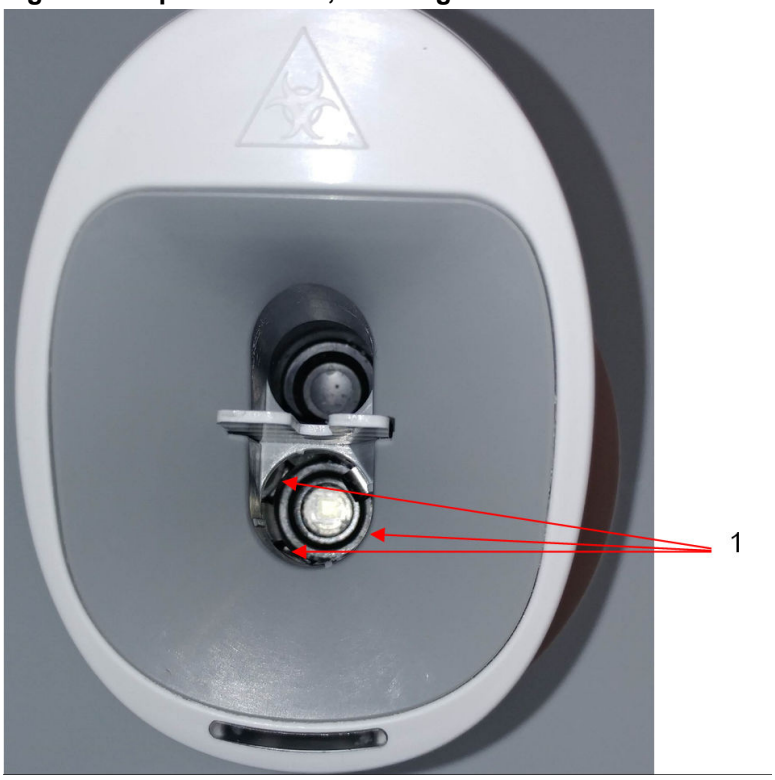
- 10% sodium hypochlorite (bleach)
- 3% – 25% hydrogen peroxide
- Vesphene IIse
- LpH se

Cleaning the Lens

1. Remove Pod from base.
2. Dampen a cotton swab with an Approved Cleaning Agents as listed above, and then squeeze out any excess liquid.
3. Carefully wipe each window of the front tube location. Be cautious not bend the metal switch tab.
4. Carefully wipe the tube light windows at the base of the front tube location.
5. Carefully wipe the RFID window at the base of the back tube location.
6. Visually inspect the tube locations to ensure no debris remains.
7. Allow Pod to completely air dry.
8. Perform McFarland Reference Check as described in Chapter 5, Performing McFarland Reference Checks.
9. Perform Chapter 5, Zeroing Saline-Filled Test Tubes.

Use the image below to locate the windows for the optical lenses, tube light and RFID.

Figure 46: Optical Lenses, Tube Light and RFID in the Pod



1. Optical Lenses

WARNING

⚠ **Only use the approved cleaning materials, agents, and tools. Using non-approved cleaning materials can damage the reading lenses. Do not use strong solvents, including alcohol.**

Cleaning the Touch Screen

Wipe theDisplay Base Touch Screen using paper towels or wipes that are dampened with with an Approved Cleaning Agent. Then dry with a soft clean cloth.. Always dampen the towel first and then clean the screen. See the list of approved cleaning agents above.

CAUTION: Do not spray cleaner directly on the screen. Spraying the screen directly can damage the device.

Cleaning the Base and Pod

Wipe the base and the Pod using paper towels or wipes that are dampened with with an Approved Cleaning Agent. See the list of approved cleaning agents above.

Once you have cleaned the base and/or the pod, allow the device to dry, and then perform a McFarland Reference check to ensure that the instrument continues to take accurate readings.

WARNING

Only use the approved cleaning agents. Using non-approved cleaning agents can damage the instrument. Do not use strong solvents, including alcohol.

WARNING

Spilling liquid in the device can cause malfunctioning. Do not dispense saline into the test tube while it is in the Pod. In the event of an accidental spill, immediately clean and dry the device, and then perform a McFarland Reference check to confirm proper operation before continuing use.

Related Links

Maintenance Schedule
Preventive Maintenance Operations

Decontamination Procedures

If decontamination is necessary due to a biological hazard, refer to Cleaning Procedures using a 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.

For information or for assistance, contact bioMérieux or your local distributor (contact information available on www.biomerieux.com).

Related Links

Cleaning Procedures

A Appendix - Maintenance Records

Maintenance Schedule

Table 15: Maintenance Schedule

Part	Frequency	Procedure
VITEK® DensiCHEK® Instrument	According to your local regulatory guidelines, or at least on a monthly basis.	Chapter 5, Performing McFarland Reference Checks.
VITEK® DensiCHEK® McFarland Reference Kit	According to your local regulatory guidelines, or at least on a monthly basis.	Chapter 5, Performing McFarland Reference Checks.
VITEK® DensiCHEK® Instrument	As Required	Chapter 6, Cleaning Procedures.

WARNING

⚠ **The VITEK® DensiCHEK® McFarland Reference Kit must be replaced if the individual vials are damaged or scratched in such a way that they cause erroneous results.**

Related Links

Cleaning Procedures

Maintenance Checklist

Checklist 1

Year:

Month:

Part name	Month	1	2	3	4	5	6	7	8	9	10	11	12
	Frequency												
VITEK® DensiCHEK® Device/ Instrument; McFarland Reference Check	M												

Frequency: **M** = Monthly, **6M** = Every 6 months, **N** = if needed

Complete with your initials. Keep a copy of the preventive maintenance charts.

Checklist 2: Daily, Part 1

Year:

Month:

Part name	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	Frequency																
VITEK® DensiCHEK® Device/ Instrument; McFarland Reference Check	N																
VITEK® DensiCHEK® Device/ Instrument; Cleaning	N																

Frequency: **M** = Monthly, **6M** = Every 6 months, **N** = if needed

Complete with your initials. Keep a copy of the preventive maintenance charts.

Checklist 3: Daily, Part 2

Year:

Month:

Part name	Day	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Frequency															
VITEK® DensiCHEK® Device/ Instrument; McFarland Reference Check	N															
VITEK® DensiCHEK® Device/ Instrument; Cleaning	N															

Frequency: **M** = Monthly, **6M** = Every 6 months, **N** = if needed

Complete with your initials. Keep a copy of the preventive maintenance charts.

B Appendix - Troubleshooting

Related Links

Cleaning Procedures

Error Messages and Recovery Procedures

This section lists the possible error messages and general problems that could occur when using the device.

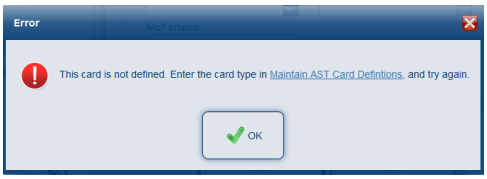
WARNING

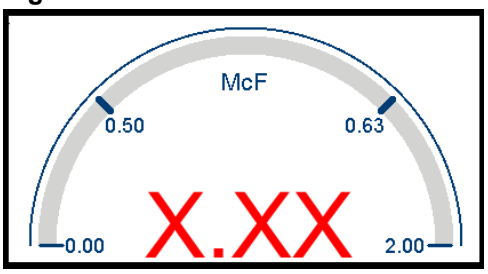
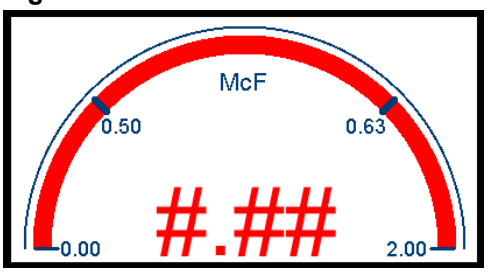
⚠ **Failure to address error messages in a proper and/or timely manner may cause the device to malfunction.**

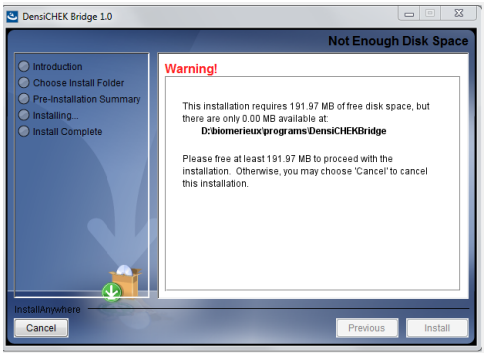
WARNING

⚠ **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.**

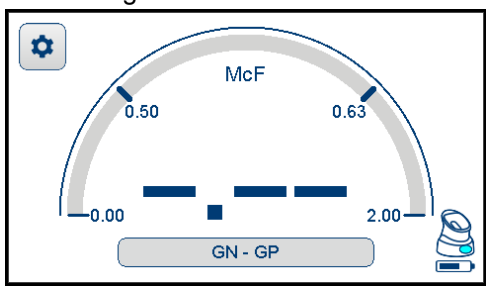
Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
McFarland value is inconsistent.	Test tubes may be dirty or scratched (inside or outside).	Replace the test tubes as required.
	Test tubes may not be filled to sufficient level.	Adjust saline level.
	Instrument is not zeroed on type of test tube in use.	Zero on tube type in use.
	Test tube does not meet required criteria.	Confirm test tube is a clean 12 mm x 75 mm polystyrene test tube that is clear, colorless, and free of scratches.
	Test tube not properly inserted in the Pod.	Insert the test tube so it is fully seated and upright in the Pod
	Ambient light is too bright to make an accurate measurement.	Relocate instrument away from bright light sources.

Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
The instrument is unable to save data.	Various causes.	Contact bioMérieux Technical Support.
The FLEXprep™ software is not reflecting what is shown on the Display Base.	The device is disconnected from the PC.	Re-seat test tube in Pod. If problem is not resolved, reconnect the Base to the PC, and then restart the FLEXprep™ software or, restart the PC and then open the FLEXprep software.
The FLEXprep™ software is not registering that a base is connected.	The device is disconnected from the PC.	Reconnect the Base to the PC, and then restart the FLEXprep™ software. If problem is not resolved, restart the PC and then open the FLEXprep software.
	The Communication Bridge or the related certificates are not installed and configured on the PC.	Connect the base to the PC, and then restart the PC. Then complete all of the procedures included in the *Configure FLEXprep™ with the Instrument* section.
Momentary loss of power.	The USB power cord gets disconnected from the base.	Reconnect the USB power cord to the base.
	The Pod does not hold its charge because of normal wear and tear.	Contact bioMérieux Technical Support.
The following error message appears: **Figure 47: Error Message** 	The card is not defined in your VITEK® 2 System.	Refer to the *VITEK® 2 Software User Manual* or *VITEK® 2 Web Software User Manual* for instructions on Maintain AST Card Definitions.

Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
A suspension with an organism is inserted into the Pod but **X.XX** appears on the screen. **Figure 48: X.XX Results** 	The device needs to be cleaned.	Follow the cleaning procedure and requirements listed in this user manual.
	One or more lenses are dirty.	Clean the test tube chamber.
	The tube is scratched.	Use a different tube.
	Alcohol was used to clean the device and one or more lenses are damaged.	Contact bioMérieux Technical Support.
A suspension with an organism is inserted into the Pod but **#.##** appears on the screen. **Figure 49: #.## Results** 	The McFarland range is over 4.0.	Create a new suspension following the instructions in this user manual.
	A clump of specimen is blocking the lens.	Continue to mix the specimen until all clumps are gone and the lens is unblocked.
	A loop or swab is blocking the lens.	Remove the loop or swab from the suspension.
A tube is inserted into the Pod but 0.00 is flashing on the screen. Figure can be gauge reading 0.00? Already shown in document.	The Pod was zeroed previously with a tube that was not as clear, and the next tube inserted is clear. The system cannot reliably calculate a McFarland value and needs to be zeroed with a clear saline-filled tube inserted.	Zero the device using a tube filled with clear saline.

Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
When installing the DensiCHEK® Bridge Communication service, the **Not Enough Disk Space** warning appears, similar to the image below: **Figure 50: Not Enough Disk Space Warning**  	The correct drive is not available to install the service.	Remove all USB memory devices, CDs, and DVDs before running the DensiCHEK® Bridge Installer.
The colored light on the Pod does not match the base. Therefore, the Pod fails to pair with the base.	The Bluetooth connection between the Pod and the base needs to be reestablished.	Place the Pod on the base to pair. Wait for the LED lights on the Pod and the base to match.
The Pod turns off.	The Pod battery needs to be charged.	Charge the Pod by placing it on a base unit.
Base physically connected to PC and the colored light on the Pod flashes red.	The Bluetooth connection between the Pod and base needs to be established.	Place the Pod on the base to pair. Wait for LED lights on the Pod and the base to match. If issue is not resolved, restart the PC.
The base turns off.	The base has been unplugged.	Ensure the correct cord is plugged into the base and a power source.
The firmware update does not complete.	The base has been unplugged from the PC.	Ensure the correct cord is plugged into the base and the VITEK® 2 Systems PC.
In FLEXprep™, after clicking **OK** to save your card data in the **Quick McFarland Entry** window, the following error message appears: The Accession Numbers for rows [#] and [#] are the same. Please resolve the duplication.	The same Lab ID was entered twice.	Click **OK**, replace the duplicated data by clicking the **Lab ID** field, entering a new Lab ID, and clicking **OK** when all the fields are entered and unique.

Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
In FLEXprep™, after clicking **OK** to save your card data in the **Quick McFarland Entry** window, the following error message appears: Row [X] is incomplete; either clear it all or fill in all values to proceed.	Not all the values are completed for a row.	• Enter the missing values and click **OK**.OR • Click **Cancel** to close the window and to clear the values, and then reopen the **Quick McFarland Entry** window to enter the values again. If the issues persists, restart the FLEXprep™ program.
If the McFarland range of the card type selected on the Display Base does not match the McFarland range of the card type scanned in FLEXprep™.	The incorrect card type was selected on the Display Base. (Ex. The user wants to scan a BCL card, but a GN - GP range was selected on the Display Base).	1. FLEXprep™ alerts the user that the McFarland range sent by the instrument is different from the McFarland range of the scanned card. 2. The user scans the correct card. The results populate correctly and the Display Base matches the scanned card (ex. a BCL card is scanned, and the GN - GP range changes to the YST - BCL range). 3. The user creates a new suspension using a correct McFarland range.

Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
A tube is inserted into the Pod, but the Pod fails to illuminate the tube.	The device sensor is malfunctioning.	Contact bioMérieux Technical Support.
	The tube is not inserted correctly.	Review the *Preparing Suspensions for ID and AST Cards* procedure.
	The tube is not pressed into the Pod completely.	Press the tube down in the Pod.
	The tube is inserted in the wrong location.The device sensor is malfunctioning.	Insert the tube in the front tube location on the Pod.Contact bioMérieux Technical Support.
Tube is not illuminated.	Pod is configured to the lowest Tube Light setting.	Access the configuration page for the base, and increase the value for Tube Light.
The base does not turn on even though it is plugged in.	Various causes.	Contact bioMérieux Technical Support.
A suspension is in the Pod, but **-.--** appears on the screen for the McFarland value similar to the image below. 	Pod is failing to sense the presence of the suspension.	Remove suspension and attempt to re-measure. If the issue still does not resolve,contact bioMérieux Technical Support.
User touches the screen and nothing happens, the screen goes blank, or the screen freezes.	Various causes.	1. Unplug and re-plug in the base. 2. Remove the Pod from the base, and the place it back on the base. 3. If the issue persists, contact bioMérieux Technical Support.
A McFarland Reference is in the Pod and the McFarland value appears on the screen, but the LOT number does not appear.	RFID tag fails, sensor fails, or reading of McFarland value fails.	Contact bioMérieux Technical Support.

Problem Resolution		
Error Message / Problem	**Cause**	**Resolution**
Device does not function as expected.	Pod or base is dropped or falls from the work bench.	1. Inspect for damage. 2. Perform a McFarland Reference check. 3. If the issue persists, contact bioMérieux Technical Support.
The McFarland value does not appear on the screen, because the Pod fails to pair with the base.	The Bluetooth connection between the Pod and the base needs to be reestablished. The Pod is still reading the suspension, but it's not sending the data from the Pod to the base.	Unplug the base, and then plug in the base again to restart it.

Related Links

Cleaning Procedures
Connecting the Device
Configure FLEXprep with the Instrument
Configuring the DensiCHEK Certificates in FLEXprep
Downloading and Installing the DensiCHEK Communication Bridge
Downloading and Installing the DensiCHEK Communication Bridge
Configuring the DensiCHEK Certificates in FLEXprep
Configuring the Display Base Settings
Configuring the Connectivity Base Settings

C Appendix - Third-Party Software

Third party software and any parts thereof identified in the left-hand column are subject to the terms and conditions under which the specific licenses identified in the right-hand column are granted.

Third-party software and parts	License
Apache server	GPL compatible (Apache version 2): http://www.apache.org/licenses/
Jboss application server	GNU LGPL: http://www.jboss.org/infinispan/license.html
Module BIRT	Eclipse public license (EPL): http://en.wikipedia.org/wiki/Eclipse_Public_License
OpenDS	Common Development and Distribution License (CDDL): https://opends.dev.java.net/OpenDS.LICENSE
PostgreSQL	BSD license: http://www.postgresql.org/about/licence

Third-party software and parts	License
Modules	ActiveMQ: http://www.apache.org/licenses/LICENSE-2.0.html Drools: http://www.apache.org/licenses/LICENSE-2.0.html Joda: http://joda-time.sourceforge.net/license.html hibernate: http://www.hibernate.org/license.html Apache common: http://www.apache.org/licenses/LICENSE-2.0.html Dozer: http://www.apache.org/licenses/LICENSE-2.0 Sun JRE 1.6.0: Sun Microsystems, Inc. Binary Code License Agreement Copyright © 2006 Sun Microsystems, Inc., 4150 Network Circle, Santa Clara, California 95054, U.S.A. All rights reserved.U.S.: http://java.sun.com/javase/6/webnotes/runtime.html RichFaces: GNU LGPL http://www.gnu.org/licenses/lgpl.html http://www.jboss.org/richfaces/download/stable.html Seam: GNU LGPL http://www.gnu.org/licenses/lgpl.html http://seamframework.org/Download Tomhawak: http://www.apache.org/licenses/LICENSE-2.0.html PrimeFaces: http://www.apache.org/licenses/LICENSE-2.0.html Facelet: http://www.apache.org/licenses/LICENSE-2.0.html slf4j: http://www.slf4j.org/license.html JfreeChart : http://www.gnu.org/licenses/lgpl.html Jackrabbit : http://www.apache.org/licenses/LICENSE-2.0
VITEK® MS module	SLF4J 1.5.6 : http://www.slf4j.org/license.html Sping 3.0.3.RELEASE : http://www.apache.org/licenses/LICENSE-2.0.html Jmzml 1.2.1 : http://www.apache.org/licenses/LICENSE-2.0.html JRE 1.6.0.20 : http://java.sun.com/javase/6/jdk-6u2-license.txt Matlab 7.14 : See the file "MATLAB-license.txt" in the "D:\biomerieux\programs\licenses" directory

Third-party software and parts	License
BCI link module	Spring: http://www.apache.org/licenses/LICENSE-2.0.html Jcalendar: http://www.toedter.com/en/jcalendar/license.html Jdom: http://www.jdom.org/docs/faq.html#a0030 Jta: https://source.db4o.com/db4o/trunk/drs/lib/jta.license.html slf4j: http://www.slf4j.org/license.html rxtx: http://users.frii.com/jarvi/rxtx/license.html

D Appendix - Glossary

Term	Definition
Connectivity Workflow	This workflow refers to using the VITEK® 2 DensiCHEK® device with the VITEK® 2 software that is compatible with the device.
Display Base	The Display Base syncs to and charges the Pod. This base has a display screen where the McFarland reading appears when a tube is inserted into the Pod. This base can also transmit information to the VITEK® 2 software that is compatible with the VITEK® DensiCHEK®, if the user has access to the software.
McFarland References	These references are dual-vials with 0.0, 0.5, 2.0, and 3.0 McFarland values that verify the calibration of the optics contained within the Pod.
McFarland Reference Check	Users must run a McFarland Reference check once a month to confirm that the calibration is accurate. This preventive maintenance activity is required to confirm the device measurements.
Pod	The Pod optically reads the turbidity of a microorganism suspension and sends the information to the base unit.
Standalone Workflow	This workflow refers to using the VITEK® DensiCHEK® instrument with a Display Base (without the VITEK® 2 software compatible with the DensiCHEK®).

Term	Definition
Connectivity Base	A base unit without a display that syncs with and charges the Pod. This base unit sends data to the VITEK® 2 software compatible with the DensiCHEK® software.

Revision History

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

048641-01.

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Notes:

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

Release Date	Part Number	Change Type	Change Summary
2017-12	048641-01	N/A	First publication

Rx only

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