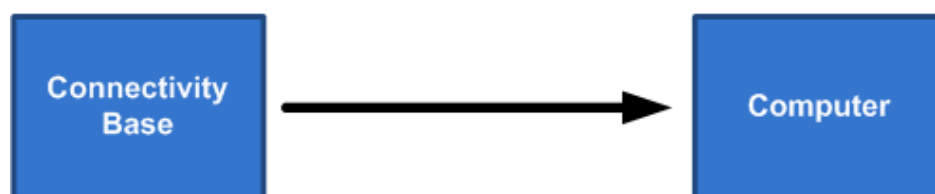


The Display Base can be plugged into the wall using the provided single-head USB cable (with no connection to the PC), or the Display Base can be plugged into a PC using the provided cable with two USB heads.

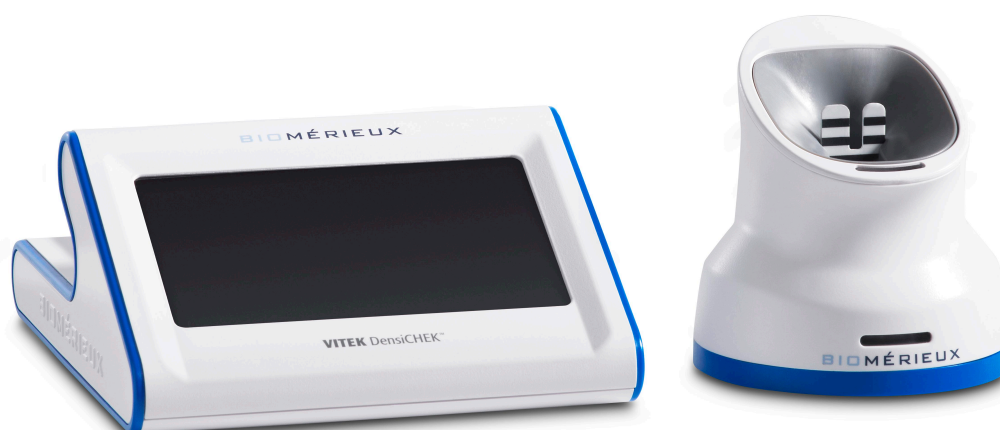
Figure 13: VITEK® DensiCHEK® System Configurations - Connectivity Base



The Connectivity Base must be plugged into a PC.

Overview of Operation Elements

Figure 14: Display Base and Pod Overview



Main Components of the VITEK® DensiCHEK® Instrument

- Display Base or Connectivity Base Unit – Syncs to and charges the Pod.
- Pod - Optically reads the McFarland value of microorganism suspensions for the user and communicates the value to the base unit.
- McFarland References – Verifies the calibration of the optics contained within the Pod. These references are dual-vials and labeled 0.0, 0.5, 2.0, and 3.0 McFarland.

Secondary Components of the VITEK® DensiCHEK® Instrument

- 12 mm x 75 mm clear polystyrene test tubes.
- VITEK® 2 software compatible with the DensiCHEK® - Assists with the following tasks:
 - Tracks individual McFarland values from the Pod.
 - Communicates between the Pod, the base unit, and a PC. (The Pod communicates via a Bluetooth wireless connection to the base unit. The base unit communicates to the PC running VITEK® 2 FLEXprep™ software via a USB wired connection.)

Pod

The Pod optically reads the turbidity of a microorganism suspension and sends the information to the base unit, so the user has a assessment of the suspension. The Pod is intended to be used with polystyrene test tubes.

Pod Lights

The Pod has two lights on the front: one for the status of the pairing connection to the base and one for the McFarland status.

The Pairing Light demonstrates connectivity by:

- A blinking red light or solid colored light that does not match that of the base unit indicates that the Pod is not synced to the base unit, or it is out of range from the base unit.
- A solid colored light matching that of the base unit indicates that the Pod is synced to the base unit.

Note: *The solid colored light is configured on the **Configuration** screen by the user. The color options are cyan, blue, pink, white, green, and yellow.*

- No illumination of the light indicates that the Pod is not charged.
- A blinking colored light (excluding red) indicates that the Pod entered Power Save mode. If you want to exit Power Save mode, insert a test tube into the paired Pod, tap the display screen, or remove and re-seat the Pod on the base unit. The Pod turns on again.

Note: *Power Save mode does not affect connected PCs.*

The McFarland Status light demonstrates performance by:

- A green light 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.
- No light indicates that a suspension is being measured with the N/A card selected, that the pod is in the process of taking a McFarland measurement, or that no measurement is in progress.

Note: *When you have selected the N/A screen, the system does not alert you when a suspension is in or out of range. N/A provides the McFarland value for suspensions, but it does not provide an acceptable range.*

Pod Button

The Pod has one button on the back of it. If the Pod is paired with a base and a test tube is inserted, when this button is pressed once, the McFarland value for the current suspension is captured on the FLEXPrep screen (if configured).

IMPORTANT: *After pressing the button on the Pod, the following happens: The saved McFarland value appears above the main number on the screen.*

If the button is held down for approximately three seconds, while a saline tube or 0.0 McFarland reference is inserted, then the instrument is zeroed.

Figure 15: Pod

1. McFarland Status Light
2. Pod Pairing Light
3. Pod Button

A contrast plate is included with the Pod. The contrast plate can be used to aid in assessing the turbidity of a suspension. This contrast plate cannot be used as an alternative manual inoculation measurement method.

Figure 16: Contrast Plate Within the Pod

1. Contrast Plate

Display Base

The Display Base syncs to and charges the Pod. This base has a display screen that displays a McFarland reading measurement of a tube inserted into the Pod. This base can also transmit information to the VITEK® 2 software compatible with the VITEK® DensiCHEK®, if the user has access to the software.

When a Pod is synced to a Display Base, the McFarland Status light on the Pod matches the McFarland Meter color on the display screen. Additionally, the Pod icon color in the corner of the display screen matches the Pairing Light color on the Pod.

Figure 17: VITEK® DensiCHEK® Display Base with the Pod



1. McFarland Status Light
2. Display Screen

Connectivity Base

The Connectivity Base syncs to and charges the Pod. This base unit does not have a display screen, so the values are transmitted directly to the VITEK® 2 FLEXprep software.

Both the Display Base and the Connectivity Base work with the Connectivity workflows; however, the connectivity base does not work with Standalone workflows. To use the Connectivity Base, you must have the instrument connected to the compatible PC with VITEK® 2 FLEXprep software using the provided USB cable.

When a Pod is synced to a Connectivity Base, the Pod Pairing Light color matches the Base Pairing Light color.

WARNING



If the Connectivity Base fails to communicate with the PC, the following occurs: (1) the McFarland measurement data is not displayed; (2) the Connectivity Base cannot download software or firmware updates; and (3) the Connectivity Base cannot send data to the connected VITEK® 2 Systems PC.

Figure 18: VITEK® DensiCHEK® Connectivity Base with the Pod

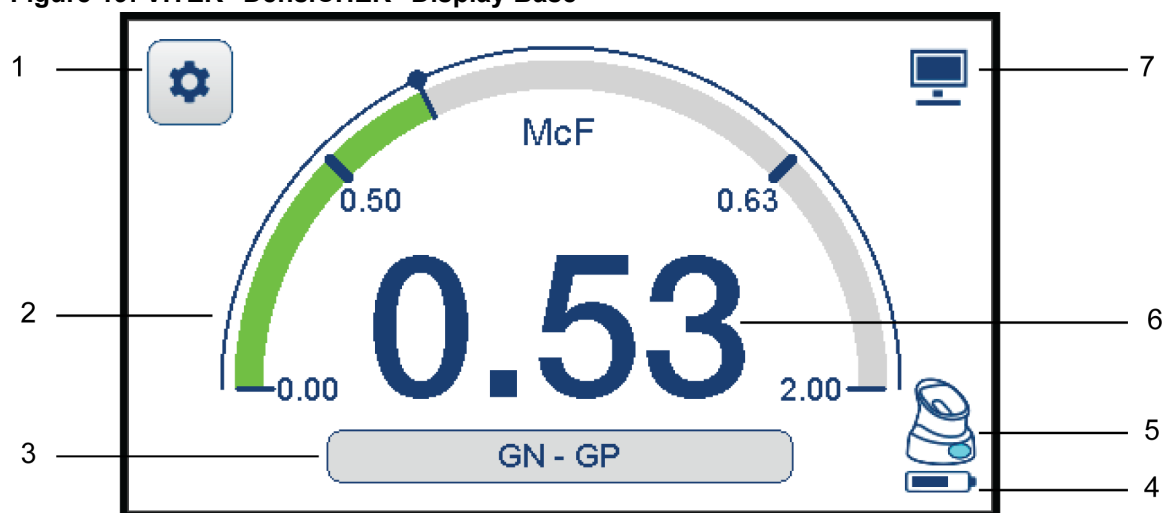
1. McFarland Status Light
2. Pod Pairing Light
3. Base Pairing Light
4. Pod Button
5. Base Charging Port

Graphical User Interface

With the user interface of the VITEK® DensiCHEK®, you can easily identify and capture the McFarland value of your suspension. When using the Display Base, the user interface is on the instrument in the form of a display screen, and, if configured, a software interface called FLEXprep. When using a Connectivity base, the user interface is with a software interface called FLEXprep.

Display Base Screen

On the Display Base touch screen, users can tap the **Card Type** button on the bottom of the display to select the appropriate card type (GN-GP, BCL-YST, ANC-CBC-NH, or N/A), or users can tap the **Configuration** button to view or alter the instrument configuration settings.

Figure 19: VITEK® DensiCHEK® Display Base

1. **Configuration** button
2. McFarland Range Meter
3. **Card Type** button
4. **Pod Battery Life** icon
5. **Pod Pairing Color** icon














6. McFarland Value (Example: **0.53** McFarland Reading)
7. **PC Connection** icon



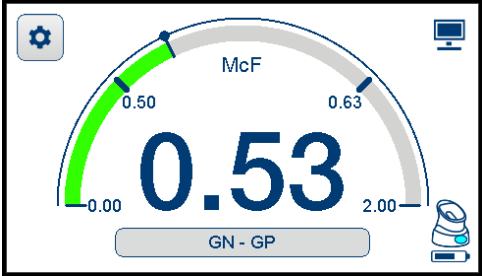

This screen is applicable for all suspension types (ex. GN, GP, ANC, etc.)

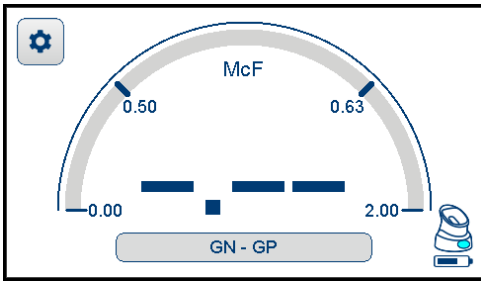

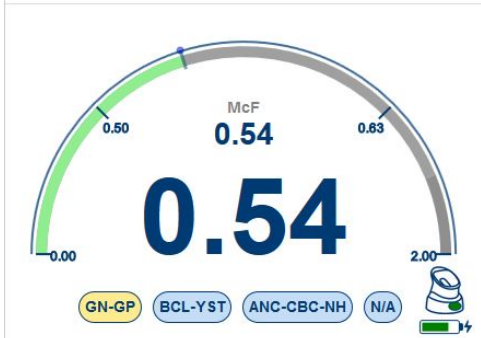
The display screen offers unique reading ranges for each of the following screen views:

- GN - GP
- BCL - YST
- ANC - CBC - NH
- N/A

Table 11: VITEK® DensiCHEK® Display Base Symbols and Screens

Symbol or Screen	Description
	Pod Battery Life icon - Pod not charging
	Pod Battery Life icon - Pod needs to be charged
	Pod Battery Life icon - Pod is charging
	Configuration button - Base and Pod pairing settings and more
	PC Connection icon - Base connected to and communicating with the PC
	Home button - McFarland screen access
	Left (decrease) Arrow button
	Right (increase) Arrow button
	Pod Pairing Color button
	Display Brightness button
	Base Sleep Time button (to enter Power Save mode)
	Tube Light Intensity button
	Pod Pairing Color buttons - Pod pairing color options

Symbol or Screen	Description
	Configuration screen
	Welcome screen
	McFarland screen
	Update screen - Pod firmware update is occurring
	McFarland Reference screen - A McFarland Reference is inserted in the Pod (LOT number value appears)
	McFarland screen - Card type is locked by FLEXprep™

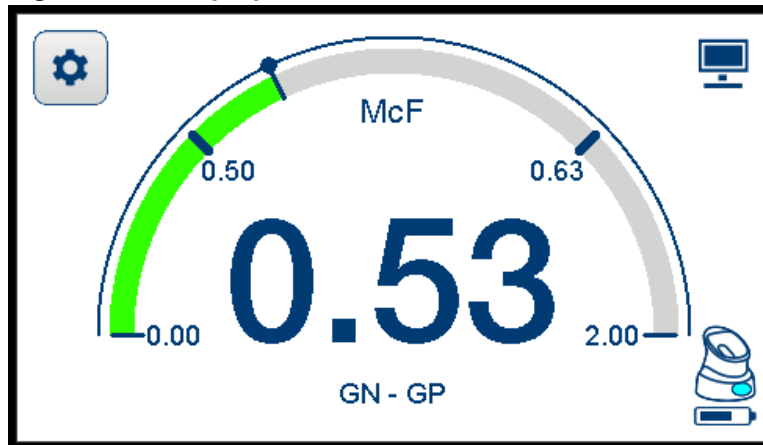
Symbol or Screen	Description
	McFarland screen - No tube is inserted
	McFarland screen - Pod is zeroed
	McFarland screen - McFarland value is captured IMPORTANT: After pressing the button on the Pod, the following happens: The saved McFarland value appears above the main number on the screen.

FLEXprep Software Interface Screen

The software interface of the VITEK® 2 software is compatible with the VITEK® DensiCHEK® and mimics the look of the Display Base screen.

The software offers the following features when the VITEK® DensiCHEK® Display Base or Connectivity base is connected to a FLEXprep™ PC:

- FLEXprep™ software mimics the VITEK® DensiCHEK® Display Base, including configuration settings. (Display Base configuration is only performed on the device.)
- The **DensiCHEK Gauge** window appears on the PC when the instrument is actively being used (i.e., a tube is inserted).
- Pressing the button on the VITEK® DensiCHEK® sends the McFarland value to the PC. FLEXprep™ only saves the value if it is configured to use a VITEK® DensiCHEK®.
- The following information appears on the connected PC:
 - McFarland Value
 - DensiCHEK Gauge window with McFarland Range
 - LOT Number (with the McFarland Reference inserted in the Pod)
- The **PC Connection** icon appears on the Display Base screen of the VITEK® DensiCHEK® when the instrument is communicating with the connected PC.
- The PC displays the McFarland meter range based on card type. The card type is locked on the base when a card type selection is made within FLEXprep. The card type and meter range unlock if the connection is lost, or if the isolate is validated or cancelled in FLEXprep™.

Figure 20: FLEXprep™ with VITEK® DensiCHEK® - Locked Card Type on Display Base**Figure 21: Configuration Screen**

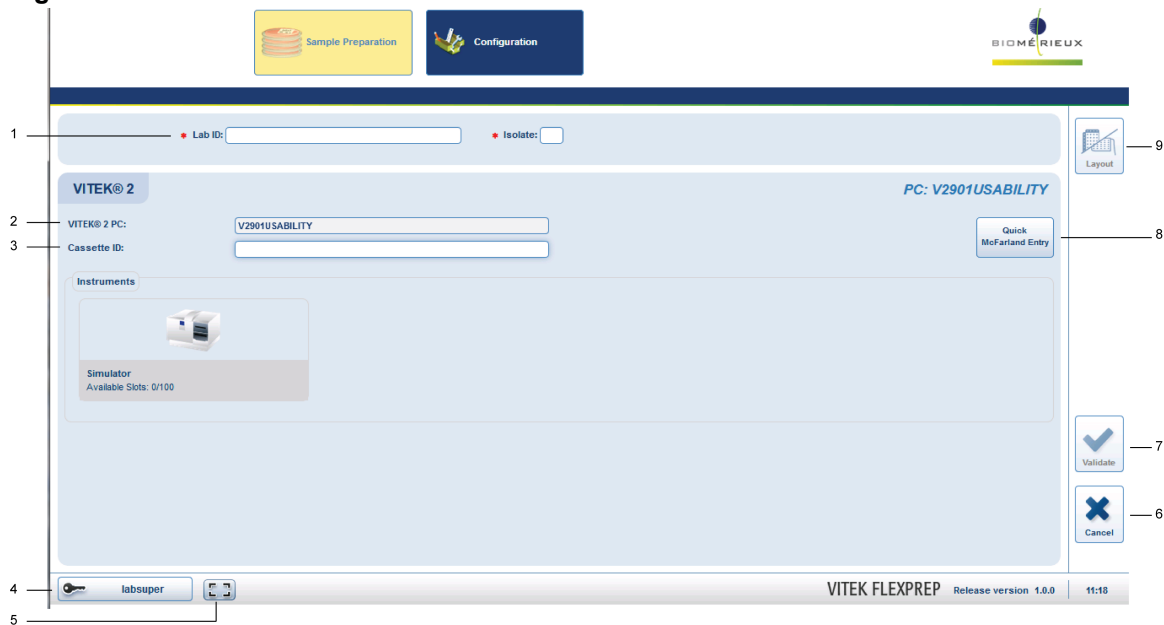
1. **Application Configuration** section
2. **VITEK® 2 Configuration** section
3. **McFarland Reference Standard** button

Figure 22: Quick McFarland Entry Screen

#	Lab ID	Isolate Number	McFarland
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

1. **Quick McFarland Entry** button
2. **McFarland** field
3. **Isolate** field
4. **Lab ID** field
5. Row Number

Figure 23: Cassette Identification Screen



1. **Lab ID and Isolate** fields
2. **VITEK® 2 PC** field
3. **Cassette ID** field
4. **User Account**
5. **Full Screen** button
6. **Cancel** button
7. **Validate** button
8. **Quick McFarland Entry** button
9. **Layout** button

Figure 24: Cassette Definition Screen

1. Lab ID: Isolate: ☐

2. **VITEK® 2**

QC

PC: V2901USABILITY

Summary

Setup Tech : Laboratory Supervisor

Slot #	QC	Accession ID	Card	Organism
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Card Type: Organism:

Organism Quantity: ☒ AST Offline Tests: BP Infection Site:

McFarland:

1

Cassette ID: bs1

3. labsuper

4.

16.

15.

14.

13.

12.

11.

10.

9.

8.

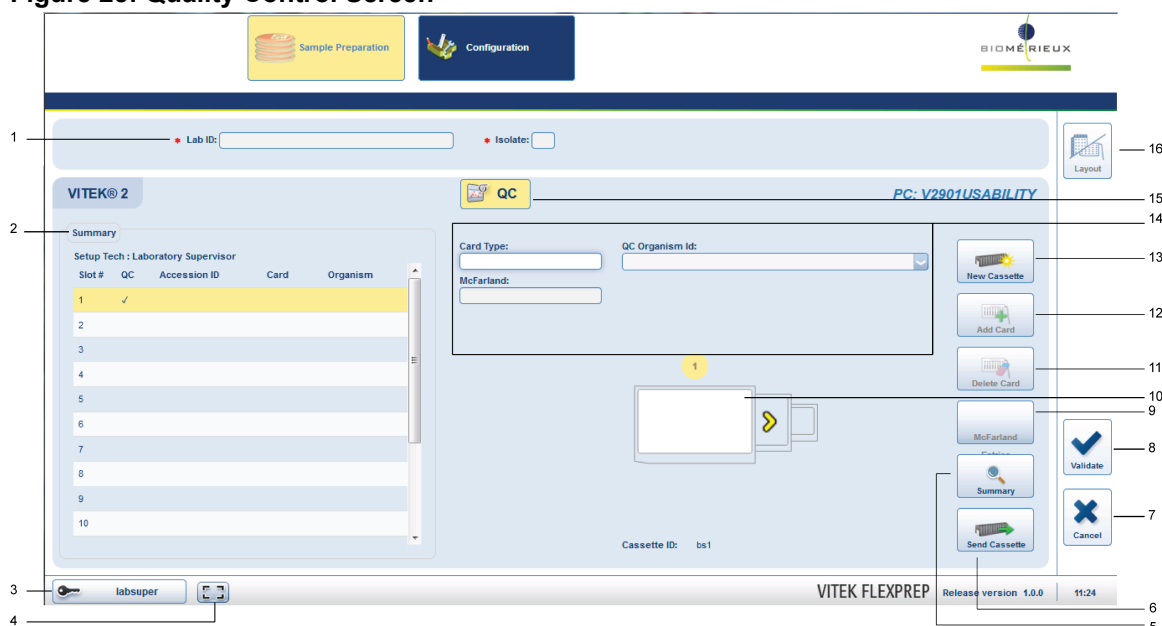
7.

6. VITEK FLEXPREP Release version: 1.0.0 11:24

5.

1. **Lab ID** and **Isolate** fields
2. **Abbreviated Summary** view
3. **User Account**
4. **Full Screen** button
5. **Full Summary** button
6. **Send Cassette** button
7. **Cancel** button
8. **Validate** button
9. **McFarland Entries** button
10. **Card Navigation** buttons
11. **Delete Card** button
12. **Add Card** button
13. **New Cassette** button
14. Card Fields
15. **QC** (Quality Control) button (disabled)
16. **Layout** button

Figure 25: Quality Control Screen



1. Lab ID and Isolate fields
2. Abbreviated Summary view
3. Labsuper (User Account)
4. Full Screen button
5. Full Summary button
6. Send Cassette button
7. Cancel button
8. Validate button
9. McFarland Entries button
10. Card Navigation buttons
11. Delete Card button
12. Add Card button
13. New Cassette button
14. Card Fields
15. QC (Quality Control) button (enabled)
16. Layout button

Figure 26: Cassette Definition Screen with Test Cards

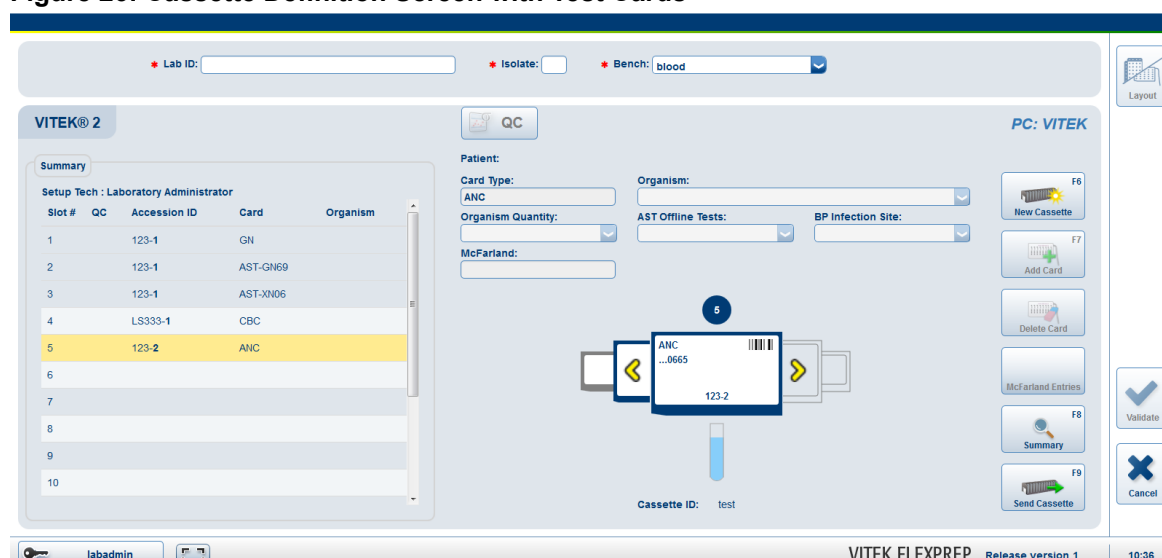
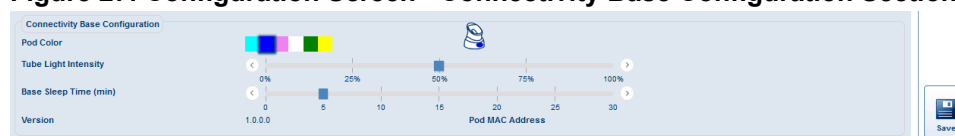


Figure 27: Configuration Screen - Connectivity Base Configuration Section

Performance Ranges

Suspensions for specific cards (ex. GN - GP) must fall within the correct performance ranges.

There are unique screen views with specific ranges for different types of cards. The McFarland reading ranges are as follows:

Table 12: 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

The McFarland meter on the screen appears green, yellow, or red to relay whether the values are in or out of range:

- If no organism suspension is inserted, the meter appears gray.
- If the organism suspension has a McFarland value that is above the defined performance range for the selected card type, the meter appears red.
- If the organism suspension has a McFarland value that is below the defined performance range for the selected card type, the meter appears yellow.
- If the organism suspension has a McFarland value that is within the defined performance range for the selected card type, the meter appears green.

Related Links

[Preparing Suspensions for ID and AST Cards \(Connectivity\)](#)

[Preparing Suspensions for ID and AST Cards \(Standalone\)](#)

GN and GP

The GN - GP screen shows a McFarland range of 0.00 to 2.00. The GN and GP suspensions must fall within the 0.50 and 0.63 range to show an appropriate McFarland reading.

Figure 28: VITEK® DensiCHEK® Display Base Screen - GN and GP

YST and BCL

The YST - BCL screen shows a McFarland range of 0.00 to 4.00. The YST and BCL suspensions must fall within the 1.80 and 2.20 range to show an appropriate McFarland reading.

Figure 29: VITEK® DensiCHEK® Display Base Screen - YST and BCL



CBC, NH, and ANC

The CBC - NH - ANC screen shows a McFarland range of 0.00 to 4.00. The CBC, NH, and ANC suspensions must fall within the 2.70 and 3.30 range to show an appropriate McFarland reading.

Figure 30: VITEK® DensiCHEK® Display Base Screen - CBC, NH, and ANC

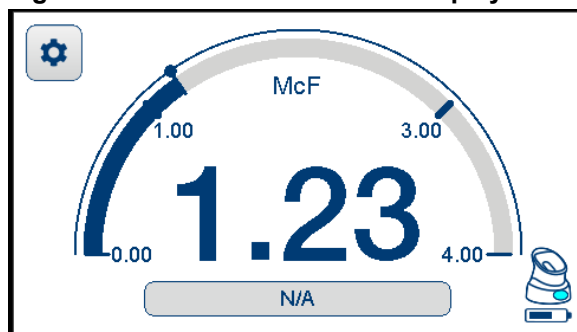


N/A

The N/A screen shows a McFarland range of 0.00 to 4.00.

When you have selected the N/A screen, the system does not alert you when a suspension is in or out of range. N/A provides the McFarland value for suspensions, but it does not provide an acceptable range.

Figure 31: VITEK® DensiCHEK® Display Base Screen - N/A



4 System Installation and Configuration

Unpacking the Instrument

1. Inspect the shipping container for external damage.
2. Open the shipping carton, and then remove the instrument from the shipping carton.
3. Carefully remove the instrument from the plastic bag.
4. Remove the remaining parts and documentation from the carton:
 - Product Certificates
 - VITEK® DensiCHEK® Instrument User Manual CD
5. Place the VITEK® DensiCHEK® instrument on a flat, horizontal surface that is dust free and away from direct sunlight.

WARNING



Failing to follow the proper installation procedures will result in incorrect device performance..

Connecting the Device

One of two methods may be used to power the Display base. One method is to connect the Display Base directly to AC power by use of a Single USB 2.0 to micro-USB and the provided AC Power Adapter. The second is to connect the Display Base to the PC by use of the 2.0 Dual USB connector to micro-USB. Only one method may be used to power the Connectivity Base. That is by connecting the Connectivity Base to the PC by use of the Single USB 2.0 to micro-USB .

If the battery life of the Display Base's Pod is completely depleted, it should be recharged at the Display Base. When doing so, ensure that either power is applied with the provided AC Power Adapter, or ensure both ends of the Dual USB connector are plugged into a PC.