CUBEscan™

REF **BioCon -900**

Operator's Manual

Man, Machine & Medicine
Mcube Technology Co., Ltd.

[for FCC]

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 CAUTION

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

[for IC]

This device complies with Industry Canada's licence-exempt RSSs. 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.

Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisee aux deux conditions suivantes :

1) l'appareil ne doit pas produire de brouillage;

2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

* Reorient or relocate the receiving antenna.
* Increase the separation between the equipment and receiver.
* Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
* Consult the dealer or an experienced radio/TV technician for help.

REF BioCon-900

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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Manufacturer

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Contents

1 GENERAL INFORMATION

1.1 PRODUCT DESCRIPTION

CUBEScan^{TM} BioCon-900 (bladder volume measurement system) is a safe and easy, non-invasive system to measure the bladder volume. CUBEScan^{TM} BioCon-900 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. Measurements are transmitted to a personal computer running CubePro software via a wireless connection. CubePro allows the user to print measurements, archive data and so on.

1.2 INTENDED USE

CUBEscan^{TM} BioCon-900 projects ultrasound energy through the lower abdomen of a patient to obtain images of bladder and calculate bladder volume.

1.3 PRESCRIPTION STATEMENT

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

1.4 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-900. This section has information on safe use of the BioCon-900 (Electrical Safety, Battery Safety, EMC (Electromagnetic Compatibility), Equipment Safety).

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-900 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.

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-900 is limited to the minimum level necessary for performance effectively. Data on acoustic output levels is listed in the Specifications chapter.

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 equipment 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 warninings and cautions.

⚠ WARNING
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with theprotective earth. - Grounding reliability can only be achieved when equipment 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.
- Disconnect the USB cable from the PC before cleaning the system.
- Do not touch PC output connectors (eg.USB, port and others) and the patient at the same time.
- Before using the system, inspect the enclosures, power cord and USB cable.
    Do not use the system if these are damaged.
- Do not use any probe that has been accidentally immersed in any liquid.
- Charge the probe only with the docking station provided.
- Only connect the docking station power supply to a mains supply rated at AC 100-240V and 50/60Hz.
- 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.

⚠ CAUTION
- The BioCon-900 has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical systems to IEC 60601-1-2:2010. 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 Electromagnetic Compatibility section.
- To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Mcube Technology.
- 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.
- 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
- When using the system with CubePro software, your computer must be minimally certified to EN/IEC/CSA/UL60950 or 60101-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 standard is maintained. Anyone connecting additional equipment to the signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with EN/IEC60601-1-1. If you need assistance, contact your biomedical staff, Mcube Technology, or your local distributor.

2.5   EQUIPMENT SAFETY

To protect your BioCon-900, and accessories, follow these warninings and cautions.

> ⚠ WARNING
> - No modification of this equipment 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 wall ventilated environment.
> - Excess bending or twisting of cables can cause a failure or intermittent operation.
> - Shut down the device before disconnecting the docking station by unplugging the plug.
> - 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   SAFE HANDLING PROCEDURES FOR TRANSPORTER

<u>Quarantine</u>: 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

CUBEScan^{TM} BioCon-900 has two main components: the probe and the docking station.

CUBEScan^{TM} BioCon-900:
- Hand-held, portable and lightweight
- Measures bladder volume with ultrasound
- Provides a live image of bladder
- Takes scans and provides measurements in a short time
- Allows for scan results and images to be transferred, reviewed and printed using CubePro software
- Easy to use: staff can easily learn to scan patients in a short time
- Battery-operated, wireless charging and wireless transmission
- Barcode reading and information capture

Figure 1 BioCon-900

3.2   SYSTEM COMPONENTS

No.	Picture	Parts	Q'ty	Description
1		BioCon-900 (Probe)	1	Hand-held, wireless, battery-operated, ultrasound volume measurement system
2		Docking station	1	Use the docking station to charge BioCon-900's internal battery, transfer data and print the results. ,
3		Power cord	1	The type of power cord depends on your country.
4		Thermal paper		For onboard printer (57mm width)
5		Package CD	1	PC Software
6	Barcode & capture module	Barcode & capture module		Barcode reading and information capture (optional)

6		USB Cable	1	USB 2.0: A - B type cable
7	-	Operator's manual	1	-

Users can replace only the following items below
-Thermal Paper, Gel

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

3.3 OUTER APPEARANCE OF PROBE

Figure 2 Front-view of probe

No.	Part	Function
1	LCD screen	Displays bladder volume and other information.
2	buttons	Variable function buttons(Contextual menu)
3	Scan button	Press to take a scan and release
4	Probe head	Generates, transmits and receives ultrasound waves, producing a 3D image of bladder. Type BF applied part
5	Reset button	Press to reactive probe
6	Charge indicator	Orange: Battery is charging. It lights off when fully charged.
7	Stand-by Indicator	Green: probe is ready for use.

Figure 3 Back-view of probe

No.	Part	Function
1	Ir window	Ir window to transfer data to the docking station
2	Safety symbol	Safety symbols for Ir transmission and red lights of barcode
3	Label	Note : Labels are subject to change without prior notice
4	Barcode read & capture module	Reads printed barcodes and captures patient information.

3.4   OUTER APPEARANCE OF DOCKING STATION

Figure 4 Front-view of docking station
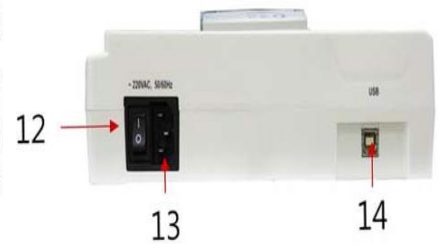
Figure 5 Back-view of docking station

No.	Item	Function
1	Ir window	Communicates with the probe.
2	Printer	Thermal printer
3	Print button	Press to print the scan result
4	Reset button	Press to reactivate the docking station.
5	Error indicator	Indicates an error.
6	Charge indicator	Indicates charging status. Blinking: Charging, On: Charging is completed.
7	Ready indicator	Indicates that the docking station is ready.
8	Power indicator	Indicates that power is supplied to the docking station.
9	Printer power indicator	Indicates that power is supplied to the printer.
10	Printer error indicator	Indicates a printer error.
11	Feed button	Roll(thermal) paper feed button
12	On/Off Switch	On/Off Switch
13	AC power inlet	AC power inlet
14	USB port	USB port

3.5   DISPLAY AND BUTTONS

The LCD screen displays the information for users and prompts that vary depending on the current function. The four buttons below the main display have variable functions according to device mode. The icons on the screen indicate the functions above each button. The button without an icon on the screen has no function. The Home screen appears when the probe is turned on. It services as a starting point for all the main functions of the device.
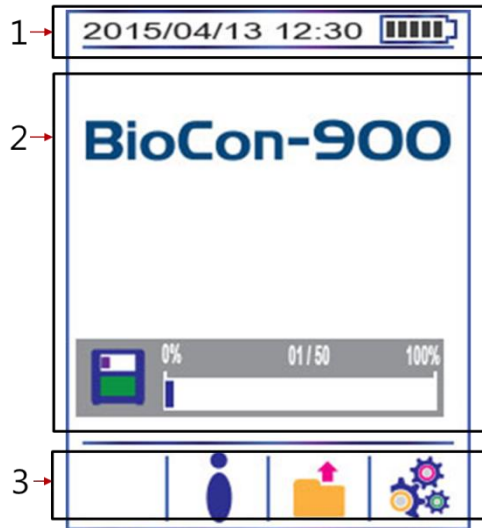
Figure 6 Main Display

No.	Description
1	Status Area which displays current date/time and battery status
2	Main display Area which shows information dependent on the each screen mode.
3	Menu Icon Area which shows menu icons dependent on the current situation.

3.6   ICON DIRECTORY

The following icons may appear on the main display.

Patient Type Icons

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

Icons on the Home screen

Icon	Description
	Missing data menu icon - Go to review the missing (unsaved) scan result.
	Review menu icon - Go to the Review screen.
	Setup menu icon - Go to the Setup screen.
	The number of saved scan results / Maximum capacity storage is 50.
	Battery status.

Icons on the Scan result screen & Review screen

Icon	Description
	Urine volume icon - Measured urine volume.
	Barcode icon - The scan result has a recorded barcode.
	Capture icon - The scan result has a capture of patient information.
	Saved icon -The scan result was saved.
P1	The 1st plane of 12 planes of the measurement (PX – The ordinal number of 12 planes)
	Next plane menu icon - Shift the next plane of 12 planes of measurement.
	Barcode menu icon - Read a barcode.
	Save menu icon - Save the Scan result.
	Home menu icon - Return to the Home screen.
	Previously saved measurement menu icon – Review the Previously saved measurements
	Delete menu icon – Delete the currently displayed measurement

Icons on the Setup

Icon	Description
Y.M.D	Date format (YY-MM-DD, DD-MM-YY,MM-DD-YY)
Y.M.D	Date
(clock)	Time (format : 24-hour)
(brightness)	Display brightness (0 to 100%, default= 50%))
(printer)	Print report format
(alarm clock)	Sleep mode (0.5min, 1min,2min,3min,5min,off)
(pre-scan)	Pre-Scan On( ) / Off( )
(barcode)	Barcode reader On( ) / Off( )
(camera)	Capture On( ) / Off( )
(trash)	Delete all saved measurement.
(self-test)	Self-test

	Phantom calibration
	Move down a setting in the list
	Move up a setting in the list.
	Move right an item.
	Select the option or perform the action.
	Return to home screen.
	Cancel the current function.
	Exit the current function/or Return to the previous setting.
	Perform the action.
	Cease the action.
	The function On
	The function Off

4   SETUP

4.1.   CHARGING BATTERY

> ⚠ WARNING
> ● The battery must be replaced by the authorized service provider only.
> ● Use only the provided docking station, and power cord to charge the battery for electric safety.
> ● Do not disassemble, heat or dispose of the battery in fire.
> ● Keep battery out of reach of children and in original sealed package.
> ● Dispose of used batteries promptly according to local recycling or waste regulations.

⚠ CAUTION
● The docking station and the power cord are not intended for patient contact. Ensure six feet (two meters) is 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.
● Risk of explosion, fire, or serious injury. The system is powered by a lithium-ion battery. Failure to note the following instructions when handing the battery may result in serious injury.
   - 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-900.
   - 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 docking station for other equipment.

- Do not charge the battery with other chargers.
- Long term storage: If you are not using BioCon-900 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.

The probe is powered by a built-in lithium ion battery. The battery is charged by docking station and the battery icon on the probe is always displayed, indicating the current capacity.

When you don't use your probe, we recommend that you mount and store it in the docking station to ensure that the probe is sufficiently charged. A battery has a protective circuit module which protects battery from overcharging and over-discharging.

Figure 7 Probe-mounting	**Figure 8 indicators of probe**	**Figure 9 indicators of docking station**
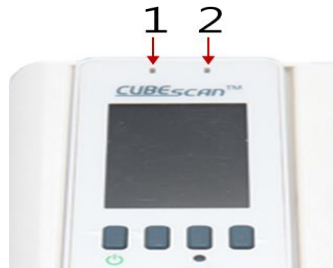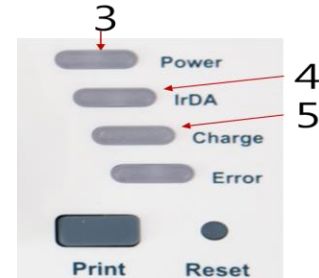
1) Plug the docking station into a wall outlet and turn the docking station on. The power indicator (3) and the Ready indicator (4) on the docking station will light on in green.
2) Mount the probe on the docking station. Make sure that the upper part of probe reaches the wall of

docking station.
3) As soon as the probe is mounted on the docking station, the beep and light indicators will work as below;
    a) A short beep: the wireless connection for charging is completed.
    b) The charge indicator (5) on the docking station will light on in green.
    c) The charge indicator (2) on the probe will light on in orange.
4) The stand-by indicator (1) will be turn on when the probe is ready to use.

The main display (LCD) will go into sleep mode after designated idle time
You can turn the sleep mode off in the setup, if necessary.

The charge indicator (2) on the probe will be turn off after fully charged.

Press the power button (⏻) until the probe goes into the sleep mode, if you want.

4.2.   CHANGING A THERMAL PAPER

	1) Open the printer lid.
	2) Take out the empty bobbin.
	3) With the printer paper in one hand, unroll a small length of the paper and insert into the unit. ● Be sure to insert the thermal paper in the correct orientation.
	4) Make the printer lid completely closed and tear off any paper extending from the printer. ⚠ When the system is operated in abnormal conditions (frozen system, burning smell, etc), press the reset button with pen or turn the switch off on the back of the docking station.

⚠ CAUTION
● To avoid damaging the system, only use the thermal paper specified by Mcube Technology and only print when the thermal paper is correctly loaded.
● If the paper appears to be stuck in the printer, open the printer cover and clear the paper jam or contact your local distributor or Mcube Technology.

5 HOW TO USE

5.1 CHECKUP BEFORE USE

Before using BioCon-900, make sure that users should be familiar with BioCon-900 and the part of BioCon-900. If you are a new user of BioCon-900, we strongly recommend that you perform 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 easier to locate.

⚠ WARNING
- If you use BioCon-900 in the presence of flammable anesthetics, explosion hazard exists.
- Do not use the BioCon-900 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 go see a doctor.

5.2 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 transmission 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

5.3 PERFORM THE BLADDER VOLUME MEASUREMENT

5.3.1. SETTING UP

See "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 measurement.
Wipe the probe head gently with a soft cloth dampened in isopropyl alcohol to clean and disinfect the probe.

5.3.2. MEASUREMENT OF 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).

1) Turn on the system
Press the power button (⏻) shortly until the probe turns on. If the Pre-Scan was not on, only normal scan performed.

2) Select patient type.
BioCon-900 supports three patient types.

Press the Patient type button (👤👩🧒) repeatedly on the probe to select the patient type.

- 👤   All other patients

- 👩 A female who has not had a hysterectomy.

- 🧒 A child with height less than 47 inches (120cm) and weight less than 55 lbs. (25kg).

3) Applying gel.
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. Place an ample amount of gel without air bubbles to the probe head. Place the probe 3~4cm above the pubic bone.

4) Aim toward bladder
Put the ultrasound probe on the patient's abdomen and aim it to the location where the bladder is expected to be.

- When measuring the urine volume of a patient, sit or stand beside the right of the patient and grab the probe with your right hand. At this point, press the scan button with your right hand thumb. Ensure the head of the patient icon on the probe will point toward the head of the patient when you place the probe head on the patient's abdomen.
- Only use the ultrasonic gel approved by FDA, CE or biocompatible ultrasonic gel.
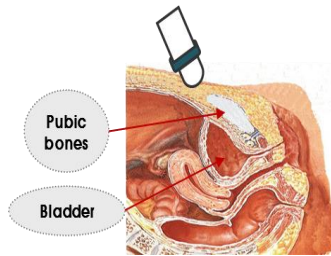
5) Find bladder with Pre-Scan
Press the Scan button to start "Pre-Scan" and start displaying the Pre-Scan image such as 2D ultrasonic image on the screen.
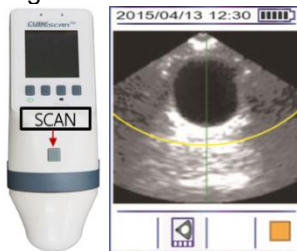
The position where the bladder image is the largest and most centered is the optimal place to start the normal scan process. To locate the bladder, keep the probe contacted the abdomen and tilt the probe forward, backward, left and right.

● The Pre-Scan is executed only when 'PRESCAN' setup is 'ON'. When 'PRESCAN' is off, a normal scan will be executed.

Locate the bladder along the centerline on the screen. It helps detect the optimal position during pre-scan.

6) Press the Scan button.

When you have located the bladder, as in the picture above, press the Scan button to start the Normal scan and then, the progress bar on the screen will appear. 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. When you hear the beep, the scan is complete.

7) Check the scan results

View the scan result (bladder volume) displayed in milliliters (ml).

The Beaker icon shows the bladder volume. (1) shows the current volume and (2) shows the maximum volume from multiple measurements for one patient. To verify the volume and check other 12 planes of bladder, press the Next plane button ( ) on the probe repeatedly

8) Record a patient information with barcode read & capture module
If you don't want to record any patient information, skip this step.

⚠ WARNING
● "LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM"
● Do not capture human being with the barcode read & capture module.
● Recording barcodes and capturing patient information is not available, after the Scan result is saved.

Move the aiming position to the center of the barcode and press the Barcode button ( ) with thumb. And then a red light guide is emitted. Keep pressing the Barcode button ( ) and do not release until getting barcodes. The barcode reader captures continuously and decodes for a good barcode scan. You will have a good barcode with a short beep. And the barcode numbers will be displayed on the screen.
Move the aiming position to the objects and release the Capture button ( ) to capture the patient information. It takes 3 seconds to capture the aimed object (patient information), so don't move your probe for 0.5 sec after releasing the button. You will have the captured object with short beep will be displayed on the screen.

And the Barcode icon () and Capture icon () will be displayed in the Review screen. When you are not satisfied with your recording, you can make a new recording and the latest barcode and captured patient information will be deleted.

Press the exit button () to exit the Barcode and Capture screen.

<good>

<bad>
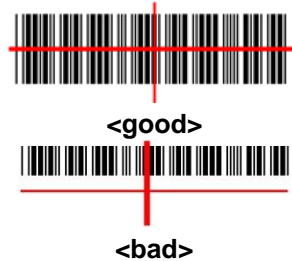
9) Save scan results

To save the scan results, press the Save button () below the display and then a saved icon () will appear on the screen. You can save the scan result before barcode reading and/or capturing the patient information. Recording the patient information is not available, after the scan result is saved.

10) Finish the measurement

After finishing scanning, take the probe away from the patient and then wipe the ultrasound gel off from the patient and the probe.

11) Mount the probe on the docking station

Mount the probe on the docking station and the probe will display the scan result screen. At the same time, the data of probe is communicated with the docking station. And the battery is recharged, if needed.

12) Print the measurement

Press the print button on the docking station.

5.4   SELECTING THE PATIENT TYPE

"All other patients" icon is firstly displayed, when the probe is turned on.

Press the Patient type button ( ) on the probe to select the patient type.
A button has three patient types. Press the button repeatedly to set the desired setup.

-    All other patients

-    A female who has not had a hysterectomy.

-    A child with height less than 47 inches (120cm) and weight less than 55 lbs. (25kg).
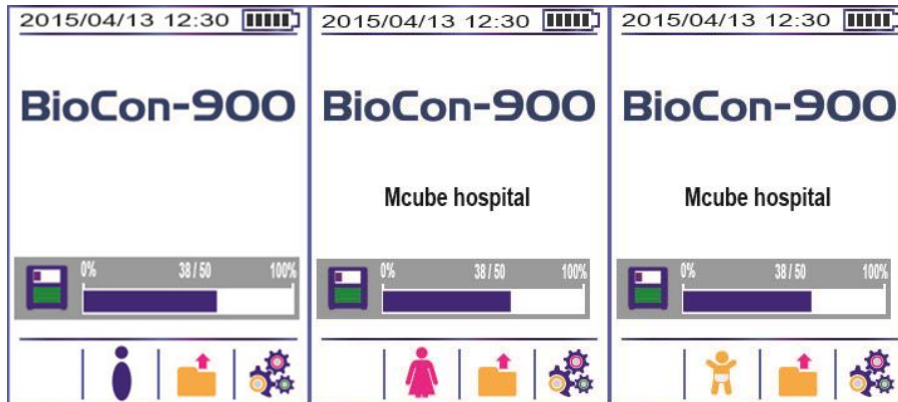
Figure 10 selecting the patient type

5.5 VERIFYING THE MEASUREMENT

Press the Next plane button ($\triangle$) repeatedly to see all planes of bladder images on the Scan result screen, if necessary. And then the aiming information (crosshair) will be rotated clockwise by 15° and displayed the 2nd&8th plane, 3rd&9th, 4th&10th, 5th&11th, 6th&12th plane of bladder in order. We strongly recommend that perform the measurement one or more times, when a bladder image is incorrectly positioned in the plane.
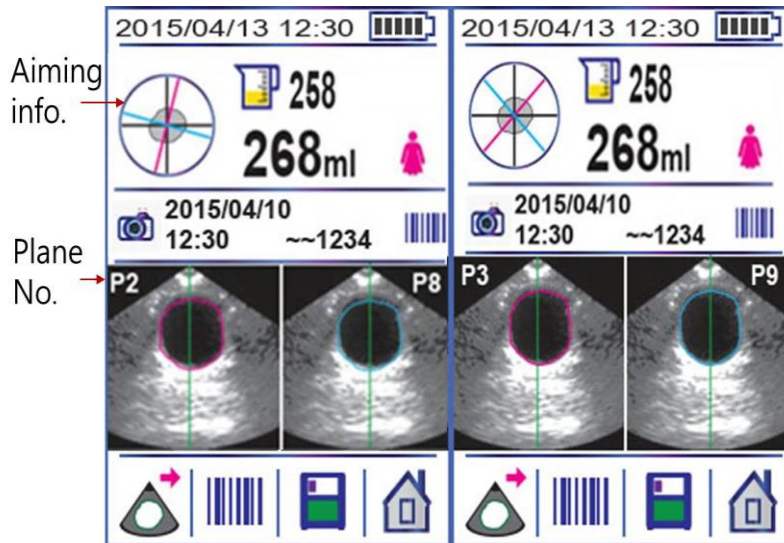
Figure 11 Planes of measurement   **Figure 12 incorrectly positioned**
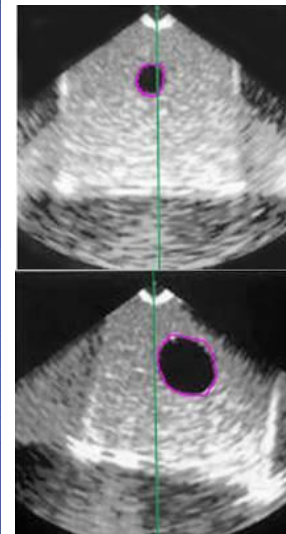
In the aiming information on the Scan results screen, if the bladder is not in the crosshairs, it is strongly recommended you re-aim and re-scan for accuracy.

To verify the scan result, the bladder contours of plane images.
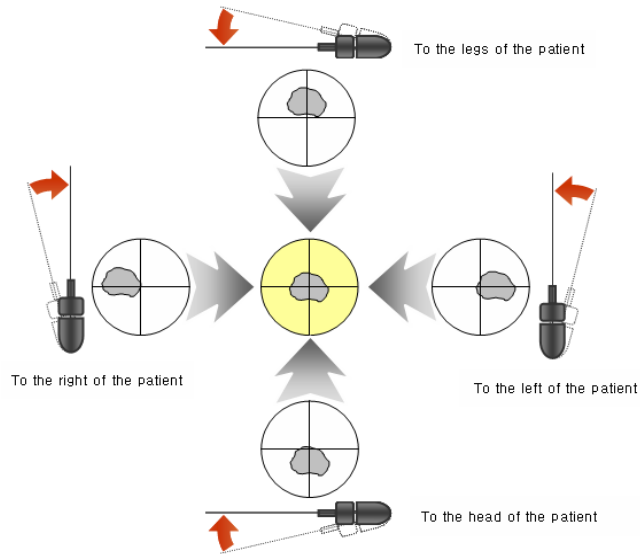
Figure 13 How to re-aim

The crosshair helps how to re-aim and the guiding arrows show that the user will have to move or tilt the probe for a more accurate scan.

5.6   PRINT OUT OF MEASUREMENT

The measurements can be printed via an onboard printer on the docking station. The currently displayed measurement is printed.

Date, time, aiming info, bladder images and maximum bladder volume appear on the printout. The barcode number (~XXXX) will be in the tag to prevent from leaking of recorded information, if the barcode is recorded. You can handwrite patient information in the tag, if the barcode is not recorded. You can adjust print report format in the setup screen.
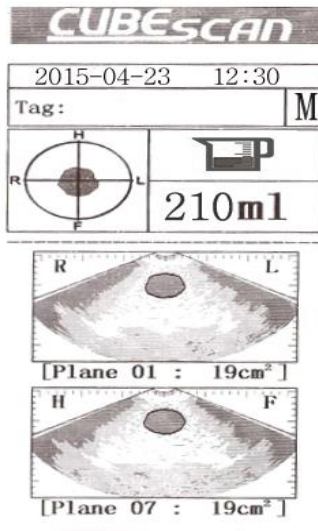
Figure 14 Print out

Range & Value	Description
Raw Images	Print grayscale B-mode images (2 planes) - Default
Volume Only	Volume only
Walls	Bladder outline only (2 planes)
All planes	All 12 planes with B-mode images

5.7   READING BARCODES AND CAPTURING THE PATIENT INFORMATION

⚠ WARNING
- **"LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM"**
- Do not capture human being with the barcode read & capture module.
- Hold the probe with both hands tightly, when you read barcodes and capture patient information.
- Recording barcodes and capturing patient information is not available, after the scan result is saved.
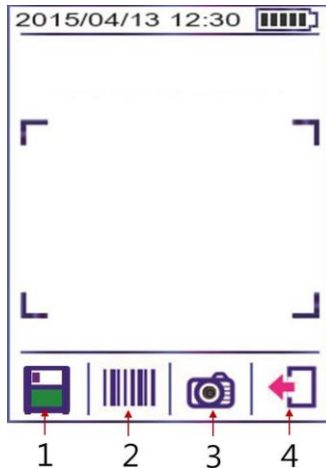
No.	Description
1	Save icon
2	Barcode icon
3	Capture icon
4	Exit icon

Figure 15 barcode & Capture screen

How to read a barcode

1) After scanning, move the aiming position to the center of the barcode and press the Barcode button (▐▐▐▐) on the Scan result screen with thumb.
2) A red light guide is emitted.
3) Keep pressing the button and do not release until getting a barcode.
4) The barcode reader captures continuously and decodes for a good barcode scan.
5) You will have a good barcode with a short beep. And the barcode numbers will be displayed on the screen.
6) To save the barcode numbers, press the Save button(▣)
7) To exit the Barcode & capture screen, Press the Exit button(◀▯)
8) Barcode icon (▐▐▐▐) will be displayed in the Review screen, after the barcode reading is saved successfully.

How to capture patient information

1) After scanning, move the aiming position to the objects and release the Capture button (📷) on the Barcode & capture screen to capture the patient information.
2) It takes 3 seconds to captures patient information, so do not move the probe after releasing the Capture button (📷) for 0.5 seconds.
3) You will have a good object with a short beep. And the captured patient information will be displayed on the screen as well.
4) To save the captured patient information,press the Save button(▣)

5) To exit the Barcode & capture screen, press the Exit button( )

6) The Capture icon( ) will be displayed in the Review screen, after the captured patient information is saved successfully.

When you are not satisfied with your recording, you can make a new recording and the latest barcode numbers and captured patient information will be deleted. You can save the measurement by pressing the Save button ( ), when you are satisfied with the recordings.
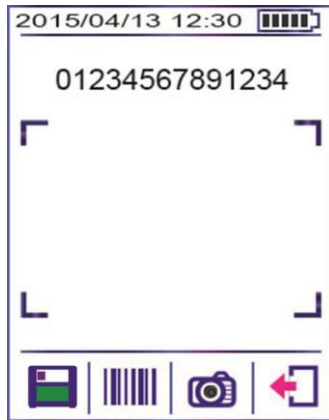
Figure 16 Recorded barcode numbers

Figure 17 Captured patient information
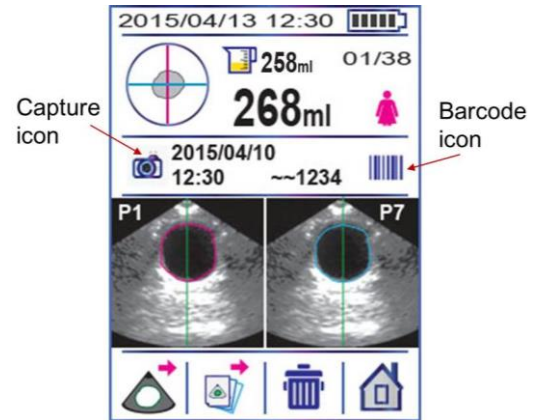
Figure 18 Barcode & Capture icon

5.8   SAVING THE SCAN RESULT

You can save the currently displayed Scan result on the Scan result screen. And also Missing scan result can be saved after fetching the Missing scan result.

Press the Save button (▣) to save the Scan result. The Saved icon (▣) appears on the screen after the Scan result is saved successfully.
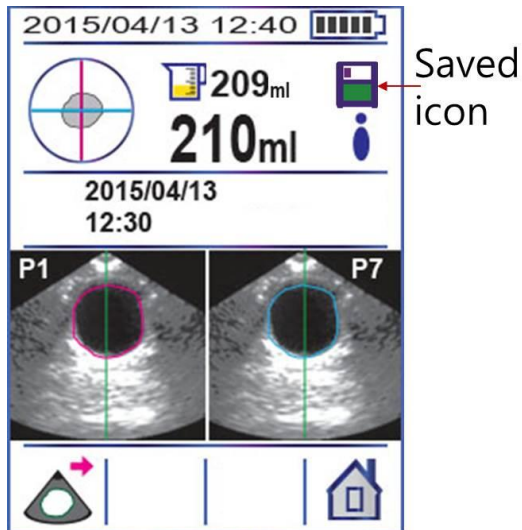
Figure 19 Saving the scan result

5.9   MISSING (UNSAVED) SCAN RESULT

If you did not save the Scan result and return to the Home screen, the Missing (unsaved) scan result icon (▆) will appear on the Home screen. Press the Missing scan result button (▆) to fetch the missing scan result. Then the Missing scan result screen will appear.
Recoding a new barcode or capturing patient information is not available for Missing scan results.

The performances below will make the Missing scan result icon disappear.
1) Fetch and save the Missing scan result.
2) A new Normal scan is performed.
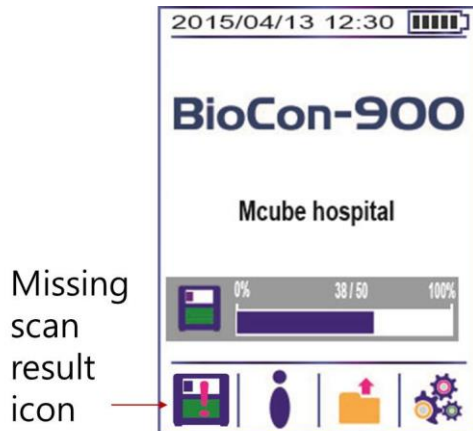
Figure 20 Home screen with Missing scan result

5.10   HOME SCREEN

Turn the probe on and the Home screen will appear. It shows the main functions of the probe. The buttons below the display allow you to select patient type, go to the Review screen and go to the Setup screen.
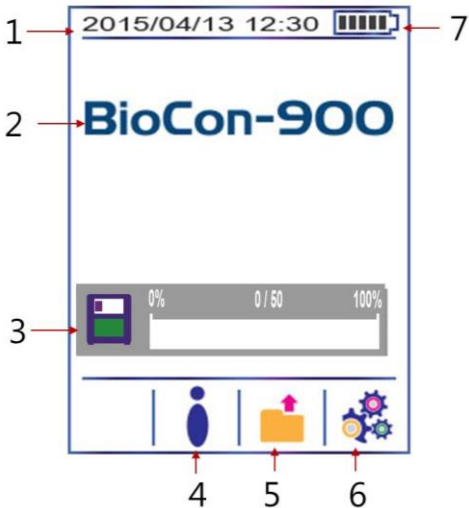
Figure 21 Home screen

No.	Description
1	Date & Time
2	Model name
3	Number of saved data
4	Patient type icons ( )
5	Review menu icon
6	Setup menu icon
7	Battery status

5.11   PRE-SCAN SCREEN

Pre-Scan- 2D ultrasound images are displayed continuously in live image basis.
This helps an operator locate bladder position and predicting 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 'PRESCAN' setup is 'ON'. When 'PRESCAN' is off, a normal scan will be executed.
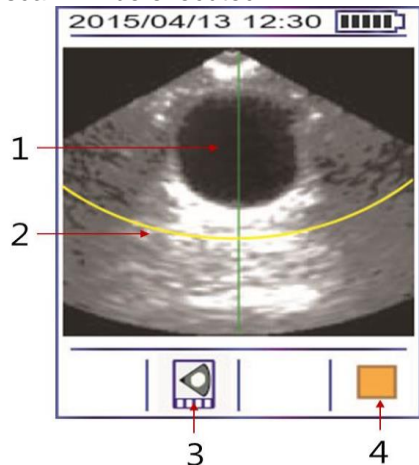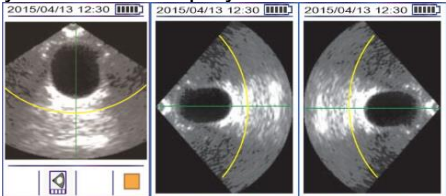
Figure 22 Pre-Scan screen

No.	Description
1	Centerline
2	Max detection depth to measure a child's bladder volume
3	Press the rotation button (⬕) repeatedly to rotate the Pre-Scan display between 3 display modes. (default, -90°, +90° display modes)
4	Cease the Pre-Scan and return to the Home screen. Press the Cease button(■) in all 3 modes

5.12 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.
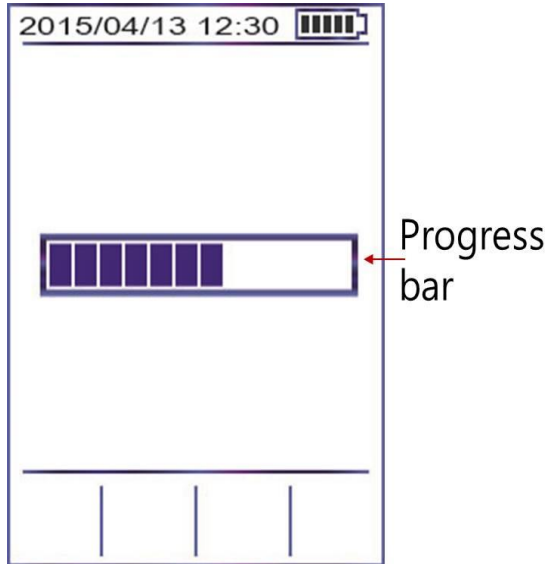
Figure 23 Normal scan screen

5.13 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 menu buttons below the display allow you to review other planes of the same measurement, read barcodes, save the measurement, and return to the Home screen.
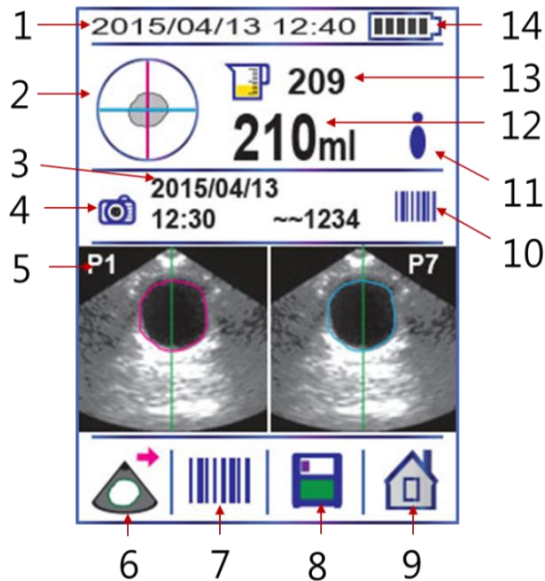
Figure 24 Scan result screen before saving

No.	Description
1	Date & Time
2	Aiming information(Crosshair)
3	Measured date & time
4	Capture icon if any image is captured.
5	The first plane of 12 planes
6	Next plane menu icon
7	Barcode menu icon
8	Save menu icon
9	Home menu icon
10	Barcode icon and part of the barcode if barcode is recorded.
11	Patient type icon(👤👩👦)
12	Maximum volume from multiple measurement
13	Current volume from multiple measurement
14	Battery status

Description of button

Press the Menu buttons below the display.

Next plane menu icon (⬤) – Shifts the next plane of the measurement.

Press the Next plan button repeatedly to shift the next plane.

Home menu icon (⌂) - Returns to the Home screen.

Barcode menu icon (||||||) – Reads a barcode and goes to the Barcode & capture screen.

Save menu icon(▣) – Saves the scan result
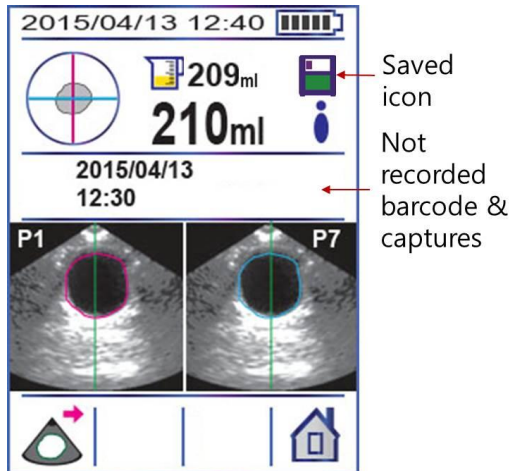
Figure 25 Not-recorded barcode & capture

If there is no recorded barcode and/or capture, the barcode and capture icons will not appear.

Press the Save button (▣) to save the scan result. The saved icon appears after the scan result is saved successfully.

5.14   REVIEWING THE MEASUREMENT (REVIEW SCREEN)

The Review screen will be displayed when you press the Review button (📤) on the Home screen. The Review screen shows the bladder volume, ultrasound images and other saved information with the selected measurement (saved scan result). While reviewing the measurement, the menu buttons below the display allow you to review other planes of the same measurement, review to the previous saved measurement, delete the current reviewing measurement and return to the Home screen.

The maximum storage capacity of measurement cannot exceed 50. 01/38 in the header, right side on the display shows the chronological order of saved measurements and the total number of saved measurements. For example, 3/49 is the 3rd saved measurement, and 49 measurements are totally saved.

Once the probe in sleep mode is mounted on the docking station, the probe is turned on and the lastly saved measurement will be displayed. The currently displayed screen will keep the displayed screen on after mounting on the docking station.(eg. Setup screen, Review screen)

DESCRIPTION OF BUTTON
Press the Menu buttons below the display.

Next plane menu icon (⬭) – Shifts the next plane of the measurement.
                  Press the Next plan button repeatedly to shift the next plane.

Home menu icon (🏠) - Returns to the Home screen.

Previously saved measurement menu icon (🔖) – Goes to the previously saved measurements.

Delete menu icon (🗑) – Delete the current reviewing measurement.
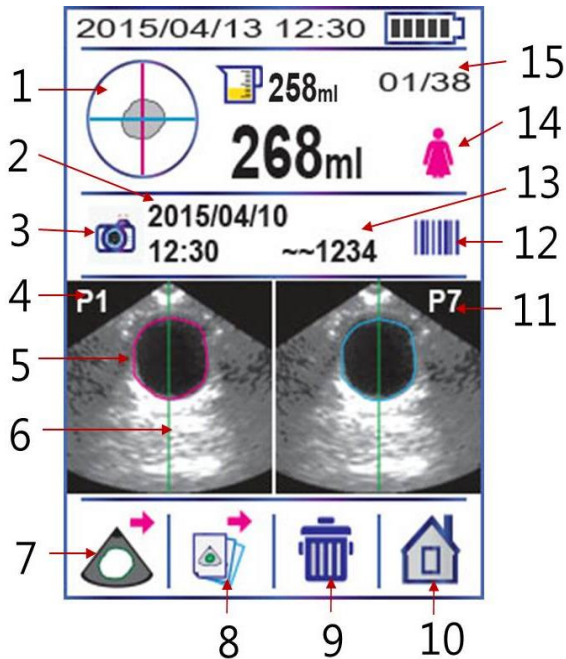
Figure 26 Review screen

No.	Description
1	Aiming information(Crosshair)
2	Date & Time
3	Capture icon shows that Captured patient information is saved
4	1st plane of 12 planes
5	Bladder outline
6	Centerline (helps detect the optimal position)
7	Next plane menu icon
8	Previously saved measurement menu icon
9	Delete menu icon
10	Home menu icon
11	7th plane of 12 planes
12	Barcode Icon shows that the barcode is saved
13	Saved barcode number
14	Patient type icon ( )
15	Chronological order of saved measurements

You can print the currently displayed measurement by pressing the print button on the docking station.

Reading a barcode and capturing the patient information are not available on the Review screen.

Transfer the saved measurement to your PC running CubePro via docking station to review the recorded barcode numbers and captures. In the Review screen only the part of the barcode will be displayed (the last four digits). The rest digits of the barcode are concealed by two tilde symbols to protect the patient information. Only you can see the saved barcode after uploading to the PC.

DELETING THE CURRENT SCAN RESULT

Press the Deletion button (🗑) and a confirm popup window (▧) will appear.

And press the Selection button (✔) to delete the scan result or press the Cancel button (✖) to cancel.
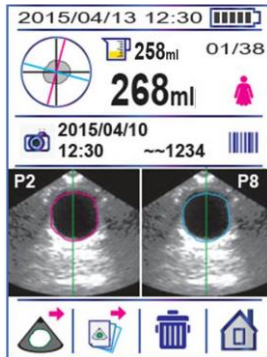
Figure 27 shifting planes
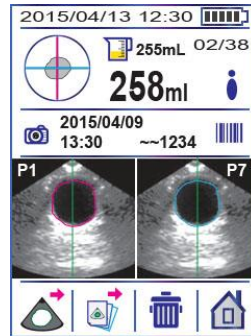
Figure 28 Previous measurement
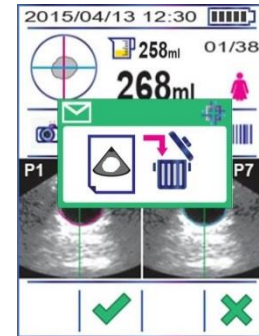
Figure 29 Popup window deleting scan result

5.15   SETUP SCREEN

Press the Setup button (⚙️) on the Home screen.

In the Setup screen the left column shows the setup menus and the right column shows the setup values.

The setup menu icon which has an outer line (eg. [Y.M.D]) is the currently focused menu.

1) Use the Move-down or up button (↓, ↑) to move to the desired menu by pressing the buttons, until the desired menu is highlighted with a green outer line.

2) To select the setup value of the desired menu, press the Selection button (✓). The green underline below the setup value will be displayed (eg. **MM-DD-YY**).

3) To adjust the setup values, use the Move-down or up button (↓, ↑) and Move-right button (➡). Press the Select button (✓) to finish adjusting the setup.

Icon	Description
Y.M.D ✎	Date format (YY-MM-DD, DD-MM-YY,MM-DD-YY)
Y.M.D	Date
🕐	Time (format : 24-hour)
🔆	Display brightness (0 to 100%, default= 50%))

🖨️	Print report format ⬛² Raw Images : Print grayscale B-mode images (2 planes) ⬛² Walls : Bladder outline only (2 planes) ⬛₁₂ All planes :　All 12 planes with B-mode images ⬛ Volume only
⏰	Sleep mode (0.5min,1min,2min,3min,5min,off)
🔺	Pre-Scan On(💡) / Off(💡)
▮▮▮	Barcode reader On(💡) / Off(💡)
📷	Capture On(💡) / Off(💡)
🗑️	Delete all saved measurement.
«Ⓢ»	Self-test : Perform (▶) & the latest calibration date on the right
«Ⓟ»	Phantom calibration : Perform (▶) & the latest calibration date on the right
⬇️	Move to next Setup Menu or show next setup value.
⬆️	Move to previous Setup Menu or show previous setup value.

→	Move to the next setup item.
✓	Select the menu, select the setup value or perform the action.
⌂	Home menu icon
✗	Cancel icon – cancel the current function.
←	Exit icon – Exit from current setup and return to the previous setup.
▶	Play icon - Perform the action.
■	Stop icon – Stop the action.
💡	Turn-on icon
💡	Turn-off icon

5.16   ADJUSTING THE DATE FORMAT

Date format: YY/MM/DD, MM/DD/YY, DD/MM/YY

1) Press the Setup button ( ) on the Home screen to open the Setup screen. Press the Home button ( ) to return to the Home screen, if you want.

2) Press the Selection button ( ) to select the Date format menu ( ) with a green outline.
3) A green underline will appear.

4) Use the Move-down or up button (,) to adjust the date format.

5) Press the Selection button ( ) again to adjust the date format. Or return to the previous date format by

pressing the exit button ( ) to return to the previous setup.
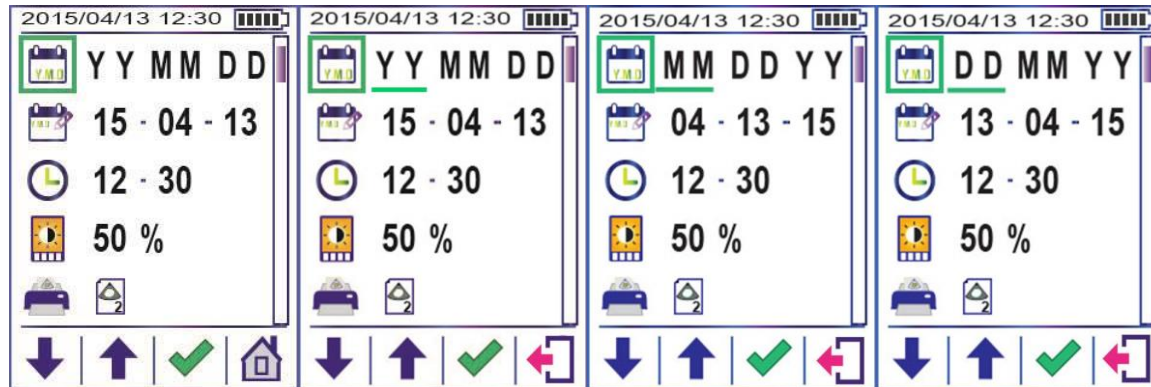
Figure 30 Date format setup

5.17   ADJUSTING THE DATE

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (⌂)
   to return to the Home screen, if you want.

2) Use the Move-down button (⬇) and select the Date menu (📅) by pressing the Selection button (✔).
3) A green underline will appear.

4) Use the Move-down (⬇), Move-up button (⬆) and Move-right button (➡) to adjust the date.
5) Press the Selection button (✔) to finish adjusting the date.
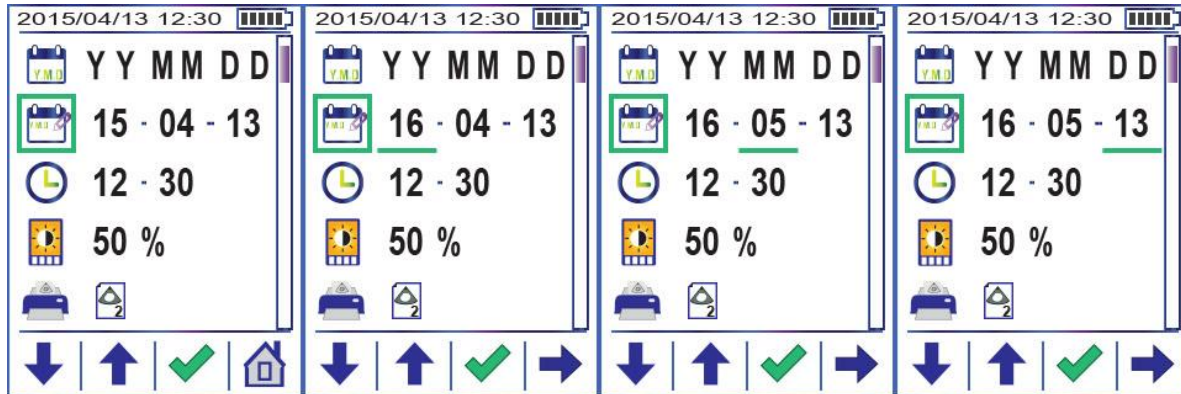
Figure 31   Date setup

5.18   ADJUSTING THE TIME

A 24-hour clock provided only.

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (⌂) to return to the Home screen, if you want.

2) Use the Move-down button (↓) and select the Time menu (🕐) with by pressing the Selection button (✔).

3) A green underline will appear.

4) Use the Move-down (↓), Move-up button (↑) and Move-right button (→) to adjust the time.

5) Press the Selection button (✔) to finish adjusting the time.
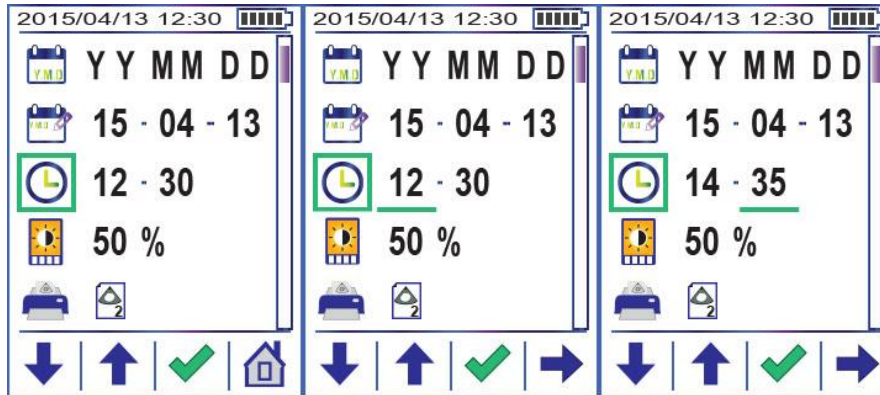
Figure 32 Time setup

53

5.19 DISPLAY BRIGHTNESS
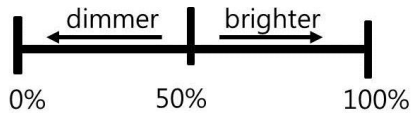
dimmer | brighter

0%   50%   100%

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (⌂) to return to the Home screen, if you want.

2) Use the Move-down button (⬇) and select the Brightness menu (▣) by pressing the Selection button (✔).

3) A green underline will appear.

4) Use the Move-down and up button (⬇,⬆) to adjust the brightness. Or press the Exit button (◀) to return to the previous setup.

5) Press the Selection button (✔) to finish adjusting the brightness
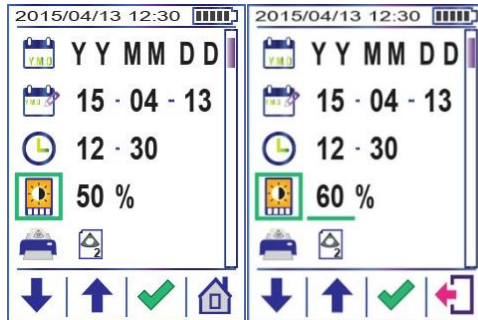
Figure 33 Brightness setup

5.20   PRINT REPORT FORMAT

There are 4 print report formats of bladder on the printout.

⬚ Raw Images : Print grayscale B-mode images (2 planes) : default

⬚ Walls : Bladder outline only (2 planes)

⬚ All planes : All 12 planes with B-mode images

⬚ Volume only

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (🏠) to return to the Home screen, if you want.

2) Use the Move-down button (⬇) and select the Print report format menu (🖨) by pressing the Selection button (✔).

3) The green underline will appear.

4) Use the Move-down and up button (⬇,⬆) to adjust the print report format. Or press the Exit button (⬅) to exit.

5) Press the Selection button (✔) to finish adjusting the print report format.
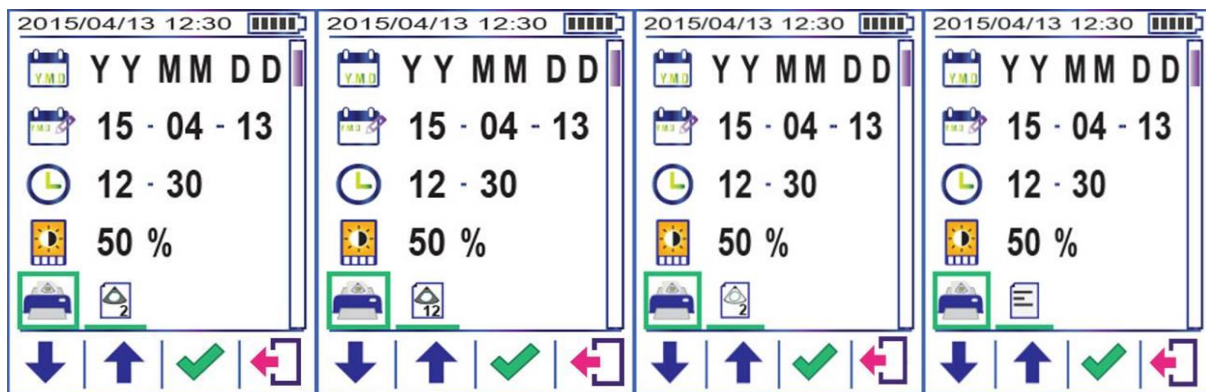
Figure 34 Print report format setup

5.21   PRE-SCAN SETTING

See "**Pre-Scan screen**". Refer to the figures below when you turn the Pre-Scan off.
And you can turn the Pre-Scan on in reverse order.

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (⌂)
   to return to the Home screen, if you want.
2) Use the Move-down button (⬇) and select the Pre-Scan menu (△) by pressing the Selection button
   (✔).
3) A green underline will appear.
4) Use the Move-down and up button (⬇,⬆) to turn the Pre-Scan on(💡)or off(💡) or Press the Exit button
   (⬅) to return to the previous setup.
5) Press the Selection button (✔) to finish setting the Pre-Scan.
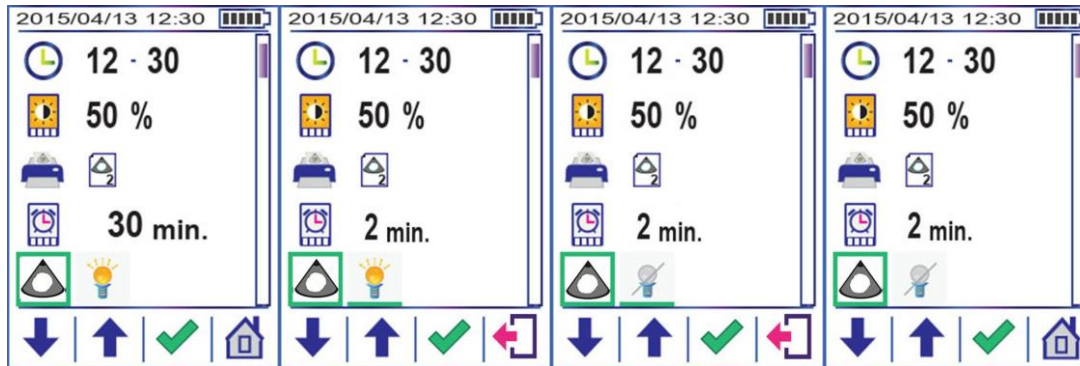
Figure 35 Pre-Scan On/Off setting

5.22   BARCODE READER SETTING

See "**READING A BARCODE AND CAPTURING THE PATIENT INFORMATION**".

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (⌂) to return to the Home screen, if you want.
2) Use the Move-down button (⬇) and select the Barcode menu (‖‖‖‖) by pressing the Selection button (✔).
3) A green underline will appear.
4) Use the Move-down and up button (⬇, ⬆) to turn the Barcode on (💡) or off (💡).
5) Press the Selection button (✔) to finish setting the Barcode.
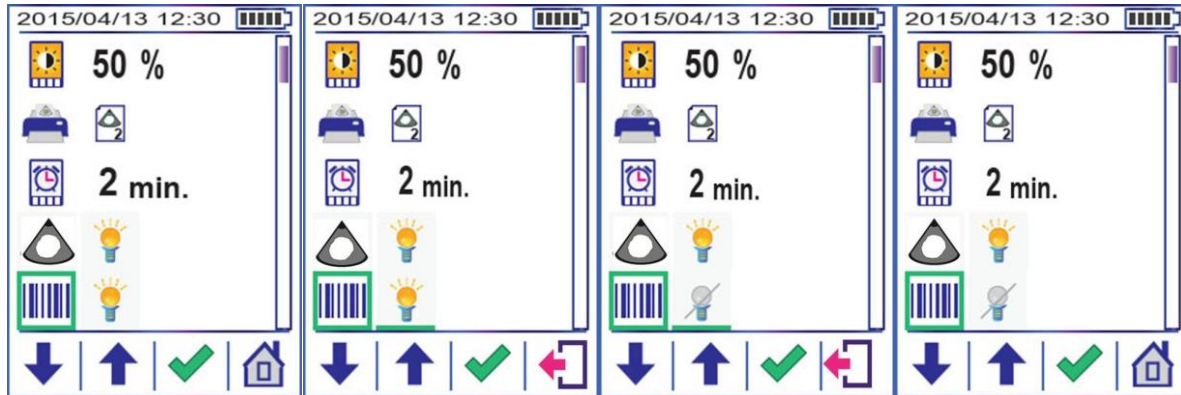
Figure 36 Barcode setting

5.23   CAPTURE SETTING

See "**READING A BARCODE AND CAPTURING THE PATIENT INFORMATION**".

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Press the Home button (⌂) to return to the Home screen, if you want.

2) Use the Move-down button (⬇) and select the Capture menu (📷) by pressing the Selection button (✔).

3) A green underline will appear.

4) Use the Move-down and up button (⬇,⬆) to turn the Capture on (💡) or off (💡).

5) Press the Selection button (✔) to finish setting the Capture.
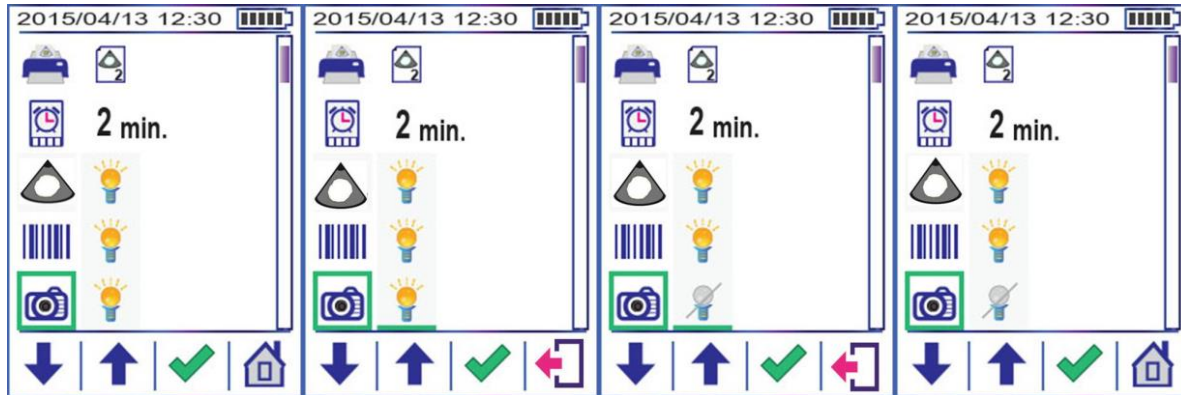
Figure 37 Capture setting

5.24　DELETING ALL SAVED MEASUREMENTS

1) Press the Setup button ( ) on the Home screen to open the Setup screen. Press the Home button ( )
   to return to the Home screen, if you want.

2) Use the Move-down button ( ) and select the Delete menu ( ) by pressing the Selection button ( ).

3) A green underline will appear.

4) Use the Move-down and up button (,) and select the Selection menu ( ) or Cancel menu ( ).

5) Press the Selection button ( ) to delete all saved measurements.

6) And a popup window ( ) to confirm will appear before deletion.

7) Press the Selection button ( ) to delete or press the Cancel button ( ) to cancel.

8) See the Home screen whether all saved measurements were deleted.
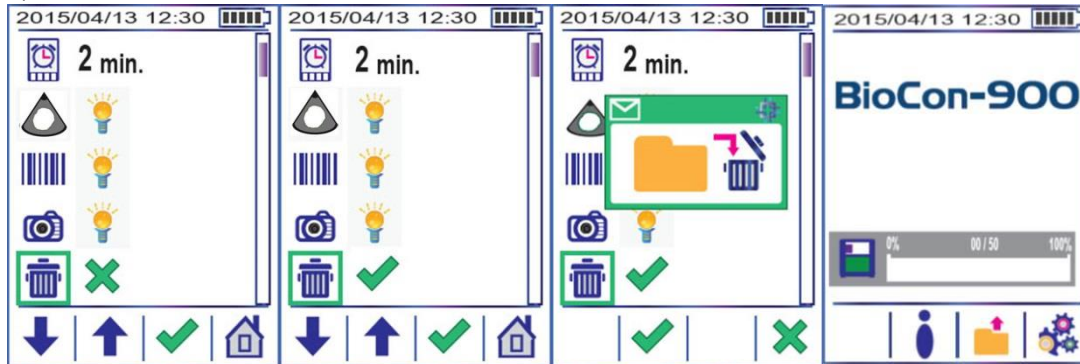
Figure 38 Deleting all saved measurements

5.25 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, a popup window will appear and need to be recharged.
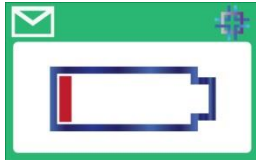
Figure 39 Popup window
- Needs to be recharged

- To conserve battery power, the probe goes into sleep mode by shutting itself down automatically when not in use. You can adjust the time to go into sleep mode in the setup. See "SLEEP MODE".
- It takes approximately 6 hours for the discharged battery to fully charge.
- Fully charged battery can provide approximately 1,500 normal scans.
- Contact your local distributor when the fully charged battery does not allow normal scan for 10min.

5.26   SLEEP MODE

Simply the probe can go into sleep mode by pressing the power button (⏻) for 2~3 seconds, when a measurement is finished.

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. However, if a battery needs to be recharged immediately, a popup window will appear shortly and goes into sleep mode. We strongly recommend that you should recharge the battery immediately. See "Charging Battery"

Press the power button (⏻) shortly to wake the probe from sleep mode.
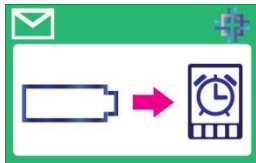
Figure 40 Popup window
- Goes into sleep mode

A time setting to go into sleep mode: 0.5min, 1min, 2min, 3min, 5min and Off (💡)

1) Press the Setup button (⚙) on the Home screen to open the Setup screen. Or press the Home button (🏠) to return to the Home screen.

2) Use the Move-down button (⬇) and select the Sleep mode menu (⏰) by pressing the Selection button (✔).

3) A green underline will appear.

4) Use the Move-down and up button (⬇,⬆) to adjust the time to go to sleep mode. Or Press the Exit button (⬅) to return to the previous setup. You can select the Sleep mode-off (💡), if you want.

5) Press the Selection button (✔) to finish adjusting the time to go into sleep mode.
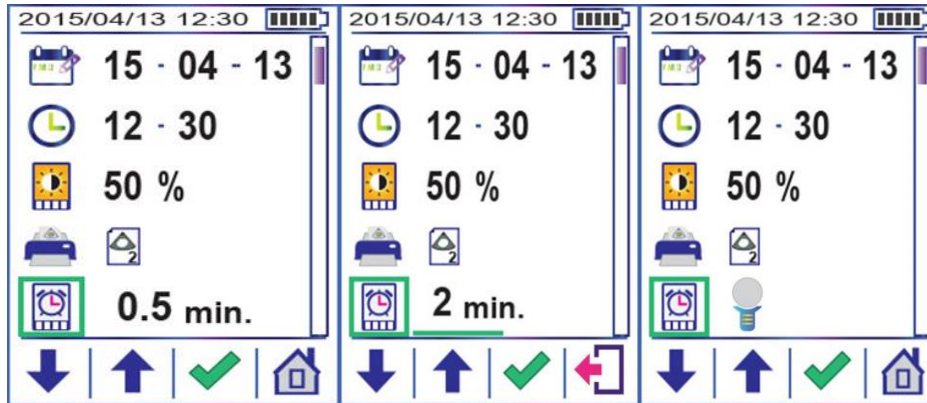
Figure 41 Time setting of Sleep mode

5.27   SHUTDOWN MODE

Shutdown mode - The probe draws little power when it is gone into sleep mode. To preserve battery power, the probe will be shut down 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.

1) First press the power button (⏻, 2). And then press the scan button (1) in a second, while keeping the power button (⏻) pressed.
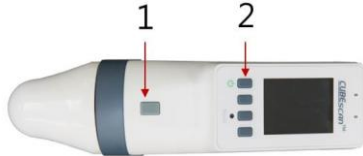
2) A popup window will appear.
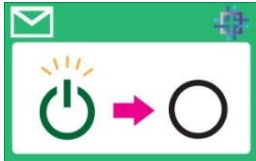
Figure 42 Popup window for shutdown mode

3) Select the OK menu (✔) to shut down BioCon-900 or select the Cancel menu (✖) to cancel the action.
4) Press the power button (1) shortly to turn the probe on.

5.28   DATA STORAGE

The data storage of measurements appears on the Home screen.
N/50 -> N: Number of currently saved measurement / 50: Maximum number of saved measurements
The blue bar increases as the number of saved measurement increases.
And the blue bar will be changed to red, when the number of saved measurement exceeds 45.
When the memory is full, a user saves a new measurement, the oldest measurement is automatically deleted.
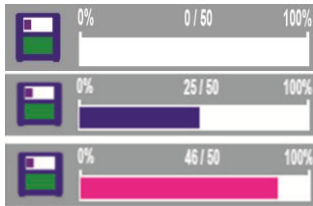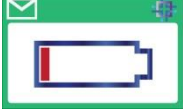
Figure 43 Data storage on Home screen

5.29   POPUP WINDOWS

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 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

5.30   UPLOADING SCAN RESULT

To upload saved scan results after measurements,
1) Turn on the docking station and check the Ready indicator is on in the docking station.
2) Confirm that the docking Station and the PC is connected via USB cable.
3) If probe is in shutdown mode, turn the Probe on and go to the Review screen. And mount the probe on the docking Station properly.
4) If probe is on, go to the Review screen. And mount the probe on the docking Station properly.
5) If probe is in sleep mode, mount the probe on the docking Station properly. When the probe is mounted on the docking station, the probe wakes up from sleep mode and will display the Review screen with the last saved measurement.
6) Now the probe is ready to transfer the saved data to the PC.
7) For next steps, see "SOFTWARE(CubePro)".

● Make sure that the green Ready indicator (1) is on. If the Ready indicator does not light on, contact Mcube Technology or your local distributor.

Figure 44 Probe mounting for uploading scan results

5.31 RESET THE PROBE AND DOCKING STATION

A reset clears any pending state in the system, in a controlled manner.

Figure 45 Resetting system

When the system is in abnormal conditions (frozen system, burning smell, etc.), press the reset button with a pen or stylus. And then press the power button to turn on the probe and/or docking Station again.

6 SOFTWARE (CubePro)

Skip this part if you do not have or use the CubePro software.

6.1 GENERAL INFORMATION

Copyright ⓒ 2009-2015 Mcube Technology Co., Ltd. All rights reserved.

The contents of this manual are the property of Mcube Technology Co., Ltd. Any reproduction in whole or in part is strictly prohibited.

This manual correctly describes the software and its functions at the time of publishing of the CD-ROM. However, as modifications may have been carried out since the production of this manual, the device package may contain one or more addenda to the manual. This manual including any such addenda must be read, before using the software.

The following situations void any guarantee(s) and obligations of Mcube Technology:

●The software is not used according to the enclosed manuals and other accompanying documentation.

●The software is installed or modified by persons other than Mcube Technology certified service technicians

This Operator Manual covers the basics of installing CubePro software and using the upload function between the BioCon-900 and a PC.

⚠ CAUTION

● Computer connection:
When connecting the BioCon-900 to a computer, the computer must be certified to EN/IEC/CSA/UL 60950 or 60101-1 standard to maintain the device's compliance to EN/IEC/CSA/UL 60601-1-1 standard.

● Transmission of data:
When transmitting data to or from a computer, make sure that the BioCon-900, any accessories, and the computer are at least 3.8 meters or 12.5 feet away from the patient

● Disconnect the USB cable from the PC before cleaning the system.

● Do not touch PC output connectors (eg.USB, port and others) and the patient at the same time.

● Before using the system, inspect the enclosures, power cord and USB cable

6.2   INTENDED USE

This software is intended to transfer and review the data from BioCon-900. The overview of the features controlled by this software is as follows:

● Uploading of the data saved in the BioCon-900 via the Docking station.
● Review of the data uploaded from the BioCon-900 to the PC.
● Printing of the data uploaded via the local printer or network printer.
● Image printing (JPG, PDF) of the data uploaded.

6.3   INSTALLING CUBEPRO SOFTWARE

Insert the software CD into the CD-ROM drive. Double-click "Setup_CubePro_V2.0.msi" file in the CD.
And then click "Next".
Select an installation folder. If you want to change the folder, click "Browse". It is recommended to install in the default directory (folder).
And then click "Next".
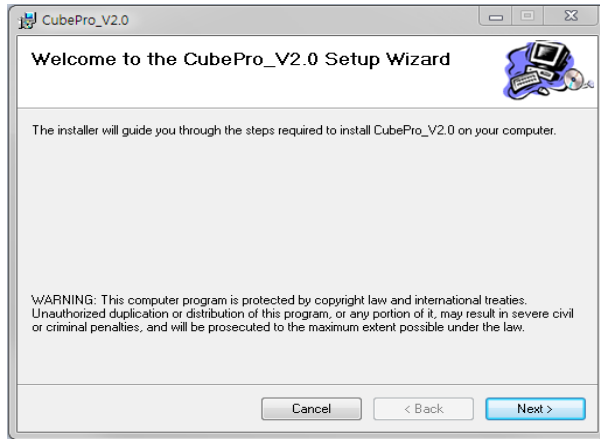
Figure 46 Initial screen for installation
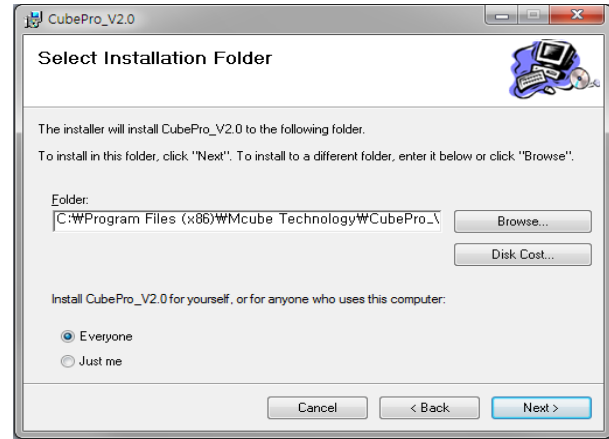
Figure 47 Selecting installation folder

Click "Next" and you will see the installing progress bar as follows:
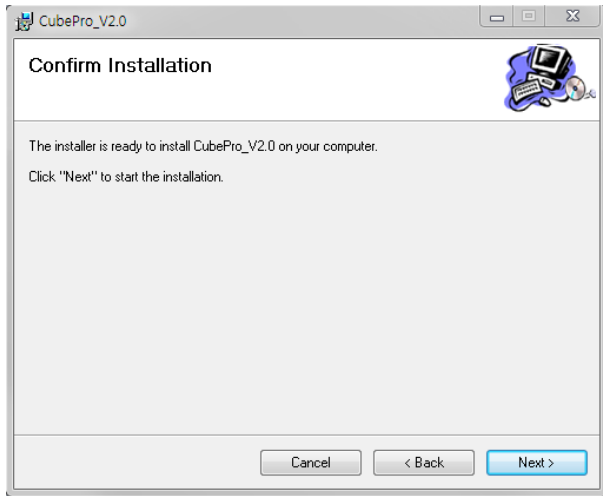
Figure 48 Confirm installation
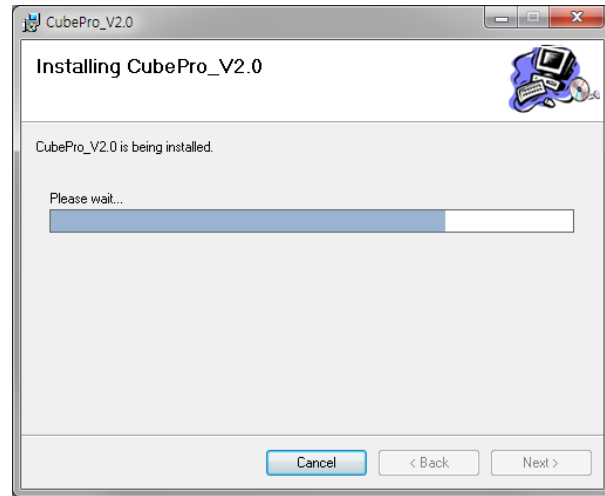
Figure 49 Installing

CubePro is installed successfully. Click "Close" to exit.
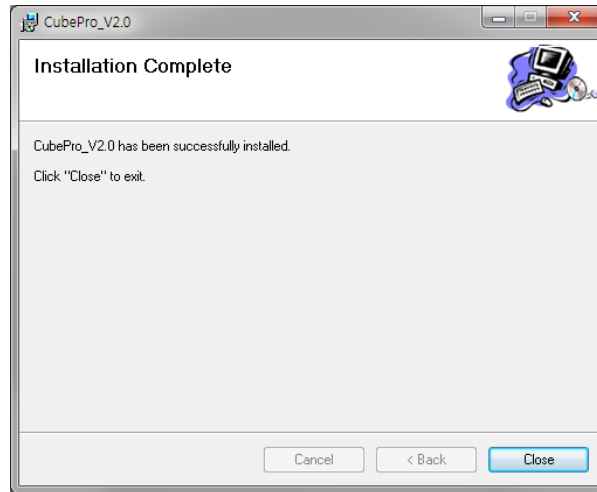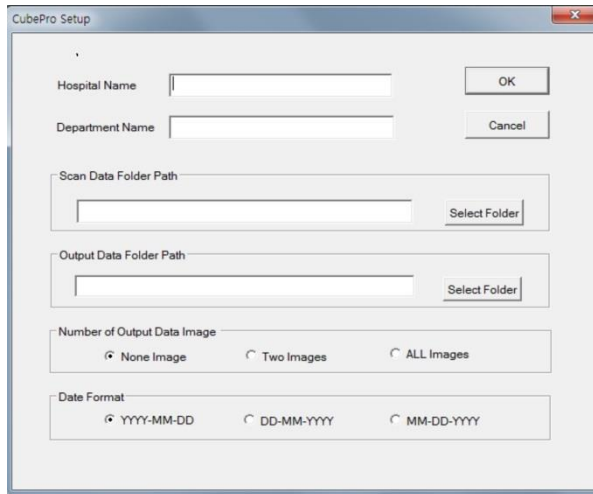
Figure 50 Installation compete

6.4   UNINSTALLING SOFTWARE

"Control panel" ➔ "Add or Remove Programs" in Control panel ➔ Remove the CubePro

6.5   SETTING UP CUBEPRO

Click from Menu bar ➔ Setup ➔ CubePro Setup

Figure 51 CubePro setup

"Hospital Name" ➔ Hospital/Clinic name

"Department Name" ➔ Department name

"Scan Data Folder Path"
➔ Select a folder to store uploaded data from BioCon-900

"Output Data Folder Path"
➔ Select a folder to store PDF or JPG output files.

"Number of Output Data Image"
➔ Select the number of ultrasound image planes on the output data.

"Date Format"
➔ Select the date format.

6.6   RUN CUBEPRO

After a successful installation CubePro icon will appear on your desktop.
Run the CubePro.exe file and the title bar shows [USB: Not Connected]
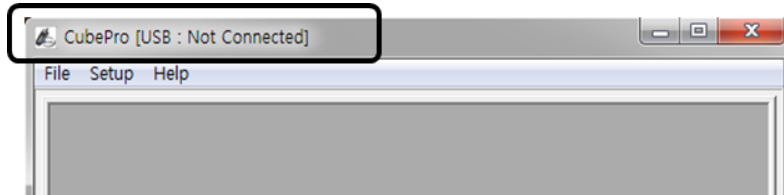
Figure 52 Running CubePro

After the docking station and your PC are connected using USB cable, the title bar shows [USB: Connected].
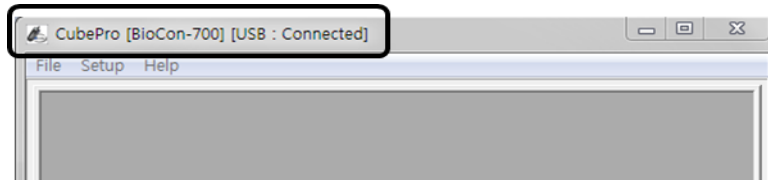
Figure 53 Title bar : USB connected

6.7   UPLOAD THE SCAN DATA

Click "file" from the menu bar.
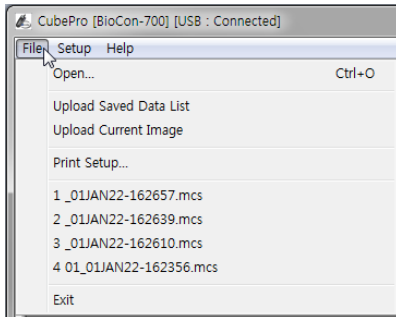
Figure 54 File from menu bar

"Open" ➔ Open the data stored in the PC.
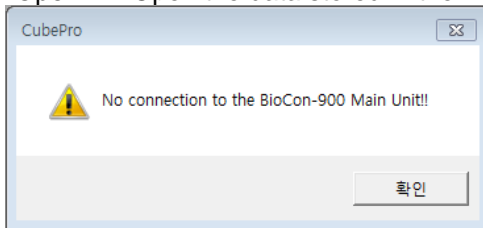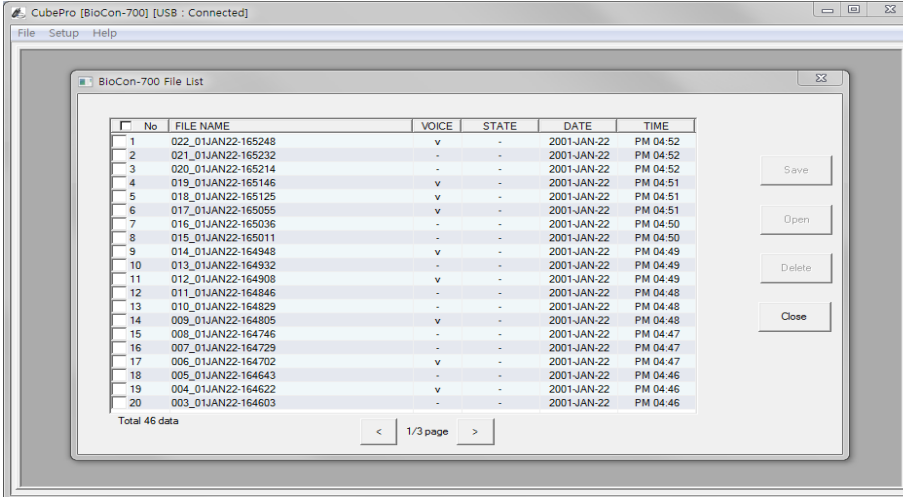
Figure 55 Popup message -" No connection"
When BioCon-900 is not mounted properly and IrDA is not working, the message will appear.

1) Upload Saved Data List

a) Connect the docking station with the PC using the USB cable.

b) Turn the probe on and press the Review button (⬆️) to go to the Review screen

c) Mount the probe on the docking station.

d) Run CubePro in your PC.

e) Check that the title bar shows [USB: Connected].

f) Click "file" from the menu bar and then click "Upload Saved Data List" from file menu.

g) The data list in the BioCon-900 is uploaded, and "BioCon-900 File List" is displayed

Figure 56 File list

Figure 57 Selecting files

- "Save", "Open" and "Delete" are not activated when No data was selected.
- "Total data" is displayed at the bottom left corner.
- Maximum 20 data is displayed in a page.
- Click "<" button to go to the previous page, or click ">" button to go to the next page.
- Maximum 40 data is uploaded from internal memory at a time.

      "File Name"   ➔   the name of data file
      "STATE"   ➔   PC uploading progress (completed: "SAVED")
      "DATE"   ➔   the date of data

"Time" ➜ the time of data

One or more selected data makes "Save", "Open" and "Delete" activate.

"Save" button ➜ Upload the data to the PC from BioCon-900 and store the uploaded data in the PC.

"Open" button ➜ Open files in the stored in the PC through "Save" function.

"Delete" ➜ Delete the data from BioCon-900.
After deletion, the data list is updated.

Click "Save" and it shows you a progress bar with percent saved.
When finished, "SAVED" is displayed.
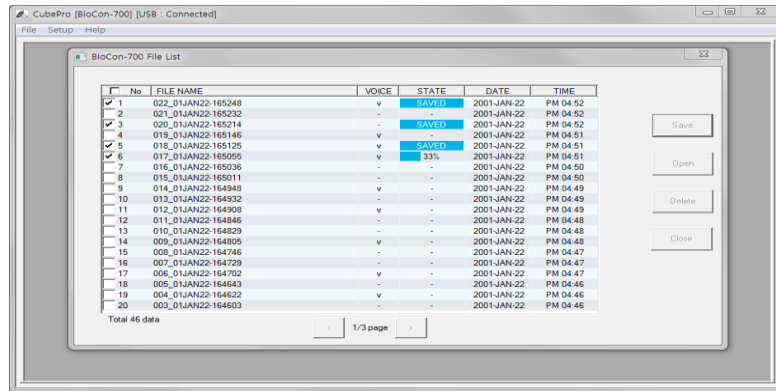
Figure 58 Uploading state

After all data selected are uploaded, "Delete" Dialog box is displayed on the screen. If you want to delete all data in the BioCon-900 which has been uploaded to the PC, click "OK" button, or if you want to keep data in the BioCon-900, click "Cancel" button.

To delete the data in the BioCon-900 without uploading, follow below steps.
- Select the data in the "BioCon-900 File List" dialog to delete by clicking the checkbox.
- Click "Delete" push button and click "OK" button in the "Delete" Dialog box.

2) Upload Current Image(data)

a) Connect the docking station with the PC using the USB cable.

b) Turn the probe on and press the review button (📤) to go to the Review screen

c) Display the data saved in the BioCon-900 to be uploaded.

d) Run CubePro in your PC

e) Check that the title bar shows [USB: Connected]

f) Click "File" from the menu bar and then click "Upload Current Image" from file menu.

g) Uploaded current data is displayed on the PC.

BioCon-900 should be "Scan Result screen" or "Review screen" to upload current data.
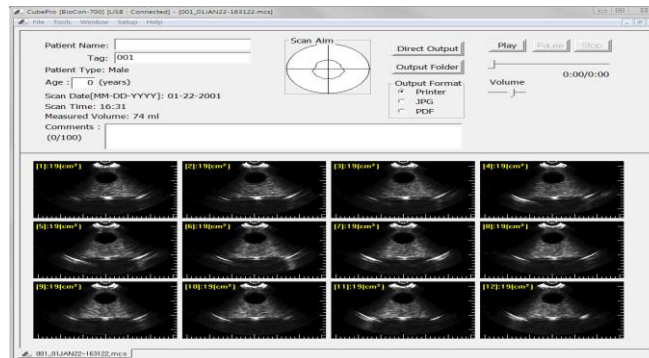
Figure 59 Screen after uploading current data

To update patient information:
Enter the new patient information (Patient name, tag, age and comments).
It is essential to enter the tag for a file name.

"Save" button is activated, if any patient information is entered. After that, click "Save" button.
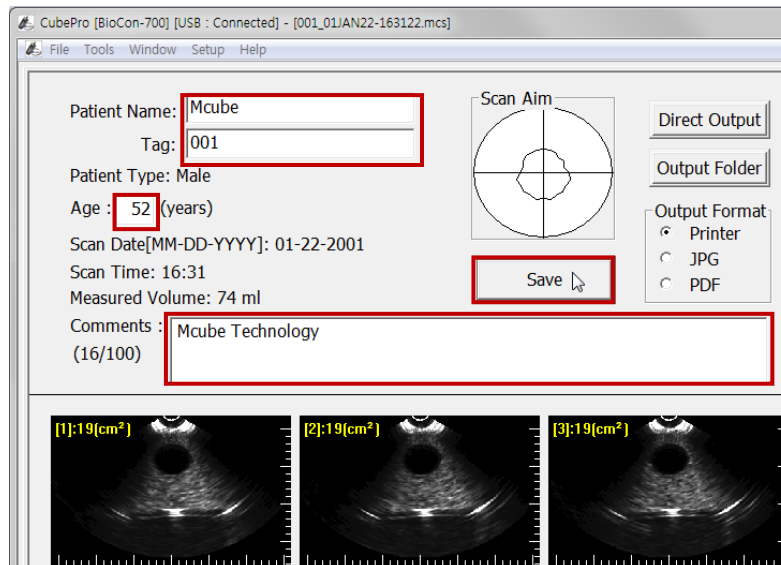
Figure 60 update patient information
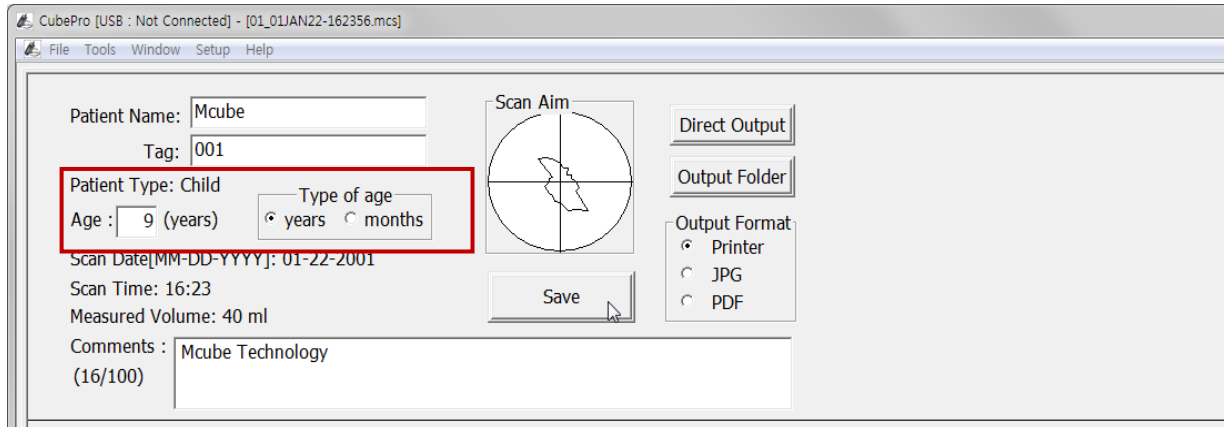
Figure 61 Modification of child age type

If the patient type is child, enter the age in years or months.
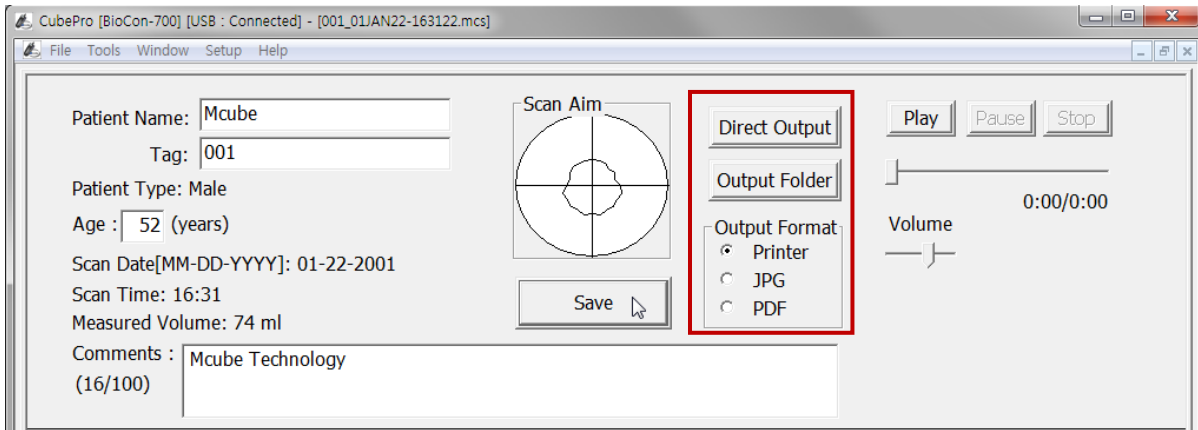
Figure 62 Control of output data

Output the data

Select the output format.
- "Printer": the data will be printed out through the network printer.
- "JPG and PDF": the data will be saved in the format.
Click the Direct Output: the data will be printed out or "Successfully, JPG (PDF) was saved" will be popped up.
Output folder is the designated folder where the PDF and JPG outputs are saved. The output folder is designated when installing CubePro.

3) Number of output images

You can set the number of image planes to be output in a setup menu: All, Two, or None.
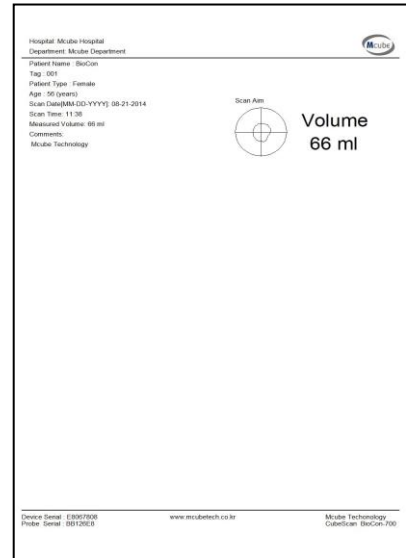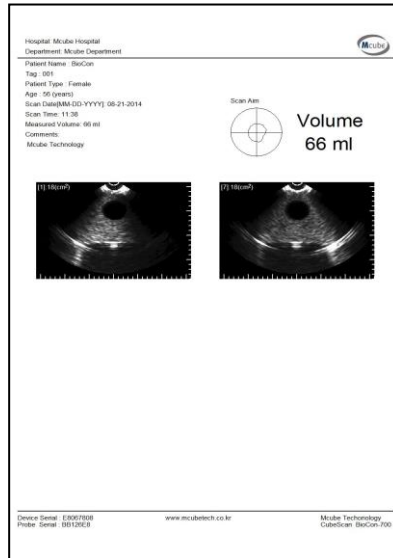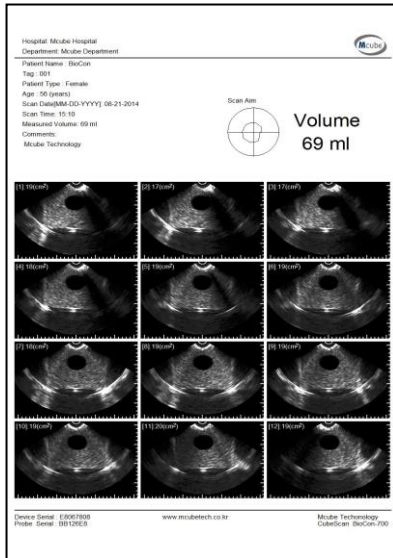
Figure 63 Output images
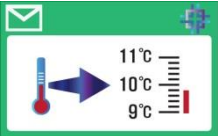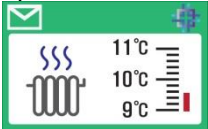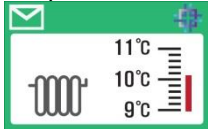
7   TROUBLESHOOTING

7.1   TROUBLESHOOTING

Error message	Description	Actions
E001	FPGA configuration error	Contact your local distributor or Mcube Technology.
E002	System information error	Contact your local distributor or Mcube Technology.
E003	Angle motor error	Contact your local distributor or Mcube Technology.
E004	Plane motor error	Contact your local distributor or Mcube Technology..
E005	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.

7.2   POPUP WINDOWS 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 popup windows appear during the progress of warming oil. When finished, press the button (✔) to return to the home screen. Warming oil lasts for 3 minutes. And then a new error code will appear, if the temperature of oil inside the probe remains below 10°C. (during warming oil) (when finished)

8 MAINTENANCE

8.1   CLEANING & DISINFECTION

⚠ CAUTION

- 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 use Cidex Plus or Metricide Plus 30 to disinfect the device. Cidex Plus or Metricide Plus 30 will damage the plastic enclosure during the disinfecting. This will be considered abused and will void the warranty.
- Do not subject the system to any method of sterilization.
- Availability of cleaning, disinfection, and sterilization products varies by country and Mcube Technology is not able to test all products in every market.
- Do not immerse the probe except the probe head, when cleaning and disinfecting.
- Do not immerse the docking station, when cleaning and disinfecting.

Cleaning
1) Cleaning outer case (housing) of the system
   a) Air dry or towel dry with a soft, clean cloth.
   b) Wipe the main body 1~2 times using soft cloth dampened with isopropyl alcohol or any other appropriate hospital cleaning solution to 1000 ppm. Do not allow liquids to leak into the device while cleaning.
   c) Dry the device completely with a clean and soft cloth before using.

2) Cleaning the probe

Since the surface of the probe affects the result of data, users should keep as follows:
a) Air dry or towel dry with a soft, clean cloth.
b) Before using the device, you have to wipe out the probe cap cleanly 4~5 times with soft cloth which was dampened with isopropyl alcohol or an appropriate hospital cleaning agent to 1000ppm. Then you can use the device after drying with a dry, clean cloth.
c) Remove the residual gel on the probe's surface after scanning finished.

Disinfection

1) Disinfection of the probe head
a) Clean the Probe prior to disinfection.
b) Dampen a soft cloth with disinfected solution listed in the table below.
c) Wipe the probe with a dampened cloth.
d) Air dry or towel dry with a soft, clean cloth.
e) Inspect the Probe for any damage such as cracks.

Disinfectants Lists for the Probe disinfection

Use any glutaraldehyde based disinfectant to disinfect the Probe. Following table lists compatible disinfectants.

Disinfection Solutions	Type	Country of Origin	Manufacturer
Cidex	Liquid	USA	Johnson & Johnson
Cidex 7	Liquid	USA	Johnson & Johnson
Metricide 14	Liquid	USA	Metrex Research Inc.
Metricide 28	Liquid	USA	Metrex Research Inc.

Chlor-Clean (max 1000ppm)	Liquid	England	Guest Medical LTD
Trigene	Wipes	England	Medichem international

⚠ CAUTION

● Do not use Cidex Plus, Metricide Plus 30, aOxivir® Tb, Oxivir® Five 16 Concentrate, Oxivir® Tb Wipes at dilution to disinfect the device. Those solutions will damage the plastic enclosure. This will be considered abused and will void the warranty.

Deep Cleaning
If either the outer case of the probe or docking station becomes contaminated with faeces, urine or blood or any other dangerous bacteria, it is advised to clean with a cleaning agent to 10000 ppm such as Chlor-Clean 4.5g Haz Tabs, following the Chlor-Clean manufacturer's dilution instructions. Following this the following must be carried out "that after surfaces have been disinfected for about 15 minutes the area should be washed off with a fresh water dampened soft, clean cloth and dried carefully afterwards". Failure to follow these instructions could lead to damage of the plastic outer casing of both the reader unit and the probe and will be considered as abuse and will void the warranty.

8.2   WEEKLY INSPECTION

a) Thoroughly inspect the probe and the docking station, if it has any cracks or leakage.
b) Inspect the power cord for any damage.
c) When scanning, check out any abnormal noise emanating from the probe head.

8.3   DISPOSAL

The device and accessories 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.

8.4   DEVICE REPAIR
.
Faults not described in section "7. Troubleshooting" are intended to be serviced by a certified technician. When any troubles unlisted in section 7 occur, contact an authorized service provider or Mcube Technology.

8.5   CALIBRATION

BioCon-900 must be calibrated every 12 months to ensure accurate measurements. Calibrating ensures accurate alignment of BioCon-900's internal system. You can take scan, even if calibration is not performed by the designated date. But measurement can be compromised.

⚠ CAUTION

● Calibrate BioCon-900 when the battery has over 60% of charge.

There are two methods for the calibration. The phantom calibration process is as follows;

Phantom Calibration

1. Place the CubeScan phantom on a flat surface. And open the cover of the phantom. 	2. Drop about 5ml water or more on the center surface of the phantom
3. Place the holder on the top of the CubeScan phantom. Check if the holder is in a stable and flat position. 	4. Put the probe head into the probe holder firmly.

5. Turn the probe on and press the Setup button (⚙) below the display on the home screen.

6. Use the Move-down button (⬇) and select phantom calibration button (⚠) by pressing the Selection button (✔).

7. Select the Action button (▶) to perform the calibration. You can cease the Phantom calibration with the Cease button (⬛)

8. The calibration progress icon and bar will appear, when the calibration is started. And the progress bar will show the calibration is progressed. It takes about 3min to complete the calibration. When the calibration is completed, 100% is displayed.

   Press the Selection button (✔) to return to the home screen and calibration date will be updated. Press the cancel button (✖) to cancel the last calibration and calibration date will not be updated.
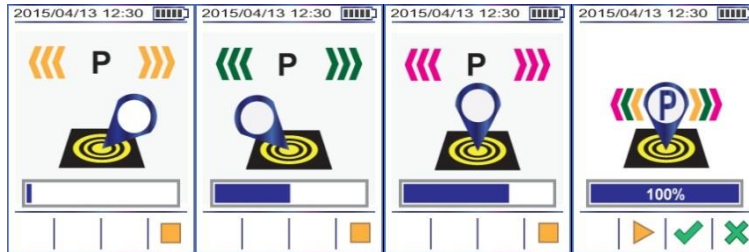
Figure 64 Phantom calibration screen

Self-test
1. Put the probe on the docking station for Self-test.
2.Turn the probe on and press the Setup button (⚙) below the display on the home screen.
3. Use the Move-down button (⬇) and select Self-test button (📶) by pressing the Selection button (✔).
4. Select the Action button (▶) to perform the calibration. You can cease the Self-test with the Cease button (🟧)
5. Self-test progress icon and bar will appear, when the calibration is started. And the progress bar will show the calibration is progressed. It takes about 3min to complete the calibration. When the calibration is completed, 100% is displayed. Press the Selection button (✔) to return to the home screen and calibration date will be updated. Press the cancel button (✖) to cancel the last calibration and calibration date will not be updated.   **Figure 65 Self-test screen**
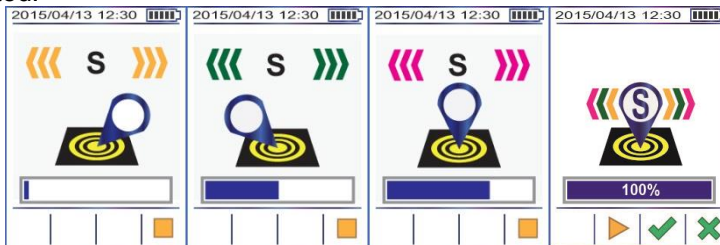
8.6   CALIBRATION REMINDER

1)   Calibration reminder popup window

Calibration reminder popup window appears on the Top screen under the conditions as follows:
- After 1 year since the last calibration

Press the Selection button (✔) to return to the home screen. And the Calibration reminder popup will disappear.

2)   Calibration reminder icon

The Calibration reminder icon (📶) will be displayed on the Home screen after the Calibration reminder popup disappears. When Phantom calibration is succeeds, the last calibration date is updated and the calibration reminder icon (📶) will disappear.

Figure 66 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-900. And 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-900 Transducer   Operating Mode: B-mode

Index Label				MI	TIS scan	TIS non-scan Aaprt 1	TIS non-scan Aaprt>1	TIB non-scan	TIC
Global Maximum Index Value:				**0.268**	**0.179**	**(a)**	**(a)**	**(b)**	**(b)**
	IEC	FDA	Units						
	p_{ra}	$p_{r.3}$	(MPa)	0.39					
	P	W_o	(mW)		-1.299	#		#	#
	min of [P z_s $I_{ta,\alpha}$ z_s]		[$W_{.3}(z_1), I_{TA.3}(z_1)$]				#		
Associated Acoustic Parameter	z_s	z_1	(cm)				#		
	z_{bp}	z_{bp}	(cm)				#		
	z_b	z_{sp}	(cm)					#	
	z at max. I_{pi},	z_{sp}	(cm)						
	$d_{eq}(z_b)$	$deq(z_{sp})$	(cm)					#	
	f_{awf}	f_c	(MHz)	2.08	2.08	#	#	#	#

	Dim of Aaprt	X	(cm)		4.991	#	#	#	#
		Y	(cm)		4.271	#	#	#	#
Other Information	t_d	PD	(µsec)	1.23					
	prr	PRF	(Hz)	320					
	p_r at max. I_{pi}	p_r@PII$_{max}$	(MPa)	2.70					
	d_{eq} at max. I_{pi}	d_{eq}@PII$_{max}$	(cm)					#	
	Focal Length	FL$_X$	(cm)		6	#	#		#
		FL$_Y$	(cm)		6	#	#		#
	I_{pa}, at max. MI	$I_{PA.3}$@MI$_{max}$	(W/cm^2)						
Operating Control Conditions	Frequency			2 and 3.4					
	…								

Notes:
(a) This index is not required for this operating mode; see section 4.1.3.1 of NEMA Standard UD-3.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for an alternate formulation in this mode.
\#   No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Measurement Precision and Uncertainty

All entries in the below table have been obtained at the same operating conditions that produce the maximum index value. The measurement precision and uncertainty values are determined by repeated

measurements.

Parameter	Precision (% of standard deviation)	Uncertainty (95%)
$p_{r.3}$	6.0%	+/- 24%
W_o	8.2%	+/- 32%
f_c	5.2%	+/- 15%

9.2 DEFINITIONS AND SYMBOLS

MI	the Mechanical Index
TIS_{scan}	the Soft Tissue Thermal Index in an auto-scanning mode
$TIS_{non\text{-}scan}$	the Soft Tissue Thermal Index in a non-auto-scanning mode.
TIB	the Bone Thermal Index.
TIC	the Cranial Thermal Index.
A_{aprt}	the area of the active aperture (square centimeters).
$p_{r.3}$	the derated peak rarefractional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals)
W_o	For TIB and TIC: time average acoustic power at the source, in milliwatts. (Also see the definitions for W_{01} and W_{01x1} that follow.) For TIS scan, $W_o = W_{o1} + W_{o1x1}$ For TIS non–scan, $W_o = W_{o1x1}$ $W_{o1:}$ For scanning modes and/or scanning components of combinational modes: time average acoustic power at the source, per cm, in milliwatts. This is the acoustic power emitted from the central 1–cm length, in the scan direction, of the aperture corresponding to the scanned pulses.

	W_{o1x1}: For non–scanning modes and/or non–scanning components of combinational modes: time average acoustic power at the source, per cm^2, in milliwatts. This is the acoustic power emitted from the central 1 cm^2 of the active non–scanned aperture through which the highest acoustic power is being transmitted.
$W_{.3}(z_1)$	the derated ultrasonic power at axial distance z_1 (milliwatts).
$I_{TA.3}(z_1)$	the derated spatial-peak, temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z_1	the axial distance corresponding to the location of max[min($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where $z = z_{bp}$ (centimeters).
z_{bp}	$1.69\sqrt{A_{aprt}}$ (centimeters).
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured for TIB, the axial distance at which TIB is a maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters).
$d_{eq}(z)$	the equivalent beam diameter as a function of axial distance z, and is equal to $[(4/\ )(W_o/I_{TA}(z))]^{0.5}$ where $I_{TA}(z)$ is the temporal-average intensity as a function of z (centimeters).
f_c	is the center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.
Dim. of A_{aprt}	the active aperture dimensions for the azimuthal and elevational planes (centimeters).
PD	the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	the pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI (Hz).

$p_r@PII_{max}$	the peak rarefactional pressure at the point where the free field, spatial-peak pulse intensity integral is a maximum (megapascals). See Section 6.2.4.1 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".
$d_{eq}@PII_{max}$	the equivalent beam diameter at the point where the free field, spatial-peak pulse intensity integral is a maximum (centimeters). See Section 6.2.5.1 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".
FL	the focal length, or azimuthal and elevational lengths, if different (centimeters).
$I_{PA.3}@MI_{max}$	the derated pulse average intensity at the point of maximum reported MI (Watts per square centimeter).

$p\_$	MPa	The Peak Rarefactional Acoustic Pressure is the maximum of the modulus of the negative instantaneous acoustic pressure expressed as a positive number.
I_{SPTA}	mW/cm^2	The maximum value of the temporal average derived intensity in an acoustic field. For systems in combined operating mode, the time interval over which the temporal average is taken is sufficient to include any period during which scanning may not be taking place.
System settings[a]		User selectable system settings which may include Application, SV and Focal Length.
I_p	mm	This is the distance from the transducer output face to the point of maximum pulse-pressure-squared integral (or max mean square acoustic pressure for continuous pressure for CW)

w_{pb6}	(‖)	mm	This is the -6dB pulse beam width in the beam axis (X) at the point of max pulse-pressure-squared integral (or max mean square acoustic pressure for continuous pressure for CW). If the beam widths in X and Y differ than less than 10%, there is no need to specify both. For scanning modes, the beam-widths shall correspond to the central scan line only.
w_{pb6}	(_|_)	mm	This is the -6dB pulse beam width in the elevational axis (Y) at the point of max pulse-pressure-squared integral (or max mean square acoustic pressure for continuous pressure for CW). If the beam widths in X and Y differ than less than 10%, there is no need to specify both. For scanning modes, the beam-widths shall correspond to the central scan line only.
Prr		kHz	Pulse Repetition Rate is the rate of successive pulses or tone bursts and applies to single element non-scanning systems and automatic scanning systems.
Srr		Hz	Scan Repetition Rate is the rate of the same identical point of successive frames, sectors, or scans and applies to automatic scanning systems (modes) only.
Output beam dimensions[b]		mm	Output beam dimensions are the dimensions of the ultrasound beam (-6dB pulse beam width) in a specified direction normal to the beam alignment axis and at the transducer output face. In scanning modes, these shall refer to the center scan line only.
F_{awf}		MHz	The Arithmetic-mean Acoustic Working Frequency is the arithmetic mean of the frequencies f1 and f2 at which the amplitude of the spectrum of the acoustic signal first becomes 3dB lower than the peak amplitude.

APF[c]	%	Acoustic Power-up Fraction is the ratio of the peak rarefactional acoustic pressure when the system is in Power-up mode to the maximum value of the peak rarefactional acoustic pressure for any system settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum pulse-pressure-squared integral (or maximum mean square acoustic pressure for CW)
AIF[d]	%	Acoustic Power-up Fraction is the ratio of the peak rarefactional acoustic pressure when the system is in Initialization mode to the maximum value of the peak rarefactional acoustic pressure for any system settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum pulse-pressure-squared integral (or maximum mean square acoustic pressure for CW)
Maximum power[e]	mW	This is the Maximum Temporal Average power output. For scanning modes, this shall be the total power output of all the acoustic pulses.
I_{ob}	mW/cm^2	Output Beam Intensity is the temporal-average power output divided by the output beam area
Power-up mode		With the probe connected cycle power on the system. Write down the mode to which the system powers up. Usually, it is "B" mode.
Initialization mode		Write down "N/A[f] " where it denotes "system settings do not change on new patient entry"
Acoustic output freeze		Write down "YES " if the system is supplied with an output freeze facility.

l_{tt}	mm	Transducer to Transducer output face distance is the distance along the beam alignment axis between the surface containing the active face of the transducer or elements and the transducer output face (usually the lens thickness)
l_{ts}	mm	Transducer Standoff distance is the shortest distance between the transducer output face and the patient entry plane. The term "contact" is used to connate direct contact between the transducer output face and the patient.
Inclusive modes		Make a note of the Inclusive Modes for this particular declaration which are not being declared separately.

9.3 ELECTROMAGNETIC COMPATIBILITY

1) Electromagnetic emissions

<table>
<tr><th colspan="3">Guidance Manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The BioCon-900 is intended for use in the electromagnetic environment specified below. The customer or the user of the BioCon-900 should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF Emissions CISPR 11</td><td>Group 1</td><td>The BioCon-900 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</td></tr>
</table>

RF Emissions CISPR 11	Class A	The BioCon-900 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

2) Electromagnetic Immunity

Guidance Manufacturer's declaration - electromagnetic immunity			
The BioCon-900 is intended for use in the electromagnetic environment specified below. The customer or the user of the BioCon-900 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV Contact ±8kV air	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	±2kV for power supply lines ± 1kV for input/output lines	±2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Uт (>95% dip in Uт) for 0.5cycle 40% Uт (60% dip in Uт) for 5 cycles 70% Uт (30% dip in Uт) for 25 cycles <5% Uт (<95% dip in Uт) for 5 sec	<5% Uт (>95% dip in Uт) for 0.5cycle 40% Uт (60% dip in Uт) for 5 cycles 70% Uт (30% dip in Uт) for 25 cycles <5% Uт (<95% dip in Uт) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioCon-900 requires continued operation during power mains interruptions, it is recommended that the BioCon-900 ultrasound system be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Uт is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BioCon-900, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	**Recommended separation distance** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 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-900 is used exceeds the applicable RF compliance level above, the BioCon-900 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-900.   b. Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V_1]$ V/m.

3) Recommended separation distance

Recommended Separation Distances between Portable and Mobile RF communications equipment and the BioCon-900		
The BioCon-900 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BioCon-900 is can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BioCon-900 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)	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
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.

4) Components conformance to standards

EMC standards for accessory	
Accessory	Max length
docking station	3.8 m(12.5ft)

9.4 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 ℃

9.5 SPECIFICATION OF COMPONENTS

Probe	
Item	**Features**
Bladder Volume Range	0 - 999ml
*Accuracy	±15%,±15ml (0 - 999ml) (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 docking station
	**Number of scanning : approximately 1500 scans.
	   - For a new battery module fully charged.
	   - Tested under Mcube Technology's test conditions.

Display	TFT-LCD 2.4 inch Format : 240 X RGB X 320 Stripe
External Interface	IrDA
Patient ID Input	1D/2D Barcode Image capture
User Interface	- Icons - 5 buttons
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 equipment
Mode of Operation	- Continuous operation
Weight	490g with battery

docking station	
Item	Features
Use	Indoor
Input Voltage	AC 100- 240V
Input Frequency	50/60Hz
Input Current	1A/60-80VA
Output	Wireless Power Transfer Charger - BioCon-900 only
Insulation	Class I with protective earth

Thermal Printer	Built in(57mm width)
External Interface	USB 2.0 IrDA
Water Resistance	IPX0 Ordinary equipment
Mode of Operation	Continuous operation.
Weight	1190g

*Accuracy:
- According to the scanning instruction, and scanning on a Mcube Technology tissue-equivalent bladder phantom.
**Number of scanning
- For a new battery module fully charged
- Tested under Mcube Technology's test conditions

9.6　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 device 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-900 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-900 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

9.6.1　PROBE

Operating conditions

Condition	Description
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

Condition	Description
Use	Indoor
Ambient temperature range	-10 - +20℃ (+14 - +68°F) ≤ 1 Year
	-10 - +45℃ (+14 - +113°F) ≤ 3 Month
	-10 - +60℃ (+14 - +140°F) ≤ 1Month
Relative humidity	+20% - +80% non-condensing
Atmospheric pressure range	+600hPa - +1060hPa

9.6.2 DOCKING STATION

Operating conditions

Condition	Description
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

Condition	Description
Use	Indoor
Ambient temperature range	-10 - +60℃ (+14 - +140°F)
Relative humidity	+20% - +80% non-condensing
Atmospheric pressure range	+600hPa - +1060hPa

10 GLOSSARY

B-Mode	A kind of ultrasound imaging mode. Displays the brightness information corresponding to the amplitude of the signal.
Probe	The main device with the LCD display.
Contextual menu	The menu displayed in the bottom of LCD based on the system state.
Session	The process a user starts to scan on the Top screen and returns to the Top screen again.
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.
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	Get 12-plane ultrasound images and calculate the residual urine in the bladder (3D scanning).
Home screen	Appears when BioCon-900 is turned on.
Pre-Scan screen	Appears when the user presses the Scan button on the probe to locate the bladder.
Normal scan screen	Appears when the user presses the Scan button on the probe during Pre-Scan. The bladder volume is calculated during Normal scan.
Scan result screen	Appears when a Normal scan is completed. It displays calculated bladder volume, patient type and aiming info and so on.

Review screen	Appears to allow users to review the saved measurement.
Setup screen	Start screen for adjusting Date format, Date and Time, Display brightness, Print report format and sleep mode. And for turning Pre-Scan on/off, Barcode reader on/off, and Capture on/off. And for deletion of all saved measurement, and doing the Self-test, and Phantom calibration
Self-test	Displays Self-test progress and results.
Phantom-calibration	Displays phantom-calibration progress and results.

11 SYMBOL DIRECTORY

Symbol	Description
CE 0120	CE marked in accordance with the Medical Device Directive
(Type BF symbol)	Type BF patient applied part (IEC 60601-1) protection against electric shock. (B= Body, F= Floating applied part)
(Crossed-out wheelie bin symbol)	Collect separately from other household waste (See European Commission Directive 2002/96/EEC.(WEEE)) Refer to local regulations for disposal.
(Manufactured date symbol)	Manufactured date
(Manufacturer symbol)	Manufacturer
EC REP	Authorized representative in the European community

SN	Serial number
REF	Catalog(Part) number
⎓DC 9V	DC jack connector and DC input voltage
IPX3	Degree of protection against harmful ingress of water as detailed in the IEC 60529:IPX3 - Protected against spraying water
(fragile symbol)	Fragile
(up arrows symbol)	This Way Up
(no hook symbol)	Use no hook
(umbrella symbol)	Keep dry

	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Do not use blades to open
Rx only	Statement of prescription
	Caution
	Operating instructions

CLASSIFIED c UL us	Underwriters Laboratories Certification Mark MEDICAL EQUIPMENT+ (ANSI/AAMI ES60601-1 AMD 1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE, AMENDMENTS - Edition 1 - Issue Date 2012/08/20 CAN/CSA C22.2 NO. 60601-1:14 MEDICAL ELECTRICAL EQUIPMENT. PT. 1, GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - Edition 3 - Issue Date 2014/01/01)
FC	Tested to Federal Communications Commission requirements
⚠	WARNING; Laser radiation, Do not stare into beam class2, Laser product
⏻	Stand-by

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CUBEscan™
BioCon-900

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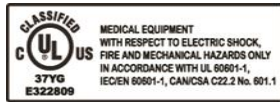#803, 123, Bonghwasan-ro,
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CE
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c UL us
37YG
E322809

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1,
IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1

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