

Document Name: DensiCHEK plus

Approved By:

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Status: **APPROVED**

PURPOSE:

The DensiCHEK plus measures the organism optical density by:

- Measurement of the optical density of the air before each actual reading, to compensate for variations in ambient parameters.
- Continuous measurement of the optical density of the solution within the tube.

Values are in McFarland units, proportional to bacterial concentrations of organisms isolated from clinical specimens.

This procedure will cover the following topics:


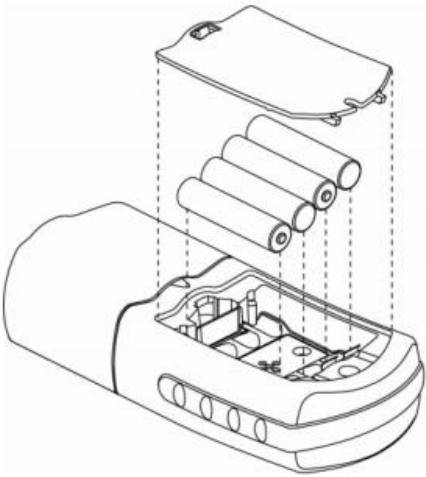
1. Replacing the batteries
2. Selecting plastic or glass test tube setting
3. Zeroing the instrument with saline blank
4. Preparing patient samples
5. Monthly maintenance
6. Cleaning



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1. Replacing the Batteries:


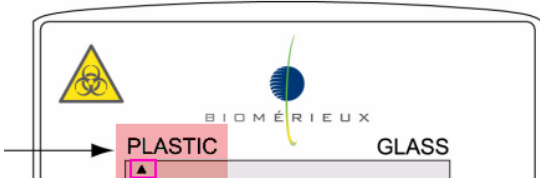
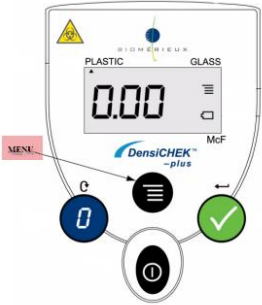

The instrument runs on 4 alkaline AAA batteries. The batteries should be replaced as soon as the low battery icon starts to display.

Step	Action
Replacing DensiCHEK plus batteries	
1	<p>Notice the low battery icon at the bottom left of the instrument window.</p>  <p>The image shows a close-up of the instrument's LCD display. At the top, it has 'PLASTIC' and 'GLASS' labels. The main display shows '0.00'. At the bottom right, there is a menu icon (three horizontal lines) and a low battery icon (a battery symbol with a lightning bolt) which is highlighted by a red box and a red arrow pointing to it from the right.</p>
2	<p>Obtain 4 <u>alkaline</u> AAA Batteries. These can be ordered from stores.</p> <p>WARNING: DO NOT USE HIGH ENERGY TYPE BATTERIES SUCH AS LITHIUM OR NiCad</p>
3	<p>Insert batteries respecting the correct polarities indicated inside the battery compartment.</p>  <p>The diagram shows the instrument with its battery cover removed. Four AAA batteries are shown being inserted into the compartment. Dashed lines indicate the correct orientation and placement of each battery. The cover is shown above the compartment, ready to be closed.</p>
4	<p>Turn on the instrument and ensure the instrument is set to the proper tube type needed. Refer to topic 2.</p>


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2. Selecting a Tube Type (Glass or Plastic):

WARNING: Users **MUST** ensure the instrument is set to the appropriate tube type prior to use. Failure to do this can lead to severe patient result errors.



Step	Action
Selecting Tube Type	
1	<p>Turn-on the instrument  and look for a black triangle on the screen to determine the currently selected tube type. The black triangle will be pointing towards the current setting (glass or plastic)</p> <p>In the example below the instrument is on the plastic setting:</p> 
2	<p>To begin changing the setting, press the menu key ONCE.</p>  <p>The screen will display the words SEL and the black triangle will be flashing below the current setting.</p>
3	<p>Press the read/enter key to toggle the triangle between settings.</p> 

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4	<p>When you have the black triangle below the desired heading press the menu key once.</p> 
5	<p>Check the main screen to ensure the tube type setting is correct.</p>


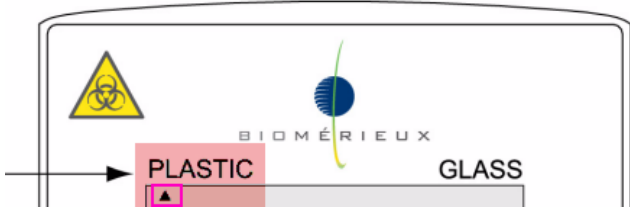
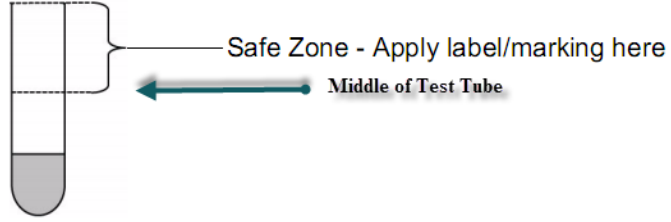
3. Zeroing the Instrument with Saline:

The instrument should be zeroed at the beginning of each set-up run.

Step	Action
Zeroing the DensiCHEK plus	
1	Turn the power on 
2	ENSURE THE TUBE TYPE SETTING IS CORRECT. If the setting is wrong, change it as per topic 2 and start again.
3	Choose a plastic test tube that is free from scratches and add 3 mL sterile saline.
4	Insert test tube into instrument.
5	<p>Press the ZERO/SCROLL key and slowly rotate the test tube.</p>  <p>Ensure one full rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by 0.00.</p>
6	Once the instrument has been zeroed it can be used to measure patient suspensions.

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4. Preparing Patient Samples:

Step	Action
Preparing Patient Samples	
1	<p>Turn the power on . The instrument should be set to PLASTIC. Refer to topic 2.</p>  <p>WARNING: FAILURE TO SET THE TUBE TYPE SETTING CORRECTLY WILL AFFECT INOCULUM DENSITY AND CAN CAUSE INCORRECT ID AND AST CARD RESULTS!!!!</p>
2	Ensure the instrument has been zeroed for the plastic setting. Refer to topic 3.
3	<p>Select a clean plastic test tube free from scratches and ensure that no labeling is placed on the tube within the instruments' reading zone.</p> 
4	Fill the test tube with 3.0mL of sterile saline and inoculate with colonies as per established procedures for Vitek card being used. Refer to MIC70180, MIC70190 and MIC70200.
5	With the instrument ON , place tube in instrument and rotate slowly. Ensure one full rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by a reading.
6	Check that the McFarland value is within the acceptable range for card type.
7	Adjust suspension if necessary. NOTE: If the instrument flashes 0.00 or 4.00 , the suspension is outside the readable range of the instrument.
8	Repeat steps for each new patient suspension.

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5. Monthly Maintenance:

The DensiCHEK plus calibration must be verified monthly using 0.0, 0.5, 2.0 and 3.0 McFarland Standards.

Step	Action												
Monthly DensiCHEK plus Calibration													
1	Set the tube type to GLASS. Refer to topic 2.												
2	Gently invert the 0.0 McFarland Standard several time then insert into instrument. DO NOT USE VORTEXER: AIR BUBBLES WILL AFFECT READING.												
3	Zero the instrument using the Zeroing key. Refer to topic 3. NOTE: Same steps as zeroing the saline blank but using the McFarland Standard instead.												
4	<p>Read each standard by gently inverting to mix, cleaning outside of tube with kim wipe, inserting into instrument and rotating one full turn. Ensure the values obtained are within acceptable range.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Standard</th> <th colspan="2">Acceptable Range</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0.5 McF</td> <td style="text-align: center;">0.44</td> <td style="text-align: center;">0.56</td> </tr> <tr> <td style="text-align: center;">2.0 McF</td> <td style="text-align: center;">1.85</td> <td style="text-align: center;">2.15</td> </tr> <tr> <td style="text-align: center;">3.0 McF</td> <td style="text-align: center;">2.79</td> <td style="text-align: center;">3.21</td> </tr> </tbody> </table>	Standard	Acceptable Range		0.5 McF	0.44	0.56	2.0 McF	1.85	2.15	3.0 McF	2.79	3.21
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5	Enter results onto MIC70110.1 Maintenance Record – Vitek 2. If results are out of range notify the Tech II.												
6	After calibration is complete, ensure the tube type is changed back to plastic for daily use.												

6. Cleaning:

The instrument should be cleaned any time a spill occurs.

Step	Action
DensiCHEK plus Cleaning	
1	Prepare a 10% bleach solution. **DO NOT USE ALCOHOL**
2	Wipe the surface of the DensiCHEK plus with the bleach solution.
3	Remove the adaptor and soak in the 10% bleach solution.
4	Use a swab dipped in 10% bleach solution to clean the reading chamber surfaces.
5	Rinse the adaptor in plain water and fully dry before re-inserting into the instrument.
6	Perform calibration check. Refer to topic 5.

REFERENCES:

- DensiCHEK plus User Manual, 2016/03

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	17-Sep-2012	Initial Release	M-L Dufresne
2.0	15-Feb-2017	Update format	L. Steven
3.0	22-Nov-2017	Update format and new instrumentation	L. Steven