BD PhoenixSpec™ Nephelometer
User's Guide

IVD bd.com/e-labeling Rx Only

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English

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INTENDED USE

The BD PhoenixSpec™ Nephelometer is a portable device designed to measure turbidity of microbial suspensions equivalent to McFarland standards 0.10 to 4.50. The instrument may be used for measurement of inoculum density for the BD BBL™ Crystal™ System and the BD Phoenix™ System. The instrument is battery operated or can be used with an AC adapter.

SUMMARY AND EXPLANATION

The visual comparison of organism suspensions to turbidity standards is an accepted method of estimating organism densities. The most widely accepted standard is the McFarland standard.[1] A McFarland standard is prepared by adding barium chloride to aqueous sulfuric acid. The density of the resulting barium sulfate precipitate can be used to approximate the colony count of a prepared suspension; e.g., McFarland 1 is the equivalent of approximately 3.0 x 10^8 colony forming units (CFU)/mL of *E. coli*, ATCC® 25922. Other standards have been used for density measurements, including titanium dioxide[2] and latex particle suspensions.[3] The BD PhoenixSpec™ Nephelometer uses latex particle suspensions as calibration standards that do not require shaking before use.

The instrumented measurement of turbidity relies on the ability of particles to scatter light while in suspension. The measurement of this scattered light is referred to as nephelometry.[4] In order to obtain an accurate density measurement, a reliable method of calibration must be used.

PRINCIPLES OF THE PROCEDURE

The BD PhoenixSpec™ Nephelometer is a solid state instrument that uses a tungsten-filament lamp as a light source, a 90° detector to monitor scattered light and a transmitted light detector. The instrument's microprocessor calculates the ratio of the signals for the 90° and transmitted light detectors. The ratiometric technique compensates for color and/or light absorbing materials, and for fluctuations in lamp intensity.

Before making measurements, the BD PhoenixSpec™ Instrument is calibrated with the BD PhoenixSpec™ or BD PhoenixSpec™ AP Calibrator Kit. To determine the McFarland equivalent of a microbial suspension, a tube is placed in the reading chamber and the test button is pressed. The results are displayed on the LCD screen in McFarland units. On a daily basis, the 0.25 and 0.5 calibrators in the BD PhoenixSpec™ Calibrator Kit, are read as a sample to assure proper operation. On a daily basis, the 0.25, 0.5 and 2.0 calibrators in the BD PhoenixSpec™ AP Calibrator Kit, are read as a sample to assure proper operation.

SPECIFICATIONS

Range	McFarland 0.10–4.50
Accuracy	0.5 ± 0.08 McFarland 2.0 ± 0.1 McFarland
Repeatability	0.5 ± 0.04 McFarland 2.0 ± 0.1 McFarland
Universal AC Adapter	Input: 100–240VAC; 50–60 Hz, 0.5A Output: 9.0VDC, 2.0A, 18W
Battery	Four Size AA Alkaline Cells
Battery Life-in-Use, Number of Tests	2,300 Tests
Ambient Operating Conditions	20 °C to 30 °C 0 to 90% RH at 30 °C Indoor use only. Altitude up to 2,000 m
Storage Temperature Range Nephelometer	-40 °C to 60 °C (-40 °F to 140 °F)
Calibrators	5 °C to 60 °C
Sample Tube Size	BD "L" tube 16 mm diameter 75 mm height
Lamp Life	~ 400,000 readings

WARNINGS AND PRECAUTIONS

For in vitro Diagnostic Use. For Use by Trained Laboratory Personnel.

1. The BD PhoenixSpec™ Nephelometer is designed to work with BD “L” tubes (16 x 75 mm) only. The minimum acceptable fill volume is 2.0 mL.
2. The BD PhoenixSpec™ Nephelometer is designed for use with BD Phoenix™ and BD BBL™ Crystal™ Systems only.

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

PROCEDURE

Materials Provided

BD PhoenixSpec™ Nephelometer, AC Adapter and 4 AA Alkaline batteries (not rechargeable). The BD PhoenixSpec™ Calibrator Kit (0.25, 0.5, 1.0, and 4.0 McFarland units) and BD PhoenixSpec™ AP Calibrator Kit (0.25, 0.5, 1.0, 2.0, and 4.0 McFarland units) are available separately. See **AVAILABILITY**.

Materials Required But Not Provided

Ancillary culture media and equipment required to prepare a bacterial suspension.

Instructions

BATTERY INSTALLATION AND REPLACEMENT: Remove the instrument and batteries from the shipping box. Remove the battery compartment cover from the instrument bottom and install the batteries. Correct battery polarity is shown on the battery holder. Reinstall the battery compartment cover.

USING THE AC ADAPTER: Plug the adapter jack into the instrument’s connector. The AC Adapter may be used with or without the batteries installed. The AC Adapter will not recharge the installed batteries. Position the equipment so the disconnecting device is easily accessible.

CALIBRATION PROCEDURE:

Notes:

- The instrument should be calibrated every 3 months, when the daily calibration verification check of the 0.25, 0.5, and/or 2.0 BD PhoenixSpec™ Calibrators read outside the 0.23–0.27, 0.45–0.55, and 1.8–2.2 McFarland range, respectively, or as dictated by the laboratory’s experience or policy.
- Use only the BD PhoenixSpec™ or BD PhoenixSpec™ AP Calibrator Kit supplied for use with the BD PhoenixSpec™ Instrument.
- Keep the BD PhoenixSpec™ Calibrators in the supplied packaging to avoid scratching the tubes, as could happen in a metal test tube rack, for example. Scratches or dirt on the surface of the tubes can affect readings.
- Do not use the BD PhoenixSpec™ Calibrators beyond the expiration date which appears on the label.
- The instrument should be placed on a stationary, level surface.
- If an error code flashes on the LCD screen during the procedure, refer to the **TROUBLESHOOTING** section.
- The BD PhoenixSpec™ Calibrators do not require shaking before use.

1. Press the power button  to turn instrument ON.
2. Insert the 0.25 BD PhoenixSpec™ Calibrator into the reading chamber. Press the Calibration button. 
3. The screen will flash S1 (Standard 1).
4. Press the Read button.  The screen will count backwards from 10.
5. The screen will flash S2. Remove the 0.25 Calibrator and insert the 1.0 Calibrator. Press the Read button. 
6. The screen will count backwards from 10, then flash S3. Remove the 1.0 Calibrator, insert the 4.0 Calibrator and press the Read button. 
7. The screen will count backwards from 10, then go back to S1. Press the calibration  button.
8. Remove the 4.0 Calibrator. Calibration is now complete.

Note: If errors occur, refer to the **TROUBLESHOOTING** section.

TESTING PROCEDURES:

Notes:

- The instrument should be placed on a stationary, level surface.
- On a daily basis, the 0.25 and 0.5 BD PhoenixSpec™ Calibrators for the BD PhoenixSpec™ Calibrator Kit or the 0.25, 0.5, and 2.0 BD PhoenixSpec™ Calibrators for the BD PhoenixSpec™ AP Calibrator Kit must be read as samples and the readings must fall between 0.23–0.27 (for the 0.25), 0.45–0.55 (for the 0.5), and 1.8–2.2 (for the 2.0). If either reading falls outside its corresponding range, recalibrate the BD PhoenixSpec™ Instrument.
- The BD PhoenixSpec™ Calibrators do not require shaking before use.

1. Press the power button to turn instrument ON.
2. Vortex the capped test sample and let bubbles disperse for 10 seconds.
3. Lift the lid, and insert the tube.
4. Press the Read button.
5. Read the display after the lamp symbol turns off.
6. Remove the tube from the reading chamber.
7. Adjust the sample suspension with more organisms if the readout is lower than expected. Vortex the sample and reread.

   Note: Refer to the *BD Phoenix™ System User's Manual* for the proper sample preparation for the BD Phoenix™ System if the reading exceeds the expected McFarland range or refer to the BD BBL™ Crystal™ System instructions for use if the reading exceeds the expected McFarland range.
8. Repeat step 7 until the desired McFarland density is achieved.
9. When testing is complete, press the power button to turn the instrument OFF.

RESULTS

The BD PhoenixSpec™ Instrument displays the measurement in McFarland units. These units represent the optical density of the suspension and may be used to estimate the CFU/mL of the suspension tested.

LIMITATIONS OF THE PROCEDURE

1. The BD PhoenixSpec™ Instrument must be calibrated with the BD PhoenixSpec™ Calibrators.
2. The BD PhoenixSpec™ Calibrators are to be used only for calibration of the BD PhoenixSpec™ Nephelometer and not as a visual, manual approximation to a barium sulfate McFarland standard.
3. Do not use the BD PhoenixSpec™ Nephelometer for measurements outside the range of 0.1–4.5 McFarland units.
4. Volumes below 2.0 mL must not be measured in the instrument.
5. BD "L" tubes—16 mm diameter x 75 mm—must be used for samples.
6. Do not operate the instrument in direct sunlight.

PERFORMANCE CHARACTERISTICS

To determine the accuracy of the BD PhoenixSpec™ Nephelometer, colony counts were performed on suspensions of *E. coli* ATCC® 25922 prepared in saline. Each test dilution was performed in replicates of six and the average of the plate counts is given in Table 1.

Table 1

McFarland	Expected CFU/mL x 10^8	Adjusted* CFU/mL x 10^8	% CV
0.25	0.75	0.9	14.1
0.5	1.5	1.7	13.2
1	3.0	3.2	7.4
2	6.0	6.1	4.2
3	9.0	9.3	3.2
4	12.0	12.6	2.7

*Because of difficulty in achieving the exact target McFarland density, these results were obtained by using the BD PhoenixSpec™ readings and adjusting the observed CFU/mL as if each dilution had been the target McFarland.

WARRANTY

The BD PhoenixSpec™ Nephelometer is warranted to be free from defects for one year from date of purchase.

MAINTENANCE

The general maintenance of the BD PhoenixSpec™ Instrument includes:

1. Wipe the exterior with a lint-free towel dampened with a mild, anti-bacterial solution.
2. Replace the batteries as needed.

TROUBLESHOOTING

Error messages

E-2	Two calibrators that were read were too close together in value (i.e., the same calibrator was read twice during the calibration procedure).
E-3	Low light error. Check for obstructed light path.
E-4	Memory failure. Press the on/off key and if the error reappears, contact service.
E-5	A/D overrange. Check for obstructed light path.
E-6	A/D underrange. Check for obstructed light path.
E-7	Light leak. Ensure the tube is capped with a black cap. Press the tube down into the well to ensure it is fully inserted.
E-8	Bad lamp or bad lamp circuit. Contact BD Technical Services.
Cal?	Do not use nephelometer. Contact BD Technical Services.
Low Battery	Replace all four AA Alkaline batteries when the  icon is flashing at the lower left corner on the display.

Note: If errors E-4, E-5, or E-6 appear consistently, an internal hardware problem is indicated and BD Diagnostic Systems Product Support should be contacted.

AVAILABILITY

Catalog Number	Description
440910	BD PhoenixSpec™ Nephelometer
440911	BD PhoenixSpec™ Calibrator Kit (contains 0.25, 0.5, 1.0, and 4.0 calibrators)
441951	BD PhoenixSpec™ AP Calibrator Kit (contains 0.25, 0.5, 1.0, 2.0, and 4.0 calibrators)
440986	BD PhoenixSpec™ Universal AC Adapter
441953	BD PhoenixSpec™ Calibrator 2.0 Mcfarland
441355	BD PhoenixSpec Calibrator 0.25 Mcfarland
441356	BD PhoenixSpec Calibrator 0.50 Mcfarland

REFERENCES

1. McFarland, J. 1907. The nephelometer: an instrument for estimating the number of bacteria in suspensions used for calculating the opsonic index for vaccines. JAMA *49*:1176-1178.
2. Roessler, W.G., and C.R. Brewer, 1967. Permanent turbidity standards. Appl. Microbiol. *15*:1114-1121.
3. Pugh, T.L., and W. Heller, 1957. Density of polystyrene and polyvinyl toluene latex particles. J. Colloid Sci., *12*:173-180.
4. Mallette, M.F. 1969. XV. Evaluation of growth by physical and chemical means, p. 521-566. *In* J.R. Norris and D.W. Ribbons (ed.), Methods in microbiology, vol 1. Academic Press Inc., New York.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Change History

Revision	Date	Change Summary
05	2022-02	Added “IVD”, “Do not use if package is damaged”, “Rx Only”, and “eIFU with URL” symbols. Added “REF” symbol with Catalog Numbers 440910, 440911, and 441951. Updated Ambient Operating Conditions under Specifications section. Updated Intended User statement and added Safe Disposal statement under Warnings and Precautions section. Added catalog numbers 441953, 41355, and 41356 under Availability section. Updated Technical Information and added Serious incident statement. Updated Symbols glossary. Updated Trademark and Copyright statement. Updated Manufacturer, EC REP, and Australian Sponsor addresses. Added CH REP and New Zealand Sponsor addresses.

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
	Patient number
	This way up
	Do not stack
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier

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