

SonoMe

User Manual

5C, 10L, 14L, 5CB, 10LB
H5C10L, H5C, H10L

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www.sonome.com

Revision History

Revision	Date	Reason for Change
Rev.1.00	2021-08-12	Initial Release
Rev.1.01	2022-03-24	Replace of wireless charger Add of FCC warning & Logo

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Chapter 1. Introduction

SonoMe is the new generation instruments for ultrasonography with the outstanding feature of wireless. Different with traditional ultrasound system with a cable connecting from probe to main unit, no cable appears at the end of the probe of the system.

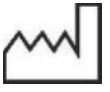
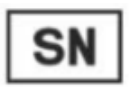
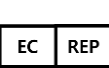
SonoMe is highly integrated with ultrasound image processing, power management and a wireless signal provider to be connected by the main units. The main units different with traditional devices are now changed to be Tablet PC or Mobile Phone which supports by iOS, Android OS System. The probe acts as a Wi-Fi Access Point and can be connected by Tablet PC or Mobile Phone. With the probe be connected through Wi-Fi and the App is running, enjoy your days of working without the troubles made by cables.

This manual is intended to provide a thorough overview of the SonoMe and should be carefully read before starting to operate the device.



[Figure 1-1] SonoMe App & Wireless Probes

1.1 Safety Symbols

Symbols	Description	Symbols	Description
	WARNING: Warnings to prevent a serious accident, or damage to property		Manufacturing date
	Follow the User Manual		Serial Number
	Type BF applied part (Classification based on degree of protection against electric hazard)		Direct Current(DC) Voltage source
	IPX1 Protected against vertically falling water drops		CAUTION: Precautions to prevent a minor accident or damage to property
	Non-ionizing electromagnetic radiation		The manufacturer's name and address are provided.
	The waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately		Recycling: Dispose of properly in accordance with all state, province, and country regulations
	This way up: For the duration of shipping/ delivery, the carton should face upright		Use no hooks: Absolutely no hand hooks should be attached to pull the parcel
	Fragile: Handle with care		Keep away from rain
	The Authorized European Representative's address is provided		Federal Communications Commission logo

1.2 Intended use

SonoMe is designed to obtain ultrasound images, measure and analyze anatomical structures and fluids

1.3 Guidelines for Safe Usage

SonoMe is indicated for examining the adult, pregnant woman, and children. This product is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices.

1.4 CONTRAINDICATIONS

- This product must not be used for ophthalmological applications, or any other use that involves the ultrasound beam passing through the eyeball.
- Do not use this product in the following situations. Doing so may produce images with inaccurate results:
 - Patients who have had surgery, which may have changed the composition of the examining tissue (for example, a mastectomy), as this could skew or alter the measured density.
 - Patients whose bodies contain foreign artifacts (for example, implants), in the examining tissue
 - Endo-cavitary use: i.e., defined as introducing a scanner within a (body) cavity or organ. E.g. atrium, esophagus, rectum or vagina

1.5 Precautions & Warnings for Use



Precautions:

- Keep this manual near the product and refer to it when using the product. Bionet is not responsible for any product issues caused by the user's careless operation or negligence in maintenance.
- The product must work in a clean environment, should avoid areas where moisture,

direct sunlight, or a heater is near the product; that are frequently exposed to vibration; that are too dusty or are not properly ventilated; or where chemicals or gases are present. Do not place anything on top of the instrument.

- The product shall be operated in undisturbed conditions to avoid data transmission interruption.
- When there is wireless channel congestion, switch the channel (Refer to Section 3.6 SETTINGS), and then restart the probe.
- Prescription Use. This product must only be used by persons who have sufficient knowledge of and/or a qualification in clinical pathology. Unqualified operators are prohibited from using the product.
- The product shall be repaired by professional recognized by Bionet.
- The product does not have shelf life. Its expected use life is 10 years. After 10 years, though the product still works normally, it is recommended to have it checked by Bionet.
- Useless components must be disposed of in compliance with local regulations.
- Be careful when holding the device, for the device is handheld, it may fall.
- The words "Insufficient Storage Space" will appear on the interface to remind the user to clean up space when storage space will be insufficient.



Warnings:

- Never use the product in the presence of flammable or anesthetic gas. Doing so may cause an explosion.
- Do not allow the interior of the product to be exposed to, or immersed in, liquid. Otherwise, fire, electric shock, injury, or damage to the product may occur.
- Changes or Modifications not expressly approved by the party responsible could void the user's authority to operate this device.
- If the product 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 product and receiver.
 - Connect the product 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.
- The device has been evaluated to meet general RF exposure requirement.
- Patients using cardiac pacemakers are guided by doctors' suggestions.
- You may lose user settings or patient information files because of physical shocks to the product or internal errors. Therefore, you should backup this information on a regular basis.

Chapter 2. Preparing for Use

FOR YOUR PROTECTION, please read safety instructions completely before turning the power on

CAUTIONS	
- Too high ultrasonic intensity and / or long exposure time may cause injury. - Please do not apply the probe of this product to the scope not covered in this manual.	

2.1 Unpacking

The product is carefully packed to prevent damage during shipment. Before unpacking, please note any visible damage to the outside of the shipping containers.

Items should be checked whether all ordered items have been received. The following table lists the items which should be received with each product.

[Table 2-1] Item List

List	H5C10L	H5C, H10L	10L,14L, 10LB, 5C, 5CB	Remarks
Probe	○	○	○	
User Manual	○	○	○	
USB Cable (1m)	○	○	○	Micro 5pin
Quick Guide	○	○	○	
Pouch	○	○	○	
Strap	-	-	○	
Wireless Charger	○	-	-	
Needle Guide	-	-	○	Only 14L

Check the item damage or defects (e.g. cracks, broken parts, liquid leaks, sharp edges, etc.). If there is any damage or defects, stop using the probe immediately and contact Bionet's Customer Service Department.

2.1.1 H5C10L



[Figure 2-1] H5C10L

#	Items	Descriptions
1	Battery Level Indicator	Indicate Battery Level
2	Wireless Signal Status	Show Wireless Signal Status
3	Convex On/Off Indicator	Indicate Convex Array's Activation Status
4	Power On/Off & Freeze	• Power ON/OFF : Press button for about 5 sec. • Freeze : Press button for about 1 sec.
5	Linear On/Off Indicator	Indicate Convex Array's Activation Status
6	USB Cable	Supply Power for Wireless Charger
7	Wireless Charger	Charging H5C10L

- Switch Probe type: Press power button for about 3 seconds
 - If Convex Array is On, #3 indicator is On.
 - If Linear Array is On, #5 indicator is On.
- Only H5C10L is available for wireless charging

2.1.2 H5C & H10L



[Figure 2-2] H5C & H10L

#	Items	Descriptions
1	Power On/Off & Freeze	- Power ON/OFF : Press button for about 5 sec. - Freeze : Press button for about 1 sec.
2	Depth Button	Control Depth
3	Gain – Button	Reduce Gain
4	Gain + Button	Increase Gain
5	Wireless Signal Status	Show Wireless Signal Status
6	Battery Level Indicator	Indicate Battery Level

2.1.3 10L, 14L, 10LB, 5C & 5CB



[Figure 2-3] 10L, 14L, 10LB, 5C & 5CB

#	Items	Descriptions
1	Power On/Off & Freeze	• Power ON/OFF : Press button for about 5 sec. • Freeze : Press button for about 1 sec.
2	Wireless Signal Status	Show Wireless Signal Status
3	Battery Level Indicator	Indicate Battery Level

2.1.4 Application for each probe

Probe	Application	
H5C10L	Convex	Abdomen, Gynecology, Obstetrics, Cardiac, Urology, Kidney, Lung
	Linear	Thyroid, Small Parts, Pediatrics, Vascular, Carotid, Breast, MSK, Nerve
H5C, 5C, 5CB	Abdomen, Gynecology, Obstetrics, Cardiac, Urology, Kidney, Lung	
H10L, 10L, 10LB, 14L	Thyroid, Small Parts, Pediatrics, Vascular, Carotid, Breast, MSK, Nerve	

2.2 How to Install App

Download the "SonoMe" app via Google Play Store or Apple App Store depending on user Tablet PC or Mobile Phone OS.

2.3 Using Probe

2.3.1 Visual Inspection

Check the probe for cracks, broken parts, liquid leaks, sharp edges, etc.

Warning
Using damaged probes may result in electric shocks and other hazards to the patients and/or users. If damaged, stop using them immediately and contact to Bionet's Customer Service Department.

2.3.2 Cleaning Probe

All probes must be cleaned and disinfected after each use. Refer to "Chapter 4.2. Cleaning and disinfection".

Warning
Probes that have not been cleaned or disinfected may cause bacterial and viral infections

2.3.3 Booting

Please check the following before scanning

1. The probe should not be abnormally heated during use. If the temperature of the probe is much higher than body temperature, or the surface temperature of the probe exceeds 40 °C, the probe is stopped

Warning
Do not use the probe which is heated abnormally to patient, as it may burn patient's skin

2. After turning on the power, check whether the functions of ultrasound image, app, button, etc. are working properly.

Warning

If there are any of the above problems, there may be a problem with the product, so please contact Bionet's Customer Service Department.

- The Indicators of Wireless Signal Status and Battery Level in the probe are not invisible till the probe is turned on.
- Press the power button for a second and turn on. After turning on, you can check the status of battery level. There are 4-Step battery level. (Refer to chapter 4 for how to charge)
- The wireless signal indicator flashes after a few seconds after turning on the probe. This lets you know that the probe is ready to connect with your tablet PC or mobile phone.
- The probe can be turned off by holding the power button down for about 5 seconds. When the probe is turned off, all indicators (wireless signal status and battery level) are turned off, too.

2.4 Wireless Connection

If the probe is ready for wireless connection as described previously, turn on Wi-Fi (if not turned on) in the settings of your tablet PC or mobile phone, and find the SSID of the probe.

The SSID is something like "SX-xxxxxxx000 (X=uppercase, x=lowercase, 0=number)".

Before connecting, check that the last 7 digits of the 11-digit ID written on the back of the probe match the last 7 digits of the SSID.

When connecting for the first time, you need to enter a password, which is a total of 11 digit ID written on the back of the probe.

After Wi-Fi is connected, launch the SonoMe app. When the app confirms the connection with the probe, the wireless signal indicator on the probe stops blinking. When the connection is complete, start to Scan.

Chapter 3. Using SonoMe

3.1 Basic Information & B Mode



[Figure 3-1] B Mode

Information:

1. Gain +: Increase the brightness of the applicable Operation mode
2. Gain -: Decrease the brightness of the applicable Operation mode
3. Depth: Adjusts the scanning depth of an image. The range varies depending on the probe in use
4. Focus: Adjusts the focus of an image
5. Dynamic: Adjusts contrast by changing the ratio of the minimum and maximum values of input signals. The higher the value, the smoother the displayed image.
6. Harmonic: Optimize image using various frequency
7. Reject: Reduces noise or echoes from an image to make the image clearer
8. Image mode
 - 8 - 1. 5CB & 10LB: B Mode Only
 - 8 - 2. 5C, 10L, 14L, H5C10L, H5C, H10L
: B Mode, B/M Mode, Color Mode, PDI Mode, PW Mode

9. Patient: Displays the Patient Information screen, which is used for selecting a patient ID from the list or entering new patient information
10. Freeze: Pauses an image being scanned or reactivates a paused image
11. Play: Play saved or stopped video
12. Measure: Starts to measure distance, circumference, area, and volume.
13. Annotation: Enter a text on the image
14. Biopsy: Draw a puncture line for puncture guidance
15. Clear: Deletes text and measurement result displayed on an image.
16. (Image) Save: Save an image
17. (Video) Save: Save a Video
18. Preset (Setting): Select Wi-Fi Channel to avoid channel blocking
19. TGC: Adjust the Gain based on the depth (When you click that area, you can find a TGC menu)

3.2 Basic Mode

3.2.1 M Mode

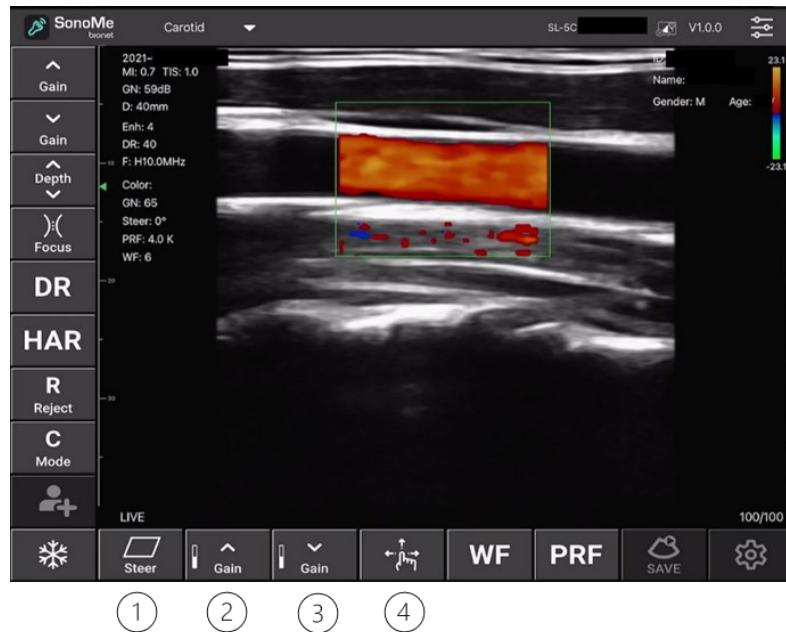


[Figure 3-2] M Mode

Information:

1. M Line: The M Line indicates the relative position of the M Mode image in the 2D image. You can move the M Line to change the observation area. Use the finger to move the M Line to the right or left.

3.2.2 Color Doppler Imaging Mode

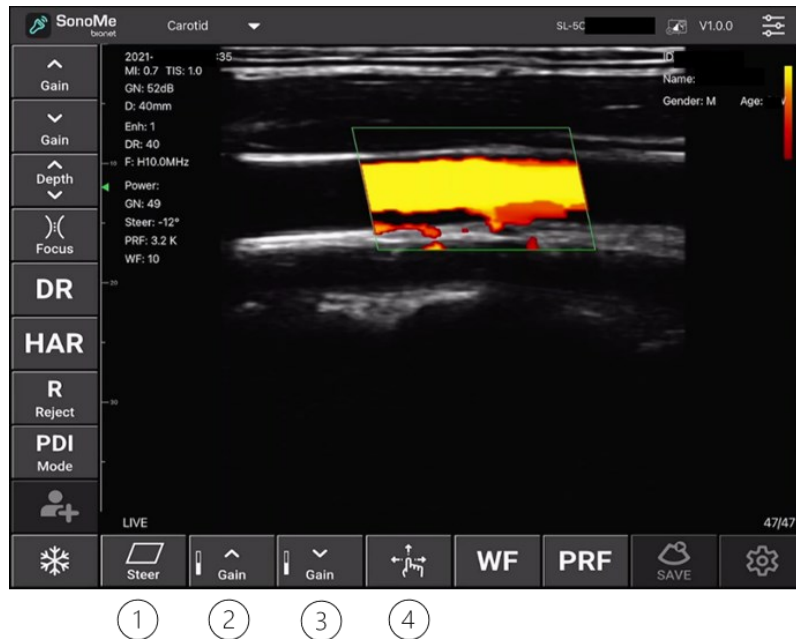


[Figure 3-3] Color Doppler Imaging Mode

Information:

1. Steer: Adjust ultrasound beam angle to minimize loss of color information
2. Gain +: Increase the color brightness
3. Gain -: Decrease the color brightness
4. Move, Zoom: Use the finger to change the location and size of ROI(Region of Interest) box

3.2.3 Power Doppler Imaging Mode

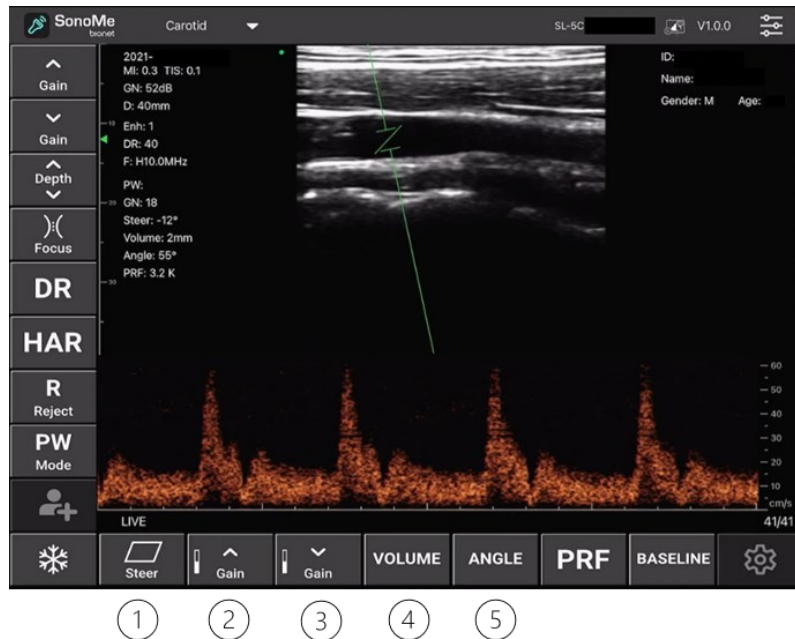


[Figure 3-4] Power Doppler Imaging Mode

Information:

1. Steer : Adjust ultrasound beam angle to minimize loss of color information
2. Gain +: Increase the color brightness
3. Gain -: Decrease the color brightness
4. Move, Zoom: Use the finger to change the location and size of ROI(Region of Interest) box

3.2.4 PW(Pulse Wave) Spectral Doppler Mode



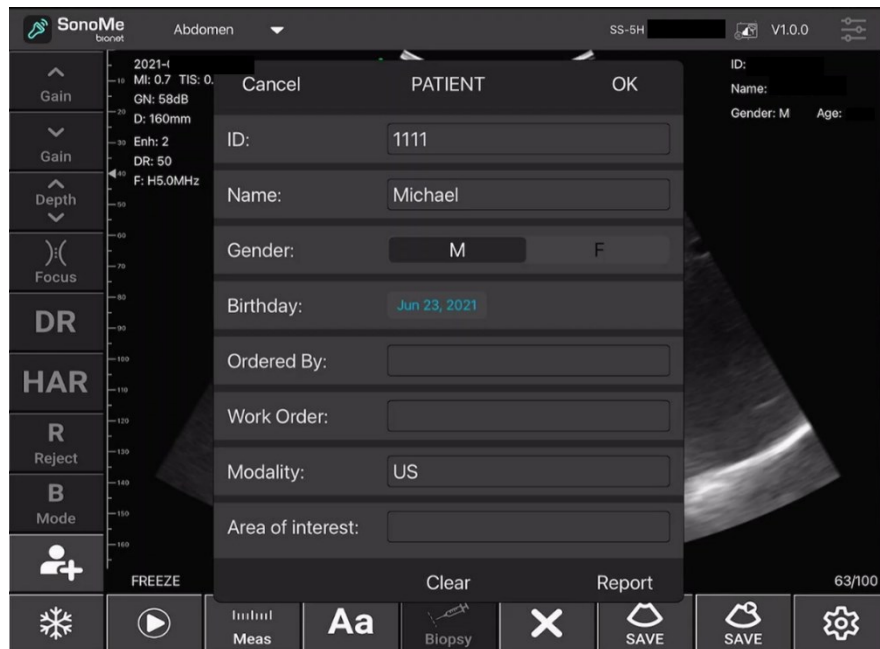
[Figure 3-5] PW Spectral Doppler Mode

Information:

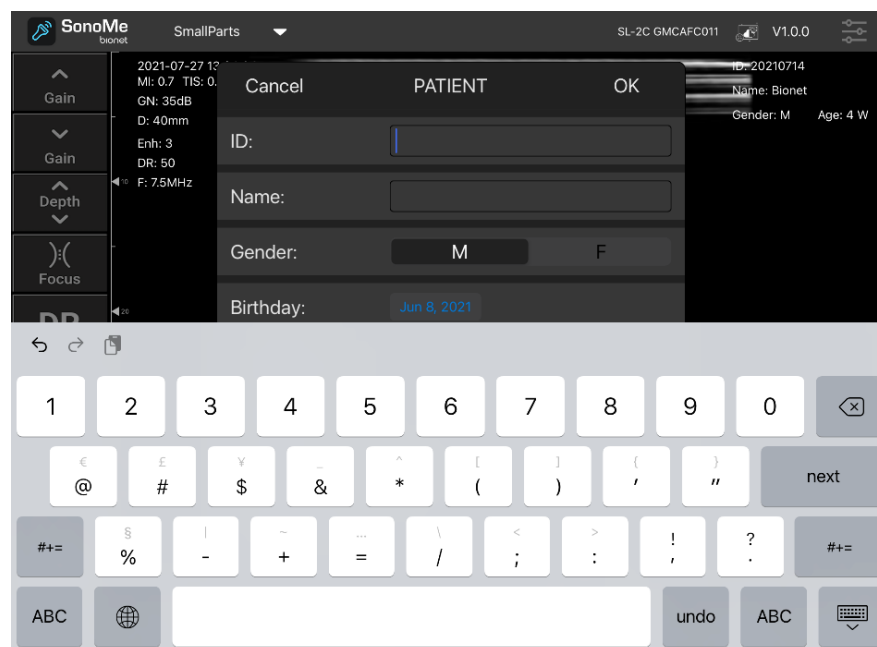
1. Steer: Changes in the direction specified in Sample Volume
2. Gain +: Increase the pulse brightness
3. Gain -: Decrease the pulse brightness
4. Volume: Adjust the size of Sample Volume
5. Angle: Adjust the angle of Sample Volume

3.3 Patient Information

When you press "PATIENT()" button, you can see a Patient Information Menu as Figure 3-6.



[Figure 3-6] Patient Information Menu



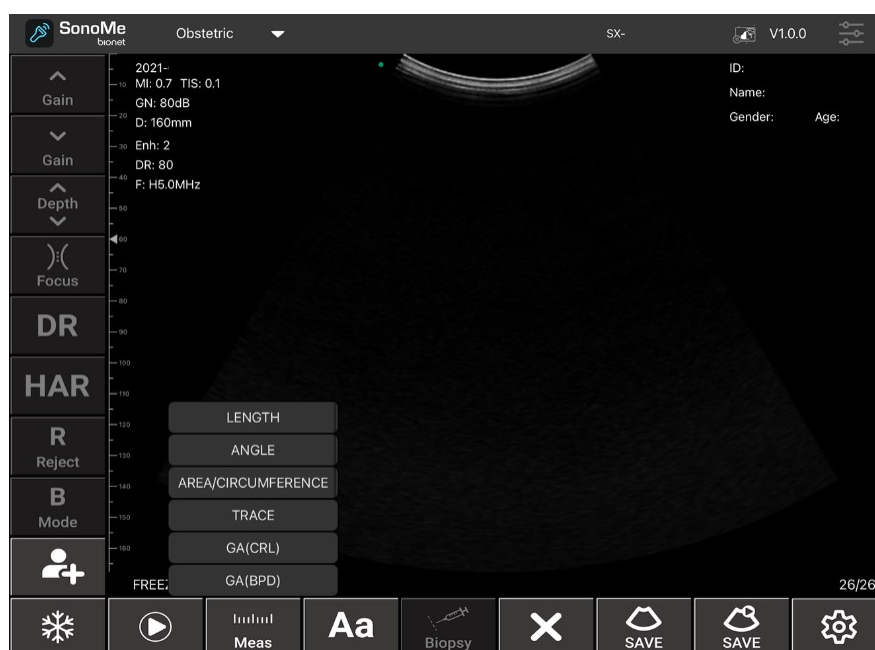
[Figure 3-7] Edit Patient Information

When you complete to enter a patient' information, Press "OK" button for save.

3.4 Measurement

3.4.1 Basic Measurement

Press "Measure" button at Freeze in B mode, you can see 10 measurement items (When scrolling, the rest of the measurements are also visible.) as Figure 3-8. The available measurement methods vary depending on the current Operation mode and Application.



[Figure 3-8] Measurement

■ LENGTH

Choose "LENGTH". Use the Finger and Set to specify both end points of the measurement area. Specify both end points and then the distance between them will be measured automatically.

If the color of both end points is green, you can move or change but if white, complete to measure and cannot move or change.



[Figure 3-9] Measure the LENGTH

■ AREA/CIRCUMFERENCE

Choose "AREA/CIRCUM". Using the Finger, Set to specify 3 points of the measurement area and then you can see elliptical trajectory. When you click the one of 3 points, you can adjust the size and location and the area and circumference will be measured automatically.

If the color of 3 points is green, you can move or change but if white, complete to measure and cannot move or change.

■ ANGLE

Choose "ANGLE". Draw a straight line at first(Please refer to "LENGTH"). Specify 3rd point and then measure the angle formed by the points automatically. When you click the one of 3 points, you can adjust the location and the area and circumference will be measured automatically.

If the color of 3 points is green, you can move or change but if white, complete to measure and cannot move or change.

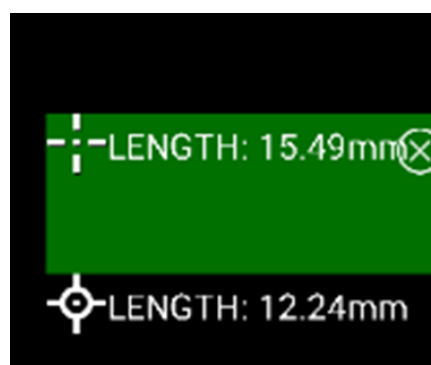
■ TRACE

Measure the area of an irregularly shaped object. Choose "TRACE". Set to specify the starting point for tracing on the contour of the area to be measured. Trace the curve so that the measurement point returns to the start point. And then you can see the area will be measured automatically

Note
Measurement for GA (CRL), GA (BPD), GA (GS), GA (FL), GA (HC), GA (AC) is ONLY available to "obstetrics" application

The above measurement functions can be fine-tuned using the on-screen virtual trackball. The virtual trackball(please refer to bottom-right corner in Figure 3-9) can be fine-tuned according to the direction of the measurement point.

Up to 4 measurements can be compared at the same time. Delete all measurements using "Clear(X)" button. When you want to delete one specific measurement, select that measurement and then you can see green column as Figure 3-10. After pressing "⊗" button, you can delete.



[Figure 3-10] Delete specific measurement

3.4.2 Heart Rate Measurement

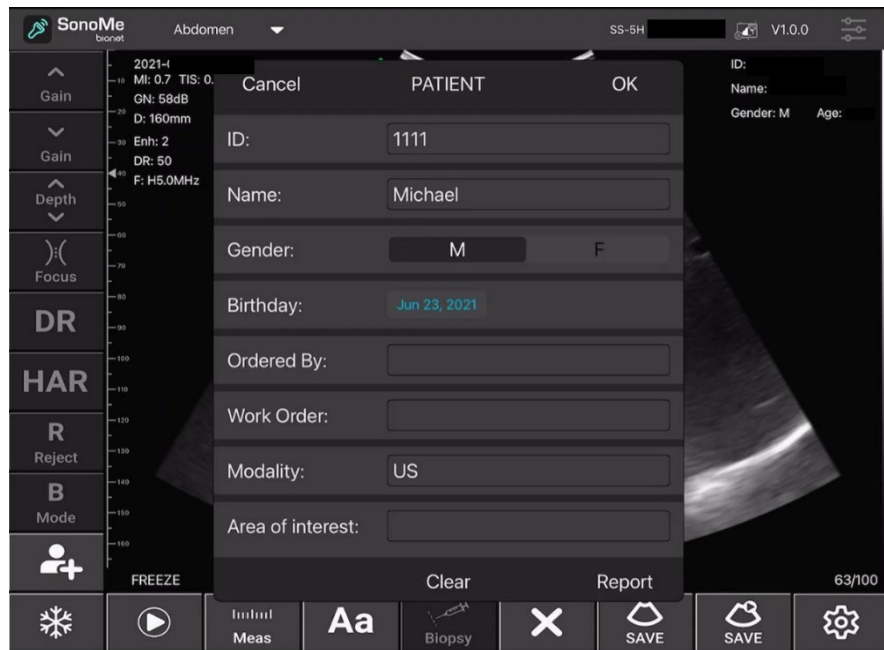


[Figure 3-11] Heart Rate Measurement

At Freeze in M Mode or PW mode, Select "Heart Rate" from the Measurement menu. A green bar appears, with which you can specify the range. To set the measurement range, use the Finger to place the bar at the desired location (In M mode, there are 3 bars, In PW mode, there are 5 bars). The system will automatically measure the heart rate within the measurement range.

3.5 Report

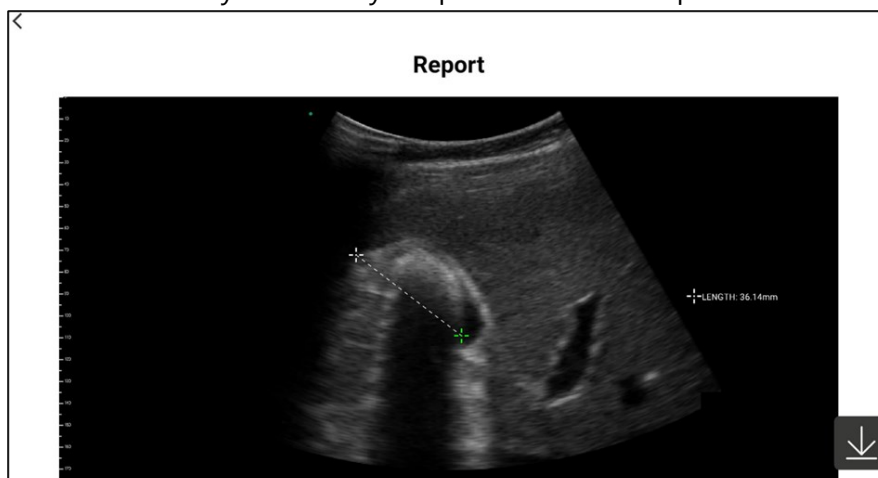
When you press "PATIENT" button, you can see a "Report" button at bottom-right in Patient Information Menu as Figure 3-12.



[Figure 3-12] Patient Information Menu

If you select "Report" at the bottom-right of the patient information, a report window appears as shown in Figure 3-13 and clicks the "Obs(Observations)" box to allow the user to input opinions or opinions. You can download the report by selecting the download icon "↓" at the bottom-right of the page.

The report is automatically saved to your phone or tablet's photo album.



[Figure 3-13] Report

3.6 Storage & Review

3.6.1 Image Storage

As shown in Figure 3-14, if you select "Save Image"  at the bottom right of the App screen, the image currently displayed on the screen is saved. The saved image is automatically saved to your phone or tablet's photo album.



[Figure 3-14] Complete to save image

3.6.2 Video Storage

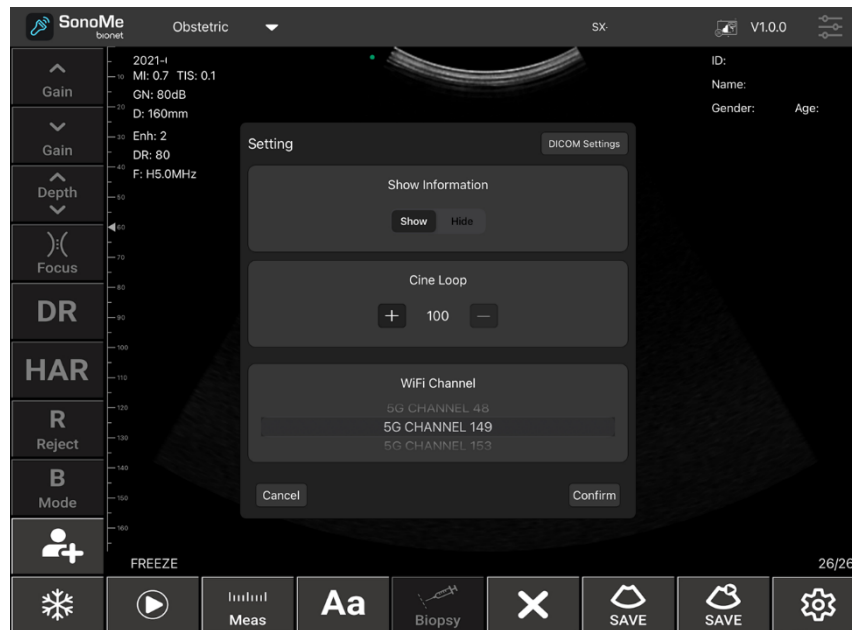
As shown in Figure 3-14, if you select "Save Video"  at the bottom-right of the App screen, the saved video is automatically saved in the photo album of your phone or tablet PC within 100 seconds.

3.6.3 Review image & Video

Open the photo album on your phone or tablet and view the saved images and videos.

3.7 Change Wi-Fi Channel

In a congested Wi-Fi environment, the user can choose a different Wi-Fi channel for the probe. Press the "Preset" () button, then select the appropriate channel selection by referring to the signal channel selection list (see Figure 3-15). Restart the probe after 2 seconds and reconnect with the mobile phone or tablet according to chapter 3.1.



[Figure 3-15] Wi-Fi Channel Setting

Chapter 4. Maintenance

4.1 Charging Probe

4.1.1 USB Charging

When the battery is low, the probe needs to be charged. Remove the rubber cover from the tip of the probe and then plug one end of the USB cable into the USB charging port in the probe as shown in Figure 4-1. The battery level indicator blinks while charging.

The battery is fully charged when both the battery level indicator and the wireless link indicator are not blinking. When charging is complete, remove the USB cable and then put the rubber cover into the USB charging port to avoid liquid and device damage.



[Figure 4-1] Probe Charging via USB Cable

4.1.2 Wireless Charging

- Plug one end of the USB cable into the wireless charging pad. Place the probe on the wireless charging pad. The probe lights up and starts charging after 1~2 seconds.
- Ensure the probe is centered on the wireless charging pad. For efficient charging, place the probe, place the probe within 7mm left and right from the center of the wireless charging pad. If it is significantly out of the range, it may be unstable or may not charge.



[Figure 4-2] Wireless Charging with wireless charging pad

Warning

It should not be used if the adapter power supply voltage is outside the adaptive range of the appliance (Normal Adapter's output voltage : $5V \pm 0.5V$).

Check the condition of power cable at first. If the power cable is damaged or broken, replace new one immediately.

4.2 Cleaning and Disinfecting Probes

All probes must be cleaned and disinfected before and after each use. Use a soft cloth or appropriate cleaning sheet, lightly dampened with Isopropyl alcohol (or proper cleaner), to remove any foreign substances left on the probe, the edges, corners, and curved parts of the probes. Dry the probe with a clean, soft cloth. Alternatively, dampen a soft cloth in a glutaraldehyde-based hospital disinfectant solution such as Cidex. Wipe the probe with a dampened cloth.

If still wet or left a stain, wipe with a clean water-dampened cloth. Before use, dry the probe completely with clean, soft cloth.

4.3 Storage

When not in use, it is recommended to put the probe in its case. During storage, the

probe must be protected from extreme operating temperatures

4.4 Troubleshooting

Inspection : Check whether connection between probe and host(smart phone or tablet) is OK or not

Error handling:

#	Symptoms	Solutions
1	No response after pressing power button	Check the status of charging and power supply
2	Wi-Fi is NOT connected between the probe and host (smart phone or tablet)	Check whether Wi-Fi signal channel is ready or not. Check whether Wi-Fi password is correct or not.
3	Displayed on the screen with noise and interference like snow	Check whether other equipment started which cause electromagnetic interference. If so, shut down the device or get far from the device.
4	The brightness of image is not enough	Adjust the brightness and gain
5	Charging is NOT work	Check whether the USB interface, circuit and electrical outlet are damaged or not.

4.5 Disposal

Warning

Do not dispose of the product carelessly.

- Battery recycling must meet local requirements.
- Waste must be disposed of in compliance with local regulations.

4.6 Maintenance & Protection

1. This product usage and storage conditions shall comply with the environmental conditions of Appendix A in this manual.
2. The product power supply shall be in accordance with Appendix A in this manual.
3. If the product is not used for a long time, charge it at least 2 times a week for at least 1 hour.
4. Do not tamper with the probe cover to clean or disassemble the components inside the probe.
5. Clean the cover with alcohol-cotton after turning off.
6. This product should not be started up and shut down too often. If you need to restart, wait at least 1 minute for booting after shutdown.
7. If any problem is happened, stop using the device and contact Bionet's Customer Service department.
8. Since the probe is vulnerable to external impact, collision or falling is prohibited.
9. If you want to pause during scanning, use the "Freeze" function. In freeze status, the device can be kept on standby for a long time.
10. Only use the appropriate ultrasound gels for medical standard.
11. The probe is waterproof but, do not immerse the probe in conductive liquid to minimize corruption.
12. Check for cracks regularly to avoid liquid immersion and damage of internal components.
13. Refer to chapter 4.2 about how to clean and disinfect.
14. To maintain the performance and safety of the system, regular electrical and mechanical safety inspections of the system must be performed by professional technicians in less than six months.
15. Excessive shocks, such as a fall, may seriously damage the product. In this case, contact Bionet's Customer Service Department for maintenance and repair.

4.7 Contact



Headquarters & International Sales & service

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Chapter 5. Biopsy (Only for 14L)

A biopsy is an examination method that surgically extracts tissue from the patient for examination. The probe and the biopsy components are used together when conducting a biopsy with the ultrasonographic image scanner.

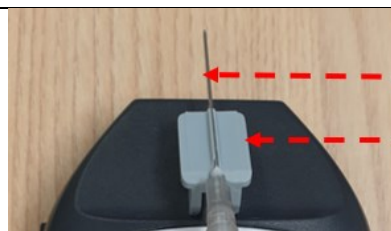
The ultrasound system shows the needle, which penetrates through the skin surface and veins, along with the examination location, minimizing the risk to the patient.

Warning

- An ultrasound examination that requires the use of a biopsy components must be performed by a physician or other certified, skilled healthcare professional. Make sure that you take preventative safety measures and ensure sterilization in all environments.
- Do not use the biopsy components for ultrasonographic studies for other purposes, such as human anatomical dissection.
- The user will be responsible for using the biopsy components for ultrasonographic studies.
- Please be sure to read the User Manual thoroughly.

5.1 Biopsy Components

The biopsy consists of the needle guide and needle.



[Figure 5-1 Biopsy Components]

- Needle Guide: Secures the needle guide to the probe tightly and guides the angle of the needle so that it may reach the biopsy target accurately.
- Needle: This is the needle that is inserted into the patient's body. The item supplied by Bionet does not contain a needle.

Warning

- Only use needle approved for use in your country.
- Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.
- The needle and guide must be sterilized before use.
- The needle may bend while penetrating tissue. Therefore, the actual location of the needle must be checked by monitoring the echo generated from the needle.

Caution

For more information about conducting ultrasonographic studies using the needle and the needle guide, contact the manufacturers. Ensure that the biopsy components you are using is compatible with only 14L.

Warning

- The needle guides not supplied by Bionet may not be compatible with the probes.
- Use Bionet-approved biopsy components only. Improper installation may adversely affect the patient.
- Be sure to read the instructions for installing and aligning the needle guide thoroughly before performing a biopsy.
- Always ensure that the probe and the needle guide are secured on both the left and the right sides.

5.2 Biopsy Procedure

The system generates a needle guideline through the displayed real-time ultrasound images to indicate the anticipated path of the needle. Use this guideline to ensure that the needle or other instrument follows the correct path.

- ① Ready the patient according to the procedure appropriate for the examination objectives.
- ② Install the needle guide.
- ③ Set the system controls for the biopsy procedure. If necessary, apply acoustic gel

to the patient.

- ④ Scan the patient. Adjust the patient so that the location for examination fits into the needle guideline on the screen.
- ⑤ Insert the needle into the needle guide. Perform the puncture by sliding the needle through the groove in the guide until the needle intercepts the target.
- ⑥ To prevent the needle from shaking, press down on the top of the needle guide with your index finger during examinations.
- ⑦ When the examination site is reached, take the needle out of the needle guide.
- ⑧ Detach the needle guide from the probe.
- ⑨ Dispose of the needle and the guide that are not designed for reuse

Caution

Dispose of non-reusable components according to infectious waste regulations

5.3 Needle Guideline Alignment

Alignment of the needle guide displayed on the system is for the purpose of verifying whether the needle and the needle guide are properly installed. This must be done prior to biopsy. If the needle fails to follow an accurate path while verifying the alignment of needle guide, stop using the product and contact Bionet.

Reverberation or other tissue artifacts may produce false needle images on the screen. Ensure that the needle path is along the guideline and that you are not using a false needle image to locate the needle.

Warning

- The needle used for alignment verification must not be used for the actual procedure. Always use a sterile needle for each biopsy procedure.
- To assist in accurate projection of the needle, use a straight, new needle for each alignment procedure.
- The needle guideline only displays the projected path of the needle. Since the default line may be different from the actual line, the actual location of the needle

must be checked by monitoring the echo from the needle.

- ① Attach the biopsy components.
- ② Set the system depth for the procedure to be performed and select the Biopsy menu.
- ③ Immerse the probe into the water bath and insert the needle into the needle guide.
- ④ Confirm that the needle image is on the needle guidelines. If it is, then the needle guide is properly aligned.
- ⑤ If the needle image displayed on the screen is outside of the needle guide lines, check the needle guide.

5.4 Biopsy Specification

Probes	Biopsy			
	Components	Reusable/ Disposable	Needle gauge	Multi Depth
14L	- Needle Guide - Needle	Disposable	21	1, 1.5, 2 (cm)

Chapter 6. Safety

To prevent damage of the equipment or injury to yourself or others, read the following safety instruction before using SonoMe.

6.1 Important Safety Considerations

Read the following safety instruction before using SonoMe.



Warnings:

- Do not use for any purpose other than the intended use. Otherwise, the system may be damaged or serious injury may result.
- This device is for diagnostic use only and is not intended for therapeutic use.

Always keep this manual with the system. Periodically review operating procedures and safety precautions.

6.1.1 Electrical Safety

- The biocompatibility has been verified so that it does not harm users or patients under normal circumstances
- Never attempt to modify the product in any way.
- The battery is a consumable and will lose performance over time. If the battery life becomes less than 2 hours, it is time for a replacement. When you want to purchase or replace a battery, please contact Customer Service Department.
- Warning: Class I The product must be connected to a power supply with a protective earth to prevent electric shock.
- Do not pour liquids on the system surface. Liquids seeping into electrical circuits can cause excessive leakage currents or system failure. If water is unavoidably poured into the system, immediately stop using the system and contact a Customer Service Department.
- Use only probes provided by the manufacturer. Otherwise, the system will not work and the worst accidents such as fire may occur.
- The system that are not maintained may not be used on patients.

- Check the probe for cracks, broken parts, liquid leaks, sharp edges, etc. If there is any damage, stop using the probe immediately and contact Customer Service Department.



Warnings:

- This product is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices.
- This system may only be maintained by persons approved or trained by Bionet.
- Always use application-specific probes in order to obtain the best quality images.
- Never use the product in the presence of flammable or anesthetic gas. Doing so may cause an explosion.
- Do not use the system simultaneously with other equipment such as electric knives, defibrillators, and other high-frequency therapy equipment. Otherwise, there is a risk of electric shock
- Keep the system dry and do not transport to sites with rapid environment changes to avoid short circuits caused by condensation or water droplets.
- The product must be connected to a power supply with a protective earth to prevent electric shock.
- After reading the manual thoroughly, set and control the acoustic power level.

6.1.2 Mechanical Safety



Warnings:

- Be careful when holding the device, for it is handheld, it may fall.
- Do not use shell cracking equipment.

6.1.3 Probe Safety Precautions

- Please only use the ultrasound gels sold legally. Always follow the instructions in the User Manual. To prevent contamination, use and take care of ultrasound gel properly.



Warnings:

- Disconnect the probe from the system after freezing the image or turning the system down. Otherwise, the system or probe may be damaged.

**Warnings:**

- Check the probe for cracks, broken parts, liquid leaks, sharp edges, etc. If there is any damage, stop using the probe immediately. Using damaged probes may result in electric shocks and other hazards to the patients and/or users.
- After disinfecting the accessory, it is necessary to flush the chemicals out of the accessory. Residual chemicals or gases left behind can not only damage the accessory but can also be harmful to human health.

6.1.4 Cyber Security

- Backup the database regularly to avoid loss or damage of the database.
- The probe can connect to Tablet PC or Smart Phone via local wireless network. The software itself cannot connect to external network. The network which is connected to the software is a local wireless network connected by the probe.
- If there are any software bugs during use, users can give feedback through Bionet e-mail account(sales@ebionet.com) and the Bionet will analyze and fix the bug, and if an update is required, the user will be notified of it by posting on the website or e-mail.

6.2 Acoustic Power Principle



Warnings:

- Guidance for the use of diagnostic ultrasound is defined by the “**As Low As Reasonably Achievable (ALARA)**” principle. By keeping ultrasound exposure as low as possible while obtaining diagnostic images, users can minimize ultrasonic bioeffects.
- The operator should notice the effect of the heat on the patient body when the exam is performed around the bones and the nearby soft tissues which can transform the ultrasound energy to heat energy. Take special care to the fetal whose bones are growing.

6.2.1 Biological Safety

Ultrasound waves may have damaging effects on cells and, therefore, may be harmful to the patient. If there is no medical benefit, minimize the exposure time and maintain the ultrasound wave output level at a low setting. Please refer to the ALARA principle.

6.2.2 Thermal Index (TI) & Mechanical Index (MI)

The system output display comprises two basic indices: a thermal index (TI) and a mechanical index (MI). These shows on the Right-Top side on the app.

- **Meaning of MI & TI**

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. However, there is no specific MI value that means that a mechanical effect will occur. The MI should be used as a guide for implementing the ALARA principle.

The TI informs the user of the potential for temperature increase occurring at the body surface, within body tissue, or at the point of focus of the ultrasound beam on bone. The TI is an estimate of the temperature increase in specific body tissues. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, and mode of operation. The TI should be used as a guide for implementing the ALARA principle. Depending on the examination and type of tissue

involved, TI could be one of three types.

- The soft tissue thermal index (TIs) : the user about the potential for heating within soft homogeneous tissue.
- The bone thermal index (TIb) : the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid, such as the skeletal structure of a 2-3 month-old fetus.
- The cranial bone thermal index (TIC) : the user about the potential heating of bone at or near the surface, for example, the cranial bone.

- **Mechanical and Thermal Indices Display Precision and Accuracy**

TI and MI values are displayed in real time on the screen. The operator should observe these index values during examinations and ensure that exposure time and output values are maintained at minimum amounts needed for effective diagnosis. The Mechanical and Thermal Indices on the system are precise to 0.1 units.

6.2.3 Acoustic Power Statement

6.2.3.1 Acoustic Measurement Precision and Uncertainty

When estimating accuracy of displayed numerical values, many factors are considered:

- The Probe Changeability
- The system changeability
- Changeability and accuracy of measurement
- Possible operating conditions and testing numbers needed to obtain displayed result accuracy of the diagnostic system
- Whether the display accuracy depends on specific system combination, mode combination, probe component and launch mode combination, or all of above
- Algorithm accuracy of the system software used to calculate the MI/TI
- Approximation engineering method used in real time computation

6.2.3.2 Differences between Actual and Displayed MI and TI

For many assumptions used in the process of measurement and calculation, they actually are conservative. For most organizations path, high estimate is made in the measurement and calculation process of tissue exposure intensity. For example, using attenuation coefficient $0.3 \text{ dBcm}^{-1} \text{ MHz}^{-1}$ much lower than the actual human tissue

attenuation coefficient, choosing conservative values of tissue characteristic.

Therefore, displayed MI and TI values should be relative information for reference, they serve to indicate to the operator whether a particular setting of the system increases or decreases the possibility of Thermal or Mechanical effect, used to help the operator be careful to use ultrasonic diagnostic system and follow the ALARA principle, these values cannot be equal to actual values.

6.2.3.3 Uncertainty of Measurement

Sound pressure is the most basic data of sound field measurement, and other sound field parameters can be deduced from sound pressure, so when analyzing measurement uncertainty, only take sound pressure for analysis and uncertainty of other parameters can be deduced from the sound pressure.

Measurement uncertainty mainly include repeated measurement uncertainty and the system uncertainty, the system uncertainty is an order of magnitude higher than repeated measurement uncertainty, so the main analysis is the system uncertainty. Mainly decided by the following factors:

- 1) The sensitivity of hydrophone: According to hydrophone calibration report provided by ONDA company, the maximum allowable error of sound pressure for hydrophone is $\pm 12\%$
- 2) Scope: according to Agilent DSO6502A specifications, its effect on the sound pressure is $\pm 2\%$
- 3) Temperature: effect of the thermocouple on sound pressure error is $\pm 4\%$

Above all uncertainty components are not related, synthetic standard uncertainty of sound pressure is $\pm 13\%$

6.2.3.4 Operator Control Property

There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA and can be divided into three categories: direct, indirect, and receiver controls

- **Direct Controls**

The direct control of the acoustic output of this system is adjusting voltage size. But its maximum acoustic output shouldn't be more than displayed acoustic output limit in any modes.

- **Indirect Controls**

The controls that indirectly affect output are many imaging parameters. These are operating modes, frequency, focal point number/position, image depth and pulse repetition frequency (PRF).

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal effect is closely connected to M Mode, PW and Color Mode.

Acoustic attenuation of tissue is directly related to transducer frequency.

The focal point number and position is related to active aperture of transducer and beam width.

For the pulse repetition frequency (PRF), the higher the PRF, the more acoustic output power increased over a period of time.

- **Receiver Controls**

The receiver control does not affect the acoustic output, including gain, dynamic range, and image processing, etc. Therefore, in the image optimization, should adjust the receiver control to optimize images firstly, the second are through direct control and indirect control.

When acquiring images, it is recommended to use the default (or as low as possible) acoustic output location and use the gain control to compensate. The default setting is commonly 70% of maximum allowed acoustic output value, which will not cause harm to the operator, and for the probe is the most effective value.

6.2.4 Acoustic Power Setting

The ultrasound system has been preset the parameters for each exam mode with different probes before shipment. When the ultrasound system is powered on, a new

patient is created or the application mode is changed, the system will retrieve the default settings. You can also reset the parameters.

6.2.5 ALARA

It is required to practice ALARA when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low-level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, the sound power which is used greater than the actual needs does not contribute to improving the quality of diagnostic information either, it will increase the risk of biological effects.

The operator must take responsibility for the safety of patients.

6.3 Electromagnetic Compatibilities

Electromagnetic compatibilities are the abilities of the system or equipment to operate normally in the electromagnetic environment and not to radiate any electromagnetic interruptions to any other objects which are in the same environment.

This system is designed in accordance with the current EMC requirement. And the ultrasound image will degrade instantly if the system is used in the electromagnetic field environment. If the degradation of the image is found, it is recommended to inspect the operation environment to confirm the radiation source.

6.3.1 Electromagnetic Emission

This product is intended for use in the electromagnetic environment specified below. Users should make sure that the product is being used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The Wireless Probe Series Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of Wireless Probe Series Ultrasound Scanner should assure that it is used in such environment.			
Type	Emission Test	Compliance	Electromagnetic environment - guidance
RF Emission	CISPR 11 EN 55011	Group1, Class A	The Ultrasound System uses RF energy for its internal functions only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission	CISPR 11 EN 55011	Group1, Class A	
Harmonic Emission	IEC 61000-3-2 EN 61000-3-2	Class A	
Flicker Emission	IEC 61000-3-3 EN 61000-3-3	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%	The Ultrasound System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

6.3.2 Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Wireless Probe Series Ultrasound Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Probe Series Ultrasound Scanner should assure that it is used in such an environment.			
Type	Immunity Test	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	IEC 61000-4-2 EN 61000-	±8 kV/Contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity

	4-2	$\pm 2, \pm 4, \pm 8, \pm 15$ kV/Air	should be at least 30%.
RF Electromag netic Immunity	IEC 61000-4-3 EN 61000-4-3	3V/m 80 MHz - 2.7GHz 80% AM at 1kHz, 2Hz	The field strength outside the shielded location from the fixed RF transmitter as determined by electromagnetic field survey should be less than 3V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 
Near Field Immunity for RF Wireless Communication Equipment	IEC 61000-4-3 EN 61000-4-3	Table #9 at IEC 60601-1-2: 2014	
Electrostatic transient burst	IEC 61000-4-4 EN 61000-4-4	± 2 kV, 100 kHz Repeated Frequency	The quality of the mains power must be that of a typical commercial or hospital environment.
Surge	IEC 61000-4-5 EN 61000-4-5	(Wire to Wire) ± 0.5 kV, ± 1 kV	The quality of the mains power must be that of a typical commercial or hospital environment.
Conducted RF	IEC 61000-4-6 EN 61000-4-6	3V 0.15 MHz - 80 MHz V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz, 2 Hz	The Ultrasound System is designed for use in electromagnetic environments where radiated RF disturbances are controlled. Customers or users of the ultrasonic scanner series can avoid electromagnetic interference by maintaining a minimum distance. It can be used between portable and mobile RF communication equipment (transmitter) and ultrasonic scanner series depending on the maximum power of the communication equipment as

			recommended below.
Power Frequency Magnetic Field Immunity	IEC 61000-4-8 EN 61000-4-8	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips	IEC 61000-4-11 EN 61000-4-11	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of atypical commercial or hospital environment. If the user of the Wireless Probe Series Ultrasound Scanner requires continued operation during power mains interruptions, it is recommended that the Wireless Probe Series Ultrasound Scanner be powered from an uninterruptible power supply or a battery.
Voltage interruptions	IEC 61000-4-11 EN 61000-4-11	0 % UT; 250/300 cycle	
[Notice] U_T is the a.c. mains voltage prior to application of the test level.			

6.3.3 Recommended Separation Distance

The SonoMe is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Wireless Probe Series Ultrasound Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SonoMe as recommended below, according to the maximum output power of the communications equipment.



Note If the system has generated the interference (confirmed by powering on and off the system), the qualified service personnel should solve the problem by following the steps as below

- Change the location of the affected system.
- Place SonoMe further away from the affected system.
- Supply power to this system in other ways other than the way used currently
- Contact Bionet's Customer Service Department ASAP

Warning

Use of this equipment adjacent to or stacked with other equipment may result in improper operation and should be avoided. If such use is required, this and other equipment should be observed to ensure normal operation.

Warning

The use of accessories, converters and cables not specified or provided by the manufacturer may increase electromagnetic emissions or decrease electromagnetic immunity of this equipment and may cause malfunction.

Caution

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). For use in a residential environment (which normally requires CISPR 11 Class B), this equipment may not provide adequate protection for radio frequency communications services. Users may need to take mitigation measures such as relocating or reorienting equipment.

Warning

- 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.

- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference 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.
- This device complies with FCC radiation exposure limits set forth for an uncontrolled environment and it also complies with Part 15 of the FCC RF Rules. This equipment must not be co-located or operating in conjunction with any other antenna or transmitter. End-users and installers must be provide with antenna installation instructions and consider removing the no-collocation statement.

Appendix A. Specification

A-1. 5C-10L-14L-5CB-10LB <Common>

Complied Standard		
EN/IEC 60601-1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance, BF, Non-continuous operation	
EN/IEC 60601-2-37:2015	Medical Electrical Equipment Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment	
EN/IEC 60601-1-2:2014	Electromagnetic Compatibility Requirement and tests, Class A	
Circumstance		
Operation	Ambient Temperature	5°C ~ +35°C
	Relative Humidity	25% ~ 80%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3000m
Storage / Shipping	Ambient Temperature	-20°C ~ +55°C
	Relative Humidity	25% ~ 93%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3000m
Safety		
Type of protection	Internal-Power Type, 3.8 VDC / 4,200 mAh	
against electric shock	Type BF Applied Parts	
Degree of protection	Non-continuous operation Operating mode: 1:2 duty cycle (ON: 5 min / OFF: 10 min)	
against electric shock	Hand-Held Type	

Degrees of protection against harmful liquid	IPX1
Degree of safety of application	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
Wireless Parameters	
WI-FI Type	2.4G Band
Supported Type	IEEE 802.11n(HT20)
Modulation	IEEE 802.11n:OFDM
Channel Number	11 Channel for 20MHz bandwidth (2,412~2,462 MHz)
Channel Separation	5 MHz
Wireless Power	10 mW/MHz or below
Common Technical Parameters	
Description	- Display: Tablet PC or Mobile Phone which supports by iOS 8.0 or above, Android OS 7.0 or above, Windows System.
Element	128
Measurement	Length, Area, Angle, Obstetrics
Image Frame Rate	16f/s
Battery Operation Time	3.5 hours
Charging Mode	USB Charging
Supported Device Brand	SAMSUNG, HUAWEI, MI / Apple
Equipment name	Specific low power wireless device (Wireless device for wireless data communication system)
Manufacturer/Country	Bionet/S.Korea

A-1. 5C-10L-14L-5CB-10LB <Difference among devices>

5C	
Type	Color Doppler
Dimension & Weight	157mm × 67mm × 29mm, 250g
Array Type	Electronic array R60
Probe Type	Convex
Display Mode	B, B/M, Color, PDI, PW
Frequency	3.2/5MHz
Depth	90mm~305mm
Application	Abdomen, Obstetrics, Gynecology
Antenna Description	Chip Antenna, 2.1dBi(Max.), AH104N2450D1
10L	
Type	Color Doppler
Dimension & Weight	157mm × 67mm × 29mm, 200g
Array Type	Electronic array L40
Probe Type	Linear
Display Mode	B, B/M, Color, PDI, PW
Frequency	7.5/10MHz
Depth	20mm~55mm
Application	Peripheral Vessel, Superficial Organ
Antenna Description	Chip Antenna, 1.6dBi(Max.), AF216M245001-T
14L	
Type	Color Doppler
Dimension & Weight	157mm × 67mm × 29mm, 200g
Array Type	Electronic array L25
Probe Type	Linear

Display Mode	B, B/M, Color, PDI, PW
Frequency	10/14MHz
Depth	20mm~55mm
Application	Peripheral Vessel, Superficial Organ
Antenna Description	Chip Antenna, 2.1dBi(Max.), AH104N2450D1
5CB	
Type	BW
Dimension & Weight	157mm × 67mm × 29mm, 250g
Array Type	Electronic array R60
Probe Type	Convex
Display Mode	B, B/M
Frequency	3.2/5MHz
Depth	90mm~280mm
Application	Abdomen, Obstetrics, Gynecology
Antenna Description	Chip Antenna, 1.6dBi(Max.), AF216M245001-T
10LB	
Type	BW
Dimension & Weight	157mm × 67mm × 29mm, 200g
Array Type	Electronic array L40
Probe Type	Linear
Display Mode	B, B/M
Frequency	7.5/10MHz
Depth	20mm~55mm
Application	Peripheral Vessel, Superficial Organ
Antenna Description	Chip Antenna, 1.6dBi(Max.), AF216M245001-T

A-2. H5C10L

Complied Standard		
EN/IEC 60601-1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance, BF, Non-continuous operation	
EN/IEC 60601-2-37:2015	Medical Electrical Equipment Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment	
EN/IEC 60601-1-2:2014	Electromagnetic Compatibility Requirement and tests, Class A	
Circumstance		
Operation	Ambient Temperature	5°C ~ +35°C
	Relative Humidity	25% ~ 80%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3,000m
Storage / Shipping	Ambient Temperature	-20°C ~ +55°C
	Relative Humidity	25% ~ 93%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3,000m
Safety		
Type of protection	Internal-Power Type, 3.8 VDC / 2,800 mAh	
against electric shock	Type BF Applied Parts	
Degree of protection	Non-continuous operation Operating mode: 1:2 duty cycle (ON: 5 min / OFF: 10 min)	
against electric shock	Hand-Held Type	
Degrees of protection against harmful liquid	IPX1	
Degree of safety of	The equipment is not suitable for use in the presence of	

application	a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
Wireless Parameters	
WI-FI Type	2.4G Band
Supported Type	IEEE 802.11n(HT20)
Modulation	IEEE 802.11n:OFDM
Channel Number	11 Channel for 20MHz bandwidth (2,412~2,462 MHz)
Channel Separation	5 MHz
Antenna Description	Chip Antenna, 2.1dBi(Max.), AH104N2450D1
Wireless Power	10 mW/MHz or below
Common Technical Parameters	
Description	- Display: Tablet PC or Mobile Phone which supports by iOS 8.0 or above, Android OS 7.0 or above, Windows System.
Element	192
Dimension & Weight	159mm × 69mm × 29mm, 250g
Array Type	Electronic array R60 / L40
Probe Type	Convex array probe, Linear array probe
Mode	B, B/M, Color, PDI, PW
Frequency	3.2/5MHz Convex, 7.5/10MHz Linear
Depth	Convex 90mm~305mm, Linear 20~80mm
Measurement	[Common] Length, Area, Angle, Velocity, HR, S/D, Depth [For Obstetrics] GA(CRL), GA(BPD), GA(GS), GA(FL), GA(HC), GA(AC), EFW(BPD), EFW(FL)
Application	Abdomen, Obstetrics, Gynecology, Peripheral Vessel, Superficial Organ
Image Frame Rate	18f/s
Battery Operation Time	2.5 hours
Charging Mode	Wireless Charging

Supported Device Brand	SAMSUNG, HUAWEI, MI / Apple
Equipment name	Specific low power wireless device (Wireless device for wireless data communication system)
Manufacturer/Country	Bionet/S.Korea

A-3. H5C & H10L <Common>

Complied Standard		
EN/IEC 60601-1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance, BF, Non-continuous operation	
EN/IEC 60601-2-37:2015	Medical Electrical Equipment Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment	
EN/IEC 60601-1-2:2014	Electromagnetic Compatibility Requirement and tests, Class A	
Circumstance		
Operation	Ambient Temperature	5°C ~ +35°C
	Relative Humidity	25% ~ 80%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3,000m
Storage / Shipping	Ambient Temperature	-20°C ~ +55°C
	Relative Humidity	25% ~ 93%, Non-Condensing
	Atmospheric Pressure, Max. Altitude	700hPa ~ 1060hPa, 3,000m
Safety		
Type of protection	Internal-Power Type, 3.8 VDC / 5,600 mAh	
against electric shock	Type BF Applied Parts	
Degree of protection	Non-continuous operation Operating mode: 1:2 duty cycle (ON: 5 min / OFF: 10 min)	
against electric shock	Hand-Held Type	
Degrees of protection against harmful liquid	IPX1	
Degree of safety of	The equipment is not suitable for use in the presence of	

application	a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
Wireless Parameters	
WI-FI Type	2.4G Band
Supported Type	IEEE 802.11n(HT20)
Modulation	IEEE 802.11n:OFDM
Channel Number	11 Channel for 20MHz bandwidth (2,412~2,462 MHz)
Channel Separation	5 MHz
Antenna Description	Chip Antenna, 2.1dBi(Max.), AH104N2450D1
Wireless Power	10 mW/MHz or below
Common Technical Parameters	
Description	Tablet PC or Mobile Phone which supports by iOS 8.0 or above, Android OS 7.0 or above, Windows System.
Element	192
Mode	B, B/M, Color, PDI, PW
Measurement	[Common] Length, Area, Angle, Velocity, HR, S/D, Depth [For Obstetrics] GA(CRL), GA(BPD), GA(GS), GA(FL), GA(HC), GA(AC), EFW(BPD), EFW(FL)
Application	Abdomen, Obstetrics, Gynecology, Peripheral Vessel, Superficial Organ
Image Frame Rate	18f/s
Battery Operation Time	5.0 hours
Charging Mode	USB Charging
Supported Device Brand	SAMSUNG, HUAWEI, MI / Apple
Equipment name	Specific low power wireless device (Wireless device for wireless data communication system)
Manufacturer/Country	Bionet/S.Korea

A-3. H5C & H10L < Difference among devices >

H5C	
Dimension	160mm × 70mm × 23mm, 250g
Array Type	Electronic array R60
Probe Type	Convex probe
Frequency	3.2/5MHz
Depth	90mm~305mm
Application	Abdomen, Obstetrics, Gynecology
H10L	
Dimension	160mm × 64mm × 23mm, 200g
Array Type	Electronic array L40
Probe Type	Linear probe
Frequency	7.5/10MHz
Depth	20mm~100mm
Application	Peripheral Vessel, Superficial Organ

Appendix B. Acoustic Output Data

These data are acquired through the test report of IEC 60601-2-37.

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MODE 5C B Mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.32	0.14		0.14		N/A
Index component value			0.14	0.14	N/A	0.14	
Acoustic Parameters	$p_{r,a}$ at z_{MI} (MPa)	2.04					
	P (mW)		29.86		29.86		N/A
	P_{1x1} (mW)		11.96		11.96		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	3.96					
	$z_{PII,a}$ (cm)	3.96					
	f_{awf} (MHz)	2.39	2.39		2.39		N/A
Other Information	p_{rr} (Hz)	1598.50					
	s_{rr} (Hz)	9.09					
	n_{pps}	2					
	$I_{pa,a}$ at $z_{PII,a}$ (W/cm ²)	143.14					
	$I_{spta,a}$ at $z_{PII,a}$ or $z_{SII,a}$ (mW/cm ²)	3.55					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	7.10					
	$p_{r,a}$ at z_{PII} (MPa)	2.83					
Operating control conditions	Display focus(mm)	40	40	40	N/A	40	N/A
	Display depth(mm)	90	90	90	N/A	90	N/A
	Working frequency(MHz)	H5.0	H5.0	H5.0	N/A	H5.0	N/A
	Display focus number	1	1	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 5C B + M Mode

Index label		<i>M/I</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.32	0.21		1.23		N/A
Index component value			B:0.14 M:N/A	B:0.14 M:0.21	N/A	B:0.14 M:1.23	
Acoustic Parameter s	$p_{r,a}$ at z_{MI} (MPa)	2.04					
	P (mW)		B:29.86 M:29.86		B:29.86 M:29.86		N/A
	P_{1x1} (mW)		B:11.96		B:11.96		
	z_s (cm)			3.06			
	z_b (cm)					3.86	
	z_{MI} (cm)	3.96					
	$z_{PII,a}$ (cm)	3.96					
	f_{awf} (MHz)	2.39	2.39		2.39		N/A
Other Information	p_{rr} (Hz)	1598.50					
	s_{rr} (Hz)	9.09					
	n_{ppe}	2					
	$I_{pa,a}$ at $z_{PII,a}$ (W/cm ²)	143.14					
	$I_{spta,a}$ at $z_{PII,a}$ or $z_{SII,a}$ (mW/cm ²)	250.46					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	481.92					
	p_r at z_{PII} (MPa)	2.83					
Operating control conditions	Display focus(mm)	40	40	40	N/A	40	N/A
	Display depth(mm)	90	90	90	N/A	90	N/A
	Working frequency(MHz)	H5.0	H5.0	H5.0	N/A	H5.0	N/A
	Display focus number	1	1	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 5C B + Color / B + PDI Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.32	0.15		0.15		N/A
Index component value			B:0.11 Color: 0.04	B:0.11 Color: 0.04	N/A	B:0.11 Color: 0.04	
Acoustic Parameters	$p_{r,u}$ at z_{MI} (MPa)	2.04					
	P (mW)		B:23.14 Color:8.31		B:23.14 Color:8.31		N/A
	P_{1x1} (mW)		B:9.27 Color:3.33		B:9.27 Color:3.33		
	z_s (cm)		N/A				
	z_b (cm)				N/A		
	z_{MI} (cm)	3.96					
	$z_{PII,u}$ (cm)	3.96					
	f_{awf} (MHz)	B:2.39	B:2.39 Color:2.44		B:2.39 Color:2.44		N/A
Other Information	p_{rr} (Hz)	2957.30					
	s_{rr} (Hz)	7.04					
	n_{pps}	2					
	$I_{pa,u}$ at $z_{PII,u}$ (W/cm ²)	143.14					
	$I_{spta,u}$ at $z_{PII,u}$ or $z_{SII,u}$ (mW/cm ²)	14.46					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	26.87					
	p_r at z_{PII} (MPa)	2.83					
Operating control conditions	Display focus(mm)	40	40	40	N/A	40	N/A
	Display depth(mm)	90	90	90	N/A	90	N/A
	Working frequency(MHz)	B:H5.0 Color:2.5	B:H5.0 Color:2.5	B:H5.0 Color:2.5	N/A	B:H5.0 Color:2.5	N/A
	Display focus number	1	1	1	N/A	1	N/A
	PRF(KHz)	2.0	2.0	2.0	N/A	2.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 5C PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.72	0.46		2.23		N/A
Index component value			N/A	0.46	N/A	2.23	
Acoustic Parameters	$p_{r,a}$ at z_{MI} (MPa)	1.14					
	P (mW)		65.16		65.16		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			3.06			
	z_b (cm)					3.28	
	z_{MI} (cm)	3.28					
	$z_{PII,a}$ (cm)	3.28					
	f_{awf} (MHz)	2.48	2.48		2.48		N/A
Other Information	p_{rr} (Hz)	2500.00					
	s_{rr} (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa,a}$ at $z_{PII,a}$ (W/cm ²)	46.12					
	$I_{spta,a}$ at $z_{PII,a}$ or $z_{SII,a}$ (mW/cm ²)	348.77					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	611.90					
	p_r at z_{PII} (MPa)	1.51					
Operating control conditions	Display focus(mm)	40	N/A	40	N/A	40	N/A
	Display depth(mm)	90	N/A	90	N/A	90	N/A
	Working frequency(MHz)	2.5	N/A	2.5	N/A	2.5	N/A
	Display focus number	1	N/A	1	N/A	1	N/A
	PRF(KHz)	2.5	N/A	2.5	N/A	2.5	N/A
	SV(mm)	1	N/A	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 10L B Mode

Index label		<i>M/I</i>	<i>T/S</i>		<i>T/B</i>		<i>T/C</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.51	0.19		0.19		N/A
Index component value			0.19	0.19	N/A	0.19	
Acoustic Parameters	$p_{r,a}$ at Z_{MI} (MPa)	1.08					
	P (mW)		9.02		9.02		N/A
	P_{1x1} (mW)		9.02		9.02		
	Z_s (cm)			N/A			
	Z_b (cm)					N/A	
	Z_{MI} (cm)	0.64					
	$Z_{PII,a}$ (cm)	0.64					
	f_{awf} (MHz)	4.38	4.38		4.38		N/A
Other Information	p_{rr} (Hz)	3765.30					
	s_{rr} (Hz)	12.99					
	n_{pps}	4					
	$I_{pa,a}$ at $Z_{PII,a}$ (W/cm ²)	34.71					
	$I_{spta,a}$ at $Z_{PII,a}$ or $Z_{SII,a}$ (mW/cm ²)	54.43					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm ²)	77.80					
	p_r at Z_{PII} (MPa)	1.18					
Operating control conditions	Display focus(mm)	4, 9	4, 9	4, 9	N/A	4, 9	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	H10.0	H10.0	H10.0	N/A	H10.0	N/A
	Display focus number	2	2	2	N/A	2	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 10L B + M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.51	0.38		0.47		N/A
Index component value			B:0.19 M:0.19	B:0.19 M:N/A	N/A	B:0.19 M:0.47	
Acoustic Parameters	$p_{r,s}$ at z_{MI} (MPa)	1.08					
	P (mW)		B:9.02 M:9.02		B:9.02 M:9.02		N/A
	P_{1x1} (mW)		B:9.02		B:9.02		
	z_s (cm)			N/A			
	z_b (cm)					1.16	
	z_{MI} (cm)	0.64					
	$z_{PII,s}$ (cm)	0.64					
	f_{awf} (MHz)	4.38	4.38		4.38		N/A
Other Information	p_{rr} (Hz)	3765.30					
	s_{rr} (Hz)	12.99					
	f_{lpps}	4					
	$I_{pa,s}$ at $z_{PII,s}$ (W/cm ²)	34.71					
	$I_{spta,s}$ at $z_{PII,s}$ or $z_{SII,s}$ (mW/cm ²)	186.55					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	238.17					
	p_r at z_{PII} (MPa)	1.18					
Operating control conditions	Display focus(mm)	4, 9	4, 9	4, 9	N/A	4, 9	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	H10.0	H10.0	H10.0	N/A	H10.0	N/A
	Display focus number	2	2	2	N/A	2	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 10L B + Color / B + PDI Mode

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.94	0.21		0.21		N/A
Index component value			B:0.12 Color: 0.09	B:0.12 Color: 0.09	N/A	B:0.12 Color: 0.09	
Acoustic Parameters	$p_{r,u}$ at z_{MI} (MPa)	2.43					
	P (mW)		B:5.79 Color:2.94		B:5.79 Color:2.94		N/A
	P_{1x1} (mW)		B:5.79 Color:2.94		B:5.79 Color:2.94		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	0.50					
	$z_{PII,u}$ (cm)	0.50					
	f_{awf} (MHz)	Color: 6.73	B:4.38 Color:6.73		B:4.38 Color:6.73		N/A
Other Information	p_{rr} (Hz)	4000.00					
	s_{rr} (Hz)	8.33					
	n_{pps}	13					
	$I_{pa,u}$ at $z_{PII,u}$ (W/cm ²)	215.64					
	$I_{spta,u}$ at $z_{PII,u}$ or $z_{SII,u}$ (mW/cm ²)	74.14					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	115.32					
	p_r at z_{PII} (MPa)	2.74					
Operating control conditions	Display focus(mm)	6	6	6	N/A	6	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	B:H10.0 Color:6.5	B:H10.0 Color:6.5	B:H10.0 Color:6.5	N/A	B:H10.0 Color:6.5	N/A
	Display focus number	1	1	1	N/A	1	N/A
	PRF(KHz)	4.0	4.0	4.0	N/A	4.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 10L PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.78	0.21		0.51		N/A
Index component value			0.21	N/A	N/A	0.51	
Acoustic Parameters	$p_{r,u}$ at Z_{MI} (MPa)	2.01					
	P (mW)		6.46		6.46		N/A
	P_{1x1} (mW)		N/A		N/A		
	Z_s (cm)		N/A				
	Z_b (cm)					1.22	
	Z_{MI} (cm)	0.52					
	$Z_{PII,u}$ (cm)	0.52					
	f_{awf} (MHz)	6.61	6.61		6.61		N/A
Other Information	p_{rr} (Hz)	4000.00					
	s_{rr} (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa,u}$ at $Z_{PII,u}$ (W/cm ²)	120.98					
	$I_{spta,u}$ at $Z_{PII,u}$ or $Z_{SII,u}$ (mW/cm ²)	581.58					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm ²)	730.66					
	p_r at Z_{PII} (MPa)	2.25					
Operating control conditions	Display focus(mm)	6	6	N/A	N/A	6	N/A
	Display depth(mm)	20	20	N/A	N/A	20	N/A
	Working frequency(MHz)	6.5	6.5	N/A	N/A	6.5	N/A
	Display focus number	1	1	N/A	N/A	1	N/A
	PRF(KHz)	4.0	4.0	N/A	N/A	4.0	N/A
	SV(mm)	1	1	N/A	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 14L B Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.41	0.15		0.15		N/A
Index component value			0.15	0.15	N/A	0.15	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.02					
	P (mW)		5.17		5.17		N/A
	$P_{1 \times 1}$ (mW)		5.17		5.17		
	z_s (cm)		N/A				
	z_b (cm)					N/A	
	z_{MI} (cm)	0.78					
	$z_{PII,\alpha}$ (cm)	0.78					
	f_{awf} (MHz)	6.15	6.15		6.15		N/A
Other Information	p_{rr} (Hz)	3955.90					
	s_{rr} (Hz)	12.99					
	n_{pps}	4					
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	29.96					
	$I_{spta,\alpha}$ at $z_{PII,\alpha}$ or $z_{SII,\alpha}$ (mW/cm ²)	15.73					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	22.66					
	p_r at z_{PII} (MPa)	1.20					
Operating control conditions	Display focus(mm)	8, 15	8, 15	8, 15	N/A	8, 15	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	H14.0	H14.0	H14.0	N/A	H14.0	N/A
	Display focus number	2	2	2	N/A	2	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 14L B + M Mode

Index label		MI	T/S		T/B		T/C
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.41	0.15		0.21		N/A
Index component value			B:0.15 M:0.14	B:0.15 M:N/A	N/A	B:0.15 M:0.21	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.02					
	P (mW)		B:5.17 M:4.83		B:5.17 M:4.83		N/A
	P_{1x1} (mW)		B:5.17 M:N/A		B:5.17 M:N/A		
	Z_s (cm)		N/A				
	Z_b (cm)					0.86	
	Z_{MI} (cm)	0.78					
	$Z_{PII,\alpha}$ (cm)	0.78					
	f_{awf} (MHz)	6.15	6.15		6.15		N/A
Other Information	p_{rr} (Hz)	3955.90					
	s_{rr} (Hz)	12.99					
	n_{pps}	B:4					
	$I_{pa,\alpha}$ at $Z_{PII,\alpha}$ (W/cm ²)	29.96					
	$I_{spta,\alpha}$ at $Z_{PII,\alpha}$ or $Z_{SII,\alpha}$ (mW/cm ²)	113.45					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm ²)	158.74					
	p_r at Z_{PII} (MPa)	1.20					
Operating control conditions	Display focus(mm)	8, 15	8, 15	8, 15	N/A	8, 15	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	H14.0	H14.0	H14.0	N/A	H14.0	N/A
	Display focus number	2	2	2	N/A	2	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

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MODE 14L B + Color / B + PDI Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.10	0.27		0.27		N/A
Index component value			B:0.09 Color: 0.18	B:0.09 Color: 0.18	N/A	B:0.09 Color: 0.18	
Acoustic Parameter s	$p_{r,\alpha}$ at Z_{MI} (MPa)	2.89					
	P (mW)		B:3.07 Color:5.45	B:3.07 Color:5.45	B:3.07 Color:5.45	B:3.07 Color:5.45	N/A
	P_{1x1} (mW)		B:3.07 Color:5.45	B:3.07 Color:5.45	B:3.07 Color:5.45	B:3.07 Color:5.45	
	Z_s (cm)			N/A			
	Z_b (cm)					N/A	
	Z_{MI} (cm)	0.82					
	$Z_{PII,\alpha}$ (cm)	0.82					
	f_{awf} (MHz)	Color:6.94	B:6.15 Color:6.94	B:6.15 Color:6.94	B:6.15 Color:6.94	B:6.15 Color:6.94	N/A
Other Information	p_{rr} (Hz)	Color: 8000.00					
	s_{rr} (Hz)	7.69					
	n_{pps}	B:4 Color:12					
	$I_{pa,\alpha}$ at $Z_{PII,\alpha}$ (W/cm ²)	342.70					
	$I_{spta,\alpha}$ at $Z_{PII,\alpha}$ or $Z_{SII,\alpha}$ (mW/cm ²)	32.74					
	I_{spta} at Z_{PII} or Z_{SII} (mW/cm ²)	49.19					
	p_r at Z_{PII} (MPa)	3.51					
Operating control conditions	Display focus(mm)	12	12	12	N/A	12	N/A
	Display depth(mm)	20	20	20	N/A	20	N/A
	Working frequency(MHz)	B:H14.0 Color: Fixed	B:H14. 0 Color: Fixed	B:H14. 0 Color: Fixed	N/A	B:H14.0 Color: Fixed	N/A
	Display focus number	1	1	1	N/A	1	N/A
	PRF(KHz)	8.0	8.0	8.0	N/A	8.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							