



BBS Revolution

PD-010-0002



OPERATIONS & MAINTENANCE MANUAL

Operations Manual Part Number: PD-010-0002-50-19

(Manual applies to console software version dB2.02 or later)

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Instructions for use developed in accordance with The Global Harmonization Task Force Label Instructions for Use for Medical Devices. Manual meets the requirements of NFPA99.

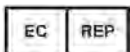
Information in this Operations Manual may change at any time without notice. Examples described or illustrated in this guide are fictitious and do not in any way represent real patient or exam data.



Caution: Federal law restricts this device to sale by or on the order of a physician.



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1. Important Information

Indication for Use:

The BBS Revolution™ device projects ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder, which is used to calculate bladder volume non-invasively. Users should consult with a healthcare professional for the interpretation of the results.



Contraindications:

- Not intended for fetal use.
- Not intended for use on pregnant patients.
- Device is for external use only.
- Do not use device on patients with open or damaged skin, or wounds in the suprapubic region.
- Do not use in conjunction with high frequency (HF) surgical equipment. Device lacks protective means for use with HF surgical equipment.



Precautions

- Do not immerse the system beyond the level specified in the Cleaning and Maintenance section.
- If the shipping package is damaged, crushed, punctured, or torn open to reveal contents, isolate the package and contact the shipper for disposition instructions.
- The patient should not have a catheter in his/her bladder. This could affect the accuracy of the instrument.
- Use care with suprapubic/pelvic surgery patients. Scar tissue, incisions, sutures and staples affect ultrasound transmission and can cause errors.
- Accuracy may be affected for patients with ascites or free floating fluid in the peritoneum.
- Scanner used without ultrasound gel may result in a poor or inaccurate reading.
- Prolonged use of scanner may result in heating of the outer surface. The scanner and console may shut down if excessive heating is detected.
- The most accurate measurements are obtained when the patient rests without movement in the supine position.
- Avoid rough handling.
- Only use supplied parts.

2. General Information

Product Name: BBS Revolution™

Product Model Number: PD-010-0002

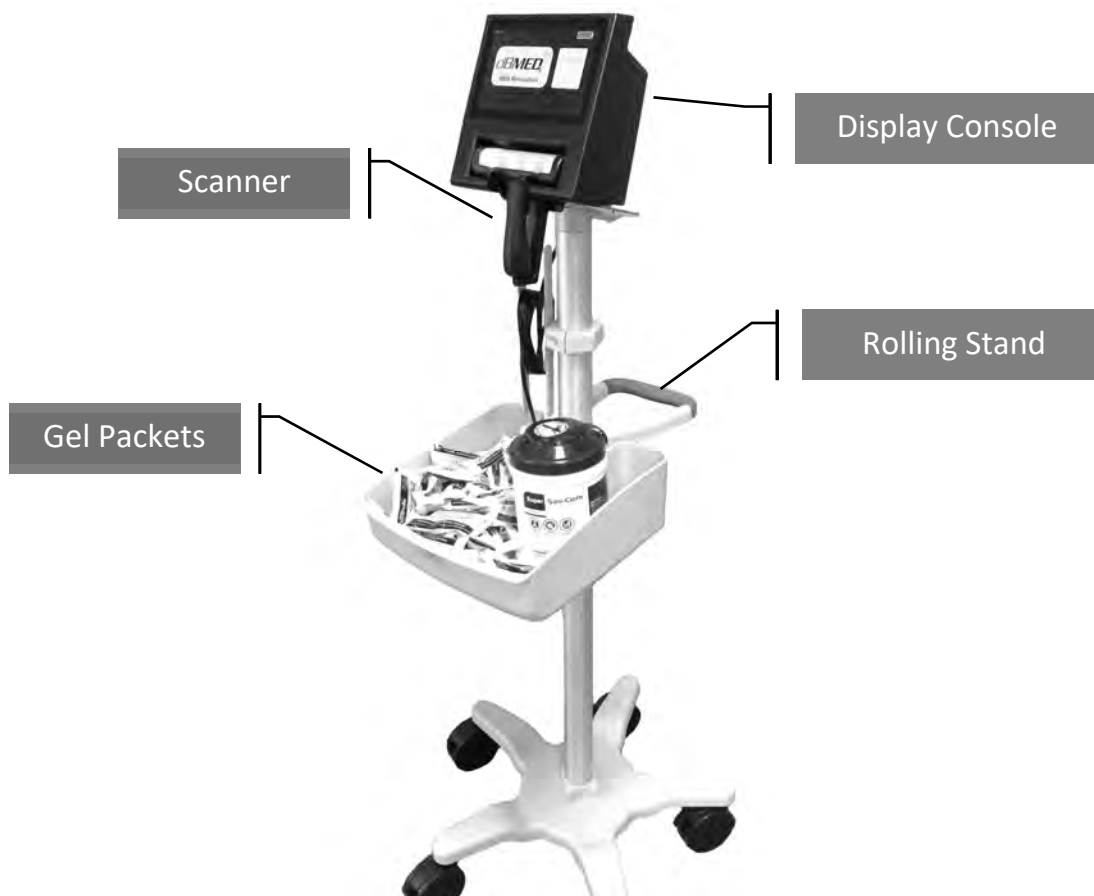
Product Description

The BBS Revolution™ is a fully automated bladder volume measurement device consisting of a wireless scanner and a display console. The system is battery powered and pole mounted for easy access, use and storage. The wireless scanner is automatically charged when docked in the console and performs the image collection and analysis automatically, transferring the results wirelessly to the console. This device combines the power and safety of ultrasound with sophisticated image processing electronics and software to provide a simple, accurate, fully automated and completely noninvasive bladder volume measurement.

Biological Safety

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should only be used when clinically indicated, using the lowest exposure times possible commensurate with clinical utility.

3. System Components



4. Assembly Instructions

Unpack all items and verify the contents match the packing list. The rolling stand will be shipped separately.

Packing List

<i>Item</i>	<i>Qty</i>	<i>Description</i>
1	1	<i>Wireless Scanner</i>
2	1	<i>Display Console and Power Cord</i>
3	1	<i>Gel Packet Starter Kit</i>

Assembly

- Assemble the rolling stand using the instructions included in that box.
- Turn on the console by toggling the power switch on the bottom of the device and remove the warning tag.
- Attach the console to the top of the mobile stand by sliding the mounting plate on the bottom of the console into the bracket on the top of the mobile stand. When the console is properly installed onto the stand, the spring-loaded tab on the bracket will lock onto the mounting plate, and the console screen will be tilted upward slightly.
- NOTE: If the screen is tilted down, remove the console from the bracket, rotate 180 degrees and reinstall onto the bracket.
- Tighten the two nylon screws under the mounting bracket to secure the display to the stand.
- Place the scanner in the display console.
- Place the gel packet starter kit into the bin.
- Connect the power cord to the display console and plug the cord into wall power for a minimum of two hours before using the system.

5. Bladder Volume Measurement Instructions

Setup - Explain the procedure to the patient and obtain the necessary supplies: clean single-use disposable gloves, BBS Revolution™ bladder scanner, dBsonx ultrasound gel packet (or equivalent). Wash hands and don clean gloves.



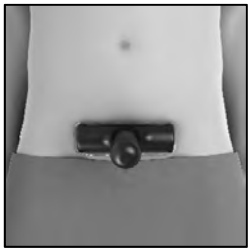
Remove the scanner from the console to wake up the system.

- The display console will show a history of prior scans, a Bluetooth icon, and a battery status icon.
- Blue lights will be visible in the scanner window indicating it is communicating with the console. You may see a small air bubble but this is normal.



Apply a generous quantity of ultrasound gel midway between the pubic bone (pubis) and navel (umbilicus).

- Apply the contents of the single packet of gel (or an equal amount from a gel bottle) to cover the full length and width of the scanner window.
- Sufficient gel is important to ensure an accurate reading.



Position the scanner in the gel so that the entire window surface of the scanner is evenly covered by the gel.

- Press until the window portion of the scanner clears the pubic bone.
- The white portion of the scanner will be completely pressed into the tissue at this point and only the black frame should be visible.



The handle should be perpendicular to patient, pointing straight up.

- Hold the scanner steady during the scan, do not move the scanner.



Press and release the button to perform a scan.

- There is no need to move or aim the scanner. The transducers will spin inside the scanner core to automatically locate the bladder.
- You can relax the pressure once the scan is complete and units stops spinning (~3 seconds).
- The volume will be displayed on the console.

IMPORTANT NOTE: The display console and rolling stand can be left outside the room to avoid contaminating the system when scanning a patient on isolation precaution. The wireless connection has a range of 33 feet or 10 meters.

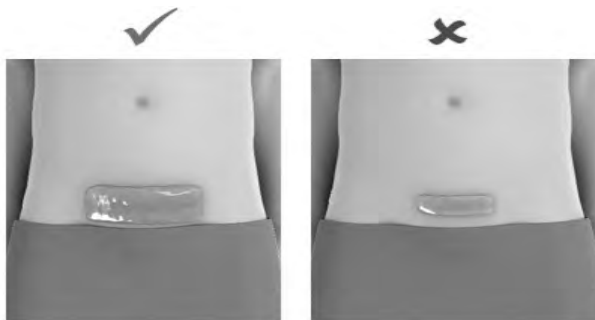
- The volume will be displayed on the left and a graphical representation of the bladder on the right. The window on the right will have a green border if the bladder was fully captured. Repeat the scan if the board is not green.
- The bladder volume is encoded in the barcode displayed at the lower left corner of the screen and can be used to scan the result into the patient's record (if supported).
- Repeat this process if additional confirmatory scans are desired.



Remove the scanner from the patient, clean and return to the console.

- Use a soft cloth to remove the gel and disinfect per your facility's protocol.
- Dock the scanner in the console to charge. Yellow lights will appear on the scanner indicating it is charging.
- The bladder volume is displayed for 3 min. once the scanner is docked.
- At the end of the day, return the unit to the storage/charging location and plug it in.

Remember three key points for an accurate scan!



#1 – GEL

Cover the window portion of the scanner completely.



#2 – HANDLE

The handle should be at the 12 o'clock position as shown, and not tilted down. This gives the scanner window a full view of the bladder.



#3 – PRESSURE

Press the scanner firmly into the patient until the white portion of the scanner is level with the pubic bone. The pressure is distributed over the face of the scanner and is not uncomfortable.

Power Management

- Yellow lights will appear on the scanner when it is docked, indicating it is charging.
- If the scanner is docked backwards, the scanner will not charge. If this occurs, the scanner icon on the screen will rotate and blink. Remove the scanner, rotate it 180 degrees to the proper position and place in the dock.
- The display will dim after 1 minute of inactivity to conserve console battery power.
- After 3 minutes of inactivity, the display will turn off to save power. Removing the scanner from the dock will turn the display back on and display the prior four scan results.
- If the scanner itself is not docked in the console after use, it will shut down after 4 minutes of inactivity to conserve scanner battery power. To resume scanning, press the button on the scanner or return to the console dock.
- At the end of the day, return the unit to the storage/charging location and plug it in.
- The console should be connected to AC power daily to ensure the main battery is fully charged. The battery status is displayed in the corner of the display and will turn red when the battery is at a low level. If the battery indicator turns red, connect the device to AC power for at least two hours. When the device is connected to AC power, the charging LED located on the left side of the console will turn red when the battery is charging. When the battery is approaching a full charge, the charging LED will turn yellow. When the battery is fully charged, the charging LED will turn green.

Scan History

- When the scanner is first removed from the console, the screen will display a history of the prior four bladder volume measurements. The window on the right side of the screen will show the most recent scan result on top with an underline.
- Below this value, up to three prior scan results are displayed in reverse chronological order as indicated by a gradually fading font color.



Printing

- If the printer option is installed, turn on the printer by pressing and holding the Power button until the green LED illuminates. The blue LEDs will indicate battery level.
- The bladder volume will automatically print a few seconds after the scanner is docked in console after a scan is completed.
- To print a second copy, or to re-print the results, simply remove the scanner from the console and then dock the scanner back in the console. It is the action of docking the scanner in the console which triggers a printout.



6. Cleaning

It is recommended that the device be cleaned after every use in the following manner:

- After each use, wipe the scanner with a soft cloth or towel to remove excess gel. A moist cleaning cloth may also be used to clean the unit.
- Disinfect the unit with bleach wipes, alcohol wipes, or any hospital disinfectant such as CaviCide[®], CaviWipes[®], Cidex[®], Cidex 7[®], or Sporocidin[®].
- After cleaning, inspect the scanner for cracks or damage.



Caution: Do not use harsh, corrosive chemicals (e.g. hydrochloric acid) or Cidex Plus[®] to perform maintenance.

7. Device Maintenance and Troubleshooting

Routine Maintenance

The BBS Revolution[™] is designed to perform for a minimum of 5 years without calibration, service, or maintenance and does not contain field serviceable parts. In case of a malfunction or fault, suspend use of the device and contact dBMEDx. The only suggested routine maintenance is a disinfection of the device after each use.

Software Updates

Software upgrades, if required, can be performed at the factory for no charge or remotely using a low-cost programming tool. Contact dBMEDx for more information.

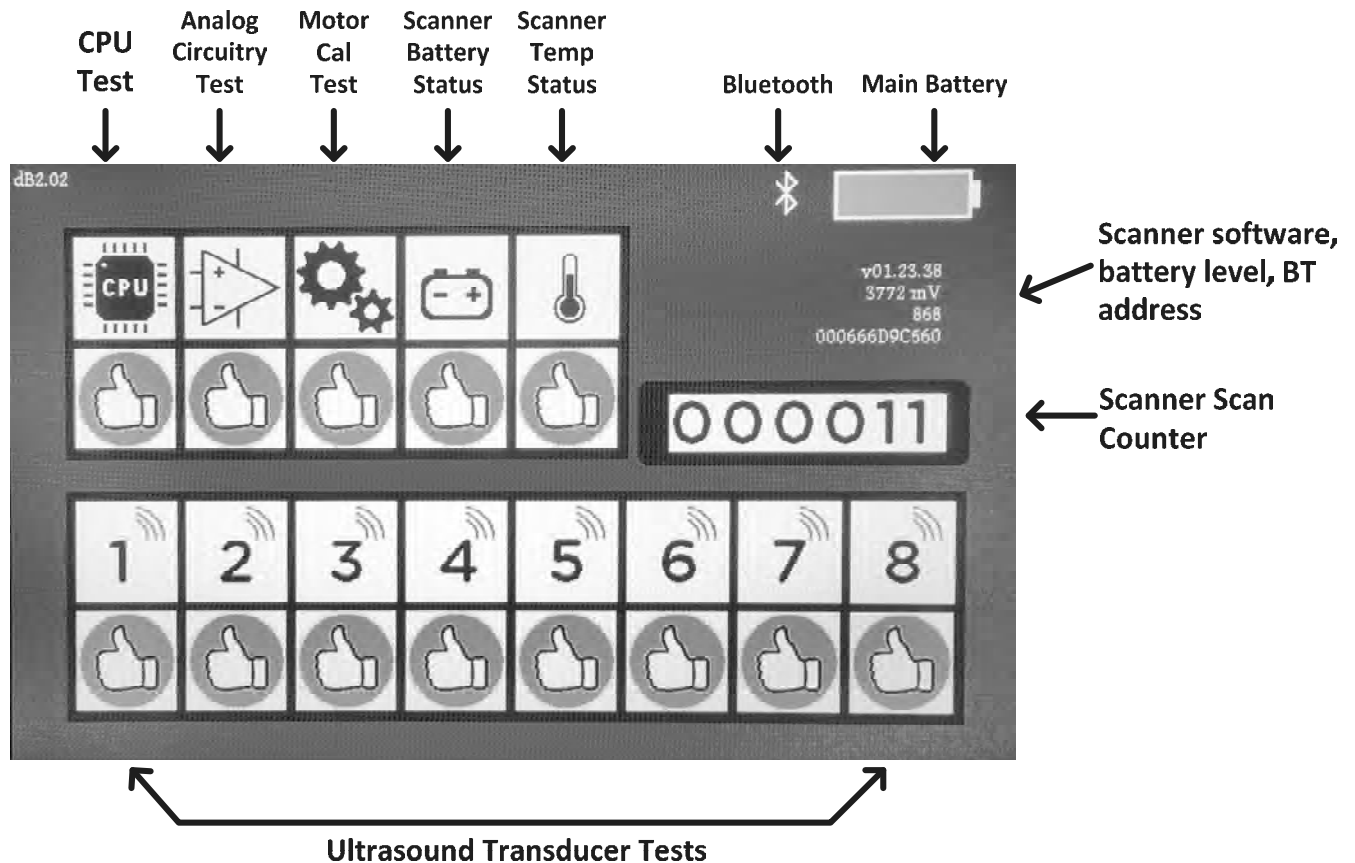
Testing and Troubleshooting

The BBS Revolution[™] is fully automatic in both its clinical testing mode and its internal self-diagnostics mode. Unlike legacy ultrasound bladder scanners, the next generation design of the BBS Revolution has built-in sensors to detect and correct scanner position and therefore does not require annual calibration. In addition, automated self-diagnostic testing and performance checks are conducted during each scan. If any of the components measures outside normal operating specification, the scanner sends an error message to the console rather than display a compromised volume result.

If any problems are suspected, the automated self-diagnostic test can be executed on demand by performing five test scans in a row while holding the scanner in the air (the scanner should be clean and not in contact with any surface). Press the scanner button, wait for “---” to be displayed on the screen, and repeat four more times to initiate the self-test sequence.

After a brief delay, the console will display the results of the self-diagnostic routine shown below. To clear the self-diagnostic data, perform one more “air scan” or simply return the scanner into its cradle location on the console and it will reset.

Status Screen Key:



In any of the tests indicate an error, with a red “thumbs down”, or in case of a suspected malfunction or device which is not responsive, try these troubleshooting steps:

- Return the scanner to the console for at least two minutes to reset the scanner. The amber LEDs should illuminate indicating the scanner is charging.
- Cycle power on the console by toggling the power switch on the underside of the device. It is necessary to remove the display console from the stand to access the power switch.
- Plug in the display console for a minimum of two hours or until the LED on the side of the display console turns green.

If these steps do not return the unit to full operation, contact dBMEDx or your authorized representative.

Bladder Phantom Testing

While it is not required, if there is a need to perform a phantom bladder measurement to verify operation, please contact dBMEDx or your distributor for recommendations on a suitable bladder phantom model. To use a phantom with the BBS Revolution™, it is critical to follow these guidelines:

- Use dBsonx single use gel packets and apply the full contents of two packets to the phantom. The contents of the first gel packet should be applied in a strip and the second gel packet should be applied on top of the first strip to create a longitudinal

mound of gel that is roughly the same length as the face of the scanner. The scanner should be well bedded into the center of this mound with the handle pointing straight up.

- Gently rock the scanner back and forth to insure it is well coated with gel and fully surrounded by gel. Press the button and hold the device still during the scanning process.
- Do not use water on top of the phantom to couple with the BBS Revolution™. The extremely wide viewing angle of the BBS Revolution™, which is extremely advantageous when measuring on a human, will allow it to see the side walls of the dam on top of the phantom and cause spurious reflections and could impact the scan result.

8. Device Repair

The BBS Revolution™ is not user serviceable and dBMEDx does not make available any circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories. All service must be performed by a qualified dBMEDx representative.



Caution: Due risk of injury or damage, do not attempt to open or disassemble the system components.

9. Disposal of Device

The BBS Revolution™ contains mineral oil, lithium batteries, PZT (Lead Zirconate Titanate) transducers and other potentially hazardous materials (similar to other medical ultrasound devices). Please follow local regulations for hazardous waste disposal or return the device to dBMEDx or a factory authorized service center for disposal.

10. Warranty

See separate warranty statement for details on the warranty coverage.

11. Safety and Performance Summary

The BBS Revolution™ is suitable for use in ISM (industrial, scientific and medical) environments, and in domestic environments under the jurisdiction of a health care professional.

The health care professional at your institution directing the use of the BBS Revolution™ is responsible for keeping current with developments in the literature on bladder volume. Please direct any questions or problems concerning bladder volume or interpretation of the bladder volume data to the responsible health care professional.

12. Regulatory Compliance

dBMEDx certifies that the BBS Revolution™ is in compliance with all applicable international and national standards and regulations, including, but not limited to, IEC-60601-1 (EN60601-

1) and EN 60601-1-2; MDD 93/42/EEC Annex 1, CSA22.2 No. 125 (Risk class 2) (LR 76129-1).
 Per the provisions of IEC-60601-1, this device is classified as:



Protection Class II, INTERNALLY POWERED EQUIPMENT



TYPE BF, suitable for CONTINUOUS USE

Per the MDD, the BBS Revolution™ is a Class IIa device.

13. Product Specifications/Technical Descriptions

Ultrasound Output

Ispta (derated):	5.0mW/cm ²
Isppa (derated):	0-60 W/cm ²
Maximum MI:	0.95
TIS/TIB/TIC Range:	0.0 – 4.0

NOTE: The Thermal Indices and the Mechanical Index are below 1.0

Accuracy

Bladder Volume Range	0–999 ml
Bladder Volume Accuracy on a Tissue Equivalent Bladder Phantom	± (12.5% + 12.5ml)

Bluetooth/ R.F. Device

- Specifications: Class 1 Bluetooth®, Frequency 2402 ~ 2480MHz, Range: up to 10m
- FCC (FCC ID: T9JRN41-3), ICS, CE, RoHS

Environmental Conditions for Use

Condition	Description
Ambient temperature range	10° to 40° C (50° to 104° F)
Relative humidity	30% to 75% non-condensing
Atmospheric pressure range	700 hPA to 1060 hPA
IP Classification	IPX0










Environmental Conditions for Storage

Condition	Description
Ambient temperature range	-20° to 60° C (-4° to 140° F)
Relative humidity	20% to 95% non-condensing
Atmospheric pressure range	500 hPA to 1060 hPA

Transportation

There are no shipping restrictions or special labeling on the BBS Revolution™. The system contains two lithium batteries, tested to UN/DOT 38.3, which are installed in equipment prepared in accordance with Section II of IATA (International Air Transport Association) Packing Instructions 967.

14. Symbol Directory

Symbol	Description
	Type BF applied part. To identify a type BF applied part with IEC-60601-1
	Attention, consult accompanying documents
	Collect separately from other household waste (See European Commission Directive 93/86/EEC). Refer to local regulations for disposal
	CE marked in accordance with the Medical Device Directive
	Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission
	Class II Equipment
	Manufacturer
	Serial Number
	Q mark from SGS US Testing service indicating compliance to listed ISO Standards.