

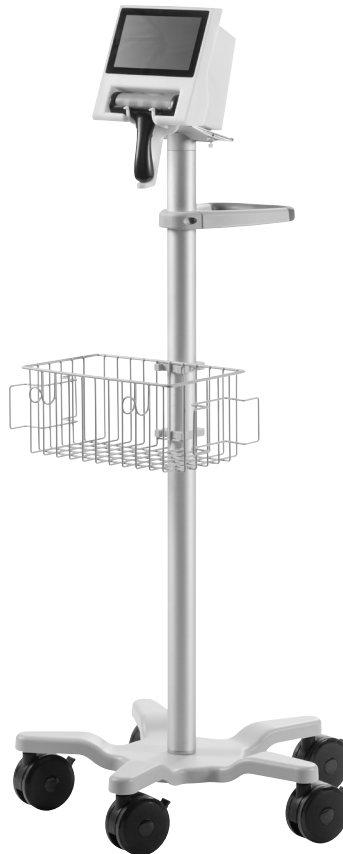


Attendant®

# PRODIGY™ BLADDER SCANNER APBS-1

## Owner's Manual

*Please keep and refer to this Owner's Manual.*



Thank you for purchasing an Attendant® Prodigy™ Bladder Scanner, distributed by Direct Supply Manufacturing, Inc. This guide will provide you with operating instructions, warnings, warranty data and other important information to be reviewed before you operate the device. Read the entire manual carefully and keep it for future reference. Share this information with your housekeeping, nursing and maintenance staff to help ensure the device is used and cared for properly.

# Introduction

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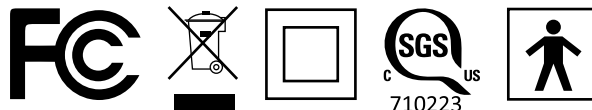
Part Number: PD-010-0010-50-00

No part of this Owner's Manual may be copied or transmitted by any method without the express written consent of Direct Supply Manufacturing, Inc.

Instructions for use developed in accordance with The Global Harmonization Task Force Label Instructions for Use for Medical Devices.

Information in this Owner's 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 resident/patient or exam data.

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



# Important Information

## Indication for Use:

The Attendant Prodigy Bladder Scanner projects ultrasound energy through the lower abdomen of the resident or patient to obtain an image of the bladder, which is used to calculate bladder volume noninvasively. Users should consult with a healthcare professional for the interpretation of the results.

## Contraindications:

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

## Warnings & Cautions:

Read and follow all directions, warnings and cautions before using this device. Do not operate the device if you do not understand the contents of this manual. Death or injury may result from improper use of this device or failing to follow directions and warnings. This device is intended for use by trained and licensed healthcare providers in normal, indoor conditions.

- ⚠ **CAUTION:** Do not immerse the system beyond the level specified in the Cleaning & Maintenance section.
- ⚠ **CAUTION:** If the shipping package is damaged, crushed, punctured or torn open to reveal contents, isolate the package and contact Direct Supply for instructions.
- ⚠ **CAUTION:** The resident or patient should not have a catheter in his or her bladder. This could affect the accuracy of the instrument.
- ⚠ **CAUTION:** Use care with suprapubic/pelvic surgery residents or patients. Scar tissue, incisions, sutures and staples affect ultrasound transmission and can cause errors.
- ⚠ **CAUTION:** Accuracy may be affected for residents or patients with ascites or free floating fluid in the peritoneum.
- ⚠ **CAUTION:** Scanner used without ultrasound gel may result in a poor or inaccurate reading.
- ⚠ **CAUTION:** Prolonged use of scanner may result in heating of the outer surface. The scanner and console may shut down if excessive heating is detected.
- ⚠ **CAUTION:** The most accurate measurements are obtained when the resident or patient rests without movement in the supine position.
- ⚠ **CAUTION:** Avoid rough handling.
- ⚠ **CAUTION:** Only use supplied parts, including the battery charger. If any part is lost or damaged, contact Direct Supply to order a replacement. Never use any battery charger or other part that is not supplied with or intended for use with the device.
- ⚠ **CAUTION:** Inspect the device prior to each use; do not use if the device or its accessories appear to be damaged in any way.
- ⚠ **CAUTION:** Do not make any modifications to the device.
- ⚠ **CAUTION:** Stop using the battery immediately if it fails to charge, has swelled or is leaking any liquid.
- ⚠ **CAUTION:** This device is intended as a tool in resident assessment. The device must be used in conjunction with other methods of assessing clinical signs and symptoms. The device is not intended for continuous monitoring or treatment.
- ⚠ **CAUTION:** Disconnect the power cord from the console prior to cleaning the device.
- ⚠ **CAUTION:** Use the device only as intended. Failure to use the device as intended may void the warranty and/or cause bodily injury.

# General Information

**Product Name: Attendant Prodigy Bladder Scanner**

**Product Model Number: APBS-1**

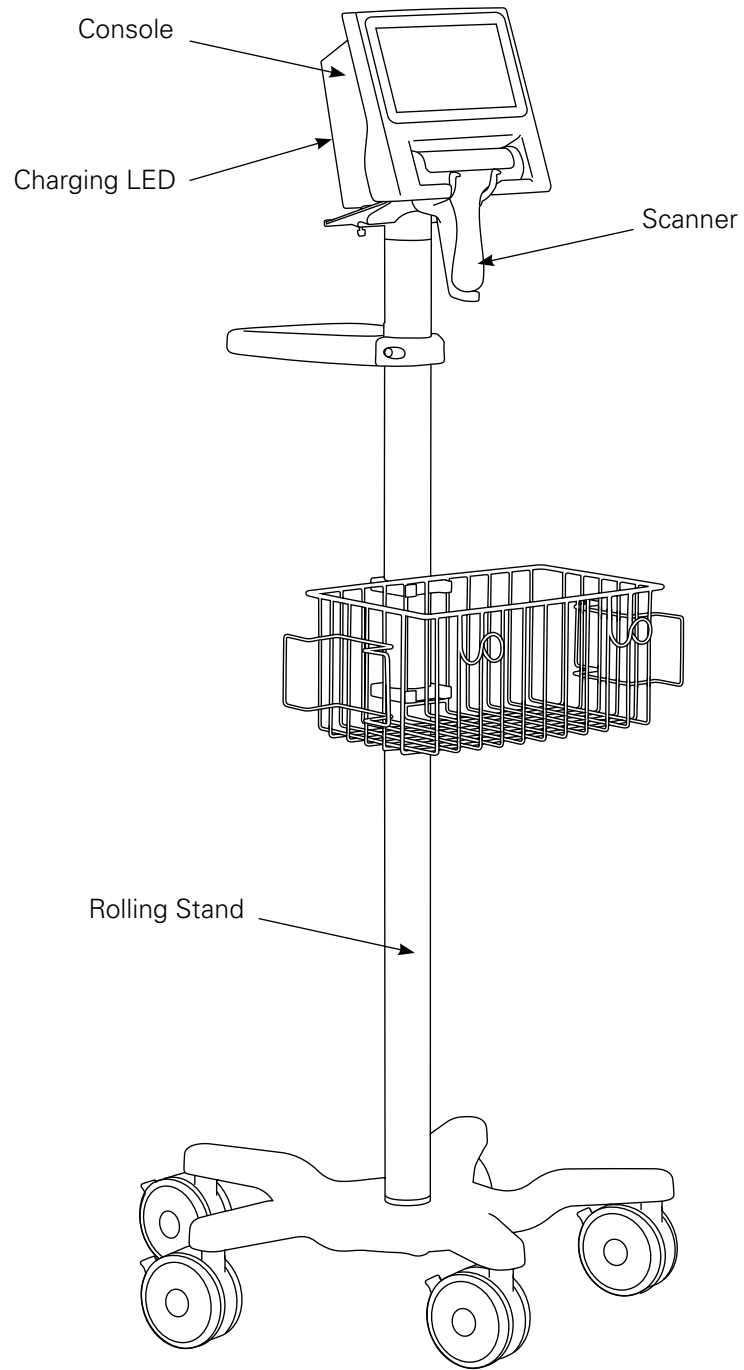
## **Product Description**

The Attendant Prodigy Bladder Scanner 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 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.

# System Components



# Unpacking & Assembly Instructions

Unpack all items and verify the contents match the packing list.

Assemble the Attendant Mobile Stand, using the instructions included in that box.

Turn on the console by toggling the power switch on the bottom of the device.

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, as shown on page 5. 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. If the screen is tilted down, remove the console from the bracket, rotate 180 degrees and reinstall onto the bracket.

Place the bag of gel packets into the basket on the stand.

Plug the Attendant Prodigy Bladder Scanner into a 120V AC outlet and charge the battery for a minimum of two hours before using the device.

## Packing List

Item	Qty	Description
1	1	Wireless Scanner
2	1	Console
3	1	Gel Packet Starter Kit
4	1	Attendant Prodigy Bladder Scanner Owner's Manual

# Operating Instructions



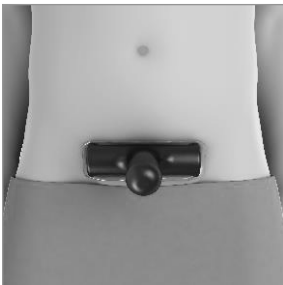
**Apply a generous quantity of ultrasound gel midway between the pubic bone (pubis) and navel (umbilicus).**

- Apply the contents of the single pack 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.



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

- Wipe down scanner if needed before proceeding.
- Blue lights will appear in the scanner window, indicating it's communicating with the console. You may see a small air bubble through the scanner window; this is normal.



**Position the scanner in the gel so 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 resident or patient, pointing straight up.**

- Hold the scanner steady during the scan (approximately 3 seconds).



**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 (~3 seconds).
- The volume will be displayed on the console.

# Operating Instructions *(cont.)*

- If more than one measurement is taken, the largest measurement in the series is displayed most prominently on the left side of the screen. This value is the most accurate measurement. The most recent measurement in the series is displayed on the right side of the screen, along with the bladder projection. The bladder projection will appear green if the bladder was scanned correctly.
- The barcode corresponds to the largest value displayed and is used to scan the result directly into the resident's or patient's record (if supported).



## **Remove the scanner from the resident or patient, clean and return to the console.**

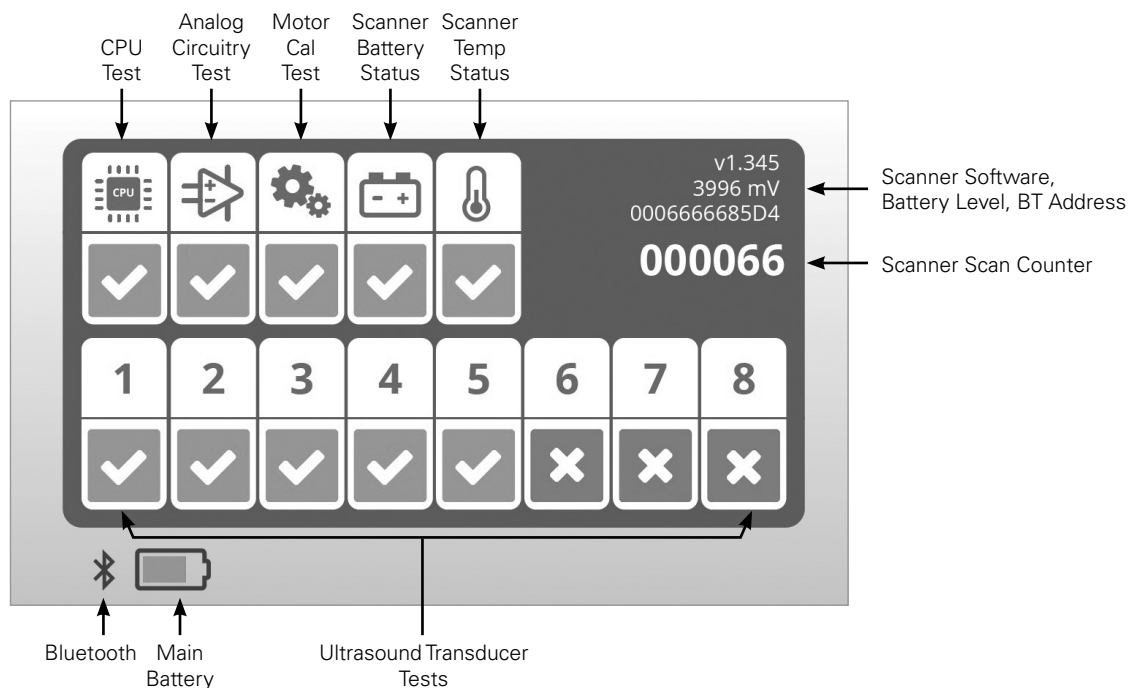
- Use a soft cloth to remove the gel and disinfect per your facility's protocol.
- Place the scanner in the holster on the console.
- The largest measurement from the series of scans will remain on the screen after holstering the scanner. The most recent scan and the bladder projection will be cleared.



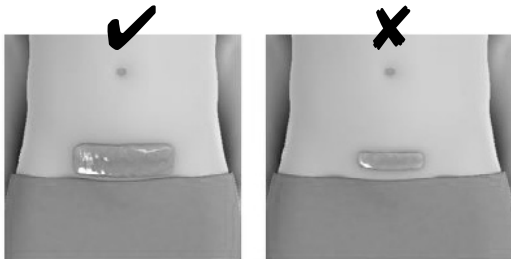
## **Power management**

- Yellow lights will appear on the scanner, indicating it is charging. After thirty minutes of non-use, the yellow lights will go out, indicating that the console battery has stopped charging the scanner battery. This is part of the power management program. If there's been an extended period of non-use (>2 weeks) with the system unplugged, the scanner battery may gradually discharge and be too low to make the Bluetooth connection to the console. If this happens, simply plug the system into the wall and allow the scanner to recharge for at least two hours.
- 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 console display will dim after 1 minute of inactivity to conserve battery power. Removing the scanner from the dock will restore full brightness.
- If the scanner is not docked in the console, it will shut down after 4 minutes of inactivity to conserve scanner battery power. To resume scanning, press the button on the scanner and wait for the blue LEDs to go solid indicating a successful Bluetooth connection. Once scanning is complete, always return the scanner to the console dock.
- After 30 minutes of inactivity, the display will power down to save power. Any readings on the display will be cleared when this occurs. Removing the scanner from the holster will turn the display back on.
- 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 console battery is fully charged. The battery status is displayed in the upper right-hand 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 display console is connected to AC power, the charging LED located on the back side of the console housing will turn yellow to indicate the battery is charging. When the battery is fully charged, the charging LED will turn green.
- By performing 5 air scans in a row, you will manually display the 'diagnostic' screen. The arrow below highlights the scanner battery charge level that is displayed by the diagnostic screen. A number above 3700 mV indicates a fully charged battery and a number below 3000 mV represents a discharged battery.





## Remember three key points for an accurate scan!



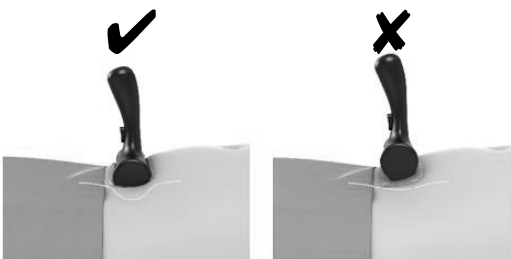
### #1 – GEL

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 resident or patient until the white window portion of the scanner is level with the pubic bone. The pressure is distributed over the entire face of the scanner and does not cause discomfort for the resident or patient.

# Cleaning & Maintenance

It is recommended that the device be regularly maintained 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 or any hospital disinfectant, such as CaviCide®, CaviWipes®, Cidex® or Cidex 7®.
- 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.

The device should be connected to AC power daily to ensure the main battery is fully charged. The battery status is displayed in the lower left hand 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 back side of the console housing will turn yellow to indicate the battery is charging. When the battery is fully charged, the charging LED will turn green.

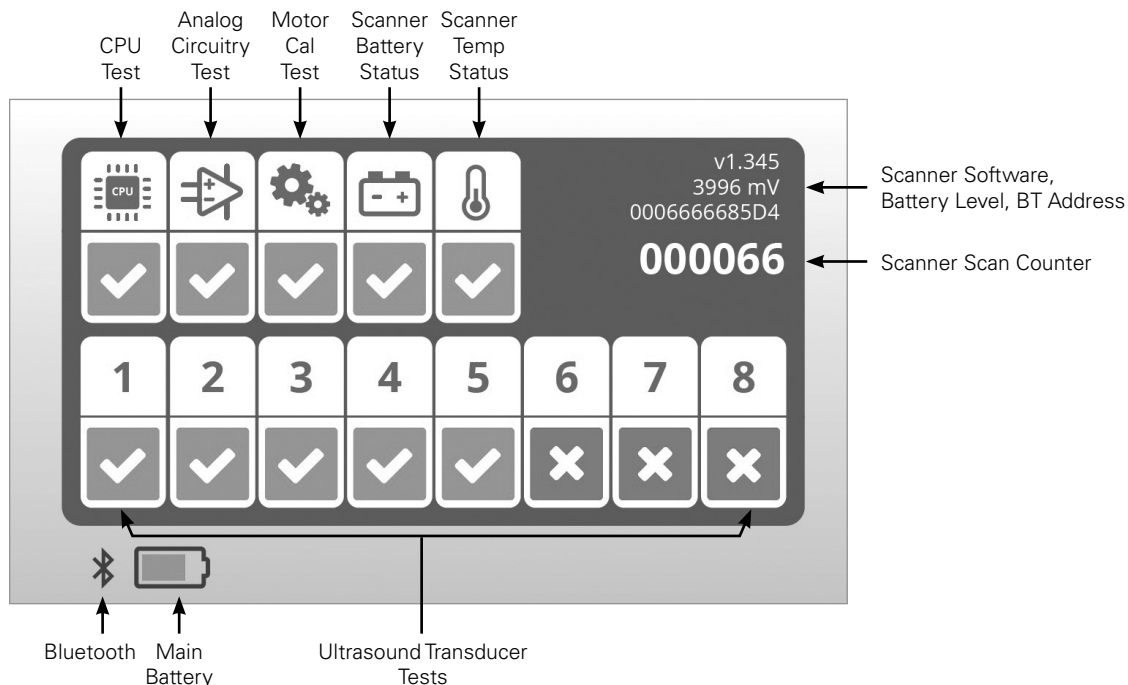
# Service Requirements & Troubleshooting

The Attendant Prodigy Bladder Scanner is designed to perform for a minimum of 5 years without service, calibration or periodic maintenance, and does not contain field serviceable parts. In case of a malfunction or fault, suspend use of the device and contact Direct Supply.

The Attendant Prodigy Bladder Scanner is fully automatic in both its clinical testing mode and its internal self diagnostics mode. Unlike other ultrasound bladder scanners, the single Attendant Prodigy Bladder Scanner is not subject to mechanical drift and does not require annual calibration. In addition, automated self-diagnostic testing and performance checks are performed 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 that should occur, do not use the device and contact Direct Supply for instructions.

To perform the self-diagnostic test on demand and see a report of the operational status, simply complete five scans while holding the scanner in the air (the scanner should be clean and not in contact with any surface) with a two-second pause between each successive scan. The console will then display the results of the self-diagnostic routine. 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 case of a suspected malfunction, try these troubleshooting steps:

- Return the scanner to the console for at least two minutes to reset the scanner.
- Check the AC power connection to make sure it is secure. Connect the device to AC power for a minimum of two hours and verify the charging light on the scanner turns green.

If these steps do not return the unit to full operation, do not use the device and contact Direct Supply.

# Disposal of Device, Safety & Performance Summary and Regulatory Compliance

## Disposal of Device

The Attendant Prodigy Bladder Scanner 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.

## Safety & Performance Summary

The Attendant Prodigy Bladder Scanner is suitable for use in ISM (industrial, scientific and medical) environments and in domestic environments under the jurisdiction of a healthcare professional.

The healthcare professional at your institution directing the use of the Attendant Prodigy Bladder Scanner 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 healthcare professional.

## Regulatory Compliance

The Attendant Prodigy Bladder Scanner 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

The Attendant Prodigy Bladder Scanner is a Class IIa device.

# Product Specifications/ Technical Descriptions

## Ultrasound Output and Frequency

Ispta (derated):	5.0mW/cm <sup>2</sup>
Isppa (derated):	0-60 W/cm <sup>2</sup>
Maximum MI:	0.95
TIS/TIB/TIC Range:	0.0 - 4.0
Ultrasound Frequency:	3.6 MHz

**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)

**NOTE:** Example accuracy limits on tissue equivalent bladder phantoms.

Volume (mL)	Upper limit (mL) + (12.5% + 12.5mL)	Lower Limit (mL) - (12.5% + 12.5mL)
50	69	31
100	125	75
500	575	425
999	1,136	862

## Batteries

- Console 58Wh LiFePO4 (Lithium Iron)
- Charge Time 2 hours
- Usage Under Normal Conditions Up to 5 days
- Scanner 3.9Wh Li-ion (Lithium Ion)
- Charge Time 1 hour
- Usage Under Normal Conditions 500 scans or 48 hours

## Dimensions

- Display 7" LCD
- Scanner 5.8" x 5.3" x 1.7", 0.8 lbs
- Console 12" x 8" x 4", 4.4 lbs
- Console & Scanner 12" x 8" x 4", 5.1 lbs

## Bluetooth/ R.F. Device

The Bluetooth® technology used in the Attendant Prodigy Bladder Scanner is compliant with:

- Bluetooth Specification as defined and approved by The Bluetooth Special Interests Group
- FCC (FCC ID: QOQWT12), ICS, CE, RoHS
- Logo certification with Bluetooth wireless technology as defined by The Bluetooth Special Interest Group
- Specifications: Class 1 Bluetooth®, Frequency 2402 ~ 2480MHz, Range: up to 10m

## Environmental Conditions for Use

Condition	Description
Ambient temperature range	50° to 104°F (10° to 40°C)
Relative humidity	30% to 75% non-condensing
Atmospheric pressure range	700 hPA to 1060 hPA
IP Classification	IPX3 (Scanner) IPX0 (Console)









## Environmental Conditions for Storage

Condition	Description
Ambient temperature range	-4° to 140°F (-20° to 60°C)
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 Attendant Prodigy Bladder Scanner. 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.

# 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
	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

# Limited Warranty

We offer to you, as the original purchaser, a warranty for the Attendant Prodigy Bladder Scanner. Our warranty applies for the limited warranty period stated below. If any product or product part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a product or product part will be at our discretion. Our warranty applies only if the product is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the product or damage caused by abuse, improper use, failure to maintain, use which exceeds the published product limitations or the combination of any product with another product. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts, and ask you to perform a repair or adjustment or replace a defective part. Our warranty gives you specific legal rights, and you may also have other rights, which vary from state to state. Please note that our limited warranty period begins when we ship the product to you. The limited warranty period and our obligations under the warranty end once you transfer the product to someone else or at the end of the applicable limited warranty period identified below, whichever is earlier.

	<b>Warranty Period</b>	<b>Anticipated Usable Product Life</b>
Attendant Prodigy Bladder Scanner	3 year limited warranty	5 years

Anticipated Usable Product Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the product as described in this guide, as the product may need to be replaced sooner than anticipated in particular situations.

DIRECT SUPPLY MANUFACTURING, INC. MAKES NO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; THESE AND ALL OTHER IMPLIED WARRANTIES ARE SPECIFICALLY DISCLAIMED. TO THE FULLEST EXTENT ALLOWED BY LAW, DIRECT SUPPLY MANUFACTURING, INC. WILL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR LOST PROFITS THAT MAY RESULT FROM THE PRODUCT OR YOUR USE OF OR INABILITY TO USE THE PRODUCT EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. OUR TOTAL LIABILITY TO YOU, IF ANY, IS LIMITED TO THE PRICE OF THE PRODUCT OR SERVICE GIVING RISE TO YOUR CLAIM.

Some states do not allow an exclusion or limitation of incidental or consequential damages, or how long an implied warranty lasts, so the above limitations or exclusions may not apply to you. If implied warranties are not excluded, and to the extent allowed by law, we limit any and all implied warranties to the applicable warranty period identified above. Except for rights under any applicable state law, the remedies provided under this warranty are your sole and exclusive remedy for any breach of our warranty and state the entire limit of our responsibilities.

# Customer Service

Our promise to you is that you will have a convenient and easy ordering experience, receive a quality Attendant Prodigy Bladder Scanner and enjoy outrageous customer service. If you have any questions about the Attendant Prodigy Bladder Scanner you have purchased or would like to request warranty service, please contact the distributor from whom you purchased the product.



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