InnoSight
Diagnostic Ultrasound System

User Manual

PHILIPS

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1

Read This First

The InnoSight 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 *User Manual* 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 manual and strictly observe all warnings and cautions. Pay extra attention to the information from “Chapter 2 Safety Information”.

This manual 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. No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system or translated into any language or computer language, in any form or by any means, electronic, mechanical, magnetic, optical, chemical or manual. We make no representations or warranties, either expressed or implied, with respect to the contents hereof and specifically disclaims any warranties, merchantability or fitness for any particular purpose. Further, we reserve the right to revise this publication and to make changes from time to time in the contents hereof without obligation to notify any person of such revision or changes.

Distributed by Philips Ultrasound, Inc.

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Manufactured by Qisda Corporation

No.157, Shan-Ying Road, Shan-Ting Li, Gueishan Dist., Taoyuan City, Taiwan, R.O.C.

Intended Audience

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

Intended Use

The system is designed for use as a diagnostic ultrasound imaging tool and fluid flow analysis of the human body. The system shall provide the ability for gathering clinically acceptable images and ultrasound data for the clinical applications and anatomies. 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.

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.

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.

Warnings

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

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 (wall/mains) 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.

Upgrades and Updates

Philips is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated user information will accompany those upgrades.

Supplies and Accessories

To order transducer covers and other supplies and accessories, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52247 9589

Telephone: 800 445 6741 (USA and Canada), +1 319 248 6757 (International)

Fax: 877 329 2482 (USA and Canada), +1 319 248 6660 (International)

E-mail: info@civco.com

Internet: www.civco.com

To order the items listed in the following table, see the referenced information and contact your Philips representative.

System Accessories

Item	Additional Information
Printers	See “Supported External Printers” on page 50.
Transducers	See “Clinical Applications and Transducers” on page 31.

Customer Service

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips representative for assistance. You can also contact the following office for referral to a customer service representative, or visit the Philips “Contact Us” website:

www.healthcare.philips.com/main/about/officelocator/index.wpd

Philips Ultrasound Headquarters

22100 Bothell Everett Hwy, Bothell, WA 98021-8431, USA

800-722-9377

Recycling, Reuse, and Disposal

Philips is concerned with helping protect the natural environment and helping ensure continued safe and effective use of this system through proper support, maintenance, and training. Philips designs and manufactures equipment in compliance with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

The European Union Directive on Waste Electrical and Electronic Equipment (WEEE) requires producers of electrical and electronic equipment to provide reuse and treatment information for each product. This product complies with WEEE.

Passing Your System to Another User

If you pass this system to another user who will use the system for its intended purpose, then pass it on in its complete state. Particularly, ensure that all the product-support documentation, including all instructions for use, are passed on to the new user. Make the new user aware of the support services that Philips provides for installing, commissioning, and maintaining the system, and for comprehensive operator training. Existing users must remember that passing on medical electrical equipment to new users may present serious technical, medical, privacy, and legal risks. The original user may remain liable, even if the equipment is given away.

Philips strongly advises you to seek advice from your local Philips representative before agreeing to pass on any equipment.

After you pass the system to a new user, you might still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions the original owner has a clear duty to communicate such safety-related information to new users. If you are unable or unprepared to do this, inform Philips about the new user, so that Philips can provide the new user with safety-related information.

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.

Do not dispose of this system (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information, which should be properly removed (scrubbed). Philips advises you to contact your Philips service organization before disposing of this system.

Perchlorate Material

In this system, perchlorate material is present in lithium coin cells or batteries. Special handling may apply to those items. For more information, see this website:

www.dtsc.ca.gov/hazardous waste/perchlorate

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.

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 electrolyte leakage occurs, wash your skin with large amounts of water to prevent skin irritation and inflammation.

Equipment List

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

- Philips Ultrasound System
- Medical grade AC/DC power adapter
- Quick Install Guide
- Operating Notes
- Philips System S/N Reference Card
- *User Manual* (this document)
- AC plugs
- One or more Philips Transducers
- Two USB flash drives containing the PDF file of the *User Manual* (this document) and the system software
- System cart (optional)
- SONY UP-X898MD thermal printer (optional)

- AC plug types vary by country/region.
- The system supports different external printers. For a list of supported printers, see "Supported External Printers" on page 50.
- Using accessories, transducers, or power supply units other than those specified may cause the warranty to void and result in increased electromagnetic emissions, decreased EMI immunity of the system, or even damages to the system and personal injuries.
- Use of other accessories results in non-compliance.

User Information Components

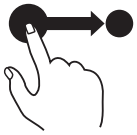
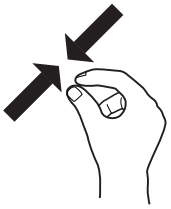
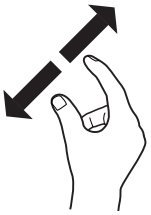
The user information provided with your product and included also on the USB flash drive contains the following components:

- *User Manual*: Introduces you to features and concepts, helps you set up and use your system, includes important safety information and provides reference and descriptions of all controls and display elements. This manual also includes acoustic output tables.
- *Quick Install Guide*: Contains illustrated instructions step-by-step on how to get the system ready for use, including installation of the peripherals.
- *Operating Notes*: Contains information that clarifies certain product responses that might be misunderstood or cause user difficulty.
- *New Product Bulletin*: Contains updated information about the features of your system.

Product Conventions

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

- Refer to the following table to control the system using gestures (See page 55).

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

- To adjust the parameter value of a function, touch the plus/minus buttons (+/-).

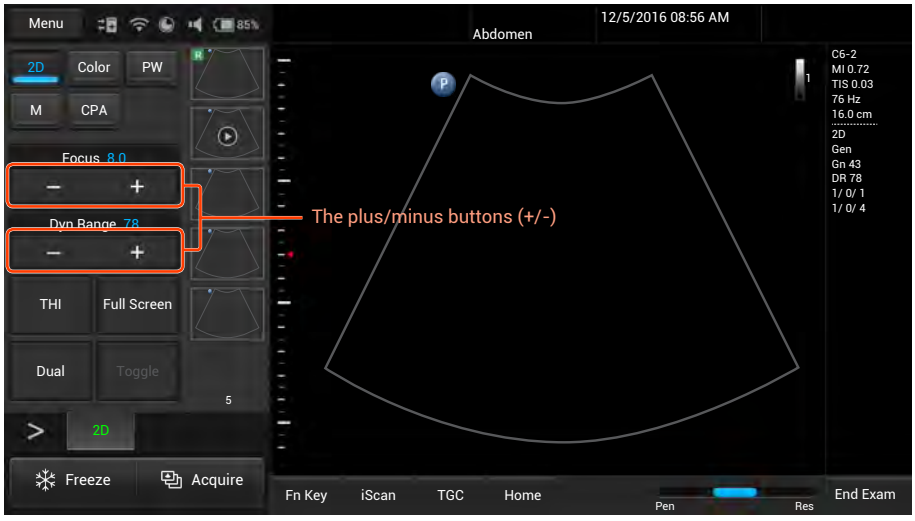


Figure 1 The plus/minus buttons (+/-)

- To type texts into a text field, touch the field and use the virtual keyboard. Alternatively, you can add pointing or input devices by connecting them to the USB ports on the system.
- To display a list, touch the down arrow  . To display the options, touch the menu icon  .

- To select/enable or deselect/disable a function, tap in the checkbox. For example, check **Registered User**  ; uncheck **Site Administrator**  .

User Information Conventions

The *User Manual* uses certain conventions throughout the book to make it easier to find the information you need.

- Control names and menu items or titles are spelled as they are on the system, and they appear in bold text.
- The on-screen menu steps needed to perform a function are shown in a condensed form. For example, touch **Menu** > **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.

This numbering style is used for steps with callouts on graphics.

This numbering style is used for steps with no callouts on graphics.

This numbering style is used for callouts not associated with steps.

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 “Servicing your system” on page 102 and “Customer Service” on page 3.

2

Safety Information

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.

- 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 “Customer Service” on page 3).

- 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.

Using accessories, transducers, peripherals, or cables not supplied with the system or recommended by Philips 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 IP22.

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" in this *User Manual* 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 Philips representative.

Symbols

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

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

System Label Icons

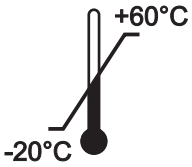
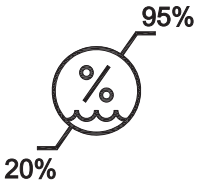
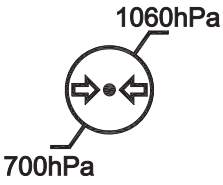
Symbols	Descriptions
REF	**Product Model**
SN	**Serial Number**

Symbols	Descriptions
SVC	**Philips Service Code**
UDI	**Unique Device Identification**
	**Manufacturer Mark** Manufacturer Qisda Corporation manufactures the system.
	**Manufacture Date**
EC REP	**EU/EC European Authorized Representative**
	**CE Marking Certification with Notified Body Number 0120**
	**Compliance to R&TTE Directive**
	**Notify Body Certificate**
	**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 “Recycling, Reuse, and Disposal” on page 3.
	**Refer to the User Manual** Indicates that the user should read the *User Manual* for information on using this equipment.
	**Operating instructions** Indicates that the user should see the instructions for use for safety information.
	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	**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**

System Button

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

Shipping Label Icons

Symbols	Descriptions
	**This Side Up**
	**Fragile**
	**Maximum Stacking Height**
	**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.

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+A12:2014, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
  - » IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests & CISPR 11: 2015 AMD1:2016 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
  - » IEC 60601-2-37:2007+AMD1:2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- EMC/EMI:
  - » IEC 60601-1-2:2007/AC:2010, CISPR 11 Group I Class B
- Harmful liquid protection:
  - » For the main system: IP22
  - » For the transducer: IPx7
  - » For the power adapter: IP21
  - » For maximum safety, observe the following guidelines strictly:

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.

Do not remove or try to circumvent the grounding wire. If the protective grounding of the system is questionable, disconnect the system from the power source and run it on its internal battery.

- 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 (wall/mains) 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 “Customer Service” on page 3).
- 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.
- C9-4v are invasive transducers. The operator should immediately stop using the C9-4v transducer when its surface temperature reaches 43°C.

Battery Usage/Disposal

- 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 Philips representative for help.

Dispose of used batteries according to the instructions.

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.

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.

All Equipment

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

On connectors labeled with the ESD sensitivity symbol  , do not touch the connector pins, and always observe the preceding ESD precautions when handling or connecting transducers.

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

Emissions test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The InnoSight 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.

Emissions test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Class B	The InnoSight 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 InnoSight Diagnostic Ultrasound System is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The InnoSight Diagnostic Ultrasound System is not suitable for interconnection with other equipment.

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	
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 InnoSight Diagnostic Ultrasound System requires continued operation during power mains interruptions, it is recommended that the InnoSight 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

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 InnoSight 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	$d = [\frac{3.5}{V_1}] \sqrt{P}$

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1] = 3 V/m	$d = [\frac{3.5}{E_1}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}] \sqrt{P}$ 800 MHz to 2.5 GHz
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey$_a$, should be less than the compliance level in each frequency range$_b$. Interference may occur in the vicinity of equipment marked with the following symbol: 

$_a$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 InnoSight 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.

- 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.

Separation Distances

The InnoSight 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.

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

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 $\frac{7\sqrt{P}}{E_1} = D$
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

Table 1 Separation distances

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.

- 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.

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

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.

Mechanical Safety

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

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.

Position external peripheral devices away from the system. Ensure that they are secure. Do not stack them on the system.

When positioning the system, move it carefully to avoid pinching hands or extremities against other objects, such as a bed rail.

Be aware of the caster wheels on the system cart, especially when moving the system. The system cart could cause injury to you or others if it rolls over feet or into shins. Use with caution when going up or down the ramps.

The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system cart is parked.

To avoid injury, we recommend against lifting the system cart.

Never park the system cart on an incline. If you park the system on a floor that is tilted 10 degrees or more and set the brakes, one of the braked casters might not be touching the floor, which can cause the system to move.

When performing a needle biopsy, if the system is not mounted correctly on the system cart, or if the system cart is not parked safely, unintended movement of the system resulting in movement of the needle during use may cause injury to you or others.

Do not roll the system over transducer cables or power cords.

Equipment Protection

Observe the following precautions to protect your system.

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 beyond its binding line.
- 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 “Chapter 10 Transducer Care” and “Chapter 11 System Maintenance”.

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.

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.

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.

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.

Safe Scanning Guideline

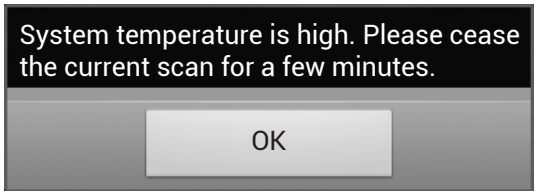
- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.

- 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. 2D 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.

- 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 engine 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.

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

Table 2 Maximum exposure time recommended for an embryo or fetus

- 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.

FDA Medical Alert on Latex

March 29, 1991, Allergic reactions to latex-containing medical devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic . Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, the FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FDA's recommendations to health professionals in regard to this problem are as follows:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.
- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "Hypoallergenic" may not always prevent adverse reactions.)
- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

The FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 FDA Drug Bulletin.) To report an incident, contact the FDA Problem Reporting Program, MedWatch, at 1-800-332-1088, or on the Internet:

www.fda.gov/Safety/MedWatch/

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

Operator Safety

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

Repetitive Strain Injury

Repetitive ultrasound scanning has been associated with carpal tunnel syndrome (CTS) and related musculoskeletal problems. Some investigators have looked at a large population of sonographers with different types of equipment. An article, with feedback from a smaller geographical area, makes the following recommendations:

- Maintain your joints in optimum positions with a balanced posture while scanning.
- Allow frequent breaks to give soft tissue a chance to recuperate from awkward positions and repetitive movement.
- Avoid gripping the transducer with excessive force.

Repetitive Strain References

Pike, I., et al. “Prevalence of Musculoskeletal Disorders and Related Work and Personal Factors Among Diagnostic Medical Sonographers.” Journal of Diagnostic Medical Sonographers, Vol. 13,No. 5: 219-227, September 1997.

Necas, M. “Musculoskeletal Symptomatology and Repetitive Strain Injuries in Diagnostic Medical Sonographer.” *Journal of Diagnostic Medical Sonographers*, 266-227, November/December 1996.

Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. See “Clinical Applications and Transducers” on page 31 for a list of the transducers that are compatible with your system. In the United States, the FDA 510(k) regulatory clearance for use of the product is applicable only when Philips-manufactured transducers are connected to the system.

Glutaraldehyde Exposure

The United States Occupational Safety and Health Administration (OSHA) has issued a regulation covering levels of acceptable glutaraldehyde exposure in the working environment. Philips does not sell glutaraldehyde-based disinfectants with its products, but this type of disinfectant is recommended for the disinfection of transducers used in TEE, intraoperative, endocavity, and biopsy procedures. To reduce the presence of glutaraldehyde fumes in the air, be sure to use a covered or ventilated soaking basin. Such systems are commercially available. The most-current information about disinfection products and Philips transducers can be found on the Philips Transducer Care website:

www.Philips.com/transducercare

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.

Removing Blood and Infectious Material from the System

It is important to clean and maintain the ultrasound system and peripherals. If the equipment has come in contact with blood or infectious material, clean and disinfect the system and peripherals according to the instructions in “Chapter 11 System Maintenance”.

Disposable Drape

If you believe contamination of the system might occur during an exam, Philips recommends 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.

Position the disposable drape so that it does not block the vents on the system, the monitors, or the peripherals.

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, such as a Civco #667-106. 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.

Component	Use	IP level
Ultrasound System	Ultrasound system	IP22
C6-2 transducer	Ultrasound transducer	IPX7 (at transducer head)
L12-4 transducer	Ultrasound transducer	IPX7 (at transducer head)
S4-2 transducer	Ultrasound transducer	IPX7 (at transducer head)
C9-4v transducer	Ultrasound transducer	IPX7 (at transducer head)

Table 3 Waterproof and dustproof ratings

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.

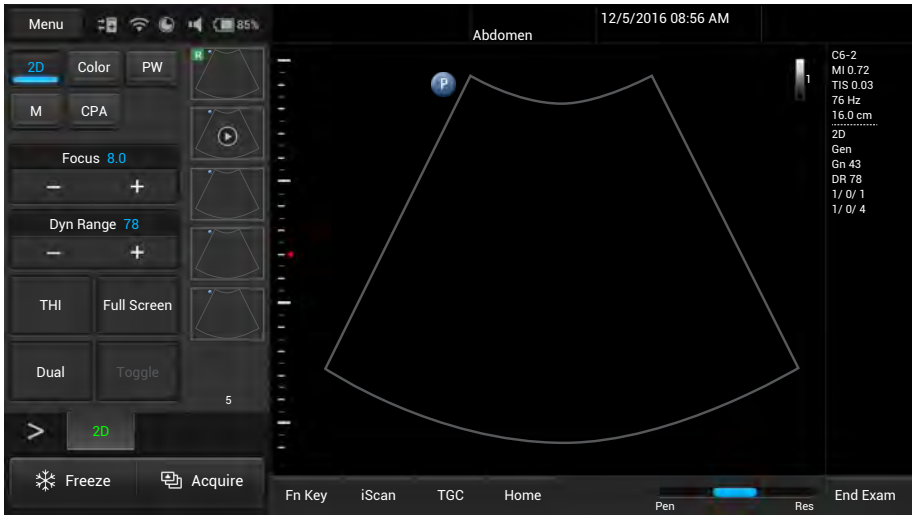


Figure 2 MI/TI on-screen display format

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

Mode / Transducer	C6-2 Curved Linear Array 2-6 MHz	L12-4 Linear Array 4-12 MHz	S4-2 Phased Array 64 elements 2-4 MHz	C9-4v Micro Curved Linear Array 4-9 MHz
2D	–	–	–	–
2D+M-Mode	–	–	–	–
THI, 2D	–	–	–	–
THI, 2D+M-Mode	–	–	–	–
PW Doppler	–	–	–	–
2D+Color	–	–	V	–
THI+Color, 2D	–	–	V	–

Table 4 MI/TI generating from applicable transducer/mode combinations

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 de-rated 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 *User Manual* 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 de-rating factor (R_F),

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

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 .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. $I_{spta.3}$).

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

Table 5

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

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.

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.

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.

Display and Report in Different Modes

For 2D Mode

Display and report only MI and TIS

For Color Mode

Display and report only MI and TIS

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 $4^{(6-TI)}$ 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'*.

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.

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.

Test	External use (°C)			Non-external Use (°C)
	C6-2	S4-2	L12-4	C9-4v
Simulated use	1.5	1.4	3.0	1.9
Still air	7.3	3.6	6.5	3.3

Table 6 Transducer surface temperature rise

3

Overview

Acquaint yourself with the system and its components in this chapter.

System Capabilities

The InnoSight Diagnostic Ultrasound System is intended for Obstetric imaging, and OB/GYN, Gynecology imaging, Cardiac imaging, Vascular imaging, and general imaging purpose, and related analysis. The system cart is ergonomically designed to be both highly mobile and adjustable for a range of users and operating conditions. The system can be used for 2D grayscale, M-Mode, Color, Doppler, 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.

Imaging

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

- 2D
- M-mode
- Anatomical M-mode
- Color Doppler
- Color Power Angio (CPA)
- Directional CPA
- Tissue Harmonic Imaging (THI)
- Pulse Inversion THI
- XRES image processing
- SonoCT Real-time Compound Imaging
- High Q Automatic Doppler

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.

Transducer Types

The available transducer types are a curved linear array transducer, a linear array transducer, a phased array transducer, and a micro-curved linear array transducer. Applications for specific transducers are listed in “Indications for Use and Supporting Transducers” on page 34.

Measurements

The system provides tools and controls for measuring distance, ellipse, angle, area 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.

Calculations

Calculations are organized in collections for the applications included in the system. The system uses measurement values to make calculations and create a patient report.

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 printer.

Patient Data Protection

The data security feature, if enabled on your system, limits access to previously stored patient data and images. To gain access to such data, you must first log into the system using a password. When you are finished using the system, the system will log you off after a set period of time if automatic logoff is enabled, or you can simply shut down the system, which logs you off automatically. For more information on protecting patient data, see “Logging Into the System” on page 51 and “Configuring Security Policies” on page 102.

Connectivity

The following network features are standard:

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

Peripherals (optional)

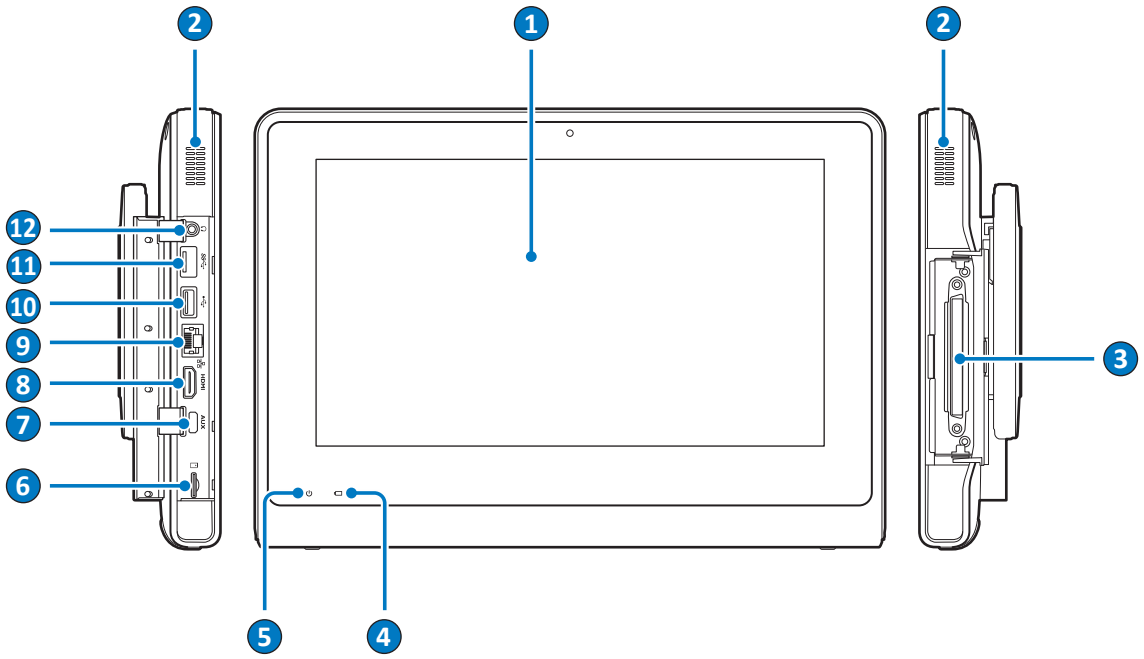
Peripheral devices include a system cart on which the system can be mounted and a B&W image printer or a color image printer (supported printers) for printing ultrasound images and studies. For information on installation of these peripheral devices, see “Chapter 4 Preparing the System” on page 39.

Service

The InnoSight Ultrasound System is designed to be a reliable robust system. In the event of a failure the system has on board service features and diagnostics which will allow for easy diagnosis. Some functionality may require technical assistance. See “Servicing your system” on page 102.

System Overview

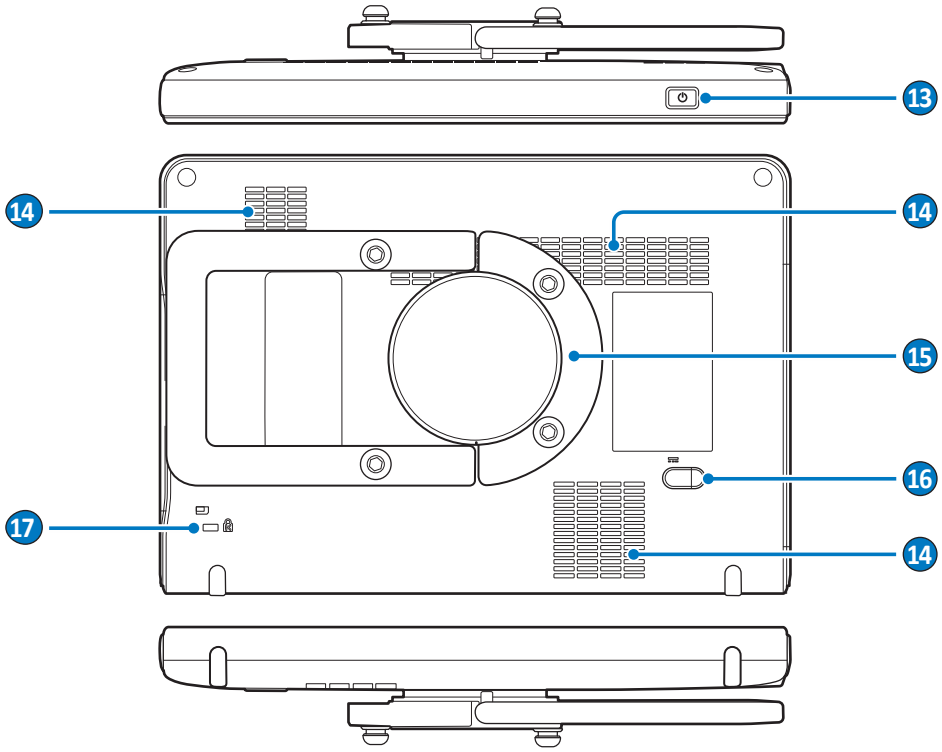
Front and Side Views



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 42)
4	Battery indicator	When the system is turned off and connected to power, 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. When the system is turned on and connected to power, the battery indicator lights off. To monitor the battery level, see "Battery Status Icons" on page 64.
5	Power indicator	Blink blue after the system enters Sleep mode. (See page 64)
6	MicroSD card slot	Insert a microSD card into the microSD card slot to exchange data from/ to the system. (See page 39)
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 50)
9	Ethernet socket	Connect the system to an Ethernet-based network. (See page 65)
10 11	USB 2.0 port USB 3.0 port	Connect the system to USB 2.0/3.0 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.

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.

Rear and Top/Bottom Views



No.	Component	Function
13	Power button	Press and hold the Power button to turn on/off the system.
14	Ventilation slots	Release excessive heat during operation to keep the system in a safe operating temperature.
15	Rotating stand	• Pull the rotating stand out to sustain the system on a flat surface. (See "Using the Stand" on page 40) • Can be used as a handle to carry the system around. (See "Using the System On The Go" on page 43)
16	Power input socket	Used to connect the system to power. (See "Charging the System" on page 41)
17	Anti-theft lock slot	Used to lock the system securely to a solid surface to protect it from theft.

Transducer Overview

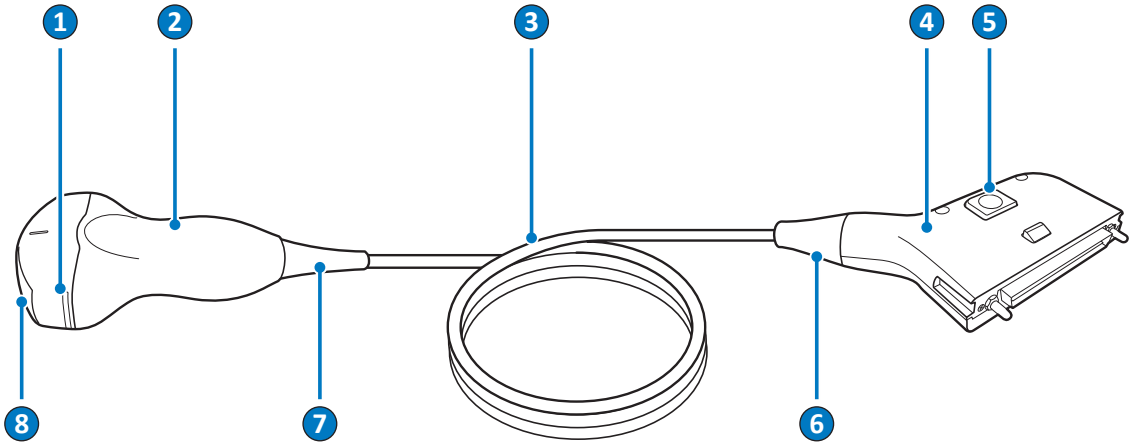


Figure 3 Transducer overview (Example transducer: C6-2)

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

Use only transducers that are approved by Philips for use with the system.

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.

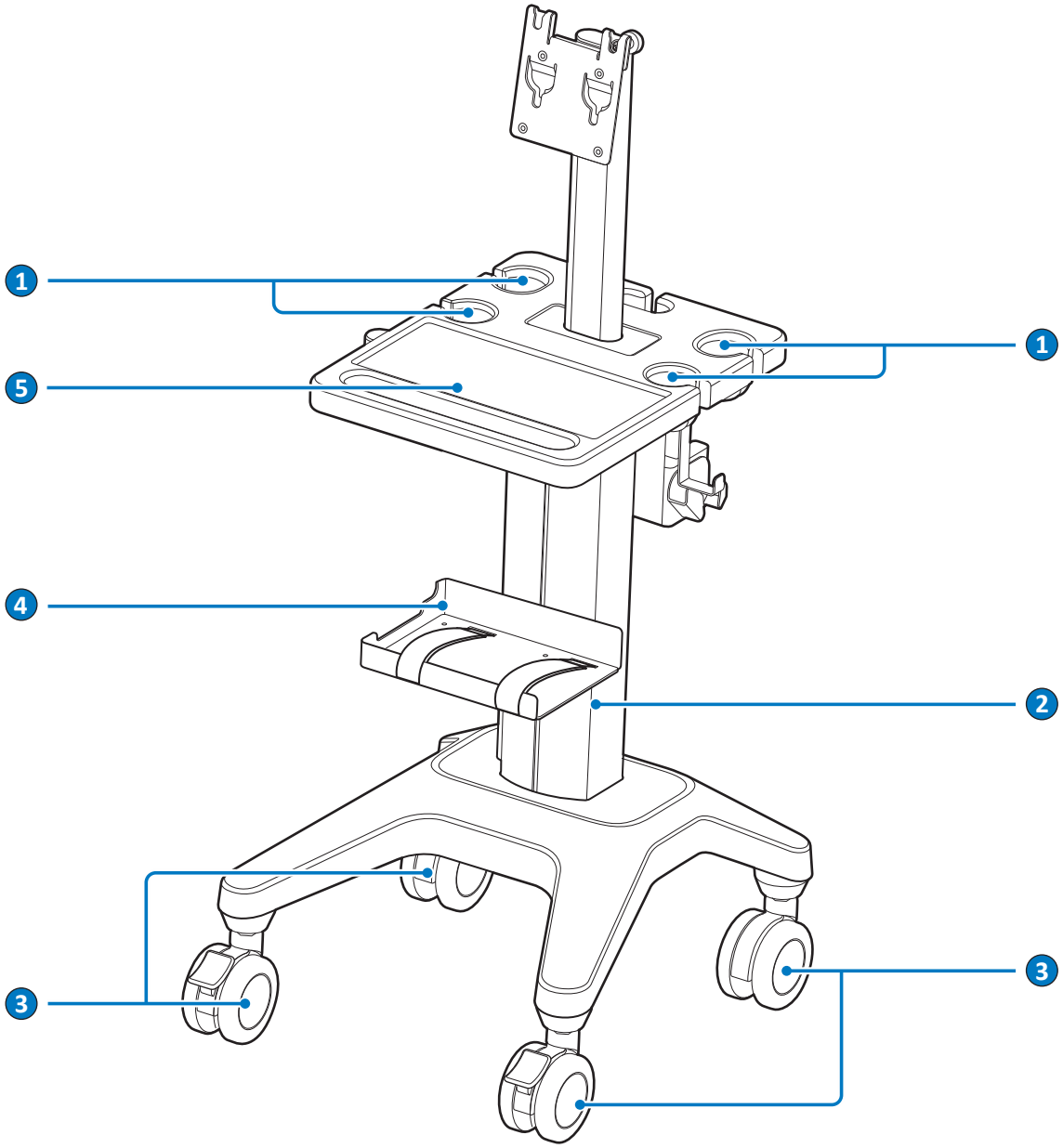
Transducer	Clinical Applications
C6-2	Abdomen, OB, GYN, Renal, Urology
L12-4	Carotid, Arterial, Venous,Thyroid, Breast, Bowel, MSK, Nerve
S4-2	Cardiac
C9-4v	OB, GYN, Prostate

For more information, see “Indications for Use and Supporting Transducers” on page 34.

System Cart Overview

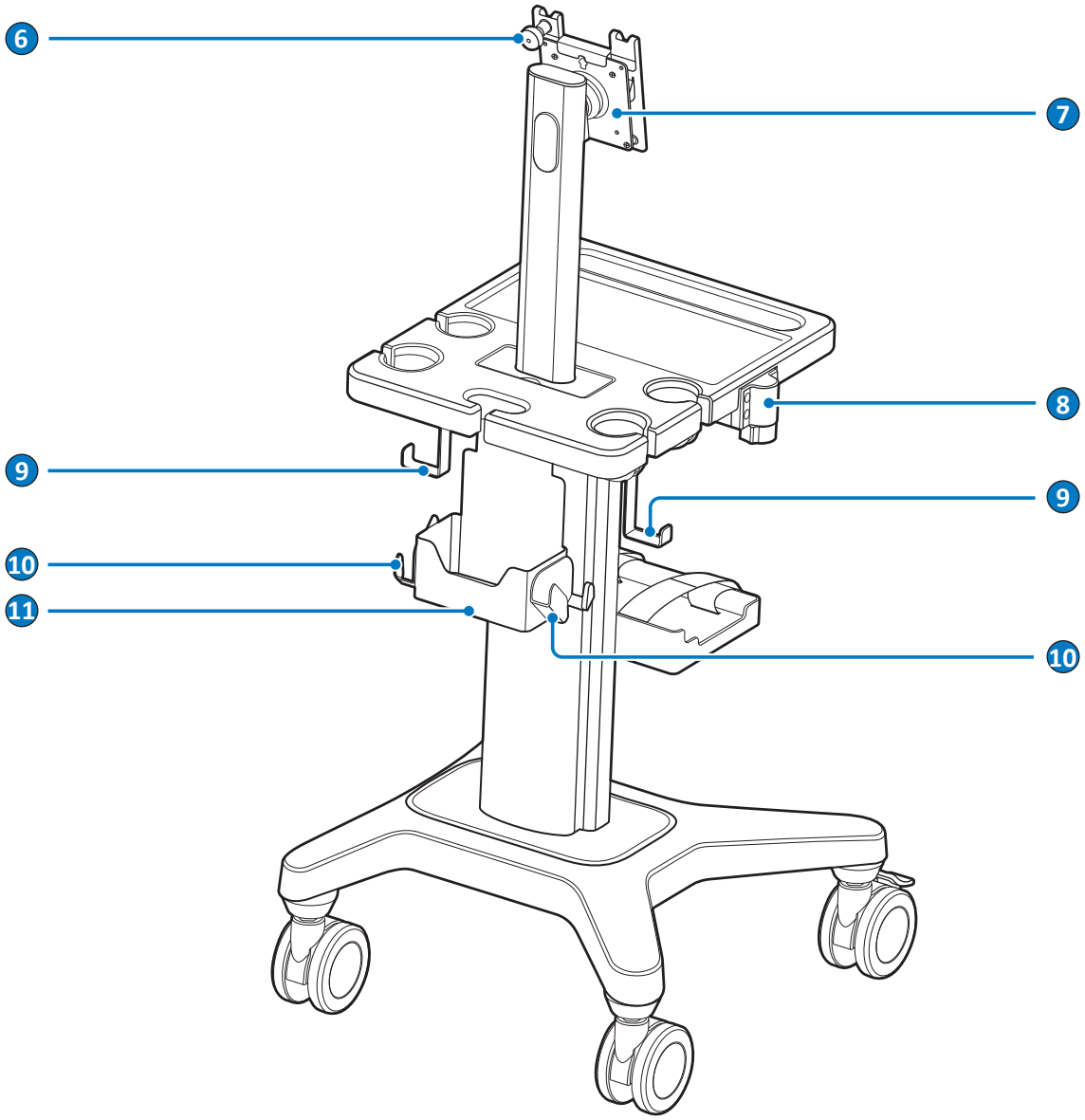
The system cart is available for purchase as an optional item.

Front View



No.	Item	No.	Item
1	Transducer/gel holder	2	Cart pillar
3	Caster wheel with brake	4	Printer holder
5	Work table		

Rear View



No.	Item	No.	Item
6	Knurled thumb knob	7	Mount plate
8	Height-adjustment button	9	Cable collector
10	Transducer hanger	11	Rear container

Observe the precautions and warnings listed in “Mechanical Safety” on page 17 and “Moving the System” on page 49 before using the system cart to avoid injury and system failure.

Indications for Use and Supporting Transducers

InnoSight Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), heart soft tissue, Peripheral Vascular, Musculoskeletal, Fetal and OB/GYN.

The following tables provide Diagnostic Ultrasound Indications for Use Forms for the transducers offered with the InnoSight Diagnostic Ultrasound System.

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM System: InnoSight Diagnostic Ultrasound System Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical application		**Mode of operation**							
General (Track 1 only)	Specific (Track 1 and 3)	2D	M-Mode	PW Doppler	CW Doppler	Color	CPA	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal imaging and others	Fetal	N	N	N		N	N	Note 1	N
	Abdominal	N	N	N		N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	N
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculoskeletal (Conventional)								
	Musculoskeletal (Superficial)								
	Intravascular								
	Other (OB/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral Vessel	N	N	N		N	N	Note 1	N
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: *Combined modes include: 2D+M-Mode; 2D+PW Doppler; 2D+Color; 2D+CPA; 2D+Color+PW Doppler and 2D+CPA+PW Doppler

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM
System: InnoSight Diagnostic Ultrasound System
Transducer: C6-2 (Curved Linear Array 2-6 MHz)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical application		**Mode of operation**							
General (Track 1 only)	Specific (Track 1 and 3)	2D	M-Mode	PW Doppler	CW Doppler	Color	CPA	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal imaging and others	Fetal	N	N	N		N	N	Note 1	N
	Abdominal	N	N	N		N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculoskeletal (Conventional)								
	Musculoskeletal (Superficial)								
	Intravascular								
	Other (OB/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral Vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: *Combined modes include: 2D+M-Mode; 2D+PW Doppler; 2D+Color; 2D+CPA; 2D+Color+PW Doppler and 2D+CPA+PW Doppler

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM
System: InnoSight Diagnostic Ultrasound System
Transducer: L12-4 (Linear Array 4-12 MHz)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical application		**Mode of operation**							
General (Track 1 only)	Specific (Track 1 and 3)	2D	M-Mode	PW Doppler	CW Doppler	Color	CPA	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal imaging and others	Fetal								
	Abdominal	N	N	N		N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculoskeletal (Conventional)	N	N	N		N	N	Note 1	N
	Musculoskeletal (Superficial)								
	Intravascular								
	Other (OB/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral Vessel	N	N	N		N	N	Note 1	N
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: *Combined modes include: 2D+M-Mode; 2D+PW Doppler; 2D+Color; 2D+CPA; 2D+Color+PW Doppler and 2D+CPA+PW Doppler

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM
System: InnoSight Diagnostic Ultrasound System
Transducer: S4-2 (Phase Array 64 elements 2-4 MHz)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical application		**Mode of operation**							
General (Track 1 only)	Specific (Track 1 and 3)	2D	M-Mode	PW Doppler	CW Doppler	Color	CPA	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal imaging and others	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculoskeletal (Conventional)								
	Musculoskeletal (Superficial)								
	Intravascular								
	Other (OB/GYN)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral Vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: *Combined modes include: 2D+M-Mode; 2D+PW Doppler; 2D+Color; 2D+CPA; 2D+Color+PW Doppler and 2D+CPA+PW Doppler

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM
System: InnoSight Diagnostic Ultrasound System
Transducer: C9-4v (Micro-curved Linear Array 4-9 MHz)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical application		**Mode of operation**							
General (Track 1 only)	Specific (Track 1 and 3)	2D	M-Mode	PW Doppler	CW Doppler	Color	CPA	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal imaging and others	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	N
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculoskeletal (Conventional)								
	Musculoskeletal (Superficial)								
	Intravascular								
	Other (OB/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral Vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: *Combined modes include: 2D+M-Mode; 2D+PW Doppler; 2D+Color; 2D+CPA; 2D+Color+PW Doppler and 2D+CPA+PW Doppler

4

Preparing the System

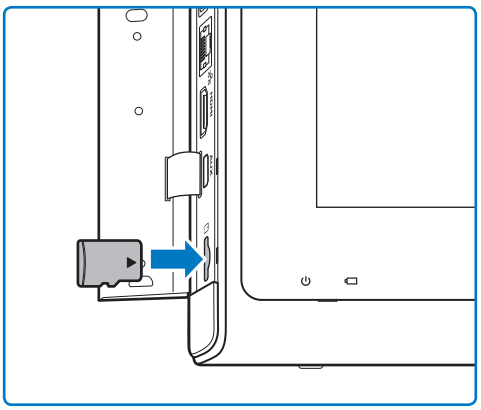
Follow the information and procedures in this section to help you prepare the system for use.

Inserting a microSD Card

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

- Supported microSD card format:
  SDXC (up to 128GB); SDHC Class 10 (up to 32GB)
- The microSD card is not supplied with the system.

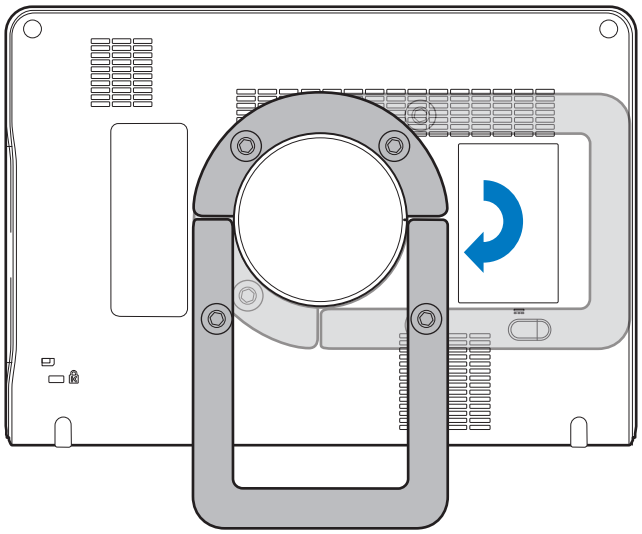
1. Flip the port cover open.
2. Align the microSD card with the mark next to the microSD card slot.
3. Fully insert the microSD card into the card slot until it clicks into place.



- 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 detailed instructions, see "Backing Up System Settings and Patient Data" on page 104.
- 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.

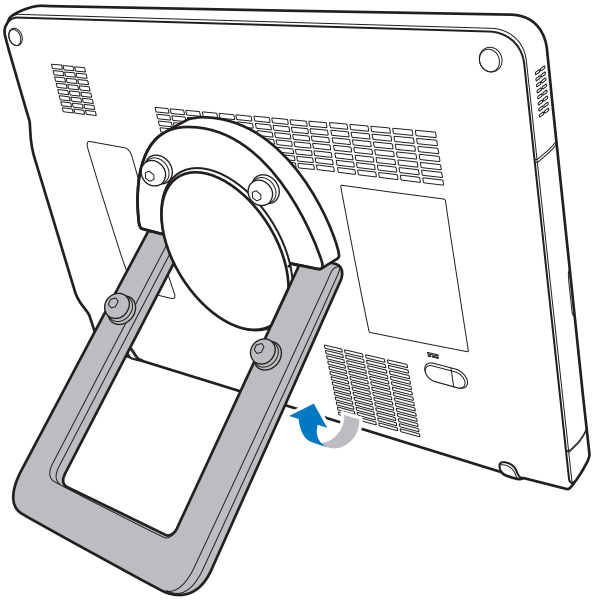
Using the Stand

1. Rotate the rotating stand clockwise by 90 degrees.



Lay the rotating stand completely flat before rotation.

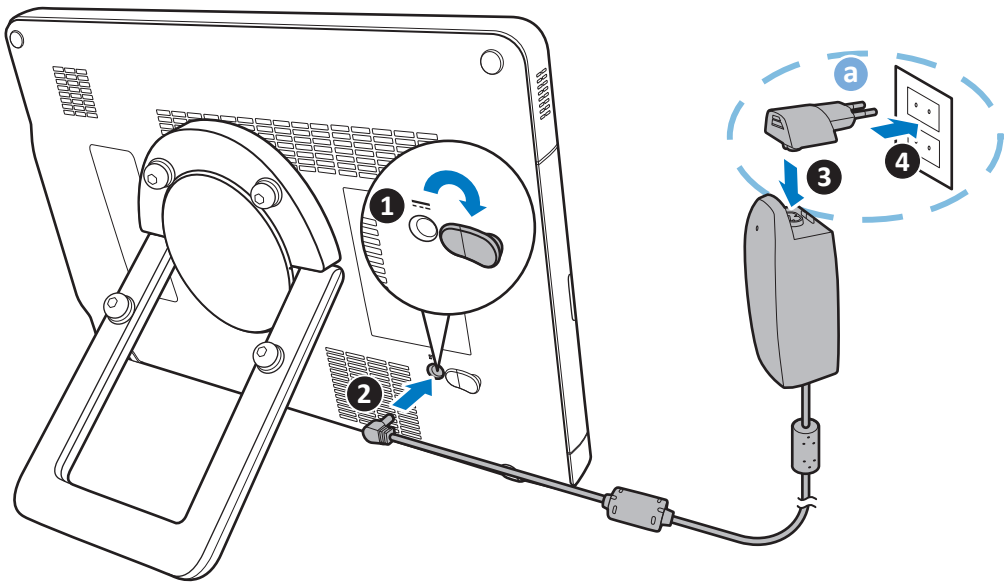
2. Gently pull out the rotating stand to the degree that suits your preferred viewing angle.



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.

- Use only the supplied power adapter and AC plugs for charging.
- AC plug and electric outlet types vary by country/region a.
- 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.



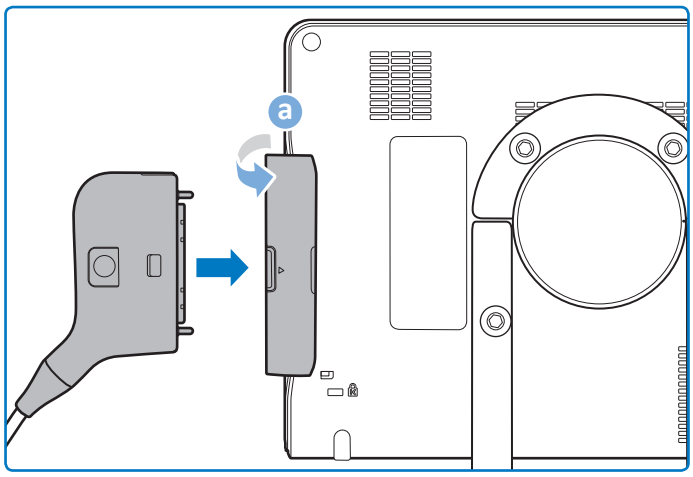
1. Lift the protective rubber cover open.
2. Connect the power adapter's connector into the system's power input socket.
3. Insert the matching AC plug fully into the power adapter.
4. Plug the AC plug of your power adapter into an electric outlet to start charging. The battery indicator lights up in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

   - 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.

5. After the battery is fully charged (around 3 hours), the battery indicator turns green.

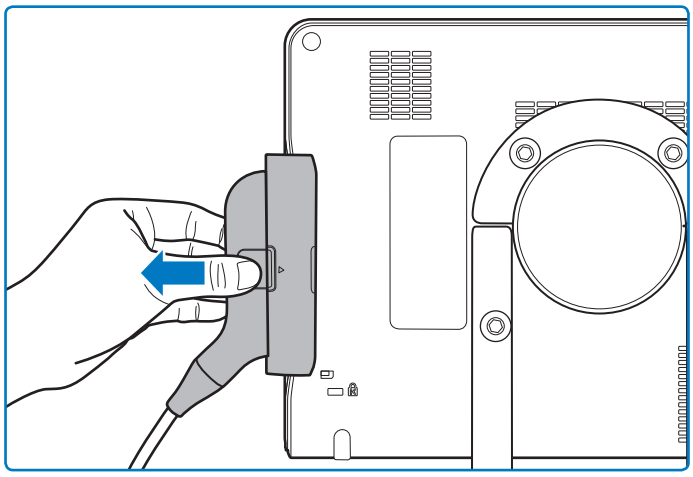
Connecting the Transducer

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



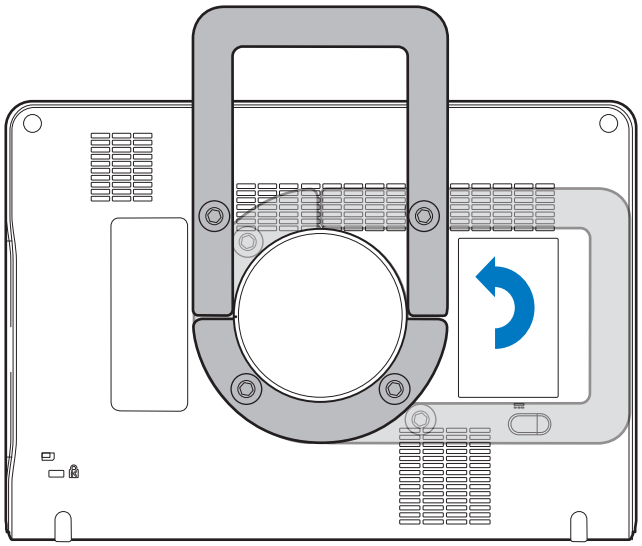
Removing the Transducer

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



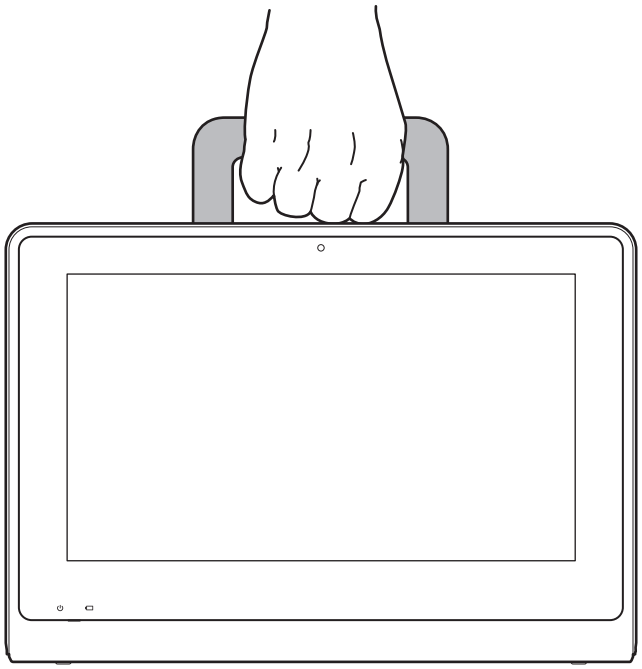
Using the System On The Go

1. Rotate the rotating stand counterclockwise by 90 degrees.



Lay the rotating stand completely flat before rotation.

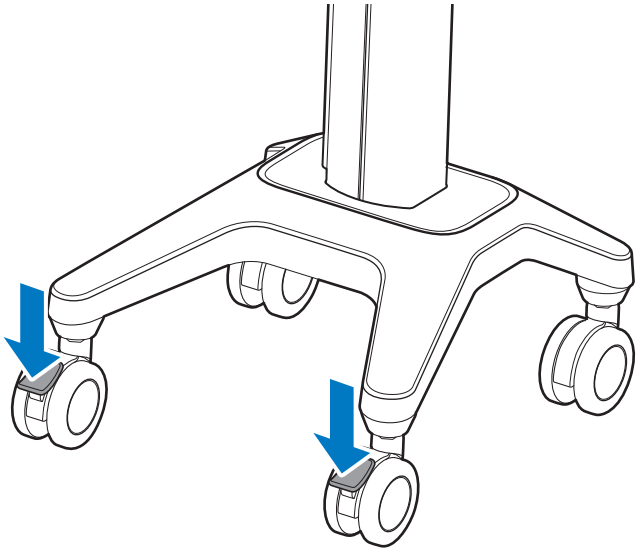
2. Use the rotating stand as a handle to carry the system around.



Using the Wheel Brakes

Use the brakes on the system cart wheels to help keep the cart stationary while in use.

- To engage the brakes, press down on the lever with your foot.

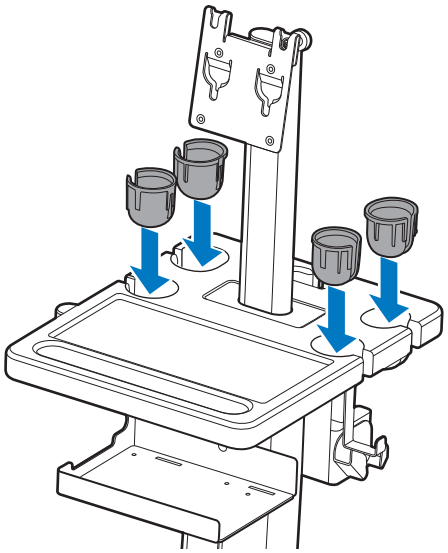


- To disengage the brakes, push the levers upward with your foot until they are fixed in place.

- Never park the system cart on an incline. If you park the system on a floor that is tilted 10 degrees or more and set the brakes, one of the braked casters might not be touching the floor, which can cause the system to move.
- Observe the precautions and warnings listed in “Mechanical Safety” on page 17.

Placing the Transducer Holder

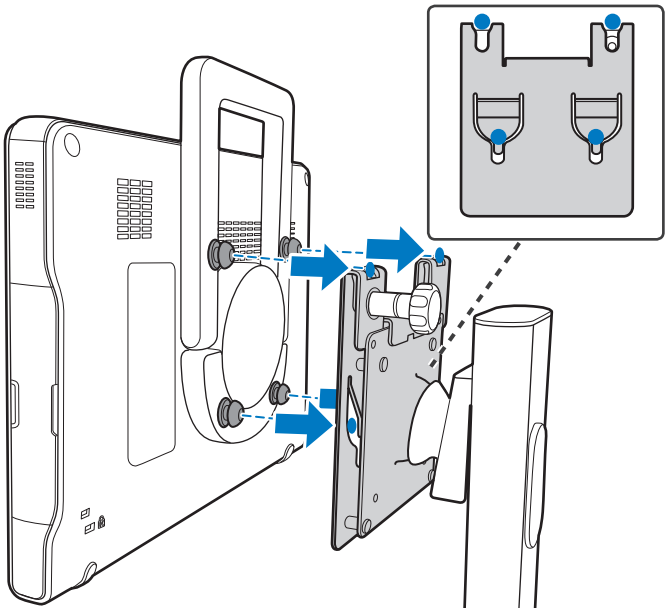
Place the transducer holders evenly onto the slots on the system cart and gently push them in until they are fixed in place.



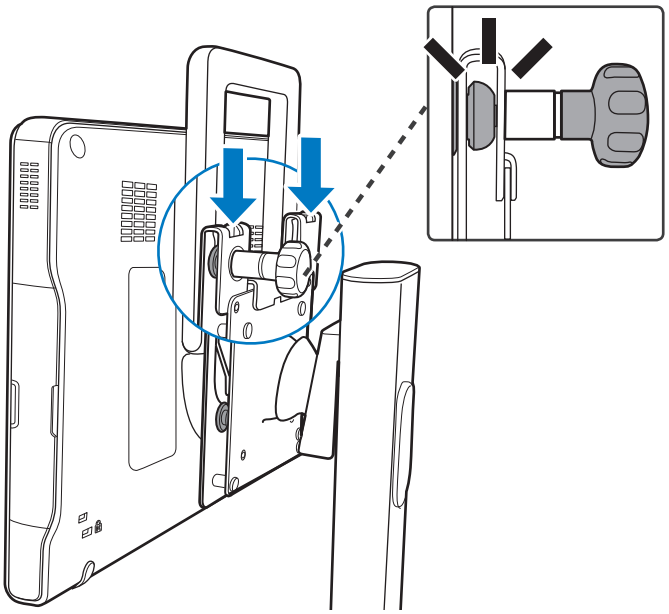
Mounting the System to the System Cart

- The system cart is available by separate purchase.
- Before mounting the system to the system cart, ensure that the caster wheels are locked in place, and the rotating stand is fixed as a handle (See page 43).

1. Hold the system firmly and position it precisely to the front of the mount plate on the cart where the four screws on the back of the system and the hole patterns of the plate meet.



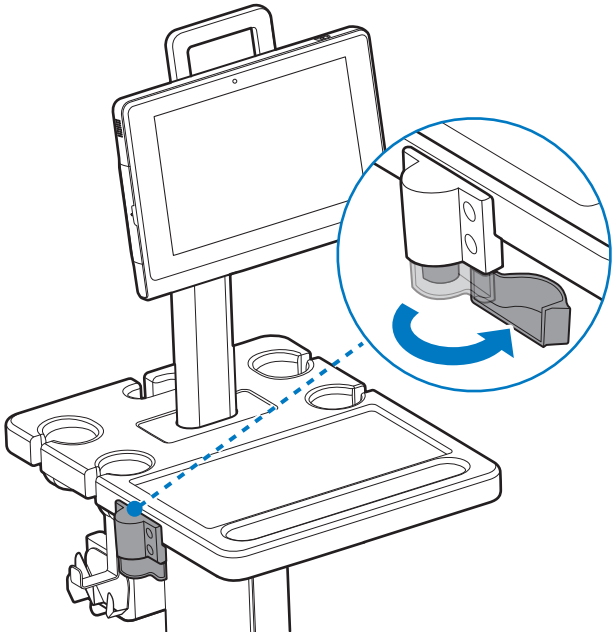
2. Attach the system fully onto the plate until you hear a click sound, indicating that it is locked in place.



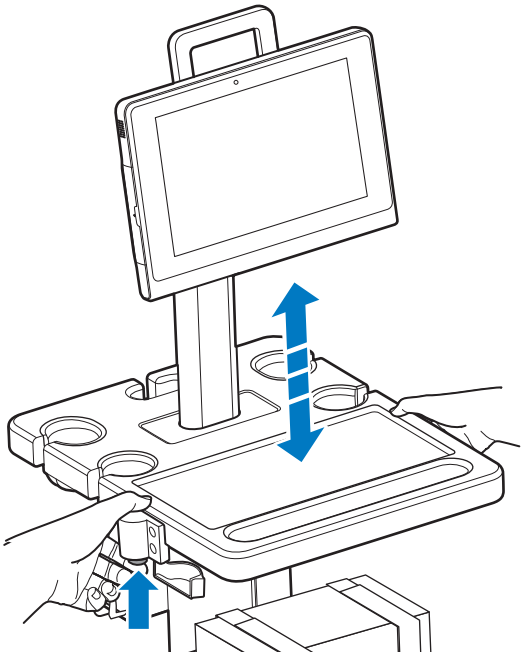
Adjusting the System Cart Height

Adjust the height of the system cart to suit different operators and operating positions.

1. Open the protective cover.



2. Press and hold the height adjustment button to loosen the cart pillar. Without releasing the button, slide the cart pillar up and down until the desired height is reached.

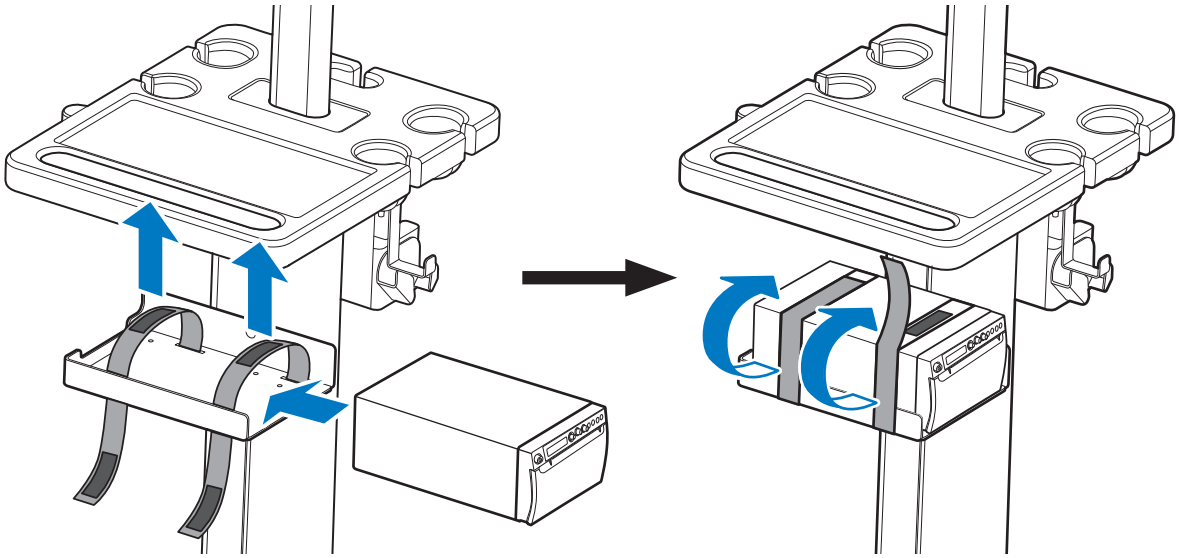


3. Release the button to lock the pillar in place.

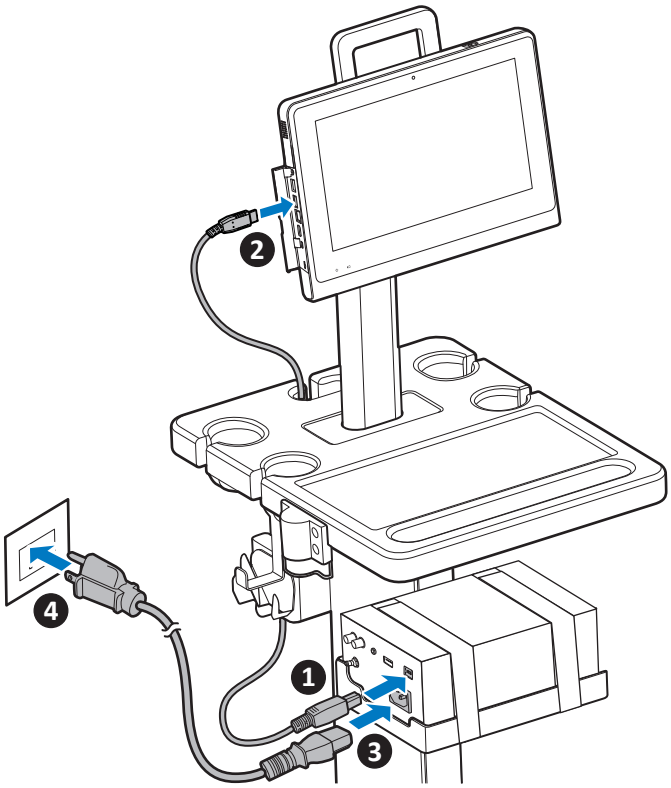
Connecting an External Printer

- Before connecting the system to an external printer, turn off the system and disconnect the power adapter from the power outlet.
- External printers are available by separate purchase. For a list of supported printers, see “Supported External Printers” on page 50.

Before connection, secure your printer onto the printer holder with the straps.



1. Insert one end of an USB cable into your printer’s USB port.
2. Insert the other end of the USB cable into the system’s USB port.
3. Insert the DC output connector of the power cord into the power socket of the printer.
4. Plug the power cord into an power outlet.



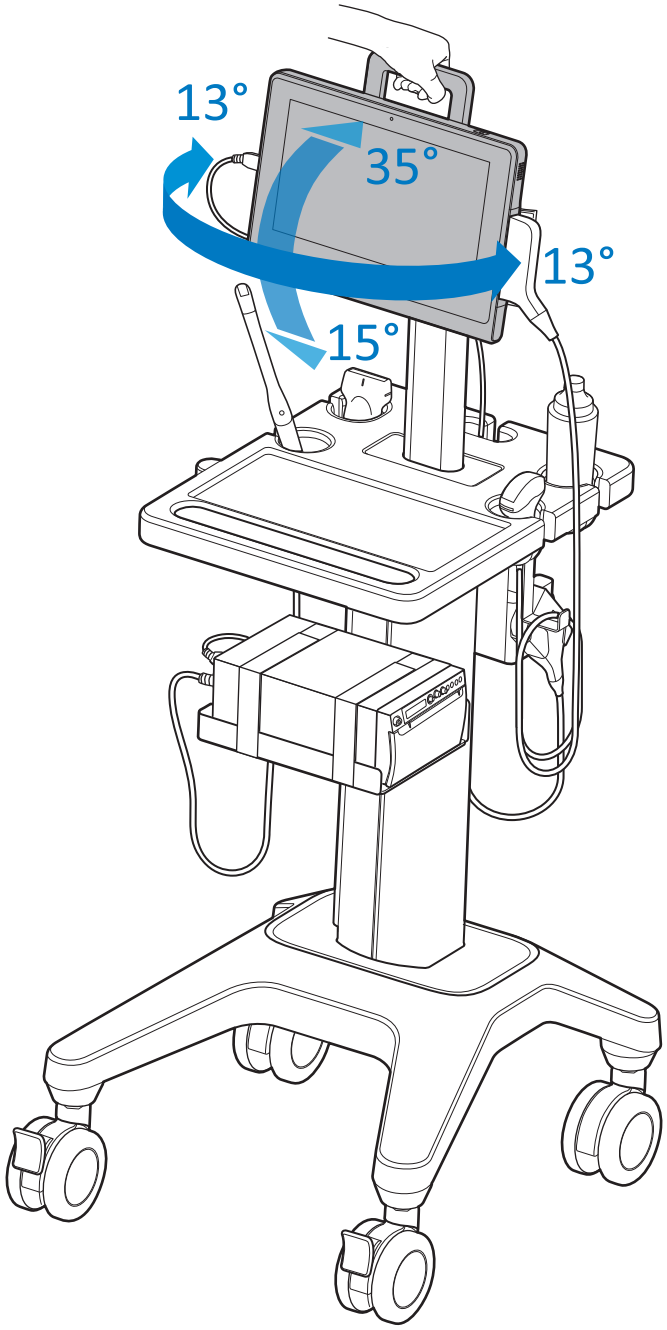
5. Turn on the printer, then turn on the system. The system installs the printer drivers automatically.
6. After successful installation of the new printer drivers, on the system imaging screen, go to **Menu** > **Settings** > **Print** and select the printer name. The printer is now ready for use.

See your printer documentation included in the sales package for detailed information on connections and settings.

Tilting the System

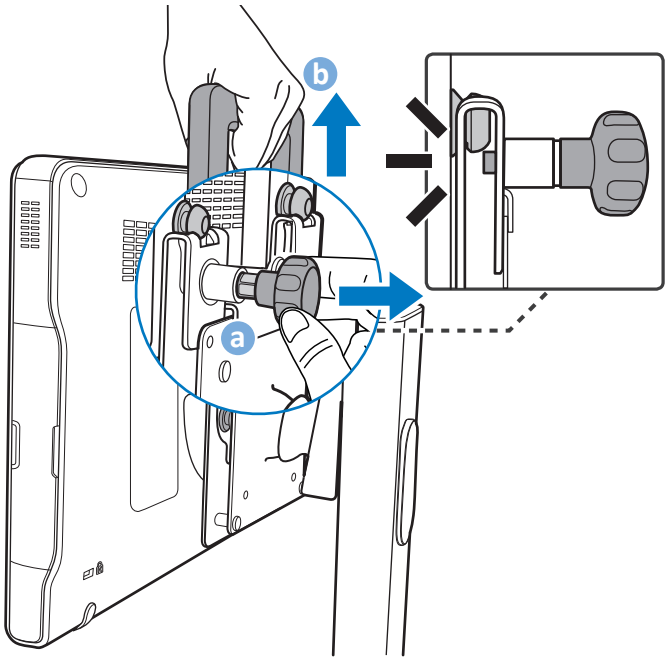
Your system, while mounted on the system cart, can be rotated and tilted to reach various viewing angles.

Hold the rotating stand as a handle to rotate the system.



Unmounting the System From the System Cart

Pull out the knurled thumb knob to unlock the system a, and simultaneously lift the system from the mount plate b.



Moving the System

Before moving the system mounted on the system cart, secure all cables, transducers, and accessories so that they do not interfere with the caster wheels.

Observe the precautions and warnings below and listed in “Mechanical Safety” on page 17 before moving the system mounted on a cart.

Ensure that the cables for all patient-applied parts are secure before moving the system.

Position external peripheral devices away from the system. Ensure that they are secure. Do not stack them on the system.

When transporting the system in a vehicle, avoid exposing the monitor to direct sunlight. Exposure to direct sunlight can permanently damage the monitor.

If system operation is abnormal after you move or transport the system, contact your Philips representative immediately. System components are installed securely and can withstand considerable shock, but excessive shock can cause a system failure.

1. Ensure the system is mounted and locked firmly on the system cart.
2. Disengage the wheel brakes.
3. Move the cart using the handle at the front of the cart.

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.

See the documentation of your HDMI-enabled television or monitor for detailed information on connections and settings.

Supported External Printers

You can connect an external printer to your system.

For thermal printers:

Use only the printer listed here with your system.

Printer type	Printer manufacturer and model number	Support USB printing	Support network printing
Black-and-white (thermal) image printers	Sony UP-X898MD	Yes	No

For report printers:

- To print out ultrasound images through USB ports, select printers equipped with PostScript®3™ language emulation.
- To print out ultrasound images through network connection, select printers that support network print protocols of Raw Port/Port 9100/Port 9100 Direct Mode.

Images printed on a report printer are intended only for reference and should not be used for diagnostic purposes.

5 Using the System

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

Turning On/Off the System

Press and hold the Power button to turn on the system. The system enters the user login 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.

- 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 64).

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 “Customer Service” on page 3).

Logging Into the System

When data security is enabled, you must log into the system before you are able to view or load patient files.

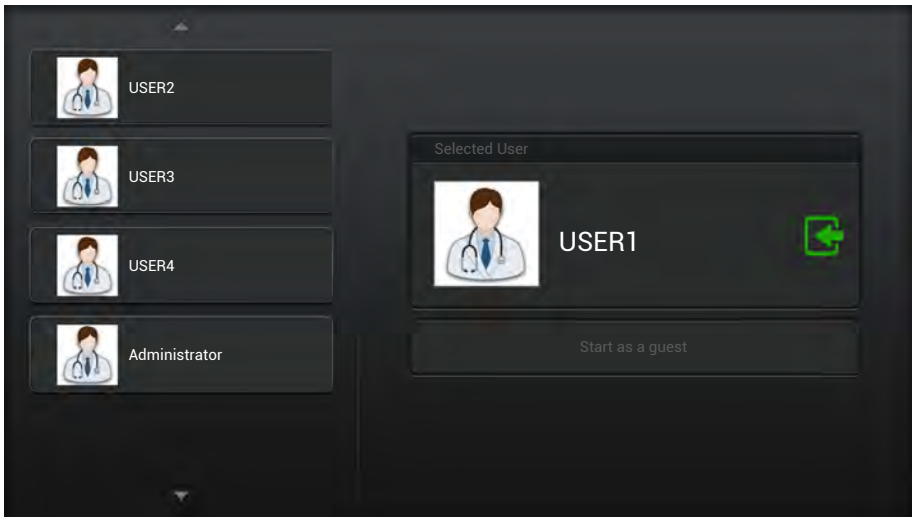


Figure 4 User login screen

Creating a New Administrator Account

1. After system startup, the default user account with administrative privileges appears on the screen. To begin the first-time-logging-in process, touch the account name, enter the default password and touch **Login**.

   Default User ID: SiteAdmin

   Default Password: {System's serial number}

   - To check your system's serial number:
     - On the system imaging screen, touch **Menu** > **Settings** > **About**.
     - Refer to the system label on the back of the system.
   - Each time after a fresh installation or restoring the system to its factory state, the system requires logging in using the default site administrator credentials.

2. Enter your personal credentials to create a new site administrator account, and touch **OK**. The default site administrator account will then be deleted automatically.

   Logging into the administrator account enables full access to complete safety settings, but not operations. To perform exams and functions, the user logged in needs to be a registered user. To enable this role, check **Registered User**  .

3. Follow the instructions in each section to set up the security policies (See page 102). Touch **Save** to save the settings.

If you choose to start the system as a guest, only restricted operations can be performed. To return to the user login screen at any time, touch **Menu** > **Security** > **Go to Login Screen**.

Adding a New User Account

Continue logged in as the administrator to have access to adding new users.

1. Touch **Menu** > **User Management**.
2. Touch **Add User**. Enter personal credentials to create a new user account, and touch **OK**.

   If you wish to enable this user as a second administrator with access to security settings, check **Site Administrator**  .

3. The user account is added with default security policies. To add more users, repeat step 1-2.

To protect user security, the next time the operator logs in as the new user, he or she is required to change the password.

Switching Users

If you are on the user settings screen, touch  first to log off current user and enter the user login screen.

On the user login screen, touch the desired user from the user list on the left, the selected user with its user ID appears on the right. Touch  , enter the password and touch **Login**.

Managing User Settings

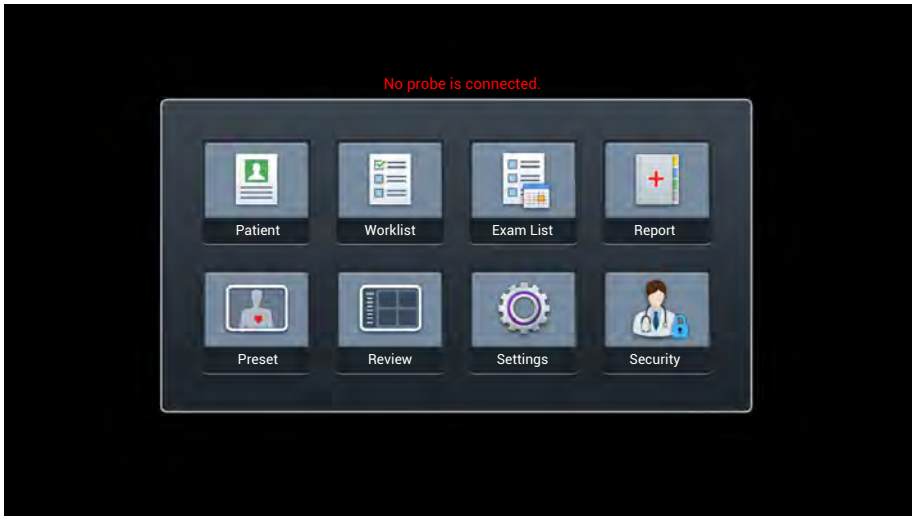
The users without administrative privileges can modify personal credentials as well as limited security settings.

- To modify personal credentials, touch **Menu** > **Security** > **User Edit**.
- To set an automated logout after a specified period of inactivity, touch **Menu** > **Security** > **Security Policies**.

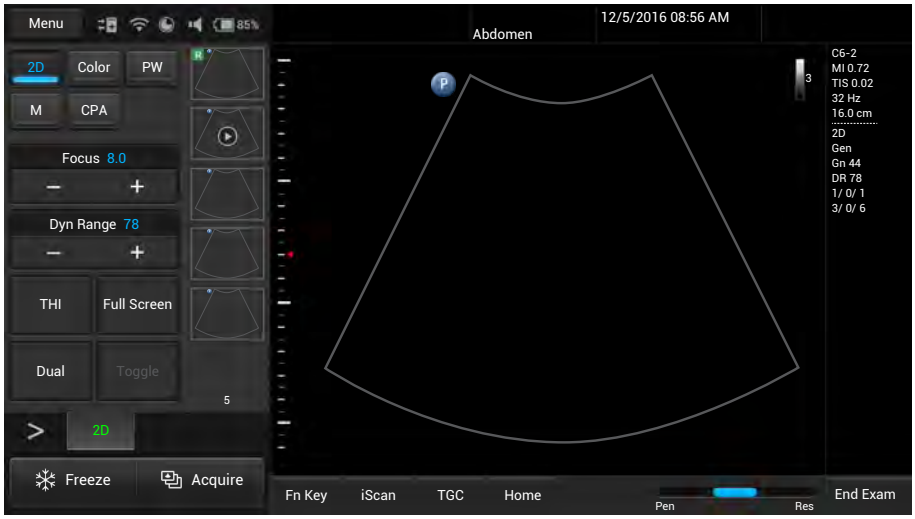
Launching the Main Screen

After successfully logging in as a registered user, 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 2D imaging screen (default).



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 **Menu** > **Settings** > **Workflow** > **Screen after Enter Ultrasound**.

Setting the System Time and Date

Managing pertinent patient data and scanning results require accurate system time and date. After logging in 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.

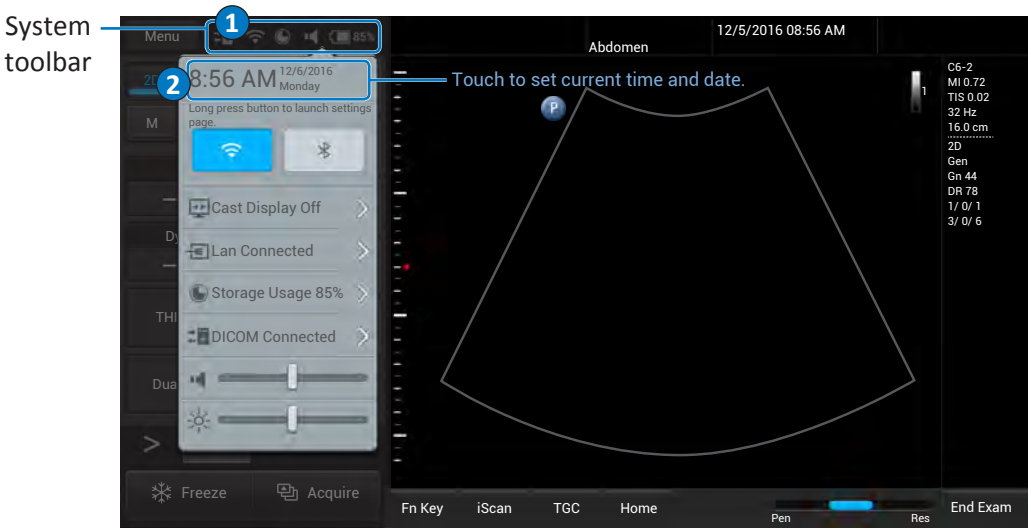


Figure 5 Setting the system time and date

1. Touch anywhere on the system toolbar to open the system tools menu (See page 61).
2. Touch the time & date section > **Set time/Set date**.
   - To set the time, scroll to select the hours, minutes, and a.m. or p.m.
   - To set the date, scroll to select the date, month and year.
3. Touch **Done**. Touch ❮ to leave the setting.

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

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.

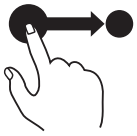
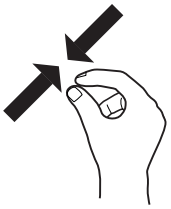
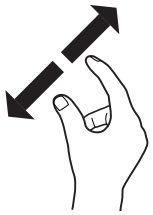
Touch	Touch and Hold	Drag
		
Double-Tap	**Press and Tap**	**Two-Finger Tap**
		
Flick	**Pinch**	**Spread**
		

Figure 6 Gestures

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 **Menu** > **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. • If you play an image loop on the frozen imaging screen, touch and hold on the scan area saves a cine loop.
Zoom/unzoom	Spread two fingers apart/pinch two fingers together.
Move the zoomed image	Touch and hold the zoomed image, and 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.

Action	Gesture
Display the second control panel page/Return to the first control panel page	On the control panel area, flick right to display the second page, flick left to return to the first page (See “Switching the Control Panel Pages” on page 62).

Gestures for Controlling the Real-time Imaging Screen

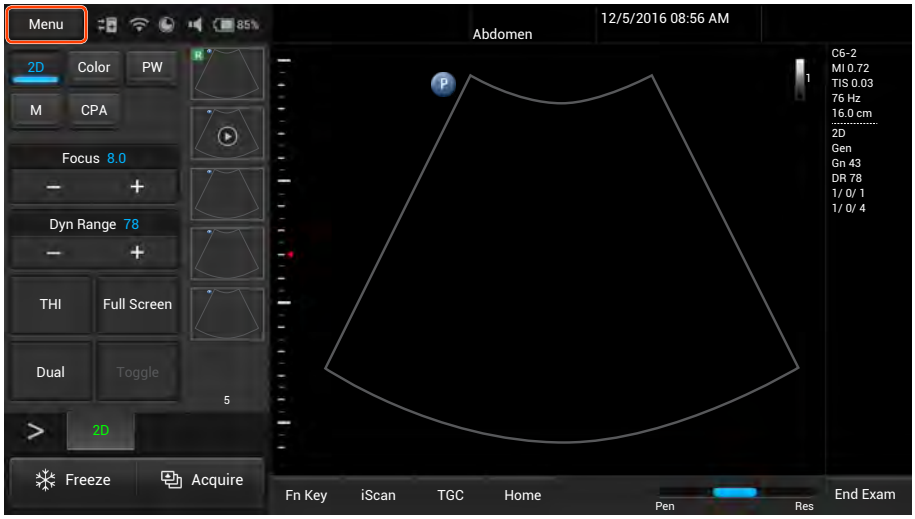
Action	Gesture
Adjust depth	Flick vertically on the scan area to increase (flick down) or decrease (flick up) depth.
Adjust gain	Flick horizontally on the scan area/time series window to increase (flick right) or decrease gain (flick left).
Adjust the sample volume size	1. Touch and hold one finger on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

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.

Setting the System Language

To set the system language you are using, touch **Menu** > **Settings** > **General** > **Language**, and the system reboots automatically for the localized language to take effect.



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 “Customer Service” on page 3).

Identifying the Main Screen Layout

System Menu Screen

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

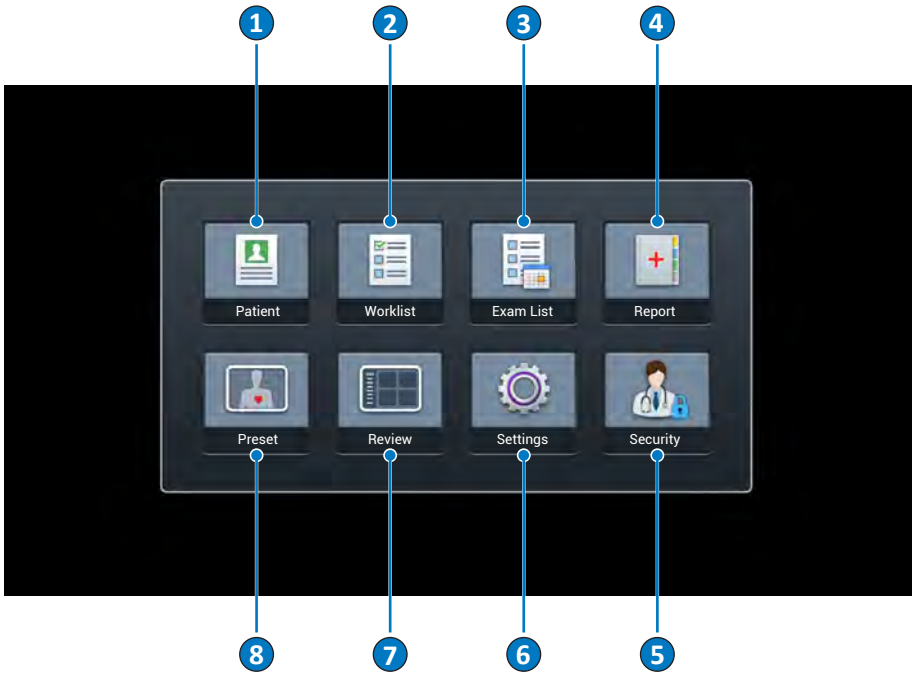


Figure 7 System menu screen

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.
3	**Exam List**	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	**Security**	Manage users and permissions to control access to ePHI (Electronic Protected Health Information) data on the system and the system features.
6	**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 102)
7	**Review**	View, add annotations and measurements to, and export a saved exam.
8	**Preset**	Select the predefined preset compatible with the connected transducer for optimized image control settings.

Imaging Screen (Real-time)

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

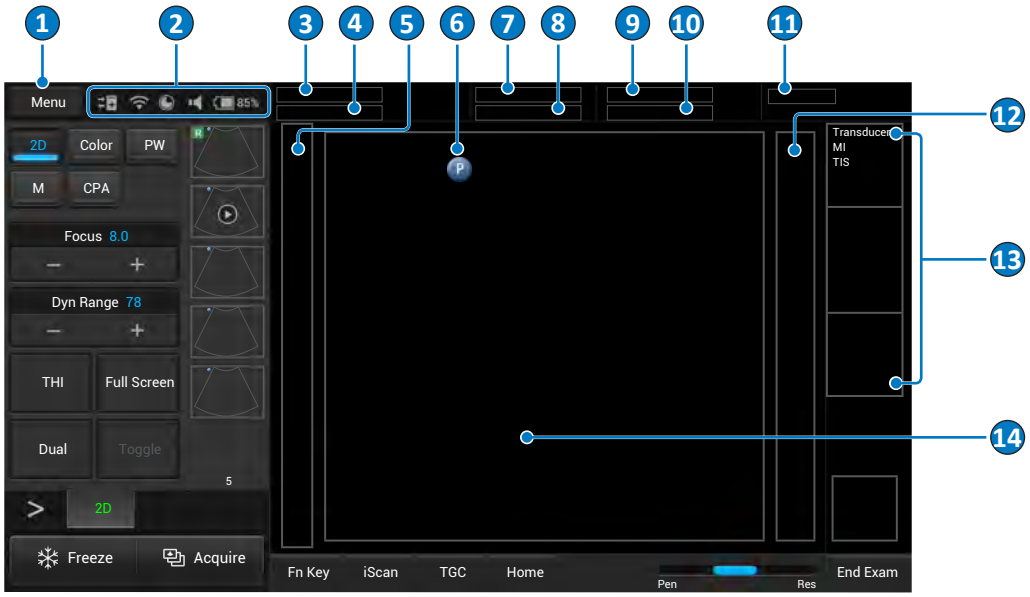


Figure 8 Real-time imaging screen (example)

No.	Function	No.	Function
1	System menu button Enter the system menu screen.	2	System toolbar Display information about current battery level, volume, system storage, and network connection status. Touch anywhere on the system toolbar to open the system tool menu for system configuration. (See page 61)
3	Patient name	4	Patient ID
5	Depth scale	6	Transducer orientation icon (See page 73)
7	Patient age/gender/DOB (date of birth)	8	Application name
9	Current date and time	10	User name
11	Institution name	12	Grayscale/spectrum wedge
13	Scan properties display area Display information about the current scan.	14	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.

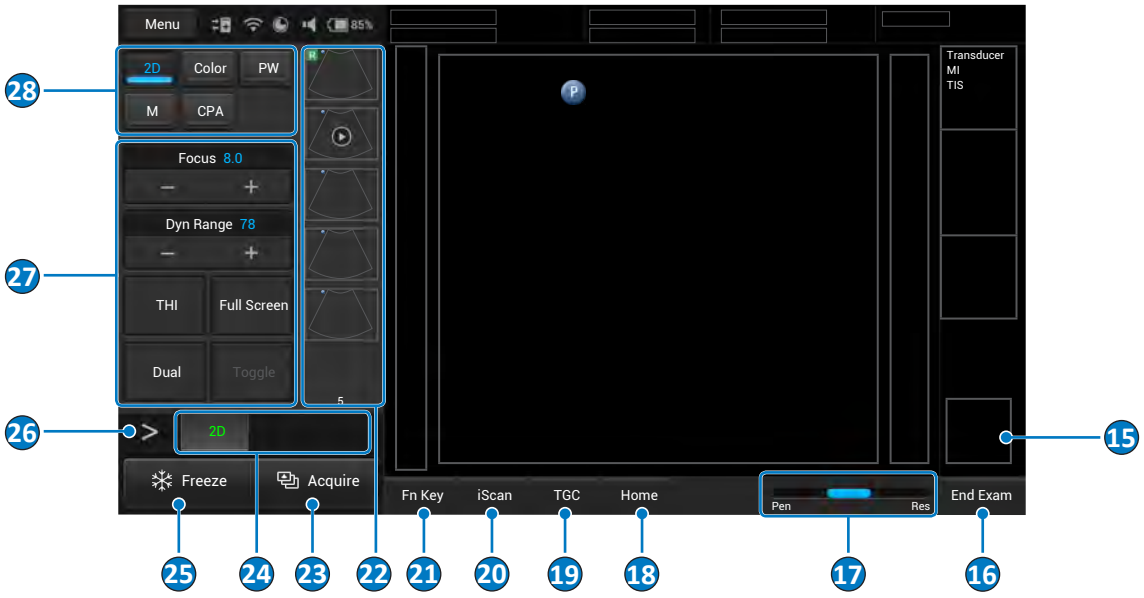


Figure 9 Real-time imaging screen (example)

No.	Function	No.	Function
15	ROI (region of interest) area Use the **Zoom** function to zoom in and pan across the current image.	16	**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.
17	• **Res** (High Resolution): Drag the cursor to the right for a clearer yet superficial image. • **Pen** (Deep Penetration): Drag the cursor to the left for a deeper yet less clear image.	18	**Home** button Return to the real-time imaging screen.
19	**TGC** (Time Gain Compensation) Slide any of the 8 TGC sliders to adjust the gain for the desired section of the 2D image.	20	**iScan** button Optimize the image quality during a real-time scan.
21	**Fn Key** button Assign this button as a shortcut to perform a function.	22	Thumbnail area Thumbnails of the scanned images/loops that are saved. Flick vertically to scroll through the list.
23	**Acquire** button* Save a default set of image frames as a loop to the system hard drive.	24	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 —27.
25	**Freeze** button Freeze the current scan.	26	Open the next page of the image control settings (See page 56).
27	Image control settings (See page 89)	28	Scan mode buttons

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

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.

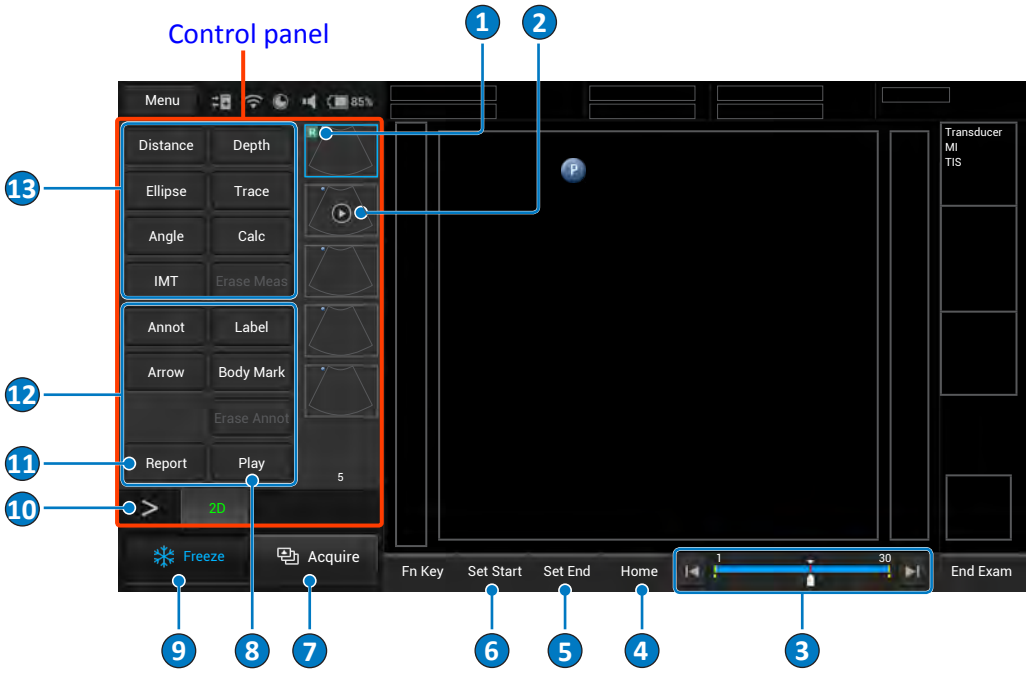


Figure 10 Frozen imaging screen (example)

No.	Function	No.	Function
1	This image is added to a report.	2	Image loop
3	The progress bar Used to track the frames (in a continuous image loop) just scanned and the number of the current frame.	4	**Home** button Return to the real-time imaging screen.
5	**Set End** button During playback of the image loop, touch this button to set the end point of the image loop.	6	**Set Start** button During playback of the image loop, touch this button to set the start point of the image loop.
7	**Acquire** button Save a frozen image from an image loop to the system hard drive.	8	**Play** button Review the image loop just scanned. Touch repeatedly to start/pause the playback.
9	**Freeze** button (Enabled) Touch this button again to return to the real-time scan.	10	Open the next page of the image control settings. (See page 62)
11	Add annotations, including arrows, texts and body marks, to the current image using the virtual keyboard.	12	Perform measurements and calculations on the current image.
13	**Report** button Generate a report from the current scan.		

System Tools

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

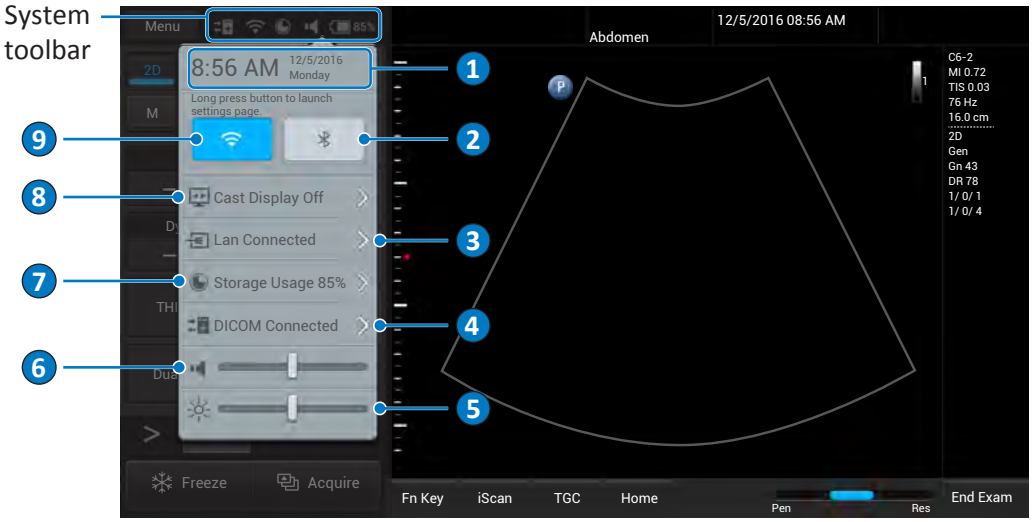


Figure 11 System tool menu

No.	Function	No.	Function
1	Set current date and time. (See page 54)	2	Enable/disable the Bluetooth function. (See page 66)
3	Manage the LAN connection. (See page 65) • : LAN Disconnected • : LAN Connected	4	Check and manage outgoing queues to the DICOM server. (See page 66) • : DICOM Disconnected • : DICOM Connected
5	Adjust the brightness.	6	Adjust the volume.
7	Display the percentage of the system storage used. (See page 64) • : Storage usage empty • : Storage usage full	8	Cast the system screen to an external display. • : Cast Display Off • : Cast Display On
9	Enable/disable the WiFi function. (See page 65)		

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 **Done**.

Figure 12 Virtual keyboard

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

Scan Properties Display

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

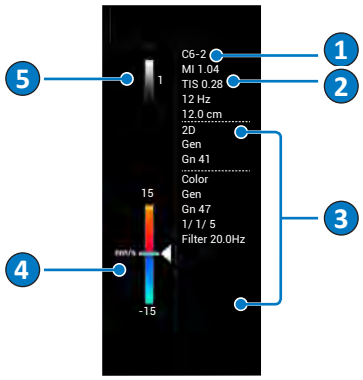


Figure 14 Scan properties display (example)

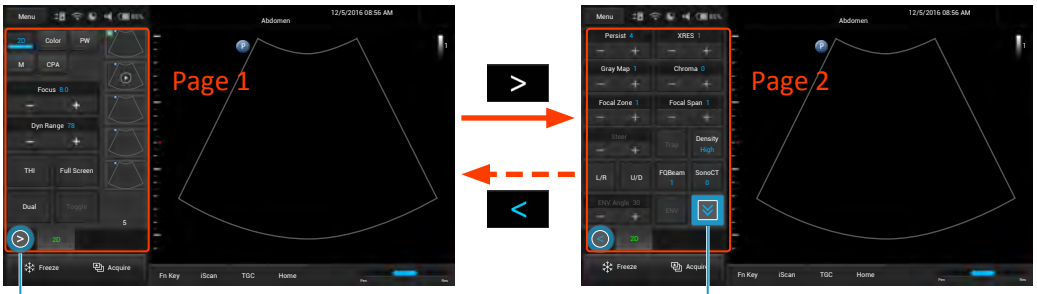
No.	Function	No.	Function
1	Transducer type	2	Thermal index/Mechanical index
3	Depending on the transducer connected and the scan mode selected, corresponding scan parameters are displayed. (See “Chapter 7 Using Image Controls” on page 89)	4	Color/CPA wedge
5	Grayscale wedge		

Switching the Control Panel Pages

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

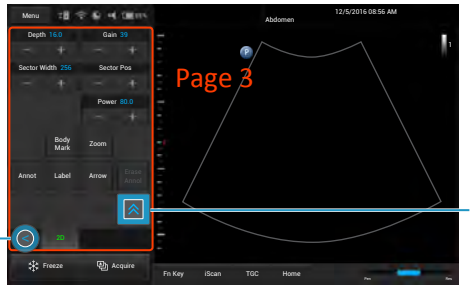
The functions available on the control panel vary, depending on the scan mode and the transducer connected.

- Use buttons:



Touch to open the next page (page 2).

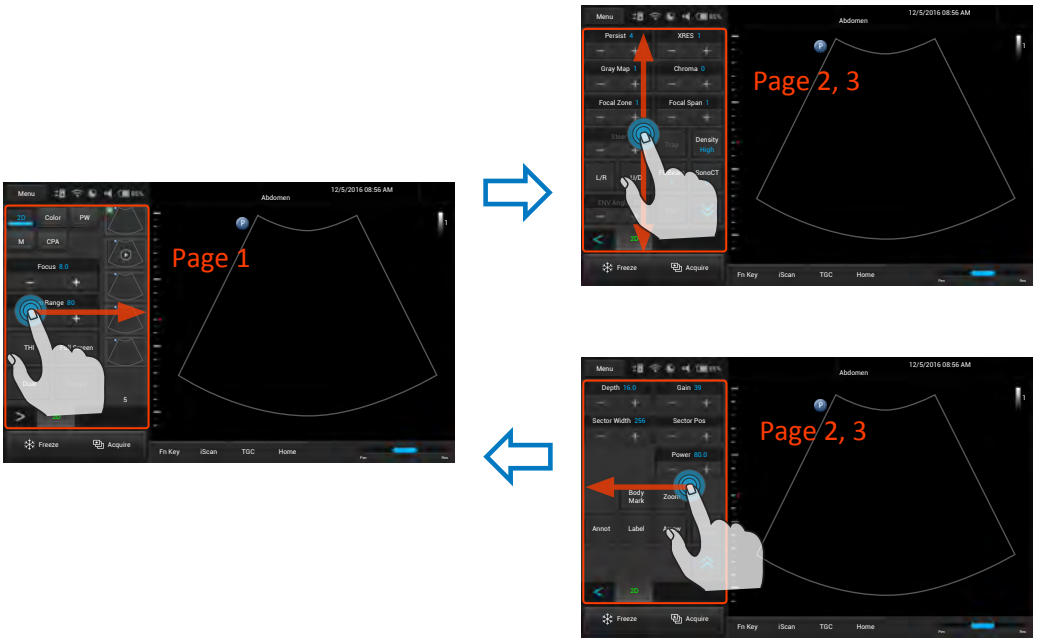
Touch to display more functions (page 3).



Touch to return to the first page (page 1).

Touch to return to the previous page (page 2).

- Use gestures:



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 64) along with the percentage of battery power remaining are shown on the system toolbar (See page 61). Always monitor the power level of the battery when you operate the system on battery power.

Battery Status Icons

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

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.

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

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.

If automatic logoff is enabled, the current user is logged off when the system enters Sleep mode.

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 system tool 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:

- **Low on disk space**: The disk space available for storing images is low. Delete some stored exams to ensure that there will be enough room for new images.
- **Critically low on disk space**: The disk space available for storing images is critically low. Immediately delete some stored exams to free up your disk space.
- **Disk 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 **Menu** > **Settings** > **Exam**, and delete stored exams in the appointed number of weeks.

Network Configuration

The system network is configured from the system tool menu (See page 61). 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.

Connecting the System to the Network by Ethernet

1. Connect one end of the provided 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 system tools menu (See page 61).
4. Touch to go to its 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.

   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.

Connecting the System to the Wireless Network

- 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. Open the system tools menu (See page 61).
2. Touch to enable the wireless network function, then touch and hold this button to go to its settings.
3. On the available network list, select an access point on an existing wireless network with your DICOM server, and enter the required settings.

   Consult your network administrator about the appropriate settings.

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

Connecting the System to a Bluetooth Device

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

- 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 8 meters.

1. Open the system tools menu (See page 61).
2. Touch  to enable the Bluetooth function, then touch and hold this button to go to its settings.
3. The system scans for and displays the IDs of available Bluetooth devices within range.

   To make your system visible to nearby devices, touch your system's name so that it shows "**Visible to all nearby Bluetooth devices**".
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.

Unpair a Bluetooth Device

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

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.

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

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

Modality Interface

DICOM standard. DICOM conformance statements for Philips products are available at this website:

www.healthcare.philips.com/main/about/connectivity/dicom_conformance_main.wpd

Adding Servers

1. Select a storage/worklist SCP 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.
5. Repeat step 1-4 to add more servers based on your needs.

- If you add a second storage SCP, when you export an exam or an image/video to the DICOM server, two tasks are created in the outgoing queues.
- 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.

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.

Consult your network administrator about the appropriate settings.

Managing Outgoing Queue

When you export an exam or an image/video to the DICOM server, you can monitor its status in the outgoing queue. The system provides three ways of exporting the exam. For more information, see "Exporting the Exam" on page 85.

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

*If you export an exam as a report, 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**.

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 (Patient screen).
   - To load a work list (Worklist screen).
   - To resume a previously saved/paused exam (Exam List screen).
2. Select an exam type and preset (Preset screen).
3. Start real-time imaging (Imaging screen (Real-time)).
4. Set the transducer orientation (See page 73).
5. Select a scan mode (See page 73) and adjust image controls (See page 89).
6. When the desired anatomy is shown, freeze the image (Imaging screen (Frozen)).
7. Add annotations (See page 76) and measurements (See page 78).
8. Save or print the image (See page 82).
9. (Optional) Review the images (See page 83), generate a report and export the exam (See page 85).
10. End the exam (See page 87).

Refer to the following sections for detailed instructions.

Starting a New Exam

The system allows skipping entering patient information if you need to start the ultrasound exam immediately. However, the system will add a temporary name/ID automatically if you wish to save the images and cine loops. You can enter the patient screen to complete the patient information during or after the exam.

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

Adding a New Patient

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

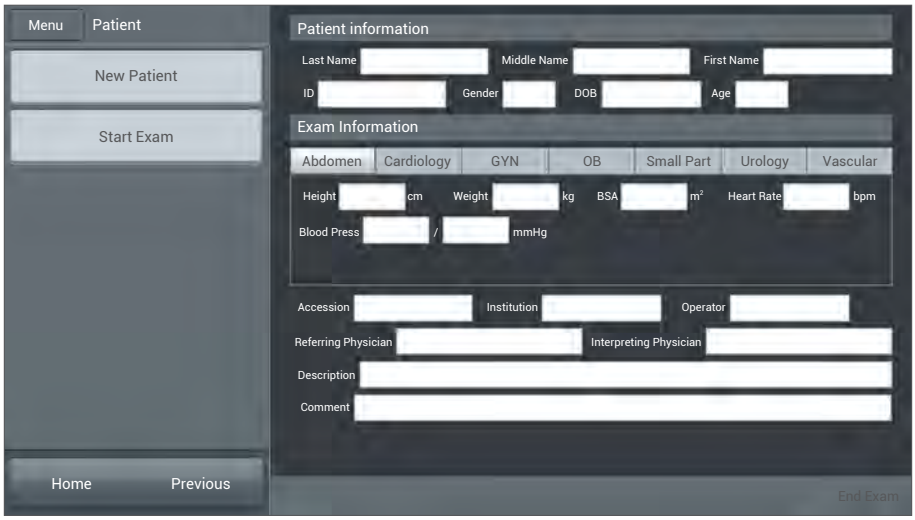


Figure 15 Patient screen

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.

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**.

Updating Patient Information

1. During real-time scanning, touch **Menu** > **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**.

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.

For more information on configuring DICOM settings, see “DICOM Configuration” on page 66.

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

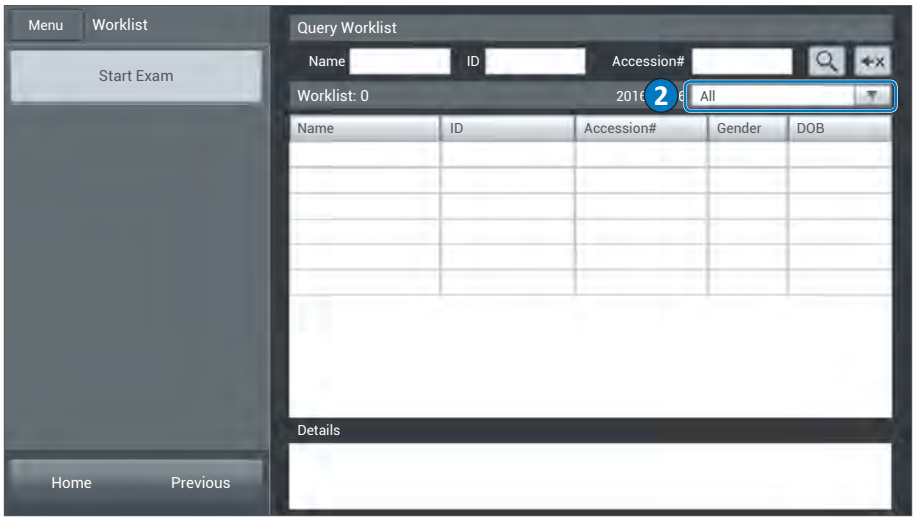


Figure 16 Worklist screen

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.

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

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 **Menu** > **Preset**. All the available presets compatible with the connected transducer display on the preset screen.

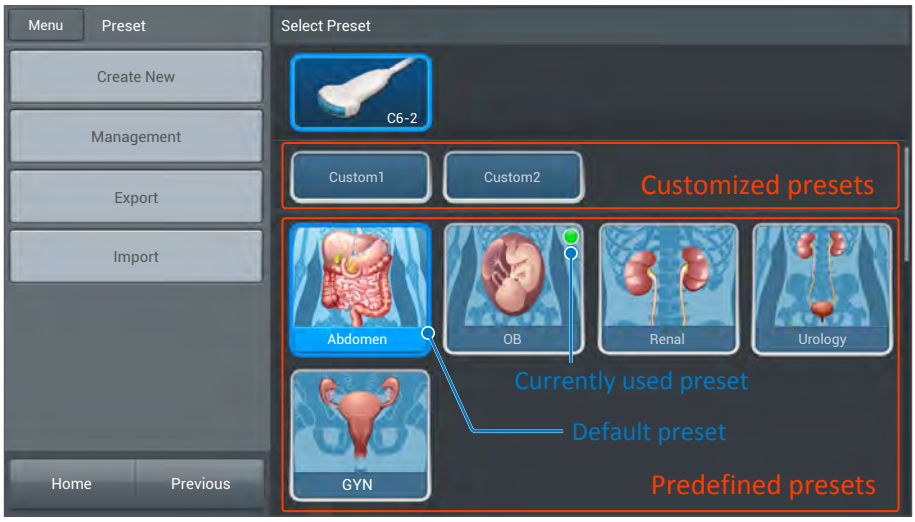


Figure 17 Preset screen

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

Customizing a Preset

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

Modifying a Preset

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

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  on the preset to edit its name; touch  on the unwanted preset to delete it.

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

Exporting and Importing Customized Presets

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

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.

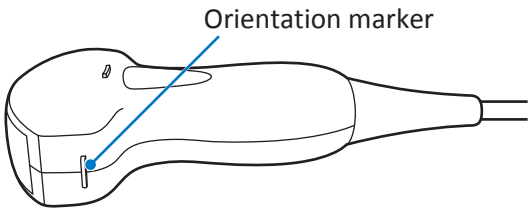


Figure 18 Transducer orientation (Example transducer: C6-2)

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**.

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.

To view a list of available scan modes, see “Imaging” on page 27.

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 “Chapter 7 Using Image Controls” on page 89)

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

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 imaging screen, touch > > **Zoom**. The ROI (Region of Interest) box appears on the center of the image.

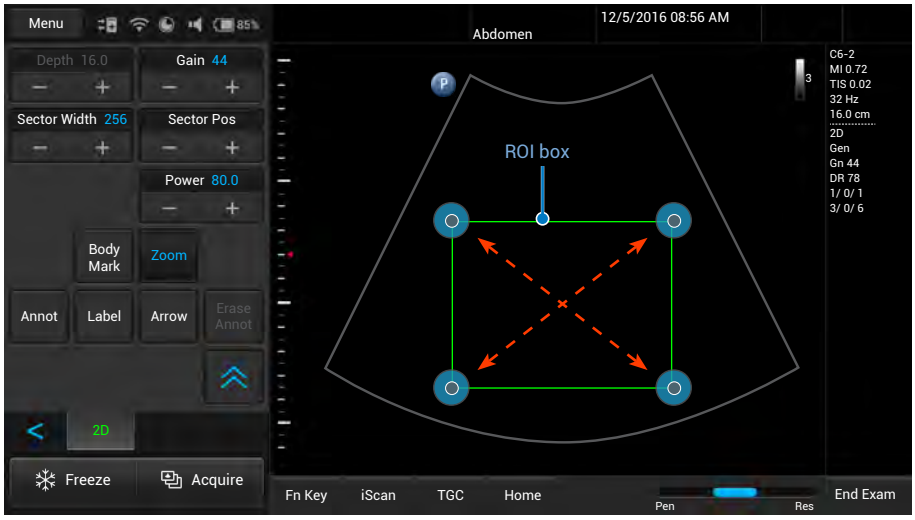


Figure 19 Enlarge an ROI (normal image)

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.

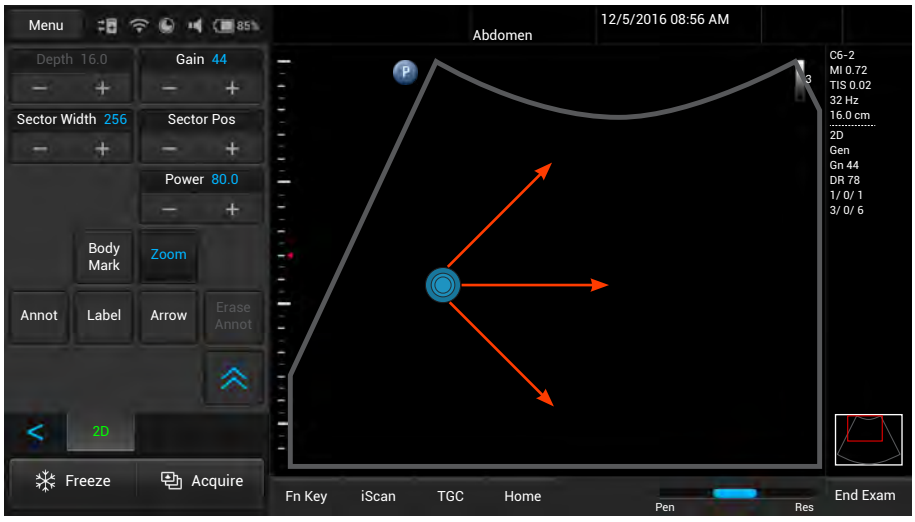


Figure 20 Enlarge an ROI (zoomed image)

3. To move the enlarged area, press and hold anywhere on the image, then drag to move it.

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 2D, 2D+Color and 2D+CPA modes.

When in 2D Mode:

On the 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.

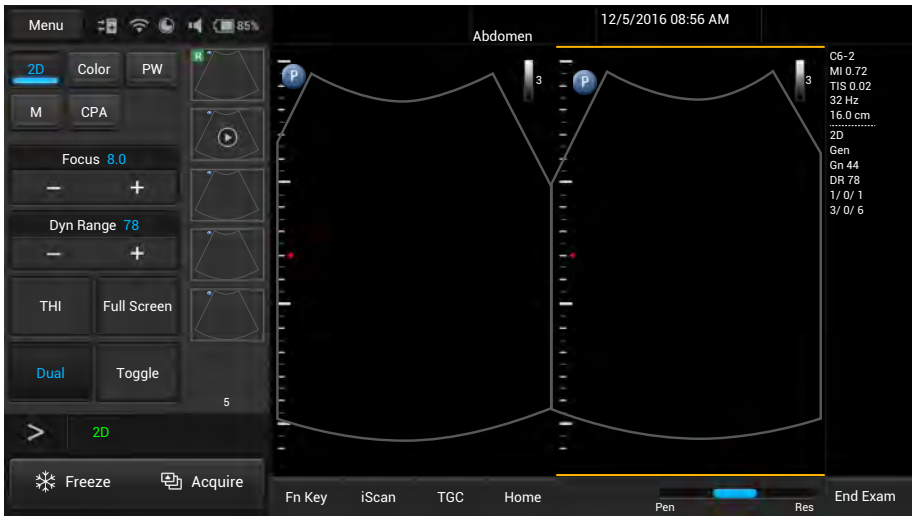


Figure 21 Dual screen: Frozen 2D mode (left) + Real-time 2D mode (right) images

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.

When in 2D+Color or 2D+CPA Mode:

On the imaging screen, touch **Dual**. The system copies the current settings for the image to the second screen in 2D mode. Both screens are in real-time but you get a clearer view under the ROI in 2D mode.

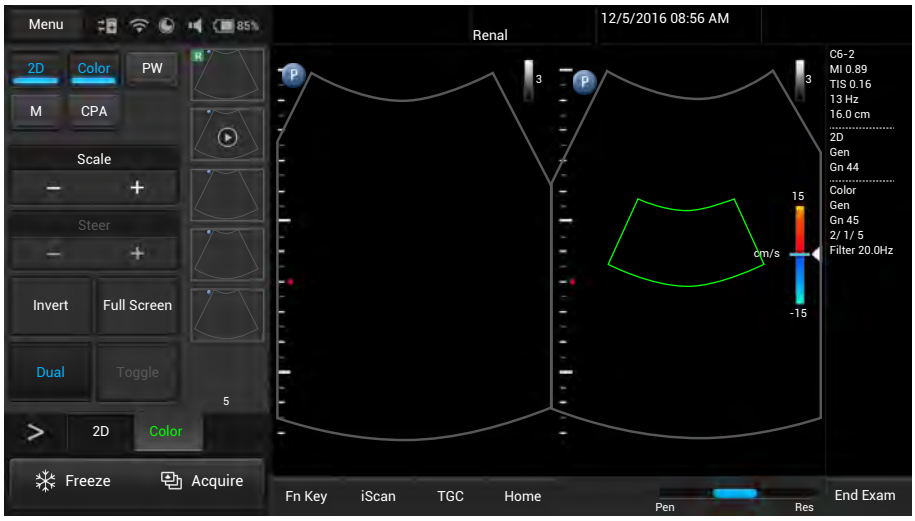


Figure 22 Dual screen: Real-time 2D mode (left) + Real-time 2D+Color mode (right) images

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

To leave the dual screen, touch **Dual**.

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

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 saved images frame by frame or to find a specific frame, touch / or drag the frame indicator horizontally.

- To restart a new real-time scan, touch **Freeze** again.
- If no frozen image or cine loop are saved, 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's imaging screen, touch **Menu** > **Settings** > **Workflow** > **(Status after Freeze)** > Select an option.

Adding Annotations

On the frozen imaging screen, you can add annotations to the ultrasound images in order to explain the anatomy.

Figure 23 Add annotations

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

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.

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 **Done** on the keyboard 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.

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. Move a set of existing texts to the desired text home position.
2. Touch the texts directly, and touch **Done** to close the keyboard.
3. Touch **Set home**.

To restore the texts to the default text home position, simply touch the texts, close the keyboard, then touch **Go home**.

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 cursor/label to where you want the texts to be.

The text labels are still editable. Touch the label to display the virtual keyboard, and start editing the texts. Touch **Done** on the keyboard to finish editing.

Body Mark

1. Touch **Body Mark** to display the body mark menu.

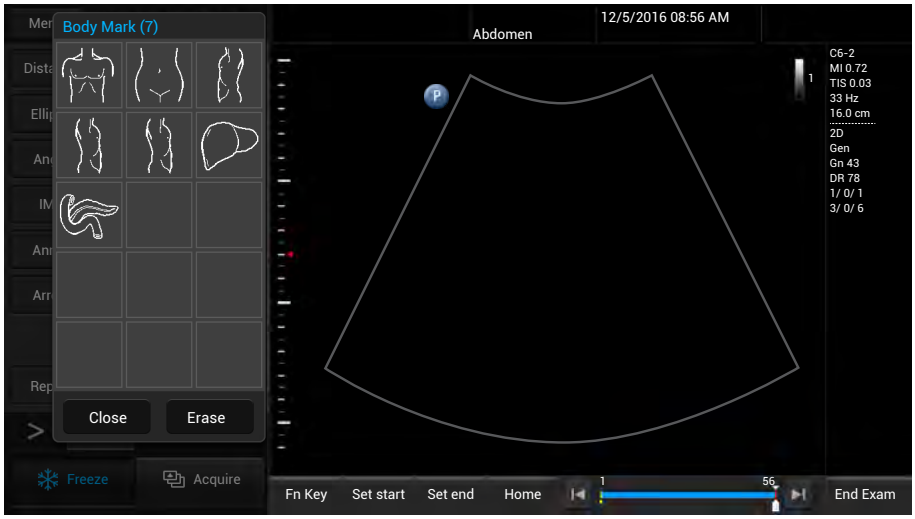


Figure 24 Add a body mark

2. Select a body mark. A pictogram of the body mark with a transducer indicator displays on the image.

Figure 25 Pictogram of the body mark (example)

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.

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

Adding Measurements

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

Figure 26 Perform measurements

Item	Measurement type	Reference page
a	Distance	(See page 79)
b	Ellipse	(See page 79)
e	Trace	(See page 79)
d	Angle	(See page 80)
e	IMT	(See page 80)

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 turns green, and the 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 **Acquire** to save the ultrasound image

- To re-position the measured results, 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 Meas** to erase the last measurement added. Repeat this action, if needed, to continue erasing measurements.
- To directly erase all measurements, touch and hold **Erase Meas**.
- You can select whether to keep or erase the measurements added after you return to the live scan by touching **Menu** > **Settings** > **Workflow** > **Auto-clear Measurement after Unfreeze**.

Measuring in 2D/Color/CPA Modes

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 to complete measurement a.

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. An oval area is then measured b.

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.

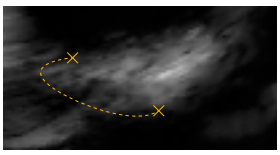


Figure 28 Trace an outline

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 c.

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 d.

IMT

Measure IMT (Intimal 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 e.

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.
5. Repeat step 3-4 to perform the rest of the measurements on the list.

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%.

Measuring in M-Mode

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.

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.

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

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.

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.

Measuring in Spectral Doppler Mode

Auto Trace

Trace the spectrum of Doppler waveforms.

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

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 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 screen to complete the trace.

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

Trace

Manually trace the Doppler spectrum.

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 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 to complete the trace.

Velocity

Measure the blood flow velocity.

Display item	Contents (units)
V	Flow Velocity (mm/s)
PG	Pressure gradient (mmHg)

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.

General Measurement

Used to perform a set of basic Spectral Doppler measurements including peak systolic velocity, velocity time integral, end diastolic velocity, pressure gradient and acceleration time.

Display item	Contents (units)
V1	Peak systolic velocity (mm/s)
V2	End diastole velocity (mm/s)
P1/P2	Pressure gradient (mmHg)
Accl	Acceleration time (mm/s^2)
Time	Time (s)

1. Touch **2-Points**. 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.

For measurement accuracy and precision in PW Doppler measurement:

- Velocity measurement will be less than ±12%.

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

Saving and Printing the Image

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

Saving an Image Loop

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

Saving an Image

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

Printing an Image

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

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.

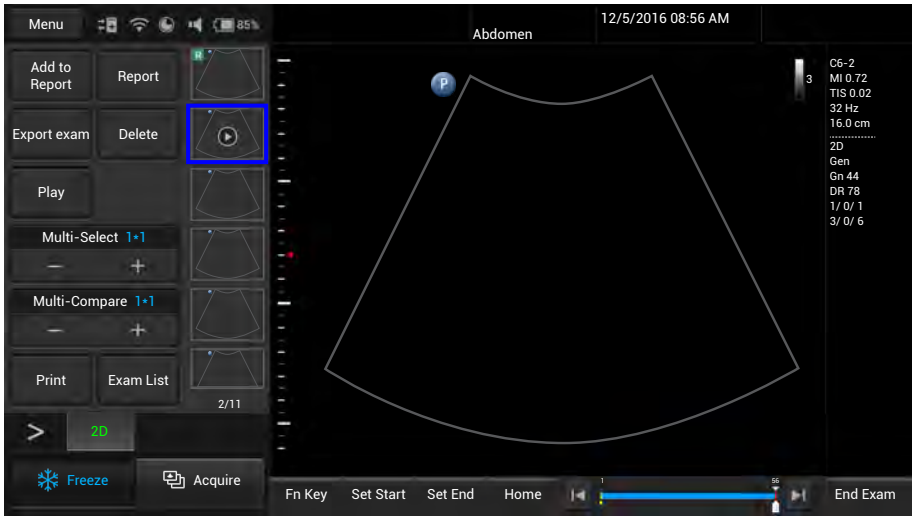


Figure 29 Review the image

Performing Multiple Selections

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

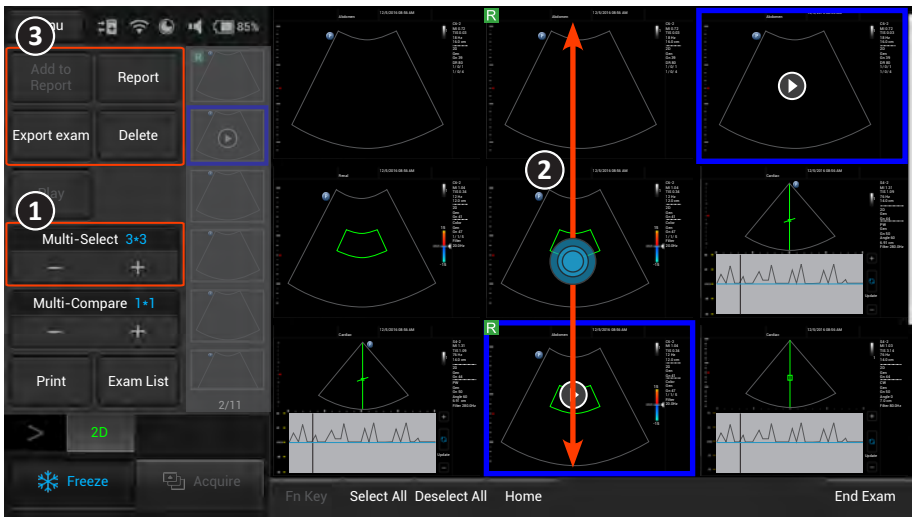


Figure 30 Perform multiple selections

1. Touch **Multi-Select +**.
2. Flick vertically on the thumbnail window and touch to select up to 9 images/loops.
   - 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.

Comparing Images

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

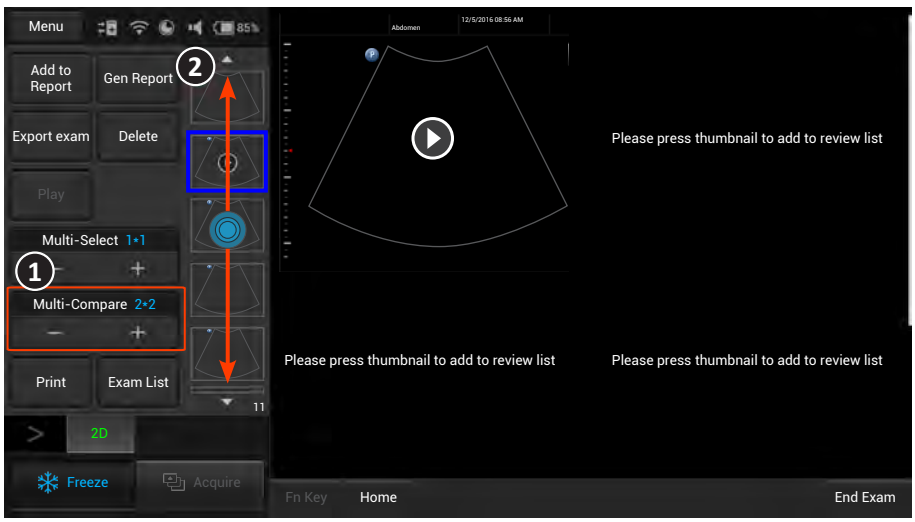


Figure 31 Compare images

1. Touch the **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.

Generating a Report

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

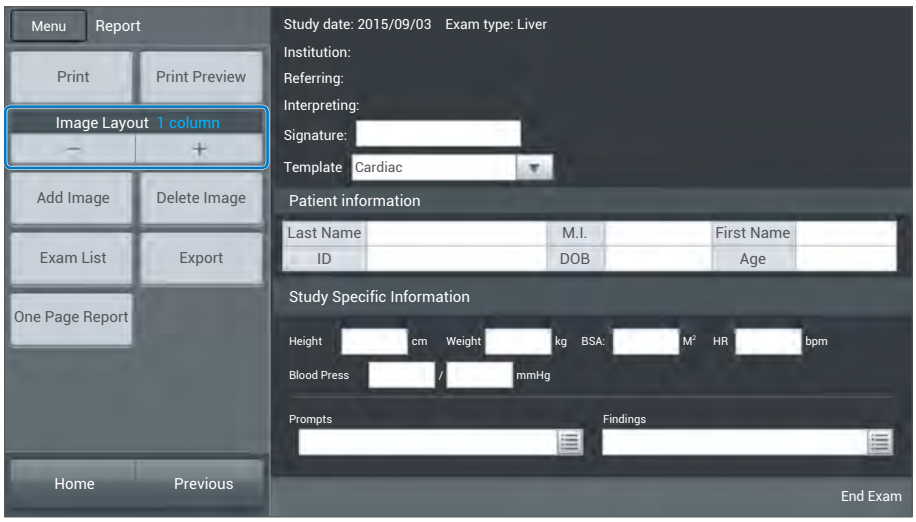


Figure 32 Report screen

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.

> 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 numbers of columns for placing the images on a report.
6. To save the report, touch **Export**, select the file format and directory, enter the file name then touch **Save as file**.

> To save the report, an external storage device must be connected to the system.

7. To print out the entire report with scanned images, first touch **Print Preview** to preview the report, then touch **Print**.

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

> On the print review screen, you can choose different ways to preview the report.

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 three ways of exporting the exam:
   - On the review screen, touch **Export exam**.
   - On the Exam List screen, check the completed exams, and touch **Export Exam**.

- On the report screen, touch **Export**.

2. Touch **Export exam to DICOM**, **Export exam to external storage** or **Export media image to external storage**.

- To set the default export directory, export to DICOM automatically after ending the exam and more, touch **Menu** > **Settings**.
- For more information on configuring DICOM settings, see “DICOM Configuration” on page 66.

Managing the Exam List

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

On the imaging screen, touch **Menu** > **Exam List**. Refer to the **Status** column to check the status of each exam. To review images/video clips of an exam, touch .

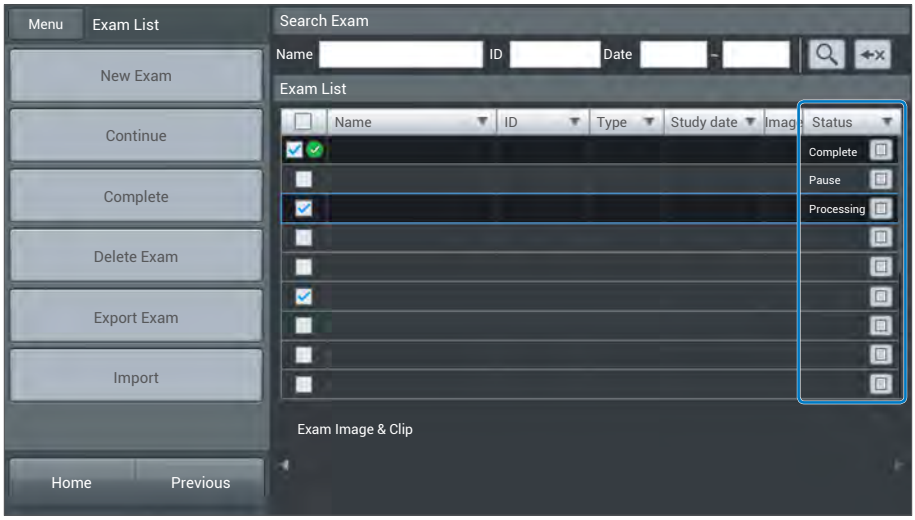


Figure 33 Exam list screen

Alternatively, you can enter the query in any of the **Name/ID/Date** fields, and touch to start the query. Patients matching the query will be listed on the screen.

Resuming an Exam

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

Starting a New Exam

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

Finishing Exams

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

Deleting Exams

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

Exporting Exams

To export exams, multi-check the exams , touch **Export Exam** and select an export method. The task status icon (See page 67) next to the checkbox indicates the uploaded result of the exam.

Importing Exams

Multi-check the exams and touch **Import** from an external storage.

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.

To check the exam status, go to **Menu** > **Exam List**.

Using Image Controls

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 76 and “Adding Measurements” on page 78.

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 58).
- Touch > > ⩔ to switch the control panel pages to go through the available functions (See “Switching the Control Panel Pages” on page 62).

2D Mode Image Controls

Overview

The system delivers 2-dimensional digital imaging 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.

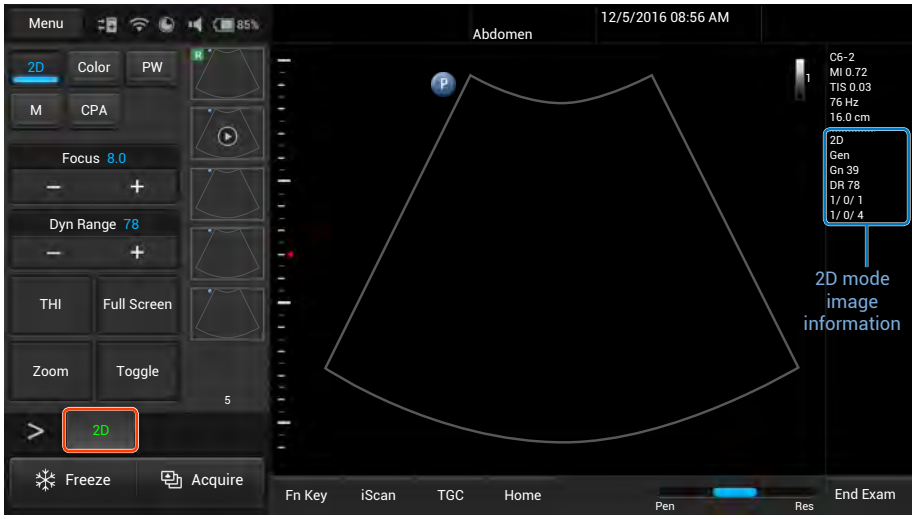


Figure 34 2D mode real-time scan

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.

Adjusting Frequency

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

To increase the frequency, touch **Res**. To decrease the frequency, touch **Pen**.

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.

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 horizontally on the scan area to set the scan depth.

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.

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.

Using Tissue Harmonic Imaging (THI)

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

Touch **THI** to enable this function.

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.

Adjusting Sharpness and Smoothing

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

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

Adjusting Gray Map

Change how the amplitude is converted to brightness.

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

Adjusting Chroma Map

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

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

Adjusting Steer Angle

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

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

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.

Adjusting Power

Adjust the acoustic output power value to the expected target.

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

Using Trapezoidal Imaging

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

Touch **Trap** to enable trapezoidal imaging.

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.

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 **SonoCT** repeatedly to enable and adjust spatial compounding.

Using ENV (Enhanced Needle Visualization)

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

- 2D mode is selected
- An L12-4 transducer is connected to the system

- A patient profile is selected

Touch **ENV** to enable this function.

A diverging dotted green line show 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** repeatedly, if needed, to toggle between lines angled from upper left to lower right and lines angled from upper right to lower left.

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.

Color/CPA Mode Image Controls

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.

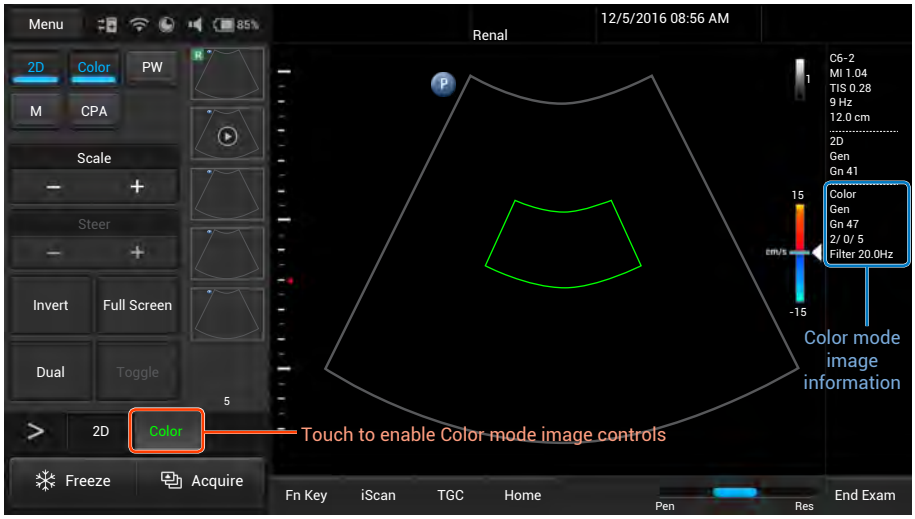


Figure 35 Color mode real-time scan

In CPA (Color Power Angio) 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.

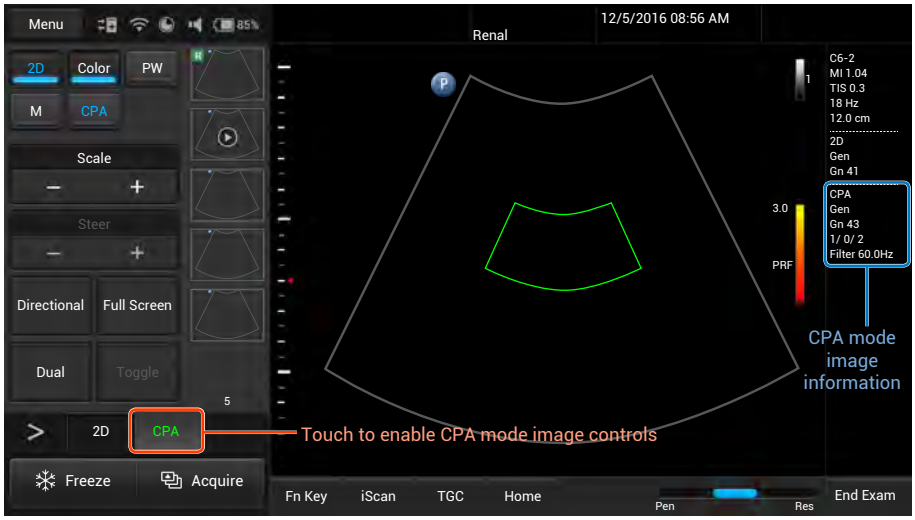


Figure 36 CPA mode real-time scan

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

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/CPA wedge and the Wall Filter setting are changed accordingly.

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

Adjusting Wall Filter (WF)

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.

Applying the Smoothing Filter

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

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

Adjusting the Color Priority

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

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

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.

Using Directional Power

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

Touch **Directional** to enable this function.

M-Mode Image Controls

Overview

M-Mode imaging is used simultaneously with 2-dimensional (2D 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 a, and the motion scan in the Time Series window b. 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.

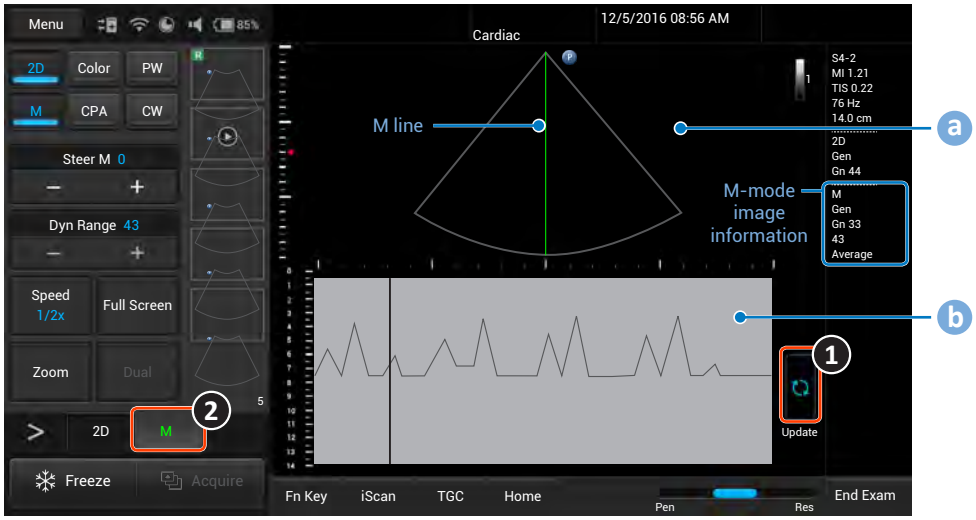


Figure 37 M-Mode real-time scan

1. Touch **Update** 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).
2. Touch M to enable M-Mode image controls.

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 cardiological 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 add a second line. Repeat step 2-3 to place it. Up to 3 M-lines can be added.

Adjusting Sweep Speed

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

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

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** repeatedly to select a desired method.

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.

Spectral Doppler Mode Image Controls

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 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 sample 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 sample gate to the proper location.

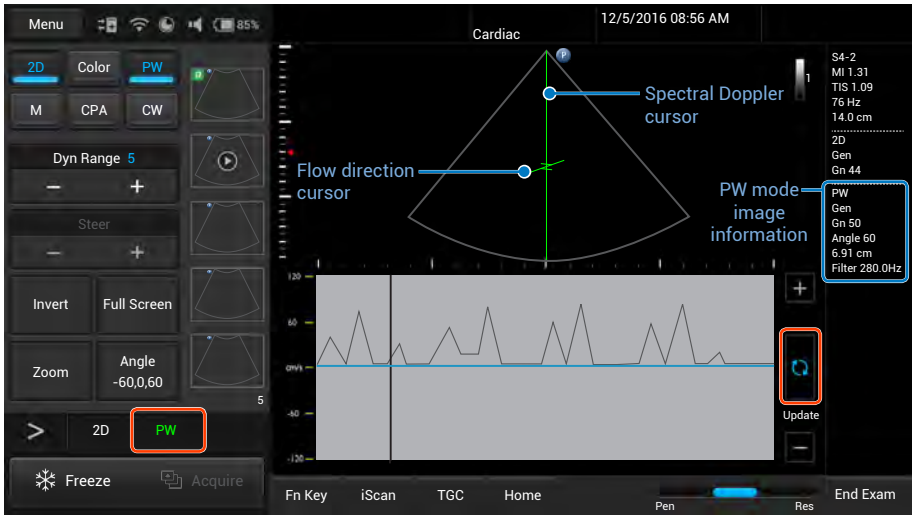


Figure 38 PW Doppler mode real-time scan

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

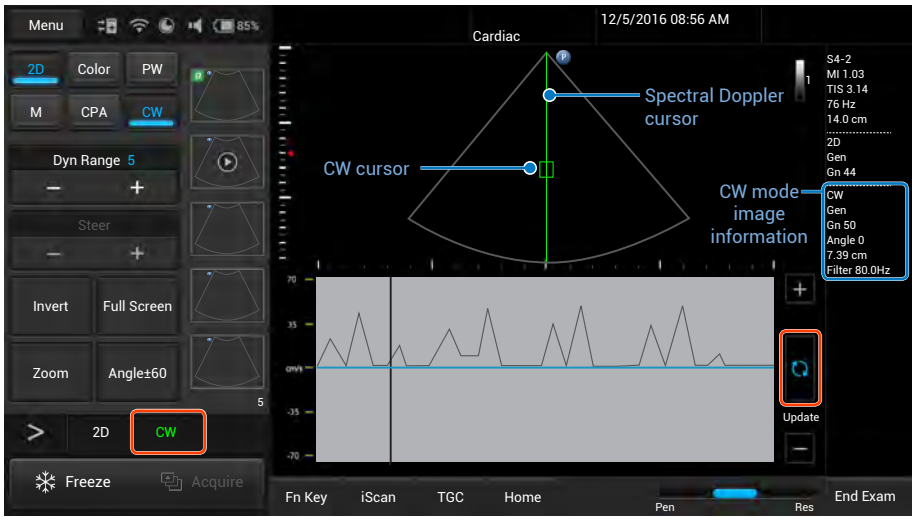


Figure 39 CW Doppler mode real-time scan

Adjusting Baseline

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

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

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 scan line, then flick another finger up or down.

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.
- To manually adjust the angle, touch and hold one finger on the scan line, then flick another finger to the left or right.

Updating the 2D Display

Select whether or not to continue scanning the anatomy while acquiring PW Doppler scan data.

Touch **Duplex** to enable/disable this function.

8

System Customization and Service

Customizing Your System

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.

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

General

- **Dock Control Panel at**: Set the control panel at the left or right side of the screen.
- **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.

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 “Selecting a Preset” on page 72)
- **Export preset/Import preset**: Export/import customized presets to/from your external storage. (See “Selecting a Preset” on page 72)

Patient

- **Auto-create Patient Name and ID**: Enable creating a set of patient name and ID every time you start a new exam.
- **Show Patient Information**: If you want to protect patient privacy, disable this function to conceal patient information during real-time scanning. However, the system does not allow acquiring images/loops without patient name.
- **Show Study Information**: If you want to protect physician privacy, disable this function to conceal physician and institution information during real-time scanning.
- **Patient Information Unit**: Set the measurement unit for filling in patient information.

Exam

- Add logos and names for the institutions and physicians.
- **Delete exams before**: Set the number of weeks ago the exams are done, then touch **Delete** > **OK**.

Workflow

- **Screen after Enter Ultrasound**: Select the screen to enter after starting/logging in 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.

Body mark

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

Annotation

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

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.

Exam

- **Screen after End Exam**: Select the screen to enter after touching **End Exam**.
- **Export DICOM after End Exam**: Enable exporting data via DICOM automatically after touching **End Exam**.

Print

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

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.

Imaging

- **Auto Focus by following CROI/Auto CROI by following SV**: Enable re-positioning ROI to the center of the image automatically upon entering Color/CPA/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 scanned 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.

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.

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**.

Body Mark

- **Default Body Mark for Application**: Touch **Edit**, select an application and touch a desired body mark to set it as default, then touch **Save**.
- **Body Mark List**: Touch **Edit**, select an application and enable/disable each body mark to re-arrange the body mark list, then touch **Save**.

Measurement

- **User Defined Measurement List/User Defined Calculation List**: Customize measurements/calculations.

  Touch **Edit**. Select a scan mode to display its available measurements/calculations.

  - » To add a new measurement/calculation, touch **New**, or use existing measurement types/equations by selecting a measurement/calculation and touching **Copy**. Edit the measurement/calculation name and measurement types/equations using the **Properties** buttons, then touch **Apply**.
  - » To edit or delete a customized measurement/calculation, select the measurement/calculation and touch **Edit** or **Delete**.
- **Configuration of Calculation List**: Touch **Edit** and check/uncheck each item to re-arrange the calculation list, then touch **Save**.
- **Result Unit**: Set the measurement unit.
- **Caliper Size/Set Result Font Size**: Select options.
- **Show Measure Line**: Enable showing the measuring lines while 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.

Report

- **Default Report Template**: Set the default report template based on the application selected.
- **Built-in Prompt String/Built-in Finding String/Built-in Comment String**: Touch **Edit**, then edit or add built-in strings used in the report.
- **Report Display**: Touch **Edit**, and select the display unit of the **Calculation Package** in the report.

DICOM

Configure DICOM settings. For more information, see “DICOM Configuration” on page 66.

Networking

- Display the network connection status of the system in the **Information window**.
  - » **Current Status**: The IP address currently connected.
  - » **Detailed Status**: All the IP addresses and MAC addresses connected.
- Configure the system network.
  - » **WLAN Configurations**: See “Connecting the System to the Wireless Network” on page 65.
  - » **Ethernet Configurations**: See “Connecting the System to the Network by Ethernet” on page 65.

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.

Configuring Security Policies

After creating user accounts, the administrator needs to enable the data security feature in order to protect patient data.

Before security configuration, log in as the administrator. The ID/Name of the administrator are shown in the **Current User** section.

Security Policies

Applying Restriction Modes

Three restriction modes are available for selection.

- **No restriction**: All the system features are available to the guest users.
- **Only Patient data is locked**: All the system features except access to ePHI information are available to guest users.
- **Complete system is locked**: None of the system features are available to guest users.

Setting the Password Policy

Enhance the user login security by applying rules to setting the password, including restricting password length, uniqueness and complexity.

Setting the Account Lockout Policy

Determine the rules of locking a user account after invalid logon attempts.

Enabling Auto Log Off

Set an automated logout after a specified period of inactivity.

User Management

Modify personal credentials and change roles of the users.

1. Touch **User Management**.
2. In the **User List** section, to modify a user, touch  ; to delete a user, touch  .

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 which are available from technical support.

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

- Managing your system: Touch **System Management**. System information, software update and 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, serial number (default password for the first-time-logging-in) and this *User Manual* can be found here.

Reinstalling Software

This requires further assistance, contact technical support (See "Customer Service" on page 3). 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**.

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

Checking the Software Version

This may be required when contacting Technical Support.

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

Checking the System's Serial Number

The System Serial Number is the unique Philip's Customer Identifier. It may need to be edited with assistance from technical support when a replacement tablet is received and no backup is available to restore from.

Touch **System Management** > (**System Information**) > (**System Serial Number**) > **Edit**.

Checking the Tablet's Serial Number

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

Touch **System Management** > (**System Information**) > (**Tablet Serial Number**).

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**).

Resetting User 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 Configuration**) > **Reset**.

Backing Up System Settings and Patient Data

- Before backing up system settings and patient data, ensure that the system is connected to an external storage device.
- It is recommended that you perform regular backups on system settings and patient data to prevent data loss.

1. Touch **System Management**.
2. In the **System Configuration** section, 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_YYYYMMDD

Restoring System Settings and Patient Data

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.

1. Touch **System Management**.
2. In the **System Configuration** section, 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.

Resetting Your System

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.

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

Testing the System

The system provides diagnostic tools to examine all the functionality of the system components. However, these operations may require assistance from technical support (See “Customer Service” on page 3).

Touch **Test & Utilities** > (**System Test**) > (**Test mode**).

Exporting System Logs

Before exporting system logs, ensure that the system is connected to an external storage device.

After testing the system, the test results will be logged and available for review. You can view all task records concerning DICOM transmission from the System Logs window, or export the log file to an external storage device and send it to your service contact (See “Customer Service” on page 3).

Touch **System Logs** > **Export**.

Reading the User Manual

This *User Manual* is also available in an electronic format.

Touch **About** > (**User Manual**) > **Open File**.

9

Transducers

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.

Transducer Maintenance

Transducers 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 Philips representative, and discontinue use of the transducer.

For all information on transducer cleaning and disinfection, see “Chapter 10 Transducer Care” on page 111.

For all information about the use of acoustic coupling gels, see “Ultrasound Transmission Gels” on page 115.

If you encounter poor image quality or transducer problems, see “Troubleshooting” on page 123.

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 115 or “Chapter 10 Transducer Care” on page 111. You can also contact your local Philips representative. For contact information, see “Customer Service” on page 3.

Acoustic artifacts

The transducer adds its own signature to the echo information in the form of beam width effects, axial resolution limitations, and frequency characteristics. The control choices made by the sonographer that affect amplification, signal processing, and echo signal display can lead to significant differences in the displayed appearance of echo data. Following is a brief discussion of acoustic artifacts. An understanding of the physical basis for the production of signals displayed on ultrasound images is helpful in minimizing artifacts on images and interpreting the results of studies.

An artifact is an echo displayed in a different position than its corresponding reflector in the body. Artifacts can also be caused by intervening tissue properties. Artifacts can originate from external noise, reverberations, multi-path reflections, or misadjusted equipment. They can also come from the ultrasonic beam geometry and unusual changes in beam intensity. Artifacts and their manifestations are listed below, and following are some definitions of various artifacts.

- Added objects displayed as speckle, section thickness, reverberation, mirror image, comet tail, or ring down
- Missing objects due to poor resolution
- Incorrect object brightness due to shadowing or enhancement
- Incorrect object location due to refraction, multi-path reflections, side lobes, grating lobes,speed error, or range ambiguity
- Incorrect object size due to poor resolution, refraction, or speed error
- Incorrect object shape due to poor resolution, refraction, or speed error

Acoustic saturation occurs when received signals reach a system's high-amplitude limit. At that point the system becomes unable to distinguish or display signal intensities. At the point of saturation, increased input will not increase output.

Aliasing occurs when the detected Doppler frequency exceeds the Nyquist limit. It is characterized on the spectral display by the Doppler peaks going off the display, top or bottom, and then continuing on the other side of the baseline. On the Color display an immediate change in color from one Nyquist limit to the other is seen.

Comet tail is a form of reverberation artifact produced when two or more strong reflectors are close together and have a high propagation speed. In this case, sound does not travel directly to a reflector and back to the transducer; and a strong linear echo appears at the reflector and extends deeper than the reflector.

Enhancement is an increased relative amplitude of echoes caused by an intervening structure of low attenuation. Focal enhancement, also known as focal banding, is the increased intensity in the focal region that appears as a brightening of the echoes on the display.

Mirror imaging artifact is most commonly seen around the diaphragm; this artifact results from sound reflecting off another reflector and back.

Mirroring is the appearance of artifacts on a spectral display when there is improper separation of forward and reverse signal processing channels. Consequently, strong signals from one channel mirror into the other.

Multi-path positioning and **refraction artifacts** describe the situation in which the paths to and from a reflector are different. The longer the sound takes traveling to or from a reflector, the greater the axial error in reflector positioning (increased range). Refraction and multi-path positioning errors are normally relatively small and contribute to general degradation of the image rather than to gross errors in object location.

Propagation speed errors occur when the assumed value for propagation speed by the ultrasound system is incorrect. If the actual speed is greater than that assumed, the calculated distance to a reflector is too small, and the reflector will be displayed too far from the transducer. Speed error can cause a structure to be displayed with incorrect size and shape.

Range ambiguity can occur when reflections are received after the next pulse is transmitted. In ultrasound imaging, it is assumed that for each pulse produced, all reflections are received before the next pulse is sent out. The ultrasound system calculates the distance to a reflect or from the echo arrival time assuming that all echoes were generated by the last emitted pulse. The maximum depth to be imaged unambiguously by the system determines its maximum pulse repetition frequency.

Reverberation is the continuing reception of a particular signal because of reverberation rather than reflection from a particular acoustic interface. This phenomenon is analogous to the effect created by mirrors positioned on opposite walls when an object, a head for instance, is placed between the mirrors. The image of the head is reflected back and forth infinitely between the two mirrors, creating the optical illusion of multiple heads. Reverberations are easily identifiable, because they are equally spaced on the display.

Scattering is the diffuse, low-amplitude sound waves that occur when acoustic energy reflects off tissue interfaces smaller than a wavelength. In diagnostic ultrasound, Doppler signals come primarily from acoustic energy back-scattered from red blood cells.

Shadowing is the reduction in echo amplitude from reflectors that lie behind a strongly reflecting or attenuating structure. This phenomenon occurs when scanning a lesion or structure with an attenuation rate higher than that of the surrounding tissue. The lesion causes a decrease in beam intensity, which results in decreased echo signals from the structures beyond the lesion. Consequently, a dark cloud behind the lesion image forms on the display. This cloud, or shadow, is useful as a diagnostic clue.

Side lobes (from single-element transducers) and **grating lobes** (from array transducers) cause objects that are not directly in front of the transducer to be displayed incorrectly in lateral position.

Speckle appears as tissue texture close to the transducer but does not correspond to scatterers in tissue. It is produced by ultrasound wave interference and results in general image degradation.

Spectral broadening is a display phenomenon that occurs when the number of energy-bearing Fourier frequency components increases at any given point in time. As a consequence, the spectral display is broadened. Spectral broadening can indicate the disturbed flow caused by a lesion, and therefore it is important diagnostically. However, broadening can also result from interaction between flow and sample volume size, in which case it is an artifact.

Speed of sound artifacts occur if the sound propagation path to a reflector is partially through bone, and the speed of sound is greater than in the average soft tissue. Echo position registration artifacts will be produced. Reflectors appear closer to the transducer than their actual distance because of this greater speed of sound, resulting in a shorter echo transit time than for paths not containing bone.

Transducer Covers

To prevent contamination by blood-borne pathogens, sterile transducer covers are required for intraoperative procedures; in China, sterile covers are also required for transrectal and intravaginal procedures; the protective covers are mandatory in China and Japan. We recommend the use of qualified covers.

Latex and talc are commonly used in sheaths marketed to help with infection control in endocavity and intraoperative imaging applications. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in “FDA Medical Alert on Latex” on page 21.

- In intraoperative applications, sterilized transducers should be used with sterile gel and a sterile transducer cover.
- Sterile transducer covers are disposable and must not be reused.

- Inspect transducer covers before and after use.
- Do not apply the transducer cover until you are ready to perform the procedure.

If an installed transducer cover is cut or contaminated before use, the transducer should be cleaned and disinfected or sterilized, and a new sterile cover installed.

When using C9-4v endocavity transducers, the transducers must be protected with a transducer sheath.

If a sterile transducer cover becomes compromised during an intraoperative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Centers for Disease Control and this document from the World Health Organization: WHO/CDS/ APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.

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 127.

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.

Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

- Always store transducers in the transducer holders on your system cart 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.

Transducer Care

All Philips transducers require proper care, cleaning, and handling. This section contains information and instructions to help you effectively clean, disinfect, and sterilize the transducers that are compatible with your system. Additionally, these instructions help avoid damage during cleaning, disinfection, and sterilization, which could void your warranty.

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.

Transducer Care and Operator Safety

Observe the following warnings and cautions during all cleaning, disinfection, and sterilization procedures and when using disinfectants. More specific warnings and cautions are included within the care and cleaning procedures and on the labels of the cleaning or disinfection solutions.

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.

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 Methods” on page 113. Also, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.

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

Do not expose transducers to direct heat such as strong sunlight or local heat sources. Heat ages the crystal and causes loss of sensitivity.

- Transducers are highly-sensitive instruments and are easily damaged due to improper operations. Use the transducers with extra care and avoid damages when not in use.
- Perform regular testing and periodic maintenance including inspection of the transducer assembly for cracks that allow the ingress of conductive fluid.

Do not immerse the transducer into liquids beyond its binding line, and never immerse the transducer connector into any liquids.

- 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.

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

- 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.

Follow the recommendations of the disinfectant manufacturer.

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.

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

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.

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.

- 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.
- To keep fluids from entering the transducer, do not disconnect the cable from the transducer during cleaning and disinfection.

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

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.

- Using non-recommended disinfectants, using incorrect solution strengths, or immersing a transducer deeper or longer than recommended can damage or discolor the transducer and void the transducer warranty.
- Use only liquid solutions to sterilize transducers. Using autoclave, gas (EtO), or other methods not approved by Philips will damage your transducer and void your warranty.

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.

For information on ordering transducer supplies, contact CIVCO Medical Solutions (See "Supplies and Accessories" on page 3).

Latex Product Alert

Transducer covers may contain natural rubber latex. Those covers may cause allergic reactions in some individuals.

For information on allergic reactions to latex-containing medical devices, see “FDA Medical Alert on Latex” on page 21.

Inspecting the Transducer

Inspect the transducer’s acoustic lens, outer cover, 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 Philips for service or replacement if any abnormalities are found. For more information on transducer care, refer to the Philips “Transducer Care” website:

www.Philips.com/transducercare

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

Transducer Care Methods

Transducer care methods are based on the use of the transducer. For more information on transducer care, refer to the Philips “Transducer Care” website:

www.Philips.com/transducercare

Care Methods by Transducer Use

Transducer Use	Example	Classification	Care Method
Contact intact skin	Curved, linear, and sector transducers	Noncritical	Low-level disinfection
Contacts mucous membranes	Endocavity transducer	Semi-critical	High-level disinfection

The care method for your transducer determines the appropriate disinfectant for your transducer.

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 “Chapter 2 Safety Information” on page 9 and “Transducer Care and Operator Safety” on page 111. After cleaning, you must disinfect or sterilize transducers by following the appropriate procedures.

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

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. You may rinse thoroughly with water up to the immersion point shown in the figure following the procedure. The transducer may be immersed up to the immersion point. No other part of the transducer, cable, or connector can be soaked or immersed in fluids.

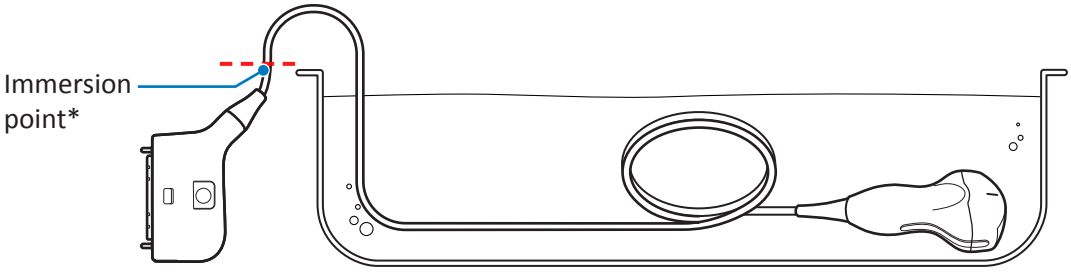


Figure 40 Immersion point for surface transducers (Example transducer-C6-2)

*Do not immerse beyond this point, 5 cm (2 in) from the strain relief; this is the maximum allowable immersion of the cable —you are not required to immerse to this point if it is unnecessary.

6. Wipe with a dry cloth if necessary. To dry the lens, use a soft cloth and a blotting motion instead of a wiping motion.
7. 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 Philips representative.

If you use cleaning wipes, it may be unnecessary to rinse the transducer with water. Always follow the product label recommendations.

Low-Level Disinfecting of Transducers

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

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.
5. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your Philips representative.

High-Level Disinfecting of Transducers

High-level disinfection of transducers typically uses an immersion method.

1. Clean the transducer and cable according to the procedures in “Transducer and Cable Cleaning” on page 113. Observe all warnings and cautions.
2. After cleaning, choose the high-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 115. 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. If a pre-mixed solution is used, be sure to observe the solution expiration date.
3. Using an appropriate disinfectant for the transducer cable, wipe or spray the cable, strain relief,and connector, following disinfectant label instructions for temperature, wipe durations, solution strengths, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector. When disinfecting the transducer cable, wipe or spray only the outer surfaces; do not allow any type of fluid to enter through the strain relief or electrical contacts.
4. Immerse the transducer into the appropriate disinfectant for your transducer as shown in the figure following the procedure. Follow the instructions on the disinfectant label for the duration of transducer immersion. Do not immerse transducers longer than the minimum time needed for your level of disinfection. The transducer may be immersed up to the immersion point shown in the figure following the procedure. No other part of the transducer or transducer cable can be soaked or immersed in fluids.
5. Using the instructions on the disinfectant label, rinse the transducer up to the point of immersion. Do not soak or immerse any other part of the transducer or cable.
6. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.
7. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your Philips representative.

Ultrasound Transmission Gels

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

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

Do not use hand sanitizing gels.

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

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

Some recommended gels include:

- Aquasonic 100
- Aquasonic Clear
- Carbogel-ULT
- ECG Gel (Nicom)
- Nemidon Gel
- Scan

Compatible Disinfectants and Cleaning Solutions

The following table lists the disinfectants and cleaning solutions compatible with the transducers available for the system.

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 or your service contract.

Disinfectants and Cleaning Solutions Table Legend

Country of Origin	Disinfectant Type	Compatibility
• AU = Australia • CA = Canada • DE = Germany • ES = Spain • FR = France • JP = Japan • UK = United Kingdom • US = United States	• CL = Cleaner • HLD = High-level disinfectant • ILD = Intermediate-level disinfectant • LLD = Low-level disinfectant • S = Sterilant	• C = Approved for use on the cable and connector (never immerse or soak a connector) • T = Approved for use on the transducer • N = Not approved for use

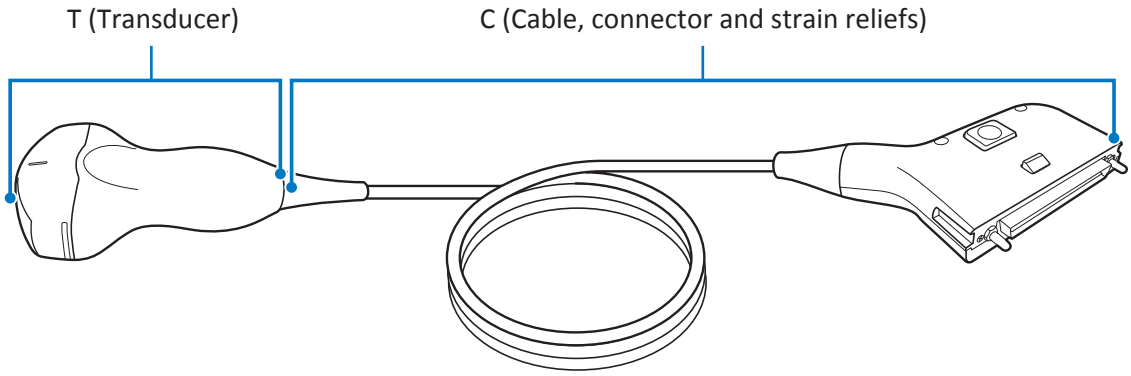


Figure 41 Transducer parts (Example transducer: C6-2)

Disinfectants and Cleaning Solutions Compatibility

Solution	Country of Origin	Qualified Use	Active Ingredient	Disinfectant Type	Compatibility
70% Isopropyl Alcohol	All	Spray/Wipe	Alcohol	LLD, ILD	T
AbcoCide	US	Soak[a]	Glutaraldehyde	HLD, S	T
AbcoCide 28	US	Soak[a]	Glutaraldehyde	HLD, S	T
Accel Wipes (all types)	CA	Wipe	Hydrogen Peroxide	LLD, ILD	T
Acecide	JP	Soak[a]	Peracetic Acid	HLD, S	N
Aidal Plus	AU	Soak[a]	Glutaraldehyde	HLD, S	T
Alkaspray	FR	Spray/Wipe	Alcohol, Alkylamine	LLD, ILD	T
Ampholysine Basique	FR	Spray/Wipe	Biguanide/QUAT	LLD, ILD	T
Aniosept Activ	FR	Soak[a]	Peracetic Acid	HLD, S	T
ANIOXY DM	FR	Soak[a]	Peracetic Acid	HLD, S	T
Anioxyde 1000	FR	Soak[a]	Peracetic Acid	HLD	T
Antigermix E1	FR	E1 System	UV-C	HLD	N
Antigermix S1	FR	S1 System	UV-C	HLD	T
Banicide Plus	US	Soak[a]	Glutaraldehyde	HLD, S	T
Bleach (0.6% NaOCl Max)	All	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T
CaviWipes	US	Wipe	Alcohol, QUAT	LLD, ILD	T
Cidex	US	Soak[a]	Glutaraldehyde	HLD, S	T
Cidex 7	US	Soak[a]	Glutaraldehyde	HLD, S	T
Cidex OPA	US	Soak[a]	Ortho-phthalaldehyde	HLD	T

Solution	Country of Origin	Qualified Use	Active Ingredient	Disinfectant Type	Compatibility
Cidex PAE 14J	FR	Soak[a]	Glutaraldehyde	HLD, S	T
Cidex Plus	US	Soak[a]	Glutaraldehyde	HLD, S	T
Cleanisept Wipes	DE	Spray/Wipe	QUAT	LLD, ILD	T
Clorox Healthcare Bleach Germicidal Cleaner	US	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T
Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectants	US	Spray/Wipe	Hydrogen Peroxide	LLD, ILD	T
Combi-Instruments-N	FR	Soak[a]	Glutaraldehyde-formacetale blend	HLD	T
Descoton Extra	DE	Soak[a]	Glutaraldehyde	HLD, S	T
Dispatch	US	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T
Endosporine	FR	Soak[a]	Glutaraldehyde	HLD, S	T
Enzol	US	Pre-cleaner	Enzymes	Cleaner	T
Epizyme Rapid	AU	Pre-Cleaner	Enzymes	Cleaner	T
Gigasept FF (neu)	DE	Soak[a]	Succinic dialdehyde	HLD	T
Gigasept PA	DE	Soak[a]	Peracetic Acid	HLD	N
Gigasept PAA Concentrate	DE	Soak[a]	Peracetic Acid	HLD	N
Incidin	DE	Spray/Wipe	Alcohol	LLD, ILD	T
Incidur Spray	DE	Spray/Wipe	Alcohol, QUAT, Aldehyde	LLD, ILD	T
Instruzyme	FR	Pre-cleaner	Enzymes, QUAT, Biguanide	Cleaner	T
Klenzyme	US	Pre-cleaner	Enzymes	Cleaner	T
Korsolex Basic	FR	Soak[a]	Aldehyde Releasing	HLD	T
Korsolex Extra	FR	Soak[a]	Aldehydes/QUAT	HLD	T
Korsolex PAE	FR	Soak[a]	Glutaraldehyde	HLD, S	T
MaxiCide Plus	US	Soak[a]	Glutaraldehyde	HLD, S	T
MedDis	UK	Soak[a]	QUAT, Sulfamic Acid	HLD	T
Medistel	UK	Soak[a]	QUAT, Sulfamic Acid	HLD	T
Medizyme	AU	Soak[a]	Enzymes	Cleaner	T
MetriCide	US	Soak[a]	Glutaraldehyde	HLD, S	T
MetriCide 28	US	Soak[a]	Glutaraldehyde	HLD, S	T
MetriCide OPA Plus	US	Soak[a]	Ortho-phthalaldehyde	HLD	T
MetriCide Plus 30	US	Soak[a]	Glutaraldehyde	HLD, S	T
MetriZyme	US	Pre-cleaner	Enzymes	Cleaner	T
mikrozid PAA wipes	DE	Wipe	Peracetic Acid	LLD, ILD	T
Mild Soap Solution	All	Pre-cleaner	Surfactants/Soap	Cleaner	T
Milton	AU	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T
NDP Med Concentrated Plus	ES	Soak[a]	N-Duopropenide, Alkylamine	HLD	T
neodisher endo CLEAN/ neodisher endo SEPT PAC	DE	AER	Cleaner/Peracetic Acid	HLD	N

Solution	Country of Origin	Qualified Use	Active Ingredient	Disinfectant Type	Compatibility
neodisher endo DIS active	DE	Soak[a]	Peracetic Acid	HLD	T
Olympic Peracetic Acid	UK	AER	Peracetic Acid	HLD	N
Omnicide 14NS	US	Soak[a]	Glutaraldehyde	HLD, S	T
Omnicide 28	US	Soak[a]	Glutaraldehyde	HLD, S	T
OPAL	AU	Soak[a]	Ortho-phthalaldehyde	HLD	T
Opticide3	US	Spray/Wipe	Alcohol, QUAT	LLD, ILD	T
Oxivir (all types)	US	Wipe	Hydrogen Peroxide	LLD, ILD	T
Oxygenon-I	FR	Soak[a]	Oxygen Generating	HLD	T
PeraSafe	UK	Soak[a]	Peracetic Acid	HLD, S	T
Perascope	UK	Soak[a]	Peracetic Acid	HLD	T
Perastel	UK	AER/Soak[a]	Peracetic Acid	HLD	T
PerCept (all types)	CA	Wipe	Hydrogen Peroxide	LLD, ILD	T
Phagocide D	FR	Soak[a]	Glutaraldehyde	HLD, S	T
Phagozyme ND	FR	Pre-cleaner	Enzymes, QUAT	Cleaner	T
PI-Spray (Formerly T-Spray)	US	Spray/Wipe	QUAT	LLD, ILD	T
PI-Spray II (Formerly T-Spray II)	US	Spray/Wipe	QUAT	LLD, ILD	T
ProCide-D	US	Soak[a]	Glutaraldehyde	HLD, S	T
ProCide-D Plus	US	Soak[a]	Glutaraldehyde	HLD, S	T
Prolystica 2X	US	Pre-cleaner	Enzymes	Cleaner	T
Protex Disinfectant (All Types)	US	Spray/Wipe	QUAT	LLD, ILD	T
Quaternary Ammonium (0.8%Active Max)	All	Spray/Wipe	QUAT	LLD, ILD	T
Rapicide	US	Soak[a]	Glutaraldehyde	HLD, S	T
Rapicide OPA	US	Soak[a]	Ortho-phthalaldehyde	HLD	T
Rapicide PA	US	Soak[a]	Peracetic Acid	HLD	T
Revital-Ox Resert XL HLD	US	Soak[a]	Hydrogen Peroxide	HLD	T
Rivascop	FR	Spray/Wipe	QUAT	LLD, ILD	T
Salvanios pH 10	FR	Spray/Wipe	QUAT	LLD, ILD	T
Sani-Cloth Active	DE	Wipe	QUAT	LLD, ILD	T
Sani-Cloth AF	US	Wipe	QUAT	LLD, ILD	T
Sani-Cloth AF3	US	Wipe	QUAT	LLD, ILD	T
Sani-Cloth Bleach	US	Wipe	Sodium Hypochlorite	LLD, ILD	T
Sani-Cloth HB	US	Wipe	QUAT	LLD, ILD	T
Sanicloth Plus	US	Wipe	Alcohol, QUAT	LLD, ILD	T
Sekucid N	FR	Soak[a]	Glutaraldehyde	HLD, S	T
Sekusept Aktiv	DE	Soak[a]	Peracetic Acid	HLD	T
Sekusept Easy	DE	Soak[a]	Peracetic Acid	HLD	T
Sekusept Plus	DE	Soak[a]	Glucoprotamine	HLD	T
Soluscope P	FR	AER	Peracetic Acid	HLD	N
Steranios 2%	FR	Soak[a]	Glutaraldehyde	HLD, S	T

Solution	Country of Origin	Qualified Use	Active Ingredient	Disinfectant Type	Compatibility
Sterrad 100S	US	Reprocessor (S)	Hydrogen Peroxide	S	N
TD-5	US	TD-100 Reprocessor	Glutaraldehyde	HLD, S	N
Tristel Duo	UK	Foam/Wipe	Chlorine Dioxide	HLD	T
Tristel Fuse for Instruments	UK	Stella System	Chlorine Dioxide	HLD	T
Tristel Multi-Shot	UK	Soak[a]	Chlorine Dioxide	HLD	T
Tristel Sporicidal Wipes	UK	Wipe	Chlorine Dioxide	HLD	T
Tristel Trio Trace	UK	Pre-clean wipe, sporicidal wipe, rinse wipe	Enzymes Chlorine Dioxide	HLD	T
Trophon EPR	AU	Trophopn EPR Reprocessor	Hydrogen Peroxide	HLD	T
Vaposeptol	FR	Spray/Wipe	Alcohol, Biguanide	LLD, ILD	T
Virox 5 RTU	CA	Wipe	Hydrogen Peroxide	LLD, ILD	T
Wavicide -01	US	Soak[a]	Glutaraldehyde	HLD, S	T
Wip'Anios	FR	Wipe	Alcohol, QUAT	LLD, ILD	T

[a]Never immerse or soak a connector.

System Maintenance

Maintenance should be performed regularly and as needed.

Cleaning the System

The system and peripherals are medical electrical equipments and require thorough cleaning. If exposed to constant and excessive environmental dust and humidity, both performance and reliability of these devices will be suffered. 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 “Chapter 10 Transducer Care”.

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.

Cleaning the System/System Cart Surfaces

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/cart surfaces 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.

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, cart or any cable, apply a small amount of specific cleaning solutions or disinfectants (See page 122) 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 products in the following table are compatible with the external plastic and painted surfaces of system and cart.

Cleaning solutions for all surfaces	Cleaning solutions for monitor screens	Disinfectants for system surfaces, including the touch screen	Disinfectants for cart surfaces
Mild soap solution	• Mild soap solution • Cleaners designed for touch screens • Purified water	• 70% isopropyl alcohol (IPA) • 75% ethanol alcohol	• 70% isopropyl alcohol (IPA) • 75% ethanol alcohol

Table 7 Disinfectants and cleaning solutions for system/system cart surfaces

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 "Chapter 10 Transducer Care" section 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.

- Do not use abrasive cleaners, or acetone, MEK, paint thinner, 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 Philips 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.

Cleaning the Power Adapter

- 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.

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 “Customer Service” on page 3).

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 41)
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 **Menu** > **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. » Use the diagnostic tools to test the functionality of the microSD (See “Testing the System” on page 104). This requires assistance from technical support. • **The microSD card slot is damaged.** » Insert another microSD card into the system for inspection.

Symptom	Possible cause and corrective action
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 50) 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. » Use the diagnostic tools to test the functionality of the ultrasound engine and the transducer (See "Testing the System" on page 104). This requires assistance from technical support.
Software installation failed	Check if the USB flash drives or the system's USB ports are damaged.
The system is overheating	• **The system's fans are not functioning.** » Use the diagnostic tools to test the functionality of the fan and the temperature (See "Testing the System" on page 104). This requires assistance from 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 Power button does not function	**The system power reaches a critically low state and is not connected to power.** » Connect the system to power. » If the power button
The system encounters unexpected shutdowns several times	**A system disk error occurred.** » Reinstall the software (See "Reinstalling Software" on page 103). 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. » Use the diagnostic tools to test the functionality of the touch screen (See "Testing the System" on page 104). This requires assistance from technical support.

Symptom	Possible cause and corrective action
No audio or noise comes from the system speakers.	• **The system is muted.** Open the system tool 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 **Menu** > **DICOM** > **Storage SCP** and touch **Edit** > **Test** for verification.
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 system tool 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.

Appendix

Appendix A: Specifications

Specifications are subject to change without prior notice.

System

Item		Specifications
Form factor		Tablet
Weight		5.42 lb (2.46 kg): With the rotating stand and 4 locator pins
Dimensions	Length	12.58" (319.6 mm)
	Width	8.79" (223.2 mm)
	Height (Thickness)	1.25" (31.8 mm): Without the rotating stand 2.07" (52.6 mm): With the rotating stand; Without 4 locator pins 2.45" (62.3 mm): With the rotating stand and 4 locator pins
Materials		Plastic, metal, rubber
Color		White
Speaker		2 built-in speakers
Console		Touch screen
Primary monitor		11.6" 1366x768
Number of transducer connectors		1 transducer
Stand		1 stand
Wall mount		Standard VESA M4 screw when removing 4 locator pins Holes: 75mm x 75mm/100mm x 100mm
Water resistant level		IP22
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

Item	Specifications
Accessories	• Power adapter Input: AC 100 ~ 240V, 50 ~ 60Hz, Max 1.7A Output: +19Vdc, 3.4A • Transducer S4-2, L12-4, C6-2, C9-4v • System cart Support Tilt and Swivel Joints, Height Adjustment, Instant dock and undock function.
Storage/transport	Temperature: -20 ~ 60°C Humidity 20% ~ 95% RH Air pressure 700 ~ 1060hPa
Environmental operating conditions	Temperature: 10 ~ 40°C Humidity: 20% ~ 85% RH, no condensation Air pressure: 700 ~ 1060 hPa
Product life	5 years

Battery

Model: QIC3000

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

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
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

Item	Rate performance	Remark
Storage temperature and humidity range	-20 ~ 35°C	Within 1 year, 45% to 85% RH
	-20 ~ 40°C	Within 6 months, 45% to 85% RH
	-20 ~ 45°C	Within 1 month, 45% to 85% RH
	-20 ~ 50°C	Within 1 week, 45% to 85% RH
Power consumption		
Normal mode	≦ 620 µA	
Sleep mode	≦ 120 µA	
Shutdown mode	≦ 5.42 µA	

Transducer

Transducer	Elements	Descriptions	Applications
S4-2	64	Phased array transducer with a maximum depth of 200 mm and a user-controllable field-of-view	• Adult abdominal • OB/GYN • Cardiac • Abdominal vascular • Fetal heart • Renal
C6-2	128	Curved array transducer with a maximum depth of 200 mm and a user-controllable field-of-view	• Adult abdominal • OB/GYN • Fetal heart • Abdominal vascular • Renal
L12-4	128	Linear array transducer with a maximum depth of 150 mm and a user-controllable field-of-view	• Dialysis access • Small parts • Musculoskeletal • Peripheral vascular • Medium depth arterial and venous studies • Breast
C9-4v	128	Curved linear array transducer with a maximum depth of 200 mm and a user-controllable field-of-view	• OB/GYN • Fetal birth defects • Placenta previa • Cysts and fibroids • Ectopic pregnancy • Pelvic pain • Infertility

Power Adapter

Item	Specifications
Brand	PowerBox
Model	EXM 80 5120-01
Input	Universal AC 100 ~ 240V, 50 ~ 60Hz, Max 1.7A
Output	+19VDC, 3.4A
Case Dimension	118 (L) x 70 (W) x 45 (H) mm without AC plugs

Item	Specifications
Water resistant level	IP21
Efficiency	Eff (av) ≥ 87%
Safety	Approved according to IEC 60601-1 Edition 3
EMC	IEC 60601-1-2, IEC 61204-3, EN 55011 Class B
Protection	OVP (Over Voltage Protection), SCP (Short Circuit Protection), OCP (Over Current Protection)
Features	• Highest output power on the market of wall plug adapters • Exchangeable AC-plugs for universal use • Suitable to power up medical systems up to BF class

Appendix B: Connectivity and Security

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.

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

Specifications

Hardware

802.11 a/b/g/n, Gigabit Ethernet

Software

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

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

Security

The system has no listening ports open to the WLAN interface. So a network entity cannot initiate a connection to the system from the WLAN. However, the system can initiate a connection to servers on the WLAN, 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 WLAN and Gigabit Ethernet.

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

Information Flow

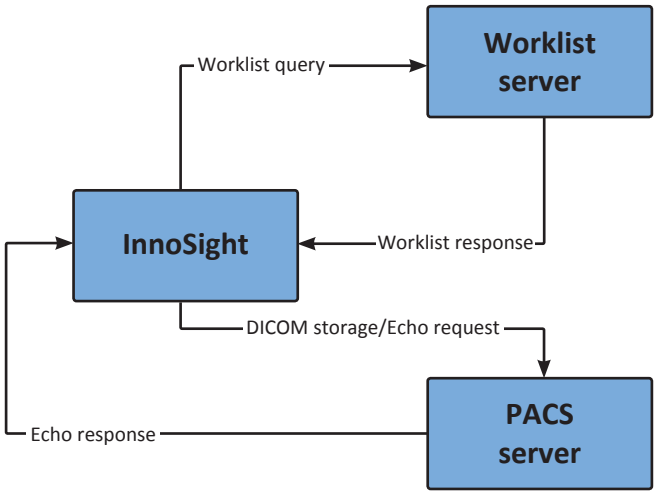


Figure 43 Information flow

Read the system's DICOM Conformance Statement for detailed instructions. DICOM conformance statements for Philips products are available at this website:

www.healthcare.philips.com/main/about/connectivity/dicom_conformance_main.wpd

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 (InnoSight) 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.

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 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.

Table 8 IT network failure recovery measures

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

Appendix C: System Acoustic Output Default Tables

C6-2 Transducer

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Abdominal	Abdomen	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
Fetal	OB	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Urology	Renal	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
	Urology	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
GYN	GYN	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

L12-4 Transducer

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Cardiac Vascular	Carotid	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
	Arterial	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
	Venous	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Small Organ (breast, thyroid)	Thyroid	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
	Breast	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
Abdominal	Bowel	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
Muscle	MSK	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Nerve	Nerve	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

S4-2 Transducer

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Cardiac	Cardiac	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

C9-4v Transducer

Exam Type	Preset	Mode	TI Label	Default TI	Default MI
Trans-vaginal Cardiac	OB	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
	GYN	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			
Trans-rectal	Prostate	2D			
		Color			
		CPA			
		M			
		PW			
		THI+Color			
		THI+CPA			
		THI+M			
		2D+Color+PW (Triplex)			
		2D+CPA+PW (Triplex)			

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 Philips.

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_{-6}: *Pulse beam width* is the distance between two points, on a specified surface in a specified direction, passing through the point of maximum pulse-pressure-squared integral (p_i) in that surface, at which the *pulse-pressure-squared integral* is a specified fraction of the maximum value in that surface.

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_{pi}: *Pulse-intensity integral* is the time integral of the instantaneous intensity at a particular point in an acoustic field integrated over the acoustic pulse waveform.

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

$I_{sppa,\alpha}$: *Attenuated spatial-peak pulse-average intensity*

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

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

$I_{ta}(z)$: *Temporal-average intensity* is the time-average of the instantaneous intensity at a particular point in an acoustic field.

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

$I_{zpta}(z)$: *Spatial-peak temporal-average intensity* is the maximum value of the *temporal-average intensity* in a specified plane at a specified distance z from the transducer.

$I_{zpta,\alpha}(z)$: *Attenuated spatial-peak temporal-average intensity* is the value of the *spatial-peak temporal-average intensity* after attenuation, at a specified distance z, and given by $I_{zpta,\alpha}(z) = I_{zpta}(z)10^{(-\alpha z f_{awf}/10)}$.

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*.

X, Y: *-12 dB output beam dimensions* are dimensions of the ultrasonic beam *(-12dB pulse beam width)* in specified directions normal to the *beam alignment axis* and at the transducer output face.

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*.

Acoustic Output Tables for InnoSight Transducers

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in 2D Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.119	0.085	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.21					
	W_0	(mW)		20.1	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	5.4					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	3.08	3.08	#	#	#	#
	Dim of A_{aprt}	X (cm)		2.75	#	#	#	#
		Y (cm)		1.3	#	#	#	#
Other information	PD	(microsec)	0.4					
	PRF	(Hz)	5900					
	$p_r@PII_{max}$	(MPa)	0.36					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		8	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	2.11					
Operating control conditions	Control 1		2D	2D	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		5882	5882	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in THI Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.145	0.168	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.248					
	W_0	(mW)		53	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	5					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.95	2.95	#	#	#	#
	Dim of A_{aprt}	X (cm)		2.75	#	#	#	#
		Y (cm)		1.3	#	#	#	#
Other information	PD	(microsec)	0.81					
	PRF	(Hz)	5900					
	$p_r@PII_{max}$	(MPa)	0.39					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		8	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	3.2					
Operating control conditions	Control 1		THI	THI	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		5882	5882	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in 2D+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.171	0.183	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.27					
	W_0	(mW)		70	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.7					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.49	2.49	#	#	#	#
	Dim of A_{aprt}	X (cm)		2.25	#	#	#	#
		Y (cm)		1.3	#	#	#	#
Other information	PD	(microsec)	1.42					
	PRF	(Hz)	5000					
	$p_r@PII_{max}$	(MPa)	0.38					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		8	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4.1					
Operating control conditions	Control 1		Color	2D+ Color	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		5000	5000	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in THI+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.172	0.166	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.272					
	W_0	(mW)		95	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.7					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.49	2.49	#	#	#	#
	Dim of A_{aprt}	X (cm)		2.25	#	#	#	#
		Y (cm)		1.3	#	#	#	#
Other information	PD	(microsec)	1.42					
	PRF	(Hz)	5000					
	$p_r@PII_{max}$	(MPa)	0.4					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		8	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4.4					
Operating control conditions	Control 1		Color	THI+ Color	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		5000	5000	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in 2D+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.147	#	#	0.0064	0.034	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.255					
	W_0	(mW)		#	#		20.5	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.45		
	z_1	(cm)				5.6		
	z_{bp}	(cm)				2.89		
	z_{sp}	(cm)					5.5	
	$z@PII_{.3max}$	(cm)	5.6					
	$d_{eq}(z_{sp})$	(cm)					4.3	
	f_c	(MHz)	3.01	#	#	3.01	3.01	#
	Dim of A_{aprt}	X (cm)		#	#	2.25	2.25	#
		Y (cm)		#	#	1.3	1.3	#
Other information	PD	(microsec)	0.41					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.46					
	$d_{eq}@PII_{max}$	(cm)					4.2	
	Focal length	FLx (cm)		#	#	6		#
		FLy (cm)		#	#	8		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	3.2					
Operating control conditions	Control 1		M-Mode	#	#	M-Mode	M-Mode	#
	Control 2		6	#	#	6	6	#
	Control 3		250	#	#	250	250	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in THI+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.145	#	#	0.0064	0.055	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.252					
	W_0	(mW)		#	#		54	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.45		
	z_1	(cm)				5.7		
	z_{bp}	(cm)				2.89		
	z_{sp}	(cm)					5.5	
	$z@PII_{.3max}$	(cm)	5.7					
	$d_{eq}(z_{sp})$	(cm)					6.9	
	f_c	(MHz)	3.01	#	#	3.01	3.01	#
	Dim of A_{aprt}	X (cm)		#	#	2.25	2.25	#
		Y (cm)		#	#	1.3	1.3	#
Other information	PD	(microsec)	0.41					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.45					
	$d_{eq}@PII_{max}$	(cm)					6.8	
	Focal length	FLx (cm)		#	#	6		#
		FLy (cm)		#	#	8		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	2.92					
Operating control conditions	Control 1		THI+M-Mode	#	#	THI+M-Mode	THI+M-Mode	#
	Control 2		6	#	#	6	6	#
	Control 3		250	#	#	250	250	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C6-2 Transducer

InnoSight Diagnostic Ultrasound System in PW Doppler Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.206	#	#	0.132	0.33	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.33					
	W_0	(mW)		#	#		52	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				11.1		
	z_1	(cm)				4.5		
	z_{bp}	(cm)				3.05		
	z_{sp}	(cm)					4.3	
	$z@PII_{.3max}$	(cm)	4.5					
	$d_{eq}(z_{sp})$	(cm)					1.67	
	f_c	(MHz)	2.5	#	#	2.5	2.5	#
	Dim of A_{aprt}	X (cm)		#	#	2.5	2.5	#
		Y (cm)		#	#	1.3	1.3	#
Other information	PD	(microsec)	1.08					
	PRF	(Hz)	1300					
	$p_r@PII_{max}$	(MPa)	0.45					
	$d_{eq}@PII_{max}$	(cm)					1.63	
	Focal length	FLx (cm)		#	#	5		#
		FLy (cm)		#	#	8		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	5.9					
Operating control conditions	Control 1		PW	#	#	PW	PW	#
	Control 2		5	#	#	5	5	#
	Control 3		1300	#	#	1300	1300	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in 2D Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.117	0.05	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.299					
	W_0	(mW)		8.5	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	1.49					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.6	6.6	#	#	#	#
	Dim of A_{aprt}	X (cm)		0.6	#	#	#	#
		Y (cm)		0.4	#	#	#	#
Other information	PD	(microsec)	0.194					
	PRF	(Hz)	13700					
	$p_r@PII_{max}$	(MPa)	0.4					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		2	#	#		#
		FLy (cm)		1.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4.6					
Operating control conditions	Control 1		2D	2D	#	#	#	#
	Control 2		2	2	#	#	#	#
	Control 3		13661	13661	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in THI Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.121	0.135	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.33					
	W_0	(mW)		6	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	1.46					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	7.3	7.3	#	#	#	#
	Dim of A_{aprt}	X (cm)		0.6	#	#	#	#
		Y (cm)		0.4	#	#	#	#
Other information	PD	(microsec)	0.34					
	PRF	(Hz)	13700					
	$p_r@PII_{max}$	(MPa)	0.46					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		2	#	#		#
		FLy (cm)		1.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	7.2					
Operating control conditions	Control 1		THI	THI	#	#	#	#
	Control 2		2	2	#	#	#	#
	Control 3		13661	13661	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in 2D+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.103	0.225	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.231					
	W_0	(mW)		39	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2.1					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	5	5	#	#	#	#
	Dim of A_{aprt}	X (cm)		3.8	#	#	#	#
		Y (cm)		0.4	#	#	#	#
Other information	PD	(microsec)	0.79					
	PRF	(Hz)	3000					
	$p_r@PII_{max}$	(MPa)	0.33					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		2	#	#		#
		FLy (cm)		1.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	5.3					
Operating control conditions	Control 1		Color	2D+Color	#	#	#	#
	Control 2		2	2	#	#	#	#
	Control 3		3000	3000	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in THI+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \le 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.101	0.241	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.226					
	W_0	(mW)		39	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2.1					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	5	5	#	#	#	#
	Dim of A_{aprt}	X (cm)		3.8	#	#	#	#
		Y (cm)		0.4	#	#	#	#
Other information	PD	(microsec)	0.79					
	PRF	(Hz)	2500					
	$p_r@PII_{max}$	(MPa)	0.33					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		2	#	#		#
		FLy (cm)		1.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	5.4					
Operating control conditions	Control 1		Color	THI+Color	#	#	#	#
	Control 2		2	2	#	#	#	#
	Control 3		2500	2500	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in 2D+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.166	#	0.126	#	0.0251	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.42					
	W_0	(mW)		#	4.1		4.1	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					1.36	
	$z@PII_{.3max}$	(cm)	1.44					
	$d_{eq}(z_{sp})$	(cm)					1.96	
	f_c	(MHz)	6.5	#	6.5	#	6.5	#
	Dim of A_{aprt}	X (cm)		#	0.71	#	0.71	#
		Y (cm)		#	0.4	#	0.4	#
Other information	PD	(microsec)	0.2					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.58					
	$d_{eq}@PII_{max}$	(cm)					1.96	
	Focal length	FLx (cm)		#	2	#		#
		FLy (cm)		#	1.9	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	10.4					
Operating control conditions	Control 1		M-Mode	#	M-Mode	#	M-Mode	#
	Control 2		2	#	2	#	2	#
	Control 3		250	#	250	#	250	#
	Control 4		100	#	100	#	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in THI+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \le 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.156	#	0.231	#	0.0312	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.4					
	W_0	(mW)		#	7.5		7.5	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					1.4	
	$z@PII_{.3max}$	(cm)	1.46					
	$d_{eq}(z_{sp})$	(cm)					2.84	
	f_c	(MHz)	6.5	#	6.5	#	6.5	#
	Dim of A_{aprt}	X (cm)		#	0.71	#	0.71	#
		Y (cm)		#	0.4	#	0.4	#
Other information	PD	(microsec)	0.199					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.53					
	$d_{eq}@PII_{max}$	(cm)					2.84	
	Focal length	FLx (cm)		#	2	#		#
		FLy (cm)		#	1.9	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	9.6					
Operating control conditions	Control 1		M-Mode	#	M-Mode	#	M-Mode	#
	Control 2		2	#	2	#	2	#
	Control 3		250	#	250	#	250	#
	Control 4		100	#	100	#	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the L12-4 Transducer

InnoSight Diagnostic Ultrasound System in PW Doppler Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.17	#	0.4	#	0.36	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.38					
	W_0	(mW)		#	16.7		16.7	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					1.28	
	$z@PII_{.3max}$	(cm)	1.33					
	$d_{eq}(z_{sp})$	(cm)					0.65	
	f_c	(MHz)	5	#	5	#	5	#
	Dim of A_{aprt}	X (cm)		#	0.41	#	0.41	#
		Y (cm)		#	0.4	#	0.4	#
Other information	PD	(microsec)	0.59					
	PRF	(Hz)	5000					
	$p_r@PII_{max}$	(MPa)	0.45					
	$d_{eq}@PII_{max}$	(cm)					0.65	
	Focal length	FLx (cm)		#	2	#		#
		FLy (cm)		#	1.9	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	7.9					
Operating control conditions	Control 1		PW Doppler	#	PW Doppler	#	PW Doppler	#
	Control 2		2	#	2	#	2	#
	Control 3		5000	#	5000	#	5000	#
	Control 4		100	#	100	#	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in 2D Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.277	0.33	#	#	#	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.43					
	W_0	(mW)		155	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.6					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.37	2.37	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.63	#	#	#	#
		Y (cm)		1.2	#	#	#	#
Other information	PD	(microsec)	0.53					
	PRF	(Hz)	7600					
	$p_r@PII_{max}$	(MPa)	0.61					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		5.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	8.7					
Operating control conditions	Control 1		2D	2D	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		7633	7633	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in THI Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.267	2.16	#	#	#	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.44					
	W_0	(mW)		269	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.5					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.71	2.71	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.63	#	#	#	#
		Y (cm)		1.2	#	#	#	#
Other information	PD	(microsec)	0.91					
	PRF	(Hz)	6300					
	$p_r@PII_{max}$	(MPa)	0.66					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		5.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	9.3					
Operating control conditions	Control 1		THI	THI	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		6349	6349	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in 2D+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.309	5.3	#	#	#	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.48					
	W_0	(mW)		840	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.2					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.44	2.44	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.63	#	#	#	#
		Y (cm)		1.2	#	#	#	#
Other information	PD	(microsec)	1.61					
	PRF	(Hz)	5000					
	$p_r@PII_{max}$	(MPa)	0.69					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		5.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	16.3					
Operating control conditions	Control 1		Color	Color	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		5000	5000	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in THI+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.33	4.6	#	#	#	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.52					
	W_0	(mW)		630	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	3.7					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.46	2.46	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.63	#	#	#	#
		Y (cm)		1.2	#	#	#	#
Other information	PD	(microsec)	1.53					
	PRF	(Hz)	6000					
	$p_r@PII_{max}$	(MPa)	0.7					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		5.9	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	18.4					
Operating control conditions	Control 1		Color	THI+Color	#	#	#	#
	Control 2		5	5	#	#	#	#
	Control 3		6000	6000	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in 2D+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.185	#	#	0.0084	0.065	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.29					
	W_0	(mW)		#	#		34	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.72		
	z_1	(cm)				5		
	z_{bp}	(cm)				2.36		
	z_{sp}	(cm)					4.8	
	$z@PII_{.3max}$	(cm)	5					
	$d_{eq}(z_{sp})$	(cm)					5	
	f_c	(MHz)	2.46	#	#	2.46	2.46	#
	Dim of A_{aprt}	X (cm)		#	#	1.63	1.63	#
		Y (cm)		#	#	1.2	1.2	#
Other information	PD	(microsec)	0.52					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.43					
	$d_{eq}@PII_{max}$	(cm)					5	
	Focal length	FLx (cm)		#	#	5		#
		FLy (cm)		#	#	5.9		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4.1					
Operating control conditions	Control 1		M-Mode	#	#	M-Mode	M-Mode	#
	Control 2		5	#	#	5	5	#
	Control 3		250	#	#	250	250	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in THI+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.173	#	#	0.0059	0.058	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.268					
	W_0	(mW)		#	#		37	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.51		
	z_1	(cm)				4.8		
	z_{bp}	(cm)				2.36		
	z_{sp}	(cm)					4.7	
	$z@PII_{.3max}$	(cm)	4.8					
	$d_{eq}(z_{sp})$	(cm)					6.4	
	f_c	(MHz)	2.41	#	#	2.41	2.41	#
	Dim of A_{aprt}	X (cm)		#	#	1.63	1.63	#
		Y (cm)		#	#	1.2	1.2	#
Other information	PD	(microsec)	0.53					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.38					
	$d_{eq}@PII_{max}$	(cm)					6.3	
	Focal length	FLx (cm)		#	#	5		#
		FLy (cm)		#	#	5.9		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	3.3					
Operating control conditions	Control 1		M-Mode	#	#	M-Mode	M-Mode	#
	Control 2		5	#	#	5	5	#
	Control 3		250	#	#	250	250	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in PW Doppler Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.187	#	#	0.135	0.26	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.292					
	W_0	(mW)		#	#		33	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				11.6		
	z_1	(cm)				4.9		
	z_{bp}	(cm)				2.36		
	z_{sp}	(cm)					4.8	
	$z@PII_{.3max}$	(cm)	4.9					
	$d_{eq}(z_{sp})$	(cm)					1.26	
	f_c	(MHz)	2.44	#	#	2.44	2.44	#
	Dim of A_{aprt}	X (cm)		#	#	1.63	1.63	#
		Y (cm)		#	#	1.2	1.2	#
Other information	PD	(microsec)	0.52					
	PRF	(Hz)	4000					
	$p_r@PII_{max}$	(MPa)	0.43					
	$d_{eq}@PII_{max}$	(cm)					1.24	
	Focal length	FLx (cm)		#	#	5		#
		FLy (cm)		#	#	5.9		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4					
Operating control conditions	Control 1		PW Doppler	#	#	PW Doppler	PW Doppler	#
	Control 2		5	#	#	5	5	#
	Control 3		4000	#	#	4000	4000	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the S4-2 Transducer

InnoSight Diagnostic Ultrasound System in CW Doppler Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.307	#	#	0.316	0.93	#
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.46					
	W_0	(mW)		#	#		147	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				30.1		
	z_1	(cm)				4.8		
	z_{bp}	(cm)				2.36		
	z_{sp}	(cm)					4.7	
	$z@PII_{.3max}$	(cm)	4.8					
	$d_{eq}(z_{sp})$	(cm)					1.73	
	f_c	(MHz)	2.2	#	#	2.2	2.2	#
	Dim of A_{aprt}	X (cm)		#	#	1.63	1.63	#
		Y (cm)		#	#	1.2	1.2	#
Other information	PD	(microsec)	0.58					
	PRF	(Hz)	4000					
	$p_r@PII_{max}$	(MPa)	0.65					
	$d_{eq}@PII_{max}$	(cm)					1.73	
	Focal length	FLx (cm)		#	#	5		#
		FLy (cm)		#	#	5.9		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	9.4					
Operating control conditions	Control 1		CW Doppler	#	#	CW Doppler	CW Doppler	#
	Control 2		5	#	#	5	5	#
	Control 3		4000	#	#	4000	4000	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C9-4v Transducer

InnoSight Diagnostic Ultrasound System in 2D Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.085	0.066	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.196					
	W_0	(mW)		7.1	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2.88					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	5.3	5.3	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.75	#	#	#	#
		Y (cm)		0.5	#	#	#	#
Other information	PD	(microsec)	0.235					
	PRF	(Hz)	8400					
	$p_r@PII_{max}$	(MPa)	0.33					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		3	#	#		#
		FLy (cm)		3	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	2.03					
Operating control conditions	Control 1		2D	2D	#	#	#	#
	Control 2		3	3	#	#	#	#
	Control 3		8448	8448	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C9-4v Transducer

InnoSight Diagnostic Ultrasound System in 2D+Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.099	0.39	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.254					
	W_0	(mW)		28.1	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.6	6.6	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.75	#	#	#	#
		Y (cm)		0.5	#	#	#	#
Other information	PD	(microsec)	0.57					
	PRF	(Hz)	4000					
	$p_r@PII_{max}$	(MPa)	0.38					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		3	#	#		#
		FLy (cm)		3	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4.3					
Operating control conditions	Control 1		Color	Color	#	#	#	#
	Control 2		3	3	#	#	#	#
	Control 3		4	4	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C9-4v Transducer

InnoSight Diagnostic Ultrasound System in THI-Color Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.101	0.38	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.258					
	W_0	(mW)		4.7	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	1.99					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.6	6.6	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.75	#	#	#	#
		Y (cm)		0.5	#	#	#	#
Other information	PD	(microsec)	0.56					
	PRF	(Hz)	4000					
	$p_r@PII_{max}$	(MPa)	0.39					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		3	#	#		#
		FLy (cm)		3	#	#		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4					
Operating control conditions	Control 1		THI-Color	THI-Color	#	#	#	#
	Control 2		3	3	#	#	#	#
	Control 3		4	4	#	#	#	#
	Control 4		100	100	#	#	#	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C9-4v Transducer

InnoSight Diagnostic Ultrasound System in 2D+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.129	#	#	0.0082	0.0123	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.301					
	W_0	(mW)		#	#		2.9	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.32		
	z_1	(cm)				2.38		
	z_{bp}	(cm)				1.79		
	z_{sp}	(cm)					2.3	
	$z@PII_{.3max}$	(cm)	2.38					
	$d_{eq}(z_{sp})$	(cm)					2.18	
	f_c	(MHz)	5.4	#	#	5.4	5.4	#
	Dim of A_{aprt}	X (cm)		#	#	2.25	2.25	#
		Y (cm)		#	#	0.5	0.5	#
Other information	PD	(microsec)	0.229					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.46					
	$d_{eq}@PII_{max}$	(cm)					2.17	
	Focal length	FLx (cm)		#	#	2.5		#
		FLy (cm)		#	#	3		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	4.8					
Operating control conditions	Control 1		M-Mode	#	#	M-Mode	M-Mode	#
	Control 2		2.5	#	#	2.5	2.5	#
	Control 3		250	#	#	250	231	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C9-4v Transducer

InnoSight Diagnostic Ultrasound System in THI+M-Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.128	#	#	0.0086	0.0134	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.298					
	W_0	(mW)		#	#		3.3	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				0.33		
	z_1	(cm)				2.4		
	z_{bp}	(cm)				1.79		
	z_{sp}	(cm)					2.29	
	$z@PII_{.3max}$	(cm)	2.4					
	$d_{eq}(z_{sp})$	(cm)					2.27	
	f_c	(MHz)	5.4	#	#	5.4	5.4	#
	Dim of A_{aprt}	X (cm)		#	#	2.25	2.25	#
		Y (cm)		#	#	0.5	0.5	#
Other information	PD	(microsec)	0.229					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.46					
	$d_{eq}@PII_{max}$	(cm)					2.27	
	Focal length	FLx (cm)		#	#	2.5		#
		FLy (cm)		#	#	3		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	5.1					
Operating control conditions	Control 1		THI+M-Mode	#	#	THI+M-Mode	THI+M-Mode	#
	Control 2		2.5	#	#	2.5	2.5	#
	Control 3		250	#	#	250	250	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Acoustic Output Reporting Table for Track 3 for the C9-4v Transducer

InnoSight Diagnostic Ultrasound System in PW Doppler Mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Global maximum index value			0.122	#	#	0.134	0.089	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.306					
	W_0	(mW)		#	#		11	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				4.5		
	z_1	(cm)				2.05		
	z_{bp}	(cm)				1.79		
	z_{sp}	(cm)					2.05	
	$z@PII_{.3max}$	(cm)	2.26					
	$d_{eq}(z_{sp})$	(cm)					1.05	
	f_c	(MHz)	6.3	#	#	6.3	6.3	#
	Dim of A_{aprt}	X (cm)		#	#	2.25	2.25	#
		Y (cm)		#	#	0.5	0.5	#
Other information	PD	(microsec)	0.59					
	PRF	(Hz)	1300					
	$p_r@PII_{max}$	(MPa)	0.49					
	$d_{eq}@PII_{max}$	(cm)					1.03	
	Focal length	FLx (cm)		#	#	2.5		#
		FLy (cm)		#	#	3		#
	$I_{pa.3}$ @ MI_{max}	(W/cm^2)	5.1					
Operating control conditions	Control 1		PW Doppler	#	#	PW Doppler	PW Doppler	#
	Control 2		2.5	#	#	2.5	2.5	#
	Control 3		1300	#	#	1300	1300	#
	Control 4		100	#	#	100	100	#

#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
(a)	This index is not required for this operating mode.
(b)	This transducer is not intended for transcranial or neonatal cephalic uses.
(c)	This formulation for TIS is less than that for an alternate formulation in this mode.
(d)	Control 1: Mode
(e)	Control 2: Focal distance (cm)
(f)	Control 3: PRF (KHz)
(g)	Control 4: Power (%)

Appendix D: FCC Statement

Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the party 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 InnoSight containing electronic components:

As a company, InnoSight 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 InnoSight 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 in 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.

CE
0120

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