CUBEscan™

BioCon -900S

OPERATOR'S MANUAL

Man, Machine & Medicine

Mcube Technology Co., Ltd.

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REF BioCon-900S

Bladder Volume Measurement System

Operator's Manual

CAUTION : In the United States, federal Law restricts this device to sale by or on the order of a physician.

"This product is not made with natural rubber latex."

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1 GENERAL INFORMATION

1.1 PRODUCT DESCRIPTION

CUBEScan™ BioCon-900S is a safe and easy, non-invasive system to measure the bladder volume. The device consists of a probe, CUBEScan Charger, and various components. The probe is a B-mode instrument, hand-held, wireless and battery-operated. A 3D-mechanical sector transducer provides cross–sectional images of the bladder from up to 12 scan planes and bladder volume is calculated based upon those images and displays 12 scan planes on a screen. Furthermore, a live image of the bladder during Pre-scan makes it easier to detect the bladder before scanning. The CUBEScan Charger is used for recharge of the probe's internal battery.

1.2 INTENDED USE / INDICATIONS FOR USE

CUBEScan™ BioCon-900S is a B-mode pulsed-echo ultrasound device. The BioCon-900S projects ultrasonic energy through the lower abdomen of a patient to obtain images of the bladder to calculate the urine volume non-invasively. BioCon-900S is intended to be used by a qualified medical professional to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-900S are fetal use and use on pregnant patients.

1.3 PATIENT/USER CHARACTERISTICS

1.3.1 PATIENT POPULATION

1) Male (All other patients)
2) Female patient
   - A female who has not had a hysterectomy
   - A female who has had a hysterectomy
3) Pediatric patient; A child with height less than 47 inches (120cm) and weight less than 55 lbs (25kg)

1.3.2 USERS

1) Physicians
2) Medical Professionals

1.3.3 MEDICAL CONDITIONS INCLUDING TARGET GROUP AND DISEAS

Bladder volume measurement system measures bladder volume, and it provides the accurate data to aid in the diagnosis of common urological condition, to assess urinary retention, to help unnecessary catheterization and to reduce rates of catheter-associated urinary tract infection.

The benefits are as below;
BioCon-900S assists to;
a. Assess urinary retention
b. Evaluate post-operative urinary retention (POUR)
c. Reduce unnecessary catheterization
d. Reduce catheter-associated urinary tract infections(CAUTIs)
e. Identify a blocked Foley catheter
f. Evaluate the need to catheterize after Foley catheter removal
g. Evaluate the need to catheterize during intermittent catheterization
h. Support to train urination and self-cathererization
i. Measure PVR (Post Void Residual)

1.4 PRESCRIPTION STATEMENT

Federal (United States) law restricts this system to sale by or on the order of a physician.

1.5 SERVICE

If you encounter difficulty with the system, please contact local distributers or Mcube Technology at mcube@mcubetech.co.kr

2 SAFETY INFORMATION

2.1 NOTICE TO ALL USERS

This guide covers components, function, maintenance, storage, and precautions needed to use this system. All users must read and thoroughly understand this entire guide prior to using the BioCon-900S. This section has information on safe use of the BioCon-900S (Biological Safety, Electrical Safety, Device Safety and Safe handling procedures for transporter).

Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

2.2 CONTRAINDICATIONS

⚠ WARNING

Do not use the BioCon-900S on following cases:

1) Fetal use or pregnant patients.
2) Patients with ascites.
3) Patients with open or damaged skin.

Wounds in the suprapubic region.

2.3 BIOLOGICAL SAFETY

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should be used only by medical professionals when clinically indicated, using the lowest possible exposure times possible commensurate with clinical utility. The ultrasonic output power of BioCon-900S is limited to the minimum level necessary for performance effectively. Data on acoustic output levels is listed in section "9. Specifications".

2.4 ELECTRICAL SAFETY

This system meets IEC 60601-1, Class I, Type BF isolated patient-applied parts safety requirements. This system complies with the applicable medical device requirements published in the Canadian Standards Association (CSA), European Harmonized Standards, and Underwriters Laboratories (UL) safety standards.

To avoid the risk of electrical shock or injury, observe the following warnings and cautions.

⚠ WARNING

- To avoid the risk of electric shock, this device must only be connected to an adapter with the protective earth. - Grounding reliability can only be achieved when device is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent.
- Do not operate the system in the presence of flammable gases or anesthetics.
- Do not use the device with any defibrillator at the same time.
- Do not use the device with any HF surgical equipment at the same time.
- Before using the system, inspect the enclosures, power cord and adapter.Do not use the system if these are damaged.
- Do not use the probe if the entire probe is accidentally immersed in solution.
- Connect only items that have been specified as part of the BioCon-900S or that have been specified as being compatible with the BioCon-900S.
- Charge the probe only with the provided Charger.
- Connect the Charger only to the provided adapter.

- Do not attempt to open the system components. This may cause serious injury to the operator or patients. All services must be made by a qualified technician only.
- Use of components and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BioCon-900S, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

⚠ CAUTION

- The BioCon-900S has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical systems to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. Medical systems must be installed and operated according to the instruction in this manual. For more information, see the section "9.2 ELECTROMAGNETIC COMPATIBILITY".
- This device is suitable for use in the professional health care environment
- Medical electric devices can be affected by portable or mobile RF communication devices. Turn off any portable or mobile RF device before operating your system.
- Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning.
- Static shock is a discharge of electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an ultrasound system. The following precautions can help reduce ESD: anti-static spray on carpet, anti-static spray on linoleum, and anti-static mats.
- The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
- Do not use the system if an error message appears on the display: note the error code; call Mcube technology or your local distributor, shut down the system

2.5 DEVICE SAFETY

To protect your BioCon-900S, and components, follow these warnings and cautions.

⚠ WARNING

- No modification of this device is allowed.
- Do not use the system if the head of probe is damaged.
- To avoid the risk of excessive heating or damage to the device, use the device in a well-ventilated environment.
- To avoid damage to cables, do not excessively twist or bend cables associated with the device.
- Turn off the device and unplug the charger if it will not be used for a long period of time.
- Do not use the system if there is evidence of leakage of internal liquids. Wash hands immediately in warm, soapy water.
- In the event that LCD is damaged, care should be taken to avoid contact with liquid crystal. Take the urgent action indicated should any of the following situations arise:
  - If liquid crystal comes in contact with your skin, clean the area with a cloth and then wash thoroughly with soap and running water.

- If liquid crystal enters your eyes, flush the affected eye with clean water for at least 15 minutes and then seek medical assistance.
- If liquid crystal is swallowed, rinse your mouth thoroughly with water. Drink large quantities of water and induce vomiting, then seek medical assistance.

⚠ CAUTION

- Use the system indoors only.
- Do not use the system if it exhibits erratic or inconsistent behavior. Shut down the system and contact Mcube Technology or your local distributor.
- Do not spill liquid on the system.

2.6 COMPLIANCE STATEMENTS

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense."

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Radiation Exposure Statement:

This equipment complied with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

⚠ CAUTION

- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

IC Statement

This Class A digital apparatus complies with Canadian ICES-003.

This device complies with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil numérique de la classe A est conforme á la norme NMB-003 du Canada.

2.7 SAFE HANDLING PROCEDURES FOR TRANSPORTER

Quarantine: Packages that are crushed, punctured or torn open to reveal contents should not be placed into deployment. Such packages should be isolated until the shipper has been contacted, provides disposition instructions and, if appropriate, arranges to have the product inspected and repacked.

Spoiled Product: In the event that damage to packaging results in damage to the battery causing released electrolyte, the spill should be contained and the shipper should be contacted for instructions.

3 INTRODUCTION

3.1 PRODUCT FEATURES

The main components of CUBEScan™ BioCon-900S are a Probe and the Charger.

BioCon-900S Probe & Charger

- Hand-held, portable and lightweight
- Touchscreen interface
- Measures bladder volume with ultrasound
- Provides a live image of bladder during Pre-scan
- Takes scans and provides scan results in a short time
- Easy to use: staff can easily learn how to scan patients in a short time
- Battery-operated, wireless charging

Figure 1 CUBEScan™ BioCon-900S

3.2 SYSTEM COMPONENTS

No.	Picture	Parts	Q'ty	Description
1		BioCon-900S (Probe)	1	Hand-held, wireless, battery-operated, touchscreen, ultrasound probe
2		Charger	1	Use the Charger to charge BioCon-900S's internal battery.
3		Mobile Cart (MRC-900S)	1	Mobile cart (Optional Component)
4		AC/DC Adapter	1	Use only with the Charger.
5		Power cord	1	The type of power cord depends on your country.

6	-	Barcode Module	1	Reading a barcode with information for a patient. (Optional Component)
7	-	Operator's manual	1	-

Users can replace only gel

- The other parts are not allowed for the users to disassemble or replace except the gel. Please contact your local distributor or Mcube Technology.
- Only use the ultrasonic gel approved by FDA, CE.

3.3 OUTER APPEARANCE – PROBE

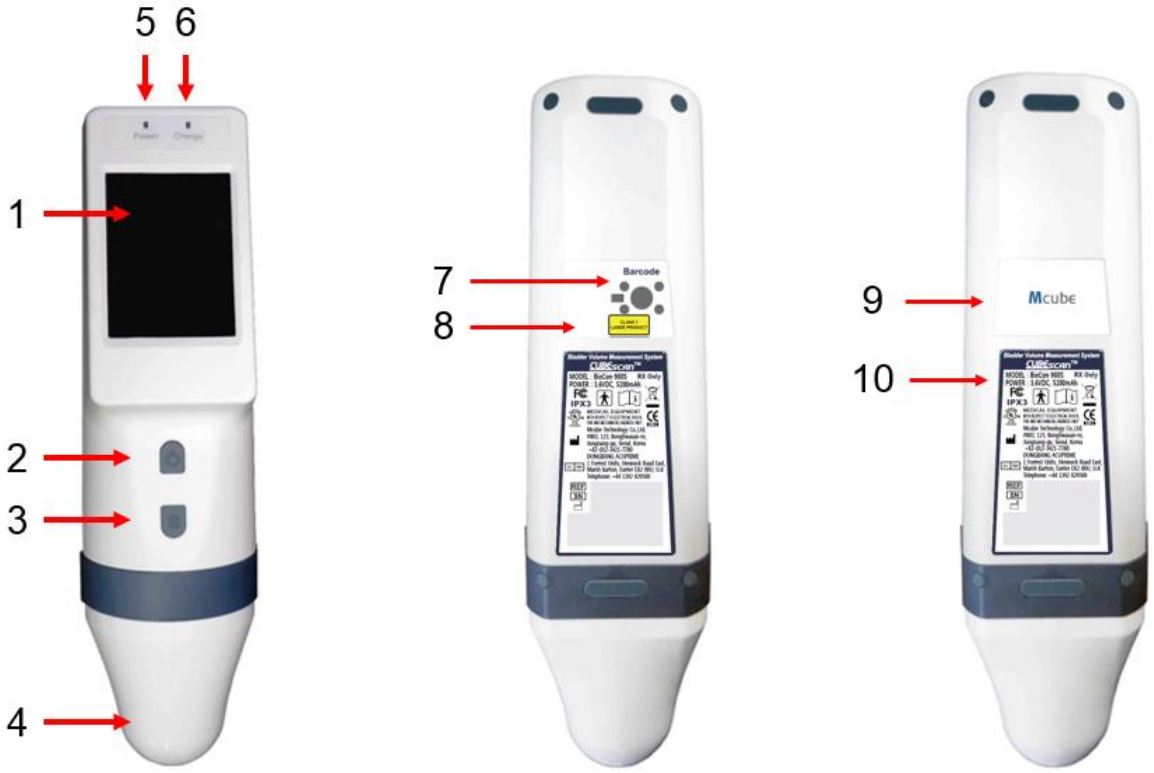


Figure 2 Probe Appearance

No.	Part	Function
1	Touchscreen Display	Displays bladder volume and other information.
2	Power Button	Press to turn the probe on or off and release
3	Scan Button	Press to take a scan
4	Probe Head	Generates, transmits and receives ultrasound waves, produces a 3D image of bladder. Type BF applied part
5	Power Indicator	Indicates power status. Orange solid – System is being booted Yellow solid – Power on status Off – Power off

6	Battery indicator	Indicates charging status. Orange solid - Battery is being charged. Off – Battery is fully charged.
7	Barcode Module	Reads printed a barcode
8	Laser Safety Label	Explanatory label – Class 1 laser product
9	Label	Put on this label when there is no optional barcode module
10	Back Label	**NOTE** : Labels are subject to change without prior notice

NOTE: The appearance of these labels(No.8 - 9) depends on wheter the barcode option is selected or not.

3.4 OUTER APPEARANCE - CHARGER

Figure 3 Charger Front-View

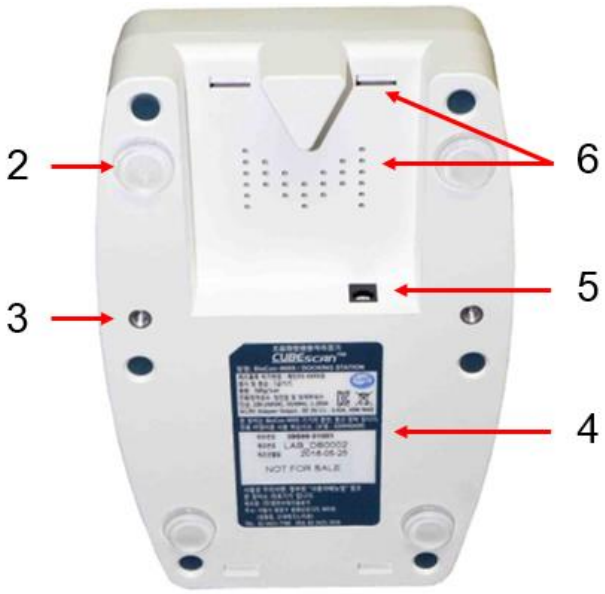
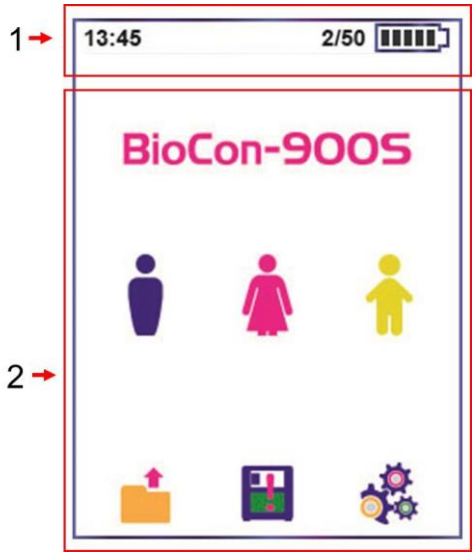


Figure 4 Charger Bottom-View

No.	Item	Function
1	Battery indicator	Indicates charging status. Green (Solid) – Power cord is connected or Charging is completed. Green (Blink) – Charging.in progress Yellow (Solid) – Error Status
2	Silicone pad	Anti-skid pad
3	Insert Nut	Insert nut to secure the Charger to the mobile cart (MRC-900S). It prevents movement or damage of Charger from shock.
4	Label	**NOTE** : Labels are subject to change without prior notice
5	AC/DC Adapter Inlet	AC/DC adapter inlet
6	Vents	Ventilate the Charger.

3.5 DISPLAY AND ICONS

A touch-screen display allows you to perform scans, manage results and setup. The Home screen appears when the probe is turned on. It services as a starting point for all the main functions of the device. You can select the desired icons by tapping them directly on the touch-screen.



No.	Description
1	**Status** – Current time, the number of saved data and battery status.
2	**Main Display** – controls the user interface

Figure 5 Home Screen

3.6 ICON DIRECTORY

Patient Type

Icon	Description
	Male (All other patients)
	Female Patient – A female who has not had a hysterectomy
	Female Patient – A female who has had a hysterectomy
	Pediatric Patient – A child with height less than 47 inches (120cm) and weight less than 55 lbs(25kg).

Home screen

Icon	Description
	Review – Go to the Review screen.
	Missing Data – Go to review the missing (unsaved) scan result.
	Setup – Go to the Setup screen.
	Battery status.

Information screen & Pre-scan screen

Icon	Description
	Barcode - Record a barcode (Optional)
	Home – Return to the Home screen.
	Scan – Perform the Normal scan or Pre-scan.
	Exit –Return to the Information screen.

Scan Result screen

Icon	Description
	Aiming Information – Rotate 15° clockwise, indicating the aiming point of the bladder.
	Urine Volume – Measured urine volume.
P1	Plane No. – The 1st plane of 12 planes of the result (PX – The ordinal number of 12 planes)
	Scan – Re-scan the bladder.
	Home – Return to the Home screen.
	Save – Save the scan result.

Review screen

Icon	Description
	Delete – On the Review screen, delete what is currently being displayed.
	OK – Select the option or perform the action.
	Cancel – Cancel the current function.
	Previous – On the Review screen, move to the previous patient scan result.
	Next – On the Review screen, move to the next patient scan result.
	Exit –Return to the Home screen.

Setup screen

Icon	Description
	Date format (YY-MM-DD, DD-MM-YY,MM-DD-YY)
	Date
	Time (format : 24-hour)

	Sleep mode (2min, 3min, 5min)
	Display brightness (0 to 100%, default= 50%))
	Pre-scan On () / Off ()
	Delete all saved results.
	Calibration Reminder On () / Off ()
	Self-test (YY/MM/DD)
	Phantom Calibration (YY/MM/DD)
	CalKit Calibration (YY/MM/DD)
	On the self-test or calibration screen, perform self-test or calibration
	Cease – On the self-test or calibration screen, cease self-test or calibration
	Exit – Return from the self-test or calibration screen to the Setting screen.
	Previous – Move to previous page.
	Next – Move to next page.
	Home – Return to Home screen.
	OK – Select the option or perform the action.
	Cancel – Cancel the current function.

4. SETUP

- See the section "4.1 ACCURACY OF MEASUREMENT" before use.
- Check the probe's battery has sufficient power through battery icon. If the battery has not been sufficiently charged, recharge the battery before bladder measurement.
- Wipe the probe head gently with a soft cloth dampened in cleaning and disinfection agents to clean and disinfect the probe. See the section "8.3 CLEANING & DISINFECTION".

4.1 ACCURACY OF MEASUREMENT

Following cases affect ultrasound transmission and accuracy of measurement.

- When a patient has had supra-pubic or pelvic surgery.
- A patient with catheter in his or her bladder.
- A patient with scar, sutures, staples or incisions in his or her abdomen.
- Use of unsuitable ultrasound gel .
- Air bubbles between probe head and the skin of the patient.
- An excessive obese patient.
- Use of the probe with an unclean probe head.
- Inappropriate patient position.

4.2 CHARGE THE BATTERY

⚠ WARNING

- The battery must be replaced by the authorized service provider only.
- Use only the provided Charger and power cord to charge the battery for electric safety.
- Do not disassemble, heat or incinerate the battery.
- Keep battery out of reach of children and in original sealed package.
- Dispose of used batteries promptly according to local recycling or waste regulations.
- To reduce the risk of leakage, explosion, fire, or serious injury, note the following when handling the lithium-ion battery included in the system:
  - Never short-circuit the battery by either accidentally or intentionally bringing the battery terminals into contact with any other conductive objects. This could cause serious injury or fire and could also damage the battery and BioCon-900S.
  - Never expose the battery to abnormal shock, vibration or pressure. The battery's internal protective covering could fail, causing it to overheat or ignite, resulting in caustic liquid leakage, explosion or fire.
- Avoid charging near fire or in the sunlight.
- Do not use the Charger for other equipment.

⚠ CAUTION

- The Charger, power cord, and adapter are not intended for patient contact. Ensure 6 ft (2 m) are maintained between the patient and these components.
- Immediately discontinue use of the battery, if the battery emits an unusual smell, feels hot, changes color or shape, or appears abnormal in any other way. Contact Mcube Technology or your local distributors.

The probe is powered by a internal lithium ion battery. The battery is charged by Charger and the **Battery**

Status icon ( ) is always displayed in the **Status** at the top of the screen, indicating the current capacity. Before using the probe for the first time, you must fully charge the battery. When you don't use your probe, we recommend that you mount and store it on the Charger to ensure that the probe is sufficiently charged. The battery is protected by protection circuit module and have the functions of overcharge, overdischarge and overcurrent prevention to maintain safety and prevent significant deterioration of cell performances.

To conserve battery life, the probe is configured to go into sleep mode. The probe goes into sleep mode when you press the **Power Button**() twice or if the probe has not been touched in the designated time with power on. You can adjust the time for sleep mode in the setup(2min/3min/5min), if necessary. See the section"7.4 SLEEP MODE SETTING". Shortly press the **Power Button**() to wake up the system.

Figure 6 Probe-mounting

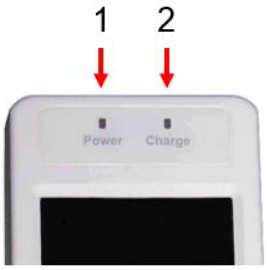


Figure 7 Probe Indicatior

Figure 8 Charger Indicator

1) Connect the AC/DC adapter to the power cord.
2) Connect the AC/DC adapter to the Charger
3) Plug the AC/DC adapter into an electric outlet
4) The battery indicator (3) on the Charger lights on in steady green (Power on).
5) Mount the probe on the Charger. Make sure that the upper part of probe reaches the wall of Charger. See **Figure 5**.
6) As soon as the probe is mounted on the Charger, the beep and light indicators work as below;
   a) A short beep: A connection for the probe's battery charging is completed.
   b) The battery indicator (3) on the Charger lights on in blinking green(Charging in progress).
   c) The battery indicator (2) on the probe lights on in steady orange (Charging in progress).

7) The Power indicator (1) is turned on in steady yellow when the probe is ready to use.
8) It takes approximately 6 hours for the discharged battery to fully charge. When fully charged, the battery indicator(2) on the probe turns off.

4.3 SCAN TYPE

You can adjust one of the following options to measure bladder volume:

Pre-scan: General 2D real-time ultrasound scanning. 2D ultrasound images are displayed continuously in live image basis. This helps an operator locate bladder position and predicting the range of residual urine to detect the bladder before normal scan.

Normal Scan: Get 12-plane ultrasound images and calculate the residual urine in the bladder (3D scanning).

5 HOW TO USE

5.1 CHECKUP BEFORE USE

Before using BioCon-900S, ensure you are familiar with the device and its parts. If you use it for the first time, we strongly recommend you to try your first bladder volume measurement on a patient with moderately full bladder using Pre-scan. Pre-scan helps you detect the bladder and moderately full bladder can be located more easily.

⚠ WARNING

- If you use BioCon-900S in the presence of flammable anesthetics, explosion hazard exists.
- Do not use the BioCon-900S on following cases:
  1) Fetal use or pregnant patients.
  2) Patients with ascites.
  3) Patients with open or damaged skin.
  4) Wounds in the suprapubic region.

⚠ CAUTION

- If the oil leaks from housing and fluid gets in contact with your eyes, skin or clothing, flush the affected area immediately with clean water and seek medical attention or see a doctor.

5.2 TURN SYSTEM ON/OFF

There are two power modes to system on/off the BioCon-900S. Loading screen depends on the power mode and it shows during start-up.

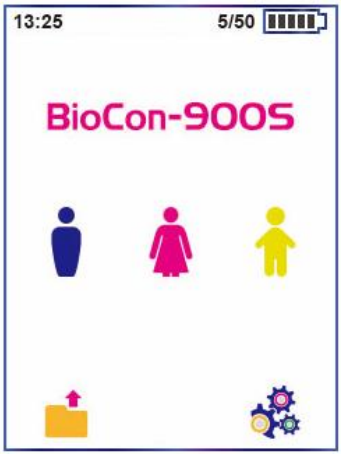
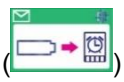


Figure 9 Loading Screen (1) **Figure 10 Loading Screen (2)** **Figure 11 Home Screen**

5.2.1 SLEEP MODE

To preserve battery power, the probe goes into sleep mode by shutting itself down automatically when not in use. You can set the time to go into sleep mode in the setup (2min/3min/5min). See the section "7.4 SLEEP MODE SETTING".

However, if a battery needs to be recharged immediately, Dialog box () appears shortly and then probe goes to sleep mode by shutting itself down. We strongly recommend that you should recharge the battery immediately. See the section "4.2 CHARGE THE BATTERY".

Turn System on

1) Press the **Power Button** (⏻) shortly to wake the probe from sleep mode.
2) Only Loading screen (2) appears on the display.
3) Home screen appears when the system is fully loaded at start up.

Turn System off

1) Press the **Power Button** (⏻) shortly twice to go into sleep mode.

5.2.2 SHUTDOWN MODE

The probe draws little power when it is gone into sleep mode. To preserve battery power, the probe shuts down the system in approximately 24 hours after going into sleep mode, if there is no activity. However, if you do not plan to use the probe for more than a week, you should shut the system down completely to prevent it from discharging completely

Turn System on

1) Press the **Power Button** (⏻) shortly to wake the probe from shutdown mode.
2) Loading screen (1) appears on the display and Loading screen (2) follows shortly.
3) Home screen appears when the system is fully loaded at start up

Turn System off

1) Press the **Power Button**(⏻) for 3~4 seconds.
2) A Shutdown dialog box appears on the Home screen.
3) Ths system shut down shortly after Shutdown screen appears.

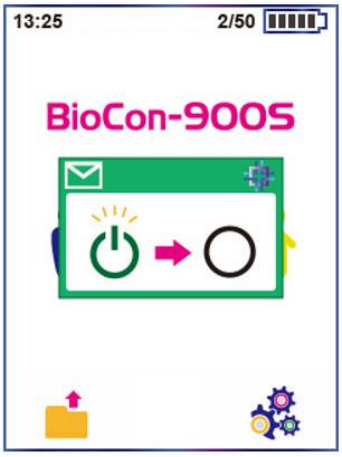


Figure 12 Shutdown Dialog Box

Figure 13 Shutdown Screen

5.3 SELECT PATIENT TYPE

BioCon-900S has several patient types. Tap the **Patient** icon on the Home screen to select the patient type.

1) Male (All other patients)
2) Female patient – Select if you are scanning a female patient. If you select the female patient type on the Home screen, the BioCon-900S allows you more granularity in chosing an female patient type on the Information screen. Select female patient by tapping the (1) of Figure 23.

   - A female who has not had a hysterectomy
   - A female who has had a hysterectomy
3) Pediatric patient – Select if you are scanning a child with height less than 47 inches (120cm) and weight less than 55 lbs. (25kg).

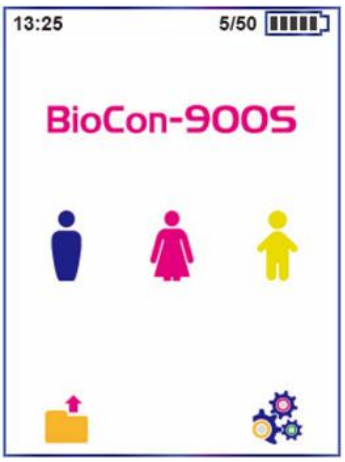
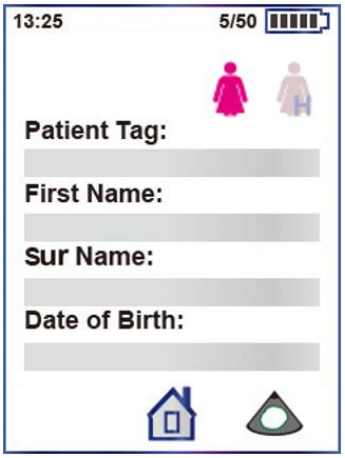


Figure 14 Patient Type



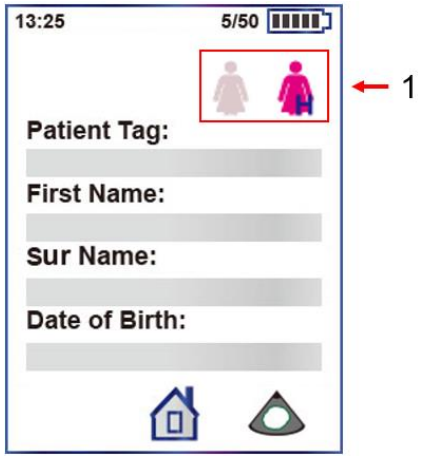


Figure 15 Female Patient Type

5.4 RECORD INFORMATION FOR A PATIENT

5.4.1 INPUT INFORMATION – VIRTUAL KEYBOARD

The Information screen appears when you tap one of the **Patient** icon on the Home screen. You can tap the text box and update information for a patient by typping the virtual keyboard. The virtual keyboard screen appears depend on the text box you select. See the section "6.4 VIRTUAL KEYBOARD SCREEN"on for information about the function of the virtual keyboard.

You can scan a bladder volume without entering patient information. If you do not enter a patient information, the patinet tag content(2) is empty on the Scan Result screen. Scanned date and time(1) automatically display and it is based on your probe's time settings. Once a scan result is saved, you cannot add or modify patient information.

You can measure bladder volume by tapping the **Scan** icon() on the Information screen or pressing the **Scan Button**(S). If you want to return to the Home screen, tap the **Home** icon()

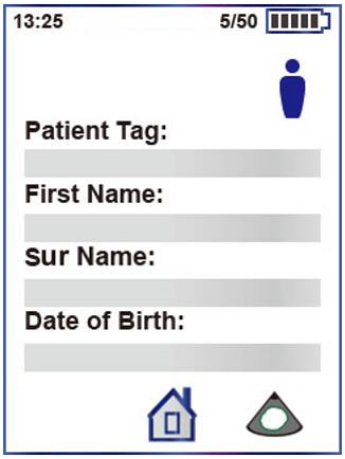


Figure 16 Information Screen

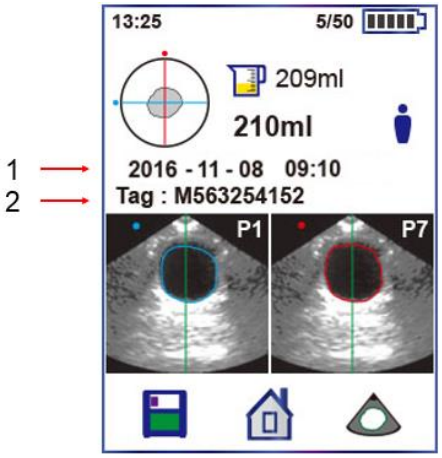


Figure 17 Scan Result Screen

Patient Tag

Tap *Patient Tag* text box, and then enter the patient's tag by typping the virtual keyboard

First Name

Tap *First Name* text box, and then enter the patient's first name by typping the virtual keyboard

Sur Name

Tap *Sur Name* text box, and then enter the patient's sur name by typping the virtual keyboard

If you would like to the change the virtual keyboard type, tap **Keyboard** icon (

) in the left corner of the virtual keyboard. The icon allows you to select an numeric, uppercase or lowercase virtual keyboard.

Figure 18 Numeric Key

Figure 19 Letter Key (Lowcase)

Figure 20 Letter Key (Uppercase)

Date of Birth

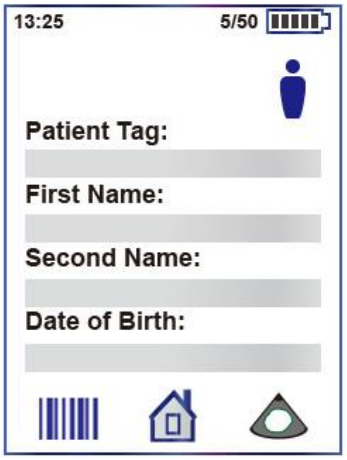
Tap *Date of Birth* text box, and then enter the patient's birthday by typping the virtual keyboard

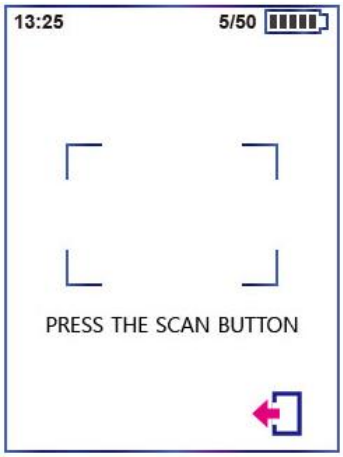
Figure 21 Date Key

5.4.2 INPUT INFORMATION – OPTIONAL BARCODE

The CUBEScan™ BioCon-900S can attach an optional barcode module. Installing the optional barcode module on the device allows you to record a patient tag as necessary. Skip Skip this section if you do not enter patient information through a barcode or if you do not have a barcode reader.

⚠ WARNING
- "LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM"
- Do not capture human being with the barcode module.
- Hold the probe with both hands tightly, when you read barcodes with patient information.
- Recording barcodes is not available, after the scan result is saved.





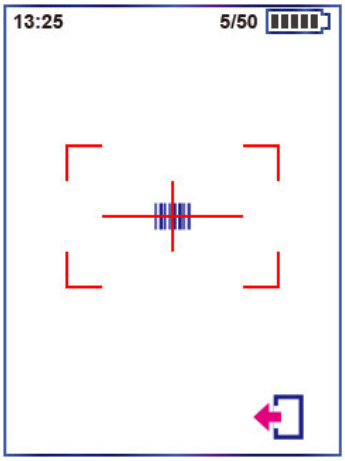


Figure 22 Information Screen **Figure 23 Barcode Scan Screen**

How to read a barcode

1) Tap the Barcode icon( ) on the Information screen.
2) Move the aiming position to the center of the barcode and press the **Scan Button(S)** with thumb.
3) A red light guide is emitted.
4) Keep pressing the **Scan Button(S)** and do not release until getting barcodes.
5) The barcode reader decodes continuously for a good barcode scan.
6) You have a good barcode with a short beep. The barcode numbers is displayed on Patient Tag of the Information screen.

<good>

<bad>

5.5 MEASURE BLADDER VOLUME

5.5.1 NORMAL SCAN

The normal scan is executed only when Pre-scan setup is 'Off( )' on the Setup screen. See the section "7.7 PRE-SCAN SETTING"

1) The patient should be lying in a supine position and lift up the patient garment exposing the abdominal region from the pubis to the navel.
2) Place an ample amount of gel without air bubbles to the probe head. In order to assure optimal transmission of energy between the patient and the probe, a conductive gel must be applied on the probe head.
3) Place the probe head on the patient's abdomen with the screen facing upwards and aim it to the location where the bladder is expected to be above 3~4cm the pubic bone.
4) Ensure that the probe head is pointing toward the patient's foot.

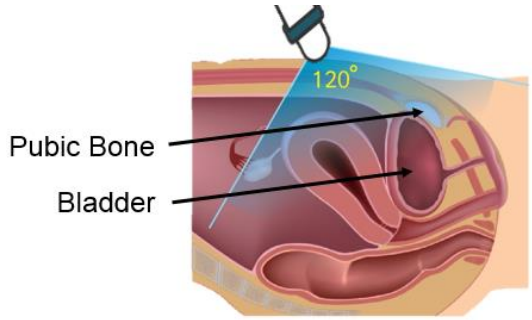


Figure 24 Positioning Bladder

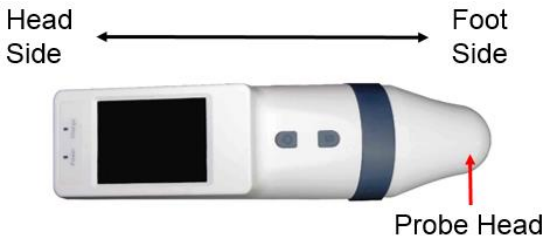


Figure 25 Probe Direction

1) Tap the **Scan** icon( ) on the Information screen or press the probe **Scan Button(S)**. The scanning process begins.
2) The progress bar on the screen appears. It takes 3 seconds to complete the normal scan. Hold the probe steady while scanning. Movement of the probe during scanning reduces the accuracy of measurement.
3) When you hear the beeps, the scan is complete.

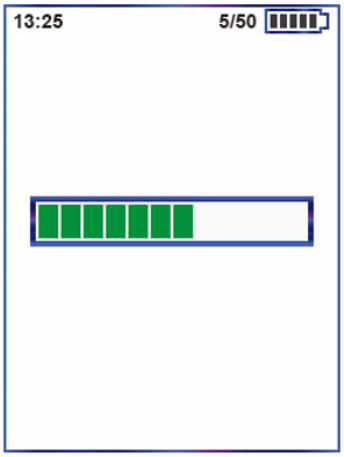


Figure 26 Normal Scan Process

5.5.2 PRE-SCAN

The Pre-scan is executed only when Pre-scan setup is 'ON( )' on the Setup screen. When Pre-scan is 'Off( )', a normal scan is executed. See the section "7.7 PRE-SCAN SETTING"

1) The patient should be lying in a supine position and lift up the patient garment exposing the abdominal region from the pubis to the navel.
2) Place an ample amount of gel without air bubbles to the probe head. In order to assure optimal transmission of energy between the patient and the probe, a conductive gel must be applied on the probe head.
3) Place the probe head on the patient's abdomen with the screen facing upwards and aim it to the location where the bladder is expected to be above 3~4cm the pubic bone.
4) Ensure that the probe head is pointing toward the patient's foot.

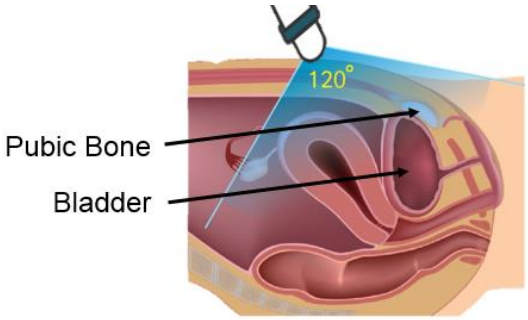


Figure 27 Positioning Bladder

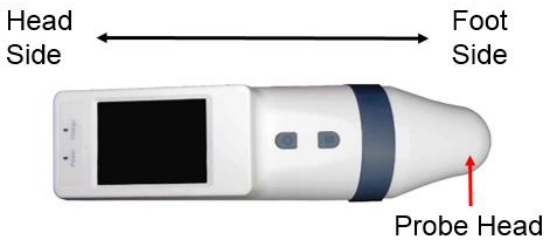
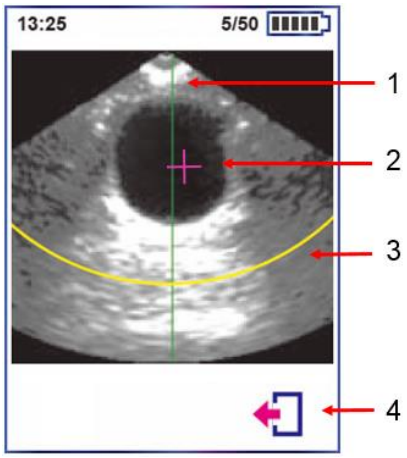


Figure 28 Probe Direction

5) Tap the **Scan** icon( ) on the Information screen or press the probe **Scan Button(S)** to start Pre-scan. A Pre-scan image such as 2D ultrasonic image appears on the probe screen.



No.	Description
1	Center Line
2	Bladder point: It helps to easily recognize the bladder. **NOTE**: It is not 100% guaranteed that the pointer shows the bladder in all cases
3	Depth Line: Max detection depth to measure a padiatric patient's bladder volume.
4	Exit Icon

Figure 29 Pre-scan Screen

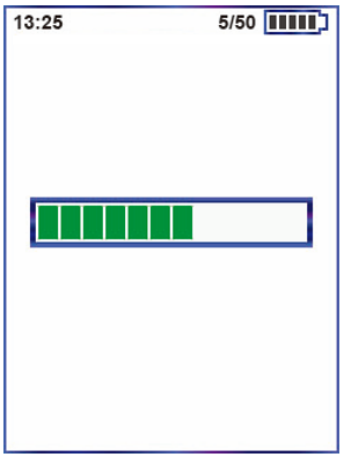


Figure 30 Normal Screen

6) To locate the bladder, keep the probe contacted the abdomen. And tilt the probe slowly back and forth, side to side. The position where the bladder image is the largest and most centered is the optimal place to start the normal scan process. Locate the bladder along the centerline(1) on the Pre-scan screen. It helps detect the optimal position during Pre-scan.

NOTE: Depth Line(3) is not displayed for male and female patient type.

7) If you want to stop the Pre-scan and return to the Information screen, tap the **Exit** icon( ).

8) Press the **Scan Button(S)** again or tap the Pre-scan screen. The progress bar on the screen appears. It takes 3 seconds to complete the normal scan Hold the probe steady while scanning. Movement of the probe during scanning reduces the accuracy of measurement.

9) When you hear the beeps, the scan is complete.

5.6 DISPLAY A SCAN RESULTS

After a scan has been completed, the Scan Result screen appears. The Scan Result screen includes the following information:

- Current Urine Volume
- Maximum Urine Volume
- Patient Type & Tag
- Scan Date & Time
- Bladder Planes
- Aiming Information

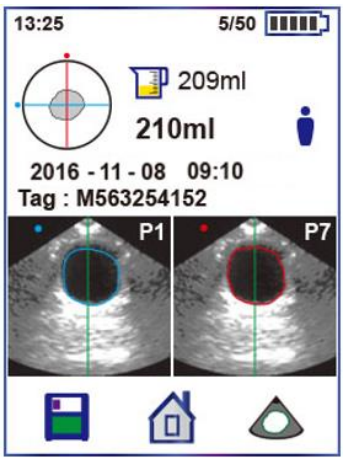
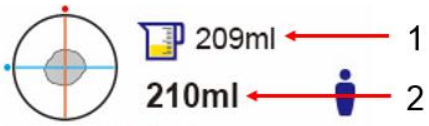


Figure 31 Scan Result Screen

5.6.1 BLADDER VOLUME

View the bladder volume displayed in milliliters (ml).

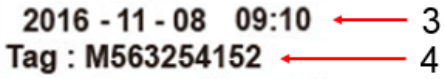
The **Urine Volume** icon( ) shows the measured urine volume. (1) shows the most recent volume and (2) shows the maximum volume from multiple results for one patient.



5.6.2 PATIENT INFORMATION AND SCAN DATE & TIME

(3) shows the date and time on the current scan.

(4) shows the patient tag entered on the Information screen.



5.6.3 BLADDER PLANES

Tap the bladder plane repeatedly with your finger to check other 12 planes of bladder on the Scan Result screen, if necessary. At the same time, the **Aiming information** (crosshair) is rotated clockwise by 15° and displayed the 2nd&8th planes, 3rd&9th, 4th&10th, 5th&11th, 6th&12th planes of bladder in order. If these plane's bladder is not centerd in the target or too small, we recommend that you scan the bladder again. See the section "5.7 RE-AIM BLADDER".

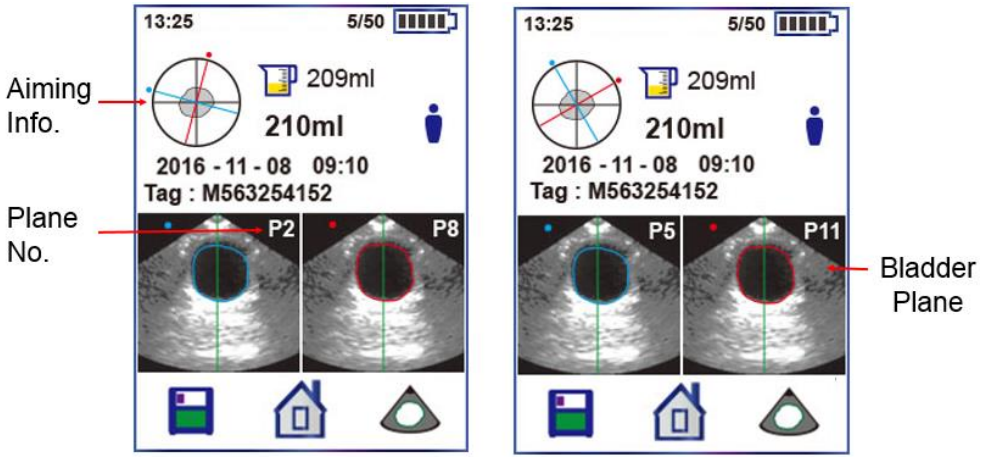


Figure 32 Planes & Aimming Information

5.7 RE-AIM BLADDER

If the bladder is not centerd in the target or too small, you can re-aim and re-scan the bladder before saving the scan result. We strongly recommend that you re-aim and re-scan more than one time for accuracy.

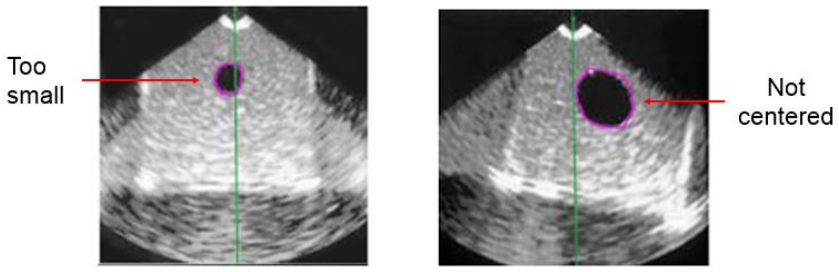


Figure 33 Incorrectly Positioned

The crosshair helps how to re-aim and the guiding arrows show that the user has to move or tilt the probe for a more accurate scan. If the bladder appears in the center of the crosshair, press the **Scan Button(S)** or tap the Pre-scan part of the screen.

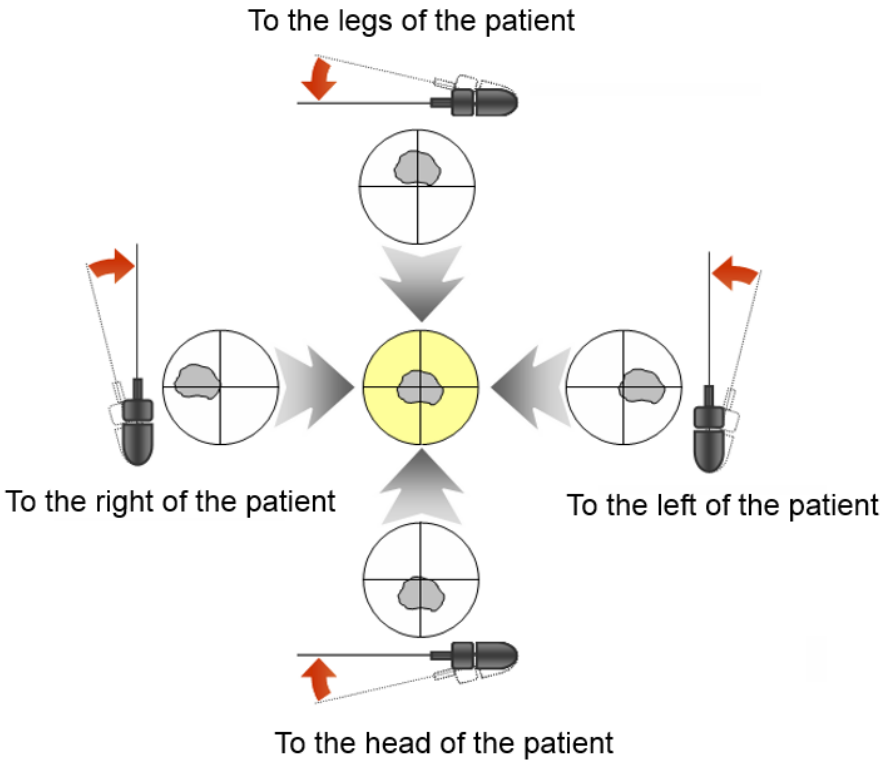


Figure 34 How To Re-aim

5.8 SAVE A SCAN RESULT

When you do not need to scan again, you can save the currently displayed scan result. And also missing scan result can be saved after fetching the missing scan result. See the section "5.9 FETCH A MISSING DATA".

To save the scan results, tap the **Save** icon ( ) below the display. The Home screen appears after the scan result is saved successfully.

5.9 FETCH A MISSING DATA

If you did not save a scan result and return to the Home screen, the **Missing Data** icon ( ) appears on the Home screen. Tap the **Missing Data** icon ( ) to fetch the unsaved scan result. The Scan Result screen on the missing data appears. The performances below make the **Missing Data** icon( ) disappear.

1) Fetch and save the missing scan result.
2) A new normal scan is performed.

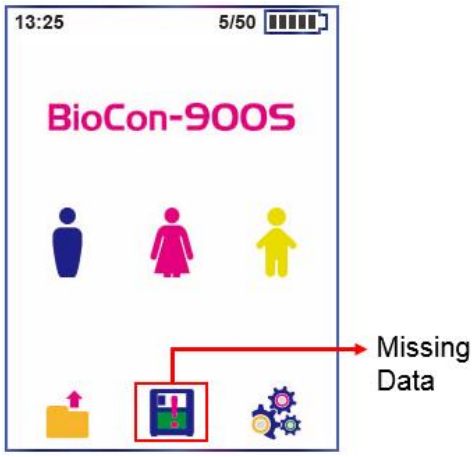


Figure 35 Home Screen

5.10 FINISH THE MEASUREMENT

After finishing scanning, take the probe away from the patient and then wipe the ultrasound gel off the probe. See the section "8.3 CLEANING & DISINFECTION"

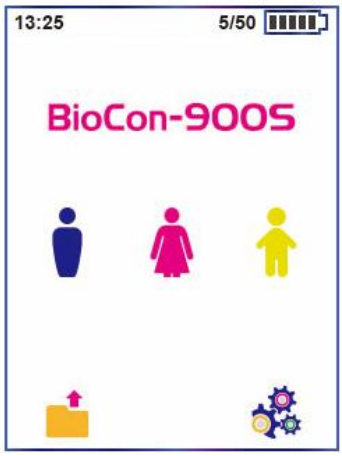
When the probe is not in use, press the **Power Button**( ) twice to place the system in sleep mode and then mount it for charging internal battery in the Charger.

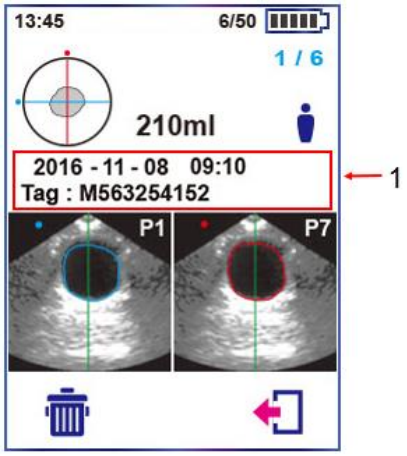
5.11 MANAGE SAVED SCAN RESULTS

1) The scan results are saved to the internal memory of BioCon-900S Probe. If you scan the patient several times using the probe, the lagest result is saved. Information can be entered and modified before the scan result is saved, but once the scan result is saved, patient information can not be modified
2) If you want to delete the saved scan result, see the section "5.11.2 DELET A SAVED SCAN RESULT"

5.11.1 REVIEW A SCAN RESULT

1) The Review screen is displayed when you tap the Review icon ( ) on the Home screen.
2) The Review screen opens, it shows the urine volume, ultrasound images and other saved information.
3) Previous & Next icon (,) allow you to review the scan results of the other patients.
4) Delete & Exit icons (,) allow you to delete the current reviewing results or return to the Home screen.
5) Tap the (1) area to review the information you entered for the patient.





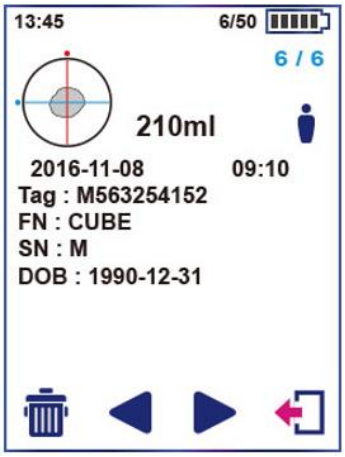
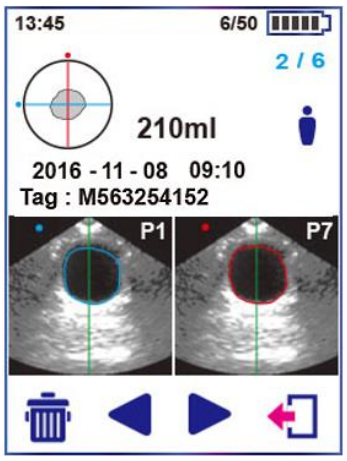


Figure 36 Home Screen **Figure 37 Review Screen**

5.11.2 DELETE A SAVED SCAN RESULT

1) The Review screen is displayed when you tap the **Review** icon ( ) on the Home screen.
2) Select the scan result you want to delete by tapping Previous & Next icon (,).
3) Tap the **Deletion** icon ( ) and a **Delete Confirm** dialog box ( ) appears.
4) Tap the **OK** icon ( ) to delete the scan result or Tap the **Cancel** icon ( ) to cancel.



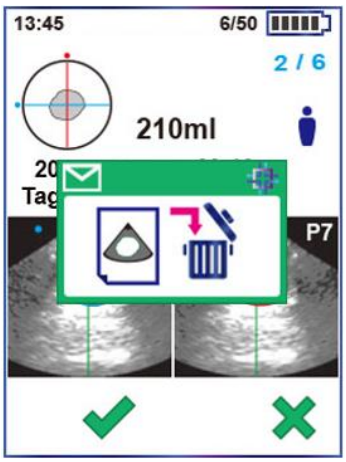


Figure 38 Review Screen **Figure 39 Delete Scan Result**

6) If you delete the last scan result, Empty Foder dialog box ( ) appears and BioCon-900S returns to the Home screen.
7) If you tap the Review icon when there is no scan result, Empty Folder dialog box ( ) appears on the Home screen.
8) You can delete all results in probe's internal memory at one time, if you want. See the section "7.8 DELETE ALL MEASUREMENTS" for information on deleting all scan results

NOTE: The scan results are saved to the internal memory, which can store 50 data. If you exceed this limit, the system deletes the oldest data to accommodate the new data.

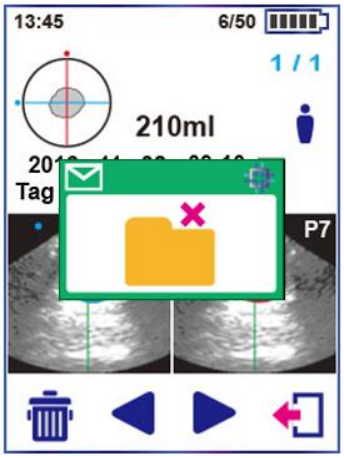


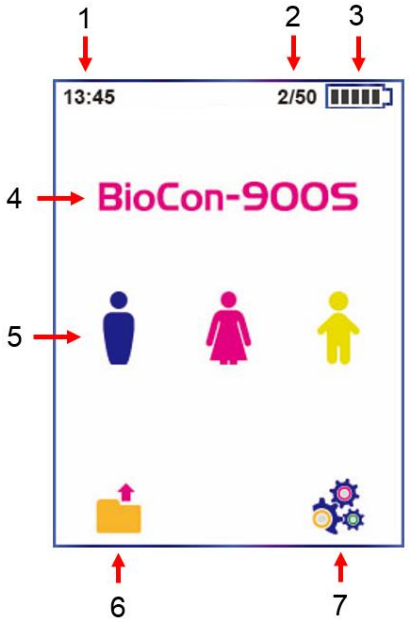
Figure 40 Delete Last Scan Result

Figure 41 Empty Folder Dialog Box

6 SCREENS

6.1 HOME SCREEN

Turn the probe on and the Home screen appears. It shows the main functions of the probe. The icons below on the screen allow you to select patient type, go to the Review screen or go to the Setup screen.



No.	Description
1	Time
2	Number of Saved Data / Internal Storage (50)
3	Battery Status
4	Model Name
5	Patient Type Icons
6	Review Icon
7	Setup Icon

Figure 42 Home Screen

6.2 INFORMATION SCREEN

The Information screen is used to enter patient data. See the section "5.4.1 INPUT INFORMATION – VIRTUAL KEYBOARD" for information on completing on the text box if you want.

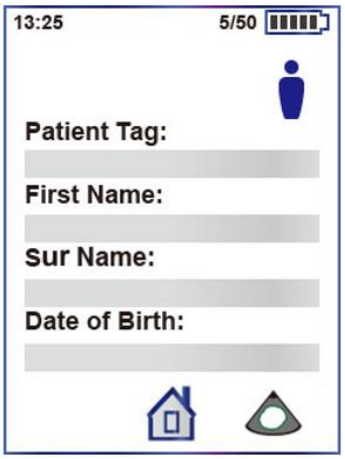


Figure 43 Information Screen (All)

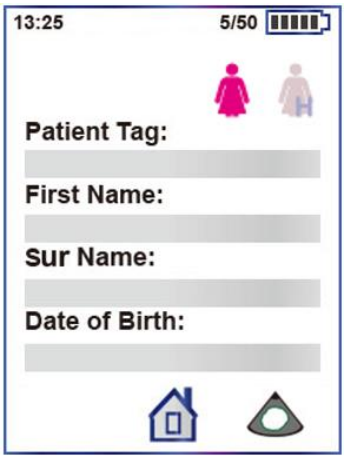


Figure 44 Information Screen (Female)

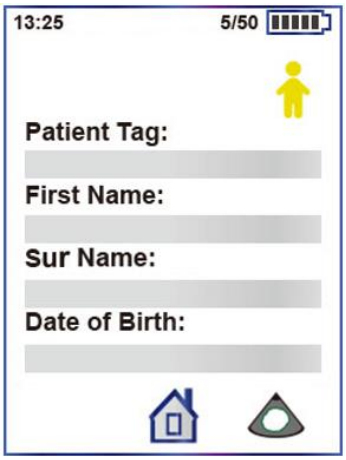


Figure 45 Information Screen (Pediatric)

6.3 BARCODE SCREEN (OPTIONAL)

The Barcode screen is used to record data by scanning barcode with patient information. See the section "5.4.2 INPUT INFORMATION – OPTIONAL BARCODE" for more information if you want.

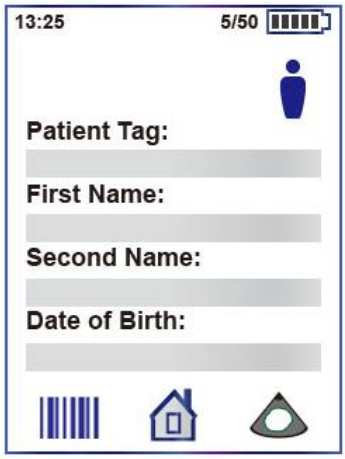
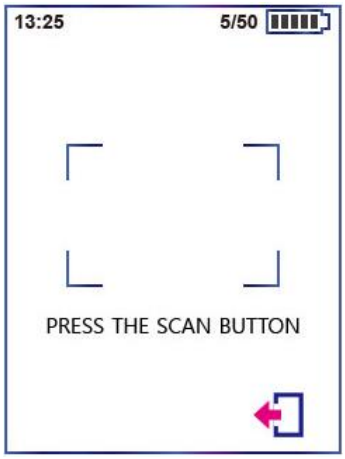


Figure 46 Information Screen (Optional Barcode)



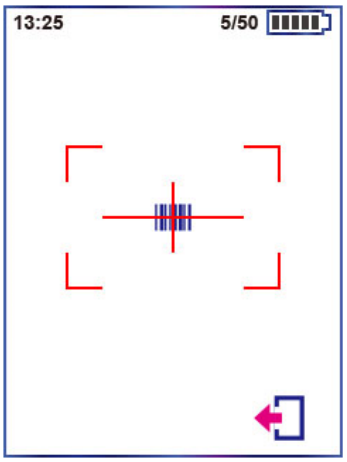


Figure 47 Barcode Screen

6.4 VIRTUAL KEYBOARD SCREEN

BioCon-900S has three different virtual keyboard types; Numeric, Letter(Uppercase, Lowcase), and Date.

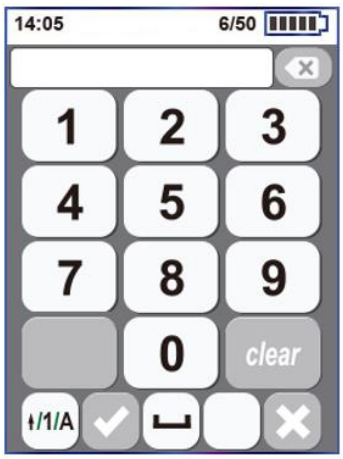


Figure 48 Numeric Keyboard

Figure 49 Letter Keyboard

Figure 50 Date Keyboard

Icon	Description
	Numeric and Letter Keyboard - Delete a character to the right of the cursor. Date Keyboard – Move the cursor to the left
	Delete all characters.
	Convert a string on a virtual keyboard.
	Exit the **Virtual Keyboard** screen after updating edited characters.

␣	Add a space.
✕	Exit the screen after recovering previous characters.

6.5 NORMAL SCAN SCREEN

Normal scan - Get 12-plane ultrasound images and calculate the residual urine in the bladder (3D scanning). It takes 3 sec to complete the Normal scan. As bladder volume is calculated, the progress bar increases until the scan is completed.

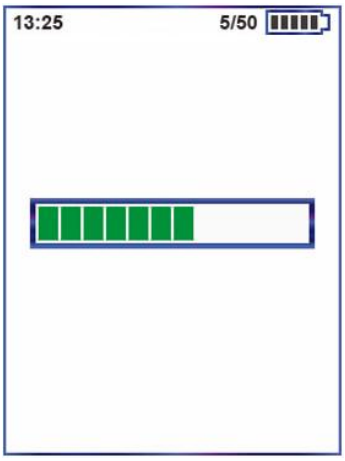
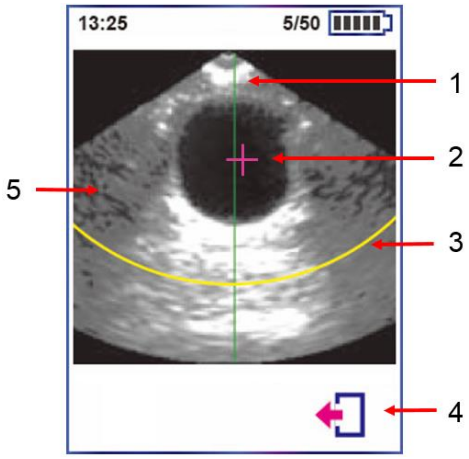


Figure 51 Normal Scan Screen

6.6 PRE-SCAN SCREEN

Pre-scan- 2D ultrasound images are displayed continuously in live image basis. This helps an operator locate bladder position and predict the range of residual urine. And also the centerline is provided during Pre-scan. Locate the bladder along the centerline on the screen. It helps detect the optimal position during Pre-scan.

The Pre-scan is executed only when 'Pre-scan' setup is 'ON ( )'. When 'Pre-scan' is 'OFF ( )', a Normal scan is executed.



No.	Description
1	Centerline.
2	Bladder point
3	Max detection depth to measure a pediatric urine volume.
4	Cease the Pre-scan and return to the Information screen.
5	Tap the Pre-scan screen, the Pre-scan is executed.

Figure 52 Pre-scan Screen (Default)

6.7 SCAN RESULT SCREEN

The Scan Result screen appears automatically when a normal 3D measurement is complete. The aiming information (crosshair) helps you verify the Scan result. The icons below on the display allow you to review other planes of the same measurement, return to the Home screen, and save the measurement. Also if you want to recan the bladder, tap the Re-Scan icon( ).

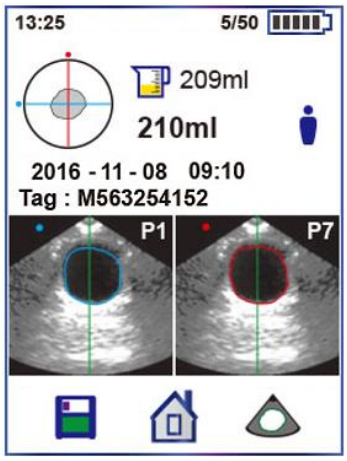


Figure 53 Scan Result (All)

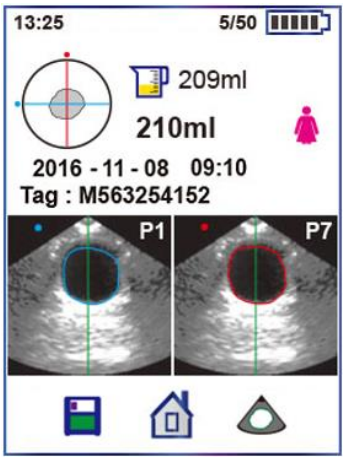


Figure 54 Scan Result (Female)

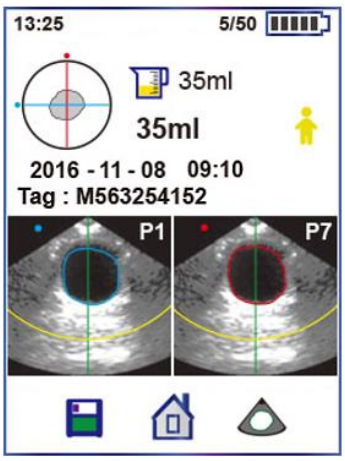


Figure 55 Scan Result (Pediatric)

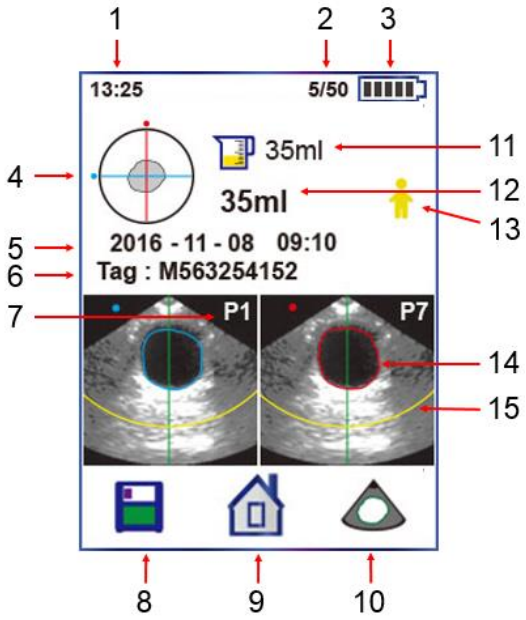


Figure 56 Scan Result Screen

No.	Description
1	Time
2	Number of Saved Data / Internal Storage (50)
3	Battery Status
4	Aiming Information(Crosshair)
5	Measured Date & Time
6	Patient Tag
7	The first plane of 12 planes
8	Save
9	Home
10	Re-Scan
11	Current Volume from Multiple Results
12	Maximum Volume from Multiple Results
13	Patient Types ( )
14	Bladder Outline
15	Max detection depth to measure a urine volume (Only pediatric patient)

6.8 REVIEW SCREEN

Tap the Review icon( ) on the Home screen, Review screen appears

The Review screen shows the bladder volume, ultrasound images and other saved information with the saved scan results. While reviewing the result, the menu icons below on the display allow you to delete the current reviewing result or return to the Home screen. If you want to review the scan results of other patients, tap the (9) icons. 2 / 6 (11) shows the chronological order of saved results and the total number of saved results. For example, 3/49 means the 3rd saved scan result of the 49 stored results.

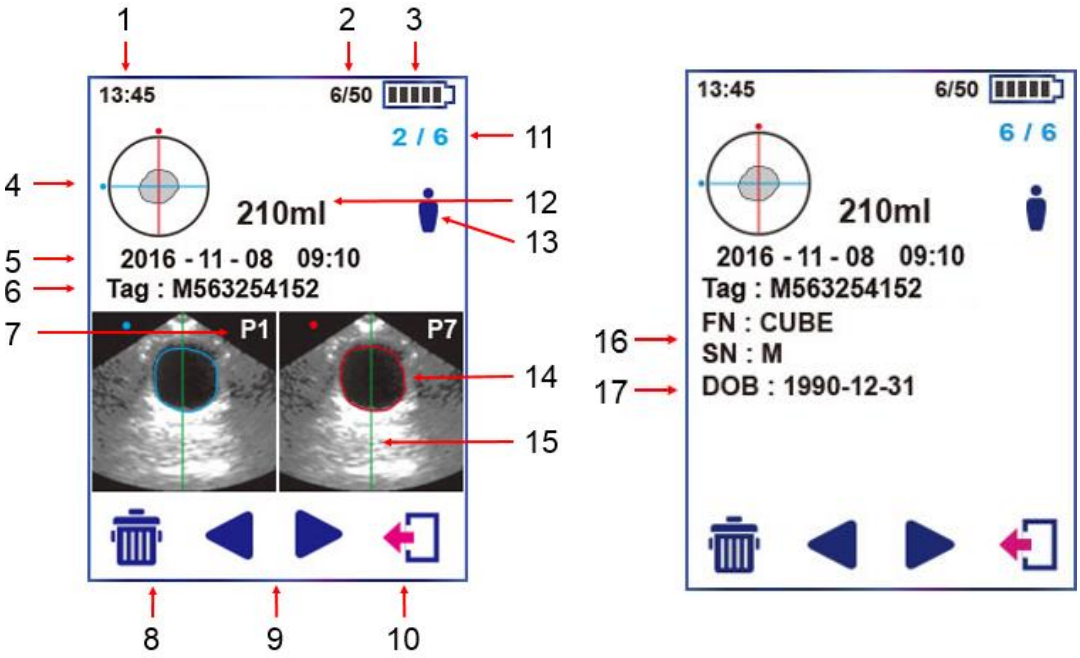
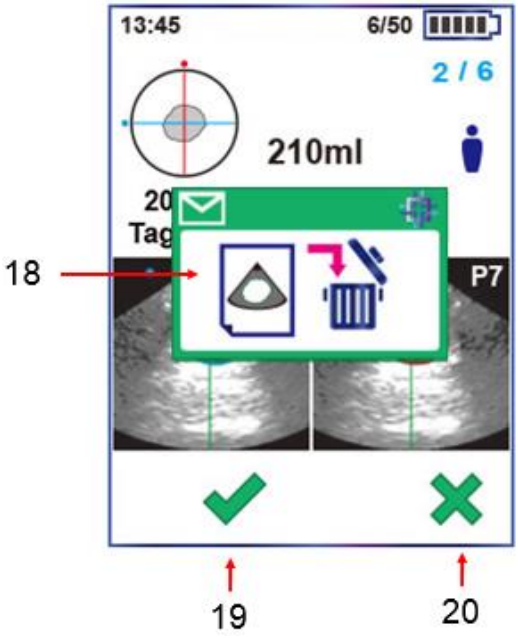


Figure 57 Review Screen



No.	Description
1	Time
2	Number of Saved Data / Internal Storage (50)
3	Battery Status
4	Aiming /information(Crosshair)
5	Measured Date & Time
6	Patient Tag
7	The first plane of 12 planes
8	Delete Icon
9	Previous & Next Patient Icon
10	Exit Icon
11	Chronological Order of Saved Results / Total Order of Saved Results
12	Bladder volume
13	Patient Types ( )
14	Bladder Outline
15	Centerline (helps detect the optimal position)
16	First Name & Sur Name
17	Date of Birth
18	Delete Dialog Box
19	OK Icon
20	Cancel Icon

Figure 58 Review Screen - Delete

6.9 SETUP SCREEN

Tap the **Setup** icon ( ) on the **Home** screen.
In the Setup screen the left column shows the **Setup Items** and the right column shows the **Setup Values**.
For more information on the system setting, see the section "7. SETTINGS"

1) Tap a Setup Value of the desired setup item.
2) Tap repeatedly a setup value untile desired setup value.
3) You can move to other Setup screen (1, 2, 3) by tapping the **Previous** or **Next** icon (,)
4) Tap the **Home** icon ( ) to finish adjusting the setup.

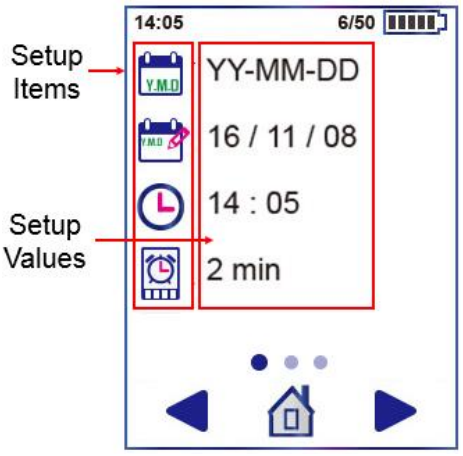


Figure 59 Setup Screen (1)

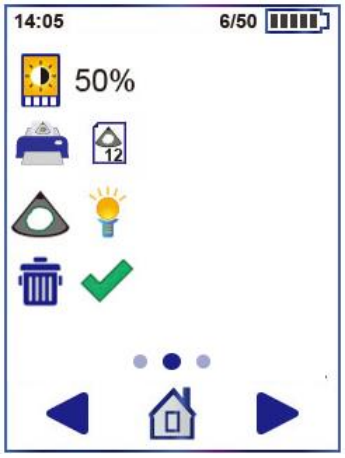


Figure 60 Setup Screen (2)

Figure 61 Setup Screen (3)

6.10 BATTERY STATUS

A fully charged battery
A battery about 80% charged.
A battery about 60% charged
A battery about 40% charged
A battery nearly depleted
Recharge the battery immediately

When the battery is nearly depleted, following dialog box appears asking you to charge the battery.

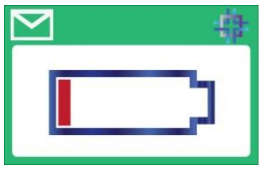
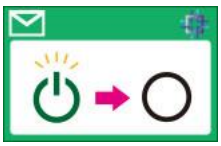
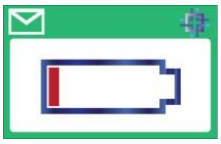
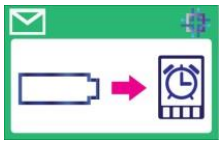
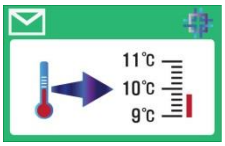


Figure 62 Dialog box - Needs to be recharged

- To conserve battery power, the probe goes into sleep mode by turning off the screen when not in use for a specified time. You can adjust the time to go into sleep mode in the setup. See the section "7.4 SLEEP MODE SETTINGS". The probe also goes into sleep mode if you press the **Power Button**( ) briefly with power on.
- To preserve battery power, the probe goes into shut down mode in approximately 24 hours after going into sleep mode, if there is no activity. However, if you do not plan to use the probe for more than a week, you should shut the probe down completely to prevent it from discharging completely.
- It takes approximately 6 hours for the discharged battery to fully charge.
- Fully charged battery can provide approximately 1,000 normal scans.
- Contact your local distributor when the fully charged battery does not allow normal scan for 10min.

6.11 DIALOG BOXES

Windows	Description
	Confirm Message: "Are you sure you want to delete this saved scan result?"
	Confirm Message: "Are you sure you want to delete all saved measurements?"
	Confirm Message: shutdown mode – To prevent the probe from discharging. "Are you sure you want to go into shutdown mode?"
	Alert Message: The message prompts you when calibration is needs.
	Alert Message: The battery is nearly depleted and needs to be recharged.
	Alert Message: The battery needs to be recharged immediately, so the probe goes to sleep mode soon by shutting itself down
	Alert Message: The temperature of oil inside the probe is below 10°C. So the thermostat inside probe makes the oil warm and the temperature of oil rises above 10°C. See the section "8.2 DIALOG BOXES FOR MAINTENANCE" for more information

7 SETTINGS

7.1 DATE FORMAT SETTINGS

1) Tap the **Setup** icon ( ) on the Home screen. Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Locate the **Date Format** option( ), and then tap the **Date Format Items (**YY-MM-DD / MM-DD-YY / DD-MM-YY**)** repeatedly to adjust the desired date format.
3) A format of date values immediately updates depending on the date format.

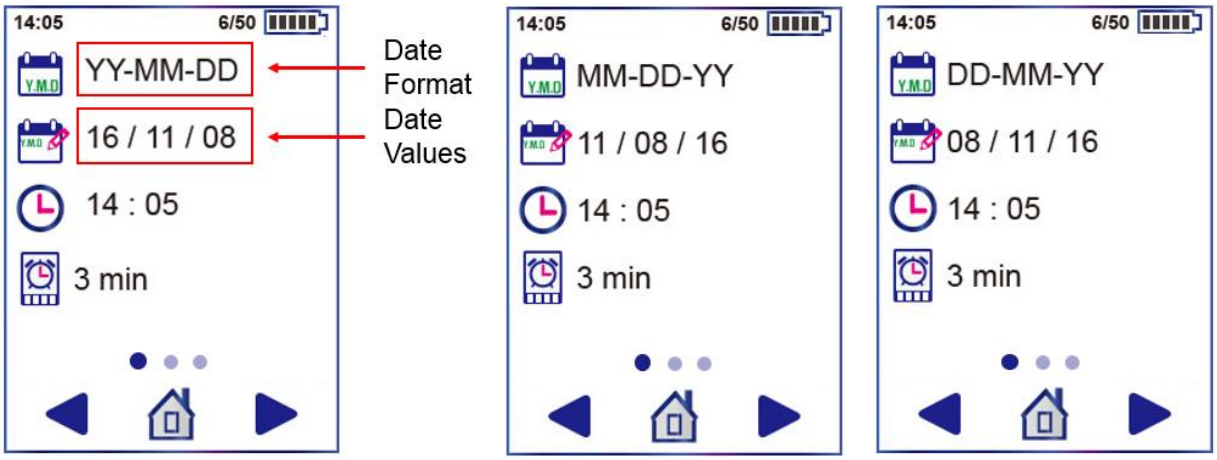


Figure 63 Date Format (YY-MM-DD, MM-DD-YY, DD-MM-YY)

7.2 DATE SETTINGS

1) Tap the **Setup** icon ( ) on the Home screen. Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Locate **Date** option( ) and tap **Date Value Item** (eg. 16 / 11 / 08), use the virtual keyboard to enter a date.
3) Tap the **OK** icon ( ) to finish adjusting the date after entering.

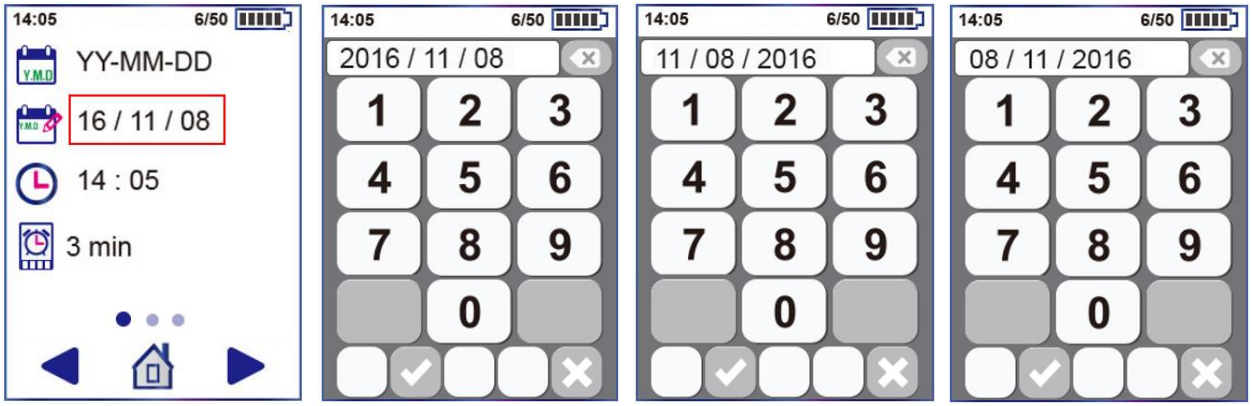


Figure 64 Date Setup **Figure 65 Enter Date Values (YY-MM-DD, MM-DD-YY, DD-MM-YY)**

7.3 TIME SETTINGS

A 24-hour clock provided only.

1) Tap the **Setup** icon ( ) on the Home screen. Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Locate the **Time** option( ) and tap **Time Item** (eg.14 : 05) to adjust the time, use the virtual keyboard to enter a time.
3) Tap the **OK** icon ( ) to finish adjusting the time.

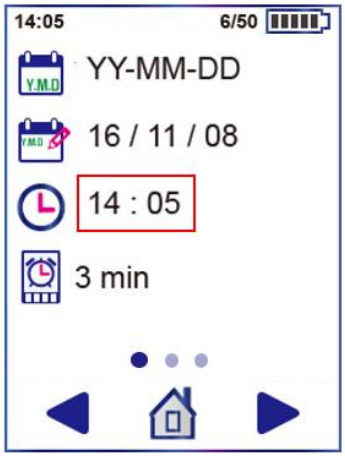


Figure 66 Time Setup **Figure 67 Enter Time Values (hour:minute)**

7.4 SLEEP MODE SETTINGS

A time setting to go into sleep mode: 2min, 3min, 5min

1) Tap the **Setup** icon ( ) on the Home screen.Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Locate the **Sleep Mode** option( ) and tap **Sleep Mode Item** (2min / 3min / 5min) repeatedly to adjust the time to go to sleep mode.

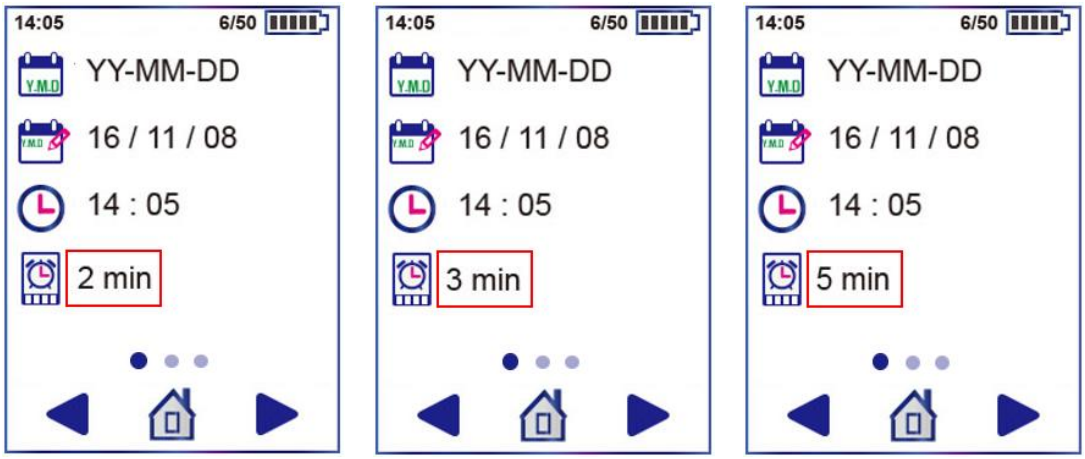
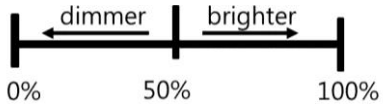


Figure 68 Time Setting of Sleep Mode (2min, 3min, 5min)

7.5 DISPLAY BRIGHTNESS SETTINGS



1) Tap the **Setup** icon ( ) on the Home screen. Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Use the **Next** icon ( ) on the Setup screen, and look for **Brightness** option( ).
3) Tap the **Brightness** Item (eg.50%, 60%, 70%) repeatedly to adjust display brightness (0%-100%).

NOTE: The display brightness setting affects battery life. To conserve battery life, adjust brightness to a lower setting

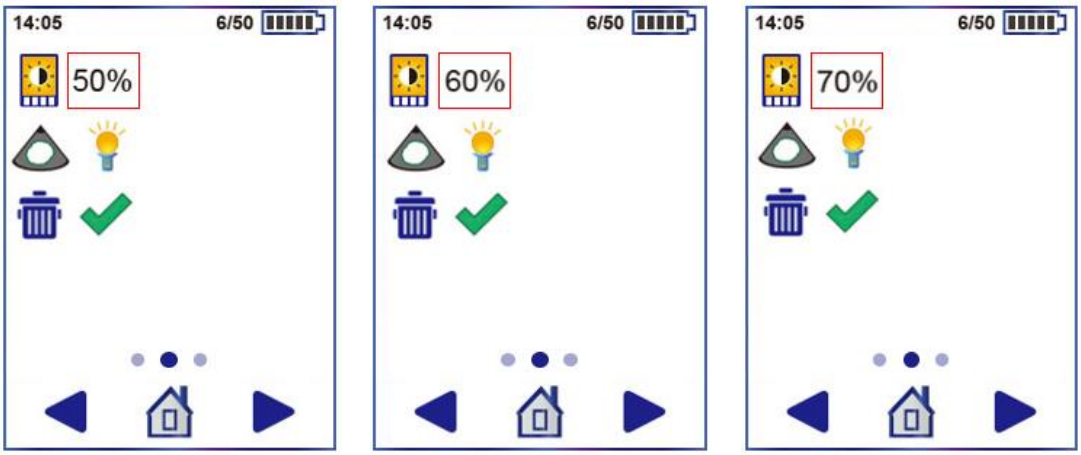


Figure 69 Brightness Setup

7.6 PRE-SCAN SETTINGS

1) Tap the **Setup** icon ( ) on the Home screen to open the Setup screen. Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Use the **Next** icon ( ) on the Setup screen, and look for **Pre-scan** option( ).
3) Turn the Pre-scan on ( ) or off ( ) by tapping the **Light Item** (or)

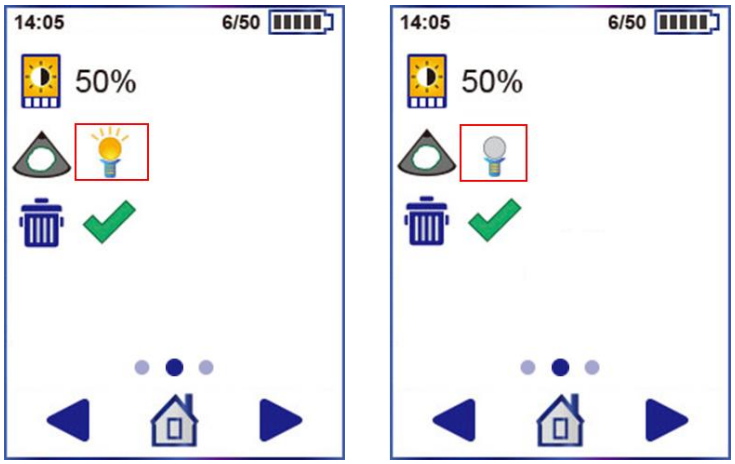


Figure 70 Pre-scan On/Off Setting

7.7 DELETE ALL MEASUREMENTS

1) Tap the **Setup** icon ( ) on the Home screen to open the Setup screen. Tap the **Home** icon ( ) to return to the Home screen, if you want.
2) Use the Next icon ( ) on the Setup screen, and look for the **Delete** option( ).
3) Tap the **Ok Item**( ) to delete all saved results.
4) And a dialog box ( ) to confirm appears before deletion.
5) Tap the **Ok** icon ( ) to delete or tap the **Cancel** icon ( ) to cancel.
6) Tap the **Home** icon ( ) to returen to the Home screen.
7) See the Home screen whether all saved results were deleted.

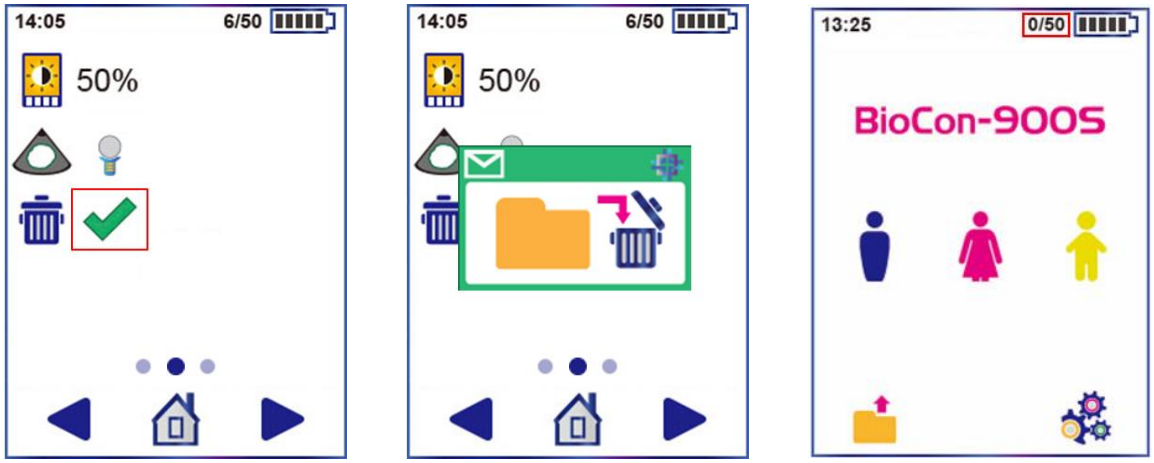


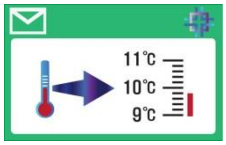
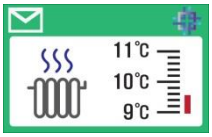
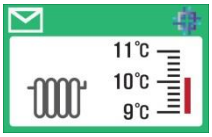
Figure 71 Delete All Data

8 MAINTENANCE

8.1 TROUBLESHOOTING

Error message	Description	Actions
	FPGA Configuration Error	Contact your local distributor or Mcube Technology.
	System Information Error	Contact your local distributor or Mcube Technology.
	Angle Motor Error	Contact your local distributor or Mcube Technology.
	Plane Motor Error	Contact your local distributor or Mcube Technology..
	High Temperature Error	Contact your local distributor or Mcube Technology.
	Low Temperature Error	Contact your local distributor or Mcube Technology.
	Data Deletion Error	Contact your local distributor or Mcube Technology.

8.2 DIALOG BOXES FOR MAINTENANCE

popup	Description
	Indicates that the temperature of oil inside the probe is below 10°C. So the thermostat inside probe makes the oil warm and the temperature of oil rises above 10°C. The following dialog boxes appear during the progress of warming oil. Warming oil lasts (about 3min or less) until the temperature of oil reaches 10°C. When finished, it goes to the Home screen.  (During warming oil)  (when finished)

8.3 CLEANING & DISINFECTION

⚠ WARNING

- Cleaning is a necessary step to perform before disinfecting the device. If the device is not cleaned properly, even after the disinfection procedure is completed, there may be contamination of the device.
- Incorrect cleaning or disinfecting of any part of the system can cause permanent damage.
- Do not use solvents such as thinner or benzene, or abrasive cleaner on any part of the system.
- Do not subject the system to any method of sterilization.
- Do not immerse the probe except the probe head in cleaning or disinfectant solution.
- Do not immerse the Charger in cleaning or disinfectant solution.
- Do not use metal or abrasive brushes. These may scratch the instrument causing permanent device damage.
- Wear protective gloves when cleaning the device.
- Availability of cleaning and disinfection products varies by country, and Mcube Technology is not able to test the products in every market. Please contact your local service provider or Mcube technology if you need more information.
- Do not spray the disinfectant spray solution directly on the surface, recessed areas, crack, etc. of the probe and the Charger.

⚠ CAUTION

- This product may only be cleaned and disinfected by using the approved processes provided in this manual. Cleaning and disinfection methods listed are recommended by Mcube Technology based on compatibility with component materials.
- Ensure that you follow the manufacturer's instructions for handling and disposing of the cleaning and disinfection solutions provided in this manual.

BioCon-900S probe is intended to contact the abdominal skin to measure the bladder volume. For this reason, cleaning and disinfecting the probe and Charger is an important procedure in using the system. The following table shows the risk assessment for the probe including the Spauling's/CDC classification for the minimum required disinfection level.

Component	Packaged	Use	Spaulding's/CDC classification	Clean	Disinfection level	
					Low	High
Probe Head	Nonsterile	Reusable	Noncritical	√	√	
Probe Except head	Nonsterile	Reusable	Noncritical	√		
Charger	Nonsterile	Reusable	Noncritical	√		

8.3.1 Compatibility

The following solutions have demonstrated cleaning or disinfection efficiency and material compatibility with system components:

- Metrex® CaviWipes™
- Metrex® CaviCide™ Spray

8.3.2 Cleaning

Ensure the power cord is not plugged into wall outlet.
Using a dry paper towel or soft cloth, wipe any ultrasound gel, soils and dirt completely off the Charger or

and probe.

1) Cleaning outer case (housing) of the Charger.

a) Put on new gloves.
b) Spray a soft-bristled brush(M16 recommended and validated) with Metrex CaviCide spray until thoroughly wet. Using the brush, scrub mated surfaces, recessed areas, cracks, crevices and other hard to reach areas until no visible contaminant is left on the Charger.
c) Use a CaviWipe towelette to completely clean the surface on the Charger.
d) Use a second CaviWipe towelette to thoroughly wet all surfaces of the Charger until all visible contaminants are removed. Allow the Charger to remain wet for 2 minutes.
e) If using an additional Metrex CaviCide towelette, leave the solution on the wiped Charger surface for about 2 minutes.
f) Visually inspect the Charger for visible contaminants.
g) Allow the Charger to air dry.

Figure 72 Charger

Please ensure that the electric inlet of Charger is not exposed to any solution during the cleaning procedure. If the inlet is exposed to the solution (such as water, isopropyl alchol or ethyl), dry the Charger completely before use.

2) Cleaning the probe

Since the surface of the probe affects the result of data, users should keep as follows:

a) Put on new gloves.
b) Spray a soft-bristled brush(M16 recommended and validated) with Metrex CaviCide spray until thoroughly wet. Using the brush, scrub mated surfaces, recessed areas, cracks, crevices and other hard to reach areas until no visible contaminant is left on the probe.
c) Use a CaviWipe towelette to completely clean the surface of the probe.
d) Use a second CaviWipe towelette to thoroughly wet all surfaces of the probe. Allow the probe to remain wet for 2 minutes.
e) If using an additional Metrex CaviWipe towelette, leave the solution on the wiped probe surface for about 2 minutes.
f) Visually inspect the probe for visible contaminants.
g) Allow the probe to air dry.

Figure 73 Probe Front-View

Figure 74 Probe Back-View

8.3.3 Disinfection

Please note the that low-level disinfection of the probe head is required before a new measurement.

a) Put on new gloves
b) Spray the probe head until it is sufficiently wet with a Metrex CaviCide spray.

Figure 75 Probe Head

c) Leave the solution on the probe head surface for about 3 minutes.
d) If you spray the Metrex CaviCide spray additionally, leave the solution on the surface for at least 3 minutes.
e) Allow the probe head to air dry.
f) Wipe the probe head thoroughly using the fresh CaviWipes.
g) Keep the probe head wet for 3 minutes.
h) Additional wipes may be used to ensure the probe remaining wet for the 3 minutes, if necessary.
i) Allow the probe head to air dry.
j) Using sterile, lint-free cloths wetted with RO/DI water thoroughly wipe the probe for at least a minute
k) Allow the probe head to air dry.

8.4 BATTERY MAINTENANCE

BioCon-900S battery cannot be removed by the user. If you do not plan to use BioCon-900S for a long period of time, you should switch the probe to shutdown mode to prevent its battery from fully discharging. The BioCon-900S should be charged every 6 months at a minimum, store it in accordance with the recommended conditions. See the section "9.5 ENVIRONMENTAL CONDITIONS".

8.5 WEEKLY INSPECTION

a) Inspect the probe and Charger thoroughly for cracks or leakages.
b) Inspect the power cord for checking if there are any damaged parts.
c) When scanning, check out any abnormal noise emanating from the probe head.

8.6 DISPOSAL

The device and components may contain environmentally hazardous materials (mineral oil, lead, battery pack, etc.). When they have reached the end of its useful service life, return them to the Mcube Technology, or follow your local regulations for hazardous waste disposal.

8.7 DEVICE REPAIR

Faults not described in section "8.1 TROUBLESHOOTING" are intended to be serviced by a certified technician. When any troubles unlisted in section "8.1 TROUBLESHOOTING" occur, contact an authorized service provider or Mcube Technology.

8.8 SELF TEST

Self-test
1) Put the probe on the Charger
2) Turn the probe on and tap the Setup icon () on the bottom right side of the Home screen.
3) Tap the Next icon () on the Setup screen and select the Self-test icon ()
4) Tap the Scan icon () to start the calibration. You can cease the Self-test by tapping the Cease icon (). Tap the Exit icon () to return to Setup screen, if you want.
5) Self-test progress bar appears, when the calibration is started. The progress bar indicates the progress of calibration. It takes about 3minutes to complete the calibration. When the calibration is completed, 100% sign is displayed. Tap the **Ok** icon () and the latest calibration date is updated. Tap the **Exit** icon () to return to the Setup screen.

8.9 CALIBRATION

BioCon-900S must be calibrated every 12 months to ensure accurate results. Calibration ensures accurate alignment of BioCon-900S's internal system. You can take scan, even if calibration is not performed by the designated date. But result can be compromised. There are following methods for the calibration.

⚠ CAUTION

- Calibrate BioCon-900S when the battery is charged over 60%.

8.9.1 PHANTOM CALIBRATION

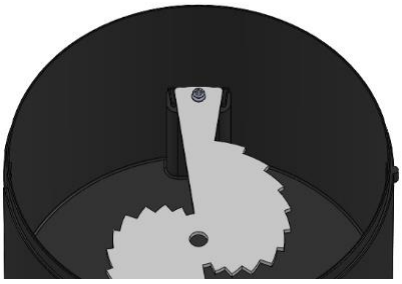
Phantom Calibration	
1) Place the CubeScan phantom on a flat surface and open the cover of the phantom. 	2) Pour about 5ml of water or more on the center surface of the phantom 
3) Place the phantom cover on the top of the CubeScan phantom. Check if the cover is in a stable and flat position. 	4) Put the probe head into the probe holder firmly. 5) Turn the probe on and Tap the Setup icon ( ) on the bottom right side of the Home screen. 6) Tap the Next icon ( ) on the Setup screen and select Phantom Calibration icon ( ) 7) Tap the Scan icon ( ) to start the calibration. You can cease the phantom calibration by tapping the Cease icon ( ). Tap the Exit icon ( ) to return to Setup screen, if you want. 8) The calibration progress bar appears, when the calibration is started. The progress bar indicates the progress of calibration. It takes about 3minutes to complete the calibration. When the calibration is completed, 100% sign is displayed on the screen. 9) Tap the Ok icon ( ) and the latest calibration date is updated. Tap the Exit icon ( ) to return to the Setup screen.

8.9.2 CALKIT CALIBRATION

Calkit Calibration

1) Open the cover of the calibration kit and pour the saline solution.

Ideal calibration condition
You can pure water instead of the saline solution. Ensure that water does not contain any air bubbles before starting the calibration.



2) There is a mark on the inside of the Calkit showing the *Water Level*. The *Water Level* is about 1cm below the top edge. Pour water to the Water Level.

3) Close the cover of the calibration Kit. Make sure that the arrow of the Calkit cover is aligned with the nipple of the Calkit body.

4) Align the probe's Scan Button **(S)** with the arrow of the cover and put the probe head firmly into the cover.
5) Turn the probe on and tap the Setup icon ( ) on the botton right side of the Home screen.
6) Tap the **Next** icon ( ) on the Setup screen and select the **CalKit Calibration** icon ( )
7) Tap the Scan icon ( ) to start the calibration. You can cease the calkit calibration by tapping the Cease icon ( ). Tap the Exit icon ( ) to return to the Setup screen, if you want.
8) The calibration progress bar appears, when the calibration is started. The progress bar indicates the progress of calibration. It takes about 3minutes to complete the calibration. When the calibration is completed, 100% sign wil be displayed on the screen.

Tap the **Ok** icon ( ) and the latest calibration date is updated. Tap the **Exit** icon ( ) to return to the Setup screen.

8.9.3 CALIBRATION REMINDER

1) Calibration Reminder Dialog box

Calibration Reminder Dialog box appears on the top screen under the conditions as follows:

- After 1 year since the last calibration

Tap the Ok icon ( ) to return to the Home screen. The Calibration Reminder Dialog box disappears.

2) Calibration Reminder icon

The **Calibration Reminder** icon ( ) is displayed on the Home screen after the Calibration Reminder

Dialog box disappears. When you finish the calibration, the last calibration date is updated and the **Calibration Reminder** icon ( ) disappears.

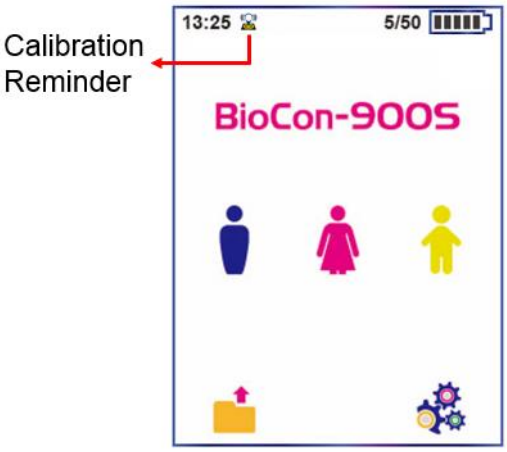


Figure 76 Calibration Reminder Icon on Home Screen

9 SPECIFICATIONS

9.1 ACOUSTIC OUTPUT TABLE

⚠ WARNING
ALARA principle (As Low As Reasonably Achievable) should be employed for all medical ultrasound exposure. Users can not adjust the acoustic output energy of the BioCon-900S. The output level is below than the levels which were referred in AIUM remarks in 1992 and there were no reported biological effects under the level. However, to minimize exposure, measurements should be kept as short as possible. Refer to the acoustic output section for more information.

Transducer Model: BioCon-900S Transducer Operating Mode: B-mode

The values in this table are the maximum readings obtained from each frequency.

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					Aaprt<=1	Aaprt >1		
Global Maximum Index Value			0.34	0.62				
Assoc Acoustic Parameter	*Pr,a*	(MPa)	0.48					
	P	(mW)		0.99				
	Min of [Pα(zs), Ita,α(zs)]]	(mW)						
	z_s	(cm)						
	z_{bp}	(cm)						
	z_b	(cm)						
	z at max. I_{pi}	(cm)	2.7					
	$d_{eq}(z_b)$	(cm)						
	*f*awf	(MHz)	2.04	2.04				
	Dim of Aaprt	X (cm)		1.1				
		Y (cm)		1.1				
Other Information	t_d	(microsec)	1.22					
	prr	(Hz)	390					
	*pr at max. I*pi	(MPa)	0.61					
	d_{eq} at max. Ipi	(cm)						
	Focal	FLx (cm)		5.5				
	Length	FLy (cm)		5.5				
	Ipa.3 at MImax	(W/cm2)	7.8					
Operating Control Conditions								

9.2 ELECTROMAGNETIC COMPATIBILITY

9.2.1 Electromagnetic emissions

Guidance Manufacturer's declaration - electromagnetic emissions		
The BioCon-900S is intended for use in the electromagnetic environment specified below. The customer or the user of the BioCon-900S should assure that it is used in such an environment.		
Phenomenon	**Test level / requirement**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The BioCon-900S uses RF energy only for its

		internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class A	The BioCon-900S is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Current Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emission IEC 61000-3-3	Complies	

9.2.2 Electromagnetic Immunity

Guidance Manufacturer's declaration - electromagnetic immunity			
The BioCon-900S is intended for use in the electromagnetic environment specified below. The customer or the user of the BioCon-900S should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 Test level**	**Compliance**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ± 2, ± 4, ± 8, ±15kV Air	In compliance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	In compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioCon-900S requires continued operation during power mains interruptions, it is recommended that the BioCon-900S ultrasound system be powered from an uninterruptible power supply or a battery.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	In compliance	
Voltage interruptions IEC 61000-4-11	0 % UT for 250/300 cycle	In compliance	
Power frequency magnetic field Immunity IEC 61000-4-8	30 A/m 50 Hz & 60 Hz	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

9.2.3 RF Immunity

Immunity test	**IEC 60601 test level**	**Compliance**	**Electromagnetic environment**

Conducted RF IEC 61000-4-6	3 V 0.15-80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15-80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the BioCon-900S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d =1.2** $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz-2.7GHz 80% AM at 1 lHz	3 V/m 80MHz-2.7GHz 80% AM at 1 lHz	**d = 1.2** $\sqrt{P}$ 80 MHz to 800 MHz **d =2.3** $\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol : 

NOTE 1) At 80MHz and 800MHz, the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioCon-900S is used exceeds the applicable RF compliance level above, the BioCon-900S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BioCon-900S.

b. Over the frequency range 0.5MHz to 80MHz, field strengths should be less than 3 V/m.

9.2.4 Recommended separation distance

Recommended Separation Distances between Portable and Mobile RF communications equipment and the BioCon-900S			
The BioCon-900S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BioCon-900S is can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BioCon-900S as recommended below, according to the maximum output power of the communications equipment.			
RATED MAXIMUM OUTPUT POWER OF	**SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)**		
	150 kHz to 80 MH	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**

TRANSMITTER (W)	d = 1.2√ P	d = 1.2√ P	d = 2.3√ P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.2.5 Components conformance to standards

To maintain electromagnetic interference (EMI) within certified limits, the device must be used with the cables, components specified or supplied by Mcube Technology. The use of cables or compoments other than those specified or supplied may result in increased emissions or decreased immunity of the system.

EMC standards	
Compoment	**Max length**
Power Cord	1.83 m(6ft)
Adapter	1 m (3.3ft)

9.3 EXCESSIVE TEMPERATURE TEST RESULT

Transducer type → / Test to be applied ↓		External use
Simulated use test	Temperature rise	The ambient temperature : 22.8 ℃ The temperature rise to: 24.6 ℃
Still air test (no gel)	Temperature rise	The ambient temperature : 23.1 ℃ The temperature rise to: 25.5 ℃

9.4 SPECIFICATIONS OF COMPONENTS

9.4.1 WIRELESS CHARGING

Main Chipset	TI (BQ500210RGZ)
Coil type	1 Coil (A10)

Power Input	1A / 60-80VA
Power Output	<5W (5V, 1A)
Charging efficiency	70%(Power max.)
Temperature sensor	NTCG163JF103FT1
LED Battery indicator	2LED (Yellow:1 / Green:1)
Operating frequency (wireless charging function)	149-156 kHz

NOTE: 1. The output power of a wireless charging is lower than 5 W.
2. The distance for wireless charging between Charger and a probe is less than 10mm.
3. The probe has to be properly mounted on the Charger for wireless charging. See the section "4.2 CHARGE THE BATTERY", if the battery is not charging.

9.4.2 SPECIFICATION OF COMPONENTS

Probe	
Item	**Features**
Bladder Volume Range	0 - 999ml
Accuracy	0-99ml±10ml, 100-999ml±10% (According to the scanning instruction, and scanning on a Mcube Technology tissue-equivalent bladder phantom.)
Scan time	Less than 3 sec
Power	MC-BA-01 (Lithium-ion rechargeable battery) - Nominal Voltage: 3.6v - Nominal capacity:5200mAh Charging time: less than 6 hours - Charged by the Charger Number of scanning : approximately 1000 scans. - For a new battery module fully charged. - Tested under Mcube Technology's test conditions.
Expected Service Life	7 years
Display	TFT-LCD 2.7 inch Format : 240 X RGB X 320 Stripe
Patient ID Input	Virtual Keyboard 1D/2D Barcode (Optional)
User Interface	- LCD Icons - 2 buttons - Touch screen
Water Resistance	Rated at IPX3
Probe Head	-Transducer : Diameter: 14mm -Sector scan -Dual frequency (2MHz, 3.4MHz) -B-mode scan image -Scan angle : 120° -Penetration depth(normal patient): 23cm -Applied part: Probe Cap -Type BF
Mode of Operation	- Continuous operation
Weight	540g with battery

Charger	
Item	**Features**
Use	Indoor
Power	**AC/DC Adapter:** Manufacturer: MEAN WELL Model: GSM60A12 Input: 100- 240VAC, 50/60Hz, 1.4-0.7A Output: 12V ⎓ 5.0 A, 60W MAX
Output	Wireless Power Transfer Charger
Insulation	Class I with protective earth
Water Resistance	IPX0
Mode of Operation	Continuous operation.
Weight	480g (without adapter and AC cord)

9.5 ENVIRONMENTAL CONDITIONS

⚠ WARNING

- Do not leave this device in places subject to extremely high temperatures such as a sealed vehicle or in direct sunlight. This can cause a fire.
- Do not place the device on an unstable surface. This can cause the device to fall or tip over and cause injury.

⚠ CAUTION

- Do not place the heavy object on the device. The davice can be damaged.
- Keep away from the humid or dusty place.
- Use the device indoors only under the environmental conditions.
- For additional protection of the device during a lightning storm, or when it is left unattended and unused for long periods of time, unplug it from the wall outlet.
- The immediate use of the probe which has been stored under 10℃ without warming may damage the probe. So take it into a room where the temperature is over 10℃ and let BioCon-900S warm up for a while. And then when the temperature of probe is over 10℃ you may use it.
- If you are not using BioCon-900S more than 3 months, remove the battery to prevent it from discharging and store it in accordance with the recommended conditions, and charge the battery every 6 months.
- Contact your local distributor or Mcube Technology, when you need to remove or replace the battery.

Enviromental Specifications	
Operating conditions	
Use	Indoor
Ambient temperature range	+10 - +40℃ (+50 - +104˚F)
Relative humidity	+30% - +75% non-condensing
Atmospheric pressure range	+700hPa - +1060hPa
Storage and transport conditions	
Use	Indoor
Ambient temperature range	-20 - +60℃ (+14 - +140˚F)

Relative humidity	+20% - +80% non-condensing
Atmospheric pressure range	+600hPa - +1060hPa

9.6 European Union Declaration of Conformity

This device complies with the essential requirements of the Radio Equipment directive: 2014 / 53 / EU. The following test methods have been applied to prove presumption of conformity with the essential requirements of the Radio Equipment directive: 2014/53/EU:

Manufacturer	Mcube Technology Co.,Ltd.
Products	CUBEScan Charger / Charger-001 Bladder Volume Measurement System / BioCon-900S
Product Description	WPT System
EU Directives	2014/53/EU – Radio Equipment Directive (RED)

Reference standards used for presumption of conformity:

Article Number	Requirement	External use
3.1a	Medical electrical equipment	IEC 60601-1 : 2005 + CORR. 1 (2006) + corr. 2 (2007) EN 60601-1 : 2006 + A1 : 2013
	RF Exposure	EN 62311:2008
3.1b	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services	EN 301 489-1 V2.1.1 EN 301 489-3 V2.1.1
3.2	Wireless power transmission systems, using technologies other than radio frequency beam, in the 19 - 21 kHz, 59 - 61 kHz, 79 - 90 kHz, 100 - 300 kHz, 6 765 - 6 795 kHz ranges	EN 303 417 V1.1.1

10 GLOSSARY

Probe	The main device with the LCD display.
Charger	CUBEScan Charger; Charge a lithium-ion battery with a probe.
Transducer	Device that transforms one form of energy into another form of energy. Ultrasound transducer transforms electric energy into acoustic energy and vice versa. Transducer in this guide means ultrasound transducer.
B-mode	A kind of ultrasound imaging mode. Displays the brightness information corresponding to the amplitude of the signal.
Pre-scan	General 2D real-time ultrasound scanning. 2D ultrasound images are displayed continuously in live image basis. This helps an operator locate bladder position and predicting the range of residual urine.
Normal Scan	Gets 12-plane ultrasound images and calculates the residual urine in the bladder (3D scanning).
Self-Test	Displays Self-test progress and results.
Phantom-Calibration	Displays phantom-calibration progress and results.

11 SYMBOL DIRECTORY

Symbol	Description	Symbol	Description
Warning	Failure to observe the warning could result in personal injury or serious damage to the system	SN	Serial number
Caution	Failure to observe the recommendations and precautions may result in system damage or failure	REF	Catalog(Part) number
NOTE	Provide information to help you use your device more efficiently		Type BF applied part (B= Body, F= Floating applied part)
	Operation instructions - Please refer to the operator's manual.	IPX3	Degree of protection against harmful ingress of water as detailed in the IEC 60529:IPX3 - Protected against spraying water
	Manufactured date		Manufacturer
EC REP	EC REP – Authorized representative in the European community	CE 0120	CE marked in accordance with the Medical Device Directive
	WEEE – Subject to waste electrical and electronic equipment regulations Refer to local regulations for disposal.	FC	Tested to Federal Communications Commission requirements
	Stand-by	RX Only	Statement of prescription
CLASS 1 LASER PRODUCT	Explanatory Sign – CLASS 1 LASER PRODUCT	CLASSIFIED c UL us	UL – Underwriters Laboratories certification mark for electrical shock, fire, and mechanical hazards only
RoHS	EU's Restriction of Hazardous Substances	MEDLINE	MEDLINE Logo
	Fragile item, Handle carefully		Temperature limitation
	This Way Up	%	Humiditylimitation

	Use no hook		Atmospheric pressure limitation
	Keep dry		Do not use blades to open

12 REFERENCES

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