T3300
Ultrasound System
Basic Operating Instructions

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CHAPTER

1

Read This First

The T3300 Diagnostic Ultrasound System (hereinafter called “system”) is an easy-to-use, portable ultrasound imaging instrument intended for use by a qualified operator for ultrasound evaluation and clinical analysis.

The *Basic Operating Instructions* provides important procedures and information on how to operate the system and service the system correctly and safely. Before attempting to operate the system, read this *Basic Operating Instructions* and strictly observe all warnings and cautions. Pay extra attention to the information from "Chapter 2 Safety Information".

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This *Basic Operating Instructions* aims to provide the most updated and accurate information to customers, and thus all contents may be modified from time to time without prior notice. Please visit http://BenQMedicalTech.com for the latest version of this operating instructions.

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1.1 Intended Audience

This document is intended for sonographers, physicians, and biomedical engineers who operate and maintain the system and are familiar with ultrasound techniques.

1.2 Intended Use

The T3300 is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for ultrasound evaluation/clinical analysis etc. It can be used in the following applications: Abdomen, Cardiology, Gynecology, Obstetric, Breast, Thyroid, Musculoskeletal, Vascular (Carotid, Venous, Arterial), Nerve, Renal, Urology and so on.

The clinical environments where the system can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

The system is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the system user information, and only for the purposes for which it was designed.

The system should only be operated by someone who has received proper training in the use and operation of an ultrasound system. This system produces images derived from sound echoes; those images must be interpreted by a qualified medical professional. This system in no way interprets these images or provides a medical diagnosis of the patient being examined.

WARNINGS

- **Do not use the system for purposes other than those intended and expressly stated above. Do not misuse the system, and do not use or operate the system incorrectly.**
- **Do not use the system in ophthalmology applications.**
- **Installation, use, and operation of the system are subject to the law in the jurisdictions in which it is used. Install, use, and operate the system only in such ways that do not conflict with applicable laws or regulations, which have the force of law. Use of the system for purposes other than those intended and expressly stated here, as well as incorrect use or operation, may relieve us or our agents from all or some responsibilities for resultant noncompliance, damage, or injury.**
- **System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis, and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.**

1.3 Warnings

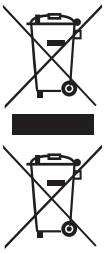
Before using the system, read these warnings and "Chapter 2 Safety Information".

WARNINGS

- **Do not attempt to disassemble or modify the system. There are no user serviceable parts inside this system. Necessary modifications must be made only by the manufacturer or its designated agents.**
- **Do not allow any liquid to get inside this system. Water and moisture may cause short-circuit to the electronic components and lead to malfunctions.**
- **Do not drop or apply shock/vibration to this system. Strong impacts may damage the components inside.**
- **Do not cut, bend, modify, place heavy objects, or step on the cable of the power adapter. Otherwise the external insulation may be damaged and result in short-circuit or fire.**
- **Do not use this system near strong electromagnetic sources, such as a microwave oven. The electromagnetic interference may cause this system to malfunction.**
- **To avoid electrical shock, use only supplied power cords and connect only to properly grounded wall outlets.**
- **The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.**

1.4 WEEE

Disposal of Waste Electrical and Electronic Equipment and/or Battery by users in private households in the European Union.



This symbol on the product or on the packaging indicates that this can not be disposed of as household waste. You must dispose of your waste equipment and/or battery by handling it over to the applicable take-back scheme for the recycling of electrical and electronic equipment and/or battery. For more information about recycling of this equipment and/or battery, please contact your city office, the shop where you purchased the equipment or your household waste disposal service. The recycling of materials will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and environment.

Recycling information: See http://www.benq.com/support/recycle for details.

1.5 Discarding the Tablet and Batteries

The tablet and internal batteries should be discarded in an environmentally safe manner. Properly dispose of batteries according to local regulations.

WARNINGS

- **Do not disassemble, puncture, or incinerate batteries. Be careful not to short the battery terminals, because that could result in a fire hazard.**
- **Use caution when handling, using, and testing the batteries. Do not short circuit, crush, drop, mutilate, puncture, apply reverse polarity, expose to high temperatures, or disassemble. Misuse or abuse could cause physical injury.**
- **If embedded electrolyte leakage occurs, wash your skin with large amounts of water to prevent skin irritation and inflammation.**

1.6 Equipment List

Check the sales package for the following items. If any item is missing or damaged, contact your place of purchase immediately.

- BenQ Medical Technology Ultrasound System
- Medical grade AC/DC power adapter
- Warranty Card
- *Basic Operating Instructions* (this document)
- AC plugs
- One or more BenQ Medical Technology Transducers

WARNINGS

- **AC plug types vary by country/region.**
- **Using accessories, transducers, or power supply units other than those specified may cause the warranty to void and result in increased emissions, decreased EMI immunity of the system, or even damages to the system and personal injuries.**
- **Use of other accessories results in non-compliance.**

1.7 Conventions

The system uses certain conventions throughout the interface to make it easy for you to learn and use:

- Refer to "Controlling the System" on page 43 to control the system using gestures.
- To adjust the parameter value of a function, touch the plus/minus buttons (+/-).
- To type texts into a text field, touch the field and use the virtual keyboard that appears. You can also use a supported USB or Bluetooth keyboard for entering texts.
- To display a list, touch the down arrow  . To display the options, touch the Menu icon  .
- To select/deselect an item or to enable/disable a function, tap in the checkbox. For example, check the exam  ; uncheck the exam  .

The *Basic Operating Instructions* uses certain conventions throughout the book to make it easier to find the information you need.

- The on-screen menu steps needed to perform a function are shown in a condensed form. For example, touch  > **Settings** > **DICOM**.
- Refer to the following graphic symbols and numbering styles to alert you to important information:

This icon marks NOTES; useful tips or additional information that help you get better use of your product.

This icon marks CAUTIONS; notices describing actions or conditions that may damage your product or cause injury, and consequently void your warranty or service contract or lose the patient or system data.

This icon marks WARNINGS; instructions that must be followed. Failure to observe can cause damages to your product, or result in personal injuries, or even death.

1.8 System Warranty

The warranty is void if unauthorized personnel perform service or maintenance on the system. To ensure correct system performance and to obtain warranty service, please contact technical support. For more information, see "Contact Information" on page 2.

This Device is for medical care person use only.
Only Professionals can install it. To maintain the device operation during the line power off, the device is battery included.

CHAPTER

2

Safety Information

This chapter covers the following topics:

WARNING

Follow the procedures carefully and ensure that the power/electrical/environmental requirements are satisfied. Failure to observe the instructions or disregard the warnings may result in damages to the system, personal injury, or even death of the operator or the patient.

Observe the following precautions carefully.

WARNINGS

- **This system complies with Type BF general equipment and the EN60601-1 standard, suitable for continuous operation when connected as a system to a medical grade AC/DC power adapter or operated from the tablet battery.**
- **Use only medical grade peripherals in the patient environment.**
- **Do not block or otherwise obstruct access to the AC plug at the wall. Operators must be able to quickly unplug the power cable at the wall in case of emergency.**
- **The system should only be used in a medical facility under the supervision of a trained physician.**
- **Only an authorized service technician should perform maintenance.**
- **Be extremely cautious when placing or moving the system.**
- **Always position the system on a stable surface where it cannot fall on the patient.**
- **Do not lift the system by the power cable or the transducer. If either disconnects, the system could fall on the patient.**
- **This system has been fully adjusted and tested prior to shipment from the factory. Unauthorized modifications will void your warranty.**
- **If this system or the transducer connected displays any signs of malfunction, turn off the system immediately, disconnect it from the wall outlet, then contact technical support** **(See "Contact Information" on page 2)**
- **Do not use a power adapter other than the one supplied with the system. Connecting the system to an unknown power adapter is very dangerous and may lead to fire or explosion.**
- **Using cables, transducers, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system.**
- **The power cable of the system should only be connected to a grounded power socket.**
- **Do not connect USB peripherals with an extended USB cable. Extended connection may cause unexpected usage fault.**
- **Only devices that comply with the EN60601-1 standard, either electronically or mechanically, can be connected to this system. Recheck the leakage current and other safety performance indices of the entire system to avoid potential system damage caused by leakage from a current superposition.**

CAUTION

Using accessories, transducers, peripherals, or cables not supplied with the system or recommended by BenQ Medical Technology can affect the system in the form of increased emissions or decreased immunity to external EMI/EMC occurrences. Non-specified peripherals, and cables in some cases, can also increase leakage current or compromise the safety of the grounding scheme.

- **This system does not incorporate any specialized protective measures in the event it is configured with high-frequency operation devices. The operator should use with caution in these types of applications.**
- **The system is in compliance with the Ingress Protection Marking ratings IP21.**

WARNINGS

- **Do not use this system under direct sunlight, near heat sources or in the presence of flammable substances, otherwise an explosion may occur.**
- **When using this system for ultrasound examinations, use only the qualified ultrasound gel that complies with system standards.**
- **Do not continuously scan the same part of a patient or expose the patient to prolonged scanning, otherwise it may harm the patient.**
- **Do not stay at the same position for too long without taking a break while scanning patients to prevent harm or neck injury.**
- **Follow the instructions on "Chapter 4 Preparing the System" on page 31 in this *Basic Operating Instructions* for complete instructions on the installation of the transducers, power supply units and all peripheral devices to the system.**
- **Improper installation of peripherals to the system may cause damage to the system, peripherals, or personal injury to the operator or the patient.**
- **Do not use the system for any application until you have read, understood, and know all the safety information, safety procedures, and emergency procedures contained in this chapter. Operating the system without a proper awareness of safe use could lead to fatal or other serious personal injury.**
- **The system can contain environmentally hazardous materials such as, but not limited to: heavy metals, general recyclable metals, and plastics. This product should be recycled according to local and national guidelines for recycling electronic equipment.**
- **When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1 and test the system to those requirements.**
- **Do not use non-medical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the non-medical peripherals receive power from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1.**
- **Images printed on a report printer are intended only for reference and should not be used for diagnostic purposes.**
- **For proper disposal of this system, contact your local BenQ Medical Technology representative.**

2.1 Symbols

The following symbols provide information about the system's labels and regulatory compliance.

CAUTION

Do not use a brush on the system's labels.

2.1.1 System Label Icons

Table 1 System Label Icons

Symbols	Descriptions
REF	**Product Model**
UDI	**Unique Device Identification**
	**Manufacturer Mark** Manufacturer Qisda Corporation manufactures the system.
	**Manufacture Date**
EC REP	**EU/EC European Authorized Representative**
CE 0120	**CE Marking Certification with Notified Body Number 0120**
CE !	**Compliance to R&TTE Directive**
	**Final Disposal of Your System** Final disposal is when you dispose of the system in such a way that it can no longer be used for its intended purposes. For more information, see "WEEE" on page 3.
	**Refer to the Basic Operating Instructions** Indicates that the user should read the *Basic Operating Instructions* for information on using this equipment
	**Type BF Equipment Applied Part** The Ultrasound System provides protection against electric shock.
	**Include RF transmitters, apply RF electromagnetic energy for diagnosis**
IP22	**Tablet IP Code, International Protection Marking**

2.1.2 System Button

Table 2 System Button

Symbols	Descriptions
	**Power button** Press and hold the Power button to turn on/off the system.

2.1.3 Shipping Label Icons

Table 3 Shipping Label Icons

Symbols	Descriptions
	**This Side Up**
	**Fragile**
	**Maximum Stacking Height**
	**Maximum Stacking Weight**
	**Sun and Rain**
	**Temperature** The system must be stored in the original shipping container in environments between -20°C and 60°C (-13°F and 140°F). The temperature while operating the system should be kept between 10°C and 40°C (32°F and 104°F).
	**Humidity** The system must be stored in the original shipping container in environments with 20% to 95% relative humidity and non-condensing. The humidity while operating the system should be kept between 20% to 85% relative humidity and non-condensing.
	**Air Pressure** The system must be stored in the original shipping container in environments between 700 hPa (525 mmHg) and 1060 hPa (795 mmHg) air pressure.

2.2 Electrical Safety

Only trained medical personnel should operate this system. This system complies with the following standards:

- Electrical:
  - IEC 60601-1:2005+AMD1:2012/EN 60601-1:2006+A1:2013+A12:2014
  - IEC 60601-2-37:2008+AM1:2011
- EMC/EMI:
  - IEC 60601-1-2:2007/AC:2010, CISPR 11 Group I Class B

- Harmful liquid protection:
  - For the main system: IP21 (without power adapter)
  - For the transducer: IPx7
  - For the power adapter: IP20
  - For maximum safety, observe the following guidelines strictly:

WARNINGS

- **The system and patient-applied parts meet the standard IEC 60601-1. Applied voltages exceeding the standard, although unlikely, may result in electrical shock to the patient or operator.**
- **Shock hazards exist if the power adapter is damaged or is not properly grounded. Use only the supplied medical grade power adapter.**
- **Plug the system into a hospital-grade, three-hole outlet, and do not circumvent the power cord.**
- **To avoid the risk of electric shock, connect the system only to properly grounded wall outlets.**
- **Only authorized service technicians can make internal replacements of the system.**
- **Do not operate the system in the presence of flammable gases or anesthetics. Explosion can result. The system is not compliant in AP/APG environments as defined by IEC 60601-1.**
- **Do not use a transducer if the transducer or cable is damaged. Contact technical support for replacement of the damaged equipment** **(See "Contact Information" on page 2).**
- **All peripheral devices connected to the system must comply with IEC 60601 or IEC 60950-1.**
- **To avoid risk of electrical shock hazards, always inspect the transducer before use. Check the face, housing, and cable before use. Do not use if the face is cracked, chipped, or torn; the housing is damaged; or the cable is abraded.**
- **Transducer cables have strain reliefs at terminations. Inspect cables regularly to detect damaged, frayed, or broken cables that might contact a patient.**

2.2.1 Battery Usage/Disposal

WARNINGS

- **Do not disassemble the system.**
- **Use only the supplied battery. Using an unapproved battery may cause the system to explode and result in serious damage to your health or property.**
- **Do not replace, heat, crush, puncture, short external contacts, or incinerate the battery.**
- **Use only the supplied power adapter to charge the battery.**
- **Incorrect use of the battery may cause a leak of chemicals or explosion. The leak of chemicals may harm the skin. If any chemicals leak from the device, use a dry cloth to wipe it clean and contact your local BenQ Medical Technology representative for help.**

CAUTION

Dispose of used batteries according to the instructions.

2.2.2 Electrical Fast Transients (EFT)

The system complies with the IEC 60601-1-2 3rd edition standard for susceptibility to electrical fast transients (EFT) on the power line. However, if the system experiences EFT on the power line,

artifacts (vertical lines, excessive noise in image, etc.) may appear on the ultrasound image. To eliminate these artifacts caused by an EFT condition, the operator should either:

- Disconnect the system from the power source by unplugging the power cord from the tablet, and run the system on its internal battery.

or

- Unplug the power cord from the wall and move to a different power source that is not experiencing this condition.

2.2.3 Electromagnetic Interference (EMI)

Medical electrical equipment such as the system requires special precautions regarding electromagnetic compatibility, and must be installed and put into service according to the following electromagnetic tables.

2.2.3.1 All Equipment

The system is intended for use in the electromagnetic environment specified below. The customer or operator of the T3300 Diagnostic Ultrasound System should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions - All Equipment

Table 4 Guidance and Manufacturer's Declaration - Electromagnetic Emissions - All Equipment

Emissions test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The T3300 Diagnostic Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The T3300 Diagnostic Ultrasound System is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A or B	
Flicker IEC 61000-3-3	Complies	
RF Emissions CISPR 14-1	Complies	The T3300 Diagnostic Ultrasound System is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The T3300 Diagnostic Ultrasound System is not suitable for interconnection with other equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity - All Equipment

Table 5 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - All Equipment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
ESD IEC 61000-4-2	±6 kV Contact ±8 kV Air	As specified	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	±2 kV Mains ± 1kV I/Os	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	As specified	

Table 5 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - All Equipment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Voltage dips/ Dropout IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 seconds	As specified	Mains power quality should be that of a typical commercial or hospital environment. If the user of the T3300 Diagnostic Ultrasound System requires continued operation during power mains interruptions, it is recommended that the T3300 Diagnostic Ultrasound System be powered from an uninterruptible power supply or battery.
Power frequency 50/ 60 Hz Magnetic field IEC 61000-4-8	3 A/m	As specified	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity - Non-life-supporting Equipment

Table 6 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - Non-life-supporting Equipment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the T3300 Diagnostic Ultrasound System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	[V1] = 3 Vrms	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1] = 3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

Table 6 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - Non-life-supporting Equipment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
			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: 
[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 T3300 Diagnostic Ultrasound System is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality, you should operate the system under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

WARNINGS

- **Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.**
- **ME equipment has been tested for radiated RF immunity only at selected frequencies.**

2.2.3.2 Separation Distances

The T3300 Diagnostic Ultrasound System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or operator of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and

mobile RF Communications Equipment and the system as recommended below, according to the maximum output power of the communications equipment.

Table 7 Separation distances

Maximum Output Power of Transmitter Watts (W)	Separation Distance According to Frequency of Transmitter Meters (m)		
	150 kHz to 80 MHz $\frac{3.5\sqrt{P}}{V_1} = D$	80 MHz to 800 MHz $\frac{3.5\sqrt{P}}{E_1} = D$	800 MHz to 2.5 GHz $\frac{7\sqrt{P}}{E_1} = D$
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

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 rate of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING

Operation of the equipment below that value may cause inaccurate results.

2.2.4 Surges to AC Power Mains

If the system is powered from AC mains that could experience surges above 1 kV (for example, from extreme lightning conditions), additional surge suppression is recommended.

2.3 Mechanical Safety

Observe the following precautions when using the system for mechanical safety.

WARNINGS

- **When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.**
- **When positioning the system, move it carefully to avoid pinching hands or extremities against other objects, such as a bed rail.**
- **Do not roll the system over transducer cables or power cords.**

2.4 Equipment Protection

Observe the following precautions to protect your system.

CAUTION

- **Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system. Do not roll the system over cables, which may damage them.**
- **Do not submerge the cables of patient-applied parts in solution. The cables are not liquid-tight beyond the applied part/cable or cable/connector interfaces.**
- **Do not submerge the transducer connector in any liquid.**
- **For optimal performance, connect your system to a circuit dedicated solely for the system. Do not connect life-support devices to the same circuit as the system.**
- **Improper cleaning or sterilization of a patient-applied part may cause permanent damage. For cleaning and disinfection instructions, see** "Transducer and System Maintenance" on page 93.

2.5 RF Safety

The system should be operated in a location that is no closer than listed in “Non-Life-Supporting Equipment” to any part of RF communications equipment that may disturb its functions. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment. The system should be separated by at least the distances specified in the table referenced above.

The system is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system according to the maximum output power of the communications equipment.

2.6 Biological Safety

This product, as with all ultrasound equipment, should be used only for valid reasons and should be used both for the shortest period of time and at the lowest power settings necessary (ALARA - As Low As Reasonably Achievable) to produce diagnostically acceptable images. The AIUM offers the following guidelines:

Clinical Safety Quoted from AIUM

Approved March 26, 1997

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use.

There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any that may be present.

2.6.1 Heating

Elevating tissue temperature during obstetrical examinations creates medical concerns. At the embryo development stage, the rise in temperature and the length of time exposed to heat combine to determine potential detrimental effects. Exercise caution, particularly during Color imaging exams. The Thermal Index (TI) provides a statistical estimate of the potential temperature elevation (in centigrade) of tissue temperature. Two forms of TI are available: TIS, for soft tissue exposures; and TIB, for instances when bone lies near the beam focus.

2.6.2 Cavitation

Cavitation may occur when sound passes through an area that contains a cavity, such as a gas bubble or air pocket (in the lung or intestine, for example). During the process of cavitation, the sound wave may cause the bubble to contract or resonate. This oscillation may cause the bubbles to explode and damage the tissue. The Mechanical Index (MI) has been created to help operators accurately evaluate the likelihood of cavitation and the related adverse effects.

2.6.3 Safe Scanning Guideline

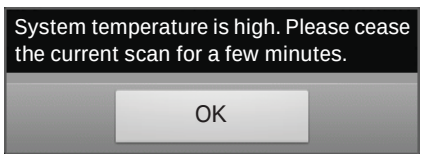
- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.

WARNINGS

- **Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the system, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).**
- **Operators should understand the likely influence of the machine controls, the operating mode (e.g. B-mode, Color or Spectral Doppler) and the transducer frequency on thermal and cavitation hazards.**
- Use a low output power default setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been adjusted to its maximum value.
- Maintain the shortest examination time necessary to produce a useful diagnostic result.

WARNINGS

- **Take particular care to reduce output and minimize exposure time of an embryo or fetus when the temperature of the mother is already elevated.**
- **Take particular care to reduce the risk of thermal hazard during diagnostic ultrasound when exposing an embryo less than eight weeks after gestation, or the head, brain or spine of any fetus or neonate.**
- **Although applicable to any transducer, take particular care during trans-vaginal exams during the first eight weeks of gestation.**
- During continuous operation, the system temperature may become too high. If the following system message displays during a real-time scan, touch **OK** and the system displays frozen imaging screen. To resume scanning, wait until the system cools down.



- Operators should continually monitor the on-screen thermal index (TI) and mechanical index (MI) values and use control settings that keep these settings as low as possible while still achieving diagnostically useful results. In obstetric examinations, TIS (soft tissue thermal index)

should be monitored during scans carried out in the first eight weeks after gestation, and TIB (bone thermal index) thereafter.

– MI> 0.3 Minor damage is likely to happen to neonatal lung or intestine. If such exposure is necessary, reduce the exposure time as much as possible.
– MI> 0.7 Risk of cavitation exists if an ultrasound contrast agent containing gas microspheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.
– TI> 0.7 The overall exposure time of an embryo or fetus should be restricted in accordance with the following table as a reference.

Table 8 Maximum exposure time recommended for an embryo or fetus

TI	Maximum exposure time (minutes)
0.7	60
1.0	30
1.5	15
2.0	4
2.5	1

- Diagnostic ultrasound has the potential for both false positive and false negative results. Misdiagnosis is far more dangerous than any effect that might result from the ultrasound exposure. Therefore, diagnostic ultrasound should be performed only by those with sufficient training and education.
- Non-diagnostic use of ultrasound equipment is not generally recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, equipment demonstration using normal subjects, and the production of souvenir pictures or videos of a fetus. For equipment of which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. Avoid frequent repeated exposure of any subject. Scans in the first trimester of pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs, nor should their production involve increasing the exposure levels or extending the scan times beyond those needed for clinical purposes.

2.7 Operator Safety

The following issues and situations can affect operator safety when you are using an ultrasound system.

2.7.1 Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection-control procedures established in your facility for the protection of both the staff and the patient.

2.7.2 Disposable Drape

If you believe contamination of the system might occur during an exam, it is recommended that you take universal precautions and cover the system with a disposable drape. Consult your facility's rules regarding equipment use in the presence of infectious disease.

2.8 Waterproof and Dustproof Ratings

The system has a degree of protection from ingress of water and particulate matter, but the tablet is not approved for use where it would be exposed to liquids. If it is used in environments where it might be exposed to liquids, the tablet must be covered by a drape. These environments include, but are not limited to, outpatient and private office procedures such as biopsies, office visits, and other traditional, non-invasive scanning.

The following table lists the applied parts and their levels of protection.

Table 9 Waterproof and dustproof ratings

Component	Use	IP level
Ultrasound System	Ultrasound system	IP21
P42B6 transducer	Ultrasound transducer	IPX7 (at transducer head)
C62B transducer	Ultrasound transducer	IPX7 (at transducer head)
L154BH transducer	Ultrasound transducer	IPX7 (at transducer head)

2.9 Understanding the MI/TI Display

The system allows full software control of acoustic output. When powering on the system or creating a new exam, scan parameters should be set to default preset. All of the default presets are compliant with FDA requirements. TI/MI information are displayed in real-time in the scan properties area.

In the following table, the MI or TI index is equal or greater than 1.0 for transducer/mode combinations marked “V”.

Table 10 MI/TI generating from applicable transducer/mode combinations

Mode / Transducer	P42B6 Phased Array 64 elements 2-4 MHz	C62B Curved Linear Array 2-6 MHz	L154BH Linear Array 4-12 MHz
B	V	–	–
B+Color	V	V	V
B+Power	V	V	V
B+M-Mode	V	–	–
PW Doppler	–	V	–

Table 10 MI/TI generating from applicable transducer/mode combinations

Mode / Transducer	P42B6 Phased Array 64 elements 2-4 MHz	C62B Curved Linear Array 2-6 MHz	L154BH Linear Array 4-12 MHz
Triplex	V	V	–
CW Doppler	–	–	–

Track-3 follows the Output Display Standard for systems which include fetal Doppler applications. The acoustic output will not be evaluated on an application-specific basis, but the global maximum de-rated I_{spta} must be ≤ 720 mW/cm^2 and either the global maximum MI must be ≤ 1.9, or the global maximum derated Isppa must be ≤ 190 W/cm^2. An exception is for ophthalmic use, in which case the TI=max (TIS) is not to exceed 1.0; I_{spta}.3 ≤ 50 mW/CM^2, and MI ≤ 0.23. Track-3 gives the operator the freedom to increase the output acoustic power for a specific exam, and still limit output acoustic power within the global maximum de-rated I_{spta} ≤ 720 mW/cm^2 under an Output Display Standard.

The system design allows full software control of the acoustic output, entry of new patient identification data or change from a non-foetal to a foetal application, and the system may switch to an appropriate default setting upon powering on. These default setting levels are established before shipping and may be reconfigured by the operator.

For any ultrasound systems, Track-3 provides an Output Indices Display Standard. The ultrasound system and its *Basic Operating Instructions* contain the information regarding an ALARA (As Low As Reasonably Achievable) education program from the clinical end-user and the acoustic output indices, MI and TI. The MI describes the likelihood of cavitation, and the TI offers the predicted maximum temperature rise in tissue as a result of the diagnostic examination. In general, a temperature increase of 2.5°C must be present consistently at one spot for 2 hours to cause possible fetal abnormalities. Avoiding a local temperature rise above 1°C should ensure that no thermally induced biologic effect occurs. When referring to the TI for potential thermal effect, a TI equal to 1 does not mean the temperature will rise 1°C. It only means an increased potential for thermal effects can be expected as the TI increases. A high index does not mean that bioeffects are occurring, but only that the potential exists and there is no consideration in the TI for the scan duration, so minimizing the overall scan time will reduce the potential for effects. These operator control and display features move the safety responsibility from the manufacturer to the operator. So it is very important to have the ultrasound systems display the acoustic output indices correctly and the well-educated operator to interpret the value appropriately.

R_F: De-rating factor

In Situ intensity and pressure cannot currently be measured. Therefore, the acoustic power measurement is normally done in the water tank, and when soft tissue replaces water along the ultrasound path, a decrease in intensity is expected. The fractional reduction in intensity caused by attenuation is denoted by the derating factor (R_F),

$$R_F = 10^{(-0.1\ a.f.z)}$$

Where a is the attenuation coefficient in dB cm^{-1} MHz^{-1}, f is the transducer center frequency, and z is the distance along the beam axis between the source and the point of interest.

De-rating factor R_F for the various distances and frequencies with attenuation coefficient 0.3 dB cm^{-1} MHz^{-1} in homogeneous soft tissue is listed in the following table. An example is if the operator uses

7.5 MHz frequency, the power will be attenuated by 0.0750 at 5 cm, or 0.3 x 7.5 x 5 = -11.25 dB. The De-rated Intensity is also referred to as '.3' at the end (e.g. $I_{spta.3}$).

Table 11

Distance (cm)	Frequency (MHz)			
	1	3	5	7.5
1	0.9332	0.8128	0.7080	0.5957
2	0.8710	0.6607	0.5012	0.3548
3	0.8128	0.5370	0.3548	0.2113
4	0.7586	0.4365	0.2512	0.1259
5	0.7080	0.3548	0.1778	0.0750
6	0.6607	0.2884	0.1259	0.0447
7	0.6166	0.2344	0.0891	0.0266
8	0.5754	0.1903	0.0631	0.0158

$I' = I * R_F$ Where I' is the intensity in soft tissue, I is the time-averaged intensity measured in water.

2.9.1 TI

TI is defined as the ratio of the In Situ acoustic power (W.3) to the acoustic power required to raise tissue temperature by 1°C (W_{deg}),

$$TI = W.3 / W_{deg}$$

Three TIs corresponding to soft tissue (TIS) for abdominal; bone (TIB) for fetal and neonatal cephalic; and cranial bone (TIC) for pediatric and adult cephalic, have been developed for applications in different exams. An estimate of the acoustic power in milliwatts necessary to produce a 1°C temperature elevation in soft tissue is:

$$W_{deg} = 210 / fc$$

For model 1 to 4, where fc is the center frequency in MHz.

$$W_{deg} = 40 \cdot K \cdot D$$

For model 5 and 6, where K (beam shape factor) is 1.0, D is the aperture diameter in cm at the depth of interest.

2.9.2 MI

Cavitation is more likely to occur at high pressures and low frequencies in pulse ultrasound wave in the tissue, which contains a bubble or air pocket (for instance, the lung, intestine, or scan with gas contrast agents). The threshold under optimum conditions of pulsed ultrasound is predicted by the ratio of the peak pressure to the square root of the frequency.

$$MI = Pr' / sqrt(fc)$$

Pr' is the de-rated (0.3) peak rare-fractional pressure in Mpa at the point where PII is the maximum, and fc is the center frequency in MHz. PII is the Pulse Intensity Integral that the total energy per unit area carried by the wave during the time duration of the pulse. The peak rare-fractional pressure is measured in hydrophone maximum negative voltage normalized by the hydrophone calibration parameter.

2.9.2.1 Display Guideline

Thermal Index (TI) consists of two indices: soft tissue (TIS) and bone (TIB). TIB is only displayed in non-scanning modes, such as M-mode, PW mode and CW mode. TIS is displayed in all scan

modes. The index is continuously displayed over a range of 0.1 to 6.0 in increments of 0.01. Mechanical Index (MI) is continuously displayed over a range of 0.1 to 1.9 in increments of 0.01.

2.9.3 Display and Report in Different Modes

2.9.3.1 For B-Mode

Display and report only MI and TIS

2.9.3.2 For Color Mode

Display and report only MI and TIS

2.9.3.3 For Doppler Mode

Display and report MI, TIS and TIB

Below is a simple guideline for the operator when TI exceeds one limit exposure time to $4^{(6\text{-TI})}$ minutes based on the *'National Council on Radiation Protection. Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms. Report No.113 1992'.*

2.9.4 Operator Control Features

The operator should be aware that certain operator controls may affect the acoustic output. It is recommended to use the default (or lowest) output power setting and compensate using Gain control to acquire an image. Other than the output power setting in the Soft Menu, which has the most direct impact on the power; the PRF (Pulse Repetition Frequency), image sector size, frame rate, depth, and focal position also slightly affect the output power. The default setting is normally around 70%, occasionally 90%, of the allowable power, depending on the exam type.

2.10 Transducer Surface Temperature Rise

The table below lists the measured surface temperature rise from ambient (23°C ± 3°C) of transducers used on the system. The temperatures were measured in accordance with EN 60601-2-37 cl.201.11 and cl.201.13 with controls and settings positioned to give maximum temperatures.

Table 12 Transducer surface temperature rise

Test	External use (°C)		
	P42B6	C62B	L154BH
Simulated use	1.4	1.5	
Still air	3.6	7.3	6.5

CHAPTER

3

Overview

Acquaint yourself with the system and its components in this chapter. This chapter covers the following topics:

3.1 System Capabilities

The T3300 Ultrasound System is intended for Obstetric imaging, Gynecology imaging, Cardiac imaging, Vascular imaging, and general imaging purpose, and related analysis. The system can be used for 2D grayscale (B-Mode), M-Mode, Color, Power, PW and CW imaging depending on the transducer. The system also supports duplex, and triplex imaging. The system provides measurement tools, analysis options, and DICOM network capabilities. Refer to the following standard features.

3.1.1 Imaging

The following scan modes and features are available, if supported by the transducer for the application:

- B-mode
- M-mode
- Color Doppler
- Power mode
- PW mode
- CW mode
- Tissue Harmonic Imaging (THI)
- QScan image processing
- SQBeam Real-time Compound Imaging
- FQBeam Real-time Compound Imaging

WARNING

The system does not support the biopsy guide function. Do not use nor assemble any kind of needle guide kits/brackets on the supported transducer to avoid transducer damage or hurting the patient.

3.1.2 Transducer Types

The available transducer types are a curved linear array transducer, a linear array transducer and a phased array transducer. Applications for specific transducers are listed in "Indications for Use and Supporting Transducers" on page 29.

3.1.3 Measurements

The system provides tools and controls for measuring distance, ellipse, angle, trace and IMT. After you perform measurements, the system makes the pertinent calculations and organizes the measurements, calculations, and patient information, which can be added into a patient report.

3.1.4 Calculations

Calculations are organized by applications supported by the system. The system uses measurement values to perform calculations which can then be added into a patient report.

3.1.5 Image Acquisition and Review

You can acquire and review single images and cineloop sequences. Images and cineloop sequences can be stored on USB devices, or sent over a wireless network to an archive server, or printed out from supported external printers.

3.1.6 Connectivity

The following features are standard:

- Patient Data and Settings export to removable media
- USB and Bluetooth connectivity to peripheral devices such as a Keyboard (not supplied with the system)
- HDMI connectivity to secondary monitors
- Printing to local/network printers
- Wireless and Wired networking
- DICOM networking
- Patient data imported from MWL server
- Image export to network storage

3.2 System Overview

3.2.1 Front and Side Views

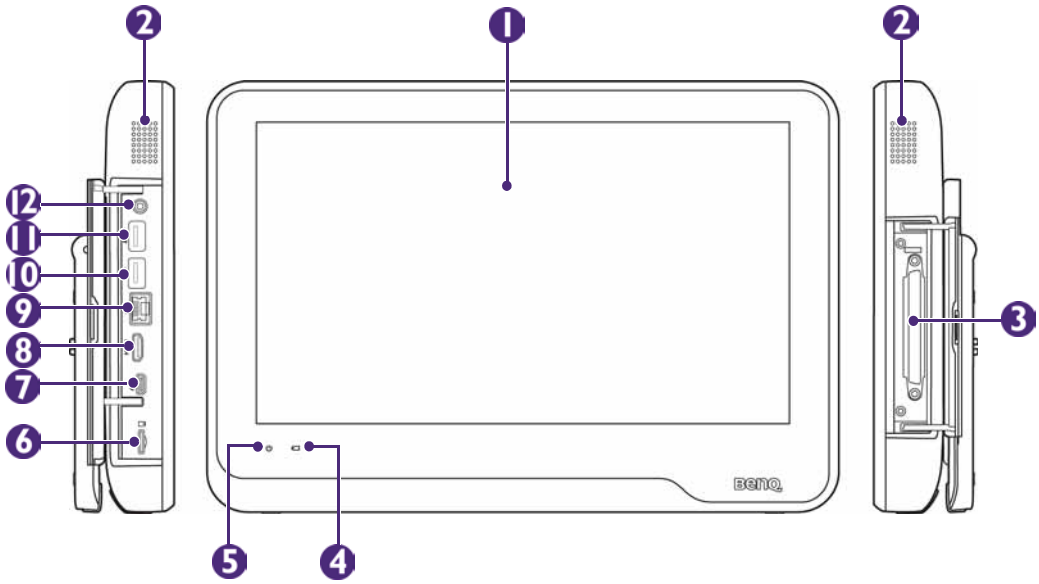


Table 1 Front and Side Views

No.	Component	Function
1	Touch screen	Display system information and allow you to perform operations using different gestures.
2	Speakers	Built-in speakers for playing sounds, which are software-controlled.
3	Transducer connection socket	Connect a transducer to the system. (See page 34)
4	Battery indicator	When the system is connected to power: • If the system is turned off or enters sleep mode, the battery indicator behaves in the following lighting patterns: – Steadily on orange when the battery is charging. – Steadily on green after the battery is charged. • If the system is turned on, the battery indicator lights off. To monitor the battery level, see "Battery Status Icons" on page 53.
5	Power indicator	Blink blue after the system enters Sleep mode. (See page 52)
6	MicroSD card slot	Insert a microSD card into the microSD card slot to exchange data from/to the system. (See page 32)
7	AUX port	For use by authorized service personnel only
8	HDMI port	Connect the system to an HDMI (High-Definition Multimedia Interface) device. (See page 39)

Table 1 Front and Side Views

No.	Component	Function
9	Ethernet socket	Connect the system to an Ethernet-based network. (See page 54)
10	USB 2.0 port	Connect the system to USB 2.0 devices, such as keyboards, pointing devices, or portable storage devices.
11	USB 3.0 port	Connect the system to USB 3.0 devices, such as keyboards, pointing devices, or portable storage devices.
12	Headphone jack	Connect the system to an audio device, such as headphones or speakers.

NOTE

The system supports access to only one external storage device at a time. If you connect more than one external storage device, they function in the following priority order: USB 3.0 > USB 2.0 > microSD card.

3.2.2 Rear and Top/Bottom Views

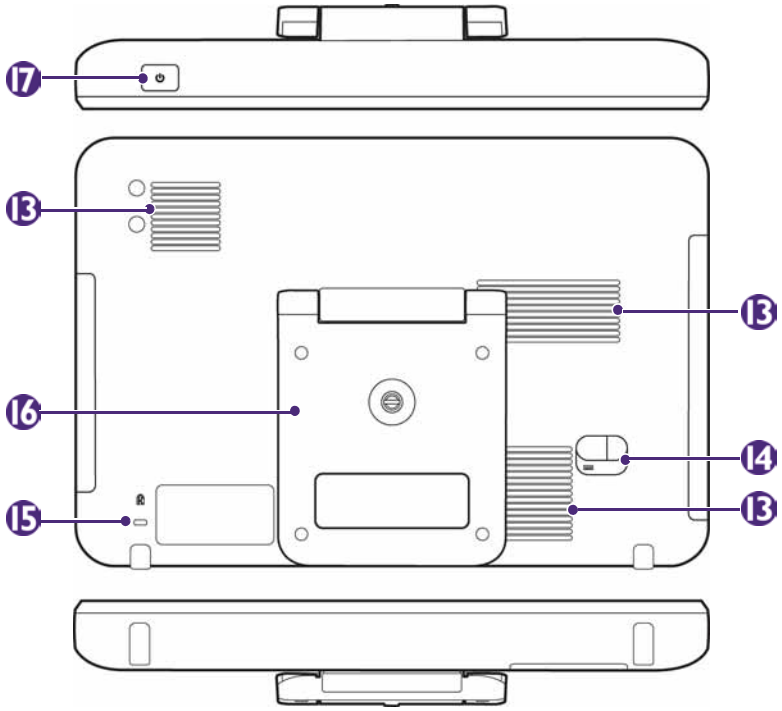


Table 2 Rear and Top/Bottom Views

No.	Component	Function
⑬	Ventilation slots	Release excessive heat during operation to keep the system in a safe operating temperature.
⑭	Power input socket	Used to connect the system to power. (See "Charging the System" on page 33)
⑮	Anti-theft lock slot	Used to lock the system securely to a solid surface to protect it from theft.
⑯	System stand	• Lift the stand to sustain the system on a flat surface. (See "Using the Stand" on page 33) • Can be used as a handle to carry the system around. (See "Using the System On The Go" on page 37)
⑰	Power button	Press and hold the Power button to turn on/off the system.

3.3 Transducer Overview

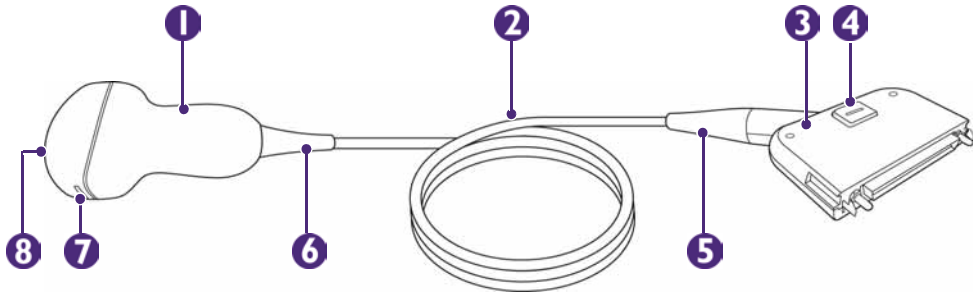


Table 3 Transducer overview (Example transducer: C62B)

No.	Component	No.	Component
1	Transducer handle	2	Transducer cable
3	Transducer connector	4	Release latch
5	Connector strain relief	6	Transducer strain relief
7	Orientation marker	8	Transducer lens

NOTE

Use only transducers that are approved by BenQ Medical Technology for use with the system.

3.3.1 Clinical Applications and Transducers

A clinical application, available for one or more transducers, optimizes the system for a specific application. A clinical application consists of exam-specific presets, and the corresponding measurement and calculation packages.

The clinical applications for each transducer available for the system are listed in the following table.

Table 4 Clinical Applications and Transducers

Transducer	Clinical Applications
P42B6	Cardiac
C62B	Abdomen, OB, Renal, Urology, GYN
L154BH	Carotid, Arterial, Venous, Thyroid, Breast, MSK, Nerve

For more information, see "Indications for Use and Supporting Transducers" on page 29.

3.4 Indications for Use and Supporting Transducers

The T3300 Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiology, Gynecology, Obstetric, Breast, Thyroid, Vascular (Carotid, Venous, Arterial), Nerve, Renal, Urology and so on.

The following table provides Diagnostic Ultrasound Indications for Use Forms for the transducers offered with the T3300 Diagnostic Ultrasound System.

Table 5 Indications for Use and Supporting Transducers

Indications for Use	Supporting Transducers
Cardiac Adult	P42B6
Obstetric	C62B
Musculoskeletal (Conventional)	L154BH
Peripheral Vessel	L154BH
Small Parts (Breast, Thyroid)	L154BH
Urology	C62B
Abdomen	C62B

CHAPTER

4

Preparing the System

Follow the information and procedures in this section to help you prepare the system for use.

This chapter covers the following topics:

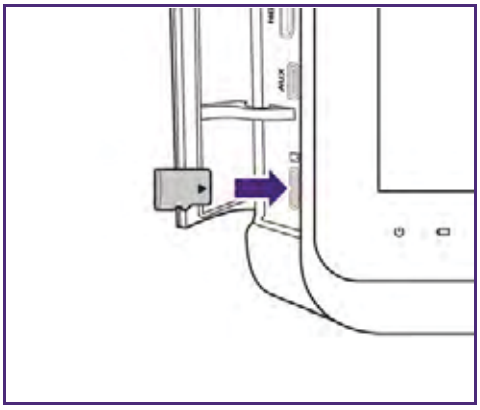
4.1 Inserting a microSD Card

Use the microSD card to import/export data to/from your system, such as patient information or user settings.

NOTES

- Supported microSD card format: SDXC (up to 128GB); SDHC Class 10 (up to 32GB)
- The microSD card is not supplied with the system.
- You can also use external USB 2.0 or 3.0 flash drives to import/export data through USB ports. Both the microSD card and the USB flash drives must be formatted in FAT32 format.

1. Flip the port cover open.
2. Align the microSD card with the mark next to the microSD card slot.
3. Fully insert the microSD card into the card slot until it clicks into place.

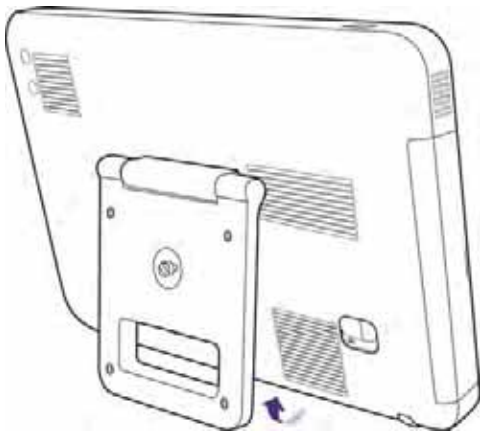


NOTES

- You can use the system's service tools to back up system settings and patient data when the system is connected to an external storage device. For more information, see "Backing Up System Settings and Patient Data" on page 92.
- The system supports access to only one external storage device at a time. If you connect more than one external storage device, they function in the following priority order: USB 3.0 > USB 2.0 > microSD card.

4.2 Using the Stand

Lift the stand to the degree that suits your preferred viewing angle.

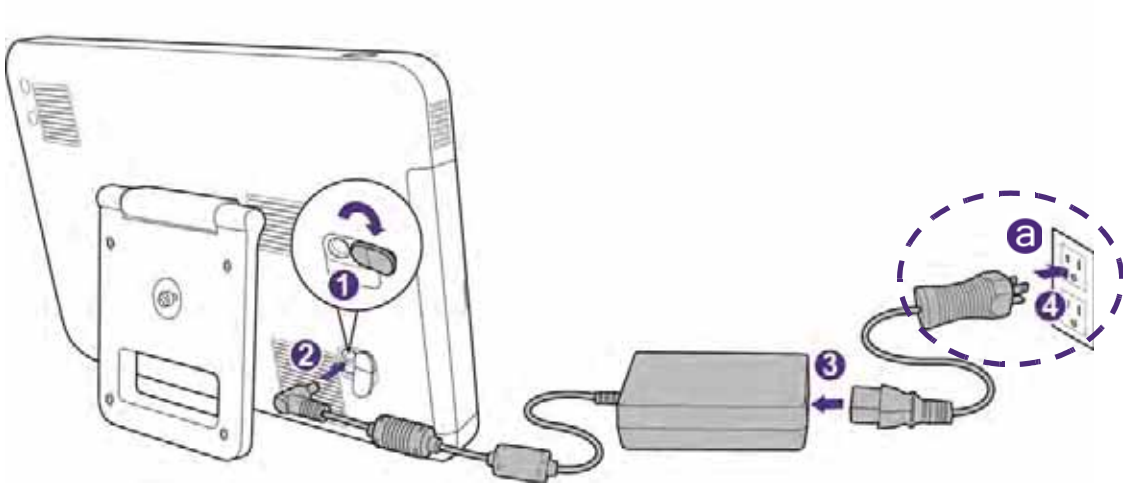


4.3 Charging the System

The system is only partially charged when first unpacked. Charge the battery fully for 5 hours before using the system for the first time.

WARNINGS

- **Use only the supplied power adapter and AC plugs for charging.**
- **AC plug and electric outlet types vary by country/region ⓐ.**
- **Do not try to repair or replace the battery or the power adapter. Any attempt to disassemble the system and the supplied accessories may cause damage to the system or result in personal injury.**



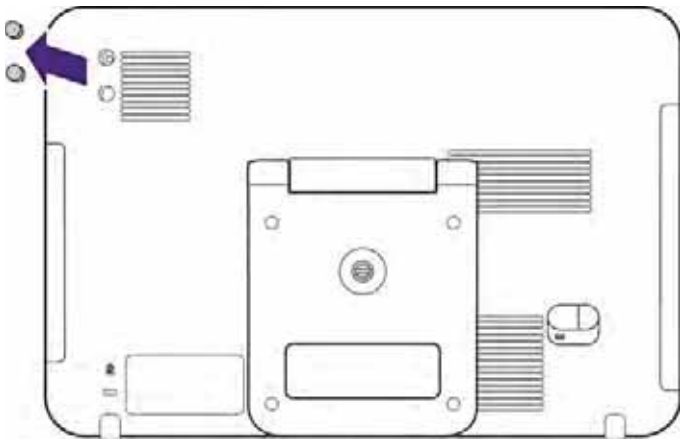
1. Lift the protective rubber cover open.
2. Connect the power adapter's connector into the system's power input socket.
3. Insert the matching AC plug fully into the power adapter.
4. Plug the AC plug of your power adapter into an electric outlet to start charging. The battery indicator lights up in solid orange.

WARNINGS

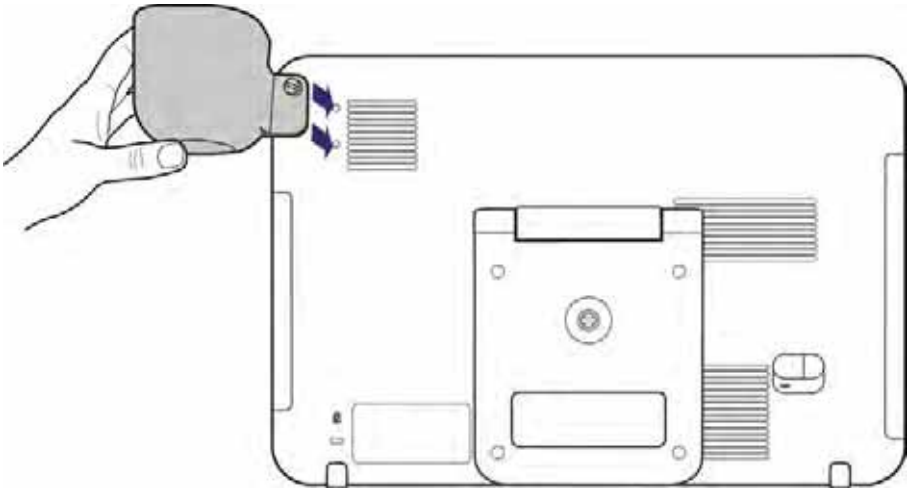
- **Keep good ventilation during charging. Do not cover the power adapter with paper or objects that will reduce cooling.**
- **Do not interrupt the connection during charging to avoid possible damage.**

4.4 Installing the Transducer Holder

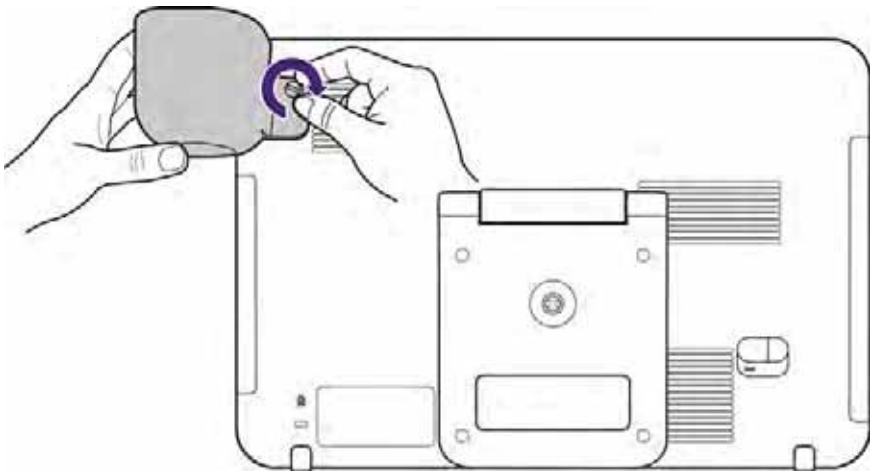
1. Use your fingertip to remove the protective rubber covers from the rear side of the system.



2. Align the hole on the transducer holder with the hole patterns of the system.

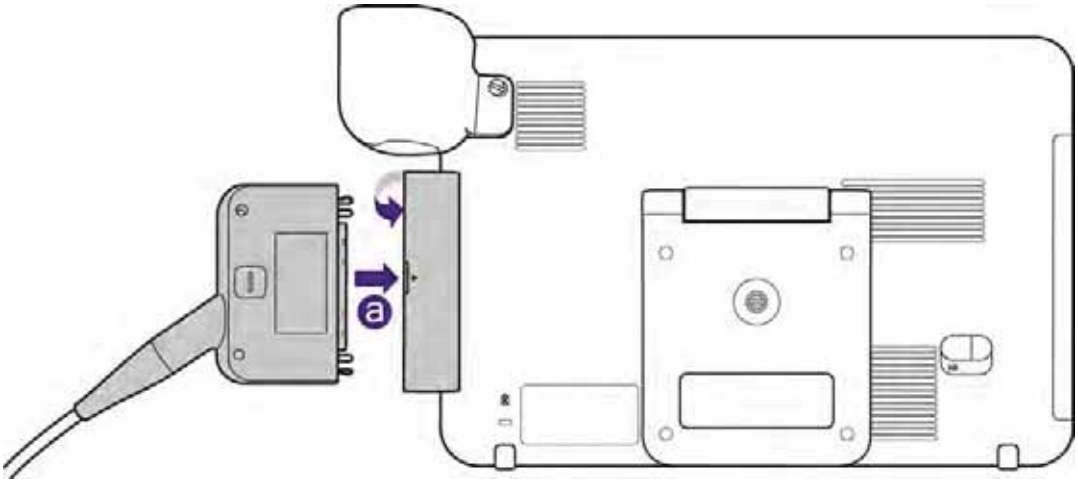


3. Rotate the screw clockwise through the upper hole of the transducer holder to tighten the transducer holder to the system.

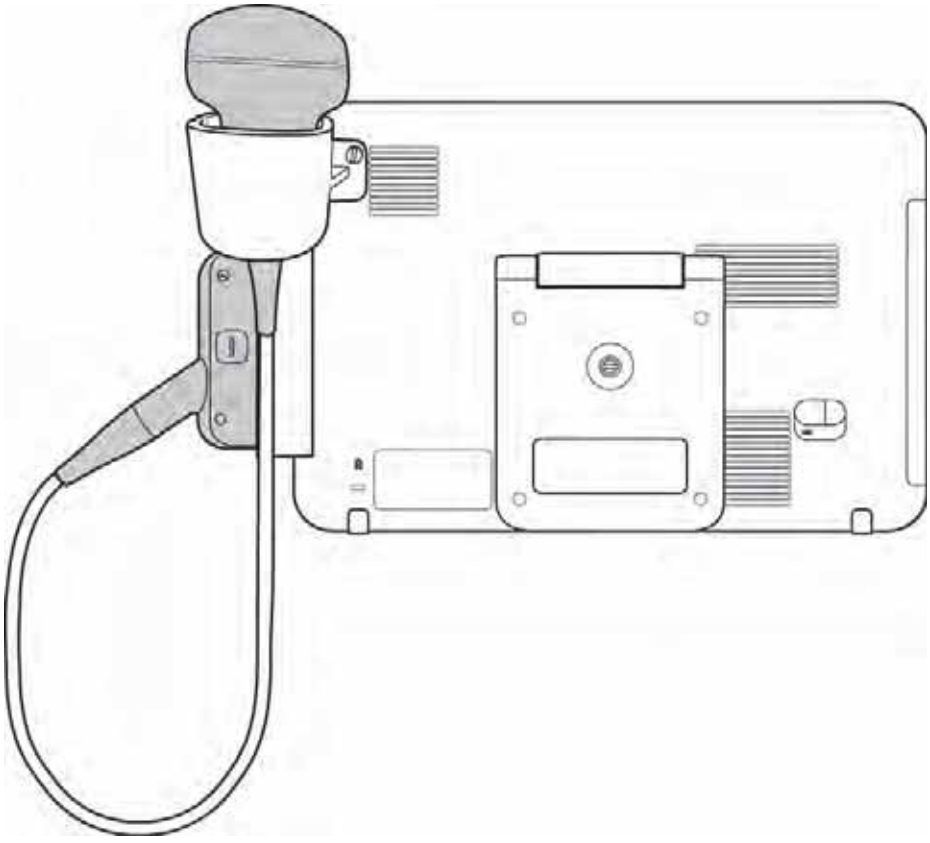


4.5 Connecting the Transducer

1. Flip the transducer cover open ⓐ and insert the transducer carefully into the transducer connection socket until it is locked in place.

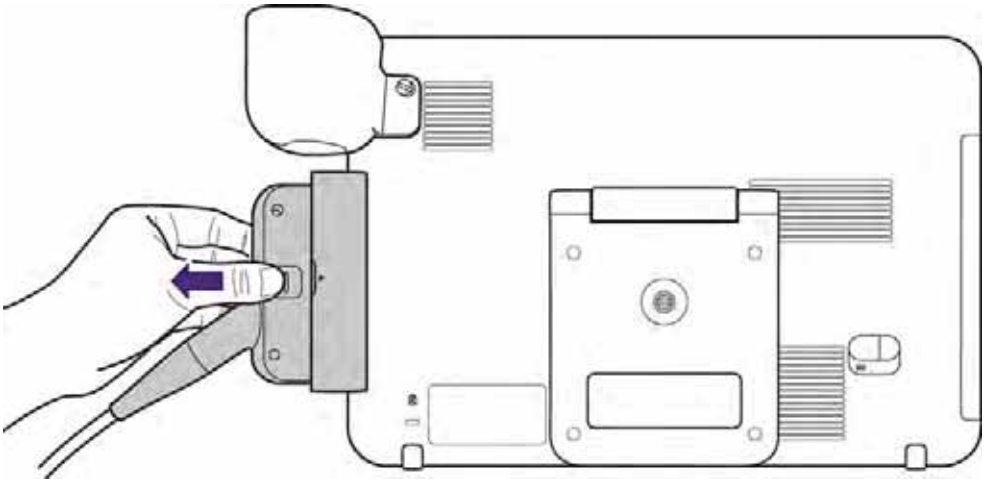


2. Place the transducer in the transducer holder and ensure that the cable hangs down smoothly from the opening of the transducer holder.



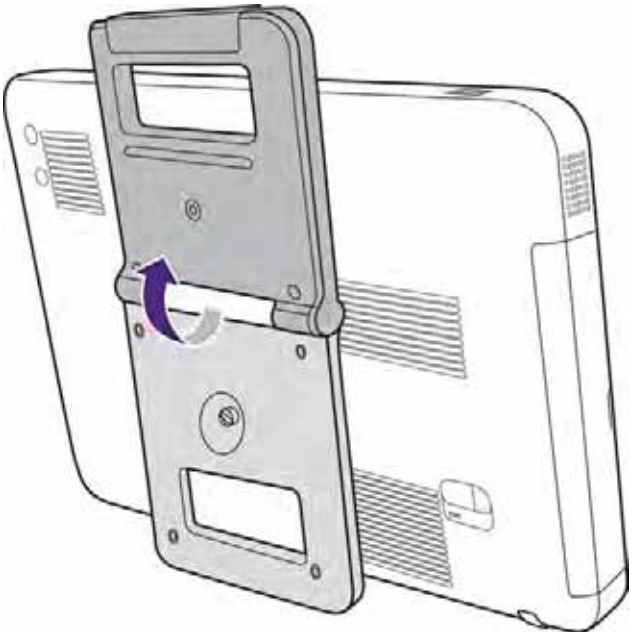
4.6 Removing the Transducer

Press and hold the release latch, and carefully pull out the transducer.

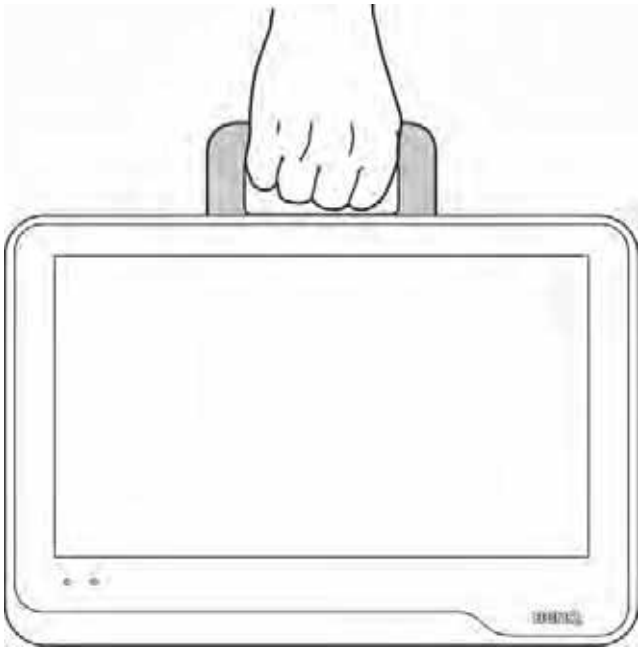


4.7 Using the System On The Go

1. Lift the stand by 180 degrees.



2. Use the stand as a handle to carry the system around.

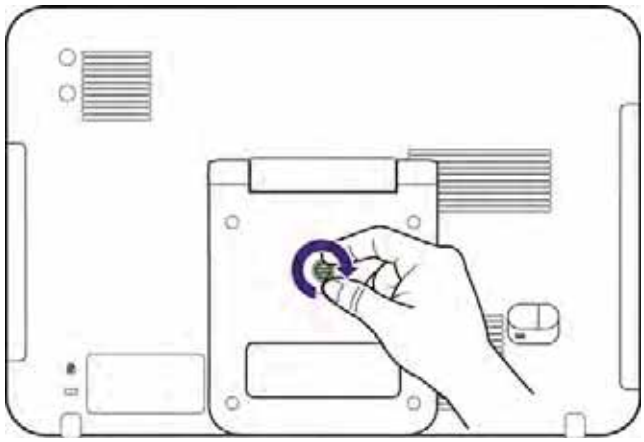


3. To release the handle from 180 degrees, apply a pulling force to overcome the resistance in the magnetic field.

4.8 Wall-mounting Your Tablet

The hole pattern on the rear side of the tablet is compliant with VESA (75mm x 75mm/100mm x 100mm) standard. Therefore, you can install your system on any VESA wall mounts or desktop mounts.

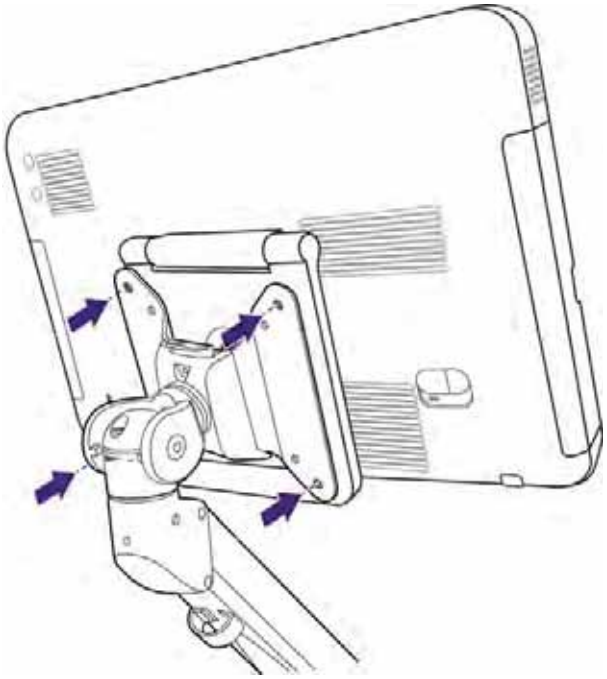
1. Rotate the fixed screw clockwise on the rear side of the stand to fix the stand firmly onto the tablet.



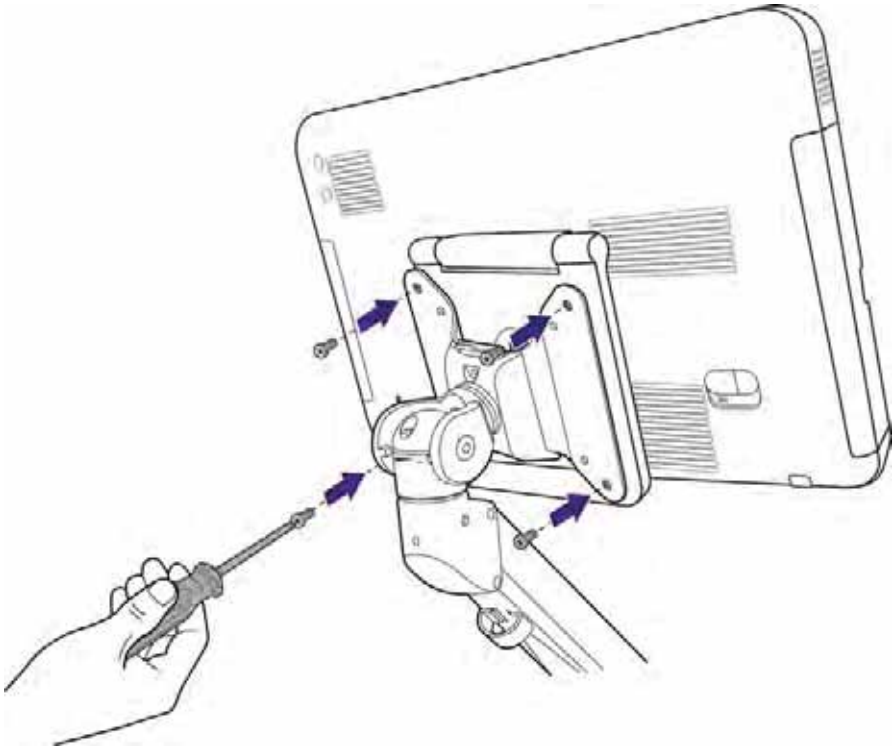
NOTE

To facilitate your operation without scratching the touch screen, lay the system face-down on a cushioned surface before fixing the stand.

2. Position the system precisely to the front of the mount plate where the hole patterns on both the back of the system and the plate meet.



3. Secure the system to the mounting plate by carefully tightening the four screws using a suitable screwdriver.



NOTE

Wall-mounting is suggested to be operated by two people.

4.9 Outputting the System Display to an HDMI-Enabled TV or Monitor

1. Insert one end of an HDMI cable to the system's HDMI port. Ensure that the arrow side faces up.
2. Insert the other end of the HDMI cable to your HDMI-enabled TV's or monitor's HDMI port.
3. Connect the TV or monitor to power.
4. On the TV or monitor, select the proper input source.

NOTES

- We suggest using a monitor or TV which supports 1080p (1920x1080) resolution as an external display for your system.
- See the documentation of your HDMI-enabled TV or monitor for detailed information on connections and settings.

CHAPTER

5

Using the System

Before performing an ultrasound exam, understand and learn the features of the system.

This chapter covers the following topics:

5.1 Turning On/Off the System

Press and hold the Power button to turn on the system. The system enters the main screen after system startup.

Press and hold the Power button until the **Power off** menu appears on the screen, then touch **OK** to turn off the system.

NOTES

- If the system is turned off abnormally, powering on the system the next time will take longer than usual for a system hardware check.
- If the system does not respond to any operations, press and hold the Power button to forcefully turn off the system.
- As the number of files saved in the system storage increases, the time it takes to power on the system will take longer than before. Consider backing up files and freeing up disk space regularly or when you are informed to do so **(See "Managing Disk Space" on page 53)**.

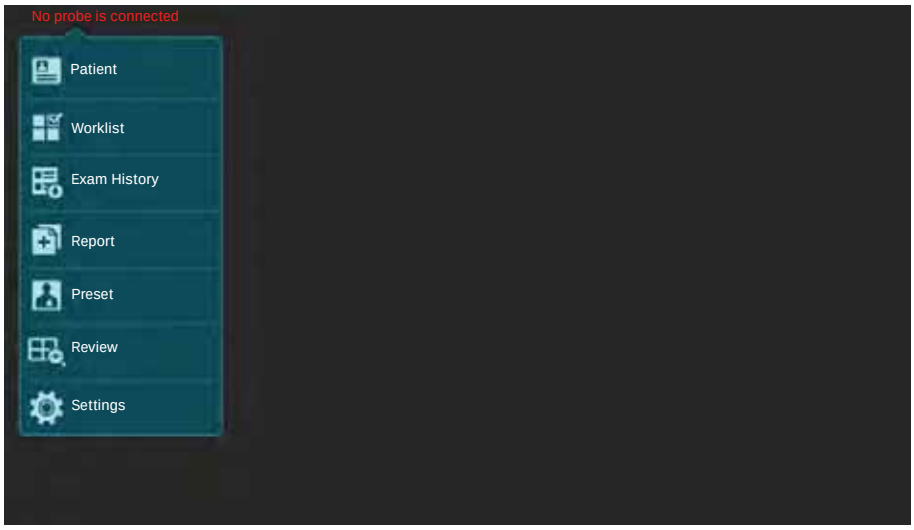
WARNING

If an error message occurs after system startup, follow the on-screen instructions to fix the problem. If the problem persists, contact technical support **(See "Contact Information" on page 2)**

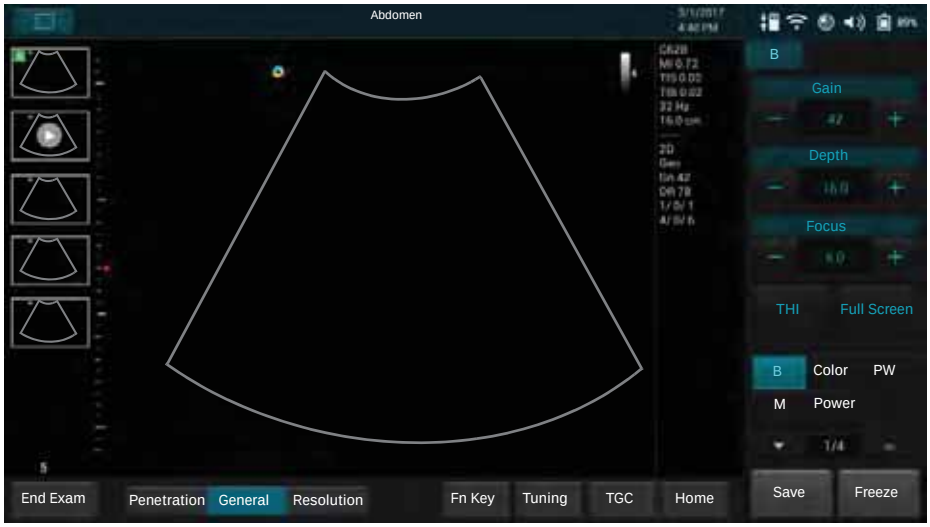
5.2 Launching the Main Screen

After turning on the system, one of the following main screens appears.

- If no transducer is connected, the system enters the system menu screen.



- If a transducer is connected, the system enters the real-time B-mode imaging screen (default).



NOTES

- If a transducer is connected and the system displays the message "**No probe is connected**", remove then re-connect the transducer. If the system still cannot detect the transducer, turn off the system. Wait for a few seconds and restart the system.
- You can choose the screen to enter after starting and logging in the system (with the transducer connected). Go to > **Settings** > **Workflow** > **Screen after Enter Ultrasound**.

5.3 Setting the System Time and Date

Managing pertinent patient data and scanning results require accurate system time and date. After entering the system for the first time, set current time and date based on your location. The system then maintains time and date settings even when the system is turned off and disconnected from power.

1. Touch anywhere on the system toolbar to open the Quick Setup menu (See page 50).
2. Touch the Time section > **Set date/Set time**.
   – To set the date, scroll to select the date, month and year.
   – To set the time, scroll to select the hours, minutes, and AM or PM.
3. Touch **Done**. Touch to leave the setting.

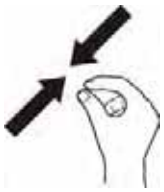
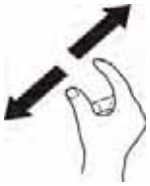
NOTE

Check and correct current system time and date based on your location every month to ensure the accuracy.

5.4 Controlling the System

The system requires operations with multi-touch controls by finger movements called gestures. Alternatively, you can add pointing or input devices by connecting them to the USB ports on the system.

Table 1 Gestures

Touch	Touch and Hold	Drag
		
Double-Tap	**Press and Tap**	**Two-Finger Tap**
		
Flick	**Pinch**	**Spread**
		

5.4.1 Gestures for Controlling the Real-time/Frozen Imaging Screens

Table 2 Gestures for Controlling the Real-time/Frozen Imaging Screens

Action	Gesture
Toggle between Real-time and frozen imaging screens	Double-tap on the scan area. To use this gesture, go to > **Settings** > **General** > (**Enable freeze gesture**) > **Yes**.
Save a single image/cine loop	(Available in full screen mode only) • Touch and hold on the scan area of the real-time/frozen imaging screens to save a cine loop/single image. • On the frozen imaging screen, two-finger tap on the scan area to play an image loop, then touch and hold on the scan area to save the image loop.
Zoom/unzoom	Spread two fingers apart/pinch two fingers together.
Move the zoomed image	Touch and hold the zoomed image until the navigation button appear, then drag to move the image.
Move and resize ROI	Touch inside the ROI and drag to move it. Touch on the four corners of the ROI and drag to resize it.
Move the BDMK/ annotatioN/Arrow indicators	Touch and hold the indicator, and drag to move it.
Scroll the thumbnail list	Flick vertically on the thumbnail area to scroll through the thumbnail list.
Display the second control panel page/Return to the first control panel page	On the control panel area, flick up to display the next page, flick down to return to the previous page (See "Switching the Control Panel Pages" on page 52).

5.4.2 Gestures for Controlling the Real-time Imaging Screen

Table 3 Gestures for Controlling the Real-time Imaging Screen

Action	Gesture
Adjust depth	Flick vertically on the scan area to increase (flick down) or decrease (flick up) depth.
Adjust gain	Flick horizontally on the scan area/time series window to increase (flick right) or decrease gain (flick left).
Adjust the sample volume size	1. Touch and hold one finger on the Spectral Doppler cursor. 2. Flick another finger up or down.
Move the Spectral Doppler cursor/sample volume	• Touch the Spectral Doppler cursor and drag it horizontally. • Touch the sample volume and drag it vertically.
Adjust the PW/CW correction angle	1. Touch and hold one finger on the Spectral Doppler cursor. 2. Flick another finger to the left or right.
Adjust the PW/CW baseline	1. Touch and hold on the baseline. 2. Flick vertically to change the baseline position.

5.4.3 Gestures for Controlling the Frozen Imaging Screen

Table 4 Gestures for Controlling the Frozen Imaging Screen

Action	Gesture
Play/pause image loops	(Available in full screen mode only) Two-finger tap on the scan area.
Scroll frames	(Available in full screen mode only) Flick horizontally on the scan area/time series window to scroll through the image frames/ waveforms.

5.5 Setting the System Language

To set the system language you are using, touch  > **Settings** > **General** > **Language**. The system reboots automatically to enable the new language.

NOTE

If you are unsure of a function displayed in localized languages, switch the system language back to English, and check again the function you want to use. If the problem persists, contact technical support (See "Contact Information" on page 2)

5.6 Identifying the Main Screen Layout

5.6.1 System Menu Screen

Touch  to display the following system menu screen. Touch an icon to perform its function.

Table 5 Function and Description of System Menu

NO.	Function	Description
1	**Patient**	Edit current or add new patient information.
2	**Worklist**	Load the DICOM Modality Worklist (MWL) that contains patient information as well as the requested procedure electronically via the MWL query.

Table 5 Function and Description of System Menu

NO.	Function	Description
3	Exam History	View a list of patients with their exam results. You can proceed with unfinished exams/reviews, or export exams according to the selection criteria all at once.
4	Report	Display exam information including patient data, exam type, study specific data, comments and saved ultrasound images.
5	Preset	Select the predefined preset compatible with the connected transducer for optimized image control settings.
6	Review	View, add annotations and measurements to, and export a saved exam.
7	Settings	• Customize the system based on the operator's habitual needs. • Use the service tools to update software, backup/restore data or examine the system functionality. (See "Servicing your system" on page 90)

5.6.2 Imaging Screen (Real-time)

With the transducer connected correctly, the system enters the real-time imaging screen each time after pressing the **Home** button.

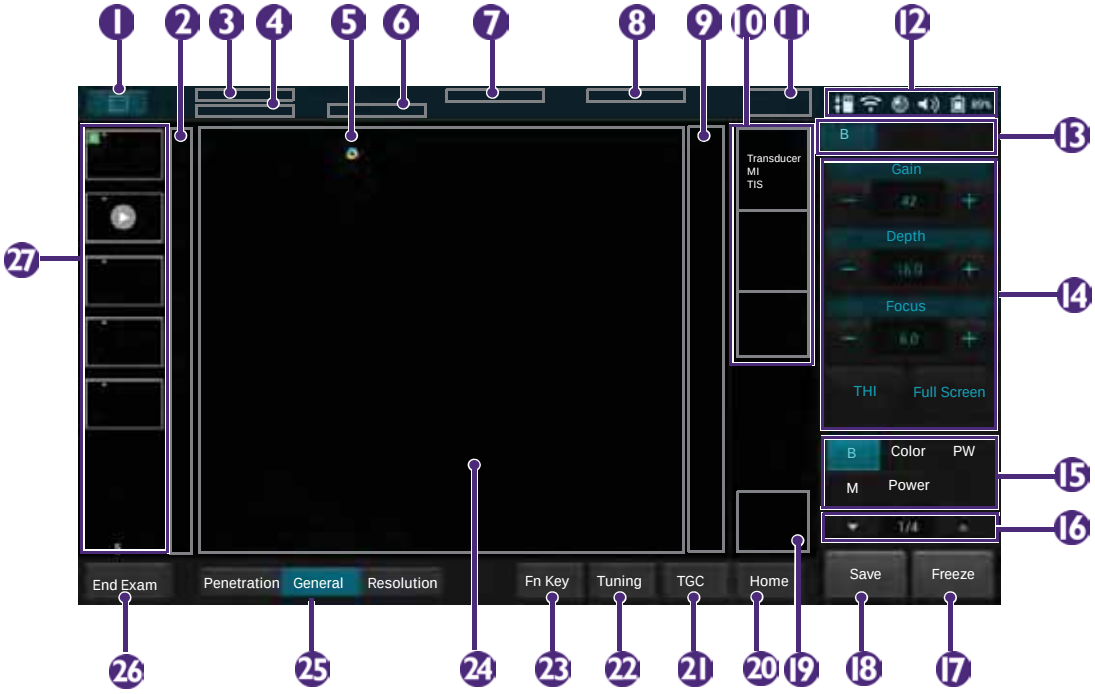


Table 6 Real-time Imaging

No.	Function
1	System menu button Enter the system menu screen.
2	Depth scale

Table 6 Real-time Imaging

No.	Function
❸	Patient name
❹	Patient ID
❺	Transducer orientation icon (See page 62)
❻	Patient age/gender/DOB (date of birth)
❼	Application name
❽	Institution name
❾	Grayscale/Color/Power wedge
❿	Scan Properties Display Display information about the current scan.
⓫	Current date and time
⓬	System toolbar Display information about current battery level, volume, system storage, and network connection status. Touch anywhere on the system toolbar to open the Quick Setup menu for system configuration. (See page 50)
⓭	Scan mode (image control) buttons When using duplex or triplex modes, touch the scan mode (image control) buttons here to display and adjust its corresponding image control settings - ⓮ .
⓮	Image control settings (See page 79)
⓯	Scan mode buttons
⓰	Open the next/previous page of the image control settings (See page 44).
⓱	**Freeze** button Freeze the current scan.
⓲	**Save** button* Save a default set of image frames as a loop to the system hard drive.
⓳	ROI (region of interest) area Use the **Zoom** function to zoom in and pan across the current image.
⓴	**Home** button Return to the real-time imaging screen in B-Mode.
㉑	**TGC** (Time Gain Compensation) Slide any of the 8 TGC sliders to adjust the gain for the desired section of the 2D image.
㉒	**Tuning** button Touch this button to enable optimizing the image quality during a real-time scan. To turn it off, press and hold the button.
㉓	**Fn Key** button Assign this button as a shortcut to perform a function.

Table 6 Real-time Imaging

No.	Function
24	Ultrasound imaging area Display the 2D imaging window in all scan modes. By default, the top area is close to the region located near the transducer surface (near field). When scanning in M-Mode/PW Doppler/Triplex modes, the Time Series window displays under the 2D imaging window. The time increases from left to right and re-starts from the left again. The imaging area displays as common usage.
25	• **Resolution** (High Resolution): Touch this button to view a clearer yet superficial image. • **General** (General Resolution): Touch this button to view a general resolution image. • **Penetration** (Deep Penetration): Touch this button to view a deeper yet less clear image.
26	**End Exam** button Close the current exam for the current patient, and start a new exam for the next patient. All the value settings adjusted during this exam will be stored automatically.
27	Thumbnail area Thumbnails of the scanned images/loops that are saved. Flick vertically to scroll through the list.

*The system does not allow acquiring images/loops with no patient name and ID. A patient name/ID will be added automatically if you proceed with saving.

5.6.3 Imaging Screen (Frozen)

During an exam, touch **Freeze** to review all the ultrasound images stored in the cine buffer frame by frame, or play back these frames in a continuous loop. You can also measure, calculate and add annotations to the frozen images or loops.

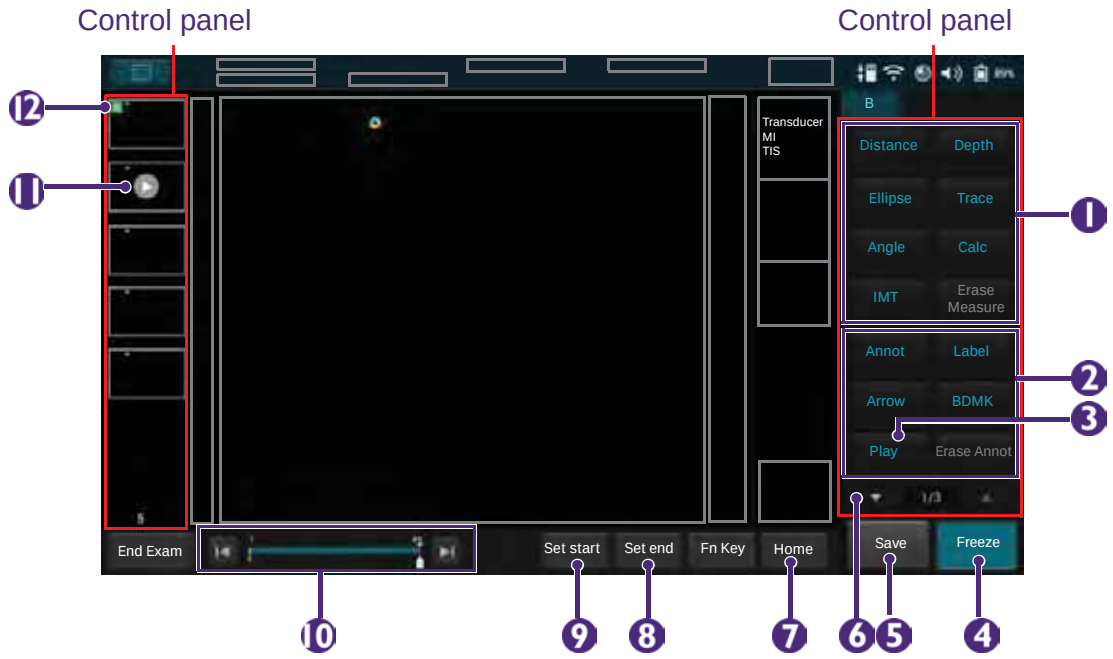


Table 7 Frozen Imaging

No.	Function
❶	Perform measurements and calculations on the current image.
❷	Add annotations, including arrows, texts and body marks, to the current image using the Virtual Keyboard.
❸	**Play** button Review the image loop just scanned. Touch repeatedly to start/pause the playback.
❹	**Freeze** button (Enabled) Touch this button again to return to the realtime scan.
❺	**Save** button Save a frozen image from an image loop to the system hard drive.
❻	Open the next/previous page of the image control settings. (See page 52)
❼	**Home** button Return to the real-time imaging screen.
❽	**Set End** button During playback of the image loop, touch this button to set the end point of the image loop.
❾	**Set Start** button During playback of the image loop, touch this button to set the start point of the image loop.
❿	The progress bar Used to track the frames (in a continuous image loop) just scanned and the number of the current frame.
⓫	Image loop.
⓬	This image is added to a report.

5.6.4 Quick Setup

Touch anywhere on the system toolbar to open the Quick Setup menu. Touch an item to adjust its setting.

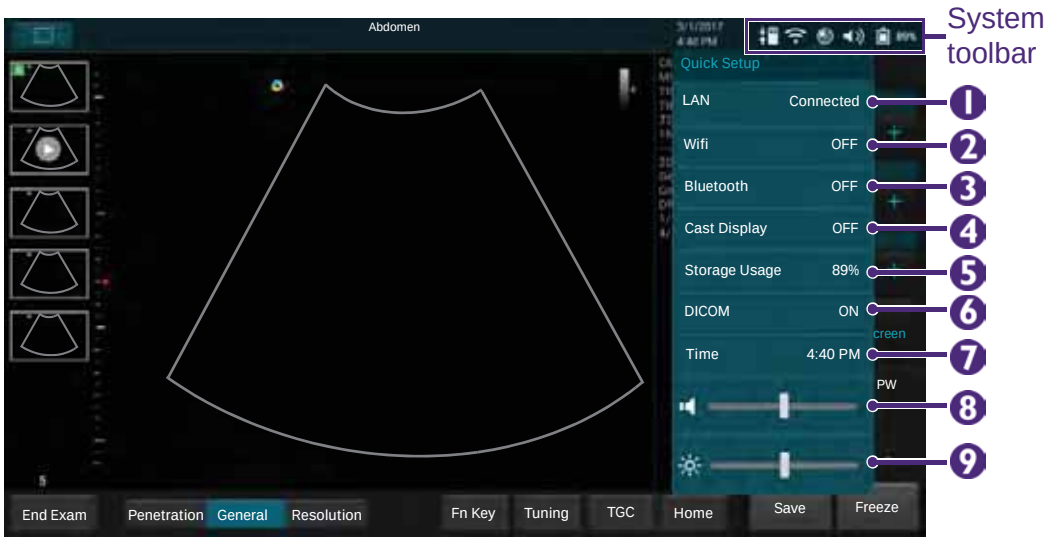


Table 8 Quick Setup

No.	Function
1	Manage the LAN connection. (See page 54) • : LAN Disconnected • : LAN Connected
2	Enable/disable the WiFi function. (See page 54)
3	Enable/disable the Bluetooth function. (See page 55)
4	Cast the system screen to an external display. (See page 57)
5	Display the percentage of the system storage used. (See page 53) • : Storage usage empty • : Storage usage full
6	Check and manage outgoing queues to the DICOM server. (See page 55) • : DICOM Disconnected • : DICOM Connected
7	Set current date and time. (See page 42)
8	Adjust the volume.
9	Adjust the brightness.

5.6.5 Virtual Keyboard

Whenever you need to enter text in a text field, simply touch the field, and a virtual keyboard appears on the lower part of the screen. Touch a letter to enter text; when finishing inputs, touch anywhere on the imaging area.

NOTE

To switch the keyboard input language, touch on the virtual keyboard and select your target language.

5.6.6 Scan Properties Display

The imaging window includes a text display information about the current scan.

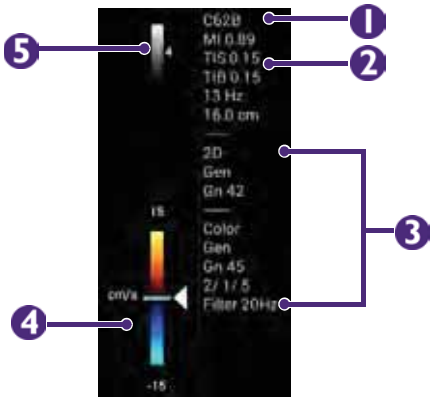


Table 9 Scan Properties Display

No.	Function
1	Transducer type
2	Thermal index/Mechanical index
3	Depending on the transducer connected and the scan mode selected, corresponding scan parameters are displayed. (See "Using Image Controls" on page 78)
4	Color/Power wedge
5	Grayscale wedge

5.7 Switching the Control Panel Pages

Use the virtual buttons or gestures to switch the control panel pages.

NOTE

The functions available on the control panel vary, depending on the scan mode and the transducer connected.

- Use button:

Touch to switch between control panel pages

- Use gestures:

5.8 Managing the System Power

The system receives its power from the power adapter whenever it is connected to the system and starts charging the battery, unless the battery is fully charged already. Battery remains charging even when the system is turned off, as long as the adapter is connected to the system and to AC power. The system can also operate on battery power. The battery status icon (See page 53) along with the percentage of battery power remaining are shown on the system toolbar (See page 50). Always monitor the power level of the battery when you operate the system on battery power.

5.8.1 Battery Status Icons

The battery level is indicated by icons shown on the system toolbar.

Table 10 Battery status

Battery status icon	Meaning
	The battery is fully charged.
	The battery is 80% to 99% charged.
	The battery is 60% to 79% charged.
	The battery is 40% to 59% charged.
	The battery is 20% to 39% charged.
	The battery is critically low.
	The battery is charging.
	The battery cannot be identified.
	Battery temperature is too high or too low and the battery stops charging.

NOTE

When the battery level reaches a critically low state, the system shuts down automatically.

5.8.2 Sleep Mode

Sleep mode is a low-power mode that conserves battery power and allows quick startup of the system.It should be used only for short periods of time, such as when you transport the system between exam locations.

To enter/exit Sleep mode, press the Power button.

5.9 Managing Disk Space

Always beware of the amount of free space in the system storage. If the disk space on the system drive is full, the system cannot acquire images. To check the system storage used, open the Quick Setup menu and watch the number of percentage next to **Storage Usage**.

The system sends warning messages when its available disk space reaches any of the following level:

- **The image storage is low**: The disk space available for storing images is low. Delete some stored exams to ensure that there will be enough room for new images.

- **The image storage extremely low**: The disk space available for storing images is critically low. Immediately delete some stored exams to free up your disk space.
- **The image storage is full**: No disk space is available and no images can be saved. You must delete stored exams in order to have space for acquiring new images.

To free up storage space, go to > **Settings** > **Exam**, and delete stored exams before selected number of weeks. Please back up required patient information before deletion. Deletion will remove the information from the system.

5.10 Network Configuration

The system network is configured from the Quick Setup menu (See page 50). The configuration information for the system includes the IP address, port number, and other attributes required for transmitting images and other study data across a network. The system network must be configured before you use either the standard network support or the capabilities available through the DICOM networking options.

5.10.1 Connecting the System to the Network by Ethernet

1. Connect one end of the network connection cable to the wall receptacle for your network.
2. Connect the other end of the cable to the Ethernet socket on the system.
3. On the imaging screen, open the Quick Setup menu (See page 50).
4. Touch **LAN** to go to Ethernet settings.
5. Check **Ethernet** to enable the Ethernet function. If your system does not use Dynamic Host Configuration Protocol (DHCP) to specify the addresses of domain name servers, continue to the next step.
6. Touch **Ethernet configuration**. Touch **Static IP** and configure the DNS settings.

NOTE

Consult your network administrator about the appropriate settings.

7. Touch **Save**. Touch to leave the setting. If the connection is successful, appears on the system toolbar.

5.10.2 Connecting the System to the Wireless Network

NOTES

- Wireless connection quality can be affected by many factors. The system may experience a connection interruption while a network job is in progress. If this occurs, the job remains in the job queue. When the connection is restored, the system resumes the job automatically.
- The system supports the following wireless security standard: WEP, WPA/WPA2 and WPS. It is your responsibility to configure the wireless network security mechanisms that are compatible with your network.

1. Perform either of the following operations to go to the wireless network settings:
   - Touch > **Settings** > **Networking** > **Wifi Configurations** > **ON**.
   - Open Quick Setup menu (See page 50). Touch **Wifi** to go to Wifi settings.
2. On the available network list, select an access point on an existing wireless network with your DICOM server, and enter the required settings.

NOTE

Consult your network administrator about the appropriate settings.

3. Touch to leave the settings. If the connection is successful, appears on the system toolbar indicating the network strength.

5.10.3 Connecting the System to a Bluetooth Device

You can connect the system to another pointing or input device via Bluetooth.

NOTES

- Using features requiring a Bluetooth connection may consume more battery power.
- To extend battery life between charges, turn off Bluetooth when not using it.
- Maximum distance between two connected Bluetooth devices cannot exceed 5 meters.

1. Open the Quick Setup menu (See page 50).
2. Touch **Bluetooth** to go to Bluetooth settings.
3. The system scans for and displays the IDs of available Bluetooth devices within range.
4. Touch the ID of the Bluetooth device to pair with it.
5. Confirm the passkey that appears and touch **Pair**. On the other Bluetooth device, accept the identical passkey for pairing.
6. Touch to leave the settings. Once your system pairs with the device, appears on the system toolbar, and they stay paired until you unpair them.

5.10.4 Unpair a Bluetooth Device

Touch beside the connected device you want to unpair, and touch **Unpair**.

5.11 DICOM Configuration

The system conforms to the Digital Imaging and Communications in Medicine (DICOM) standard. DICOM format is used for patient studies that are transferred among PACS, which make up a hospital information management system, and for studies that are accessed by physicians at remote viewing stations.

The DICOM networking option settings are usually obtained from a network administrator.

NOTE

Before DICOM configuration, ensure that the system is successfully connected to a wireless or wired network.

To configure DICOM settings, touch > **Settings** > **DICOM**.

5.11.1 Adding Servers

1. Select a storage/worklist SCP (Service Class Provider) and touch **Edit**.
   - **Storage SCP**: Used to take responsibility for and provide receipt of content sent by the system.
   - **Worklist SCP**: Contain scheduled patient procedure data and is used to import the data into the patient information form.
2. Assign a name to the server and enter it in the **Name** field.

3. Enter the **IP Address**, **Port** and **AE Title** specified by your network administrator in the respective fields.
4. To test the server connection, touch **Test** in the **Echo Test** section. A verification message confirms a successful connection within a few seconds.

NOTES

- To start exams by loading patient information in a worklist, you need to configure the worklist SCP first.
- Consult your network administrator about the appropriate settings.

5.11.2 Local Host

In the **Local Host** section, touch **Edit**.

The system's default **Name** and **IP Address**, if connected successfully to the network, display in the respective fields.

In the **AE Title** field, enter the application entity title of your system, which identifies you as the sender and must be unique on its network.

NOTE

Consult your network administrator about the appropriate settings.

5.11.3 Managing Outgoing Queue

When you export an exam or an image/video to the DICOM server, you can monitor its status on the upper right side of the imaging screen or in the outgoing queue (from > **Settings** > **DICOM** >(**Outgoing Queue**) > **Edit**). The system provides three ways of exporting the exam. For more information, see "Exporting the Exam" on page 75.

Table 11 Task status

Task status icon*	Description
	Upload is pending.
	Upload is processing.
	Upload is complete.
	Upload failed.

*If you export the report to the DICOM server, the task status icon includes R.

In the Outgoing Queue section, touch **Edit**.

- To re-send the task to the DICOM server, touch **Retry**.
- To cancel the ongoing task, touch **Stop**.
- To clear all tasks from the outgoing queue, touch **Clear all history**.

5.12 Casting the System Screen to an External Display

You can cast your system screen which allows you to mirror your system to a monitor or TV that supports wireless display function.

1. On your system, open the Quick Setup menu (See page 50). Touch **Wifi** to enable the wireless network function. Then touch **Cast Display Off** to go to its settings.
2. On the top right corner of the system screen, touch  and check **Enable wireless display**  to see your available wireless display devices in a list. Touch the device to connect to.
3. On the display device, follow the on-screen instructions to give permission for connection from and to the system.
4. If connected successfully, the device name on the system screen shows “Connected”. The contents shown on the system screen are mirrored to the display device screen automatically.

NOTE

To disable the casting display function:

On the system, open the Quick Setup menu and touch **Cast Display Off** > the device name > **Forget**.

CHAPTER

6

Performing an Exam

To perform an exam, complete the general procedure:

1. Start an exam. It can be a new exam, or a previously saved/paused exam.
   - To start a new patient exam, add a new patient (See page 59).
   - To load a work list (See page 60).
   - To resume a previously saved/paused exam (See page 75).
2. Select an exam type and preset (See page 60).
3. Start real-time imaging (Imaging Screen (Real-time)).
4. Set the transducer orientation (See page 62).
5. Select a scan mode (See page 62) and adjust image controls (See page 78).
6. When the desired anatomy is shown, freeze the image (Imaging Screen (Frozen)).
7. Add annotations (See page 65) and measurements (See page 68).
8. Save or print the image (See page 72).
9. (Optional) Review the images (See page 72), generate a report and export the exam (See page 75).
10. End the exam (See page 77).

Refer to the following sections for detailed instructions.

6.1 Starting a New Exam

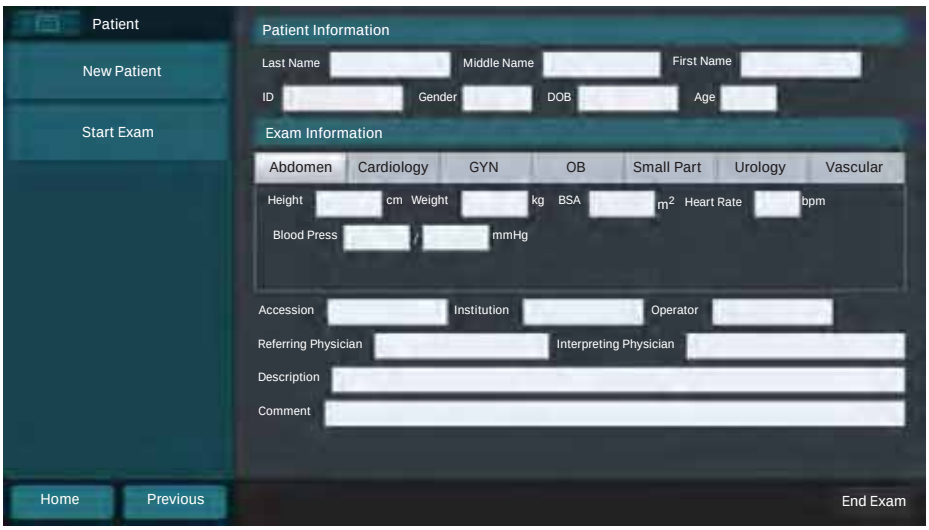
The system allows skipping entering patient information if you need to start the ultrasound exam immediately. You can enter the Patient screen to complete the patient information during or after the exam. However, once you touch **Save** to save images/cine loops, the system will add a last name/ID to the patient automatically, and the last name/ID cannot be modified.

NOTE

To avoid confusion and to generate reports, define the patient within the system before scanning.

6.2 Adding a New Patient

1. On the imaging screen, touch > **Patient**.



2. Touch **New Patient**. Enter the patient information as much detailed as possible:
   - Touch in a text entry field, and use the virtual keyboard to input contents.
   - Touch **Next** on the keyboard to go to the next field.
   - Touch **Done** on the keyboard. The patient information is saved automatically.

NOTE

To create a valid patient profile, at least the patient's **Last Name** and **ID** number should be filled in.

3. To start scanning the patient, touch **Start Exam**.

6.2.1 Updating Patient Information

1. During real-time scanning, touch > **Patient**. Existing information of the current patient displays on the Patient screen.
2. Enter the new information in the desired fields.
3. The patient information is saved automatically. Proceed with real-time scanning of this patient by touching **Start Exam**.

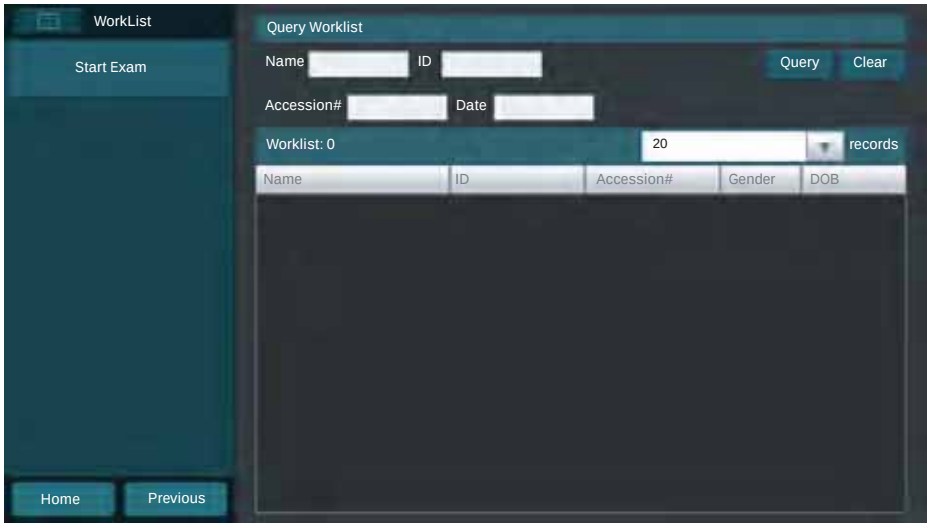
6.3 Loading a Worklist

The system conforms with the Digital Imaging and Communications in Medicine (DICOM) standard, which is the industrial standard for the communication and management of patient data between devices in the hospital. You can load patient information in a worklist via the DICOM server.

NOTE

For more information on configuring DICOM settings, see "DICOM Configuration" on page 55.

1. On the imaging screen, touch > **Worklist**.



2. Select the number of patients to scan on the worklist from the drop-down menu.
3. Select a patient, then touch **Start Exam** to start scanning.

NOTE

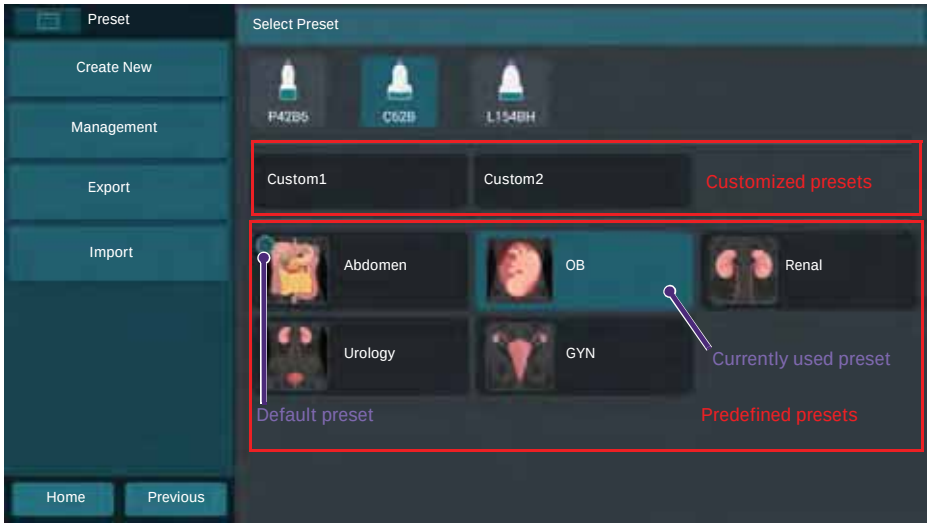
To scan patients following a specific rule, enter the query criteria in any of the **Name** / **ID** / **Accession#** fields, and touch **Query** to start the query. Patients matching the query criteria will be listed on the screen.

6.4 Selecting a Preset

The system provides predefined presets for all supported transducers. Choosing an exam loads optimized presets for image control settings, based on the anatomy to be scanned, the transducer used, and the scan mode. The presets also specify the measurements appropriate for the exams.

You can directly use the optimized presets, or adjust any of the image control settings as necessary for the specific patient and the specific exam.

1. On the imaging screen, touch > **Preset**. All the available presets compatible with the connected transducer display on the Preset screen.



2. Touch the preset to scan, and you will be redirected automatically to the real-time imaging screen.

6.4.1 Customizing a Preset

1. On the Preset screen, touch **Create New**.
2. Enter a name for the customized (currently used) preset and touch **Save**.

6.4.2 Modifying a Preset

If you have modified the parameters of an existing customized preset, go to the Preset screen and touch **Modify Current** to save changes.

6.4.3 Managing Presets

1. On the Preset screen, touch **Management**.

- Touch **Move**, and drag to re-arrange the order of the presets.
- To set a frequently used preset as default, touch **Set default** > the desired preset.
- To hide an unwanted predefined preset, touch **Hide & Show** and touch **Off** on the preset.
- To further edit customized presets, touch **Edit** and touch on the preset to edit its name; touch on the unwanted preset to delete it.

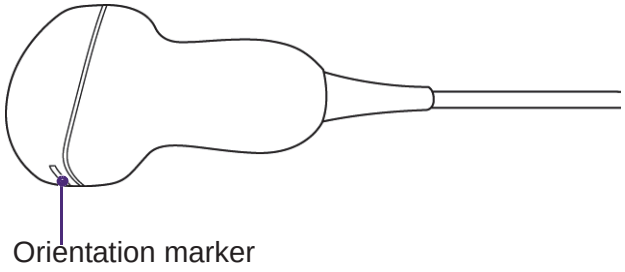
2. Touch **Save** to save changes.

6.4.4 Exporting and Importing Customized Presets

On the Preset screen, touch **Export/Import** to export/import customized presets to/from your external storage.

6.5 Setting the Transducer Orientation

Upon entering all scan modes, the orientation marker displays at the default location (usually at the top left side of the image), and suggests you the direction of holding the transducer. The orientation marker on the screen corresponds to the position of the orientation marking on the side of the transducer.



You can change the left/right orientation of the image (real-time or frozen) in various imaging (single or dual) without rotating the transducer head itself.

- To reverse left and right

  On the imaging screen (real-time or frozen), touch ▼ > **L/R**.

- To reverse up and down

  On the imaging screen (real-time or frozen), touch ▼> **U/D**.

6.6 Selecting/Switching a Scan Mode

On the real-time imaging screen, directly touch the scan mode buttons on the control panel to select/switch the scan mode in use.

NOTE

To view a list of available scan modes, see "Imaging" on page 24.

6.7 Adjusting the Displayed Image

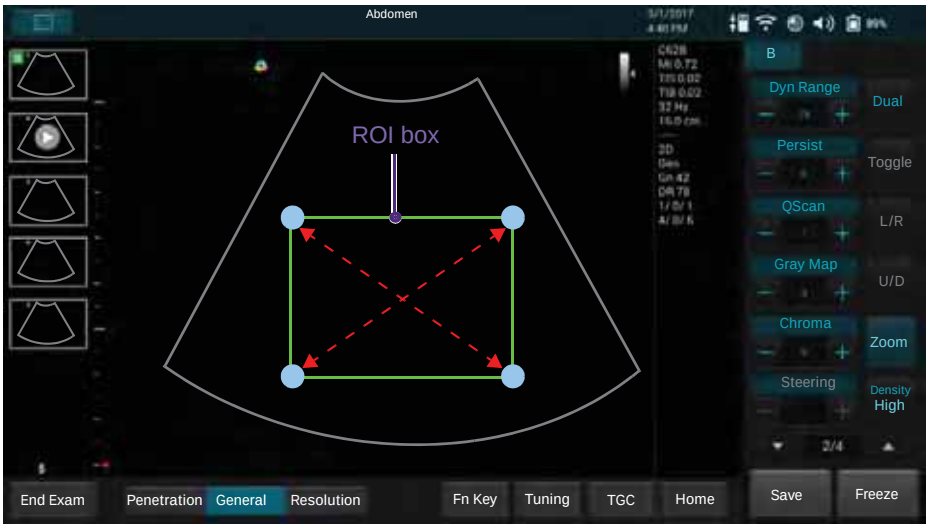
On the real-time imaging screen, touch the corresponding scan mode (image control) button to select a scan mode. Use the image control settings to further optimize the image. (See "Using Image Controls" on page 78)

You can also perform the following operations to adjust the contents of the imaging window.

6.7.1 Enlarging an Area of the Image

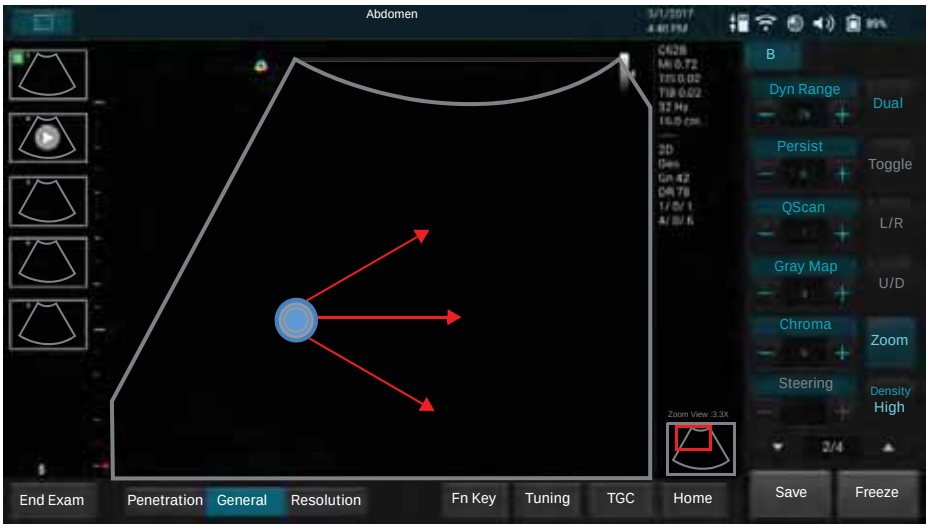
To further examine the anatomy by enlarging a region of the image (real-time or frozen), use the zoom function.

1. On the real-time imaging screen, touch ▼> **Zoom**, or on the frozen imaging screen, touch ▼> **Zoom**. The ROI (Region of Interest) box appears on the center of the image.



Touch and drag inside of the ROI box to move it to the area to enlarge. Touch on any of the box's four corners and drag to resize the ROI box.

2. Touch anywhere outside the ROI box to enlarge the selected area.



3. To move the enlarged area, touch and hold anywhere on the image until the navigation button appear, then drag to move it.

6.7.2 Splitting the Imaging Screen

The system allows splitting the imaging screen into two sections to view two current scans for a patient. You can acquire one scan for the patient, enable dual screen, then acquire another scan from a different angle, location or with a different scan mode. This function is only available in B, B+Color and B+Power modes.

6.7.2.1 When in B-Mode:

On the real-time imaging screen, touch **Dual**. The system immediately freezes the current scan, and copies the current settings for the image to the second screen. Two yellow bars will be added to the

top/bottom of the currently active screen. To toggle between screens, touch **Toggle**. Only one screen can be active at a time.

You can compare then apply any image control settings and use scan modes independently to either screen. For example, you can acquire a 2D scan, activate dual screen, then acquire a Color scan in the second screen.

6.7.2.2 When in B+Color or B+Power Mode:

On the real-time imaging screen, touch **Dual**. The system copies the current settings for the image to the second screen in B-mode. Both screens are in real-time but you get a clearer view under the ROI in B-mode.

Touching **Dual** again freezes the 2D real-time scan and turns it into a frozen B+Color or B+Power mode image.

To leave the dual screen, touch **Dual**, or touch **Home** to return to the real-time B-mode.

NOTE

To enable dual screen when the scan is frozen, touch ▼> **Compare**.

6.8 Freezing an Image

During a real-time scan, touch **Freeze** to freeze live ultrasound images recorded by frame and stored temporarily in the cine buffer. Depending on the mode selected, a certain number of frames are recorded.

- To play back saved images in a continuous cine loop, touch **Play**.
- To adjust the playback speed, touch ▼ > **Loop Speed +/-**.
- To view the stored images frame by frame or to find a specific frame, touch / or drag the frame indicator horizontally.

NOTES

- To restart a new real-time scan, touch **Freeze** again.
- Restarting real-time scanning erases the frame data. Make sure any needed images are saved or printed before acquiring new scan data.
- To change the screen to enter after you freeze the scan, on the system imaging screen, touch > **Settings** > **Workflow** > (**Status after Freeze**) > select an option.

6.9 Adding Annotations

On the real-time or frozen imaging screen, touch **Annot** to add annotations to the ultrasound images in order to explain the anatomy.

After you are done adding annotations, you can still move the annotated texts or arrows anytime by touching and dragging them to your desired location.

NOTE

You can select whether to keep or erase the annotations added after you return to the live scan by touching > **Settings** > **Workflow** > (**Auto-clear Annotation after Unfreeze**) > select an option.

6.9.1 Arrow

Touch **Arrow**. An arrow appears at the text home position. Drag the arrow to the desired location, and release it to place the arrow (a).

6.9.2 Annot

6.9.2.1 Text

1. Touch **Annot**. A virtual keyboard and a text cursor (I-beam) appear at the text home position.
2. Type the texts directly. Touch anywhere on the imaging area to finish inputs.
3. Drag the text cursor to where you want the new texts to be, and release it to place the texts (b).

6.9.2.2 Setting the Text Home Position

You can choose a specified position in the image display as the starting location, which is the text home position.

1. Drag a set of annotated texts to the desired text home position.
2. Touch the texts directly, then touch  to close the keyboard.
3. Touch **Set home**.

6.9.3 Label

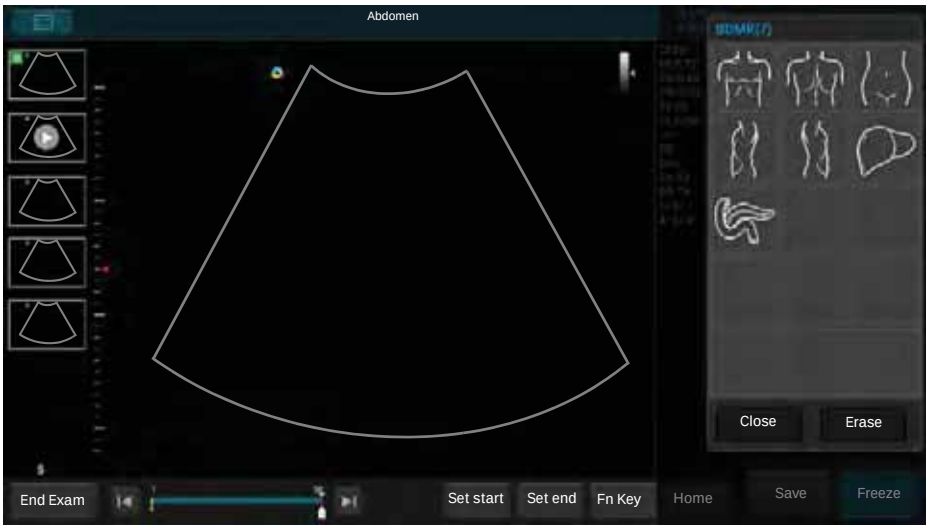
1. Touch **Label**. A predefined text menu appears at the control panel area (c), and a text cursor (I-beam) appears at the text home position.
2. Select a text label to place it at the current cursor position, and touch **Close**.
3. Drag the label to where you want the texts to be, and release it to place the label.

NOTES

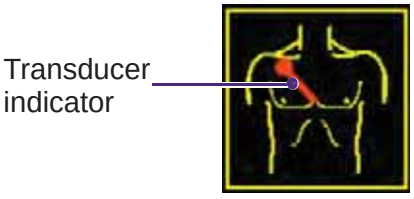
- The annotated texts or text labels are still editable. Touch a set of texts to display the virtual keyboard, and start editing the texts. Touch anywhere on the imaging area to finish editing.
- To restore the annotated texts or text labels to the default text home position, simply touch a set of texts, touch  to close the keyboard, then touch **Go home**.

6.9.4 Body Mark

1. Touch **BDMK** to display the body mark menu.



2. A pictogram of the default body mark with a transducer indicator displays on the image. If you wish to change the body mark, select one from the **BDMK** menu that appears, then touch **Close**.



3. Touch anywhere on the image, and drag the transducer indicator to the desired location on the body mark.
4. Touch anywhere on the image and move to rotate the transducer indicator.
5. Touch and hold the pictogram, and drag it to the desired location on the image.

NOTES

- You can change the default body mark by touching > **Settings** > **BDMK** >(**Default BDMK for Application**) > **Edit** > select an option.
- To delete annotations, including texts and arrows, touch **Erase Annot** to erase the last annotation added. Repeat this action, if needed, to continue erasing annotations.
- To directly erase all annotations, touch and hold **Erase Annot**.
- To delete the body mark added, touch **BDMK** > **Erase**.

- To set whether to show all or the last annotations, or to hide them all, touch > **Show Annot +/-**.

6.10 Adding Measurements

Measurements accompanying ultrasound images supplement other clinical procedures available to the attending physician. You can perform as many measurements as needed.

On the real-time imaging screen, touch **Freeze** to display a set of measurement buttons based on the scan mode selected. To perform a single type of measurement, touch the corresponding button. To perform a set of predefined measurements from the Calculation Package, touch **Calc** (See "Calculation Package" on page 70).

When you are measuring, the indicators/lines display in yellow, allowing you to adjust as many times as needed. When you are done with measuring, use any of the following methods to complete the measurement. The indicators/lines then turn green, and the final measured results (values) appear on the top left side of the imaging screen.

- Two-finger tap on the scan area
- Proceed with the next measurement
- Touch **Save** to save the ultrasound image

NOTES

- To re-position the measured results to the imaging screen's **Left Top**, **Left Bottom**, **Right Top**, or **Right Bottom** side, touch ▼ > **Result Pos +/-**.
- To set whether to show all or the last measured results, or to hide them all, touch ▼ > **Show Result +/-**.
- To delete measurements, touch **Erase Measure** to erase the last measurement added. Repeat this action, if needed, to continue erasing measurements.
- To directly erase all measurements, touch and hold **Erase Measure**.
- You can select whether to keep or erase the measurements added after you return to the live scan by touching > **Settings** > **Workflow** > (**Auto-clear Measurement after Unfreeze**) > select an option.

6.10.1 Measuring in B/Color/Power Modes

6.10.1.1 Distance

Measure a distance.

1. Touch **Distance**. A crosshair cursor appears on the image. Drag the target cursor to where you want to start measuring and release it.
2. Drag the target cursor to where you want to finish measuring, then release it (a).

6.10.1.2 Depth

Measure depth.

Touch **Depth**. A crosshair cursor appears on the image. Drag the target cursor to where you want to finish measuring the depth, then release it (b).

6.10.1.3 Ellipse

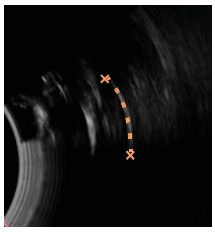
Measure a circumference.

1. Touch **Ellipse**. A crosshair cursor appears on the image. Drag the target cursor to one end of the area you want to measure and release it to set the start point of measurement.
2. Drag the target cursor to the other end of the desired area, and release it to set the end point of measurement.
3. Touch the center of the oval area and drag out to increase or drag in to decrease the size of the circle (c).

6.10.1.4 Trace

Manually trace an irregular shape.

1. Touch **Trace**. A crosshair cursor appears on the image. Drag the cursor to where you want to start measuring and release it.
2. Drag the cursor along the outline of the object to trace.



3. When the tracing is nearly done, release the cursor and the system completes the loop by drawing a line from the current cursor position to the starting point (d).

6.10.1.5 Angle

Measure an angle.

1. Touch **Angle**. A crosshair cursor appears on the image. Drag the target cursor to the desired location and release it to set the start point of measurement.
2. Drag the first target cursor along one side of the desired area, and release it to draw the first line.
3. Drag the second target cursor along the other side of the area, and release it to draw the second line. The angle between the two lines is then formed (e).

6.10.1.6 IMT

Measure IMT (Intima-Media Thickness) of the carotid artery, which is useful for detecting early signs of arteriosclerosis.

1. Touch **IMT**. A crosshair cursor appears on the image. Drag the target cursor to the desired location and release it to set the start point of measurement.
2. Drag the target cursor to the other end of the desired area, and release it to set the end point of measurement. The automatic tracing of the IMT will be enclosed and measured within the rectangle area marked by the four corners (f).

6.10.1.7 Calculation Package

Perform a set of predefined measurements based on the scan mode/calculation method you select.

1. Touch **Calc** to open the **Calculation Package** menu.
2. Touch a desired calculation method. The items to measure display in a list of order under the selected method.
3. Touch the first item and the screen displays the corresponding cursor. Drag it to perform measurement.
4. After you have finished with the measurement, touch the second item. The first item is checked automatically  with the measured result displayed beside it.
5. Repeat step 3-4 to perform the rest of the measurements on the list, then touch **Close**.

NOTES

For measurement accuracy and precision in 2D measurement:

- Linear distance measurement errors will be less than ±5%.
- Perimeter, and ellipse circumference measurement errors will be less than ±5%.
- Area measurement errors are related to the linear distance measurement and will be less than ±10%.

6.10.2 Measuring in M-Mode

6.10.2.1 Distance

Measure the length between two horizontal lines that lean on two cursors. The position of the vertical time lines does not affect the distance measurement.

1. Touch **Distance**. A crosshair cursor with horizontal and vertical axes appears on the time series window. Drag the cursor to a desired start point on the vertical axis and release it.
2. A second cursor appears. Drag it to the end point on the vertical axis then release it to complete measurement.

6.10.2.2 Slope

Measure the length between the intersections of two cursors. Slope can be positive or negative and measures the rate of change between the two points defined by the intersections of the cursors in cm/sec.

1. Touch **Slope**. A crosshair cursor with horizontal and vertical axes appears on the time series window. Drag the cursor to a desired start point and release it.
2. A second cursor appears. Drag it to the end point then release it to complete measurement.

NOTE

The slope measurement is not restricted to either the horizontal or the vertical axis of the start marker.

6.10.2.3 Time

Measure the length between two vertical time lines created by two cursors. The position of the horizontal distance lines does not affect time measurements.

1. Touch **Time**. A crosshair cursor with horizontal and vertical axes appears on the time series window. Drag the cursor to a desired start point on the horizontal axis and release it.
2. A second cursor appears. Drag it to the end point on the horizontal axis then release it to complete measurement.

6.10.2.4 Heart Rate

Measure the length between two vertical lines created by two cursors in beat per minute (BPM). The position of the horizontal distance lines does not affect the heart rate.

1. Touch **Heart Rate**. A crosshair cursor with horizontal and vertical axes appears on the time series window. Drag the cursor to a desired start point on the horizontal axis and release it.
2. A second cursor appears. Drag it to the end point on the horizontal axis then release it to complete measurement.

6.10.3 Measuring in Spectral Doppler Mode

NOTE

The measured results of performing Trace, Semi-Trace and Auto Trace vary depending on the transducer connected.

6.10.3.1 Velocity

Measure the blood flow velocity.

Touch **Velocity**. A crosshair cursor with vertical axis appears on the time series window. Drag the cursor to the measurement point, and release your finger to place it.

6.10.3.2 Trace

Manually trace the Doppler spectrum.

1. Touch **Trace**. A crosshair cursor with vertical axis appears on the time series window. Drag the cursor to a desired peak of the graph and release it.
2. A second cursor appears. Drag the cursor along the waveform on the graph to end diastole then release it.
3. A third cursor appears. Drag it to the second peak of the graph and release it to complete the trace.

6.10.3.3 Auto Trace

Trace the spectrum of Doppler waveforms.

Touch **Auto Trace**. The trace for the Doppler spectrum will be performed automatically with measurements calculated and displayed on the screen.

6.10.3.4 Semi-Trace

Trace the Doppler spectrum with better accuracy in the measurement calculation.

1. Touch **Semi Trace**. A crosshair cursor with vertical axis appears on the time series window. Drag the cursor to a desired peak of the graph and release it.
2. A second cursor appears. Drag it along the waveform to end diastole on the graph then release it.
3. A third cursor appears. Drag it to the second peak of the graph and release it
4. Touch anywhere on the imaging area to complete the trace.

NOTE

To obtain an accurate auto-trace and measurement result, a high-quality Spectral Doppler image with clean noise background is required.

6.10.3.5 2-Points Measurement

Used to perform a set of basic Spectral Doppler measurements which may include peak systolic velocity, end diastole velocity, mean velocity, time, slope, pulsatility index, resistive index, systolic/diastolic ratio, pressure half-time and maximum pressure gradient, depending on the transducer connected and the application selected.

1. Touch **2 pt. Meas**. A crosshair cursor with vertical axis appears on the time series window. Drag the cursor to a desired peak of the graph and release it.
2. A second cursor appears. Drag it to end diastole on the graph and release it. The measured results (values) appear on the screen.

NOTE

For measurement accuracy and precision in PW Doppler measurement:

Velocity measurement will be less than ±12%.

6.11 Saving and Printing the Image

After adding annotations/measurements to the image, you can save or print the image.

6.11.1 Saving an Image Loop

On the real-time imaging screen, touch **Save** to save a default set of frames as an image loop. The saved image loop will be displayed in the thumbnail list.

6.11.2 Saving an Image

On the frozen imaging screen, touch **Save** to save the current frame as an image. The saved image will be displayed in the thumbnail list.

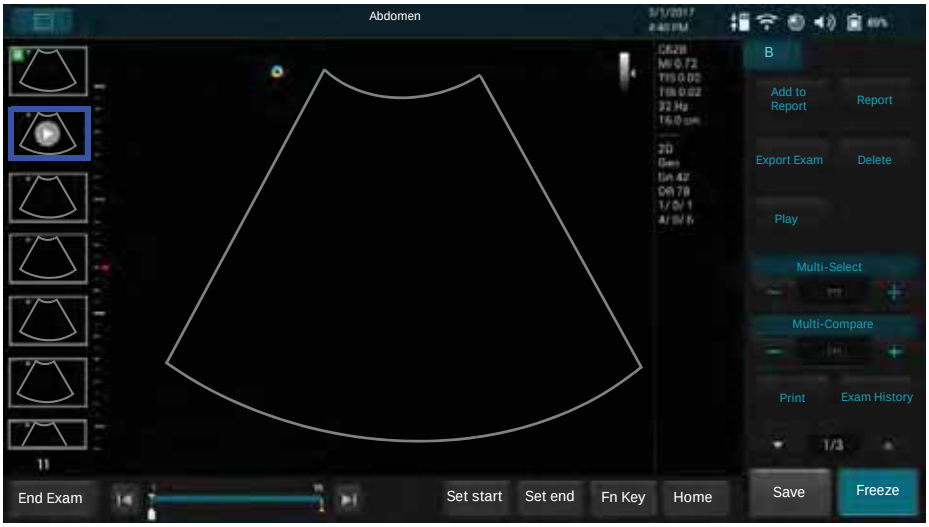
6.11.3 Printing an Image

On the frozen imaging screen, touch **Print** to print out the current image.

6.12 Reviewing the Image

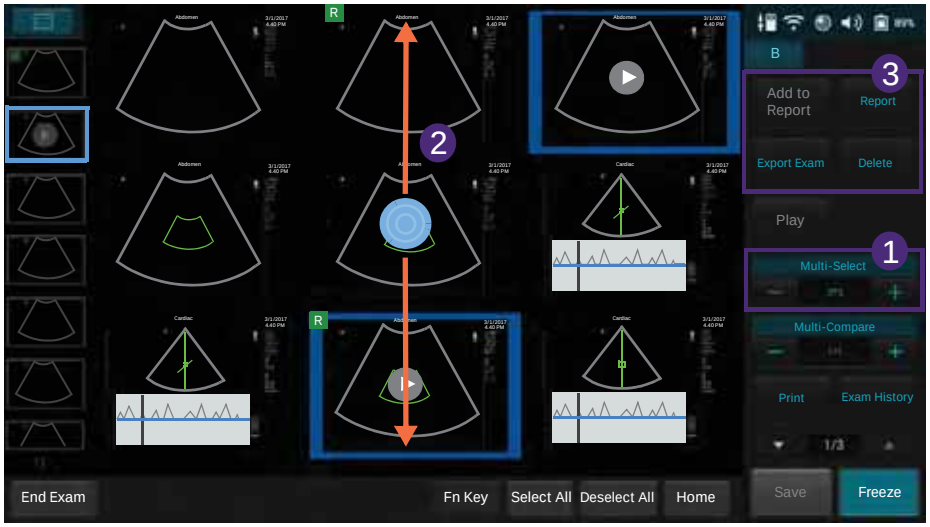
On the frozen imaging screen, flick vertically on the thumbnail list to view the thumbnails of all the saved images/loops.

To further examine one or a set of images/loops, touch the thumbnail of the desired image or image loop to display the Review screen.



6.12.1 Performing Multiple Selections

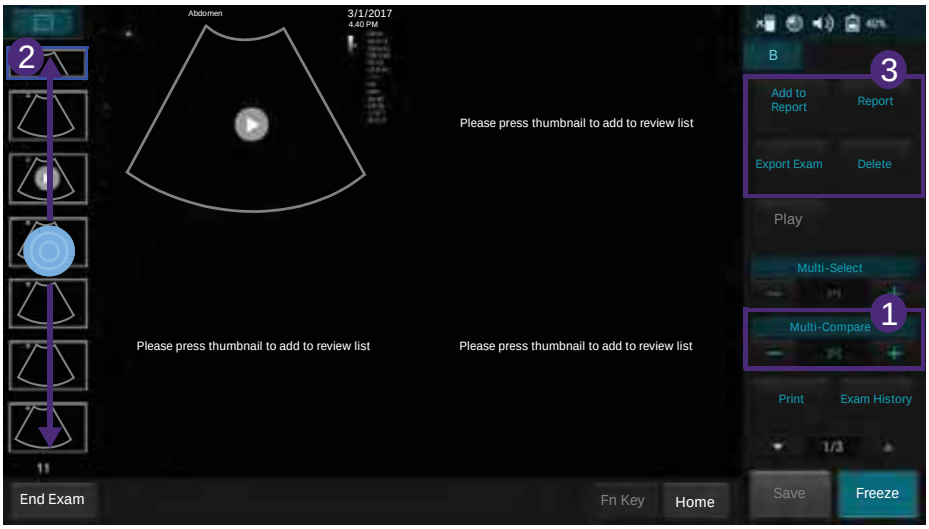
You can perform actions to more than one image/loop at a time.



1. Touch **Multi-Select +/-**.
2. Flick vertically on the thumbnail window and touch to select multiple images/loops as expected.
   – To quickly select all images, touch **Select All**.
   – To cancel all selections, touch **Deselect All**.
3. Touch an action button. For example, touch **Delete** to delete all selected images/loops.

6.12.2 Comparing Images

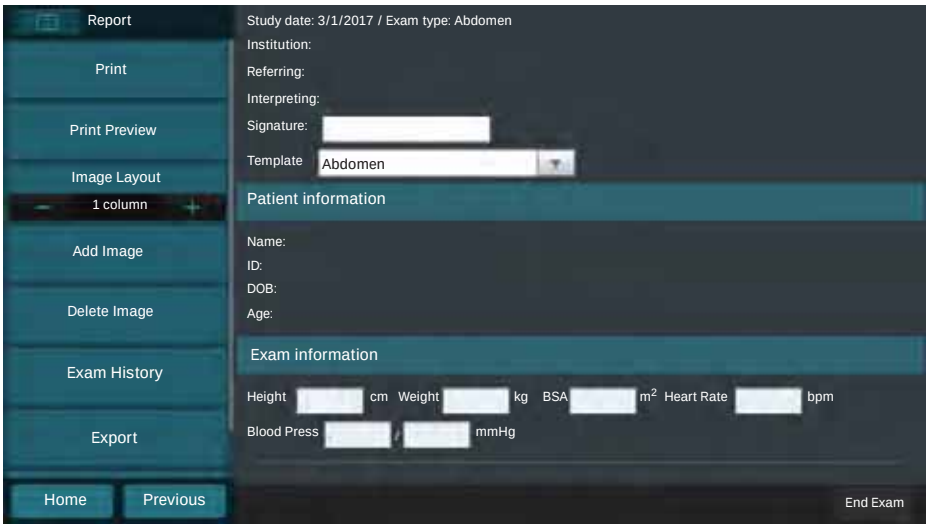
You can compare the scanned images/loops by displaying selected ones on the screen.



1. Touch **Multi-Compare +/-**.
2. Flick vertically on the thumbnail list, and touch to select up to 4 images/loops to display for comparison.
3. Touch an action button. For example, touch **Delete** to delete all selected images/loops.

6.12.3 Generating a Report

1. On the Review screen, touch the thumbnails of the desired images and touch **Add to Report**.
2. Touch **Report** to display the following screen.



3. Fill in information about the patient and the study, if not complete, and add comments using the virtual keyboard.
4. Flick down to review the images added, and add comments to individual images, if needed.

NOTE

You can still add/remove images to/from the report without going back to the Review screen. Touch **Add Image** to display the image editing screen. Check/uncheck the desired images and touch **Add to Report**.

5. Touch **Image Layout +/-** to select the number of columns for placing the images on a report.

6. The system provides two ways of saving the report:
   – Ensure an external storage device is connected to the system, then touch **Export**. Select the file format and directory, enter the file name then touch **Save as file**.
   – Touch **Export** and select to export the report to the DICOM server.
7. To print out the entire report with scanned images, first touch **Print Preview** to preview the report, then touch **Print**.

NOTE

Use the buttons on the Print Preview screen to zoom in/out the report or select a preferred page layout style to view the report.

To print out the report in texts only, touch **One Page Report** > **Print**.

6.13 Exporting the Exam

You can export exams and images to an external storage or the DICOM server. When exporting an exam, an image or a cine loop, the system creates a uniquely named subdirectory for each exam, image or loop.

1. The system provides two ways of exporting the exam:
   – On the Review screen, touch **Export Exam**.
   – On the Exam History screen, check the completed exams, and touch **Export Exam**.
2. Select to export the exam in DICOM file format to the DICOM server, external storage or network, or to export with common media formats to external storage or network.

NOTES

- To enable exporting an exam to DICOM automatically after ending the exam, touch  > **Settings** > **Workflow** > (**Export DICOM after End Exam**) > **Yes**.
- To configure DICOM settings, see "DICOM Configuration" on page 55.

6.14 Managing the Exam History

You can check and update status of all the stored exams from the Exam History screen.

On the imaging screen, touch > **Exam History**. Refer to the **Status** column to check the status of each exam (See "Exam status" on page 76). To review images/video clips of an exam, touch ( ).

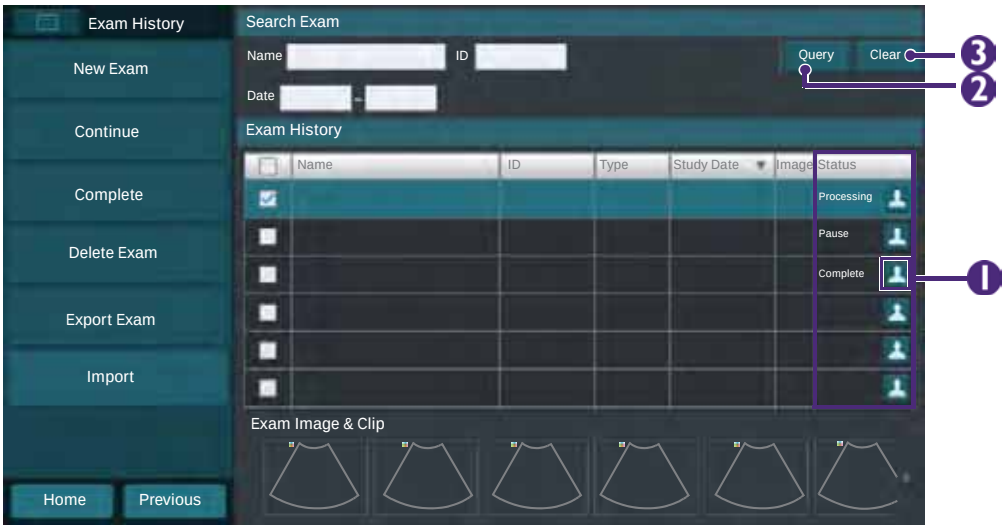


Table 1 Exam status

Exam status	Meaning
Complete	Ended exam
Processing	Ongoing exam
Pause	Proceed to the next exam while leaving the currently ongoing exam not ended

Alternatively, you can enter the query in any of the **Name/ID/Date** fields, and touch **Query** (2) to start the query. Patients matching the query will be listed on the screen. To clear all search criteria, touch **Clear** (3).

6.14.1 Resuming an Exam

To resume an exam, check the exam and touch **Continue** to enter real-time scanning.

6.14.2 Starting a New Exam

To start a new exam from a patient with an existing exam, check the exam and touch **New Exam**.

6.14.3 Finishing Exams

To update the exam status as “Complete”, multi-check the exams and touch **Complete**.

6.14.4 Deleting Exams

Multi-check the exams and touch **Delete Exam** to delete exams.

6.14.5 Exporting Exams

To export exams, multi-check the exams  , touch **Export Exam** and select an export method. If you select to export to DICOM, the task status icons (See page 56) next to the checkboxes indicate the uploaded results of the exams.

6.14.6 Importing Exams

To import exams from the connected external storage device, touch **Import** > select an import item.

6.15 Ending the Exam

An exam is not complete if you proceed with a new exam without ending the previous one. To end the exam, touch **End Exam** on the imaging screen. The exam will then be exported in DICOM file format to the DICOM server if you have enabled the Export DICOM after Exam feature (See page 89). If this feature is disabled, you will enter the Patient or Worklist screen or a new scan starts automatically, based on your selection from  > **Settings** > **Workflow** > (**Screen after End Exam**).

After ending the exam, you can still save images/cine loops, add annotations, perform measurements and modify the patient information within 24 hours, except the patient ID and the patient's last name. To do so, go to the Exam History screen, check the ended exam  and touch **Continue**.

NOTES

- To export exams to the DICOM server, you need to configure the DICOM settings first. (See "DICOM Configuration" on page 55)
- To check the exam status, touch  > **Exam History**. (See "Managing the Exam History" on page 75)

CHAPTER

7

Using Image Controls

This chapter covers the following topics:

All of the information in this chapter pertains to real-time imaging. Many of the controls and functions change when you freeze the scan. For information on using functions when the scan is frozen, see "Adding Annotations" on page 65 and "Adding Measurements" on page 68.

On the real-time imaging window:

- Touch the scan mode (image control) buttons to select the scan mode (See "Imaging Screen (Real-time)" on page 46).
- Touch / or use gestures to switch the control panel pages to go through the available functions (See "Switching the Control Panel Pages" on page 52).

7.1 B-Mode Image Controls

7.1.1 Overview

The system delivers 2-dimensional digital imaging (B-mode) using 256-level gray map. This scan mode delivers excellent image uniformity, tissue contrast resolution, and steering flexibility in frequencies from 2 MHz to 15 MHz.

7.1.2 Adjusting Gain

Adjust amplification of the returning echoes, which adjusts the amount of echo information displayed in an image. The overall brightness of the image can be elevated, but the “noise” may also be added to the image with excessive increase in gain.

Touch **Gain +/-** or flick horizontally on the scan area to adjust the gain value.

7.1.3 Adjusting Frequency

Change the scan frequency to obtain higher resolution as frequency increases, or deeper penetration as frequency decreases.

To increase the frequency, touch **Resolution**. To decrease the frequency, touch **Penetration**.

7.1.4 Adjusting Time Gain Compensation (TGC)

Adjust the gain which compensates for the attenuation (a reduction in sound amplitude) of the echo signals in proportion to their depth (based on travel time).

Touch **TGC** to display the TGC sliders on the screen. To increase/decrease the gain at the desired section (depth) of the image, drag the corresponding slider to the right/left.

7.1.5 Adjusting the Scan Depth

Adjust the field of view. To view larger or deeper structures, increase the depth. To enlarge the display of structures near the skin line, decrease the depth. The system automatically adjusts the frame rate (FPS) and acoustic power indices (TI/MI) based on the scan depth.

Touch **Depth +/-** or flick vertically on the scan area to set the scan depth.

7.1.6 Adjusting the Focus Depth, Focal Zone and Focal span

Focus optimizes the image by increasing the resolution for a specific area and is displayed by a red arrow marker indicated at the depth ruler. Depending on the transducer in use and the mode selected, multiple focus depths can be added. Increasing the number of focal zones decreases the frame rate. If the frame rate is not high enough, try decreasing the number of focal zones.

Touch **Focus +/-** to adjust the depth value. Touch **Focal Zone +/-** to select the desired number of focal zones. Touch **Focal Span +/-** to adjust the distance between the focal zones.

7.1.7 Adjusting Dynamic Range

Control the range of acoustic levels displayed in the image, which affects the contrast of the image. Touch **Dyn Range +/-** to adjust the amount of compression.

7.1.8 Using Tissue Harmonic Imaging (THI)

Reduce superficial artifact and provide better gray scale contrast by processing an integer multiple of the fundamental frequency, a harmonic wave.

Touch **THI** to enable this function.

7.1.9 Adjusting Persistence

Adjust the amount of frame averaging from real-time images or loops. Higher persistence produces less speckled and smoother image but reduces the temporal resolution.

Touch **Persist +/-** to adjust the value.

7.1.10 Adjusting Sharpness and Smoothing

Improve the sharpness of the image by enhancing the edge contrast and smoothening the tissue speckle.

Touch **QScan** +/- to adjust the value.

7.1.11 Adjusting Gray Map

Change how the amplitude is converted to brightness.

Touch **Gray Map +/-** to adjust the value.

7.1.12 Adjusting Chroma Map

Adjust the chroma (color tone and saturation) value with different brightness.

Touch **Chroma +/-** to adjust the tone.

7.1.13 Adjusting Steer Angle

Optimize the viewing area by adjusting the steer angle. This function works only with linear array transducers.

Touch **Steering +/-** to adjust the angle.

7.1.14 Adjusting the Sector Width and Position

Adjust the ROI of the imaging area for image width and image position. A smaller sector width increases the frame rate.

Touch **Sector Width +/-** to adjust the width. Touch **Sector Pos +/-** to adjust the position.

7.1.15 Adjusting Power

Adjust the acoustic output power value to the expected target.

Touch **Power +/-** to adjust the value.

7.1.16 Using Trapezoidal Imaging

Increase the range of view of the ultrasound image when using a linear transducer.

Touch **Trap** to enable trapezoidal imaging.

7.1.17 Adjusting Density

Adjust the density of the scan lines. Higher density obtains better horizontal resolution with lower frame rate, while lower density obtains higher frame rate.

Touch **Density** repeatedly to select a desired line density.

7.1.18 Using Compound Imaging

Reduce speckles and improve contrast resolution.

- Frequency compounding: Combine multiple images acquired from different frequencies. Touch **FQBeam** to enable frequency compounding.
- Spatial compounding: Combine multiple images acquired from different beam angles. Touch **SQBeam** repeatedly to enable and adjust spatial compounding.

7.1.19 Using ENV (Enhanced Needle Visualization)

When performing a biopsy with the supported transducer, the system offers on-screen needle assistance to further enhance imaging of the needle. Before using the ENV function, make sure the following conditions are met:

- B-mode is selected
- An L154BH transducer is connected to the system
- A patient profile is selected

Touch **ENV** to enable this function.

A diverging dotted green line shows in the Imaging window. The point of the needle should be close to vertical to the dotted line. The part of the needle image that goes beyond the limit will not be brightened and can't be seen. Tap **ENV Angle +/-**, if needed, to toggle between lines angled from upper left to lower right and lines angled from upper right to lower left.

NOTE

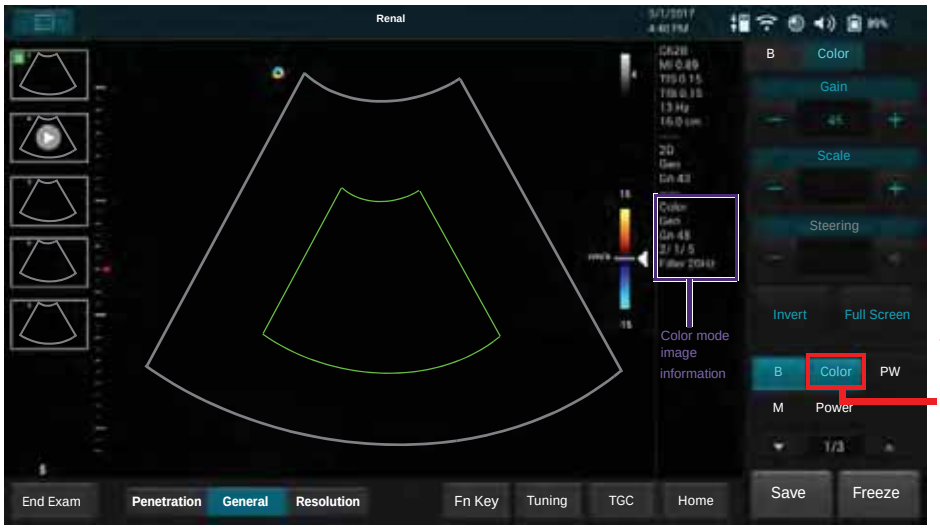
The system does not support the biopsy guide function. Do not use nor assemble any kind of needle guide kits/brackets on the transducer supported to avoid transducer damage or hurting the patient.

7.2 Color/Power Mode Image Controls

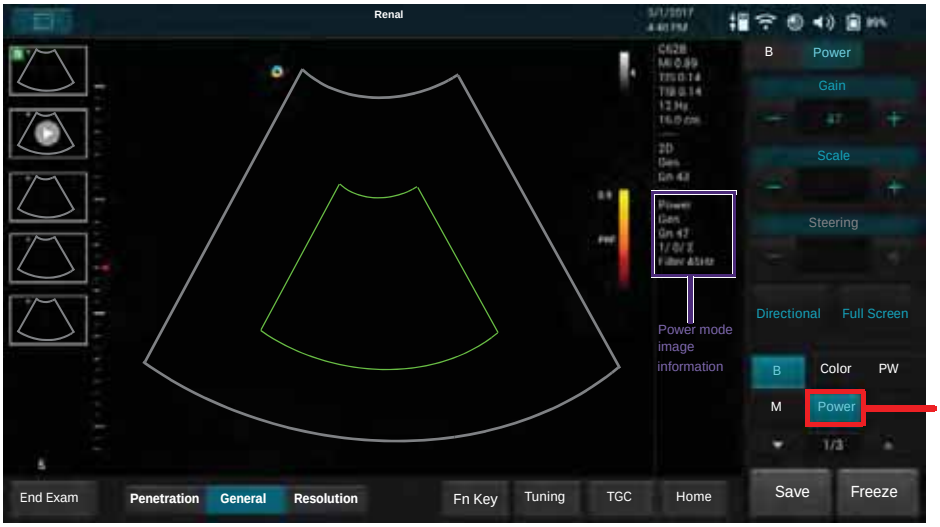
7.2.1 Overview

Color mode is used to detect the presence, direction, and relative velocity of blood flow by assigning color-coded information to these parameters. The color is depicted in a region of interest (ROI) that is overlaid on the 2D image. Non-inverted flow towards the transducer is assigned shades of red, and flow away from the transducer displays in shades of blue.

All forms of ultrasound-based imaging of red blood cells are derived from the received echo of the transmitted signal. The primary characteristics of this echo signal are its frequency and its amplitude (or power). The frequency shift is determined by the movement of the red blood cells relative to the transducer – flow towards the transducer produces a higher-frequency signal and flow away from the transducer produces a lower-frequency signal. Amplitude depends on the amount of moving blood within the volume sampled by the ultrasound beam. Large frequency shift generated by rapid flow is displayed in lighter colors, and smaller frequency shift in darker colors.



In Power (Doppler Power Image) mode, low flow rate in small vessels are clearly observed. Colors are carried out only to demonstrate the blood flow, but contain no velocity information, thus, offer no directional information.



Both Color and Power modes can work with other scan modes to form duplex and triplex modes.

7.2.2 Adjusting Pulse Repetition Frequency (PRF)

Adjust the velocity range of the color flow display. The maximum velocity range depends on the transducer in use and the location of the sample volume. Set the PRF high enough to prevent aliasing, and low enough to provide adequate detection of slow blood flow. Upon adjusting the PRF value, the velocity scale shown on the Color/Power wedge and the Wall Filter setting are changed accordingly.

Touch **Scale +/-** to adjust the value.

7.2.3 Inverting the Color Display

Invert the color display in relation to the blood flow direction in Color mode. Normally, the color red is assigned to positive frequency shifts (flow toward the transducer), and blue is assigned to negative frequency shifts (flow away from the transducer). Use this function to reverse this color assignment and invert the colors on the color wedge.

Touch **Invert** to invert the color scale.

7.2.4 Using Directional Power

Activate Directional Power in Power mode for use in applications where sensitivity and directional information are both required.

Touch **Directional** to enable this function.

7.2.5 Selecting a Color Map

Select which of five color maps is used to show Color Doppler data. Some maps use more colors than others, while some display in a smoother gradient than others.

Touch **Color Map +/-** to select a color map.

7.2.6 Adjusting Wall Filter

Reduce or eliminate unwanted low-frequency, high-intensity signals generated by movements of blood vessel walls or by rapid movement of the transducer. Set the wall filter high enough to ensure that the Color Doppler flash artifacts from tissue or wall motion are not displayed, but low enough to display slow flow. The adjustable range of the Wall Filter value is related to the current PRF value.

Touch **Wall Filter +/-** to adjust the value.

7.2.7 Applying the Smoothing Filter

Reduce color noise by applying a smoothing filter to the image.

Touch **Smoothing +/-** to adjust the value.

7.2.8 Adjusting the Color Priority

Define the amount of color displayed over bright echoes, and help confine color within the vessel walls.

Touch **Reject +/-** to adjust the value.

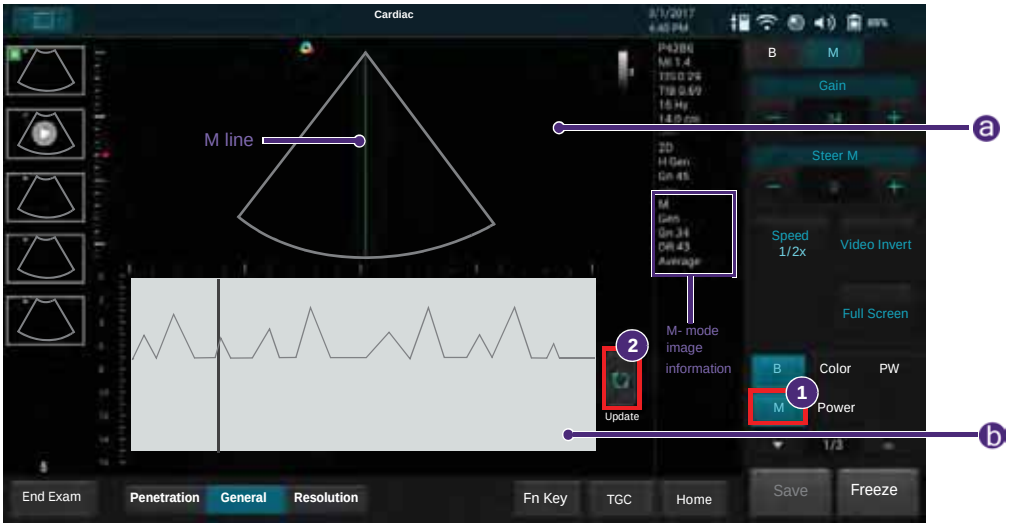
7.3 M-Mode Image Controls

7.3.1 Overview

M-Mode imaging is used simultaneously with 2-dimensional (B-mode) imaging to determine patterns of motion for objects within the ultrasound beam. M-Mode displays scan data of the anatomy in the

2D Imaging window ⓐ, and the motion scan in the Time Series window ⓑ. The M-Mode cursor line (M-line) appears vertically in the central area of the active 2D image, indicating the position of the M-Mode beam. Typically, this mode is used for viewing motion patterns of the heart.

Drag the M-line to the target position to determine the presence of motion occurred along the singular line.



1. Touch **M** to enable M-Mode image controls.
2. Touch  to initiate the M-Mode trace which produces a scrolling display of movement (along the vertical Y axis), plotted against time (along the horizontal X axis).

7.3.2 Using Steer M

Allow steering the sample volume to any angle you choose by adding multiple M-lines, rather than sampling in a strict vertical position. This function is particularly useful in cardiology applications.

1. Touch **Steer M +/-**.
2. A crosshair cursor appears on the image. Drag the cursor to where you want to start sampling and release it.
3. Drag the cursor to where you want to end sampling and release it.
4. Touch **Steer M +/-** to display a second crosshair cursor. Repeat step 2-3 to place the second line. Up to 3 M-lines can be added.

7.3.3 Adjusting Sweep Speed

Adjust how fast the timeline is scanned across the Time Series window.

Touch **Speed** repeatedly to select a desired velocity.

7.3.4 Selecting M Process

Select the detection method processing the M-Mode trace display. The system provides retrieving average or peak scan data from the M-Mode trace.

Touch **M Process +/-** to select a desired method.

7.3.5 Inverting the M-Mode Trace Display

Invert the M-Mode trace display in relation to brightness.

Touch **Video Invert** to swap the colors on the M-Mode trace display.

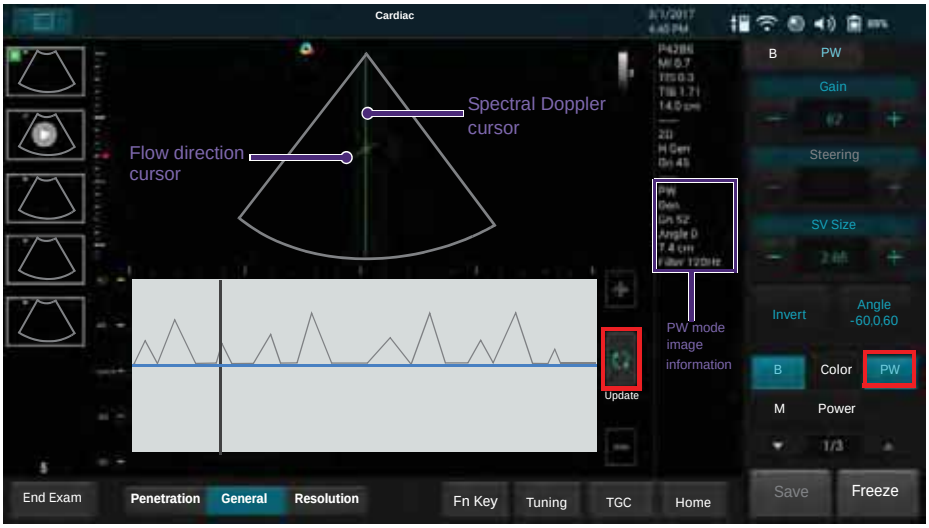
7.4 Spectral Doppler Mode Image Controls

7.4.1 Overview

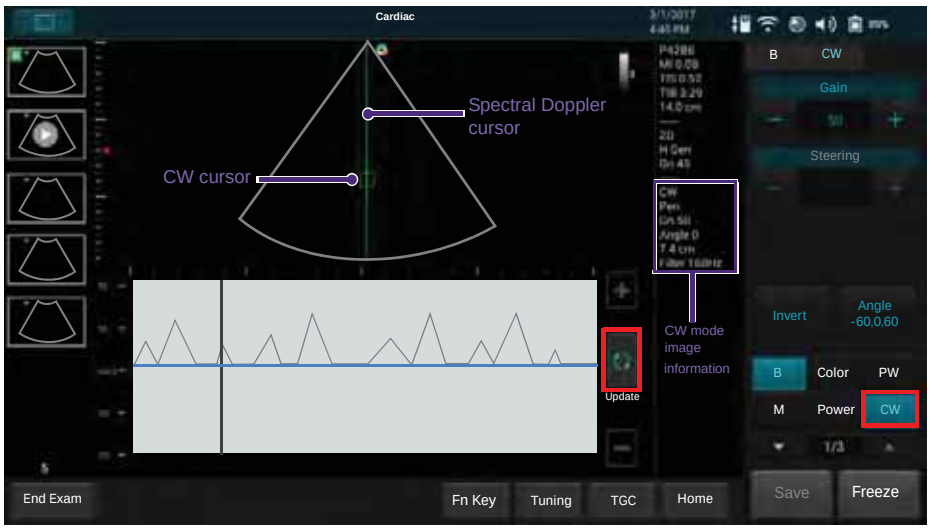
Pulsed-Wave Doppler (PW) and Continuous Wave Doppler (CW) are collectively called Spectral Doppler mode. A Spectral Doppler scan produces a series of pulses used to study the motion of blood flow selectively in the region of interest. PW/CW modes display scan data of the anatomy in the 2D Imaging window for monitoring the exact location of the sample volume, and display the PW/CW data acquired in the Time Series window. The X axis of the graph represents time, and the Y axis represents Doppler frequency shift. The shift in frequency between successive ultrasound pulses, caused mainly by moving red blood cells, can be converted into velocity and flow if an appropriate angle between the insonating beam and blood flow is known.

PW mode examines blood flow data selectively in a small region along a desired ultrasound cursor (the Spectral Doppler cursor), called the sample volume or range gate. A short line across the sample volume is called the Flow Direction cursor. This cursor line should be aligned to the blood flow direction when measuring the flow velocity.

Drag the Spectral Doppler cursor horizontally and the sample volume vertically to the target position to determine the presence of blood motion.



CW mode examines the flow data along the Spectral Doppler cursor rather than a small region.



7.4.2 Adjusting Baseline

Adjust the zero baseline up or down in the Time Series window.

To adjust the baseline:

- Touch **Baseline +/-**.
- Touch and hold the baseline in Time Series window, then drag the baseline vertically to move it.

7.4.3 Adjusting Sample Volume (SV) Size

Adjust the SV size which controls the size of the Doppler region being examined in PW mode.

To adjust the SV size:

- Touch **SV Size +/-**.
- Touch and hold one finger on the Spectral Doppler cursor, then flick another finger up or down.

7.4.4 Adjusting Correction Angle

Adjust the correction angle to obtain accurate velocity. At angles greater than 70°, the error in the velocity calculation is usually too large to use.

- To toggle the angle between -60° and 60°, touch **Angle -60,0,60** repeatedly.
- Touch **Angle +/-** to adjust the angle to the desired number.
- To manually adjust the angle, touch and hold one finger on the Spectral Doppler cursor, then flick another finger to the left or right.

7.4.5 Updating the 2D Display

Select whether or not to continue scanning the anatomy while acquiring PW Doppler scan data. Touch **Duplex** or **Triplex** to enable/disable this function.

CHAPTER

8

System Customization

You can customize your system to streamline your workflow and increase efficiency. Use the setup tools to adjust sets of controls for defaults and other settings.This chapter covers the following topics:

8.1 Customizing Your System

On the system screen, touch  > **Settings**. The setup tools are categorized into various sections listed below. Touch each section to access the settings.

8.1.1 General

- **Enable freeze gesture**: Enable double-tapping the screen to freeze the real-time scan.
- **Language**: Set the system language, and the system restarts automatically.
- **Export Settings/Import Settings**: Insert an external storage, touch **Export/Import** and select the storage directory.

8.1.2 Preset

- **Default preset/Preset list**: Touch **Edit**, set the default preset and re-arrange the preset list on the Preset screen, then touch **Save**. (See "Managing Presets" on page 61)
- **Export preset/Import preset**: Export/import customized presets to/from your external storage. (See "Exporting and Importing Customized Presets" on page 61)

8.1.3 Patient

- **Auto-create Patient Name and ID**: Enable creating a set of patient name and ID every time you start a new exam.
- **Show Study Information**: If you want to protect user privacy, disable this function to conceal user and institution information during real-time scanning.
- **Patient Information Unit**: Set the measurement unit for filling in patient information.

8.1.4 Exam

- Add logos and names for the institutions and operators.
- **Delete exams before**: The system will automatically delete exams performed a certain period of time ago. Select the time period from the drop-down menu, then touch **Delete** > **OK** to delete exams matching the selected time period.

8.1.5 Workflow

- **Screen after Enter Ultrasound**: Select the screen to enter after starting/logging into the system.
- **Auto-freeze after Minutes**: Set the number of minutes of waiting before the scan is frozen automatically.
- **Status after Freeze**: Assign the first action to perform after freezing the scan.

8.1.5.1 BDMK (Body mark)

- **Auto-clear BDMK after Unfreeze**: Enable clearing all the body marks added automatically after returning to the real-time scan.
- **Auto-add BDMK after Live Scan**: Enable adding a body mark each time you start a new scan.

8.1.5.2 Annotation

- **Auto-clear Annotation after Unfreeze**: Enable clearing all the annotations added automatically after returning to the real-time scan.

8.1.5.3 Measurement

- **Auto-clear Measurement after Unfreeze**: Enable clearing all the measurements added automatically after returning to the real-time scan.
- **Continue Next Measurement**: Enable initiating a second measurement automatically after the first one is complete.

8.1.5.4 Exam

- **Screen after End Exam**: Select the screen to enter after touching **End Exam**.
- **Export DICOM after End Exam**: Enable exporting the exam in DICOM file format to the DICOM server automatically after touching **End Exam**.

8.1.5.5 Print

- **Print while Save**: Enable printing out the scanned image automatically after touching **Save**.

8.1.5.6 Function Key

The system provides a function (configurable) key for quick access to your frequently used action.

- **Function Key Actions**: Touch **Edit**, assign a desired action to the function key, then touch **Save**.
- **Function Key Display Name**: Edit the name for the function key.

8.1.6 Imaging

- **Auto Focus by following CROI**: Enable re-positioning focus to the center of the ROI automatically when moving the ROI on the image in real-time Color/Power modes.
- **Auto CROI by following SV**: Enable re-positioning ROI to keep the sample volume in the center of the ROI when moving the sample volume on the image in real-time B+Color/Power+PW/CW modes.
- **Auto Zoom-in Image for PW/CW Mode/Auto Zoom-in Ratio**: Enable zooming-in images automatically with the assigned ratio upon entering PW/CW modes. To change the zoom ratio, select a desired percentage.
- **Image Format**: Select the saved image format.
- **Cine Loop Length in Seconds (Length may vary depending on frame rate)**: Set the cine loop length for each recording.
- **PW Output Unit/CW Output Unit**: Set the velocity display unit in PW/CW modes.

8.1.6.1 Display Layout

- **M Mode Display Format/PW Mode Display Format/CW Mode Display Format**: Set the aspect ratio between the 2D imaging window and the time series window on the imaging screen.

8.1.7 Annotation

- **Annotation Font Size/Arrow Size**: Select a desired size.
- **Label List**: Touch **Edit**, select an application and check/uncheck each label to re-arrange the label list, then touch **Save**.

8.1.8 BDMK (Body Mark)

- **Default BDMK for Application**: Touch **Edit**, select an application and touch a desired body mark to set it as default, then touch **Save**.

- **BDMK List**: Touch **Edit**, select an application and enable/disable each body mark to re-arrange the body mark list, then touch **Save**.

8.1.9 Measurement

- **Configuration of Calculation List**: Touch **Edit**. Select a preset from the Calculation Package to display available calculations below. To display/hide the calculation result after a set of measurements are done, check/uncheck the calculation name. If you select OB, more than one calculation method can be used in a calculation. Select the Author name to your desired method/formula.
- **Result Unit**: Set the measurement unit.
- **Caliper Size/Set Result Font Size**: Select a desired size.
- **Show Measure Line**: Enable showing the measuring lines after performing a measurement.
- **Result Position**: Set the position of the measured results.
- **Show Result**: Set whether to show all or the last measured results, or to hide them all.

8.1.10 Report

- **Default Report Template**: Select an application and set its default report template based on the preset selected, then touch **Save**.
- **Built-in Prompt String/Built-in Finding String/Built-in Comment String**: Touch **Edit**, edit or add built-in strings used in the report, then touch **Save.**
- **Report Display**: Touch **Edit**, and select the display type of the Calculation Package in the report.

8.1.11 DICOM

Configure DICOM settings. For more information, see "DICOM Configuration" on page 55.

8.1.12 Networking

- Display the network connection status of the system in the **Information window**.
  - **Current Status**: The IP address currently connected.
  - **Detailed Status**: All IP addresses and MAC addresses.
- Configure the system network.
  - **Wifi Configurations**: See "Connecting the System to the Wireless Network" on page 54.
  - **Ethernet Configurations**: See "Connecting the System to the Network by Ethernet" on page 54“.

8.1.13 Print

- **Image Printer/Report Printer**: Assign the printer for use when printing images/reports.
- **Network Printing**: Configure printer settings.
- **Image Color Invert**: Print out the image with colors inverted.

8.2 Servicing your system

If you encounter any problem using the system, need to update software, backup and restore data or use the on board diagnostic tools, select the service tools. Some functionality may require access keys and consultation available from technical support.

On the system screen, touch  > **Settings** > **Service**. The service tools are categorized into the following sections.

- Managing your system: Touch **System Management**. System information, software update, backing up and restoring data can be found here.
- Testing your system: Touch **Test & Utilities**. Use the diagnostic tools here to test the system functionality.
- Exporting system logs: Touch **System Logs**. Test results of the system functionality can be found here.
- About your system: Touch **About**. The system's main version and the tablet's serial number (default password for the first-time-logging-in) can be found here.

8.2.1 Reinstalling Software

This requires further assistance. Please contact technical support (See "Contact Information" on page 2). An access key is required. Once the access key is provided, the installation will require a USB flash drive with the software ZIP file. Please allow five to ten minutes for installation. The system will restart after completed. All settings and patient data are preserved but it is good practice to ensure recent backups have been performed.

Touch **System Management** > **(Software Maintenance)** > **(Reinstall Software)** > **Update**.

NOTE

Ensure regular backups of patient data and settings. It may be important in the event of a failure to have current configuration data.

8.2.2 Checking the Software Version

This may be required when contacting Technical Support.

Touch **System Management** > **(Software Maintenance)** > **(Software Version)**.

8.2.3 Checking the Tablet's Serial Number

List the serial number of the tablet. This is assigned and cannot be changed.

To check your tablet's serial number:

- Touch **System Management** > **(System Information)** > **(Tablet Serial Number)**.
- Refer to the spec label on the back of your system.

8.2.4 Checking the License Status

List current licenses and options that are installed. It may need to be reinstalled with assistance from technical support when a replacement tablet is received and no licenses are installed.

Touch **System Management** > **(System Information)** > **(License Status)**.

8.2.5 Resetting System Settings

Performing this action will reset all system settings of the current user and is irreversible. Consider backing up your settings to an external storage device first.

Touch **System Management** > **(System Configuration)** > **(Reset System Settings)** > **Reset**.

8.2.6 Backing Up System Settings and Patient Data

CAUTION

In the event a system issue occurs and a replacement system is required all configuration settings and patient data may be lost. It is your responsibility to back up data regularly!

NOTE

Before backing up system settings and patient data, ensure that the system is connected to an external storage device.

1. Touch **System Management** > **(System Configuration)**.
2. Touch **Backup** in the following fields:
   - **Backup System Settings & Patient Data**: All the system settings, presets and exams are saved to the external storage device. The following file naming convention is applied to the backup file: Backup_YYYYMMDD_HHMMSS
   - **Backup Patient Data**: All the exams are saved to the external storage device. The following file naming convention is applied to the backup file: Backup_PATIENT_YYYYMMDDHHMMSS

8.2.7 Restoring System Settings and Patient Data

NOTE

Before restoring system settings and patient data, ensure that the system is connected to an external storage device containing stored system settings and patient data.

Touch **System Management** > **(System Configuration)**.

Touch **Restore** in the following fields, and select a backup file:

- **Restore System Settings & Patient Data**: All the system settings, presets and exams are restored to the system from the external storage device.
- **Restore Patient Data**: All the exams are restored to the system from the external storage device.

8.2.8 Resetting Your System

NOTE

This action is irreversible. Consider backing up your up system settings and patient data to an external storage device first.

Performing this action will restore your system to its factory state and erase all your user settings and patient data from the system storage, except the tablet serial number.

Touch **System Management** > **(System Configuration)** > **(Factory Reset)** > **Erase**.

CHAPTER

9

Transducer and System Maintenance

The transducers and the system require proper care, cleaning, and handling. This chapter contains information and instructions to help you effectively clean, disinfect, and sterilize the transducers and the system.

This chapter covers the following topics:

The transducer is the most important factor in image quality. Optimal imaging cannot be obtained without the correct transducer. The system is optimized for use based on your transducer selection.

9.1 Transducer Maintenance

Transducers are highly-sensitive instruments and require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization, as necessary. Inspect the transducer, cable, and lens before each use. Check for cracks or other damage that jeopardizes the integrity of the transducer. Report any transducer damage to your BenQ Medical Technology representative, and discontinue use of the transducer.

For all information on transducer cleaning and disinfection, see "Transducer Care" on page 95.

For all information about the use of acoustic coupling gels, see "Ultrasound Transmission Gels" on page 98.

If you encounter poor image quality or transducer problems, see "Troubleshooting" on page 103".

NOTE

Some ultrasound coupling gels, as well as some solutions for pre-cleaning, disinfecting, and sterilizing can damage a transducer. Before using a gel or solution on a transducer, see "Ultrasound Transmission Gels" on page 98 or "Transducer Care" on page 95". You can also contact your local BenQ Medical Technology representative. For contact information, see "Contact Information" on page 2.

9.2 Transducer Storage

Use the appropriate guidelines for storing transducers for transport, and daily and long-term storage. For information on temperature and humidity requirements, see "Appendix A: Specifications" on page 108.

9.2.1 Storage for Transport

If a carrying case is provided with your transducer, always use the carrying case to transport the transducer from one site to another. Follow these guidelines to properly store transducers for transport:

- Make sure that the transducer is clean and disinfected before placing it in the case to avoid contaminating the foam that lines the carrying case.
- Place the transducer in the case carefully to prevent kinking of the cable.
- Before closing the lid, make sure no part of the transducer is protruding from the case.
- Wrap the case in plastic material containing air-filled pockets (such as Bubble Wrap material), and pack the wrapped case in a cardboard carton.

9.2.2 Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

- Always store transducers in the transducer holders or on a securely mounted wall rack when you are not using them.
- Ensure the transducer holders are clean before storing transducers.
- Avoid storing transducers in areas of temperature extremes or in direct sunlight.
- Store transducers separately from other instruments to avoid inadvertent transducer damage.
- Before storing transducers, make sure they are thoroughly dry.

9.3 Transducer Care

Reasonable care includes inspection, cleaning, and disinfection or sterilization, as necessary. Transducers must be cleaned after each use. Inspect all parts of the transducer carefully before each use. Check for cracks or other damage that jeopardizes the integrity of the transducer.

9.3.1 Transducer Care and Operator Safety

Observe the following warnings and cautions during all cleaning, disinfection, and sterilization procedures and when using disinfectants.

WARNING

Disinfectants are recommended because of their chemical compatibility with product materials, not their biological effectiveness. For the biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.

WARNING

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the disinfectant type is appropriate for the type of transducer and the transducer application. For information on the levels of disinfection requirements, see "Transducer Care" on page 95**.**

WARNINGS

- **Do not drop the transducer on a hard surface, as this will damage the transducer elements and compromise the electrical safety of the transducer.**
- **Do not allow sharp objects, such as scissors, scalpels, or cauterizing knives, to touch transducers or cables.**
- **Do not use damaged or flawed transducers.**

WARNINGS

- **Use only the approved ultrasound coupling gels.**
- **Use only couplants specifically designed for ultrasound examinations. Do not use mineral-oil or vegetable-based couplants, which can damage transducers.**

WARNING

If a pre-mixed solution is used, be sure to observe the solution expiration date.

WARNINGS

- **Transducers must be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization. Be sure to follow the manufacturer's instructions when using disinfectants.**
- **When sterilizing a transducer, ensure that the sterilant solution's strength and duration of contact are appropriate for sterilization. Be sure to follow the manufacturer's instructions.**

WARNING

Attempting to clean or disinfect a transducer, cable, or connector by using a method other than the procedures provided here can damage the device and voids the warranty.

WARNING

Do not use a surgeon's brush when cleaning transducers. Even the use of soft brushes can damage transducers.

WARNING

Do not use paper products or products that are abrasive when cleaning the transducer. They damage the soft lens of the acoustic window of the transducer.

WARNING

During cleaning, disinfection, and sterilization, orient the connector and cable that must remain dry higher than the wet parts, until all parts are dry. This helps keep liquid from entering unsealed areas of the transducer.

WARNING

When cleaning and disinfecting transducers, do not allow any fluid to enter electrical connections or metal portions of the connector. Damage due to fluids in these areas is not covered by the warranty or your service contract.

WARNING

When using an enzymatic cleaner, be sure to use the proper concentration and rinse thoroughly.

WARNING

Before storing transducers, ensure that they are thoroughly dry. If it is necessary to dry the transducer lens or acoustic window after cleaning, use a soft cloth and a blotting motion, instead of a wiping motion.

WARNING

Use only liquid solutions to sterilize transducers. Using autoclave, gas (EtO), or other methods not approved by BenQ Medical Technology will damage your transducer and void your warranty.

WARNING

Do not soak the transducer for extended periods of time. Limit the time and depth that transducers are soaked in disinfectant solution to the minimum time recommended by the disinfectant manufacturer.

9.4 Inspecting the Transducer

Inspect the transducer's acoustic lens, the cable, and the transducer connector before each use. Check the transducer carefully and see if there are cracks, cuts, or any other damages which may admit fluids. Do not use the transducer if it is damaged.

If the transducer is dropped, examine it immediately for signs of damage. Perform a sample scan to make sure it operates correctly. Contact BenQ Medical Technology for service or replacement if any abnormalities are found.

NOTE

To avoid any possibilities of hurting the patient, check if the transducer has a smooth edge and an even surface before each use.

9.5 Transducer Care Method

The transducers supported by this system are classified as non-critical types which require low-level disinfection.

Low-level disinfection of transducers uses the spray or wipe method, with a low-level or intermediate-level disinfectant.

1. Clean the transducer and cable according to the procedures in "Transducer and Cable Cleaning" on page 97. Observe all warnings and cautions.
2. After cleaning, choose the low- or intermediate-level disinfection solutions compatible with your transducer, cable, and connector. For a list of disinfectants compatible with your transducer, see "Ultrasound Transmission Gels" on page 98. Follow the label instructions for preparation, temperature, solution strength and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device.
3. Wipe or spray the transducer, cable, strain relief, and connector with the disinfectant, following the disinfectant label instructions for temperature, wipe durations, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector. Do not allow any type of fluid to enter the connector. Ensure that fluid does not enter through the strain relief, through the connector, or through the electrical contacts. Fluid in the connector may void the device warranty.
4. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.

9.6 Transducer and Cable Cleaning

These general cleaning instructions are indicated for all supported transducers, cables, and connectors. It is important that you clean the transducer, cable, and connector according to the following procedures. Before cleaning a transducer, read "Safety Information" on page 6. After cleaning, you must disinfect or sterilize transducers by following the appropriate procedures.

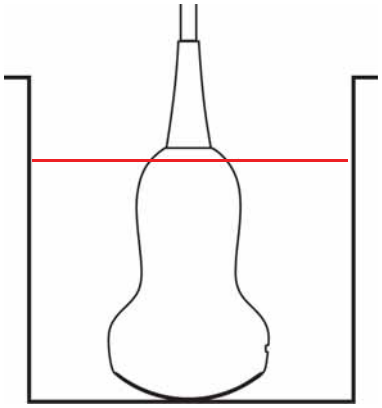
NOTE

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

9.6.1 Cleaning Instructions

1. After every patient exam, use a moist cloth to remove the ultrasound transmission gel from the transducer.
2. Disconnect the transducer from the system, and remove any accessories attached to or covering the transducer.
3. To remove all organic matter and other residue, use a pre-cleaner or detergent to assist in removing protein residuals. Enzymatic cleaners must be diluted prior to use per the manufacturer’s instructions for dilution. Enzymatic cleaners are generically approved for use.
4. When cleaning the lens, use a blotting motion rather than a wiping motion.
5. To remove remaining particulate and cleaning residue, use cleaning wipes according to the manufacturer’s instructions.

6. Transducers can be submerged up to, but not including, the strain relief of the transducer array. Do not immerse or soak any other part of a transducer in any cleaning material. The following figure defines how much of the transducer can be submerged.



Do Not Submerge Transducers Above Line (Example transducer C62B)

7. Wipe with a dry cloth if necessary. To dry the lens, use a soft cloth and a blotting motion instead of a wiping motion.
8. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your BenQ Medical Technology representative.

NOTE

The cable and connector are not waterproof. Do not immerse the cable or allow liquid to contact the connector.

9.7 Ultrasound Transmission Gels

For proper transmission of the acoustic beam, use the ultrasound transmission gel supplied by or recommended by BenQ Medical Technology, or another glycol-, glycerol-, or water-based acoustic coupling medium.

WARNING

For intraoperative applications, use only the Sterile Aquasonic or Sterile Ultraphonic gel provided with the transducer cover.

CAUTION

Do not use hand sanitizing gels.

CAUTION

Do not use lotion-based products or gels that contain mineral oil. Such products damage the transducer and void the warranty.

CAUTION

Do not apply the transducer gel until you are ready to perform the procedure. Transducers should not be left soaking in gel.

CAUTION

Gels listed here are recommended because of their chemical compatibility with product materials.

Some recommended gels include:

- Aquasonic 100
- Aquasonic Clear
- Carbogel-ULT
- Scan

9.8 Compatible Disinfectants and Cleaning Solutions

The following list is the disinfectants and cleaning solutions compatible with the transducers available for the system.

- Mild soap solution
- Purified water
- 70% isopropyl alcohol (IPA)
- 75% Ethanol alcohol
- Bleach (500~1000ppm solution in water)
- MinutenSpary
- M415
- OROLIN® Burbath

WARNINGS

- **The only parts of the transducer that may be cleaned with isopropyl alcohol are the transducer housing and lens or acoustic window. Ensure that the solution is only 70% alcohol or less. Do not wipe any other part of a transducer with isopropyl alcohol (including cables, connectors, or strain reliefs), as it can damage those parts of the transducer. This damage is not covered by the warranty.**
- **Do not use any ammonia based disinfectants. If used it can cause damage to the plastics or to the system.**

9.9 System Maintenance

Maintenance should be performed regularly and as needed.

9.9.1 Inspecting the System

Inspect the system's touch glass, outer cover, port cover, probe cover and the stand before each use. Check the system carefully and see if there are cracks, cuts, or any other damages which may admit fluids.

If the system is dropped, examine it immediately for signs of damage. Perform a sample scan to make sure it operates correctly. Contact BenQ Medical Technology for service or replacement if any abnormalities are found.

9.9.2 Cleaning the System

The system and peripherals are medical electrical equipment and require thorough cleaning. If exposed to constant and excessive environmental dust and humidity, both performance and reliability of these devices will suffer. Clean the power adapter, ventilation slots, all connection ports/sockets and the touch screen regularly or whenever you observe dust or other particles.

For information on transducer cleaning and disinfection, see "Transducer Care" on page 95.

WARNINGS

- **Before cleaning the system, perform the following operations to avoid the risk of electric shock:**

1. **Turn off the system power.**
2. **Disconnect the power adapter from the system and the power outlet.**

- **Running the system for a long period of time may generate excessive heat. Do not clean the system until it completely cools down.**

9.9.2.1 Cleaning the System/Surfaces/probe holder

WARNING

The system connection ports, external monitor port, power adapter port and other openings in the enclosure are most likely to be affected by liquid spills and other materials such as excessive amounts of gel. These materials may seep into electrical components under the enclosure and cause intermittent failures. During preventive maintenance, look for potential problems, such as gaps or cracks.

1. Gently wipe the system/surfaces/probe holder with a lint-free, non-abrasive and dry cloth.
2. Moisten the cloth with soapy water and gently wipe it across the surfaces in one direction.

WARNING

Moving the cloth back and forth on the touch screen will damage the screen.

3. Remove any solid matter around the ventilation slots, connection ports, and power adapter port with a cotton swab or toothpick to ensure that solids are not pushed into the system.
4. If blood or other infectious material comes in contact with the system, or any cable, apply a small amount of specific cleaning solutions or disinfectants (See page 100) to the cloth, and gently wipe it across the surfaces in one direction. Repeat the application and cleaning process several times until the spots are dissolved.
5. Remove any residue with a cloth moistened with sterile water.
6. Wipe off any excess moisture then leave the surfaces completely dry before powering the system back on.

The compatibility of disinfection and cleaning solutions varies depending on the item on which they are used. The following products are compatible with the external plastic and painted surfaces of system.

- Cleaning solutions for all surfaces:
  - Mild soap solution
- Cleaning solutions for the touch screen:
  - Mild soap solution
  - Cleaners designed for touch screens
  - Purified water

- Disinfectants for system surfaces, including the touch screen:
  - 70% isopropyl alcohol (IPA)
  - 75% ethanol alcohol
  - RBS M415 (Quaternary ammonium compounds based)
  - ALPRO MinutenWipes (Ethanol/IPA/chlorhexidine-digluconate/ dialkyldimethylammoniumchioride/alkylamine derivatives based)
  - ALPRO MinutenSpary (Ethanol/IPA/chlorhexidine-digluconate/ dialkyldimethylammoniumchioride/alkylamine derivatives based)

WARNING

If blood or other infectious material comes in contact with a transducer or transducer cable, do not wipe with isopropyl alcohol until you have read the "Transducer Care" on page 95 **for specific cleaning guidelines. Isopropyl alcohol should not be used on some parts of the transducer and should never be used on any parts of the transducer cable. Additional cleaning agents are also available for transducers.**

CAUTION

- **Do not use abrasive cleaners, or acetone, MEK, or other strong solvents on the system, peripherals, or transducers.**
- **Do not use Sani-Cloth AF4 or Super Sani-Cloth to disinfect the system.**
- **On display screens, do not use glass cleaners or products containing bleach. Immediately wipe away disinfectants or cleaners to prevent residue buildup.**
- **On display screens, use microfiber cloth; do not use paper towels.**
- **System surfaces and transducers are resistant to ultrasound gel, alcohol, and disinfectants, but if you use those substances, you must wipe them off to prevent permanent damage.**
- **Always use protective eyewear and gloves when cleaning and disinfecting any equipment.**
- **Attempting to disinfect a cable or connector by using a method other than the one included here can damage the device and voids the warranty.**
- **Orient the parts that must remain dry higher than the wet parts until all parts are dry.**
- **Do not use strong solvents, common cleaning products, or abrasive cleansers, which will**
- **damage the system surfaces.**
- **When cleaning the system surface with cleaning solutions or disinfectants, take care not to wipe repeatedly or rub heavily on the BenQ Medical Technology logo and model name. The printing inks may start to appear faded or stained.**
- **Do not touch the display with sharp objects or use paper towels to clean it, which may damage it.**
- **When cleaning the system, take care not to get any solution inside the protective enclosure. Also take care not to scratch the face of the screen while cleaning it.**
- **Do not use cleaners containing bleach on the touch screen. It may damage the surface.**

9.9.2.2 Cleaning the Power Adapter

CAUTION

- **Do not immerse the power adapter.**

- **Keep moisture and liquid away from the power adapter. Do not spill or spray liquid on the adapter.**

1. Wipe the power adapter with a dry cloth.
2. If spot cleaning is necessary, wipe with a cloth dampened with soapy water. If disinfection is necessary, wipe with an alcohol-moistened cloth.
3. Remove any solid matter with a cotton swab or toothpick to ensure that solids are not pushed into the adapter.
4. Wipe off any excess moisture then leave the power adapter completely dry before plugging it into the system or power outlet.

CHAPTER

10 Troubleshooting

Frequently asked questions and common problems that may occur while using the system are explained in this section. Observe the following table containing a list of symptoms and the actions to take to solve the problems.

If a problem persists after performing the following actions, contact technical support (See "Contact Information" on page 2).

Table 1 Troubleshooting

Symptom	Possible cause and corrective action
The system does not power on	• **Battery fully discharged.** Connect the AC power adapter. • **Power adapter does not function correctly.** > Check if the power adapter has blue light illuminated. > Check if the AC plug is connected firmly and correctly to the power adapter and matches the plug type of your country. > Check if the power adapter is connected firmly and correctly to the system. (See "Charging the System" on page 33)
The system can't charge or experience short runtime between charges	**Power supply is damaged/battery reaches end of life.** > Allow the battery to charge overnight and check again the battery status. > Contact technical support.
Unsure of a function displayed in localized languages	> Switch the system language back to English from  > **Settings** >**General** > **Language**, and check again the function you want to use. > Contact technical support.
The system can't read/ write data from the microSD card	• **One or two USB storage devices are connected to the system at the same time.*** > Remove all the connected USB storage devices from the system. • **The microSD card is damaged.** > Insert the microSD card into a computer for inspection. • **The microSD card slot is damaged.** > Insert another microSD card into the system for inspection.
The system can't read/ write data from the USB storage device	• **Two USB storage devices are connected to the system at the same time.*** > Ensure the USB storage device you wish to read/write data from is connected to the system through the USB 3.0 port. • **The USB storage device is damaged.** > Insert the USB storage device into a computer for inspection. • **The USB ports are damaged.** > Insert another USB storage device into the system for inspection.
No image or abnormal display on the system screen	**The system screen is not functioning.** > Output the system display to an external monitor (See page 39) and check if images display normally on the external screen. > Contact technical support
Image Artifacts occur on the imaging screen	• **Electrical interference occurs.** > Move system away from any electromagnetic sources. > Remove the power adapter and other external devices (if any) from the system while keeping the transducer plugged for inspection. • **The transducer connected is damaged.** > Replace current transducer with another for inspection.

Table 1 Troubleshooting

Symptom	Possible cause and corrective action
Software installation failed	Check if the USB flash drives or the system's USB ports are damaged.
The Power button does not function	**The system power reaches a critically low state and is not connected to power.** > Connect the system to power.
The system is overheating	• **The system's fans are not functioning.** > Contact technical support. • **Ventilation slots are blocked.** > Place the system in a well-ventilated area. > Remove any dust particles or stains found on or nearby the ventilation slots.
The system encounters unexpected shutdowns several times	**A system disk error occurred.** > Reinstall the software (See "Reinstalling Software" on page 91). This requires assistance from technical support.
Touch screen is unresponsive or misconfigured	• **Touch screen is damaged.** > Inspect the panel surface carefully for cracks, cuts or any other damages. • **Software malfunctions.** > Connect a pointing device to the system through the USB port, and check if the pointer is displayed correctly on the screen.
No audio or noise comes from the system speakers	• **The system is muted.** > Open the Quick Setup menu and adjust the volume. • **The speakers are damaged.** > Contact technical support.
HDMI does not function	**The HDMI cable/port is damaged.** > Use another HDMI cable for connection. > Connect the system to a computer through HDMI connection for inspection.
Bluetooth connection failed	• **The Bluetooth settings are not correct.** > Turn off the Bluetooth function, then turn it back on. • **The Bluetooth module is not functioning.** > Connect another Bluetooth device to the system for inspection.
DICOM connection failed	**The DICOM server is not responding or the DICOM settings are not correct.** > Go to  > **Settings** > **DICOM** > **Storage SCP** and touch **Edit** > **Test** for verification.

Table 1 Troubleshooting

Symptom	Possible cause and corrective action
Ethernet does not function	• **The Ethernet settings are not correct.** > Contact your network administrator. • **The Ethernet cable/socket is damaged.** > Use another Ethernet cable for connection. > Connect the system to a computer through Ethernet connection for inspection.
Wireless connection failed	• **The wireless device is turned off or not functioning.** > Check the power of the wireless device. > Restart the wireless device. > Connect another wireless product to this device for inspection. • **The wireless network settings are not correct.** > Open the Quick Setup menu and check if the wireless network function is enabled. > Contact your network administrator.

*The system supports access to only one external storage device at a time. If you connect more than one external storage device, they function in the following priority order: USB 3.0 > USB 2.0 > microSD card.

CHAPTER

11

Appendices

This chapter covers the following topics:

11.1 Appendix A: Specifications

11.1.1 System

Table 1 System Specifications

Item	Specification	
Form factor	Tablet	
Weight	5.73 lb (2.6 kg): with stand	
Dimensions	Length	13.70" (348.2 mm)
	Width	9.39" (238.5 mm)
	Height (Thickness)	1.52" (38.5 mm): without stand 2.22" (56.4 mm): with stand
Materials	Plastic, metal, rubber	
Color	Black and White	
Speaker	2 built-in speakers	
Console	Touch screen	
Primary monitor	13.3" 1920x1080	
Number of transducer connectors	1 transducer connector	
Stand	1 stand	
Mounting	VESA standard (75mmx 75mm/100mm x 100mm)	
Water resistant level	IP21	
CPU	Qualcomm APQ8074AB	
User interface languages	English, T/S Chinese, French, German, Spanish, Russian	
Memory	16GB eMMC	
Storage	mSATA 128GB SSD; support up to 512GB	
Connectivity	• HDMI x 1 • Audio output x 1 • Ethernet RJ45 x1 • USB 2.0 x1 • USB 3.0 x1 • MicroSD slot x1 • Transducer x1	
Power	Battery power/chargeable with up to 19V AC adapter	
Battery	Non-removable battery with 1.5 hour run-time	
Accessory	Adapter: • Input: AC 100 ~ 240V, 50 ~ 60Hz, Max 1.6A • Output: +19Vdc, 3.43A Transducer: C62B, L154BH, P42B6	
Storage/transport	Temperature: -20 ~ 60°C Humidity: 20% ~ 95% RH Air pressure: 700 ~ 1060hPa	

Table 1 System Specifications

Item	Specification
Environmental operating conditions	Temperature: 10 ~ 40°C Humidity: 20% ~ 85% RH, no condensation Air pressure: 700 ~ 1060 hPa No condensation
Product life	5 years

CAUTION

To avoid electrical shock, keep the system in dry location.

11.1.2 Transducer

Table 2 Transducer specifications

Transducer	Elements	Descriptions	Applications
P42B6	64	Phased-linear array transducer with a maximum depth of 200 mm and a user-controllable field-of-view	• Cardiac
C62B	128	Curved linear array transducer with a maximum depth of 200 mm and a user-controllable field-of-view	• Abdominal • OB • GYN • Renal • Urology
L154BH	128	Linear wideband array transducer with a maximum depth of 150 mm and a user-controllable field-of-view	• Carotid • Arterial • Venous • Thyroid • Breast • MSK • Nerve

11.1.3 Adapter

Table 3 Adapter Specifications

Item	Specifications
Brand	Adapter Technology Co., Ltd.
Model	ATM065-P190
Input	Universal AC 100 ~ 240 Vac/50 ~ 60Hz Input, without any slide switch
Output	+19Vdc, 3.43A
Case Dimension	119 (L) * 60 (W) * 36 (H) mm
Efficiency	Eff (av) ≥ 87%
Safety	I.T.E. - PSE / BSMI / CCC Medical - UL / cUL / T-mark
EMI	CE / FCC Class B, Conduction and Radiation Met.
Protection	OVP (Over Voltage Protection), SCP (Short Circuit Protection), OCP (Over Current Protection)
Features	• High frequency design, less power consumption • Suitable for usage at Medical Equipment • Meet DoE / ErP (Stage 2) / NRCan

CAUTION

To avoid electrical shock, keep the adapter in dry location.

NOTE

Specifications are subject to change without prior notice.

11.1.4 Battery

Model: APP00201

Battery type (non-removable): 3S2P Panasonic-3070mAh, compliant with IEC62133 standard

Table 4 Battery Specifications

Item	Rate performance	Remark
Battery Cell	3070 mAh	Panasonic
Typical capacity	Above 6140 mAh	Rate discharge capacity after rate charge
Nominal capacity	Above 5833 mAh	Rate discharge capacity after rate charge
Nominal voltage	10.8 V	Mean operation voltage during rate discharge after rate charge
Maximum charge voltage	12.6 V	CV mode charging voltage
Voltage at end discharge	9.0 V	Stop discharge when any cell reaches tc 2.7 ± 0.02 V

Table 4 Battery Specifications

Item	Rate performance	Remark
Suggested charge current (Standard)	1.2 A	
Suggested charge current (maximum)	3.0 A	
Suggested continuous discharge current	3.0 A	≦ 33 W
Suggested maximum discharge current	7.0 A	≦ 78 W
END of charge condition	150 mA	1 min
Operating temperature	0 ~ 45°C 10 ~ 45°C -0 ~ 60°C	Standard charging In max. charging Standard discharging
Power consumption Normal mode Sleep mode Shutdown mode	 ≦ 620 μA ≦ 120 μA ≦ 5.42 μA	

11.2 Appendix B: Connectivity and Security

11.2.1 Introduction

To exchange ultrasound images and patient data, the system conforms with the Digital Imaging and Communications in Medicine (DICOM) standard and can therefore be connected to Picture Archiving and Communication System (PACS) and Modality Worklist (MWL). The former allows the system to store the acquired examination data (static images or image loops) in PACS, while the latter allows the system to query examination orders from the MWL server and start the examinations. In order to achieve the purposes above, the system offers two ways of connecting to the IT network, hard-wired LAN and wireless LAN connections, for DICOM communication.

NOTE

To ensure the data security, use an IT network isolated from the external environment by a firewall.

11.2.2 Specifications

11.2.2.1 Hardware

802.11 a/b/g/n, Gigabit Ethernet

11.2.2.2 Software

The system is connected to PACS and MWL by DICOM standard.

NOTE

Read the system's DICOM Conformance Statement for detailed instructions.

11.2.2.3 Security

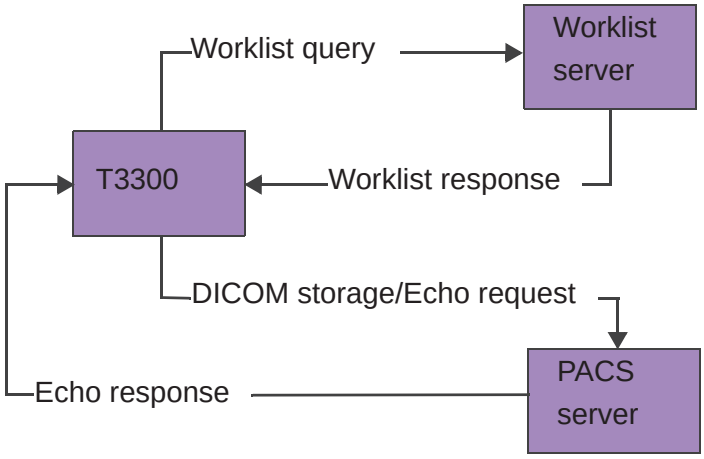
The system has no listening ports open to the Wifi interface. So a network entity cannot initiate a connection to the system from the Wifi. However, the system can initiate a connection to servers on the Wifi, Gigabit Ethernet and beyond. Computer access to the system through the USB port is blocked.

The system allows connection via Bluetooth with limited devices (HID) only.

Use the following TCP/IP ports for outgoing communication to the Wifi and Gigabit Ethernet.

- Port for DICOM communication (typically port 104, 2762 or 11112; to specify the port, on the system's imaging screen, touch  > **Settings** > **DICOM**.
- Port 80 for HTTP web servers (not supported by the system)
- Anti-virus software is not installed on the system

11.2.2.4 Information Flow



11.2.2.5 IT Network Failure Recovery Measures

IT network connection stability depends on many factors. Unreliable connection may later lead to failure and cause the following hazardous situations.

Any connection of the equipment, this system (T3300) or/and other systems, to the IT network risks the unidentified data leakage of the patients, operators or third parties. It is recommended to set up the device in a secure network and behind the firewall. The potential risks and suitable countermeasures are evaluated and identified in the following table before connecting the equipment to an uncontrolled IT network. Therefore, you must evaluate and identify all potential

risks as well as prepare suitable countermeasures before connecting the equipment to an uncontrolled IT network. For guidance addressing these risks, refer to IEC 80001-1:2010.

Table 5 IT network failure recovery measures

IT Network failure	Impact on the equipment	Hazard	System countermeasures
IT network becomes unstable	Unable to transmit exam data to a PACS	Delay of diagnosis	Exam data is stored in the system's internal storage. After the IT network has resumed Delay of transmission to a stability, you can re-initiate the data transfer.
	Delay of transmission to a PACS		
	Incorrect data transmitted to a PACS	Mis-diagnosis	The system uses the TCP/IP and DICOM protocols to ensure the integrity of the data.
	Unable to retrieve order data from an MWL server	Delay of exam	You can initiate/create a new exam from the system.
	Delay of retrieving order data from an MWL server		
	Incorrect data from a MWL server	Incorrect exam	The system uses the TCP/IP and DICOM protocols to ensure the integrity of the data.
Firewall has broken down	Attack via network	Manipulation of the exam data	The system closes unnecessary network ports.
	Infection by computer virus	Exam data leakage	The system forbids installation of any software by any user.

Even when the connection to an IT network is trusted, any change of the network settings requires immediate checkup and possible measures taken. Should any of the changes below occur, perform additional evaluation to the IT network.

- Changes in the network configuration (IP address, router, proxy, and so on)
- Connection of additional items
- Disconnection of items
- Equipment update
- Equipment upgrade

11.3 Appendix C: System Acoustic Output Default Tables

11.3.1 C62B Transducer

Table 6 System Acoustic Output Default Table (C62B transducer)

Preset	Mode	TI Label	Default TI	Default MI
Abdomen	B	TIS=TIB	0.024	0.631
	Color	TIS=TIB	0.265	0.826
	Power	TIS=TIB	0.267	0.826
	M	TIB	0.163	0.645
	PW	TIB	1.154	0.688
	Color-Triplex	TIB	1.623	0.753
	Power-Triplex	TIB	1.586	0.761
OB	B	TIS=TIB	0.021	0.628
	Color	TIS=TIB	0.380	0.752
	Power	TIS=TIB	0.379	0.746
	M	TIB	0.173	0.646
	PW	TIB	1.137	0.689
	Color-Triplex	TIB	1.839	0.718
	Power-Triplex	TIB	1.688	0.757
Renal	B	TIS=TIB	0.026	0.710
	Color	TIS=TIB	0.352	0.849
	Power	TIS=TIB	0.362	0.845
	M	TIB	0.229	0.735
	PW	TIB	0.988	0.715
	Color-Triplex	TIB	1.296	0.721
	Power-Triplex	TIB	1.225	0.804
Urology	B	TIS=TIB	0.037	0.704
	Color	TIS=TIB	0.250	0.950
	Power	TIS=TIB	0.247	0.945
	M	TIB	0.153	0.724
	PW	TIB	0.969	0.716
	Color-Triplex	TIB	1.550	0.734
	Power-Triplex	TIB	1.473	0.803

Table 6 System Acoustic Output Default Table (C62B transducer)

Preset	Mode	TI Label	Default TI	Default MI
GYN	B	TIS=TIB	0.030	0.773
	Color	TIS=TIB	0.211	1.048
	Power	TIS=TIB	0.208	1.039
	M	TIB	0.213	0.798
	PW	TIB	0.746	0.701
	Color-Triplex	TIB	1.476	0.805
	Power-Triplex	TIB	1.399	0.801
Nerve	B	TIS=TIB	0.012	0.619
	Color	TIS=TIB	0.271	0.825
	Power	TIS=TIB	0.249	0.823
	M	TIB	0.164	0.643
	PW	TIB	1.131	0.686
	Color-Triplex	TIB	1.627	0.754
	Power-Triplex	TIB	1.566	0.748

11.3.2 L154BH Transducer

Table 7 System Acoustic Output Default Table (L154BH transducer)

Preset	Mode	TI Label	Default TI	Default MI
Carotid	B	TIS=TIB	0.003	0.692
	Color	TIS=TIB	0.162	1.222
	Power	TIS=TIB	0.150	1.107
	M	TIB	0.583	0.628
	PW	TIB	0.172	0.796
	Color-Triplex	TIB	0.872	0.576
	Power-Triplex	TIB	1.031	0.754
Arterial	B	TIS=TIB	0.043	0.692
	Color	TIS=TIB	0.154	1.231
	Power	TIS=TIB	0.187	1.125
	M	TIB	0.186	0.845
	PW	TIB	0.417	0.817
	Color-Triplex	TIB	0.860	0.580
	Power-Triplex	TIB	0.881	0.573
Venous	B	TIS=TIB	0.006	0.685
	Color	TIS=TIB	0.168	1.242
	Power	TIS=TIB	0.171	1.125
	M	TIB	0.488	0.628
	PW	TIB	0.395	0.602
	Color-Triplex	TIB	0.747	0.574
	Power-Triplex	TIB	0.734	0.565
Thyroid	B	TIS=TIB	0.008	0.685
	Color	TIS=TIB	0.112	1.156
	Power	TIS=TIB	0.108	1.123
	M	TIB	0.530	0.614
	PW	TIB	0.322	0.596
	Color-Triplex	TIB	0.721	0.572
	Power-Triplex	TIB	0.583	0.564
Breast	B	TIS=TIB	0.004	0.681
	Color	TIS=TIB	0.148	1.232
	Power	TIS=TIB	0.138	1.140
	M	TIB	0.181	0.611
	PW	TIB	0.309	0.595
	Color-Triplex	TIB	0.589	0.576
	Power-Triplex	TIB	0.562	0.566

Table 7 System Acoustic Output Default Table (L154BH transducer)

Preset	Mode	TI Label	Default TI	Default MI
Bowel	B	TIS=TIB	0.011	0.711
	Color	TIS=TIB	0.212	1.278
	Power	TIS=TIB	0.205	1.138
	M	TIB	0.100	0.683
	PW	TIB	0.363	0.591
	Color-Triplex	TIB	1.379	0.572
	Power-Triplex	TIB	0.545	0.563
MSK	B	TIS=TIB	0.008	0.682
	Color	TIS=TIB	0.222	1.247
	Power	TIS=TIB	0.189	1.126
	M	TIB	0.866	0.597
	PW	TIB	0.436	0.594
	Color-Triplex	TIB	0.729	0.596
	Power-Triplex	TIB	0.670	0.567
Nerve	B	TIS=TIB	0.005	0.682
	Color	TIS=TIB	0.146	1.249
	Power	TIS=TIB	0.110	1.121
	M	TIB	0.161	0.591
	PW	TIB	0.308	0.593
	Color-Triplex	TIB	0.624	0.596
	Power-Triplex	TIB	0.408	0.568

11.3.3 P42B6 Transducer

Table 8 System Acoustic Output Default Table (P42B6 transducer)

Preset	Mode	TI Label	Default TI	Default MI
Cardiac	B	TIS=TIB	0.193	1.280
	Color	TIS=TIB	0.764	1.282
	Power	TIS=TIB	0.874	1.282
	M	TIB	1.079	1.386
	PW	TIB	1.127	0.697
	CW	TIB	1.761	0.062
	Color-Triplex	TIB	2.261	0.994
	Power-Triplex	TIB	2.245	0.992

11.4 Appendix D: Acoustic Output Reporting Tables for Track 3

We follow Track 3 of the FDA's information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. All table entries have been obtained at the same operating conditions that give rise to the maximum index value. Due to the complexities of the system user interface, it may be difficult to exactly replicate the declared condition. For more information, contact BenQ Medical Technology.

11.4.1 Definition of Terms Used in Acoustic Output Tables

Symbols used in the tables are described below:

α : Acoustic attenuation coefficient is the coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point.

A_{aprt}: *-12 dB output beam area* is the area of the ultrasonic beam derived from the *-12 dB* output beam dimensions.

C_{MI}: Normalizing coefficient *1 MPa MHz*$^{-1/2}$

D_{eq}: Equivalent aperture diameter is the diameter of a circle whose area is the *-12dB output beam area* and given by $D_{eq} = \sqrt{\frac{4}{\pi}A_{aprt}}$.

d_{eq}: *Equivalent beam diameter* is the value of the diameter of the acoustic beam at the distance z, in terms of the equivalent beam area, and given by $d_{eq}(z) = \sqrt{\frac{4}{\pi}A_{eq}(z)}$.

f_{awf}: *Acoustic working frequency* is the arithmetic mean of the most widely separated frequencies f_1 and f_2 at which the amplitude of the pressure spectrum of the acoustic signal is 3 dB lower than the peak amplitude.

I_{pa}: *Pulse-average intensity* is the ratio of the *pulse-intensity integral* I_{pi} to the pulse duration t_d.

$I_{pa,\,\alpha}$: *Attenuated pulse-average intensity* is the value of the *acoustic pulse-average intensity* after attenuation and at a specified point and given by $I_{pa,\,\alpha} = I_{pa}(z)10^{(-\alpha z f_{awf}/10)}$.

I_{spta}: *Spatial-peak temporal-average intensity*

$I_{spta,\,\alpha}$: *Attenuated spatial-peak temporal-average intensity*

MI: *Mechanical index* is given by $MI = \frac{P_{ra} f_{awf}^{-1/2}}{C_{MI}}$.

n_{pps}: *Number of pulses per ultrasonic scan line*

P: *Output power* is the time-average power radiated by an ultrasonic transducer into an approximately free field under specified conditions in a specified medium, preferably water.

P_α: *Attenuated output power* is the value of the acoustic *output power* after attenuation, at a specified distance from the transducer, and given by $p_\alpha = p10^{(-\alpha z f_{awf}/10)}$.

p_i: *Pulse-pressure-squared integral* is the time integral of the square of the instantaneous acoustic pressure at a particular point in an acoustic field integrated over the acoustic pulse waveform.

pii: *Pulse-intensity integral*

pii_α: *Attenuated Pulse-intensity integral*

p_r: *Peak-rarefactional acoustic pressure* is the maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field during an acoustic repetition period.

$p_{r,\,\alpha}$: *Attenuated peak-rarefactional acoustic pressure* is the value of the *peak-rarefactional acoustic pressure* after attenuation, at a specified point, and given by $p_{r,\,\alpha+}(z) = p_r(z)10^{(-\alpha z f_{awf}/20)}$.

prr: *Pulse repetition rate* is the inverse of the time interval between two successive acoustic pulses.

srr: *Scan repetition rate*

TI: *Thermal index* is the ratio of attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1°C.

TIB: *Bone thermal index* is the thermal index for applications, such as fetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue, and a focal region is in the immediate vicinity of bone.

TIC: Cranial-bone thermal index is the thermal index for applications, such as pediatric and adult-cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.

TIS: *Soft-tissue thermal index* is the thermal index related to soft tissues.

t_d: *Pulse duration* is 1.25 times the interval between the time when the time integral of intensity in an acoustic pulse at a point reaches 10% and when it reaches 90% of the *pulse-intensity integral*.

z: Distance from the source to a specified point.

z_b: Depth for *TIB*.

z_{bp}: *Break-point depth* is the value equal to 1.5 times the *equivalent aperture diameter* and given by $z_{bp} = 1.5D_{eq}$.

z_{pii}: *Depth for peak pulse-intensity integral*.

z_{MI}: Depth for *MI*.

$z_{pii,\alpha}$: *Depth for peak attenuated pulse-intensity integral*.

z_{sii}: *Depth for peak sum of pulse-intensity integrals*.

$z_{sii,\alpha}$: *Depth for peak sum of attenuated pulse-intensity integrals*.

z_s: Depth for *TIS*.

11.4.2 Acoustic Output Tables for T3300 Transducers

11.4.2.1 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (B-Mode)

Table 9 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (B-Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.0241	0.1925		0.1925		n/a
Index component value				0.1925	0.1925	0.1925	0.1925	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8359					
	P	(mW)		42.6		42.6		n/a
	P_{1x1}	(mW)		13.5		13.5		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.51					
	$z_{pii,\alpha}$	(cm)	5.79					
	f_{awf}	(MHz)	3.32	2.985		2.985		n/a
Other information	*prr*	(Hz)	166					
	srr	(Hz)	166					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	171.93					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	23.48					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	84.2					
	p_r at z_{pii}	(MPa)	3.3539					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, B mode, 2D Focus 5.0, Density Low, FQBeam off, SQBeam off, 2D Depth 5.5, 2D Gain 44, Sector Width 70, Power 100, Freq Gen

Control 2: Abdominal, B mode, 2D Focus 8.0, Density Low, FQBeam off, SQBeam off, 2D Depth 9, 2D Gain 44, Sector Width 46, Power 100, Freq Pen

11.4.2.2 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (Color Mode)

Table 10 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (Color Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.3343	1.0173		1.0173		n/a
Index component value				1.0173	1.0173	1.0173	1.0173	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8612					
	P	(mW)		B: 8.54 Col: 252.6		B: 8.54 Col: 252.6		n/a
	P_{1x1}	(mW)		B: 2.81 Col: 76.3		B: 2.81 Col: 76.3		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.05					
	$z_{pii,\alpha}$	(cm)	5.57					
	f_{awf}	(MHz)	2.058	B: 3.012 Col: 2.688		B: 3.012 Col: 2.688		n/a
Other information	prr	(Hz)	495					
	srr	(Hz)	45					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	117.7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	23.04					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	41.99					
	p_r at z_{pii}	(MPa)	2.5971					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, Color mode, ROI box minimized @ max depth, Focus 5.0, 2D/Color Density Low, FQBeam off, SQBeam off, Depth 5.5, Gain 44, Sector Width 70, Power 100, 2D/ Color Freq Pen, Color Scale 102cm/s

Control 2: Abdominal, B/Color mode, ROI box minimized @ min depth, Focus 14.0, 2D/Color Density High, FQBeam off, SQBeam off,2D Depth 15, 2D Gain 44, Sector Width 46, Power 100, Freq 2D Pen/ ColorRes, Color Scale 42cm/ss

11.4.2.3 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (Power Mode)

Table 11 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (Power Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.3123	1.2129		1.2129		n/a
Index component value				1.2129	1.2129	1.2129	1.2129	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8315					
	P	(mW)		B: 8.55 Power: 240		B: 8.55 Power: 240		n/a
	P_{1x1}	(mW)		B: 2.59 Power: 76.3		B: 2.59 Power: 76.3		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.07					
	$z_{pii,\alpha}$	(cm)	5.79					
	f_{awf}	(MHz)	2.058	B: 2.992 Power: 3.24		B: 2.992 Power: 3.24		n/a
Other information	*prr*	(Hz)	495					
	srr	(Hz)	45					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	112.31					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	25.07					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	45.58					
	p_r at z_{pii}	(MPa)	2.5014					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, Power mode, ROI box minimized @ max depth, Focus 5.0, 2D/CPA Density Low, FQBeam off, SQBeam off, Depth 5.5, Gain 44, Sector Width 70, Power 100, 2D/CPA Freq Pen, CPA Scale PRF6

Control 2: Abdominal, B/Power mode, ROI box minimized @ min depth, Focus 14.0, Density 2D Low/CPA High, FQBeam off, SQBeam off,2D Depth 15, 2D Gain 44, Sector Width 46, Power 100, Freq 2D Gen/ ColorRes, CPA Scale PRF3

11.4.2.4 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (M Mode)

Table 12 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (M Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.0516	0.2309		0.4883		n/a
Index component value				0.1898	0.2309	0.1898	0.4883	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.0449					
	P	(mW)		B: 31.2 M: 9.14		B: 31.2 M: 9.14		n/a
	P_{1x1}	(mW)		B: 9.75 M: 2.56		B: 9.75 M: 2.56		
	z_s	(cm)			2.5			
	z_b	(cm)					5.02	
	z_{MI}	(cm)	5.43					
	$z_{pii,\alpha}$	(cm)	5.85					
	f_{awf}	(MHz)	3.89	B: 3.046 M: 3.24		B: 3.046 M: 3.24		n/a
Other information	*prr*	(Hz)	250					
	srr	(Hz)	250					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	332.42					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	69.6					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	278.9					
	p_r at z_{pii}	(MPa)	3.784					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, M mode, 2D Focus 5.0, Density Low, FQBeam off, SQBeam off, 2D Depth 5.5, 2D Gain 44, Sector Width 128, Power 100, Freq Gen

Control 2: Abdominal, M mode, 2D Focus 5.0, Density Low, FQBeam off, SQBeam off, 2D Depth 5.5, 2D Gain 44, Sector Width 46, Power 100, Freq Pen

11.4.2.5 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (PW Mode)

Table 13 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (PW Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.2848	0.68		1.87		n/a
Index component value				0.519	0.68	0.519	1.871	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8557					
	P	(mW)		93.2		93.2		n/a
	P_{1x1}	(mW)		33.9		33.9		
	z_s	(cm)			3.34			
	z_b	(cm)					6	
	z_{MI}	(cm)	5.23					
	$z_{pii,\alpha}$	(cm)	5.67					
	f_{awf}	(MHz)	2.197	3.21		3.21		n/a
Other information	prr	(Hz)	1300					
	srr	(Hz)	1300					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	98.56					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	261.4					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	528					
	p_r at z_{pii}	(MPa)	2.5817					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, PW mode, 2D Focus 5.0, Density Low, FQBeam off, SQBeam off,2D Depth 5.5, 2D Gain 44, Sector Width 70, Power 100, Freq Pen, Filter 65Hz

Control 2: Abdominal, PW mode, 2D Focus 9, Density Low, FQBeam off, SQBeam off,2D Depth 10, 2D Gain 44, Sector Width 128, Power 100, Freq Res, Filter 200Hz

11.4.2.6 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (Triplex Mode)

Table 14 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (Triplex Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.137	0.8799		1.6959		n/a
Index component value				0.7181	0.8799	0.7181	1.6959	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.586					
	P	(mW)		B: 11.02 Col: 106.2 PW: 67.6		B: 11.02 Col: 106.2 PW: 67.6		n/a
	P_{1x1}	(mW)		B: 3.33 Col: 33.5 PW: 20.3		B: 3.33 Col: 33.5 PW: 20.3		
	z_s	(cm)			B/col: 0 PW: 4.02			
	z_b	(cm)					B/col: 0 PW: 4.64	
	z_{MI}	(cm)	5.04					
	$z_{pii,\alpha}$	(cm)	5.02					
	f_{awf}	(MHz)	1.947	B: 3.145 Col: 2.689 PW: 2.474		B: 3.145 Col: 2.689 PW: 2.474		n/a
Other information	prr	(Hz)	1300					
	srr	(Hz)	1300					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	92.2					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	246.7					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	496					
	p_r at z_{pii}	(MPa)	2.18					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, Triplex mode, ROI box flat wide @ max depth, Focus 5.0, SV 5.0, 2D/Color Density High, FQBeam off, SQBeam off, Depth 5.5, Gain 44, Sector Width 46, Power 100, 2D/Color/PW Freq Pen, Color Scale 26cm/s, Wall Filter 65Hz

Control 2: Abdominal, Triplex mode, ROI box minimized @ min depth, Focus 13.0, SV 13.0, 2D/ Color Density High, FQBeam off, SQBeam off, Depth 14, Gain 44, Sector Width 46, Power 100, 2D/Color/PW Freq Gen/Res/Gen, Color Scale 28cm/s, Wall Filter 100Hz

11.4.2.7 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI Mode)

Table 15 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.2529	0.366		0.366		n/a
Index component value				0.366	0.366	0.366	0.366	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.1868					
	P	(mW)		80.2		80.2		n/a
	P_{1x1}	(mW)		24.7		24.7		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.23					
	$z_{pii,\alpha}$	(cm)	5.47					
	f_{awf}	(MHz)	3.158	3.109		3.109		n/a
Other information	prr	(Hz)	166					
	srr	(Hz)	166					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	328.24					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	74.78					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	223.66					
	p_r at z_{pii}	(MPa)	3.718					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, THI mode, Focus 5.0, Density Low, FQBeam off, SQBeam off, Depth 5.5, Gain 44, Sector Width 70, Power 100, Freq Gen

Control 2: Abdominal, THI mode, Focus 8.0, Density Low, FQBeam off, SQBeam off, Depth 9, Gain 44, Sector Width 46, Power 100, Freq Res

11.4.2.8 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI+Color Mode)

Table 16 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI+Color Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.3376	1.0681		1.0681		n/a
Index component value				1.0681	1.0681	1.0681	1.0681	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8667					
	P	(mW)		THI: 16.5 Col: 250.3		THI: 16.5 Col: 250.3		n/a
	P_{1x1}	(mW)		THI: 5 Col: 78.3		THI: 5 Col: 78.3		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.07					
	$z_{pii,\alpha}$	(cm)	5.61					
	f_{awf}	(MHz)	2.057	THI: 2.691 Col: 2.693		THI: 2.691 Col: 2.6939		n/a
Other information	*prr*	(Hz)	495					
	srr	(Hz)	45					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	116.71					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	23.52					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	42.66					
	p_r at z_{pii}	(MPa)	2.5839					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, Color mode, ROI box minimized @ max depth, Focus 5.0, 2D/Color Density Low, FQBeam off, SQBeam off, Depth 5.5, Gain 44, Sector Width 70, Power 100, 2D/ Color Freq Pen, Color Scale 102cm/s

Control 2: Abdominal, THI/Color mode, ROI box minimized @ min depth, Focus 14.0, THI/Color Density High, FQBeam off, SQBeam off,2D Depth 15, 2D Gain 44, Sector Width 46, Power 100, Freq 2D Pen/ ColorRes, PRF Scale 42cm/s

11.4.2.9 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI+Power Mode)

Table 17 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI+Power Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.3365	1.1025		1.1025		n/a
Index component value				1.1025	1.1025	1.1025	1.1025	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8656					
	P	(mW)		THI: 15.9 Power: 241.2		THI: 15.9 Power: 241.2		n/a
	P_{1x1}	(mW)		THI: 5.1 Power: 67		THI: 5.1 Power: 67		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.17					
	$z_{pii,\alpha}$	(cm)	5.69					
	f_{awf}	(MHz)	2.058	THI: 2.987 Power: 3.23		THI: 2.987 Power: 3.23		n/a
Other information	*prr*	(Hz)	495					
	srr	(Hz)	45					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	115.72					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	24.76					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	44.97					
	p_r at z_{pii}	(MPa)	2.5619					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, Power mode, ROI box minimized @ max depth, Focus 5.0, 2D/CPA Density Low, FQBeam off, SQBeam off, Depth 5.5, Gain 44, Sector Width 70, Power 100, 2D/CPA Freq Pen, CPA Scale PRF6

Control 2: Abdominal, THI/Power mode, ROI box minimized @ min depth, Focus 14.0, Density 2D Low/CPA High, FQBeam off, SQBeam off,2D Depth 15, 2D Gain 44, Sector Width 46, Power 100, Freq 2D Gen/ ColorRes, CPA Scale PRF3

11.4.2.10 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI+M Mode)

Table 18 Acoustic Output Reporting Table for Track 3 for the C62B Transducer (THI+M Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.2881	0.3806		0.638		n/a
Index component value				0.3395	0.3806	0.3395	0.638	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.2759					
	P	(mW)		THI: 62.4 M: 9.14		THI: 62.4 M: 9.14		n/a
	P_{1x1}	(mW)		THI: 19.5 M: 2.56		THI: 19.5 M: 2.56		
	z_s	(cm)			2.5			
	z_b	(cm)					5.02	
	z_{MI}	(cm)	5.27					
	$z_{pii,\alpha}$	(cm)	5.55					
	f_{awf}	(MHz)	3.234	THI: 3.24 M: 2.56		THI: 3.24 M: 2.56		n/a
Other information	*prr*	(Hz)	250					
	srr	(Hz)	250					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	426.8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	102.8					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	328					
	p_r at z_{pii}	(MPa)	3.883					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Abdominal, THI/M mode, 2D Focus 5.0, Density Low, FQBeam off, SQBeam off,2D Depth 5.5, 2D Gain 44, Sector Width 128, Power 100, Freq Gen

Control 2: Abdominal, THI/M mode, 2D Focus 5.0, Density Low, FQBeam off, SQBeam off,2D Depth 5.5, 2D Gain 44, Sector Width 46, Power 100, Freq Pen

11.4.2.11 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (B-Mode)

Table 19 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (B-Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.9603	0.2516		0.2516		n/a
Index component value				0.2516	0.2516	0.2516	0.2516	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.4574					
	P	(mW)		12.49		12.49		n/a
	P_{1x1}	(mW)		8.07		8.07		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	2.03					
	$z_{pii,\alpha}$	(cm)	2.07					
	f_{awf}	(MHz)	6.7	6.55		6.55		n/a
Other information	*prr*	(Hz)	300.03					
	srr	(Hz)	300.03					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	376.2					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	17.24					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	39.43					
	p_r at z_{pii}	(MPa)	3.74					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, B mode, 2D Focus 2.5, Density Low, SQBeam off, 2D Depth 3, 2D Gain 64, Sector Width 46, Power 100, Freq Pen

Control 2: Carotid, B mode, 2D Focus 5.5, Density High, SQBeam off, 2D Depth 6, 2D Gain 64, Sector Width 46, Power 100, Freq Pen

11.4.2.12 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (Color Mode)

Table 20 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (Color Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.2595	1.4371		1.4371		n/a
Index component value				1.4371	1.4371	1.4371	1.4371	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.1053					
	P	(mW)		B: 3.18 Col: 99.9		B: 3.18 Col: 99.9		n/a
	P_{1x1}	(mW)		B: 1.67 Col: 57.8		B: 1.67 Col: 57.8		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	1.79					
	$z_{pii,\alpha}$	(cm)	1.93					
	f_{awf}	(MHz)	6.23	B: 6.55 Col: 5.03		B: 6.55 Col: 5.03		n/a
Other information	*prr*	(Hz)	398.123					
	srr	(Hz)	36.193					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	704					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	13.27					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	27.27					
	p_r at z_{pii}	(MPa)	4.191					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, Color mode, ROI box minimized @ max depth, Focus 2.5, 2D/Color Density Low/High, SQBeam off, Depth 3, Gain 64, Sector Width 46, Power 100, 2D/Color Freq Res, Color Scale 44cm/s

Control 2: Carotid, B/Color mode, ROI box minimized @ min depth, Focus 7.5, 2D/Color Density High, SQBeam off, 2D Depth 8, 2D Gain 64, Sector Width 46, Power 100, Freq 2D Pen/ColorGen, Color Scale 46cm/s, Steer 0

11.4.2.13 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (Power Mode)

Table 21 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (Power Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.2419	0.9966		0.9966		n/a
Index component value				0.9966	0.9966	0.9966	0.9966	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.0591					
	P	(mW)		B: 2.9 Power: 57.2		B: 2.9 Power: 57.2		n/a
	P_{1x1}	(mW)		B: 1.55 Power: 39.48		B: 1.55 Power: 39.4		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	1.81					
	$z_{pii,\alpha}$	(cm)	1.89					
	f_{awf}	(MHz)	6.22	B: 6.59 Power: 5.05		B: 6.59 Power: 5.05		n/a
Other information	*prr*	(Hz)	398.123					
	srr	(Hz)	36.193					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	705.1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	13.05					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	26.87					
	p_r at z_{pii}	(MPa)	4.257					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, Power mode, ROI box minimized @ max depth, Focus 2.5, 2D/CPA Density Low/ High, SQBeam off, Depth 3, Gain 64, Sector Width 46, Power 100, 2D/CPA Freq Gen, CPA Scale PRF 7

Control 2: Carotid, B/Power mode, ROI box minimized @ min depth, Focus 7.5, Density 2D Low/ Color High, SQBeam off, 2D Depth 8, 2D Gain 64, Sector Width 46, Power 100, Freq 2D Pen/ CPA Pen, CPA Scale PRF 4, Steer 0

11.4.2.14 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (M Mode)

Table 22 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (M Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.9999	0.14081		0.1794		n/a
Index component value				0.14081	0.1308	0.14081	0.1794	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.6851					
	P	(mW)		B: 10.7 M: 0.5625		B: 10.7 M: 0.5625		n/a
	P_{1x1}	(mW)		B: 3.9 M: 0.5589		B: 3.9 M: 0.5589		
	z_s	(cm)			1.47			
	z_b	(cm)					1.47	
	z_{MI}	(cm)	1.92					
	$z_{pii,\alpha}$	(cm)	2					
	f_{awf}	(MHz)	7.35	B: 6.54 M: 7.26		B: 6.54 M: 7.26		n/a
Other information	prr	(Hz)	250					
	srr	(Hz)	250					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	551.1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	64.7					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	159.2					
	p_r at z_{pii}	(MPa)	4.114					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, M mode, 2D Focus 2.5, Density Low, SQBeam off, 2D Depth 3, 2D Gain 64, Sector Width 128, Power 100, Freq Pen

Control 2: Carotid, M mode, 2D Focus 7.5, Density High, SQBeam off, 2D Depth 8, 2D Gain 64, Sector Width 46, Power 100, Freq Pen

11.4.2.15 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (PW Mode)

Table 23 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (PW Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.9804	0.698		2.152		n/a
Index component value				0.698	0.676	0.698	2.152	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.4264					
	P	(mW)		44.8		44.8		n/a
	P_{1x1}	(mW)		23.9		23.9		
	z_s	(cm)			1.56			
	z_b	(cm)					1.56	
	z_{MI}	(cm)	1.86					
	$z_{pii,\alpha}$	(cm)	2.13					
	f_{awf}	(MHz)	6.19	6.13		6.13		n/a
Other information	*prr*	(Hz)	1300					
	srr	(Hz)	1300					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	409.2					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	651.6					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	1664.4					
	p_r at z_{pii}	(MPa)	3.6936					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, PW mode, 2D Focus 3, Density Low, SQBeam off, 2D Depth 3.5, 2D Gain 64, Sector Width 128, Power 100, Freq Res

Control 2: Carotid, PW mode, 2D Focus 8.5, Density High, SQBeam off, 2D Depth 9, 2D Gain 64, Sector Width 256, Power 100, Freq Res

11.4.2.16 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (Triplex Mode)

Table 24 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (Triplex Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.952	1.3865		3.0245		n/a
Index component value				1.3335	1.3865	1.3335	3.0245	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.914					
	P	(mW)		B: 3.54 Col: 62.6 PW: 36.8		B: 3.54 Col: 62.6 PW: 36.8		n/a
	P_{1x1}	(mW)		B: 1.89 Col: 33.5 PW: 19.9		B: 1.89 Col: 33.5 PW: 19.9		
	z_s	(cm)			B/col: 0 PW: 1.47			
	z_b	(cm)					B/col: 0 PW: 1.47	
	z_{MI}	(cm)	1.42					
	$z_{pii,\alpha}$	(cm)	1.55					
	f_{awf}	(MHz)	4.04	B: 6.5 Col: 5.02 PW: 5		B: 6.5 Col: 5.02 PW: 5		n/a
Other information	*prr*	(Hz)	1300					
	srr	(Hz)	1300					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	183.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	479					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	755					
	p_r at z_{pii}	(MPa)	2.317					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, Triplex mode, ROI box flat wide @ max depth, Focus 2.5, SV 2.5, 2D/Color Density High, SQBeam off, Depth 3, Gain 64, Sector Width 46, Power 100, 2D/Color/PW Freq Pen/Res/Pen, Color Scale 8cm/s, Wall Filter 39Hz, Steer 0

Control 2: Carotid, Triplex mode, ROI box minimized @ min depth, Focus 7.5, SV 7.5, 2D/Color Density High, SQBeam off, 2D Depth 8, 2D Gain 64, Sector Width 46, Power 100, 2D/Color/PW Freq Pen/Gen/Gen, Color Scale 10cm/s, Wall Filter 39Hz, Steer 0

11.4.2.17 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI Mode)

Table 25 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.0351	0.2323		0.2323		n/a
Index component value				0.2323	0.2323	0.2323	0.2323	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.464					
	P	(mW)		13.5		13.5		n/a
	P_{1x1}	(mW)		9.1		9.1		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	1.97					
	$z_{pii,\alpha}$	(cm)	2.1					
	f_{awf}	(MHz)	5.82	5.36		5.36		n/a
Other information	prr	(Hz)	300.03					
	srr	(Hz)	300.03					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	368.5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	21.3882					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	40.5836					
	p_r at z_{pii}	(MPa)	3.3594					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, THI mode, 2D Focus 2.5, Density Low, SQBeam off, 2D Depth 3, 2D Gain 64, Sector Width 46, Power 100, Freq Pen

Control 2: Carotid, THI mode, 2D Focus 6.5, Density High, SQBeam off, 2D Depth 7, 2D Gain 64, Sector Width 46, Power 100, Freq Pen

11.4.2.18 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI+Color Mode)

Table 26 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI+Color Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.2496	1.5142		1.5142		n/a
Index component value				1.5142	1.5142	1.5142	1.5142	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.08					
	P	(mW)		THI: 4.58 Col: 103.4		THI: 4.58 Col: 103.4		n/a
	P_{1x1}	(mW)		THI: 2.43 Col: 58		THI: 2.43 Col: 58		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	1.8					
	$z_{pii,\alpha}$	(cm)	1.86					
	f_{awf}	(MHz)	6.22	THI: 5.33 Col: 5.04		THI: 5.33 Col: 5.04		n/a
Other information	prr	(Hz)	398.123					
	srr	(Hz)	36.193					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	701.8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	13.17					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	27.14					
	p_r at z_{pii}	(MPa)	4.323					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, Color mode, ROI box minimized @ max depth, Focus 2.5, THI/Color Density Low/High, SQBeam off, Depth 3, Gain 64, Sector Width

Control 2: Carotid, THI/Color mode, ROI box minimized @ min depth, Focus 8.5, 2D/Color Density High, SQBeam off, 2D Depth 9, 2D Gain 64, Sector

11.4.2.19 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI+Power Mode)

Table 27 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI+Power Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.232	1.244		1.244		n/a
Index component value				1.244	1.244	1.244	1.244	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.0349					
	P	(mW)		THI: 8.28 Power: 60.4		THI: 8.28 Power: 60.4		n/a
	P_{1x1}	(mW)		THI: 3.96 Power: 32.9		THI: 3.96 Power: 32.9		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	1.81					
	$z_{pii,\alpha}$	(cm)	1.9					
	f_{awf}	(MHz)	6.22	THI: 5.62 Power: 7.26		THI: 5.62 Power: 7.26		n/a
Other information	prr	(Hz)	398.123					
	srr	(Hz)	36.193					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	699.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	12.75					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	26.3					
	p_r at z_{pii}	(MPa)	4.202					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, Power mode, ROI box minimized @ max depth, Focus 2.5, 2D/CPA Density Low/ High, SQBeam off, Depth 3, Gain 64, Sector Width 46, Power 100, 2D/CPA Freq Gen, CPA Scale PRF 7

Control 2: Carotid, THI/Power mode, ROI box minimized @ min depth, Focus 8.5, Density 2D High/ Color High, SQBeam off, 2D Depth 9, 2D Gain 64, Sector Width 46, Power 100, Freq THI Gen/ CPA Res, CPA Scale PRF 4, Steer 0

11.4.2.20 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI+M Mode)

Table 28 Acoustic Output Reporting Table for Track 3 for the L154BH Transducer (THI+M Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.3805	0.16429		0.2108		n/a
Index component value				0.16404	0.16429	0.16404	0.2108	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.0987					
	P	(mW)		THI: 11.6 M: 0.5589		THI: 11.6 M: 0.5589		n/a
	P_{1x1}	(mW)		THI: 6.1 M: 0.2732		THI: 6.1 M: 0.2732		
	z_s	(cm)			1.47			
	z_b	(cm)					1.47	
	z_{MI}	(cm)	1.85					
	$z_{pii,\alpha}$	(cm)	1.9					
	f_{awf}	(MHz)	5.19	THI: 5.32 M: 7.26		THI: 5.32 M: 7.26		n/a
Other information	prr	(Hz)	250					
	srr	(Hz)	250					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	660					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	110.3					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	186.3					
	p_r at z_{pii}	(MPa)	3.828					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Carotid, THI/M mode, 2D Focus 2.5, Density Low, SQBeam off, 2D Depth 3, 2D Gain 64, Sector Width 128, Power 100, Freq Pen

Control 2: Carotid, THI/M mode, 2D Focus 7.5, Density High, SQBeam off, 2D Depth 8, 2D Gain 64, Sector Width 46, Power 100, Freq Pen

11.4.2.21 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (B-Mode)

Table 29 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (B-Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.0818	0.46		0.46		n/a
Index component value				0.46	0.46	0.46	0.46	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.7784					
	P	(mW)		50.2		50.2		n/a
	P_{1x1}	(mW)		43.3		43.3		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	5.09					
	$z_{pii,\alpha}$	(cm)	5.48					
	f_{awf}	(MHz)	2.824	2.23		2.23		n/a
Other information	*prr*	(Hz)	275.86					
	srr	(Hz)	275.86					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	220.59					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	219.17					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	346.37					
	p_r at z_{pii}	(MPa)	2.6955					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, B mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 6.5, 2D Gain 45, Sector Width 62, Power 100, Freq Gen

Control 2: Cardiac, B mode, 2D Focus 5.0, Density Low, FQBeam off, 2D Depth 6, 2D Gain 45, Sector Width 70, Power 100, Freq Res

11.4.2.22 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (Color Mode)

Table 30 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (Color Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.1601	1.6911		1.6911		n/a
Index component value				1.6911	1.6911	1.6911	1.6911	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8333					
	P	(mW)		B: 7 Col: 234.2		B: 7 Col: 234.2		n/a
	P_{1x1}	(mW)		B: 6.3 Col: 138.3		B: 6.3 Col: 138.3		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	4.79					
	$z_{pii,\alpha}$	(cm)	5.06					
	f_{awf}	(MHz)	2.619	B: 2.036 Col: 2.475		B: 2.036 Col: 2.475		n/a
Other information	prr	(Hz)	435.732					
	srr	(Hz)	39.612					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	324.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	100.3					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	202.06					
	p_r at z_{pii}	(MPa)	2.754					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, Color mode, ROI box minimized @ max depth, Focus 6.0, 2D/Color Density Low, FQBeam off, Depth 6.5, Gain 45, Sector Width 62, Power 100, 2D/Color Freq Gen, Color Scale 69cm/s

Control 2: Cardiac, B/Color mode, ROI box minimized @ min depth, Focus 8.0, 2D/Color Density High, FQBeam off, 2D Depth 9, 2D Gain 45, Sector Width 86, Power 100, Freq 2D Gen/ ColorGen, Color Scale 61cm/s

11.4.2.23 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (Power Mode)

Table 31 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (Power Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.1637	1.26056		1.26056		n/a
Index component value				1.26056	1.26056	1.26056	1.26056	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8396					
	P	(mW)		B: 1.16 Power: 129.3		B: 1.16 Power: 129.3		n/a
	P_{1x1}	(mW)		B: 0.71 Power: 77.5		B: 0.71 Power: 77.5		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	4.82					
	$z_{pii,\alpha}$	(cm)	5.03					
	f_{awf}	(MHz)	2.618	B: 2.532 Power: 3.39		B: 2.532 Power: 3.39		n/a
Other information	*prr*	(Hz)	457.853					
	srr	(Hz)	41.623					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	326.7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	109.024					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	217.985					
	p_r at z_{pii}	(MPa)	2.7081					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, Power mode, ROI box minimized @ max depth, Focus 6.0, 2D/Color Density Low, FQBeam off, Depth 6.5, Gain 45, Sector Width 62, Power 100, 2D/Color Freq Gen, CPA Scale PRF 5

Control 2: Cardiac, B/Power mode, ROI box minimized @ min depth, Focus 10.0, Density 2D Low/ CPA High, FQBeam off, 2D Depth 11, 2D Gain 45, Sector Width 86, Power 100, Freq 2D Gen/ CPARes, CPA Scale PRF 4

11.4.2.24 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (CW Mode)

Table 32 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (CW Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.6048	0.606		2.259		n/a
Index component value				0.606	0.502	0.606	2.259	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.0855					
	P	(mW)		69.8		69.8		n/a
	P_{1x1}	(mW)		63.6		63.6		
	z_s	(cm)			2.03			
	z_b	(cm)					2.96	
	z_{MI}	(cm)	3.23					
	$z_{pii,\alpha}$	(cm)	3.53					
	f_{awf}	(MHz)	2.12	2		2		n/a
Other information	*prr*	(Hz)	n/a					
	srr	(Hz)	n/a					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	0.24813					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	275.7					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	431					
	p_r at z_{pii}	(MPa)	0.10629					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, CW mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 6.5, 2D Gain 45, Sector Width 128, Power 100, Freq Gen

11.4.2.25 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (M Mode)

Table 33 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (M Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.1412	0.6077		0.943		n/a
Index component value				0.6077	0.5861	0.6077	0.943	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.9647					
	P	(mW)		B: 49.1 M: 12.6		B: 49.1 M: 12.6		n/a
	P_{1x1}	(mW)		B: 33.61 M: 9.4		B: 33.61 M: 9.4		
	z_s	(cm)			2.3			
	z_b	(cm)					5	
	z_{MI}	(cm)	4.85					
	$z_{pii,\alpha}$	(cm)	5.09					
	f_{awf}	(MHz)	3.086	B: 2.711 M: 2.965		B: 2.711 M: 2.965		n/a
Other information	*prr*	(Hz)	250					
	srr	(Hz)	250					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	379.8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	122.8					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	351					
	p_r at z_{pii}	(MPa)	3.204					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, M mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 6.5, 2D Gain 45, Sector Width 128, Power 100, Freq Gen

Control 2: Cardiac, M mode, 2D Focus 7.0, Density Low, FQBeam off, 2D Depth 8, 2D Gain 45, Sector Width 70, Power 100, Freq Gen

11.4.2.26 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (PW Mode)

Table 34 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (PW Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.0773	0.2972		1.915		n/a
Index component value				0.2641	0.2972	0.2641	1.915	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.7055					
	P	(mW)		43.1		43.1		n/a
	P_{1x1}	(mW)		27.6		27.6		
	z_s	(cm)			2.36			
	z_b	(cm)					4.76	
	z_{MI}	(cm)	4.85					
	$z_{pii,\alpha}$	(cm)	5.36					
	f_{awf}	(MHz)	2.625	2.009		2.009		n/a
Other information	*prr*	(Hz)	5000					
	srr	(Hz)	5000					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	231.66					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	363					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	616					
	p_r at z_{pii}	(MPa)	2.3076					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, PW mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 6.5, 2D Gain 45, Sector Width 128, Power 100, Freq Pen

Control 2: Cardiac, PW mode, 2D Focus 8.0, Density Low, FQBeam off, 2D Depth 9, 2D Gain 45, Sector Width 70,

11.4.2.27 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (Triplex Mode)

Table 35 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (Triplex Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.262	1.0341		2.727		n/a
Index component value				0.9969	1.0341	0.9969	2.727	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.786					
	P	(mW)		B: 5.5 Col: 108 PW: 42.2		B: 5.5 Col: 108 PW: 42.2		n/a
	P_{1x1}	(mW)		B: 2.6 Col: 59.6 PW: 26.4		B: 2.6 Col: 59.6 PW: 26.4		
	z_s	(cm)			B/col: 0 PW: 2.39			
	z_b	(cm)					B/col: 0 PW: 4.85	
	z_{MI}	(cm)	3.41					
	$z_{pii,\alpha}$	(cm)	3.95					
	f_{awf}	(MHz)	2.004	B: 2.775 Col: 2.502 PW: 2.008		B: 2.775 Col: 2.502 PW: 2.008		n/a
Other information	*prr*	(Hz)	1300					
	srr	(Hz)	1300					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	170.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	395					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	678					
	p_r at z_{pii}	(MPa)	2.237					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, Triplex mode, ROI box flat wide @ max depth, Focus 6, SV 6, 2D/Color Density

High, FQBeam off, Depth 6.5, Gain 45, Sector Width 70, Power 100, 2D/Color/PW Freq Gen/Gen/Pen, Color Scale 20cm/s, Wall Filter 91Hz

Control 2: Cardiac, Triplex mode, ROI box minimized @ min depth, Focus 9, SV 9, 2D/Color Density High, FQBeam off, 2D Depth 10, 2D Gain 45, Sector Width 46, Power 100, 2D/Color/PW Freq Res/Gen/Pen, Color Scale 30cm/s, Wall Filter 140Hz

11.4.2.28 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI Mode)

Table 36 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.3338	0.742		0.742		n/a
Index component value				0.742	0.742	0.742	0.742	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8243					
	P	(mW)		94		94		n/a
	P_{1x1}	(mW)		73.2		73.2		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	3.86					
	$z_{pii,\alpha}$	(cm)	4.19					
	f_{awf}	(MHz)	1.99	2.129		2.129		n/a
Other information	*prr*	(Hz)	275.7					
	srr	(Hz)	137.85					
	n_{pps}		2					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	158.85					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	211.15					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	319.24					
	p_r at z_{pii}	(MPa)	2.1906					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, THI mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 6.5, 2D Gain 45, Sector Width 62, Power 100, Freq Gen

Control 2: Cardiac, THI mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 7, 2D Gain 45, Sector Width 70, Power 100, Freq Res

11.4.2.29 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI+Color Mode)

Table 37 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI+Color Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.1808	2.0127		2.0127		n/a
Index component value				2.0127	2.0127	2.0127	2.0127	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8675					
	P	(mW)		B: 35.6 Col: 262.4		B: 35.6 Col: 262.4		n/a
	P_{1x1}	(mW)		B: 20.8 Col: 154.9		B: 20.8 Col: 154.9		
	z_s	(cm)			n/a		n/a	
	z_b	(cm)						
	z_{MI}	(cm)	4.76					
	$z_{pii,\alpha}$	(cm)	5.18					
	f_{awf}	(MHz)	2.62	THI: 1.885 Col: 2.475		THI: 1.885 Col: 2.475		n/a
Other information	*prr*	(Hz)	435.732					
	srr	(Hz)	39.612					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	324.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	104.317					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	208.415					
	p_r at z_{pii}	(MPa)	2.6424					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, Color mode, ROI box minimized @ max depth, Focus 6.0, 2D/Color Density Low, FQBeam off, Depth 6.5, Gain 45, Sector Width 62, Power 100, 2D/Color Freq Gen, Color Scale 69cm/s

Control 2: Cardiac, THI/Color mode, ROI box minimized @ min depth, Focus 8.0, 2D/Color Density High, FQBeam off, 2D Depth 9, 2D Gain 45, Sector Width 86, Power 100, Freq 2D Gen/ ColorGen, Color Scale 61cm/s

11.4.2.30 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI+Power Mode)

Table 38 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI+Power Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.1718	1.6591		1.6591		n/a
Index component value				1.6591	1.65917	1.6591	1.6591	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.8522					
	P	(mW)		THI: 44 Power: 203.2		THI: 44 Power: 203.2		n/a
	P_{1x1}	(mW)		THI: 25.7 Power: 119		THI: 25.7 Power: 119		
	z_s	(cm)			0			
	z_b	(cm)					0	
	z_{MI}	(cm)	4.79					
	$z_{pii,\alpha}$	(cm)	5.12					
	f_{awf}	(MHz)	2.619	THI: 2.101 Power: 2.475		THI: 2.101 Power: 2.475		n/a
Other information	*prr*	(Hz)	457.853					
	srr	(Hz)	41.623					
	n_{pps}		11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	324					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/ cm^2)	108.18					
	I_{spta} at z_{pii} or z_{sii}	(mW/ cm^2)	216.13					
	p_r at z_{pii}	(MPa)	2.6604					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, Power mode, ROI box minimized @ max depth, Focus 6.0, 2D/Color Density Low, FQBeam off, Depth 6.5, Gain 45, Sector Width 62, Power 100, 2D/Color Freq Gen, CPA Scale PRF 5

Control 2: Cardiac, THI/Power mode, ROI box minimized @ min depth, Focus 8.0, Density 2D Low/ CPA High, FQBeam off, 2D Depth 9, 2D Gain 45, Sector Width 86, Power 100, Freq 2D Res/ CPAGen, CPA Scale PRF 4

11.4.2.31 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI+M Mode)

Table 39 Acoustic Output Reporting Table for Track 3 for the P42B6 Transducer (THI+M Mode)

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			1.4238	0.6226		0.933		n/a
Index component value				0.5999	0.6226	0.5999	0.933	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.9224					
	P	(mW)		THI: 88.5 M: 11.4		THI: 88.5 M: 11.4		n/a
	P_{1x1}	(mW)		THI: 58.3 M: 5.5		THI: 58.3 M: 5.5		
	z_s	(cm)			2.3			
	z_b	(cm)					5	
	z_{MI}	(cm)	3.95					
	$z_{pii,\alpha}$	(cm)	4.25					
	f_{awf}	(MHz)	1.944	THI: 1.882 M: 2.973		THI: 1.882 M: 2.973		n/a
Other information	*prr*	(Hz)	250					
	srr	(Hz)	250					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	185.67					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	103.1					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	158.3					
	p_r at z_{pii}	(MPa)	2.2644					
Operating control conditions	Control 1		MI					
	Control 2			TIS		TIB		
	Control 3							
	Control 4							

Control 1: Cardiac, THI/M mode, 2D Focus 6.0, Density Low, FQBeam off, 2D Depth 6.5, 2D Gain 45, Sector Width 128, Power 100, Freq Gen

Control 2: Cardiac, THI/M mode, 2D Focus 7.0, Density Low, FQBeam off, 2D Depth 8.0, 2D Gain 45, Sector Width 70, Power 100, Freq Gen

11.5 Appendix E: FCC Statement

11.5.1 Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15. 105(b)

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.

This device complies with part 15 of the FCC Rules. 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.

RF Radiation Exposure Statement:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

***CE**

Statement regarding the disposal of T3300 products containing electronic components:

As a company, T3300 is committed to sustainable business practices, which are aimed to preserve, protect and improve the quality of the environment. We apply these to product technologies, design

and the selection of the materials used in our products. Adhering to corresponding environmental laws, directives and guidelines are a core element of our sustainability principles. Since the T3300 concept is equipped with electronic components, we will ensure that it complies with actual or planned directives and laws, which are mandatory for electronic products and may require specific measures regarding labeling, collection and recycling.

NOTE: If not disposed of properly, batteries can be harmful. Protect the environment by taking exhausted batteries to authorized disposal stations.

European Commission (CE) Statement

European Union Regulatory Notice

This device bearing the CE marking is compliance with the essential requirements and other relevant provisions of Directive 2004/108/EC, 2014/53/EU, 2011/65/EU, 2012/19/EU and 93/42/EEC.

This device complies with the following harmonized European standards:

EMC: EN55022, EN55024

Radio: EN300328,EN301893,EN301489-1,EN301489-17, EN62311

Medical: IEC 60601-1, EN60601-1-2, IEC 60601-1-6, IEC 60601-2-37, IEC 62304, EN ISO10993-1, EN ISO10993-5, EN ISO10993-10, EN ISO 14971

ROHS: EN50581

The following CE marking is valid for EU harmonized telecommunications products.

BenQMedicalTech.com

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