



InnoSight Diagnostic Ultrasound System

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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 *User Manual* and strictly observe all warnings and cautions. Pay extra attention to the information from “[Chapter 2 Safety Information](#)”.

This *User 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 disclaim 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.

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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 InnoSight Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in 2D, M-Mode, PW and CW Spectral Doppler, CPA, Tissue Harmonic imaging and Color Doppler modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Other (OB/GYN, Urology, Nerve), Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and Carotid. The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients except environments where the intensity of electromagnetic disturbances is high. 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 or vibration to this system. Strong impacts may damage the components inside.



Do not cut, bend, modify, place heavy objects, or step on the cable of the power adapter. Otherwise the external insulation may be damaged and result in short-circuit or fire.



Do not use this system near strong electromagnetic sources, such as a microwave oven. The electromagnetic interference may cause this system to malfunction.



To avoid electrical shock, use only supplied power cords and connect only to properly grounded wall outlets.



The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

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 supplies and accessories, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

2301 Jones Blvd.

Coralville, Iowa 52241

Phone: 319.248.6757 / 800.445.6741

Fax: 319.248.6660 / 877.329.2482

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 29.
Biopsy kits	See “Needle Guide Kits” on page 97.

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/hazardouswaste/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.

The accessories/parts listed here are restricted to use with InnoSight only.

- Philips Diagnostic Ultrasound System
- Medical grade AC/DC power adapter
- *Quick Install Guide*
- Philips system S/N *Reference Card*

- *User Manual* (this document)
- AC plugs
- One or more InnoSight transducers (C6-2/L12-4/S4-2/C9-4v/C83B)
- Two USB flash drives containing the PDF file of the *User Manual* (this document) and the system software
- Ultrasound transmission gel
- Carry case (optional)
- System cart (optional)
- Multiple transducer module (optional)*
- SONY UP-X898MD or SONY UP-D898MD thermal printer (optional)

*The multiple transducer module is not available in all geographies and its availability is subject to local regulatory laws.



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



- 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](#).






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.
- *Quick Install Guide*: Contains illustrated instructions step-by-step on how to get the system ready for use, including installation of the peripherals.

Product Conventions

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

- Use gestures to control the system ([See page 55](#)).
- To adjust the parameter value of a function on the screen, touch the plus/minus buttons (+/-) .
- To type texts into a text field, touch the field and use the virtual keyboard that appears. You can also use a supported USB or Bluetooth keyboard for entering texts.
- To display a list, touch the down arrow . To display the options, touch the menu icon .
- To select or deselect an item, or to enable or disable a function, touch in the checkbox. For example, check the exam ; uncheck the exam .

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**.
- 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 93](#) and [“Customer Service” on page 3](#).

Safety Information



Follow the procedures carefully and ensure that the power, electrical, and 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 receptacle.
- 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 is not qualified for ophthalmic use. Never use the system for eye scanning.

- 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.





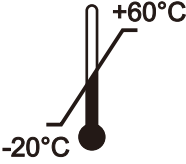
Product Label Icons

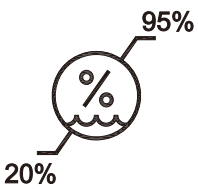
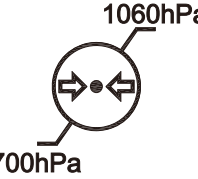
Symbol	Title of Symbol and Description	Standard Designation Number/Title of Standard
	Catalogue Number Indicates the product model.	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
	Serial Number Indicates the serial number of the system.	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements

Symbol	Title of Symbol and Description	Standard Designation Number/Title of Standard																											
	Philips Service Code	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements																											
	Unique Device Identification Indicates the UDI number of the system.	N/A																											
	Manufacturer Qisda Corporation manufactures the system.	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements																											
	Date of Manufacture	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements																											
	Authorized Representative in the European Community	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements																											
	CE Marking Certification with Notified Body Number 1639	Medical Devices Directive, MDD, 93/42/EEC																											
 <table border="1" data-bbox="282 1258 836 1415"><tr><td>AT</td><td>BE</td><td>BG</td><td>HR</td><td>CY</td><td>CZ</td><td>DK</td></tr><tr><td>EE</td><td>FI</td><td>FR</td><td>DE</td><td>EL</td><td>HU</td><td>IE</td></tr><tr><td>IT</td><td>LV</td><td>LT</td><td>LU</td><td>MT</td><td>NL</td><td>PL</td></tr><tr><td>PT</td><td>RO</td><td>SK</td><td>SI</td><td>ES</td><td>SE</td><td>UK</td></tr></table> <p>This device is restricted to indoor use</p>	AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SK	SI	ES	SE	UK	Radio equipment directive 2014/53/EU (RED) COMMISSION IMPLEMENTING REGULATION (EU) 2017/1354
AT	BE	BG	HR	CY	CZ	DK																							
EE	FI	FR	DE	EL	HU	IE																							
IT	LV	LT	LU	MT	NL	PL																							
PT	RO	SK	SI	ES	SE	UK																							
	Notified Body Certificate	ANSI/AAMI ES60601-1:2005 (R2012) + C1(2009) + A1 (2012) + A2 (2010); CAN/CSA C22.2 No. 60601-1:14																											
	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.	DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)																											
	Refer to the User Manual Indicates that the user should read the <i>User Manual</i> for information on using this equipment.	IEC 60601-1:2005 + A1:2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance																											


Symbol	Title of Symbol and Description	Standard Designation Number/Title of Standard
	Type BF Equipment Applied Part The system provides protection against electric shock.	IEC 60601-1:2005 + A1:2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
	Include RF Transmitters, apply RF Electromagnetic Energy for Diagnosis	IEC 60417 Graphical Symbols for Use on Equipment
IP22	Tablet IP Code, International Protection Marking	IEC 60601-1:2005 + A1:2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
	Regulatory Compliance Mark (RCM) Australian RCM compliance requirements	AS/NZS 4417.1:2012 Regulatory Compliance Mark For Electrical And Electronic Equipment
	Consult Instructions for Use Indicates that the user should see the instructions for use for safety information.	IEC 60601-1:2005 + A1:2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance

Shipping Label Icons

Symbol	Title of Symbol and Description	Standard Designation Number/Title of Standard
	This Way Up	ISO 7000 Fifth Edition 2014-01-15 Graphical Symbols For Use On Equipment – Registered Symbols
	Fragile	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
	Stacking Limit By Number	ISO 7000 Fifth Edition 2014-01-15 Graphical Symbols For Use On Equipment – Registered Symbols
	Keep Dry	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
	Temperature limit 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).	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements

Symbol	Title of Symbol and Description	Standard Designation Number/Title of Standard
	Humidity limitation 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.	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
	Atmospheric pressure limitation The system must be stored in the original shipping container in environments between 700 hPa (525 mmHg) and 1060 hPa (795 mmHg) air pressure.	ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements

System Button

Symbol	Description
	Power button <ul style="list-style-type: none"> • Press and hold the Power button to turn on/off the system. • Press the Power button to enter or exit Suspend mode.

Electrical Safety

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

- Electrical:
 - » IEC 60601-1 / EN 60601-1
 - » ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1
 - » IEC 60601-2-37 / EN 60601-2-37
- EMC/EMI:
 - » IEC 60601-1-2, 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 outlet, and do not circumvent the power cord.



To avoid the risk of electric shock, connect the system only to properly grounded wall outlets.

- Only authorized service technicians can make internal replacements of the system.



Do not operate the system in the presence of flammable gases or anesthetics. Explosion can result. The system is not compliant in AP/APG environments as defined by IEC 60601-1.

- Do not use a transducer if the transducer or cable is damaged. Contact technical support for replacement of the damaged equipment (See “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 and 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 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.

Conducted Susceptibility (CS)

The system complies with the IEC 60601-1-2 standard for susceptibility to Conducted Susceptibility (CS) on the power line. However, if the system experiences CS on the power line, artifacts (vertical lines, excessive noise in image, etc.) may appear on the ultrasound image. To eliminate these artifacts caused by a CS 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.

Electrostatic Discharge (ESD)

The system complies with the IEC 60601-1-2 standard for susceptibility to Electrostatic discharge (ESD). However, if the system experiences ESD, abnormal behaviors (screen hangs, or screen appears abnormal color or pattern, system power-off, or system reset. Brief flashes in the displayed or recorded image and cine loop, etc.) may appear while operating ultrasound diagnostic system. To eliminate these abnormal behaviors caused by an ESD condition, the operator should operate step by step as below:

1. Press and hold the Power button to turn off the tablet.
2. Press and hold the Power button again to turn on the tablet.

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.

The medical electrical equipment is suitable for the professional healthcare environment per 60601-1-2. It is suitable for use in physician offices, clinics, hospitals, and other professional healthcare environments except near HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging or other environments where the intensity of electromagnetic disturbances is high.

All Equipment

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

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


Emissions test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The 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 system is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The 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	±8 kV Contact ±15 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 ±1 kV 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	100% dip for 0.5 cycle 30% dip for 25 cycles 100% dip for 1 cycle 100% dip for 5 seconds	As specified	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or battery.
Power frequency 50/60 Hz Magnetic field IEC 61000-4-8	30 A/m	As specified	Power frequency magnetic fields should be that of a typical commercial or hospital environment. If image distortion occurs, it may be necessary to position the ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

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

Immunity test	Professional healthcare facility environment	Home healthcare environment	Compliance level	Electromagnetic environment - Guidance
Conducted RF IEC 61000-4-6	0.15~80 MHz, 3 Vrms 6 Vrms in ISM bands	0.15~80 MHz, 3 Vrms 6 Vrms in ISM bands & amateur radio bands	[V1] = 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{6}{E_1} \right] \sqrt{P}$

Immunity test	Professional healthcare facility environment	Home healthcare environment	Compliance level	Electromagnetic environment - Guidance
Radiated RF IEC 61000-4-3	80~2700 MHz, 3 V/m Proximity Fields from wireless communications equipment: Per IEC60601-1-2, Table 9	80~2700 MHz, 10 V/m Proximity Fields from wireless communications equipment: Per IEC60601-1-2, Table 9	[E1] = 10 V/m	<p>Portable RF communications equipment (including peripherals, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>If higher EM DISTURBANCES than those specified are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in the following:</p> $d = \left[\frac{6}{E_1} \right] \sqrt{P}$ <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Electrical transient conduction along supply lines ISO 7637-2	Not applicable	As specified in ISO 7637-2	Not applicable	Do not support being installed inside passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems

^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 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 (Medical Electrical) equipment has been tested for radiated RF immunity only at selected frequencies.

Separation Distances

The 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 2700 MHz $\frac{7\sqrt{P}}{E_1} = D$
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

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.



ECC/DEC/(04)08:

The use of the frequency band 5150-5350 MHz is restricted to indoor operation because of the protection requirements of satellite services.



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



- 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.
- Use an ultrasound phantom periodically to verify the imaging quality and accuracy of the system.

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.



Ensure all external peripheral devices are securely positioned. 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 hits 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.



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 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 of a patient-applied part may cause permanent damage. For cleaning and disinfection instructions, see [“Chapter 11 Transducer Care”](#) and [“Chapter 12 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.

Operation frequency and radio-frequency power are listed as below:

Mode	Frequency Range	EIRP (Max.)
Bluetooth Low Energy	2402~2480 MHz	-1.0 dBm
Bluetooth BR+EDR	2402~2480 MHz	7.0 dBm
Wi-Fi 802.11b	2412~2472 MHz	18.0 dBm
Wi-Fi 802.11g	2412~2472 MHz	18.0 dBm
Wi-Fi 802.11n	2412~2472 MHz	18.0 dBm
Wi-Fi 802.11n	5150~5250 MHz	18.0 dBm
Wi-Fi 802.11a	5150~5250 MHz	18.0 dBm

Table 2 Operation frequency and radio-frequency power

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. Three forms of TI are available: TIS, for soft tissue exposures; TIB, for instances when bone lies near the beam focus; and TIC, for instances when bone is near the tissue surface and in close proximity to the transducer aperture, specifically for applications involving transcranial scanning.

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 a system message displays prompting to cease the current scan for a few minutes during a real-time scan, touch **OK** to freeze the images. To resume scanning, wait until the system cools down.
- Operators should continually monitor the on-screen thermal index (TI) and mechanical index (MI) values and use control settings that keep these settings as low as possible while still achieving diagnostically useful results. In obstetric examinations, TIS (soft tissue thermal index) should be monitored during scans carried out in the first eight weeks after gestation, and TIB (bone thermal index) thereafter.
 - MI > 0.3 Minor damage is likely to happen to neonatal lung or intestine. If such exposure is necessary, reduce the exposure time as much as possible.
 - MI > 0.7 Risk of cavitation exists if an ultrasound contrast agent containing gas microspheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.
 - TI > 0.7 The overall exposure time of an embryo or fetus should be restricted in accordance with the following table as a reference.

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

Table 3 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 anaphylaxis. 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 29](#) 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 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.

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 12 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 BIOPSY. 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)
C83B transducer	Ultrasound transducer	IPX7 (at transducer head)

Table 4 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.

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	L12-4 Linear Array	S4-2 Phased Array	C9-4v Micro Curved Linear Array	C83B Curved Linear Array
2D			V		
2D+Color		V	V		V
2D+CPA		V	V		V
2D+M-Mode			V		V
PW Doppler	V		V		
Triplex	V	V	V	V	
CW Doppler	—	—	V	—	—

Table 5 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 $\leq 720 \text{ mW/cm}^2$ and either the global maximum MI must be ≤ 1.9 , or the global maximum de-rated I_{sppa} must be $\leq 190 \text{ W/cm}^2$. An exception is for ophthalmic use, in which case the $TI=\max(TIS)$ is not to

exceed 1.0; $I_{\text{spta},3} \leq 50 \text{ mW/cm}^2$, and $MI \leq 0.23$. 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 $I_{\text{spta}} \leq 720 \text{ mW/cm}^2$ 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.

Display Guideline

Thermal Index (TI) consists of three indices: soft tissue (TIS), bone (TIB) and cranial bone (TIC). TIS/TIB is displayed in all scan modes. TIC is only displayed when using adult cephalic application 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.

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.

Transducer Surface Temperature Rise

The table below lists the measured surface temperature rise from ambient ($23^\circ\text{C} \pm 3^\circ\text{C}$) 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 ($^\circ\text{C}$)				Invasive Use ($^\circ\text{C}$)
	C6-2	S4-2	L12-4	C83B	C9-4v
Simulated use	2.5	4.8	4.3	3	3.9
Still air	5.8	6	4.2	3.2	10.3

Overview

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

System Capabilities

The InnoSight Diagnostic Ultrasound System is intended for Obstetric imaging, 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
- PW and CW Spectral Doppler
- Tissue Harmonic Imaging (THI)
- Pulse Inversion THI
- iScan optimization of image processing parameters
- XRES image processing
- SonoCT and FQBeam Real-time Compound Imaging
- High Q Automatic Doppler

Transducer Types

The available transducer types are two curved linear array transducers, 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 32](#).

Measurements

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

Calculations

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

Image Acquisition and Review

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

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 53](#), [“Ending the Exam” on page 79](#) and [“Configuring Security Policies” on page 92](#).

Connectivity

The following network features are standard:

- Patient data and settings exported to removable media
- USB and Bluetooth connectivity to peripheral devices such as a Keyboard (not supplied with the system)
- HDMI connectivity to secondary monitors
- Printing to local or network printers
- Wireless and wired networking
- Export to DICOM archive
- Patient data imported from MWL server
- Images exported to network storage

Peripherals (Optional)

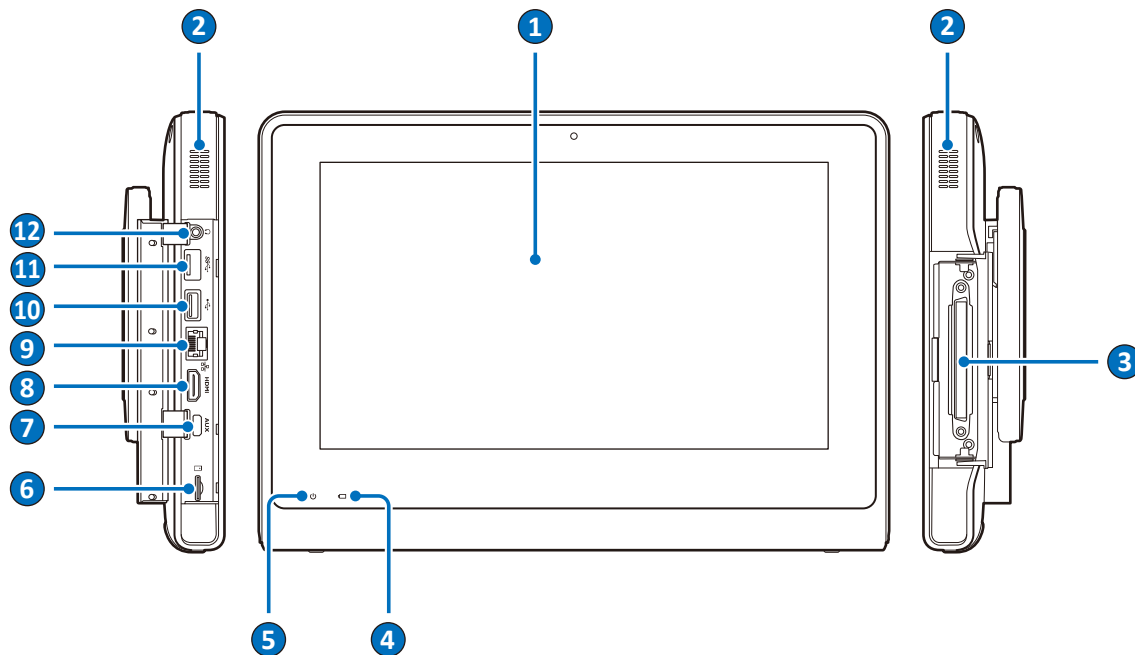
Peripheral devices include a carry case, a system cart on which the system can be mounted, a multiple transducer module which provides three extra transducer receptacles for connection, and a B&W image printer or a color image printer (supported printers) for printing ultrasound images and studies. For information on installation of these peripheral devices, see [“Chapter 4 Preparing the System” on page 33](#).

Service

The InnoSight Diagnostic 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 93](#).

System Overview

Front and Side Views

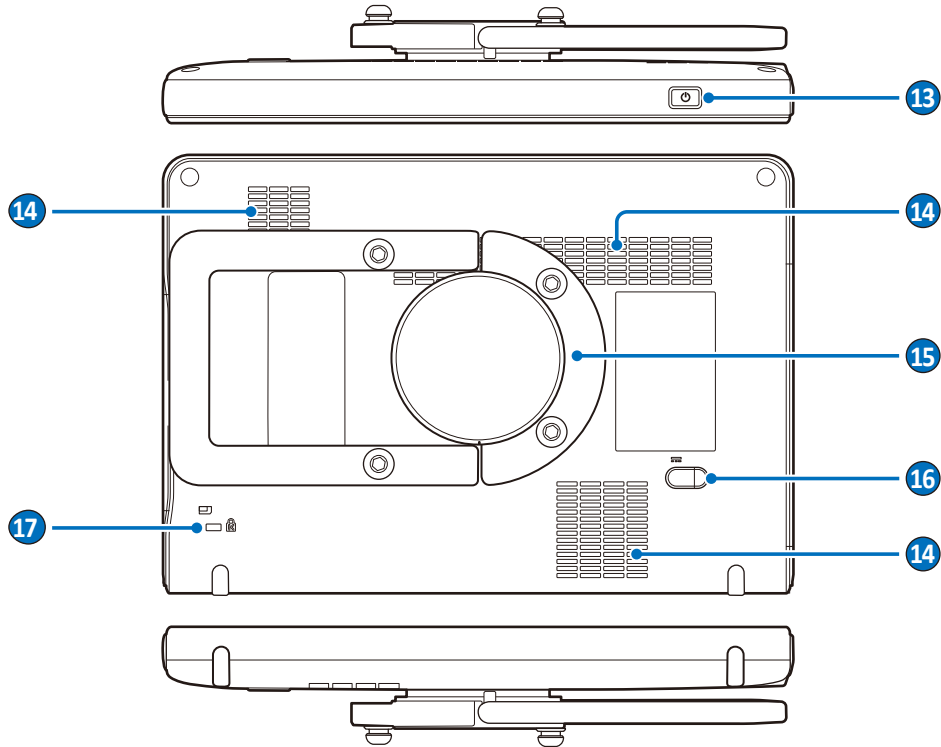


No.	Component	Function
1	Touch screen	Display system information and allow you to perform operations using different gestures.
2	Speakers	Built-in speakers for playing sounds, which are software-controlled.
3	Primary receptacle for a directly connected transducer or the multiple transducer module connector	When you use the system without the system cart, the system uses this receptacle for imaging transducers. (See page 36) When you use the system with the system cart configured with the multiple transducer module, the system uses the module's three receptacles for imaging transducers. (See page 43)
4	Battery indicator	When the system is connected to power: <ul style="list-style-type: none"> • If the system is turned off or enters Suspend mode, the battery indicator behaves in the following lighting patterns: <ul style="list-style-type: none"> » Steadily on orange when the battery is charging. » Steadily on green after the battery is charged. • If the system is turned on, the battery indicator goes off. To monitor the battery level, see "Battery Status Icons" on page 62 .
5	Power indicator	Steadily on blue after the system enters Suspend mode. (See page 63)
6	MicroSD card slot	Insert a microSD card into the microSD card slot to exchange data from and to the system. (See page 33)
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 receptacle	Connect the system to an Ethernet-based network. (See page 63)
10	USB 2.0 port	Connect the system to USB 2.0/3.0 devices, such as keyboards, pointing devices, or portable storage devices.
11	USB 3.0 port	
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	<ul style="list-style-type: none"> Press and hold the Power button to turn on/off the system. Press the Power button to enter or exit Suspend mode.
14	Ventilation slots	Release excessive heat during operation to keep the system in a safe operating temperature.
15	Rotating stand	<ul style="list-style-type: none"> Pull the rotating stand out to sustain the system on a flat surface. (See “Using the Stand” on page 34) Can be used as a handle to carry the system around. (See “Carrying the System” on page 37)
16	Power receptacle	Used to connect the system to power. (See “Charging the System” on page 35)
17	Anti-theft lock slot	Used to lock the system securely to a solid surface to protect it from theft.

Transducer Overview

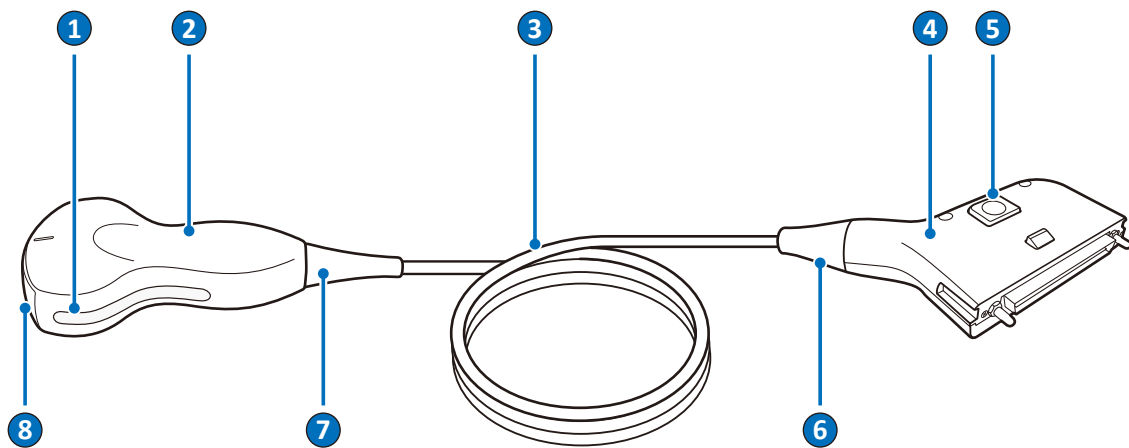


Figure 1 Transducer overview (Example transducer: C6-2)

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	Fetal/OB, Abdominal, Pediatric, GYN, Urology, Nerve
L12-4	Abdominal, Small Organ (breast, thyroid, testes), Musculo-skel. (Conventional), Peripheral Vessel, Carotid, Nerve
S4-2	Abdominal, Adult Cephalic, Cardiac Adult
C9-4v	GYN, OB, Trans-rectal, Trans-vaginal
C83B	Abdominal, Pediatric, Cardiac Pediatric

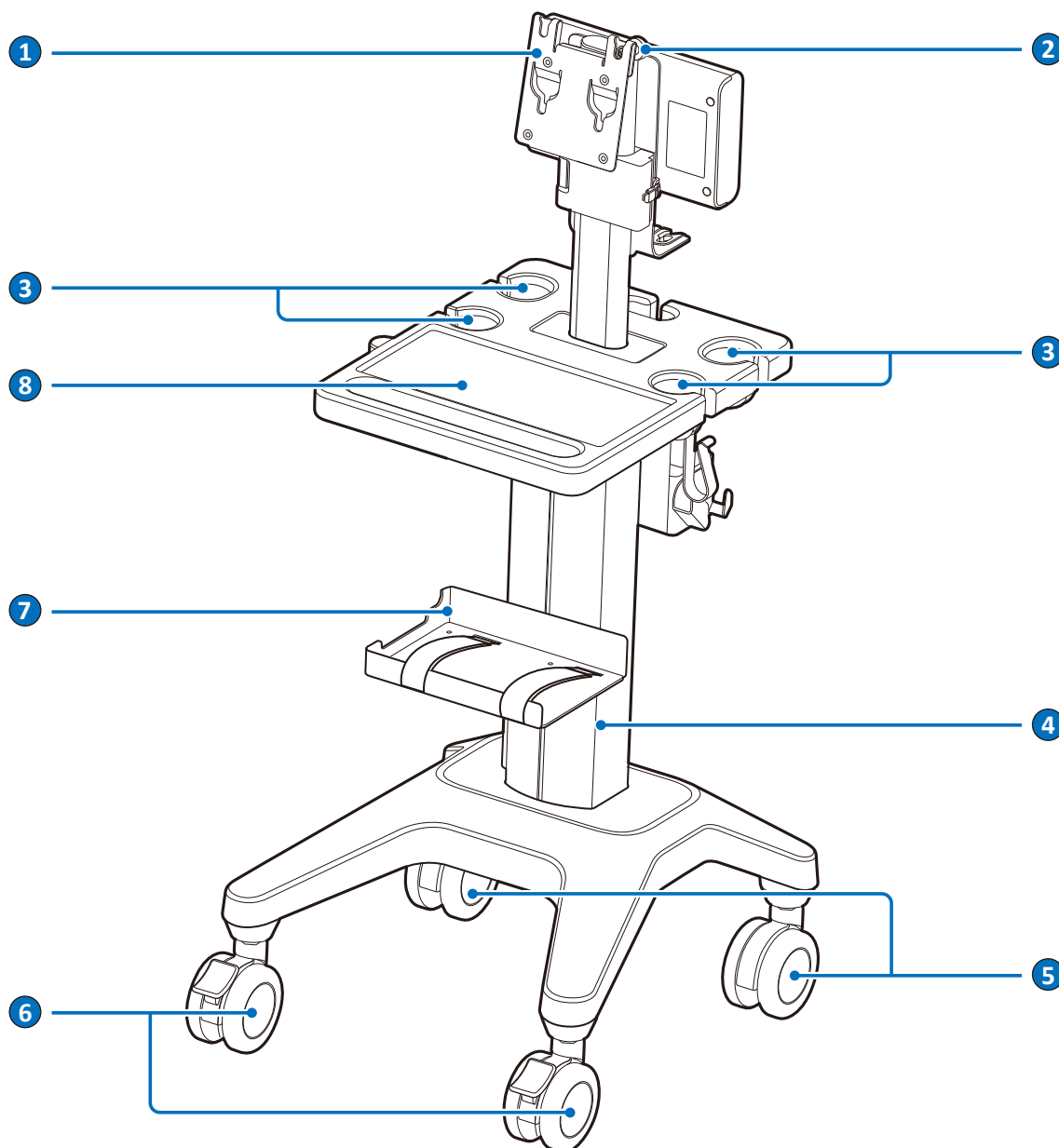
For more information, see [“Indications for Use and Supporting Transducers”](#) on page 32.

System Cart Overview



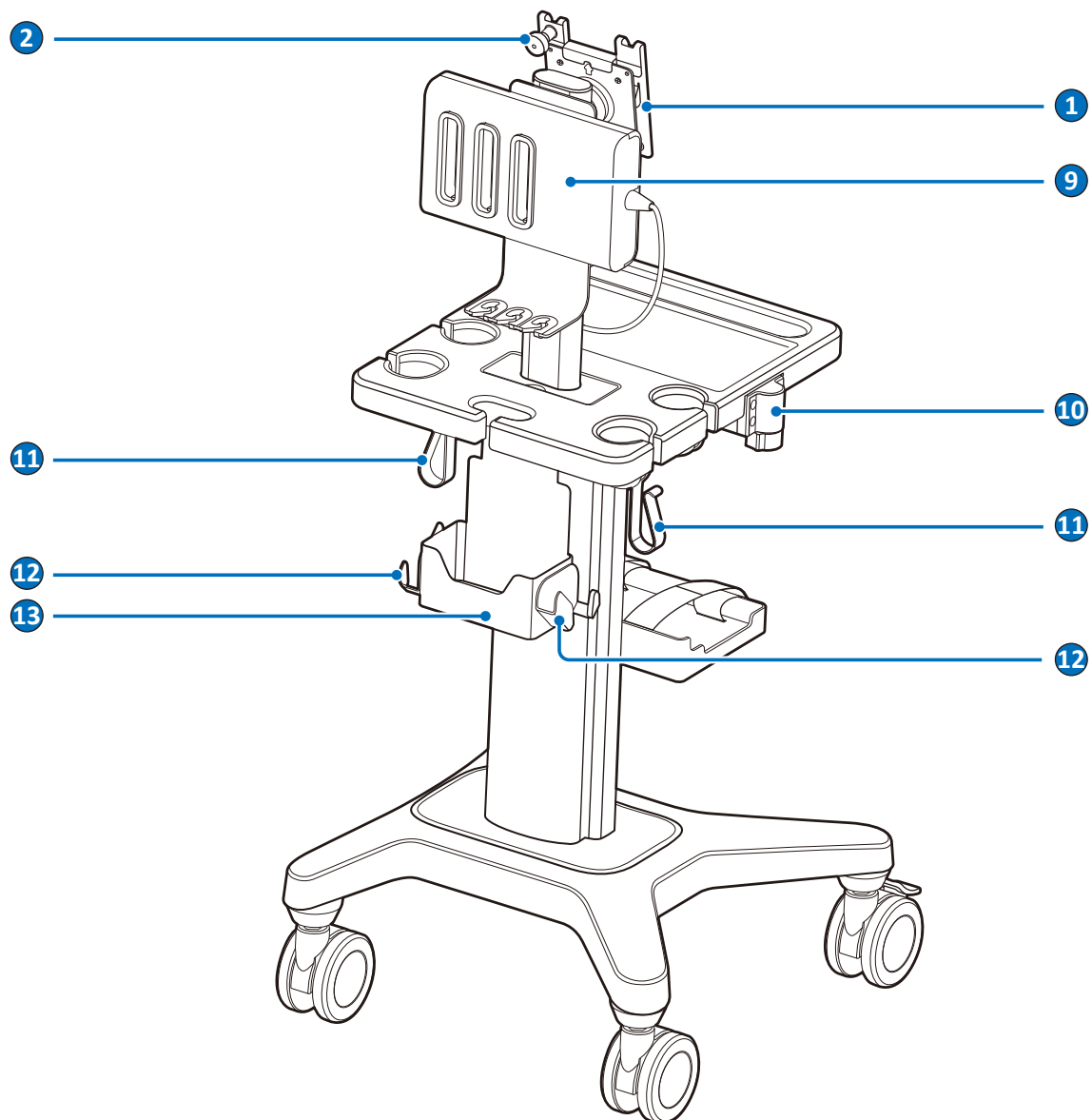
The system cart and the multiple transducer module are available for purchase as optional items.

Front View



No.	Item	No.	Item
1	Mount plate	2	Knurled thumb knob
3	Transducer and gel holder	4	Cart pillar
5	Caster wheel without brake	6	Caster wheel with brake
7	Printer holder	8	Work table

Rear View



No.	Item	No.	Item
1	Mount plate	2	Knurled thumb knob
9	Multiple transducer module*	10	Height-adjustment button
11	Cable collector	12	Transducer connector hanger
13	Rear container		

*The multiple transducer module is not available in all geographies and its availability is subject to local regulatory laws.



Observe the precautions and warnings listed in [“Mechanical Safety” on page 17](#) and [“Moving the System” on page 47](#) before using the system cart to avoid injury and system failure.

Indications for Use and Supporting Transducers

The InnoSight Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Other (OB/GYN, Urology, Nerve), Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and Carotid. Ultrasound exams should be performed only for medical purposes with a prescription from a licensed physician.



United States federal law restricts this device to sale by or on the order of a physician.

The following are the indications for use for this system and the transducers supporting each indication.

Indications for Use	Supporting Transducers
Fetal/OB	C6-2, C9-4v
Abdominal	C6-2, L12-4, S4-2, C83B
Pediatric	C6-2, C83B
Small Organ (breast, thyroid, testes)	L12-4
Adult Cephalic	S4-2
Trans-rectal	C9-4v
Trans-vaginal	C9-4v
Musculo-skel. (Conventional)	L12-4
Other: GYN	C6-2, C9-4v
Other: Urology	C6-2
Cardiac Adult	S4-2
Fetal Echo	C6-2
Peripheral Vessel	L12-4
Carotid	L12-4
Cardiac Pediatric	C83B



The system is not qualified for ophthalmic use. Never use the system for eye scanning.

Preparing the System

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

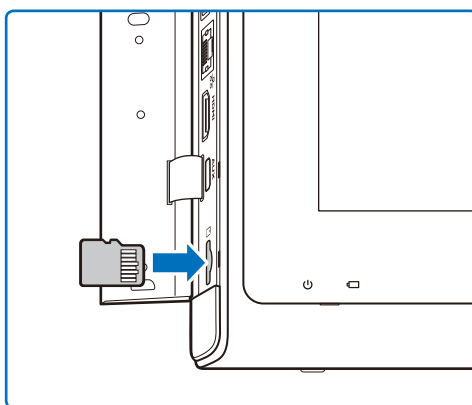
Inserting a microSD Card

Use the microSD card to import data to your system or to export data 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.
- You can also use external USB 2.0 or 3.0 flash drives to import or export data through USB ports. Both the microSD card and the USB flash drives must be formatted with FAT32 format.

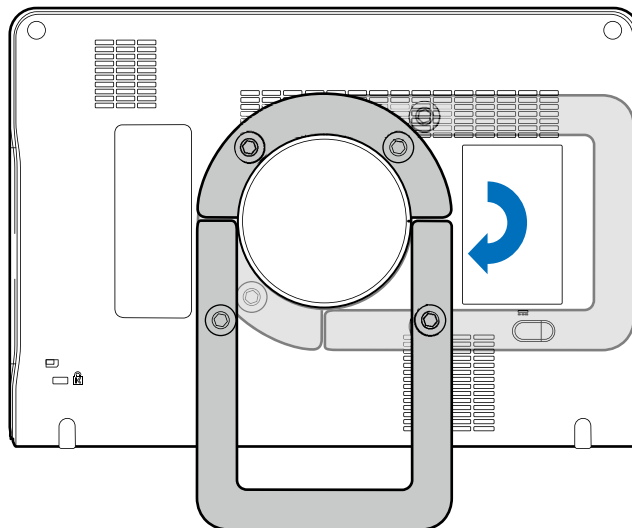
1. Flip the port cover open.
2. Align the microSD card with the mark next to the microSD card slot.
3. Fully insert the microSD card into the card slot until it clicks into place.



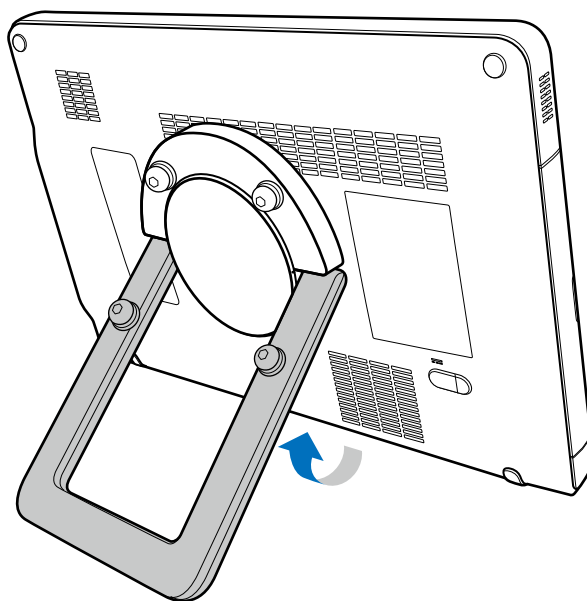
- You can use the system's service tools to back up system settings and patient data when the system is connected to an external storage device. For detailed instructions, see [“Backing Up System Settings and/or Patient Data” on page 95](#).
- The system supports access to only one external storage device 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.



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

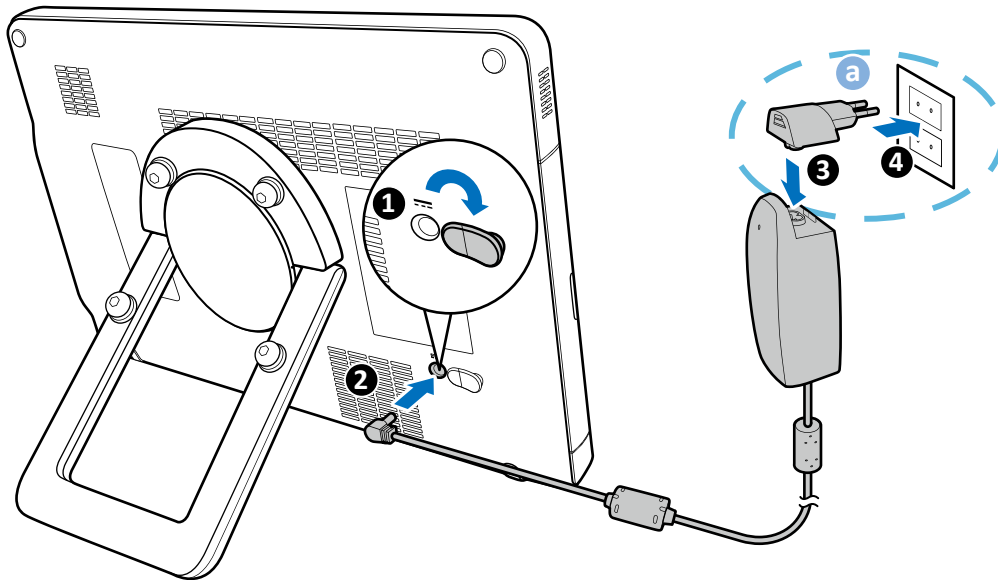


Charging the System

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 receptacle.
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.

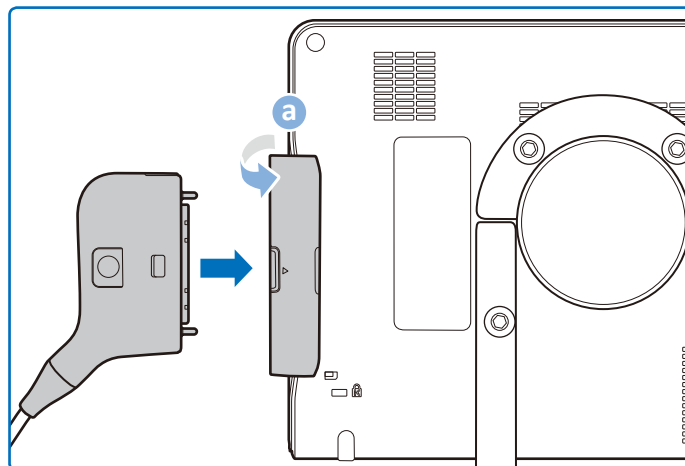


The battery indicator lights up only when the system is charging while turned off or in Suspend mode. If the system is turned on and charging at the same time, please monitor the battery status from the system toolbar (See [“System Tools”](#) on page 61 and [“Battery Status Icons”](#) on page 62).

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

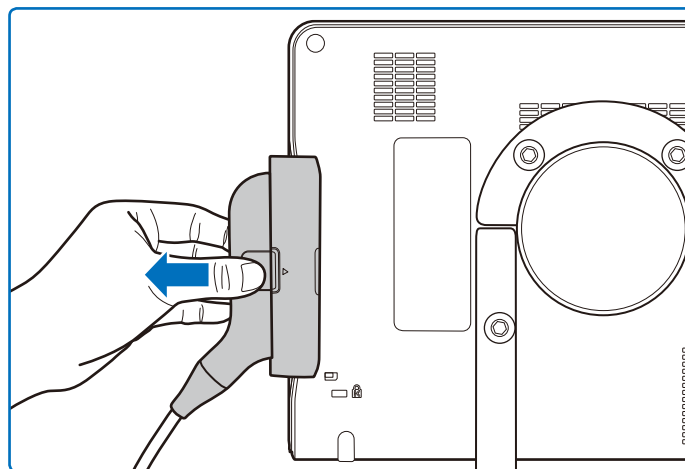
Connecting the Transducer

Flip the transducer cover open **a** and insert the transducer connector carefully into the transducer receptacle until it is locked in place.



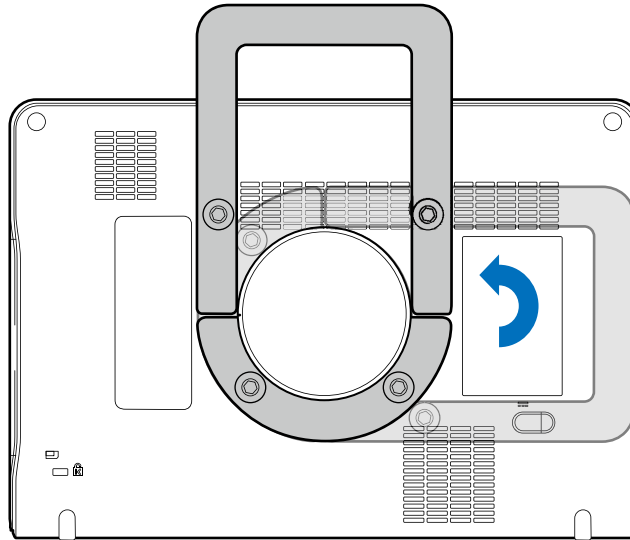
Removing the Transducer

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

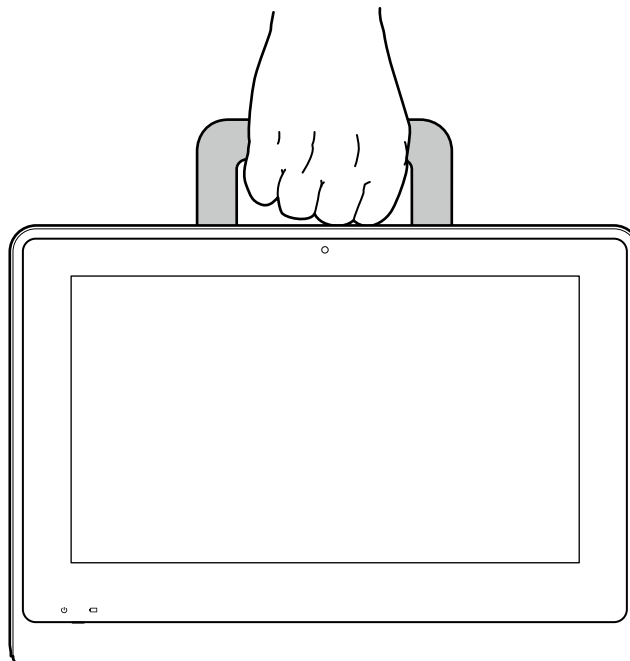


Carrying the System

1. Rotate the rotating stand counterclockwise by 90 degrees.



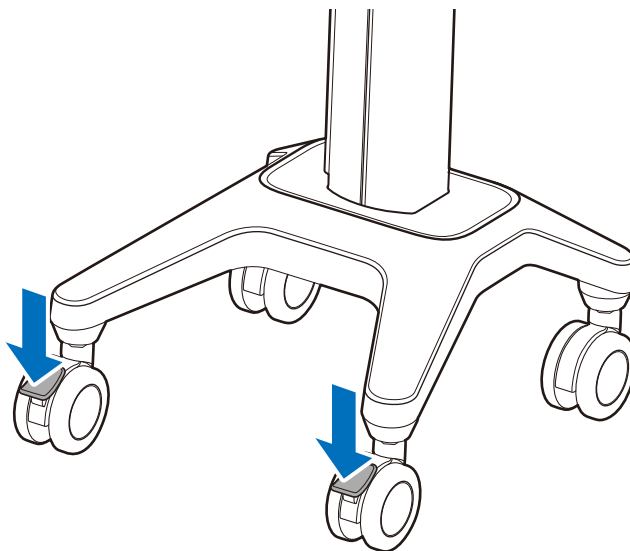
2. Use the rotating stand as a handle to carry the system around.



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.



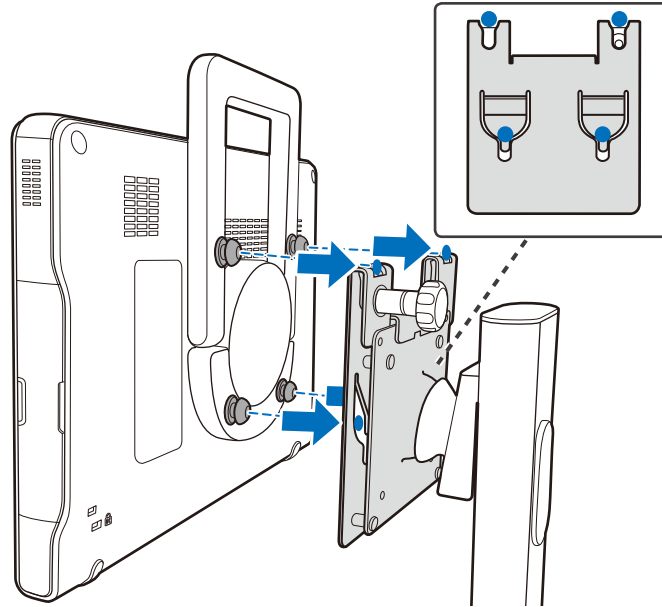
- Never park the system cart on an incline.
 - Observe the precautions and warnings listed in [“Mechanical Safety” on page 17](#).
-

Mounting the System to the System Cart

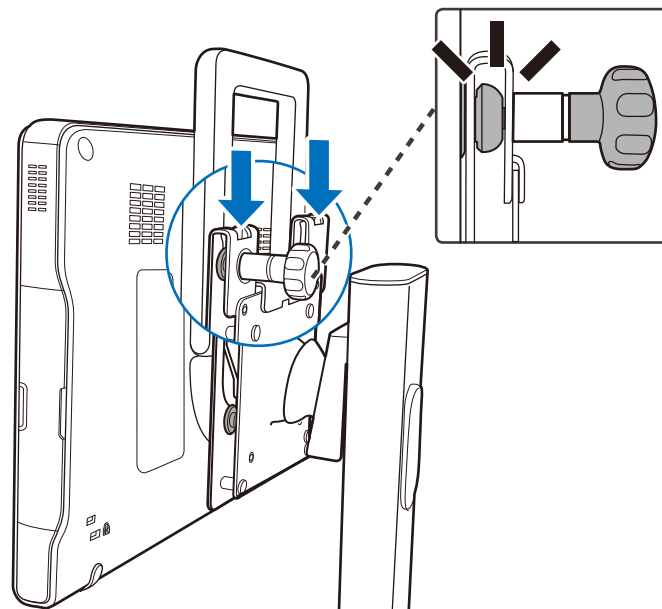


- The system cart and the multiple transducer module are available by separate purchase.
- Before mounting the system to the system cart, ensure that the caster wheels are locked in place, and the rotating stand is fixed as a handle ([See page 37](#)).

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.



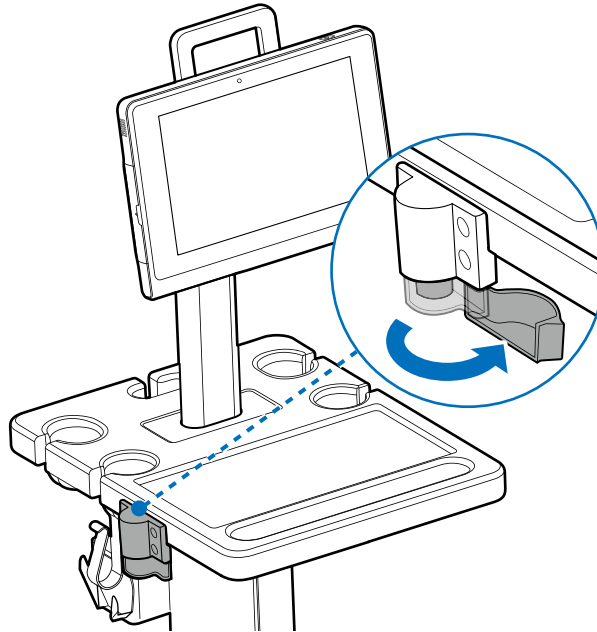
2. Attach the system fully onto the plate until you hear a click sound, indicating that it is locked in place.



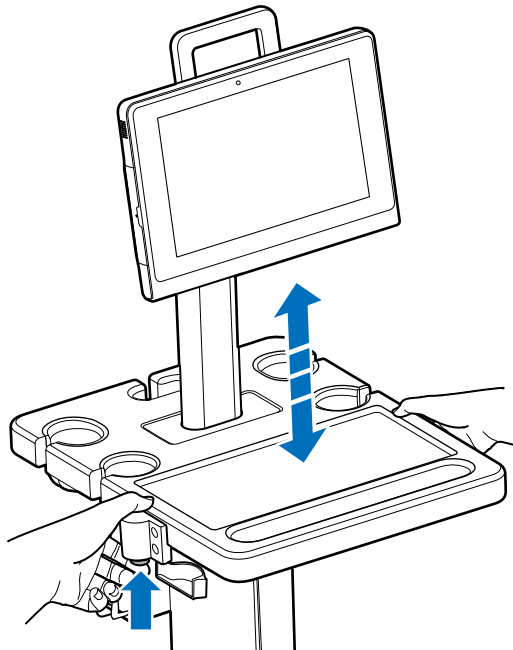
Adjusting the System Cart Height

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.

Assembling the Multiple Transducer Module



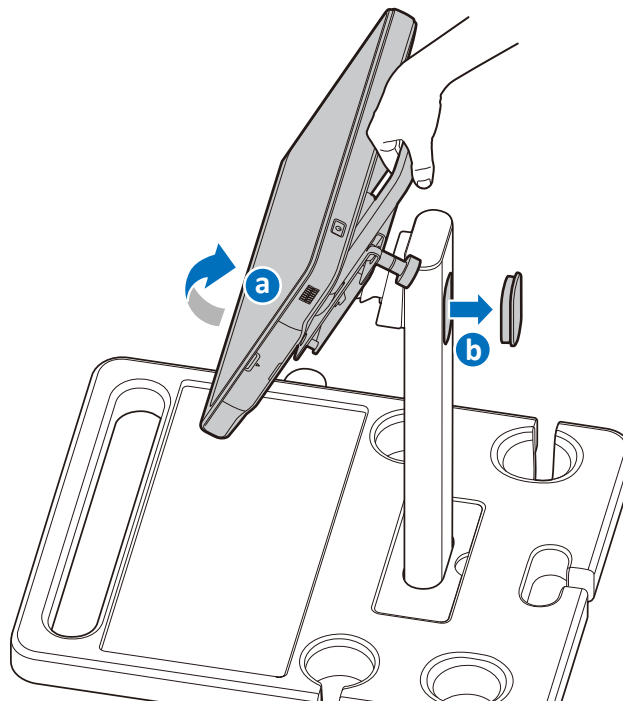
- When holding the module and its joint clamp, move it carefully to avoid pinching hands.
- When assembling and disassembling the module, never place your fingers inside the cart pillar slot or over the edge of the sheet metal to avoid the possibilities of being cut.
- Keep liquid away from the cart pillar slot and the module's sealing areas or other openings of the metal parts. Any liquid or gel spills on the areas mentioned above may cause short-circuit to the electronic components and lead to malfunctions.
- After assembling the module onto the system cart, the draw latch must remain locked securely at all times, especially during or after moving the cart, to avoid the module falling over into you or others and resulting in injury or damage.
- Secure all transducers, cables and accessories so that they do not interfere with the wheels.



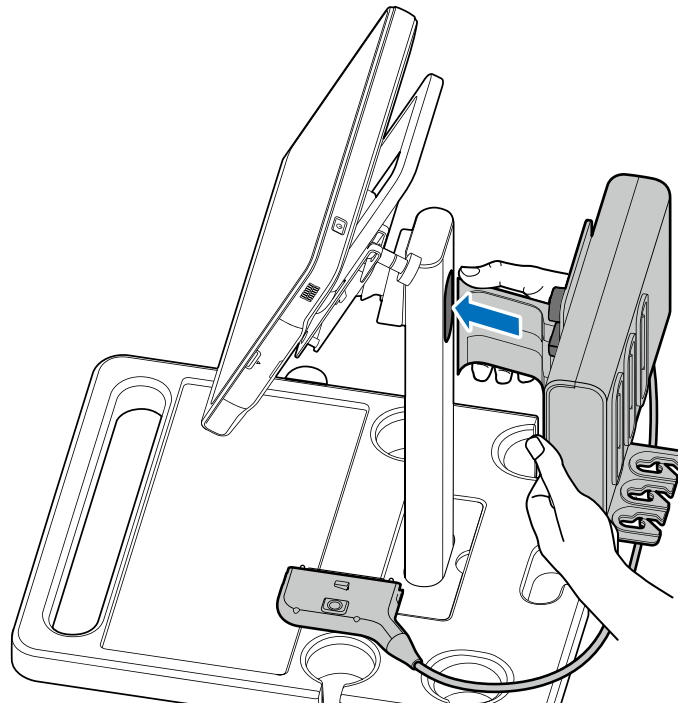
The multiple transducer module is available by separate purchase. It is not available in all geographies and its availability is subject to local regulatory laws.

If you purchase the multiple transducer module as a separate item, you will need to assemble the module onto the system cart. If your module is assembled already onto the system cart, proceed to [“Using the Multiple Transducer Module” on page 43](#).

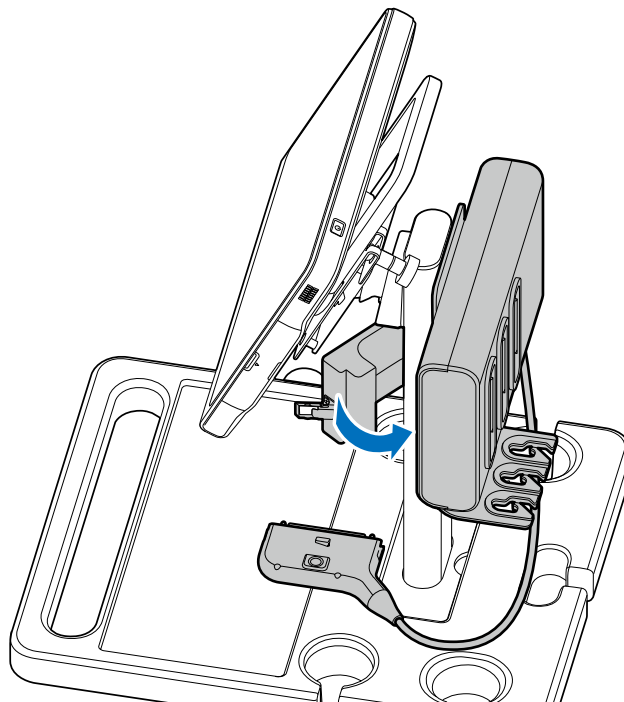
1. Lock the caster wheels of the system cart ([See page 38](#)) and swivel the system up **a**. Remove the cap from the cart pillar **b**.



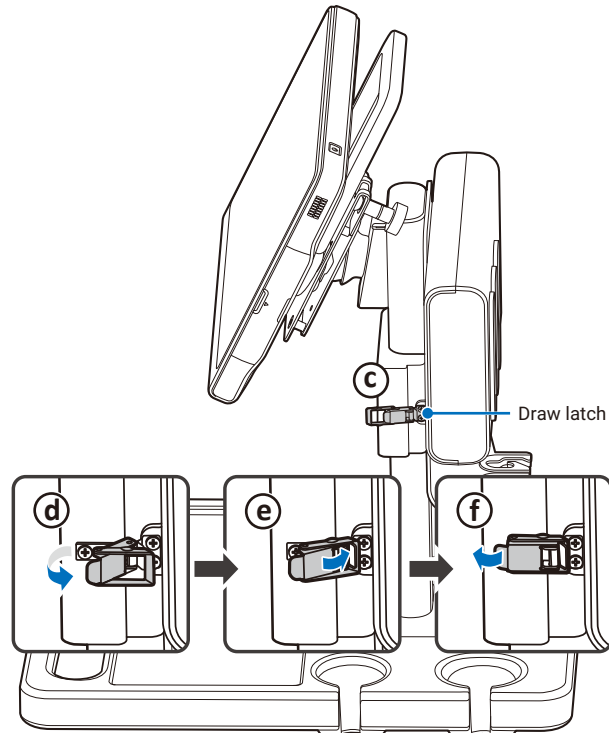
2. Use both hands to hold the multiple transducer module firmly with its joint clamp flipped open. Position and carefully insert the protrusion parts of the module into the slot.



3. Hold the bottom of the module with one hand and use another hand to close the arm of the clamp around the pillar.



- Secure the draw latch to lock the module in place.



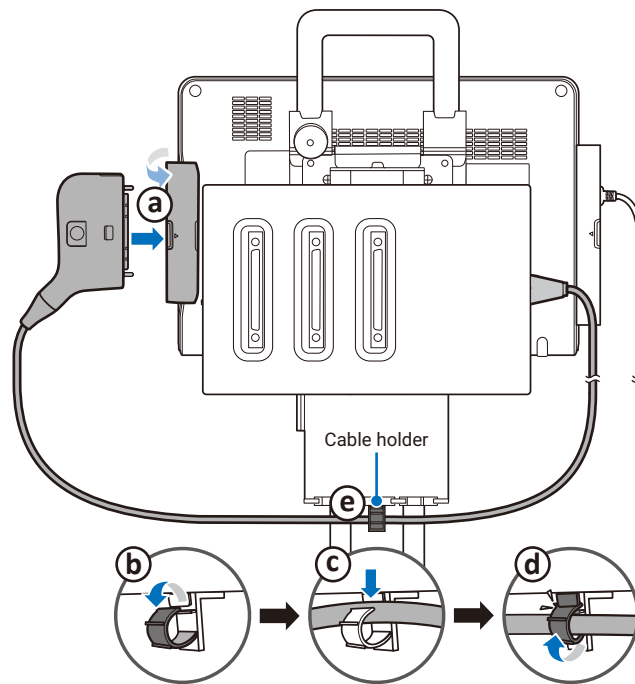
Using the Multiple Transducer Module



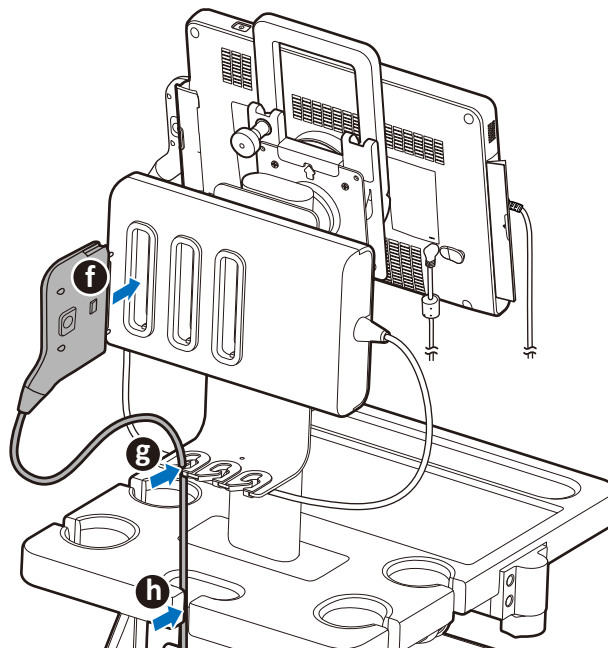
- The multiple transducer module is available by separate purchase.
- Before using the multiple transducer module, ensure that you have already upgraded the system software to v1.1. If you need assistance with the software upgrade, please contact technical support ([See “Customer Service” on page 3](#)).

The multiple transducer module provides three extra transducer receptacles to allow you to connect multiple transducers to the system.

1. Insert the module's transducer connector into the transducer receptacle on the side of the system (a). Then, secure your transducer cable using the cable holder (e): Flip the cable holder open (b), place the transducer cable into the hole the cable holder creates (c) and push to lock the cable holder (d).



2. Insert the transducer connector of a transducer into the transducer receptacle on the back of the multiple transducer module (f), and route the cable properly (g and h). You can connect up to three transducers.



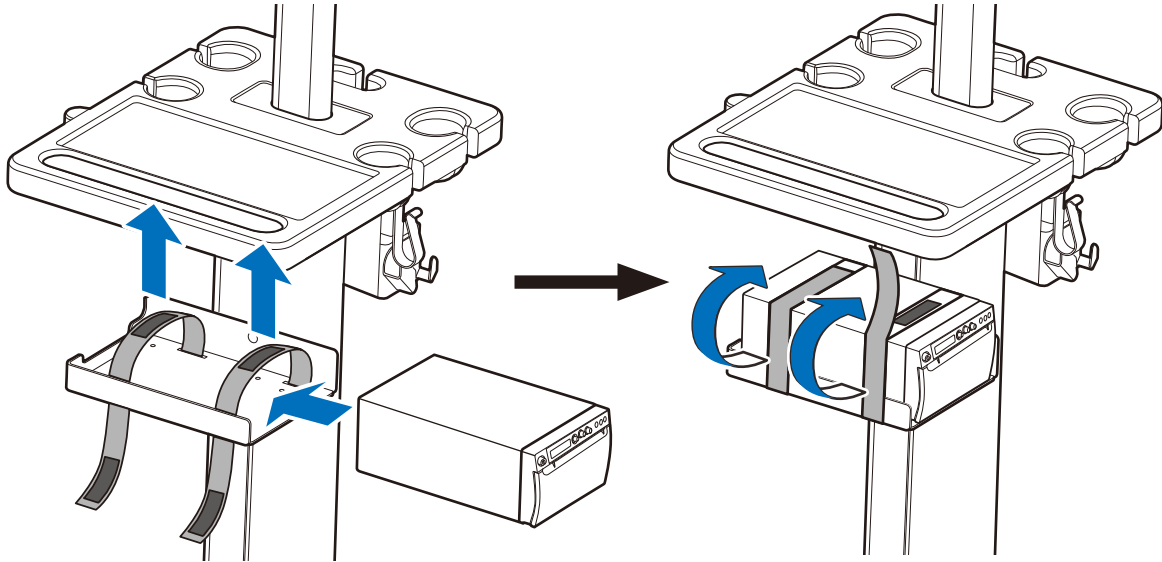
3. The system detects the connected transducers and displays them on the Preset screen. To select a transducer, touch the transducer name. All the applications available for the transducer appear below. Select the application you want, and the system starts live imaging immediately. (See [“Selecting a Preset”](#) on page 68)

Connecting an External Printer

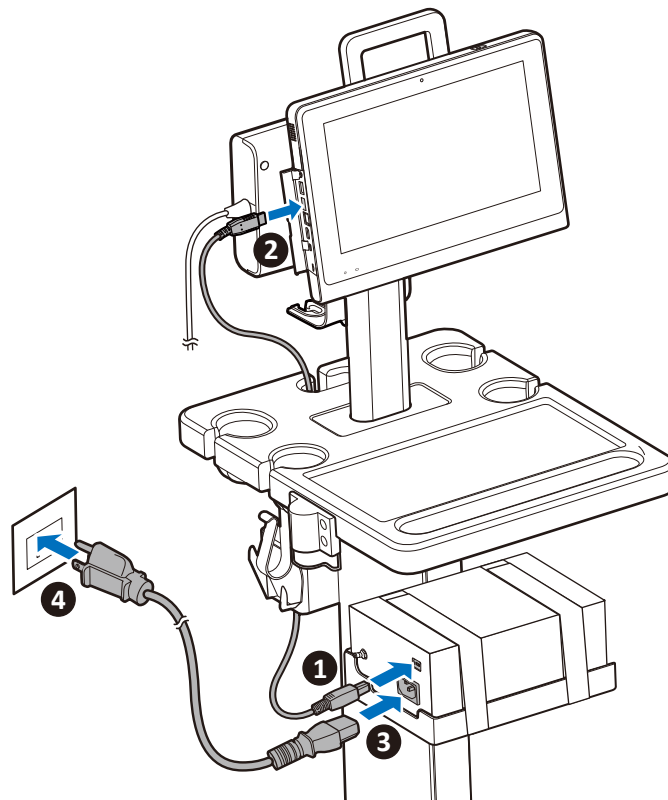


- Before connecting the system to an external printer, turn off the system and disconnect the power adapter from the power outlet.
- External printers are available by separate purchase. For a list of supported printers, see [“Supported External Printers”](#) on page 50.

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



1. Insert one end of a 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 receptacle of the printer.
4. Plug the power cord into an power outlet.



5. Turn on the printer, then turn on the system. The system detects the printer and installs the driver automatically. If not, proceed to the next step.
6. On the system imaging screen, go to **Menu > Settings > Print** and select the printer name. The printer is now ready for use.

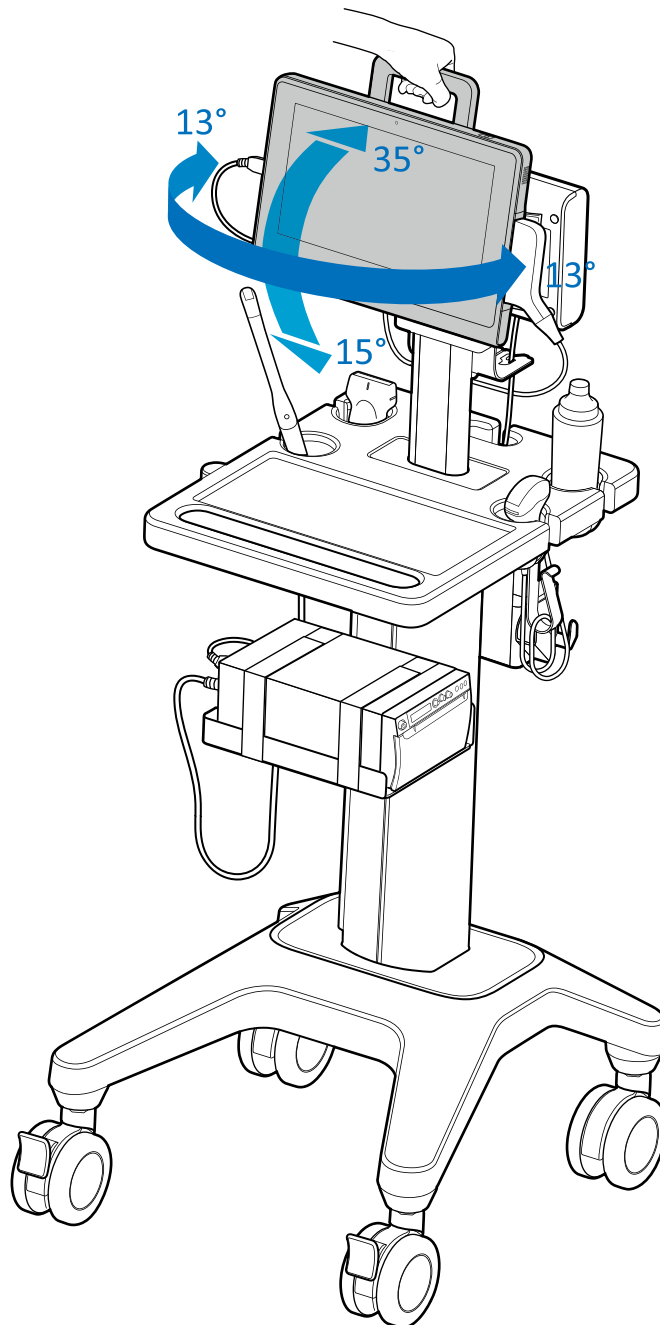


See your printer documentation included in the sales package for detailed information on connections and settings.

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.



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.



Ensure all external peripheral devices are securely positioned. 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.

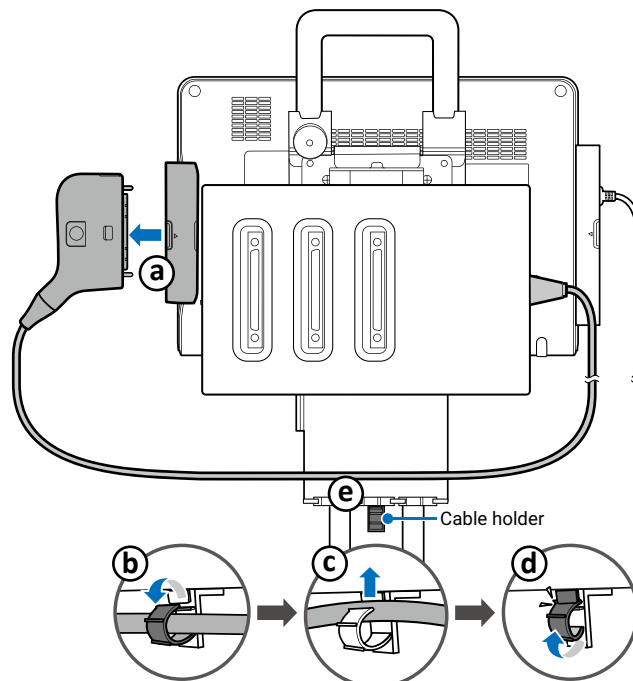


If system operation is abnormal after you move or transport the system, contact your Philips representative immediately. System components are installed securely and can withstand considerable shock, but excessive shock can cause a system failure.

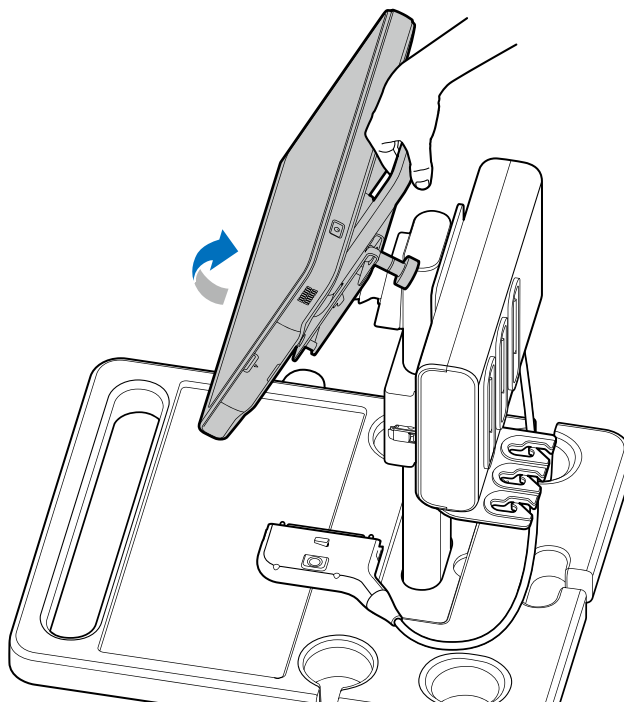
1. Ensure the system is mounted and locked firmly on the system cart.
2. Disengage the wheel brakes.
3. Move the cart using the handle at the front of the cart.

Disassembling the Multiple Transducer Module

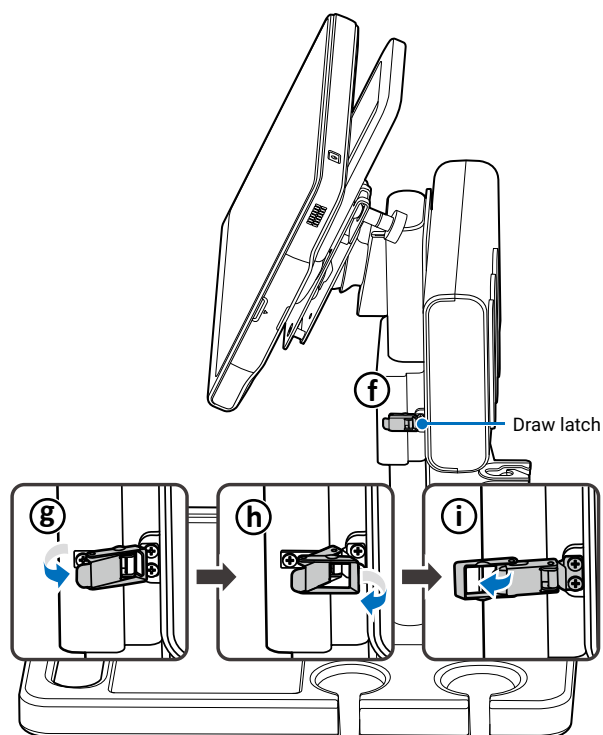
1. Lock the caster wheels of the system cart (See page 38), and remove all the connected transducers from the transducer receptacles on the back of the multiple transducer module.
2. Remove the module's transducer connector from the transducer receptacle on the side of the system (a). Then, release your transducer cable from the cable holder (e): Flip the cable holder open (b), pull out the transducer cable (c) and push to lock the cable holder (d).



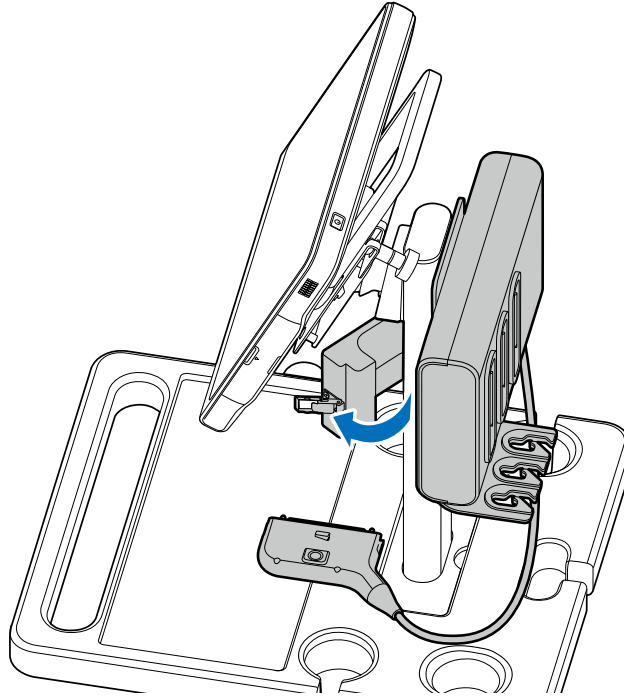
3. Swivel the system up.



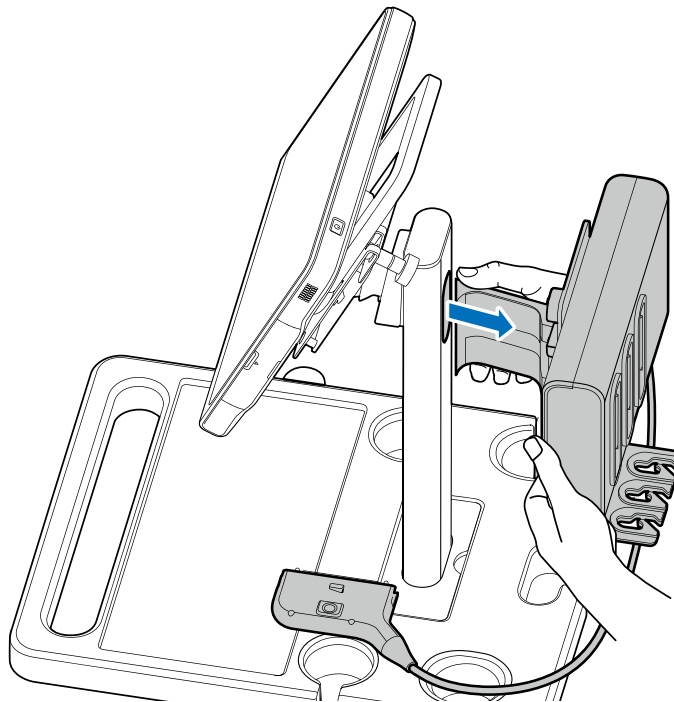
4. Release the draw latch.



5. Hold the bottom of the module with one hand and use another hand to open the arm of the clamp.

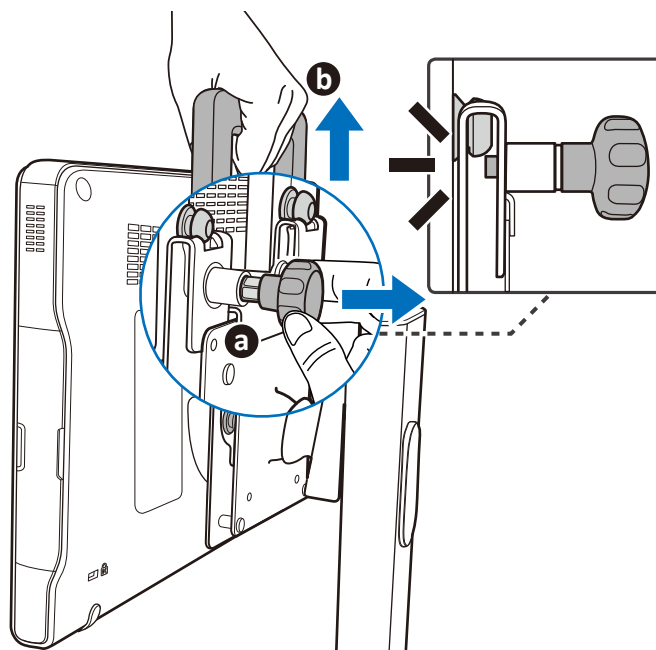


6. Use both hands to hold the multiple transducer module firmly with its joint clamp flipped open, and carefully pull out the module from the slot.



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**.



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.
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.



- We suggest using a monitor or TV which supports 1080p (1920x1080) resolution as an external display for your system.
- See the documentation of your HDMI-enabled 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 SONY UP-D898MD	Yes	No

For report printers:

- The system supports SONY UP-X898MD/SONY UP-D898MD, Epson and HP 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.

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 [“Backing Up System Settings and/or Patient Data” on page 95](#) and [“Managing Disk Space” on page 63](#).



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.

Creating a New Administrator Account

1. After system startup for the first time, the system automatically logs you in as a guest user and enters the real-time 2D imaging screen. To begin the first-time-logging-in process, touch **Menu > Security > Go to Login Screen**. The default user account with administrative privileges then appears on the screen. Touch the account name, enter the default password and touch **Login**.

Default User ID: SiteAdmin


Default Password: {Tablet's serial number}



- The tablet's serial number is assigned and cannot be changed. For more information about the tablet's serial number, see [“Checking the Tablet's Serial Number” on page 94](#). To check your tablet's serial number:
 - On the system screen, touch **Menu > Settings > Service > About > Serial Number**.
 - On the system screen, touch **Menu > Settings > Service > System Management > System Information > Tablet Serial Number**.
 - See the spec label on the back of your system.
- Each time after restoring the system to its factory state, the system requires logging in using the default site administrator credentials.

2. Create a new site administrator account by entering personal credentials, 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** . Or follow the instructions in the next section to add a new user account.

3. Follow the instructions in each section to set up the security policies ([See page 92](#)). Touch **Save** to save the settings.




If you choose to start the system as a guest, you can return to the user login screen at any time by touching **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 **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 Admin 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, and 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 into the system (with the transducer connected). Touch **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 into the system for the first time, set current time and date based on your location. The system then maintains time and date settings even when the system is turned off and disconnected from power.

1. Touch anywhere on the system toolbar from the upper part of the display to open the system tools menu (See page 61), then touch the time and date section. Or, on the imaging screen, touch **Menu > Settings > General > Date & Time > Edit**.
2. Touch **Select time zone**. Scroll to select the time zone you are in.
3. Touch **Choose date format** and select a preferred date format.
4. Touch **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.
5. Touch **Done**. Touch  to leave the setting.

Alternatively, you can use the network as the time source. On the same date and time setting screen, check **Automatic date & time** .



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.



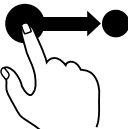



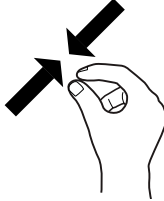
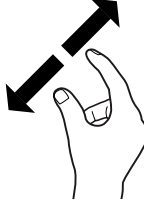

Touch	Touch and Hold	Drag	Swipe
			
Double-Tap	Two-Finger Tap	Pinch	Spread
			

Figure 2 Gestures

Gestures for Controlling the Real-time, Frozen and Review Imaging Screens

Action	Gesture
Save a single image or cine loop	(Available in full screen mode only) <ul style="list-style-type: none"> • Touch and hold on the scan area to save a cine loop or single image. • On the frozen imaging screen, two-finger tap on the imaging area to play or pause a cine loop, then touch and hold on the scan area to save the cine loop or a single image.
Zoom or unzoom	Spread two fingers apart or pinch two fingers together.
Move the zoomed image	Touch and hold the zoomed image until the navigation button appears, then drag to move the image.
Move the BDMK/annotation/arrow indicators	Touch and hold the indicator, and drag to move it.
Scroll the thumbnail list	Swipe vertically on the thumbnail area to scroll through the thumbnail list.
Adjust the PW/CW baseline	<ol style="list-style-type: none"> 1. Touch and hold on the baseline. 2. Swipe vertically to change the baseline position.
Adjust the PW/CW correction angle	<ol style="list-style-type: none"> 1. Touch and hold one finger on the Spectral Doppler line. 2. Swipe another finger to the left or right.

Gestures for Controlling the Real-time and Frozen Imaging Screens

Action	Gesture
Toggle between real-time and frozen imaging screens	<p>Double-tap on the scan area.</p> <p> To use this gesture, go to Menu > Settings > General > Enable freeze gesture.</p>

Gestures for Controlling the Real-time Imaging Screen

Action	Gesture
Adjust depth	Swipe vertically on the scan area to increase (swipe down) or decrease (swipe up) depth.
Adjust gain	Swipe horizontally on the scan area or the time series window to increase (swipe right) or decrease gain (swipe left).
Move and resize ROI	Touch inside the ROI and drag to move it. Touch on any of the four corners of the ROI and drag to resize it.
Adjust the sample volume size	<ol style="list-style-type: none"> 1. Touch and hold one finger on the Spectral Doppler line. 2. Swipe another finger up or down.
Move the Spectral Doppler line or the sample volume	Touch the Spectral Doppler line and drag it horizontally.

Gestures for Controlling the Frozen Imaging Screen

Action	Gesture
Play or pause cine loops	(In full screen mode) Two-finger tap on the imaging area.
Scroll frames	(In full screen mode) Swipe horizontally on the scan area or the time series window to scroll through the image frames or the waveforms.

Gestures for Controlling the Review Imaging Screen

Action	Gesture
Play or pause cine loops	(In full screen mode, multiple-selection or multiple-comparison view) Two-finger tap on the imaging area. (See “Reviewing the Image” on page 77)
Scroll frames	(In full screen mode) Swipe horizontally on the scan area to scroll through the image frames.

Setting the System Language

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



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 system menu screen. Touch an option to perform its function.

Function	Description
Patient	Edit current or add new patient information.
Worklist	Load the DICOM Modality Worklist (MWL) that contains patient information as well as the requested procedure electronically via the MWL query.
Exam List	View a list of patients with their exam results. You can proceed with unfinished exams or reviews, or export exams according to the selection criteria all at once.
Report	Display exam information including patient data, exam type, study-specific data, comments and saved ultrasound images.
Preset	Select the predefined preset compatible with the connected transducer for optimized image control settings.
Review	View, add annotations and measurements to, and export a saved exam.
Settings	<ul style="list-style-type: none"> Customize the system based on the operator’s habitual needs. Use the service tools to update software, backup and restore data or examine the system functionality. (See “Servicing Your System” on page 93)
Security	Manage users and permissions to control access to ePHI (Electronic Protected Health Information) data on the system and the system features.
Tutorial	Provide quick reference to commonly used gestures. For a list of gestures available under different imaging status, see “Controlling the System” on page 55 .

Imaging Screen (Real-time)

With the transducer connected correctly, the system enters the 2D real-time imaging screen each time after touching the **Home** button.

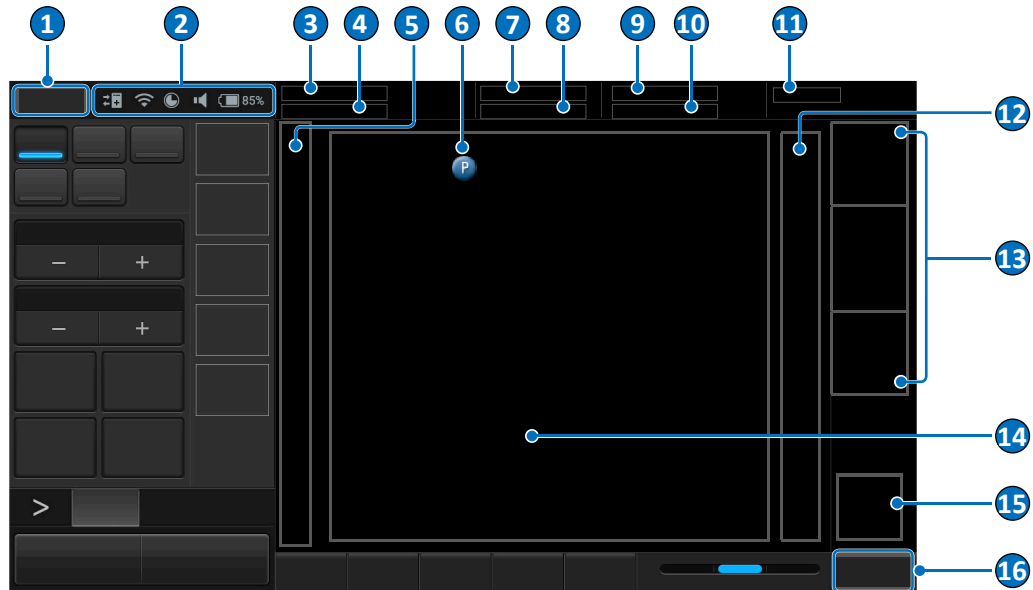


Figure 3 Real-time imaging screen (example)

No.	Function	No.	Function
1	Menu button Enter the system menu screen.	2	System toolbar Displays information about current battery level, volume, system storage, and network connection status. Touch anywhere on the system toolbar to open the system tools menu for system configuration. (See page 61)
3	Patient name*	4	Patient ID*
5	Depth scale	6	Transducer orientation icon (See page 69)
7	Patient age/gender/DOB (date of birth)	8	Application name
9	Current date and time	10	User name
11	Institution name	12	Grayscale/Color/CPA wedge
13	Scan Properties Display area Displays information about the current scan, including the transducer type, thermal index (TI)/mechanical index (MI) and scan parameters.	14	Ultrasound imaging area Displays 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, Spectral Doppler and 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.
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.

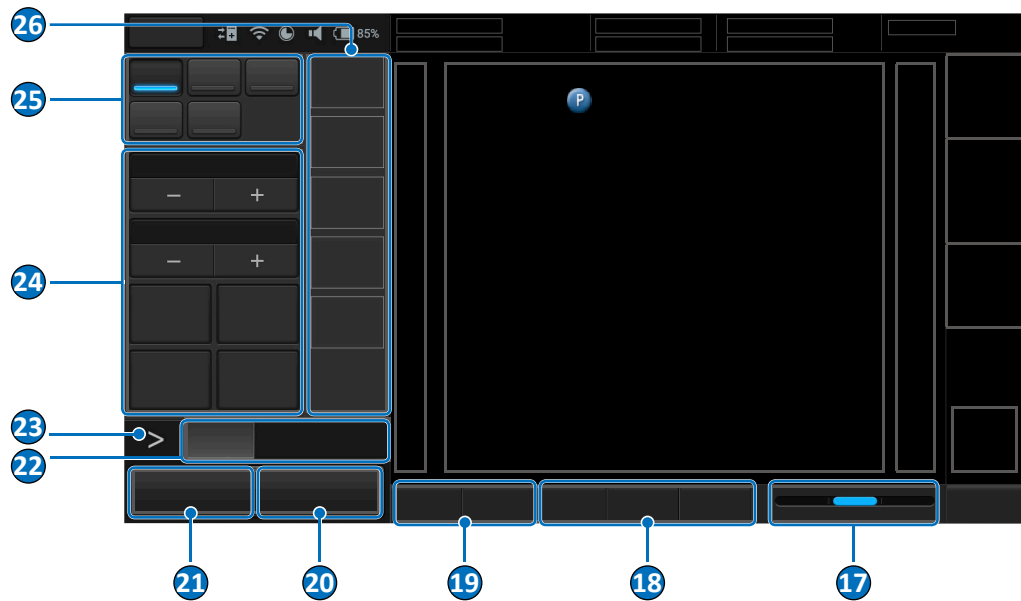




Figure 4 Real-time imaging screen (example)

No.	Function	No.	Function
17	Adjust the overall resolution. <ul style="list-style-type: none"> • Res (High Resolution): Drag the cursor to the right for a clearer yet superficial image. • Gen (General resolution): Drag the cursor to the middle for a general resolution image. • Pen (Deep Penetration): Drag the cursor to the left for a deeper yet less clear image. 	18	<ul style="list-style-type: none"> • Home button: Return to the 2D real-time imaging screen. • TGC (Time Gain Compensation): Slide any of the 8 TGC sliders to adjust the gain for the desired section of the 2D image. • iScan button: Touch this button to enable optimizing the image quality during a real-time scan. To turn it off, touch and hold the button.
19	Fn.Key1/Fn.Key2 buttons Assign each of these buttons as a shortcut to perform a function. The Fn.Key2 button is available only in real-time imaging modes.	20	 Acquire button** Save a default set of image frames as a loop to the system hard drive.
21	 Freeze button Freeze the current scan.	22	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 — 24.
23	Open the next page of the image control settings (See page 62).	24	Image control settings*** (See page 81)
25	Scan mode buttons	26	Thumbnail area Thumbnails of the scanned images or loops that are saved. Swipe vertically to scroll through the list.

*To manually hide or show patient information on the imaging screen, touch and hold on the patient name and ID area for selection.

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

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

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.

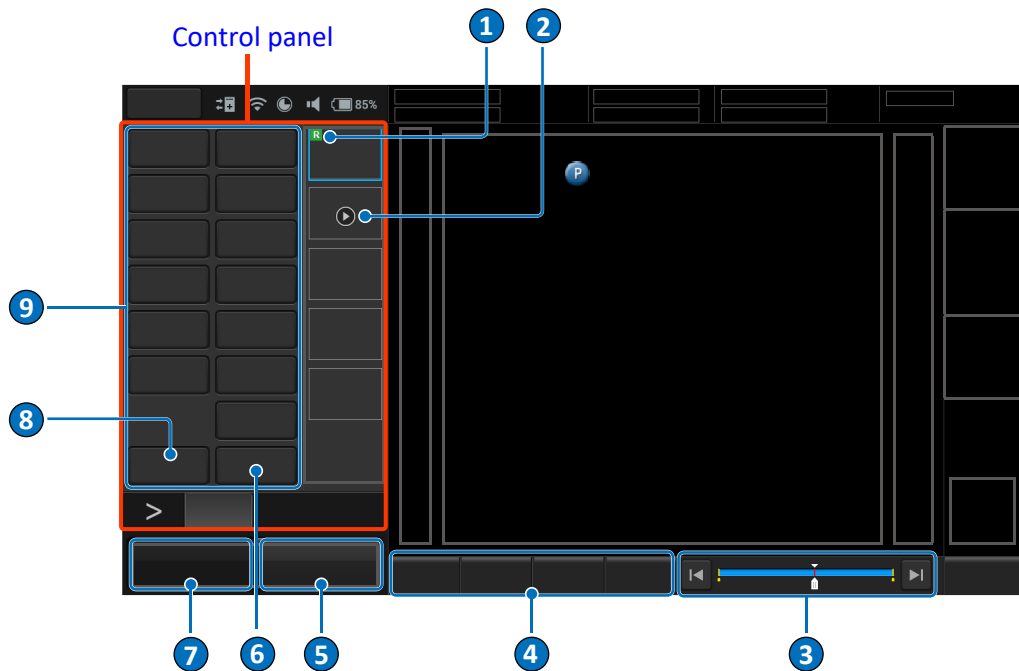




Figure 5 Frozen imaging screen (example)

No.	Function	No.	Function
1	This image is added to a report.	2	Cine loop
3	The progress bar Used to track the frames (in a continuous cine loop) just scanned and the number of the current frame.	4	Depending on the scan mode selected, the following buttons may be available: <ul style="list-style-type: none"> • Fn.Key1 button: Assign this button as a shortcut to perform a function. • Set Start button: During playback of the cine loop, touch this button to set the start point of the cine loop. • Set End button: During playback of the cine loop, touch this button to set the end point of the cine loop. • Speed button: Adjust the playback speed. • Home button: Return to the 2D real-time imaging screen.
5	 Acquire button Save a frozen image from a cine loop to the system hard drive.	6	Play button Review the cine loop just scanned. Touch repeatedly to start and pause the playback.
7	 Freeze button (Enabled) Touch this button again to return to the real-time scan.	8	Report button Generate a report from the current scan.
9	Perform measurements and calculations on the current image. Then, add annotations, including arrows, texts and body marks, to the current image using the virtual keyboard .		

System Tools

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

















Item	Function
Date and time section	Set current date and time. (See page 55)
	Enable or disable the Wi-Fi function. (See page 64)
	Enable or disable the Bluetooth function. (See page 64)
	Cast the system screen to an external display. (See page 66) <ul style="list-style-type: none"> : Cast Display Off : Cast Display On
	Manage the LAN connection. (See page 63) <ul style="list-style-type: none"> : LAN Disconnected : LAN Connected
	Display the percentage of the system storage used. (See page 63) <ul style="list-style-type: none"> : Storage usage empty : Storage usage full
	Check and manage outgoing queues to the DICOM server. (See page 66) <ul style="list-style-type: none"> : DICOM Disconnected : DICOM Connected
	Adjust the volume.
	Adjust the brightness.

Table 6 Functions available on the system tools menu

Virtual Keyboard

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



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

Scan Properties Display


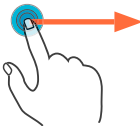





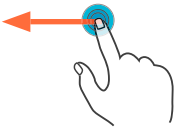
The scan properties display includes information about the current scan in the upper right corner of the display. (See “Chapter 7 Using Image Controls” on page 81)

Switching the Control Panel Pages

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



- The functions available on the control panel vary, depending on the scan mode selected and the transducer connected.
- The following buttons and gestures serve when the control panel is docked to the left side of the screen (default). If you re-locate the control panel to the right ([See page 89](#)), the buttons and gestures work in a reverse horizontal direction.






Action	Use Button	Use Gesture
Open the next page (page 2)		
Display more functions (page 3)		
Return to the previous page (page 2)		
Return directly to the first page (page 1)		





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 62](#)) 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.

Battery status icon	Meaning
	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.

Suspend Mode

Suspend 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 or exit Suspend mode, press the Power button.

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 tools 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 performed before selected number of weeks. Please back up required patient information before deletion. Deletion will remove the information from the system.

Network Configuration

The system network is configured from the system tools 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 network connection cable to the wall receptacle for your network.
2. Connect the other end of the cable to the Ethernet receptacle on the system.
3. To go to the Ethernet settings, open the system tools menu ([See page 61](#)) and touch , or touch **Menu > Settings > Networking > Ethernet Configurations**.

4. 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.
5. Touch **Ethernet configuration**. Touch **Static IP** and configure the DNS settings.




Consult your network administrator about the appropriate settings.

6. 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. Perform either of the following operations to go to the wireless network settings:
 - Touch **Menu > Settings > Networking > Wifi Configurations > ON**.
 - Open the system tools menu (See page 61). Touch  to enable the wireless network function, then touch and hold this button.
2. 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.


3. 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 5 meters.

1. Perform either of the following operations to go to the Bluetooth settings:
 - Touch **Menu > Settings > General > Bluetooth > Edit**. Then touch **ON** to enable the Bluetooth function.
 - Open the system tools menu (See page 61). Touch  to enable the Bluetooth function, then touch and hold this button.
2. The system scans for and displays the IDs of available Bluetooth devices within range.
3. Touch the ID of the Bluetooth device to pair with it.
4. Confirm the passkey that appears and touch **Pair**. On the other Bluetooth device, accept the identical passkey for pairing.

5. 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 (Version 3.0). 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.
- The system is not IHE certified.

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

Modality Interface

DICOM standard. The DICOM conformance statement for InnoSight is available at this website:

<https://www.usa.philips.com/healthcare/resources/support-documentation/dicom-third-party-venture>

Adding Servers

1. Select a storage or worklist SCP (Service Class Provider) and touch **Edit**.
 - **Storage SCP:** Used to take responsibility for and provide receipt of content sent by the system.
 - **Worklist SCP:** Contains 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.



- 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 or a cine loop to the DICOM server, you can monitor its status on the upper right side of the imaging screen or in the outgoing queue (from **Menu > Settings > DICOM > Outgoing Queue > Edit**). To export exams and images to an external storage or a network drive, please see “Exporting the Exam” on page 78, “Exporting Exams” on page 79 and “Network Drive” on page 89.

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 .

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 a task from the outgoing queue, touch ; to clear all tasks from the outgoing queue, touch **Clear all history**.





Setting SCP Data Encoding Type

When querying the DICOM worklist server, you may need to set the SCP code page.

Touch **Current SCP Data Encoding**, and select an option.



Casting the System Screen to a Remote Display

With the system’s built-in casting function, you can mirror the system screen to a network-enabled display remotely.

1. On your system, open the system tools menu (See page 61). Touch  to enable the wireless network function.
2. To go to the screen mirroring settings, touch  from the system tools menu, or touch **Menu > Settings > General > Cast Display > Edit** on the imaging screen.
3. On the top right corner of the system screen, touch  and check **Enable wireless display**  to see your available wireless display devices in a list. Touch the device to connect to.
4. On the display device, follow the on-screen instructions to give permission for connection from and to the system.
5. If connected successfully, the device name on the system screen shows “Connected”. The contents shown on the system screen are mirrored to the display device screen automatically.

To disable the casting display function:



1. On the system, open the system tools menu, and touch .
2. Directly touch the device name > **Disconnect**, or touch  > **Forget**.

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 or paused exam.
 - Add a new patient to start a new patient exam (See page 67).
 - Load a worklist (See page 68).
 - Resume a previously saved or paused exam (See page 78).
2. Select an exam type and preset (See page 68).
3. Start real-time imaging (Imaging screen (Real-time)).
4. Set the transducer orientation (See page 69).
5. Select a scan mode (See page 69) and adjust image controls (See page 81).
6. When the desired anatomy is shown, freeze the image (Imaging screen (Frozen)).
7. Add annotations (See page 71) and measurements (See page 72).
8. Save or print the image (See page 76).
9. (Optional) Review the images (See page 77), generate a report and export the exam (See page 78).
10. End the exam (See page 79).

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. You can enter the Patient screen to complete the patient information during or after the exam. However, once you touch **Acquire** to save images or cine loops, the system will add a last name and ID to the patient automatically, which can be modified once only from the Patient screen.




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

Adding a New Patient



If the **Auto-create Patient Name and ID** function is enabled from **Menu > Settings > Patient**, a set of patient ID and Last Name will be added automatically upon starting a new exam with a new patient.

1. On the imaging screen, touch **Menu > Patient** to open the Patient screen.
2. Touch **New Patient** and type the patient information in the text entry fields.
 - » To go to the next field, touch **Next**.
 - » To finish and close the keyboard, touch .



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

3. The system saves patient information automatically when you touch **Start Exam**.

Updating Patient Information



The patient **ID** and **Last Name** can only be modified once. And, after you modify them, the complete patient information is considered fixed and can no longer be changed, except information related to exams.

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 65](#).

1. On the imaging screen, touch **Menu > Worklist** to open the 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# / Date** 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**.
2. If the multiple transducer module is connected to the system, all the transducers connected to the module appear on the Preset screen. Touch a transducer to display its compatible presets. If the multiple transducer module is not connected, proceed to the next step.
3. 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 customized preset, 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** > the switch on the preset.
- To further edit customized presets, touch **Edit**. 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** to export customized presets to your external storage, or touch **Import** to import customized presets from your external storage.

Setting the Transducer Orientation

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

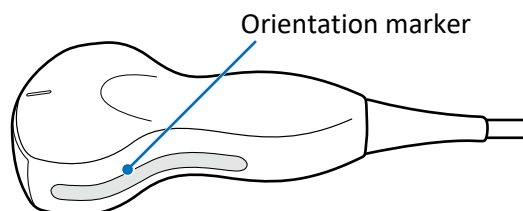


Figure 6 Transducer orientation (Example transducer: C6-2)

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

- To reverse left and right
On the imaging screen, touch > > L/R.
- To reverse up and down
On the imaging screen, touch > > U/D.

Selecting a Scan Mode

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



To view a list of available scan modes, see [“Imaging” on page 25](#).

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 81)

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, frozen or review), use the zoom function.

1. On the imaging screen, touch **Zoom**. The ROI (Region of Interest) box appears on the center of the image.
2. 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.
3. Touch anywhere outside the ROI box to enlarge the selected area.
4. To move the enlarged area, touch and hold anywhere on the image until the navigation button appears, 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 real-time imaging screen, touch **Dual**. The system immediately freezes the current scan, and copies the current settings for the image to the second screen. Two yellow bars will be added to the top and bottom of the currently active screen. To toggle between screens, touch **Toggle**. Only one screen can be active at a time. You can compare then apply any image control settings and use scan modes independently to either screen. For example, you can acquire a 2D scan, activate dual screen, then acquire a Color scan in the second screen.

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




On the real-time 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. 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**, or touch **Home** to return to the real-time 2D mode.



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

Adding Annotations

On the real-time, frozen or review imaging screen, you can add annotations to the ultrasound images in order to explain the anatomy. After you are done adding annotations, you can still move the annotated texts or arrows anytime by touching and dragging them to the location you want.



- 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 > select an option.**
- To delete annotations, including texts and arrows, touch **Erase Annot** to erase the last annotation added. Repeat this action, if needed, to continue erasing annotations.
- To directly erase all annotations, touch and hold **Erase Annot**.
- To set whether to show all or the last annotations, or to hide them all, touch **Show Annot +/-**.

Arrow


1. Touch **Arrow**. An arrow appears at the text home position.
2. Touch anywhere on the imaging area, and drag the arrow to the location you want.
3. Release your finger to place the arrow. The arrow then turns green.
4. Touch anywhere on the imaging area and drag to rotate the arrow.
5. Release your finger to place the arrow. The arrow turns yellow and is fixed.

Text

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

Setting the Text Home Position


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

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

Label

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



- The annotated texts or text labels are still editable. Touch a set of texts to display the virtual keyboard, and start editing the texts. Touch anywhere on the imaging area to finish editing.
- To restore the annotated texts or text labels to the default text home position, simply touch a set of texts, touch  to close the keyboard, then touch **Go home**.
- You can change the default Label list by going to **Menu > Settings > Annotation > Label List**.

Body Mark

1. Touch **Body Mark** to display the **Body Mark** menu.
2. A pictogram of the default body mark with a transducer indicator displays on the image. If you wish to change the body mark, select one from the **Body Mark** menu.

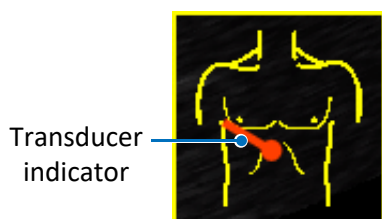


Figure 7 Pictogram of the body mark (example)

3. Touch anywhere on the image, drag the transducer indicator to the location you want on the body mark and release it.
4. Touch anywhere on the image, drag to rotate the transducer indicator, then release it.
5. Touch and hold the pictogram, and drag it to the location you want on the image.









- You can change the default body mark and body mark list by going to **Menu > Settings > Body Mark > Default Body Mark for Application and Body Mark List**.
- To delete the body mark added, touch **Body Mark > Erase**.

Adding Measurements

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

On the real-time imaging screen, touch **Freeze** to display the a set of measurement buttons based on the scan mode selected. To perform a single type of measurement, touch the corresponding button. To perform a set of predefined measurements from the Calculation Package, touch **Calc** (See “Calculation Package” on page 74).

Measurement type	Reference page	Measurement type	Reference page
Distance 	(See page 73)	Depth 	(See page 73)
Ellipse 	(See page 73)	Trace 	(See page 73)
Angle 	(See page 74)	IMT 	(See page 74)

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

- Two-finger tap on the scan area
 - Proceed with the next measurement
 - Touch **Acquire** to save the ultrasound image
-
- To re-position the measured results to any of the imaging screen's four corners, 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 >** select an option.



Measuring in 2D, Color and 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.

Depth

Measure depth.

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

Ellipse

Measure a circumference.

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

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.

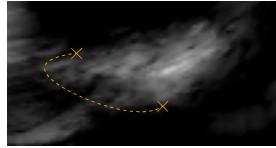


Figure 8 Trace an outline

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.

Angle

Measure an angle.

1. Touch **Angle**. A crosshair cursor appears on the image. Drag the target cursor to the location you want and release it to set the start point of measurement.
2. Drag the first target cursor to the origin of the desired angle, and release it to draw the first line.
3. Drag the second target cursor to create the second line extending out from the origin point, and release it to place the end point of measurement. The angle between the two lines is then formed.


IMT

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

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

Calculation Package

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

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

For measurement accuracy and precision in 2D measurement:



- Linear distance measurement errors will be less than $\pm 9\%$.
 - Perimeter, and ellipse circumference measurement errors will be less than $\pm 10\%$.
 - Area measurement errors are related to the linear distance measurement and will be less than $\pm 10\%$.
-

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 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. The measured result from the start point to the end point should include only the variation in the peak-to-peak interval over one complete cardiac cycle.

Measuring in Spectral Doppler Mode



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

Velocity

Measure the blood flow velocity.

Touch **Velocity**. A crosshair cursor with vertical axis appears on the time series window. Drag the cursor to the measurement point, and release your finger to place a sampling marker (triangular arrow).

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. Adjustment of the measurement is still possible by repositioning the peaks (peak systole) and trough (end diastole). Touch any of the sampling markers (triangular arrows) you wish to reposition, touch anywhere on the imaging area and drag to move the marker, then release it and the measured result is re-calculated accordingly.

You can also decide your spectrum trace on only above or below the baseline of the Doppler waveforms. Touch **High Q Direction +/-** to select a desired option.



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

Trace

Manually trace the Doppler spectrum.

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



If heart rate is not required for this tracing, you can skip step 3 by two-finger tapping anywhere on the imaging area after step 2 is done.

2-Points Measurement

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

1. Touch **2-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 $\pm 12\%$.

Saving and Printing the Image

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

Saving a Cine Loop

On the real-time imaging screen, touch **Acquire** to save a default set of frames as a cine loop. The saved cine 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 imaging screen, swipe vertically on the thumbnail list to view the thumbnails of all the saved images and loops. To further examine one or a set of images and cine loops, touch the thumbnail of the desired image or cine loop to display the Review screen. Alternatively, you can enter the Review screen anytime by touching **Menu > Review**.

Performing Multiple Selections

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

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

Comparing Images

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

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

Generating a Report

1. On the Review screen, touch the thumbnails of the desired images and touch **Add to Report**.
2. Touch **Report** to display the Report screen.
3. Select a template to apply to the report from the drop-down menu next to **Template**.
4. Type in information about the study and add comments.
5. Swipe down to review the images added, and add comments to individual images, if needed.



To add or remove images to or from the report without returning to the Review screen, touch **Image List** and select or deselect the images.

6. Touch **Image Layout +/-** to select the numbers of columns for placing the images on a report.
7. Touch **Export**. Select a preferred file format, then select to export the report to an external storage device, a network drive, a Bluetooth device or the DICOM server (image files only).

8. To print out the entire report with scanned images, first touch **Print Preview** to preview the report, then touch **Print**. Or, you can skip preview by directly touching **Quick Print**.



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

To print out the report with images only, touch **Print Images > Print**. To print out the report in texts only, touch **Print Calc > Print**.

Exporting the Exam

You can export exams and images to an external storage, a network drive 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.

- The system provides the following ways of exporting the exam:
 - On the Review screen, touch **Export Exam**.
 - On the Exam List screen, check the exams and touch **Export Exam**.
 - On the Report screen, touch **Exam List** to go to Exam List screen. Check the exams and touch **Export Exam**.
- Select to export the exam in DICOM file format to the DICOM server, an external storage device or a network drive, or to export as PC formats or raw data to an external storage device or a network drive. (See [“Exporting Exams” on page 79](#))




- To enable exporting an exam to DICOM automatically after ending the exam, go to **Menu > Settings > Workflow > Export to DICOM server after End Exam**.
- The system limits the export of image files via Bluetooth to devices compatible with HID and OBEX profiles only. For detailed Bluetooth pairing process, see [“Connecting the System to a Bluetooth Device” on page 64](#).
- A report will be generated automatically upon exporting an exam if you have enabled this feature: **Menu > Settings > Workflow > Export exam with report**.
- To configure DICOM settings, see [“DICOM Configuration” on page 65](#).

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 and cine loops of an exam, touch .

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

Alternatively, you can enter the query in any of the **Name/ID/Date** fields, and touch  to start the query.

Patients matching the query will be listed on the screen. To clear all search criteria, touch .

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 Exam** to delete exams.

Exporting Exams

1. Multi-check the exams and touch **Export Exam**.
2. Select the file format you want the exams to be exported as: **DICOM**, **PC** (image or cine loop) or **Raw Data**.
3. Select the destination you want the exams to be exported to: DICOM server (for DICOM files only), Bluetooth devices* (for image files only), external storage or network drives. If the exams are exported successfully in DICOM or PC formats, the  icons are shown next to the checkboxes of these exams.


*Only Bluetooth devices that support HID and OBEX profiles are permitted to receive image files from the system.

Importing Exams

To import exams from the connected external storage, touch **Import Exam** > select the import items. If the import is successful, the  icons are shown next to the checkboxes of the imported exams. Only exams in raw data format can be imported to the system.

Ending the Exam

An exam is not complete if you proceed with a new exam without ending the previous one. To end the exam, touch **End Exam** on the imaging screen. The exam will then be exported in DICOM file format to the DICOM server if you have enabled this feature (See “Export DICOM after End Exam” on page 90). If this feature is disabled, you will enter the Patient or Worklist screen or a new scan starts automatically, based on your selection from **Menu > Settings > Workflow > Screen after End Exam**.

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



- To export exams to the DICOM server, you need to configure the DICOM settings first. (See “DICOM Configuration” on page 65)
- To check the exam status, touch **Menu > Exam List**. (See “Managing the Exam List” on page 78)

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 71](#) and [“Adding Measurements” on page 72](#).

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 **>>** or use gestures 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.

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 swipe horizontally on the imaging 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 or decrease the gain at the desired section (depth) of the image, drag the corresponding slider to the right or 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 swipe vertically on the imaging area to set the scan depth.

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.

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.

Using Tissue Harmonic Imaging (THI)

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

Touch **THI** to enable this function.

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 **2D Size +/-** to adjust the width. Touch **2D Position +/-** to adjust the position.

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.

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.

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** to enable spatial compounding.

Using Central Line

Display a dotted line drawn in the center of the transducer as a reference.

Touch **Central Line** to enable this function.



The C9-4v transducer does not support the central line display.

Using iScan Imaging

Optimize the scanning parameters automatically for the current image.

Touch **iScan** to enable this function.

Using Biopsy

Display biopsy guidelines which are intended for directing needles into a target location when you perform biopsies. For detailed instructions, see [“Chapter 9 Performing a Biopsy” on page 97](#).

Touch **BIOPSY** to enable this function.

Using Quad View

In obstetric imaging, the system provides the quad view function to work with the Amniotic Fluid Index (AFI) measurement.

1. On the real-time 2D imaging screen, touch **Quad View**. The screen is then divided into four quadrants with the first live image appearing on the upper left one.
2. When the deepest and unobstructed vertical length of this pocket of fluid is seen, touch **Toggle** to freeze the current image and proceed to the next quadrant of scan. Repeat this step until all four quadrants of images are acquired.



During quad-view imaging, you can still adjust the gain or scan depth by swiping horizontally or vertically, or enable the color view by touching **Color** to any of the four images.

3. Touch **Toggle** again, and the default AFI calculation method under **Calculation Package** menu displays automatically. Follow the list of items to perform and complete measurement. The sum of the measured results, the AFI values, then appear on the screen.
4. To leave the quad view, touch **Freeze**.

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 dotted green line shows in the Imaging window. The point of the needle should be close to vertical to the dotted line. The part of the needle image that goes beyond the limit will not be brightened and may not be visualized. Touch **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.

Color and 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.

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

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.

Selecting a Color Map

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

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

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.

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

Drag the M-line to the target position to determine the presence of motion occurred along the singular line. Touch  to initiate the M-Mode trace which produces a scrolling display of movement (along the vertical Y axis), plotted against time (along the horizontal X axis).

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. When you enable this function, the system automatically reduces the 2D image size to increase the resolution of the motion scan. This function is particularly useful in cardiology applications.

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

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 +/-** to select a desired method.

Inverting the M-Mode Trace Display

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

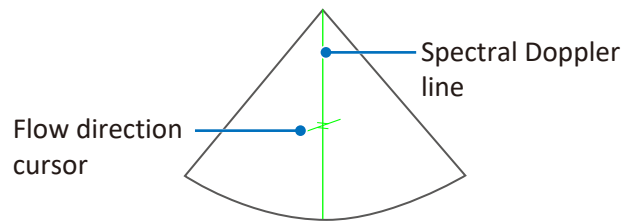
Touch **Video Invert** to swap the colors on the M-Mode trace display.

Spectral Doppler Mode Image Controls

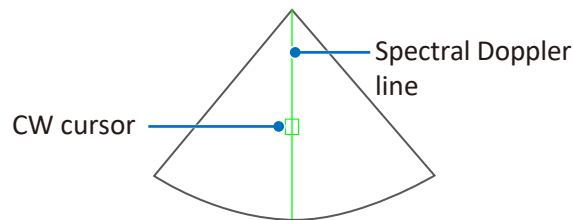
Overview

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 and CW modes display scan data of the anatomy in the 2D Imaging window for monitoring the exact location of the sample volume, and display the PW and 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 line), called the sample volume or range gate. A short line across the sample volume is called the Flow Direction cursor. This cursor line should be aligned to the blood flow direction when measuring the flow velocity. Drag the Spectral Doppler line horizontally and the sample volume vertically to the target position to determine the presence of blood motion.



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



Adjusting Baseline

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

To adjust the baseline:

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

Adjusting Sample Volume (SV) Size

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

To adjust the SV size:

- Touch **SV Size +/-**.
- Touch and hold one finger on the Spectral Doppler line, then swipe 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.
- Touch **Angle +/-** to adjust the angle to the desired value.
- To manually adjust the angle, touch and hold one finger on the Spectral Doppler line, then swipe another finger to the left or right.

Adjusting Cursor Steer

Adjust the angle of the Spectral Doppler line to increase or decrease its steering angle. This function is available only with the L12-4 transducer.

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

Updating the 2D Display

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

Touch **Duplex** or **Triplex** to enable or disable this function.

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

General

- **Dock Control Panel at:** Set the control panel on the left or right side of the screen.
- **Enable freeze gesture:** Enable double-tapping the screen to freeze the real-time scan.
- **Bluetooth:** Connect the system to another pointing or input device via Bluetooth. (See [“Connecting the System to a Bluetooth Device” on page 64](#))
- **Cast Display:** Cast the system screen to a remote display. (See [“Casting the System Screen to a Remote Display” on page 66](#))
- **Date & Time:** Set the system date and time. (See [“Setting the System Time and Date” on page 55](#))
- **Language:** Set the system language, and the system restarts automatically. (See [“Setting the System Language” on page 57](#))
- **Beep after acquire completes:** Set whether the system makes a beep sound after acquiring images or loops.
- **Enable virtual keyboard while physical text input device is connected.:** Set whether to show the [virtual keyboard](#) once a text input device, such as keyboards, is connected to the system through the USB 2.0/3.0 ports (See [“Front and Side Views” on page 27](#)).
- **Network Drive:** Set up the configuration information of a network drive to which you wish to send data from the system. Touch **Edit** and enter the IP address, name and password of the network drive, and the full path to the shared folder. To check the connectivity, touch **Test** in the **Connecting Test** section.

Preset

- **Default preset and Preset list:** Set the default preset and re-arrange the preset list on the Preset screen. (See [“Managing Presets” on page 69](#))
- **Export preset or Import preset:** Export or import customized presets to or from your external storage. (See [“Exporting and Importing Customized Presets” on page 69](#))

Patient

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

Exam

- Add logos for institutions.
- Add names for institutions, operators and exported exam folders.

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

Workflow

- **Screen after Enter Ultrasound:** Select the screen to enter after starting or logging into the system.
- **Auto-freeze after Minutes:** Set the number of minutes of waiting before the scan is frozen automatically.
- **Status after Freeze:** Assign the first action to perform after freezing the scan.
- **Show M/D Cursor for current preset:** Display M-Mode and Doppler cursors when scanning in 2D, Color and CPA modes to help locate the target position.

Body Mark

- **Auto-clear Body Mark after Unfreeze:** Enable clearing all the body marks 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 to DICOM server after End Exam:** Enable exporting the exam in DICOM file format to the DICOM server automatically after touching **End Exam**.
- **Export to DICOM server after Acquire:** Enable exporting the exam in DICOM file format to the DICOM server automatically after touching **Acquire**.
- **Export exam with report:** Enable generating a report automatically upon exporting an exam.

Print

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

Function Key

The system provides function (configurable) keys for quick access to your frequently used actions. Assign a desired action to a function key, and edit its name.

Imaging

- **Auto Focus by following CROI:** Enable re-positioning focus to the center of the ROI automatically when moving the ROI on the image in real-time Color and CPA modes.
- **Auto CROI by following SV:** Enable re-positioning ROI to keep the sample volume in the center of the ROI when moving the sample volume on the image in real-time 2D+Color/CPA+PW/CW modes.
- **Auto Zoom-in Image for PW/CW Mode and Auto Zoom-in Ratio:** Enable zooming-in images automatically with the assigned ratio upon entering PW and CW modes. To change the zoom ratio, select a desired percentage.

- **Exported Image Format:** To export a particular format of image (bmp, png, jpg), select the format before exporting the images.
- **Cine Loop Length in Seconds (Length may vary depending on frame rate):** Set the cine loop length for each recording.
- **PW Output Unit or CW Output Unit:** Set the velocity display unit in PW or CW modes.
- **HPRF:** Enable this function (High Pulse Repetition Frequency) to measure higher velocities in PW mode by allowing an increase in the sampling frequency.

Display Layout

Set the aspect ratio between the 2D imaging window and the time series window on the imaging screen in M-Mode, PW and CW modes.

Annotation

- **Annotation Font Size and Arrow Size:** Select a desired size.
- **Label List:** Select an application and check or uncheck each label to re-arrange the label list.
- **Show Labels by Application:** Enable showing only labels relevant to the application in use.

Body Mark

- **Default Body Mark for Application:** Select an application and touch a desired body mark to set it as default.
- **Body Mark List:** Select an application and enable or disable each body mark to re-arrange the body mark list.
- **Show Body Marks by Application:** Enable showing only body marks relevant to the application in use.

Measurement

- **User-Defined Measurement or User-Defined Calculation:** Select a measurement or calculation mode to display available measurements or calculations. Select an existing or create a new measurement or calculation and use the editing tools to modify its properties.
- **Calculation Configuration:** Select an application from the **Calculation Package** to display available calculations below. To display or hide the calculation result after a set of measurements are done, check or uncheck the calculation name. If you select **OB**, more than one calculation method can be used in a calculation. Select the **Author** name to your desired method or formula.
- **Calculation Menu:** Customize the calculation options available for measurement under each mode.
- **Show Calculations by Preset:** Enable showing only calculations relevant to the application in use.
- **Result Unit and EFW Result Unit:** Set the measurement unit.
- **Caliper Size and Set Result Font Size:** Select a desired size.
- **Show Measure Line:** Enable showing the measuring lines after performing a measurement.
- **Show Mean Velocity Trace Line of Doppler Waveform:** Select whether to show or hide the mean velocity trace line when tracing the spectrum of Doppler waveforms.
- **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.
- **WaveTrace/HighQ Results Configuration:** Set which items of the measured results to show after tracing an image.

Report

- **Default Report Template:** Select an application and set its default report template based on the preset selected.

- **User-Defined Template:** Select a report template and use the editing tools to modify the fields within the template.
- **Built-in Prompt String, Built-in Finding String and Built-in Comment String:** Edit or add built-in strings used in the report.
- **Report Display:** Select the display type of the **Calculation Package** in the report.
- **EFW Percentile Author:** Select a desired author.
- **Growth Curve and Gestational Age Data:** Select a data type and use the editing tools to modify its figures or formulas.

DICOM

Configure DICOM settings. For more information, see [“DICOM Configuration” on page 65](#).

Networking

- Display the network connection status of the system in the window below.
 - » **Current Status:** The IP address currently connected.
 - » **Detailed Status:** All IP addresses and MAC addresses.
- Configure the system network.
 - » **Wifi Configurations:** See [“Connecting the System to the Wireless Network” on page 64](#).
 - » **Ethernet Configurations:** See [“Connecting the System to the Network by Ethernet” on page 63](#).

Print

- **Image Printer and Report Printer:** Assign the printer for use when printing images or reports.
- **Network Printing:** Configure printer settings. The IP address of the currently selected printer can be found here. You can select another printer from the **Network Printer List**, if available, or use the **Delete** and **Scan & Add** tools to manage the printer list.
- **Image Color Invert:** Print out the image with colors inverted.
- **Multi-images print layout for image printer:** This option is available only when at least one non-thermal printer is detected by the system. First, select the numbers of images to place on one page for printing. Then, go to the Review screen, touch **Multi-Select +/-** or **Multi-Compare +/-** and select the desired images, then touch **Print**. The selected images will be printed out based on the print layout you’ve chosen.



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

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 administrator will then enter the Admin Settings screen with his or her ID and Name shown in **Menu > Security > Security Policies > Current User**. Use the following settings to manage users and security policies.

Setting Up Security Policies

Applying Restriction Modes

Touch **Security Policies > Access**.

Three restriction modes are available for selection.

- **No restriction (Scanning and patient data are available without a login):** All the system features are available to all users, including the guest users.
- **Only patient data is locked (Scanning is available without a login):** All the system features except access to ePHI information are available to guest users.
- **Complete system is locked (Both scanning and patient data require a login):** None of the system features are available to guest users.

Setting the Password Policy

Touch **Security Policies > Password Policy**.

Enhance the user login security by applying rules to the password, including setting password history, restricting password length, password age (days) and enforcing password complexity (uniqueness).

Setting the Account Lockout Policy

Touch **Security Policies > Account Lockout Policy**.

Set the rules of locking a user account after a specific number of invalid logon attempts, including setting lockout threshold, lockout duration, and counter reset time.

Enabling Auto Log Off

Touch **Security Policies > Auto Log Off**.



Set an automated logout after a specified period of inactivity.

Saving and Resetting Security Policies

After setting up security policies, you must touch **Save** for the policy changes to take effect. To revert security policies to the last saved version, touch **Revert**.

User Management

Modify personal credentials and change roles of the users.

Touch **User Management > User List**. 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 and consultation available from technical support (See “Customer Service” on page 3).

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

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

Reinstalling Software

Use only the supplied USB flash drive with pre-installed software ZIP file for software re-installation. An access key is required. Please contact technical support ([See “Customer Service” on page 3](#)) to obtain your access key. Once provided, please follow the on-screen instructions and allow ten to fifteen 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 ([See “Customer Service” on page 3](#)).

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

Checking the System’s Serial Number


The System Serial Number is the unique Philips’ Customer Identifier and is presented on the *Reference Card*. Please preserve the *Reference Card* and keep it handy.

The number can be backed up and restored on a system by backing up and restoring system settings (see [“Backing Up System Settings and/or Patient Data” on page 95](#) and [“Restoring System Settings and/or Patient Data” on page 95](#)). If a replacement tablet is received and no backup is available to restore from, you will need to enter the system’s serial number. Keep the *Reference Card* safe for future reference.

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

To check your system’s serial number:



- On the system screen, touch **Menu > Settings > Service > System Management > System Information > System Serial Number**.
- Refer to the spec label (see ) on the *Reference Card*.

Checking the Tablet’s Serial Number

List the serial number of the tablet. This is assigned and cannot be changed. Use this number as the default password for first-time-logging-in. ([See “Logging Into the System” on page 53](#))

To check your tablet’s serial number:

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

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 and Imaging License Status**.

Backing Up System Settings and/or Patient Data



- In the event a system issue occurs and a replacement system is required, all configuration settings and patient data may be lost. It is your responsibility to back up data regularly!
- Risks of losing personal data on backup storage devices still occur in the event the system becomes functionally obsolete.



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

1. Touch **System Management > System Configuration**.
2. Touch **Backup** in the following fields:
 - **Full System: > Patient Data and User Account Data:** Save all the system settings, presets and exams to the external storage device. The following file naming convention is applied to the backup file:
Backup_YYYYMMDD_HHMMSS



Backing up the full system requires the administrator's credential.

- **Current User: > System Settings:** Save all the system settings and presets to the external storage device. The following file naming convention is applied to the backup file:
USERNAME_EXPORTED_SETTINGS_YYYYMMDDHHMMSS
- **Current User: > Patient Data:** Save selected exams to the external storage device or the network drive. The following file naming convention is applied to the backup file:
BACKUP_PATIENT_YYYYMMDDHHMMSS

Restoring System Settings and/or Patient Data



The system allows restoring system settings and patient data separately. 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 > System Configuration**.
2. Touch **Restore** in the following fields, and select a backup file:
 - **Full System: > Patient Data and User Account Data:** Restore all the system settings, presets and exams to the system from the external storage device.
 - **Current User: > System Settings:** Restore all the system settings and presets to the system from the external storage device.
 - **Current User: > Patient Data:** Restore all the exams to the system from the external storage device.

Resetting Your System



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

- **Resetting the full system:** Performing this action will restore your system to its factory state and erase all your user settings and patient data from the system storage, except the system serial number and the tablet serial number. Touch **System Management > System Configuration > Full System: > Factory Reset > Erase**.
- **Resetting the system settings only:** Performing this action will restore your system settings to default. Touch **System Management > System Configuration > Current User: > System Settings Reset > Reset**.

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.

Export the test results of the system functionality to the connected external storage device. Your technical support representative will need to be consulted to review the results. ([See “Customer Service” on page 3](#))

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

Exporting Keystroke Logs



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

Export the tracking records of keystrokes to the connected external storage device. Your technical support representative will need to be consulted to review the results. ([See “Customer Service” on page 3](#))

Touch **Keystroke Logs**, select the desired log files, then touch **Export**.

About

View information about your system, including the system’s software version, tablet’s serial number and this *User Manual*.

Touch **About**.

Performing a Biopsy

When you perform medical procedures such as biopsies, the system provides the biopsy feature to aid you in positioning transducers with needle guide attachment. Guidelines are displayed on the image to show the anticipated path of the needle. Use those guidelines to ensure that the needle or instrument is following the correct path.

Prior to performing a biopsy, ensure you have read the instructions for selecting the display, installing the sterile transducer cover and verifying alignment of the needle guide.



Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Philips recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.



The needle guidelines that display on the system monitor are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.



To reduce the risk of injury to the patient, conduct a biopsy procedure during real-time imaging. When an image is frozen, the correct positioning of the needle cannot be assured.



Ensure the accessories for a transducer are properly cleaned as appropriate before each use to avoid possible patient contamination.



- For needle guide kits in sterile packaging: The needle guide kits are packaged sterile and are single-use items. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.
- For needle guide kits not in sterile packaging, follow the instructions in the packages for proper sterilization before their first use.



If a needle guide becomes contaminated with tissue or fluids of a patient known to have Creutzfeldt-Jacob disease, then the needle guide should be destroyed. Sterilization is not effective against Creutzfeldt-Jacob contamination.

Needle Guide Kits



Use only Philips-approved biopsy guides, transducers, covers, brackets, supplies, components, and accessories. Other brands may not properly fit Philips transducers. Improper installation may result in patient injury.



Do not attempt to use a needle guide kit until you have read the instructions for selecting the settings and verifying the alignment of the guide lines. Improper use of biopsy needles can cause injury to the patient. If a needle guide kit is open when you receive it, or if it has been damaged or has condensation inside, do not use it. Contaminated medical equipment can cause patient infection.



Inspect all components and the transducer. Ensure that the biopsy guide you are using is the correct one for the transducer, the system, and system software. If you have problem identifying these items, contact technical support ([See "Customer Service" on page 3](#)).

A needle guide kit contains several parts that fit together to attach the needle to the transducer and provide a guide that directs the needle into the patient. Two types of needle guide kits, the starter kit and the procedure kit, and other supplies are available from CIVCO Medical Solutions (See “Supplies and Accessories” on page 2).

The starter kits contain the reusable biopsy guide bracket and sterile procedure kits that you need to perform a biopsy. The procedure kit contain only disposable parts, including the biopsy guide. After the first time, you must use a new procedure kit each time you perform a biopsy. Different needle guide kits are required for each type of transducer. The following table lists the Philips transducers that can be used to perform biopsies, and lists the matching starter kits that must be ordered for each transducer.

Transducer	Needle Guide kit
C6-2	Civco 667-075
L12-4	Civco 667-106
C9-4v	Civco 667-114

Table 7 Transducer needle guide kit numbers



To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose of hazardous or infectious materials according to local, state, and regional regulations.



Prevent heat damage to needle guides. Keep them below 50°C (122°F).

Displaying the Biopsy Guideline



Do not attempt to use the needle guide until you have read the instructions for selecting the display, installing the sterile transducer cover and verifying alignment of the needle guide.

The system generates biopsy guidelines that are displayed on the image to show the anticipated path of the needle. Use those guidelines to ensure that the needle or instrument is following the correct path. The biopsy guidelines are two parallel, dotted lines, which indicate the most typical path of the needle when the appropriate hardware is used. A needle-length crosshair cursor also appears with the needle-length value shown above the image. When the depth is changed and the cursor is no longer positioned in the boundaries of the images, it moves to the new edge of the image and its value changes accordingly.

Assembling the Biopsy Bracket and the Needle Guide

Each transducer works with only one bracket. Before performing a biopsy, you must assemble the needle guide parts and prepare the transducer for the biopsy. Follow the procedure provided in the biopsy kit to assemble the bracket and the needle guide. For detailed instructions, visit the CIVCO website: www.civco.com.



Use only the ultrasound transmission gel supplied by or recommended by Philips. (See “Ultrasound Transmission Gels” on page 109).

Verifying the Alignment

To ensure that the transducer and biopsy attachment are accurately aligned, and that the needle path is within the stated specification, perform the alignment verification before each use of the biopsy attachment. To conduct this verification, you must have an assembled biopsy bracket, a needle guide, a new and straight biopsy needle, and a water tank (or an ultrasound phantom). Use 2D imaging to verify the alignment, and do not use the **Zoom** tool. The needle guides do not show on zoomed images.

To verify the alignment of the transducer and biopsy attachment:

1. Assemble the bracket, the needle guide and other needle guide parts (if applicable) following the procedure provided in the biopsy kit.
2. On the system, select the appropriate preset and set the system depth for the procedure to be performed.
3. Touch **BIOPSY**. The biopsy guidelines and the needle length crosshair cursor appear on the Imaging window. The distance between the guideline is fixed at 1 cm.
4. Move the needle length crosshair cursor to the middle of the image, and then note the needle length value displayed above the image.
5. Select a new, straight needle that matches the needle-gauge size on the needle guide or needle guide clip you are using (if applicable), and use **BIOPSY Angle** (A, B, and so on) to select the matching guide channel angle setting (if applicable).
6. From the tip of the needle, measure a distance equal to the value noted in step 4. Mark this point on the needle.
7. Insert the needle into the biopsy guide.
8. Move the needle down into the water tank (or Phantom) until its ultrasound image is visible on the display. Ensure that you do not touch the side or bottom of the water tank (which can bend the needle and produce an inaccurate reading).
9. Continue sliding the needle in, until the mark on the needle aligns with the biopsy guide stop. (The biopsy guide stop is the point at which the needle enters the biopsy guide.)
10. Move the needle-length crosshair cursor to the tip of the needle, as seen on the display, and verify that the displayed depth is within 1 cm of the value noted in step 4.
11. Confirm that the needle appears clearly between the two guidelines. If so, then the biopsy alignment is completed.

Performing a Biopsy Procedure

When all of the preparatory steps are complete, and you have recently verified the alignment ([See page 99](#)), perform the biopsy on the patient. Note the following warnings that pertain to the biopsy procedure.



The biopsy guidelines indicate only the expected path of the needle. Verify the actual needle position by identifying the echoes from the needle.



For each procedure, use a straight, new needle. Using a bent needle, or re-using a needle, can injure or infect the patient.



If the needle enters from the unexpected side of the display or cannot be seen, verify that the biopsy guide is correctly mounted on the transducer and that the orientation of the transducer is correct. If the needle is still not following the expected path along the guideline, do not use the biopsy guide. Contact technical support ([See “Customer Service” on page 3](#)).



If any item from the needle guide kit is damaged during operation, the biopsy guidelines shall not be referenced.


The biopsy feature can be used with the following transducers and imaging modes:

- C6-2, L12-4 and C9-4v
- 2D, Color and CPA modes

1. Assemble the bracket, the needle guide and other needle guide parts (if applicable) following the procedure provided in the biopsy kit.
2. Set the system imaging controls for the biopsy procedure.



To display a central line during a biopsy procedure, touch **Central Line**. The C9-4v transducer does not support the central line display.

3. Touch **BIOPSY**. The biopsy guidelines and the needle length crosshair cursor appear on the Imaging window. The distance between the guidelines is fixed at 1 cm.
4. Select a new, straight needle that matches the needle-gauge size on the needle guide or needle guide clip you are using (if applicable), and use **BIOPSY Angle** (A, B, and so on) to select the matching guide channel angle setting (if applicable).
5. Orient the transducer using the orientation icon () to match image presentation.
6. If necessary, apply sterile acoustic coupling gel to the patient.
7. Begin scanning the patient. Position the transducer so that the puncture target is intersected by the guideline on the display.
8. Insert the needle into the biopsy guide.
9. Perform the puncture by sliding the needle through the biopsy guide until the needle intercepts the target.



Do not push strongly to avoid the needle offsetting from the previous path in the tissue.

10. Remove the biopsy guide after use.

Transducer and Bracket Maintenance

The transducer must be cleaned and high-level disinfected between patients. For detailed instructions, see [“Chapter 11 Transducer Care” on page 105](#).

The biopsy procedure kit components are disposable and must not be reused. For information and instructions on cleaning, disinfecting, and sterilizing the bracket, see the instructions provided with the needle guide kit.

Needle Visualization

When performing a biopsy with the L12-4 transducer, the system provides on-screen needle guides to optimize needle visualization. For instructions, see [“Using ENV \(Enhanced Needle Visualization\)” on page 84](#).

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, 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 11 Transducer Care” on page 105](#).

For all information about the use of acoustic coupling gels, see [“Ultrasound Transmission Gels” on page 109](#).

If you encounter poor image quality or transducer problems, see [“Troubleshooting” on page 113](#).



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 109](#) or [“Chapter 11 Transducer Care” on page 105](#). 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 reflector 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 trans-rectal 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 20](#).



- In intraoperative applications, 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, and a new sterile cover installed.



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.



When using C9-4v endocavity transducers, the transducers must be protected with a transducer sheath. Pull the transducer sheath over the transducer lens until the full contact area ([See page 119](#)) is enclosed with the sheath. Check for and remove wrinkles and air bubbles by pulling the sheath tightly over the cable. Inspect the sheath to ensure that there are no holes or tears. For detailed instructions on utilizing the transducer sheath, refer to the instructions in the packages. To order transducer sheaths, see [“Supplies and Accessories” on page 2](#).

Transducer Storage

Use the appropriate guidelines for storing transducers for transport, and daily and long-term storage. For information on temperature and humidity requirements, see [“Appendix A: Specifications” on page 117](#).

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 and disinfect, the transducers that are compatible with your system. Additionally, these instructions help avoid damage during cleaning and disinfection, which could void your warranty.

Reasonable care includes inspection, cleaning, and disinfection, 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 and disinfection 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 107](#). 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 a 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 damage 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.



- 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. Be sure to follow the manufacturer's instructions when using disinfectants.



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 void 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 or the acoustic window of the transducer.



During cleaning and disinfection, 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.



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 or methods approved by Philips to disinfect transducers. Otherwise, they may 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 2) or visit <http://civco.com/mmi/Contact-Us.htm>.

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 20.

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.



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

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 7](#) and [“Transducer Care and Operator Safety” on page 105](#). After cleaning, you must disinfect 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.

- 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 below 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.

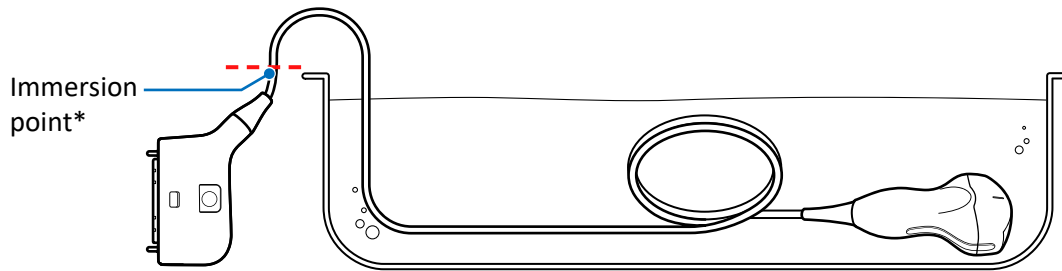


Figure 9 Immersion point for surface transducers (Example transducer: C6-2)

*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.

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

- Clean the transducer and cable according to the procedures in [“Transducer and Cable Cleaning” on page 107](#). Observe all warnings and cautions.
- 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 [“Compatible Disinfectants and Cleaning Solutions” on page 110](#). 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.
- 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.
- Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.
- 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 107](#). 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 [“Compatible Disinfectants and Cleaning Solutions” on page 110](#). 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. 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 ([See page 108](#)) 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 intraoperative applications, use only the Sterile Aquasonic or Sterile Ultraphonic gel provided with the transducer cover.



Do not use hand sanitizing gels.



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



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.

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. Follow the manufacturer's instructions when using the commercially produced ultrasound gels.

Compatible Disinfectants and Cleaning Solutions



- 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.
 - Do not use any ammonia based disinfectants. If used it can cause damage to the plastics or to the system.
-

For disinfectants and cleaning solutions compatible with the transducers available for the system, please visit:

www.philips.com/transducercare

System Maintenance

Maintenance should be performed regularly and as needed.

Cleaning the System

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

For information on transducer cleaning and disinfection, see [“Chapter 11 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 and 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 and 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 112](#)) 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 the touch screen	Disinfectants for system surfaces, including the touch screen	Disinfectants for cart surfaces
Mild soap solution	<ul style="list-style-type: none"> • Mild soap solution • Cleaners designed for touch screens • Purified water 	<ul style="list-style-type: none"> • 70% isopropyl alcohol (IPA) • 75% ethanol alcohol 	<ul style="list-style-type: none"> • 70% isopropyl alcohol (IPA) • 75% ethanol alcohol

Table 8 Disinfectants and cleaning solutions for system and 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 11 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, 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 void 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	<ul style="list-style-type: none"> • Battery fully discharged. <ul style="list-style-type: none"> » Connect the AC power adapter. • Power adapter does not function correctly. <ul style="list-style-type: none"> » 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 35)
The system can't charge or experience short runtime between charges	<p>Power supply is damaged or battery reaches end of life.</p> <ul style="list-style-type: none"> » Allow the battery to charge overnight and check again the battery status. » Contact technical support.
Unsure of a function displayed in localized languages	<ul style="list-style-type: none"> » 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 or write data from the microSD card	<ul style="list-style-type: none"> • One or two USB storage devices are connected to the system at the same time.* <ul style="list-style-type: none"> » Remove all the connected USB storage devices from the system. • The microSD card is damaged. <ul style="list-style-type: none"> » 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 96). This requires assistance from technical support. • The microSD card slot is damaged. <ul style="list-style-type: none"> » Insert another microSD card into the system for inspection.
The system can't read or write data from the USB storage device	<ul style="list-style-type: none"> • Two USB storage devices are connected to the system at the same time.* <ul style="list-style-type: none"> » Ensure the USB storage device you wish to read or write data from is connected to the system through the USB 3.0 port. • The USB storage device is damaged. <ul style="list-style-type: none"> » Insert the USB storage device into a computer for inspection. • The USB ports are damaged. <ul style="list-style-type: none"> » Insert another USB storage device into the system for inspection.
No image or abnormal display on the system screen	<p>The system screen is not functioning.</p> <ul style="list-style-type: none"> » Output the system display to an external monitor (See page 50) and check if images display normally on the external screen. » Contact technical support.

Symptom	Possible cause and corrective action
Image artifacts occur on the imaging screen	<ul style="list-style-type: none"> • Electrical interference occurs. <ul style="list-style-type: none"> » Move the 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. <ul style="list-style-type: none"> » 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 96). 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	<ul style="list-style-type: none"> • The system’s fans are not functioning. <ul style="list-style-type: none"> » Use the diagnostic tools to test the functionality of the fan and the temperature (See “Testing the System” on page 96). This requires assistance from technical support. • Ventilation slots are blocked. <ul style="list-style-type: none"> » 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. <ul style="list-style-type: none"> » Connect the system to power.
The system encounters unexpected shutdowns several times	A system disk error occurred. <ul style="list-style-type: none"> » Reinstall the software (See “Reinstalling Software” on page 94). This requires assistance from technical support.
Touch screen is unresponsive or misconfigured	<ul style="list-style-type: none"> • Touch screen is damaged. <ul style="list-style-type: none"> » Inspect the panel surface carefully for cracks, cuts or any other damages. • Software malfunctions. <ul style="list-style-type: none"> » 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 96). This requires assistance from technical support.
No audio or noise comes from the system speakers	<ul style="list-style-type: none"> • The system is muted. <ul style="list-style-type: none"> » Open the system tools menu and adjust the volume. • The speakers are damaged. <ul style="list-style-type: none"> » Contact technical support.
HDMI does not function	The HDMI cable or port is damaged. <ul style="list-style-type: none"> » Use another HDMI cable for connection. » Connect the system to a computer through HDMI connection for inspection.
Bluetooth connection failed	<ul style="list-style-type: none"> • The Bluetooth settings are not correct. <ul style="list-style-type: none"> » Turn off the Bluetooth function, then turn it back on. • The Bluetooth module is not functioning. <ul style="list-style-type: none"> » 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. <ul style="list-style-type: none"> » Go to Menu > Settings > DICOM > Storage SCP and touch Edit > Test for verification.

Symptom	Possible cause and corrective action
Ethernet does not function	<ul style="list-style-type: none"> • The Ethernet settings are not correct. <ul style="list-style-type: none"> » Contact your network administrator. • The Ethernet cable or receptacle is damaged. <ul style="list-style-type: none"> » Use another Ethernet cable for connection. » Connect the system to a computer through Ethernet connection for inspection.
Wireless connection failed	<ul style="list-style-type: none"> • The wireless device is turned off or not functioning. <ul style="list-style-type: none"> » 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. <ul style="list-style-type: none"> » Open the system tools 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.

Appendices

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 Db output: 77.5dB +- 3dB at 1.0W 0.5M distance
Console		Touch screen
Primary monitor		11.6" 1366x768
Number of transducer connectors		1 transducer connector
Stand		1 stand
Mounting		Capable of quickly docking and releasing on the system cart with default 4 locator pins. (The M4 screw holes for the 4 locator pins are compliant with VESA standard (75mm x 75mm/100mm x 100mm) if removing 4 locator pins.)
Water resistant level		IP22
CPU		Qualcomm APQ8074AB
User Interface Languages		English, Dutch, Traditional Chinese, Simplified Chinese, French, German, Italian, Brazilian Portuguese, Spanish, Russian
Memory		16GB eMMC
Storage		mSATA 128GB SSD ; support up to 512GB
Connectivity		<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Power adapter Input: AC 100 ~ 240V, 50 ~ 60Hz, Max 1.7A Output: +19Vdc, 3.4A • Transducer S4-2, L12-4, C6-2, C9-4v, C83B • SONY UP-X898MD or SONY UP-D898MD thermal printer (optional) • System cart (optional) Support Tilt and Swivel Joints, Height Adjustment, Instant dock and undock function. • Multiple transducer module (optional)* Provide three extra transducer receptacles. • Carry Case (optional)
Storage/transport	Temperature: -20 ~ 60°C Humidity: 20% ~ 95% RH Air pressure: 700 ~ 1060 hPa
Environmental operating conditions	Temperature: 10 ~ 40°C Humidity: 20% ~ 85% RH, no condensation Air pressure: 700 ~ 1060 hPa
Product life	5 years

*The multiple transducer module is not available in all geographies and its availability is subject to local regulatory laws.

Battery

Model: APP00201

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

Item	Rate performance	Remark
Typical capacity	6700 mAh	Constant current and constant voltage » Charge voltage: 12.6 V \pm 0.03 V. Cut off 60 mA » Charge current: 1300 mA » When discharged at 1300 mA to 7.5 V end.
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 2.7 \pm 0.02 V
Suggested charge current (Standard)	1.3 A @ 10 ~ 45°C 0.78 A @ 0 ~ 10°C	
Suggested charge current (maximum)	3.25 A @ 10 ~ 45°C	
Suggested standard discharge current	1.3 A	
Suggested maximum discharge current	6.5 A, below 45°C	
Operating temperature	0 ~ 45°C 10 ~ 45°C -20 ~ 60°C	Standard charging In max. charging Standard discharging

Transducer

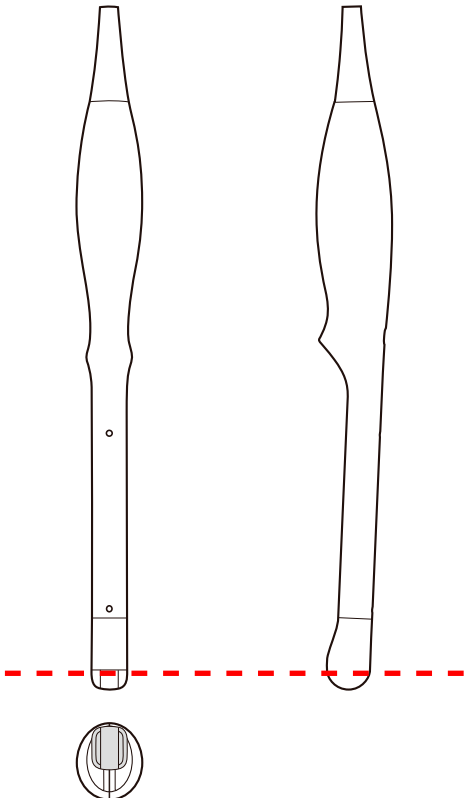
Transducer	Elements	Frequency (MHz)	Descriptions	Applications
C6-2	128	2~6	Curved array transducer with a user-controllable field-of-view	<ul style="list-style-type: none"> • Fetal/OB • Abdominal • Pediatric • Fetal Echo • GYN • Urology
L12-4	128	4~12	Linear array transducer with a user-controllable field-of-view	<ul style="list-style-type: none"> • Abdominal • Small Organ (breast, thyroid, testes) • Musculo-skel. (Conventional) • Peripheral Vessel • Carotid
S4-2	64	2~4	Phased array transducer with a user-controllable field-of-view	<ul style="list-style-type: none"> • Abdominal • Adult Cephalic • Cardiac Adult
C9-4v	128	4~9	<p>Curved linear array transducer with a user-controllable field-of-view</p> <ul style="list-style-type: none"> • Maximum outer diameter: equal to or less than 24 mm • Operating length: 130 mm; deviation errors: $\pm 3\%$ 	<ul style="list-style-type: none"> • GYN • OB • Prostate • Trans-rectal • Trans-vaginal
C83B	128	3~8	Curved array transducer with a user-controllable field-of-view	<ul style="list-style-type: none"> • Abdominal • Pediatric • Cardiac Pediatric

Figure 10 Cross-sectional diagram

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
Water resistant level	IP21
Efficiency	Eff (av) ≥ 87%
Safety	Approved according to IEC 60601-1
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	<ul style="list-style-type: none"> • 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

Cable

Item	Maximum Cable Length
Tablet	N/A
Multiple Transducer Module	0.75 m
AC Adapter	2.0 m
C6-2 Transducer	1.8 m
L12-4 Transducer	1.8 m
S4-2 Transducer	1.8 m
C9-4v Transducer	1.8 m
C83B Transducer	1.8 m
USB Mass Storage	N/A
Thermal Printer (SONY UP-X898MD, SONY UP-D898MD)	AC Cord Length = 1.9 m USB Cable Length = 1.8 m
System Cart	N/A
Carry Case	N/A

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 cine 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.
 - The system is not IHE Certified.
-

Security

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

Use the following TCP/IP ports for outgoing communication to the Wi-Fi 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

The system limits connection via Bluetooth to devices compatible with HID and OBEX profiles only. Security countermeasures for such connection include:

1. Configured as an hidden device: Other Bluetooth devices cannot see InnoSight, nor can they connect to InnoSight.
2. Restrictions on data transfer: InnoSight does not accept data from other Bluetooth devices, but only send data (limited file formats) to other Bluetooth devices.

Information Flow

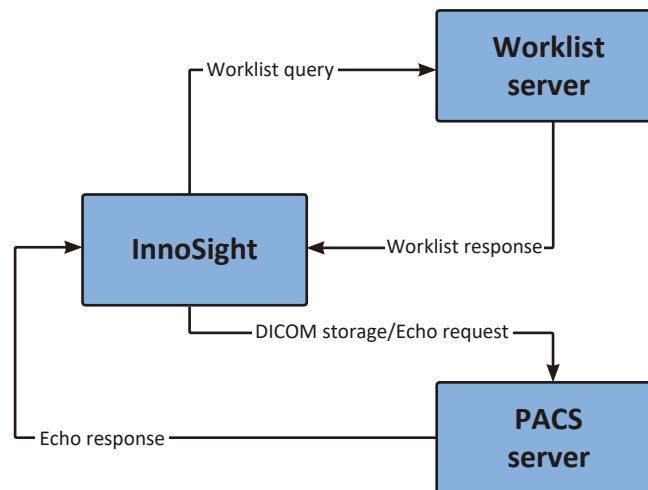


Figure 11 Information flow

- The system performs data encryption to secure data transferred between the system and the server or external devices.
- Read the system's DICOM Conformance Statement for detailed instructions. The DICOM conformance statement for InnoSight is available at this website:
<https://www.usa.philips.com/healthcare/resources/support-documentation/dicom-third-party-venture>

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 or 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.

IT network failure	Impact on the equipment	Hazard	System countermeasures
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 9 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

Preset	Mode	TI Label	Default TI	Default MI
Abdomen	2D	TIS=TIB	0.211	0.803
	Color	TIS=TIB	0.120	1.098
	CPA	TIS=TIB	0.149	1.118
	M	TIB	0.150	0.817
	PW	TIB	1.565	0.869
	Color-Triplex	TIB	1.678	0.965
	CPA-Triplex	TIB	1.150	0.976
OB	2D	TIS=TIB	0.036	0.943
	Color	TIS=TIB	0.177	1.018
	CPA	TIS=TIB	0.183	1.020
	M	TIB	0.236	0.952
	PW	TIB	1.573	0.899
	Color-Triplex	TIB	1.738	0.961
	CPA-Triplex	TIB	1.755	0.972
Renal	2D	TIS=TIB	0.002	0.914
	Color	TIS=TIB	0.197	1.160
	CPA	TIS=TIB	0.206	1.202
	M	TIB	0.196	0.915
	PW	TIB	1.350	0.906
	Color-Triplex	TIB	0.896	0.918
	CPA-Triplex	TIB	1.488	0.936

Preset	Mode	TI Label	Default TI	Default MI
Urology	2D	TIS=TIB	0.037	0.908
	Color	TIS=TIB	0.128	1.233
	CPA	TIS=TIB	0.143	1.247
	M	TIB	0.205	0.908
	PW	TIB	1.412	0.915
	Color-Triplex	TIB	1.654	1.004
	CPA-Triplex	TIB	1.207	1.017
GYN	2D	TIS=TIB	0.015	0.980
	Color	TIS=TIB	0.133	1.353
	CPA	TIS=TIB	0.117	1.372
	M	TIB	0.279	0.992
	PW	TIB	1.320	0.882
	Color-Triplex	TIB	1.214	0.979
	CPA-Triplex	TIB	1.347	0.999
Nerve	2D	TIS=TIB	0.005	0.929
	Color	TIS=TIB	0.188	1.389
	CPA	TIS=TIB	0.129	1.419
	M	TIB	0.159	0.951
	PW	TIB	1.091	0.900
	Color-Triplex	TIB	1.170	0.868
	CPA-Triplex	TIB	1.299	0.905
Pediatric Abdomen	2D	TIS=TIB	0.026	1.014
	Color	TIS=TIB	0.141	1.398
	CPA	TIS=TIB	0.169	1.415
	M	TIB	0.228	1.021
	PW	TIB	1.071	0.905
	Color-Triplex	TIB	0.817	1.088
	CPA-Triplex	TIB	0.894	1.137
FAST	2D	TIS=TIB	0.001	0.959
	Color	TIS=TIB	0.129	1.096
	CPA	TIS=TIB	0.140	1.116
	M	TIB	0.285	0.974
	PW	TIB	1.559	0.883
	Color-Triplex	TIB	1.706	0.957
	CPA-Triplex	TIB	1.894	0.909
Early Obstetric	2D	TIS=TIB	0.015	0.993
	Color	TIS=TIB	0.162	1.247
	CPA	TIS=TIB	0.197	1.212
	M	TIB	0.201	0.971
	PW	TIB	1.317	0.887
	Color-Triplex	TIB	1.223	0.911
	CPA-Triplex	TIB	1.294	0.951

Preset	Mode	TI Label	Default TI	Default MI
Fetal echo	2D	TIS=TIB	0.015	0.985
	Color	TIS=TIB	0.317	1.354
	CPA	TIS=TIB	0.335	1.369
	M	TIB	0.210	0.970
	PW	TIB	1.131	0.886
	Color-Triplex	TIB	0.557	0.913
	CPA-Triplex	TIB	0.614	0.949
Lung	2D	TIS=TIB	0.022	0.804
	Color	TIS=TIB	0.111	1.259
	CPA	TIS=TIB	0.162	1.275
	M	TIB	0.135	0.801
	PW	TIB	1.251	1.010
	Color-Triplex	TIB	1.212	0.981
	CPA-Triplex	TIB	1.376	1.033

L12-4 Transducer

Preset	Mode	TI Label	Default TI	Default MI
Carotid	2D	TIS=TIB	0.043	0.765
	Color	TIS=TIB	0.929	1.503
	CPA	TIS=TIB	0.678	1.325
	M	TIB	0.341	0.807
	PW	TIB	0.618	0.915
	Color-Triplex	TIB	1.310	1.022
	CPA-Triplex	TIB	1.271	1.004
Arterial	2D	TIS=TIB	0.026	1.082
	Color	TIS=TIB	0.572	1.453
	CPA	TIS=TIB	0.517	1.106
	M	TIB	0.571	0.910
	PW	TIB	0.527	0.958
	Color-Triplex	TIB	0.828	0.809
	CPA-Triplex	TIB	0.607	0.794
Venous	2D	TIS=TIB	0.143	0.766
	Color	TIS=TIB	0.561	1.235
	CPA	TIS=TIB	0.517	1.095
	M	TIB	0.146	0.830
	PW	TIB	0.694	0.931
	Color-Triplex	TIB	0.857	0.915
	CPA-Triplex	TIB	0.712	0.909

Preset	Mode	TI Label	Default TI	Default MI
Thyroid	2D	TIS=TIB	0.039	0.859
	Color	TIS=TIB	0.671	1.126
	CPA	TIS=TIB	0.476	1.084
	M	TIB	0.224	0.843
	PW	TIB	0.498	0.958
	Color-Triplex	TIB	0.700	0.880
	CPA-Triplex	TIB	0.632	0.774
Breast	2D	TIS=TIB	0.092	0.837
	Color	TIS=TIB	0.648	1.425
	CPA	TIS=TIB	0.436	1.103
	M	TIB	0.277	0.827
	PW	TIB	0.502	0.728
	Color-Triplex	TIB	0.738	0.687
	CPA-Triplex	TIB	1.147	0.711
Bowel	2D	TIS=TIB	0.074	0.755
	Color	TIS=TIB	1.008	1.431
	CPA	TIS=TIB	0.980	1.206
	M	TIB	0.291	0.748
	PW	TIB	0.527	0.660
	Color-Triplex	TIB	1.341	0.655
	CPA-Triplex	TIB	1.209	0.654
MSK	2D	TIS=TIB	0.047	0.844
	Color	TIS=TIB	0.492	1.480
	CPA	TIS=TIB	0.506	1.107
	M	TIB	0.110	0.753
	PW	TIB	0.536	0.730
	Color-Triplex	TIB	1.079	0.700
	CPA-Triplex	TIB	1.067	0.718
Nerve	2D	TIS=TIB	0.081	0.840
	Color	TIS=TIB	0.627	1.420
	CPA	TIS=TIB	0.461	1.103
	M	TIB	0.463	0.848
	PW	TIB	0.517	0.728
	Color-Triplex	TIB	1.012	0.713
	CPA-Triplex	TIB	0.917	0.721
Lung	2D	TIS=TIB	0.0515	0.51
	Color	TIS=TIB	1.741	1.347
	CPA	TIS=TIB	1.666	1.238
	M	TIB	0.1464	0.611
	PW	TIB	1.169	0.792
	Color-Triplex	TIB	1.7414	0.774
	CPA-Triplex	TIB	1.5833	0.778

Preset	Mode	TI Label	Default TI	Default MI
Testicle	2D	TIS=TIB	0.107	1.197
	Color	TIS=TIB	0.6343	1.348
	CPA	TIS=TIB	0.5574	1.344
	M	TIB	0.5433	1.523
	PW	TIB	0.65	0.718
	Color-Triplex	TIB	0.9443	0.701
	CPA-Triplex	TIB	0.5924	0.702

S4-2 Transducer

Preset	Mode	TI Label	Default TI	Default MI
Cardiac	2D	TIS=TIB	0.182	1.385
	Color	TIS=TIB	0.823	1.414
	CPA	TIS=TIB	0.844	1.391
	M	TIB	0.596	1.424
	PW	TIB	1.622	0.877
	CW	TIB	1.535	0.066
	Color-Triplex	TIB	2.590	1.373
	CPA-Triplex	TIB	2.736	1.340
FAST	2D	TIS=TIB	0.163	1.421
	Color	TIS=TIB	1.164	1.529
	CPA	TIS=TIB	1.148	1.526
	M	TIB	0.591	1.328
	PW	TIB	1.733	0.992
	CW	TIB	2.225	0.079
	Color-Triplex	TIB	2.133	1.370
	CPA-Triplex	TIB	1.779	1.368
Lung	2D	TIS=TIB	0.268	1.511
	Color	TIS=TIB	0.968	1.455
	CPA	TIS=TIB	0.959	1.494
	M	TIB	0.746	1.679
	PW	TIB	1.689	1.035
	CW	TIB	2.612	0.078
	Color-Triplex	TIB	2.100	1.428
	CPA-Triplex	TIB	1.805	1.420

Preset	Mode	TI Label	Default TI	Default MI
Abdomen	2D	TIS=TIB	0.209	1.571
	Color	TIS=TIB	0.871	1.542
	CPA	TIS=TIB	0.882	1.547
	M	TIB	0.780	1.727
	PW	TIB	1.676	0.985
	CW	TIB	2.382	0.092
	Color-Triplex	TIB	1.962	1.371
	CPA-Triplex	TIB	1.687	1.375
TCD	2D	TIC	0.428	1.387
	Color	TIC	1.795	1.532
	CPA	TIC	1.904	1.540
	M	TIC	0.821	1.341
	PW	TIC	1.51	0.867
	CW	TIC	1.983	0.062
	Color-Triplex	TIC	2.407	1.365
	CPA-Triplex	TIC	2.077	1.392

C9-4v Transducer

Preset	Mode	TI Label	Default TI	Default MI
OB	2D	TIS=TIB	0.025	0.778
	Color	TIS=TIB	0.345	1.012
	CPA	TIS=TIB	0.381	1.020
	M	TIB	0.163	0.899
	PW	TIB	0.976	0.843
	Color-Triplex	TIB	1.473	0.832
	CPA-Triplex	TIB	1.596	0.818
GYN	2D	TIS=TIB	0.018	0.780
	Color	TIS=TIB	0.338	1.023
	CPA	TIS=TIB	0.399	1.005
	M	TIB	0.252	0.896
	PW	TIB	0.979	0.853
	Color-Triplex	TIB	1.539	0.830
	CPA-Triplex	TIB	1.440	0.816
Prostate	2D	TIS=TIB	0.015	0.785
	Color	TIS=TIB	0.336	1.023
	CPA	TIS=TIB	0.443	1.009
	M	TIB	0.209	0.893
	PW	TIB	0.997	0.849
	Color-Triplex	TIB	1.421	0.830
	CPA-Triplex	TIB	1.558	0.814

Preset	Mode	TI Label	Default TI	Default MI
Early Obstetric	2D	TIS=TIB	0.008	0.779
	Color	TIS=TIB	0.361	1.026
	CPA	TIS=TIB	0.240	1.012
	M	TIB	0.192	0.898
	PW	TIB	1.112	0.850
	Color-Triplex	TIB	0.830	1.568
	CPA-Triplex	TIB	1.504	0.814

C83B Transducer

Preset	Mode	TI Label	Default TI	Default MI
Abdomen Res	2D	TIS=TIB	0.052	0.704
	Color	TIS=TIB	0.589	1.131
	CPA	TIS=TIB	0.647	1.141
	M	TIB	0.412	1.112
	PW	TIB	0.691	0.752
	Color-Triplex	TIB	1.069	0.752
	CPA-Triplex	TIB	1.221	0.758
Abdomen Gen	2D	TIS=TIB	0.091	0.674
	Color	TIS=TIB	0.449	1.023
	CPA	TIS=TIB	0.288	1.017
	M	TIB	0.178	1.005
	PW	TIB	1.066	0.761
	Color-Triplex	TIB	1.386	0.752
	CPA-Triplex	TIB	1.312	0.759
Abdomen Pen	2D	TIS=TIB	0.043	0.490
	Color	TIS=TIB	0.454	0.908
	CPA	TIS=TIB	0.271	0.905
	M	TIB	0.244	0.891
	PW	TIB	1.291	0.869
	Color-Triplex	TIB	2.144	0.869
	CPA-Triplex	TIB	1.834	0.873
Cardiac Res	2D	TIS=TIB	0.028	0.790
	Color	TIS=TIB	0.435	1.012
	CPA	TIS=TIB	0.521	0.987
	M	TIB	0.366	0.743
	PW	TIB	0.994	0.752
	Color-Triplex	TIB	1.792	0.752
	CPA-Triplex	TIB	1.379	0.761

Preset	Mode	TI Label	Default TI	Default MI
Cardiac Gen	2D	TIS=TIB	0.062	0.866
	Color	TIS=TIB	0.437	1.011
	CPA	TIS=TIB	0.360	0.987
	M	TIB	0.270	1.205
	PW	TIB	1.105	0.753
	Color-Triplex	TIB	1.726	0.751
	CPA-Triplex	TIB	1.169	0.756
Cardiac Pen	2D	TIS=TIB	0.091	0.831
	Color	TIS=TIB	0.291	1.010
	CPA	TIS=TIB	0.283	0.985
	M	TIB	0.247	1.214
	PW	TIB	0.980	0.753
	Color-Triplex	TIB	1.359	0.753
	CPA-Triplex	TIB	1.090	0.759

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 $1 \text{ MPa MHz}^{-1/2}$

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

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 $d_{\text{eq}}(z) = \sqrt{\frac{4}{\pi} A_{\text{eq}}(z)}$.

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 $MI = \frac{P_{raf_{awf}}^{-1/2}}{C_{MI}}$.

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.

p_{ii} : *Pulse-intensity integral*

$p_{ii, \alpha}$: *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*.

Transducer Model and Operating Mode: C6-2, 2D mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.315	0.2902		0.2902		N/A
Index component value			0.2902	0.2902	0.2902	0.2902	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.29					
	P (mW)		76.2		76.2		N/A
	P_{1x1} (mW)		21.4		21.4		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	5.16					
	$z_{pii,\alpha}$ (cm)	5.16					
	f_{awf} (MHz)	3.032	3.075		3.075		N/A
Other information	p_{rr} (Hz)	300					
	s_{rr} (Hz)	300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	301.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	96					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	280.9					
	p_r at z_{pii} (MPa)	3.82					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen, THI On, Focus 5.0, Density Low, FQBeam Off, SonoCT Off, Depth 5.5, Gain 44, 2D Size 62, Power 100, Freq Gen

Control 2: Abdomen, THI On, Focus 8.0, Density Low, FQBeam Off, SonoCT Off, Depth 9, Gain 44, 2D Size 46, Power 100, Freq Res

Transducer Model and Operating Mode: C6-2, 2D+Color mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.412	0.43679		0.43679		N/A
Index component value			0.43679	0.43679	0.43679	0.43679	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.97					
	P (mW)		2D: 3.8 Color: 113.8		2D: 3.8 Color: 113.8		N/A
	P_{1x1} (mW)		2D: 0.3 Color: 33.7		2D: 0.3 Color: 33.7		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	4.94					
	$z_{pii,\alpha}$ (cm)	4.94					
	f_{awf} (MHz)	1.947	2D: 2.695 Color: 2.654		2D: 2.695 Color: 2.654		N/A
Other information	prr (Hz)	1144					
	srr (Hz)	52					
	n_{pps}	22					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	128.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	32.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	58.6					
	p_r at z_{pii} (MPa)	2.828					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen, Color mode, THI Off, ROI box minimized @ max depth, Focus 5.0, 2D/Color Density Low, FQBeam Off, SonoCT Off, Depth 5.5, Gain 44, 2D Size 70, Power 100, 2D/Color Freq Pen, Color Scale 92cm/s

Control 2: Abdomen, Color mode, THI On, ROI box minimized @ max depth, Focus 13.0, 2D/Color Density High, FQBeam Off, SonoCT Off, 2D Depth 14, 2D Gain 44, 2D Size 46, Power 100, Freq 2D Pen/Color Res, Color Scale 7cm/s

Transducer Model and Operating Mode: C6-2, 2D+CPA mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.413	0.53155		0.53155		N/A
Index component value			0.531551	0.531551	0.531551	0.531551	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.971					
	P (mW)		2D: 5.6 CPA: 116.1		2D: 5.6 CPA: 116.1		N/A
	P_{1x1} (mW)		2D: 0.2 CPA: 34.3		2D: 0.2 CPA: 34.3		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	4.86					
	$z_{pii,\alpha}$ (cm)	4.86					
	f_{awf} (MHz)	1.947	2D: 2.678 CPA: 3.24		2D: 2.678 CPA: 3.24		N/A
Other information	prr (Hz)	1109					
	srr (Hz)	50.4					
	n_{pps}	22					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	129.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	31.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	57.2					
	p_r at z_{pii} (MPa)	2.787					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen, CPA mode, THI Off, ROI box minimized @ max depth, Focus 5.0, 2D/CPA Density Low, FQBeam Off, SonoCT Off, Depth 5.5, Gain 44, 2D Size 70, Power 100, 2D/CPA Freq Pen, CPA Scale PRF4

Control 2: Abdomen, CPA mode, THI On, ROI box minimized @ max depth, Focus 13.0, Density 2D/CPA High, FQBeam Off, SonoCT Off, 2D Depth 14, 2D Gain 44, 2D Size 46, Power 100, Freq 2D Pen/CPA Res, CPA Scale PRF1.5

Transducer Model and Operating Mode: C6-2, 2D+M-Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.311	0.2901		0.593		N/A
Index component value			0.26409	0.2901	0.26409	0.593	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.313					
	P (mW)		2D: 75.4 M: 6.1		2D: 75.4 M: 6.1		N/A
	P_{1x1} (mW)		2D: 19.4 M: 1.8		2D: 19.4 M: 1.8		
	z_s (cm)			2.5			
	z_b (cm)					5.12	
	z_{MI} (cm)	5.12					
	$z_{pii,\alpha}$ (cm)	5.12					
	f_{awf} (MHz)	3.116	2D: 2.608 M: 2.694		2D: 2.608 M: 2.694		N/A
Other information	prr (Hz)	250					
	srr (Hz)	250					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	423					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	112.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	353					
	p_r at z_{pii} (MPa)	3.94					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen, M-Mode, THI On, 2D Focus 5.0, Density Low, FQBeam Off, SonoCT Off, 2D Depth 5.5, 2D Gain 44, 2D Size 128, Power 100, Freq Gen

Control 2: Abdomen, M-Mode, THI On, 2D Focus 5.0, Density Low, FQBeam Off, SonoCT Off, 2D Depth 5.5, 2D Gain 44, 2D Size 46, Power 100, Freq Pen

Transducer Model and Operating Mode: C6-2, PW mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.417	0.79		2.432		N/A
Index component value			0.56	0.79	0.56	2.432	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.977					
	P (mW)		113.1		113.1		N/A
	P_{1x1} (mW)		37		37		
	z_s (cm)			3.52			
	z_b (cm)					5.44	
	z_{MI} (cm)	4.92					
	$z_{pii,\alpha}$ (cm)	4.92					
	f_{awf} (MHz)	1.946	3.18		3.18		N/A
Other information	prr (Hz)	1300					
	srr (Hz)	1300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	131.2					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	347					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	639					
	p_r at z_{pii} (MPa)	2.708					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen, PW mode, 2D Focus 5.0, Density Low, FQBeam Off, SonoCT Off, 2D Depth 5.5, 2D Gain 44, 2D Size 128, Power 100, Freq Pen, PRF 1300

Control 2: Abdomen, PW mode, 2D Focus 10, Density Low, FQBeam Off, SonoCT Off, 2D Depth 11, 2D Gain 44, 2D Size 128, Power 100, Freq Res, PRF 4000

Transducer Model and Operating Mode: C6-2, Triplex mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.419	0.1538		0.738		N/A
Index component value			0.1119	0.1538	0.1119	0.7328	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.98					
	P (mW)		2D: 6.5 Color: 8.5 PW: 12.6		2D: 6.5 Color: 8.5 PW: 12.6		N/A
	P_{1x1} (mW)		2D: 3.3 Color: 2.5 PW: 2.8		2D: 3.3 Color: 2.5 PW: 2.8		
	z_s (cm)			2D/Color: 0 PW: 3.34			
	z_b (cm)					2D/Color: 0 PW: 8.6	
	z_{MI} (cm)	5.08					
	$z_{pii,\alpha}$ (cm)	5.08					
Other information	f_{awf} (MHz)	1.947	2D: 2.977 Color: 2.686 PW: 2.485		2D: 2.977 Color: 2.686 PW: 2.485		N/A
	prr (Hz)	1300					
	srr (Hz)	1300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	133.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	354					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	641					
Operating control conditions	p_r at z_{pii} (MPa)	2.659					
	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen, Triplex mode, ROI box flat wide @ max depth, Focus 5.0, SV Depth 5.0, 2D/Color Density High, FQBeam Off, SonoCT Off, Depth 5.5, Gain 44, 2D Size 46, Power 100, 2D/Color/PW Freq Pen, Color Scale 26cm/s, PRF 1300

Control 2: Abdomen, Triplex mode, ROI box minimized @ max depth, Focus 9.0, SV Depth 9.0, 2D/Color Density High, FQBeam Off, SonoCT Off, Depth 10, Gain 44, 2D Size 46, Power 100, 2D/Color/PW Freq Gen/Res/Gen, Color Scale 28cm/s, PRF 2000

Transducer Model and Operating Mode: L12-4, 2D mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.174	0.034		0.034		N/A
Index component value			0.034	0.034	0.034	0.034	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.719					
	P (mW)		2.6		2.6		N/A
	P_{1x1} (mW)		1.3		1.3		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	1.13					
	$z_{pii,\alpha}$ (cm)	1.13					
	f_{awf} (MHz)	5.36	5.49		5.49		N/A
Other information	p_{rr} (Hz)	128					
	s_{rr} (Hz)	128					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	310.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	6.14					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	8.96					
	p_r at z_{pii} (MPa)	3.21					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Carotid, THI On, 2D Focus 1, Density Low, SonoCT Off, 2D Depth 2, 2D Gain 64, 2D Size 46, Power 100, Freq Res

Control 2: Carotid, THI On, 2D Focus 3, Density High, SonoCT Off, 2D Depth 3.5, 2D Gain 64, 2D Size 46, Power 100, Freq Res

Transducer Model and Operating Mode: L12-4, 2D+Color mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.337	0.588		0.588		N/A
Index component value			0.588	0.588	0.588	0.588	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.29					
	P (mW)		2D: 6.3 Color: 38.3		2D: 6.3 Color: 38.3		N/A
	P_{1x1} (mW)		2D: 1.2 Color: 20.3		2D: 1.2 Color: 20.3		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	1.17					
	$z_{pii,\alpha}$ (cm)	1.17					
	f_{awf} (MHz)	6.04	2D: 5.50 Color: 6.08		2D: 5.50 Color: 6.08		N/A
Other information	prr (Hz)	518.1					
	srr (Hz)	47.1					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	659					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	17.85					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	29.18					
	p_r at z_{pii} (MPa)	4.08					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Carotid, Color mode, ROI box minimized @ max depth, Focus 1, 2D/Color Density Low/High, SonoCT Off, Depth 2, Gain 64, 2D Size 46, Power 100, 2D/Color Freq Res, Color Scale 44cm/s

Control 2: Carotid, Color mode, THI On, ROI box minimized @ min depth, Focus 4.5, 2D/Color Density High, SonoCT Off, 2D Depth 5, 2D Gain 64, 2D Size 46, Power 100, Freq 2D Res/Color Res, Color Scale 51cm/s, Steer 0

Transducer Model and Operating Mode: L12-4, 2D+CPA mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.318	0.807		0.807		N/A
Index component value			0.807	0.807	0.807	0.807	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.24					
	P (mW)		2D: 5.3 CPA: 39.8		2D: 5.3 CPA: 39.8		N/A
	$P_{1 \times 1}$ (mW)		2D: 3 CPA: 23.4		2D: 3 CPA: 23.4		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	1.19					
	$z_{pii,\alpha}$ (cm)	1.19					
	f_{awf} (MHz)	6.04	2D: 5.50 CPA: 7.24		2D: 5.50 CPA: 7.24		N/A
Other information	p_{rr} (Hz)	518					
	s_{rr} (Hz)	47.1					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	646					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	18.03					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	29.93					
	p_r at z_{pii} (MPa)	4.13					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Carotid, CPA mode, ROI box minimized @ max depth, Focus 1, 2D/CPA Density Low/High, SonoCT Off, Depth 2, Gain 64, 2D Size 46, Power 100, 2D/CPA Freq Gen, CPA Scale PRF 7

Control 2: Carotid, CPA mode, THI On, ROI box minimized @ min depth, Focus 4.5, Density 2D High/CPA High, SonoCT Off, 2D Depth 8, 2D Gain 64, 2D Size 46, Power 100, Freq 2D Res/CPA Res, CPA Scale PRF 4, Steer 0

Transducer Model and Operating Mode: L12-4, M-Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.452	0.4438		0.536		N/A
Index component value			0.4438	0.4195	0.4438	0.536	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.39					
	P (mW)		2D: 13.1 M: 2.1		2D: 13.1 M: 2.1		N/A
	P_{1x1} (mW)		2D: 12.3 M: 1.8		2D: 12.3 M: 1.8		
	z_s (cm)			1.31			
	z_b (cm)					1.31	
	z_{MI} (cm)	1.16					
	$z_{pii,\alpha}$ (cm)	1.16					
	f_{awf} (MHz)	5.46	2D: 6.4 M: 7.21		2D: 6.4 M: 7.21		N/A
Other information	prr (Hz)	250					
	srr (Hz)	250					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	699					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	114.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	175.8					
	p_r at z_{pii} (MPa)	4.13					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Carotid, M-Mode, THI On, 2D Focus 1, Density Low, SonoCT Off, 2D Depth 2, 2D Gain 64, 2D Size 128, Power 100, Freq Res

Control 2: Carotid, M-Mode, 2D Focus 3, Density High, SonoCT Off, 2D Depth 3.5, 2D Gain 64, 2D Size 46, Power 100, Freq Pen

Transducer Model and Operating Mode: L12-4, PW mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.934	0.2451		1.381		N/A
Index component value			0.2255	0.2451	0.2255	1.381	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.112					
	P (mW)		20.4		20.4		N/A
	P_{1x1} (mW)		11.7		11.7		
	z_s (cm)			1.69			
	z_b (cm)					1.69	
	z_{MI} (cm)	1.55					
	$z_{pii,\alpha}$ (cm)	1.55					
	f_{awf} (MHz)	5.12	4.05		4.05		N/A
Other information	p_{rr} (Hz)	4000					
	s_{rr} (Hz)	4000					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	211.1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	367					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	648					
	p_r at z_{pii} (MPa)	2.76					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Carotid, PW mode, 2D Focus 1, Density Low, SonoCT Off, 2D Depth 2, 2D Gain 64, 2D Size 128, Power 100, Freq Gen, PRF 4000

Control 2: Carotid, PW mode, 2D Focus 5, Density High, SonoCT Off, 2D Depth 5.5, 2D Gain 64, 2D Size 256, Power 100, Freq Pen, PRF 4000

Transducer Model and Operating Mode: L12-4, Triplex mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.84	0.87083		1.22133		N/A
Index component value			0.82363	0.87083	0.82363	1.22133	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.688					
	P (mW)		2D: 1.2 Color: 24 PW: 17.8		2D: 1.2 Color: 24 PW: 17.8		N/A
	P_{1x1} (mW)		2D: 0.6 Color: 21.3 PW: 9.9		2D: 0.6 Color: 21.3 PW: 9.9		
	z_s (cm)			2D/Color: 0 PW: 1.309			
	z_b (cm)					2D/Color: 0 PW: 1.42	
	z_{MI} (cm)	2.07					
	$z_{pii,\alpha}$ (cm)	2.07					
Other information	f_{awf} (MHz)	4.04	2D: 7.47 Color: 6.04 PW: 4.04		2D: 7.47 Color: 6.04 PW: 4.04		N/A
	prr (Hz)	1300					
	srr (Hz)	1300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	119.7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	297.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	523					
Operating control conditions	p_r at z_{pii} (MPa)	2.219					
	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Carotid, Triplex mode, ROI box flat wide @ max depth, Focus 1, SV Depth 1, 2D/Color Density High, SonoCT Off, Depth 2, Gain 64, 2D Size 46, Power 100, 2D/Color/PW Freq Pen/Res/Pen, Color Scale 8cm/s, Wall Filter 39Hz, Steer 0, PRF 1300

Control 2: Carotid, Triplex mode, ROI box minimized @ min depth, Focus 3, SV Depth 3, 2D/Color Density High, SonoCT Off, 2D Depth 3.5, 2D Gain 64, 2D Size 46, Power 100, 2D/Color/PW Freq Pen/Res/Pen, Color Scale 8cm/s, Wall Filter 39Hz, Steer 0, PRF 1300

Transducer Model and Operating Mode: S4-2, 2D mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.463	0.2857		0.2857		N/A
Index component value			0.2857	0.2857	0.2857	0.2857	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.001					
	P (mW)		32.2		32.2		N/A
	P_{1x1} (mW)		28.4		28.4		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	3.89					
	$z_{pii,\alpha}$ (cm)	3.89					
	f_{awf} (MHz)	1.871	2.113		2.113		N/A
Other information	p_{rr} (Hz)	272.5					
	s_{rr} (Hz)	136.2					
	n_{pps}	2					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	158					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	188.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	282.7					
	p_r at z_{pii} (MPa)	2.52					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Cardiac, THI On, 2D Focus 6.0, Density Low, FQBeam Off, 2D Depth 6.5, 2D Gain 45, 2D Size 62, Power 100, Freq Gen

Control 2: Cardiac, THI On, 2D Focus 6.0, Density Low, FQBeam Off, 2D Depth 7, 2D Gain 45, 2D Size 70, Power 100, Freq Res

Transducer Model and Operating Mode: S4-2, 2D+Color mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.369	0.63225		0.63225		N/A
Index component value			0.63225	0.63225	0.63225	0.63225	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.164					
	P (mW)		2D: 4.7 Color: 83.7		2D: 4.7 Color: 83.7		N/A
	P_{1x1} (mW)		2D: 2.9 Color: 51.3		2D: 2.9 Color: 51.3		
	z_s (cm)			0			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.67					
	$z_{pii,\alpha}$ (cm)	4.67					
	f_{awf} (MHz)	2.499	2D: 1.828 Color: 2.486		2D: 1.828 Color: 2.486		N/A
Other information	prr (Hz)	480					
	srr (Hz)	43.7					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	293.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	98.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	197.7					
	p_r at z_{pii} (MPa)	3.058					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						TIC
	Control 4						

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

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

Transducer Model and Operating Mode: S4-2, 2D+CPA mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.409	0.5778		0.5778		N/A
Index component value			0.5778	0.5778	0.5778	0.5778	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.228					
	P (mW)		2D: 19.3 CPA: 100.7		2D: 19.3 CPA: 100.7		N/A
	P_{1x1} (mW)		2D: 9.7 CPA: 40.7		2D: 9.7 CPA: 40.7		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	4.61					
	$z_{pii,\alpha}$ (cm)	4.61					
	f_{awf} (MHz)	2.499	2D: 2.117 CPA: 2.478		2D: 2.117 CPA: 2.478		N/A
Other information	prr (Hz)	459					
	srr (Hz)	41.8					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	317					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	102.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	204.7					
	p_r at z_{pii} (MPa)	3.063					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

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

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

Transducer Model and Operating Mode: S4-2, 2D+M-Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.471	0.377		0.693		N/A
Index component value			0.377	0.376	0.377	0.693	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.986					
	P (mW)		2D: 52.4 M: 8		2D: 52.4 M: 8		N/A
	P_{1x1} (mW)		2D: 36.4 M: 6.1		2D: 36.4 M: 6.1		
	z_s (cm)			2.3			
	z_b (cm)					4.3	
	z_{MI} (cm)	3.71					
	$z_{pii,\alpha}$ (cm)	3.71					
	f_{awf} (MHz)	1.824	2D: 1.871 M: 1.824		1.824		N/A
Other information	pr (Hz)	250					
	srr (Hz)	250					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	156.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	78.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	130.1					
	p_r at z_{pii} (MPa)	2.496					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Cardiac, M-Mode, THI On, 2D Focus 6.0, Density Low, FQBeam Off, 2D Depth 6.5, 2D Gain 45, 2D Size 128, Power 100, Freq Gen

Control 2: Cardiac, M-Mode, THI On, 2D Focus 7.0, Density Low, FQBeam Off, 2D Depth 8.0, 2D Gain 45, 2D Size 70, Power 100, Freq Gen

Transducer Model and Operating Mode: S4-2, CW mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.0666	0.447		2.082		N/A
Index component value			0.0486	0.447	0.0486	2.082	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.0941					
	P (mW)		62.1		62.1		N/A
	P_{1x1} (mW)		5.1		5.1		
	z_s (cm)			2.03			
	z_b (cm)					2.87	
	z_{MI} (cm)	3.17					
	$z_{pii,\alpha}$ (cm)	3.17					
	f_{awf} (MHz)	2	2		2		N/A
Other information	p_{rr} (Hz)	N/A					
	s_{rr} (Hz)	N/A					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	0.2654					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	265.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	406					
	p_r at z_{pii} (MPa)	0.1152					
Operating control conditions	Control 1	MI	TIS		TIB		
	Control 2						
	Control 3						
	Control 4						

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

Transducer Model and Operating Mode: S4-2, PW mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.093	0.284		1.988		N/A
Index component value			0.1549	0.284	0.1549	1.988	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.56					
	P (mW)		41.2		41.2		N/A
	P_{1x1} (mW)		16.2		16.2		
	z_s (cm)			2.34			
	z_b (cm)					4.76	
	z_{MI} (cm)	4.04					
	$z_{pii,\alpha}$ (cm)	4.04					
	f_{awf} (MHz)	2.037	2.008		2.008		N/A
Other information	prr (Hz)	5000					
	srr (Hz)	5000					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	96.8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	447					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	796					
	p_r at z_{pii} (MPa)	2.042					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

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

Control 2: Cardiac, PW mode, 2D Focus 8.0, Density Low, FQBeam Off, 2D Depth 9, 2D Gain 45, 2D Size 70, Power 100, Freq Pen

Transducer Model and Operating Mode: S4-2, Triplex mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.272	1.074		3.509		N/A
Index component value			1.074	1.064	1.074	3.509	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.8					
	P (mW)		2D: 9.9 Color: 74.4 PW: 68.3		2D: 9.9 Color: 74.4 PW: 68.3		N/A
	P_{1x1} (mW)		2D: 6 Color: 44.5 PW: 50.2		2D: 6 Color: 44.5 PW: 50.2		
	z_s (cm)			2D/Color: 0 PW: 2.36			
	z_b (cm)					2D/Color: 0 PW: 2.99	
	z_{MI} (cm)	3.89					
	$z_{pii,\alpha}$ (cm)	3.89					
Other information	f_{awf} (MHz)	2.004	2D: 2.557 Color: 2.473 PW: 1.996		2D: 2.557 Color: 2.473 PW: 1.996		N/A
	pr (Hz)	1300					
	sr (Hz)	1300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	127.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	302.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	518					
Operating control conditions	p_r at z_{pii} (MPa)	2.242					
	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Cardiac, Triplex mode, ROI box flat wide @ max depth, Focus 6, SV Depth 6, 2D/Color Density High, FQBeam Off, Depth 6.5, Gain 45, 2D Size 70, Power 100, 2D/Color/PW Freq Gen/Gen/Pen, Color Scale 20cm/s, Wall Filter 91Hz, PRF1300

Control 2: Cardiac, Triplex mode, ROI box minimized @ min depth, Focus 9, SV Depth 9, 2D/Color Density High, FQBeam Off, 2D Depth 10, 2D Gain 45, 2D Size 46, Power 100, 2D/Color/PW Freq Res/Gen/Pen, Color Scale 30cm/s, Wall Filter 140Hz, PRF2000

Transducer Model and Operating Mode: C9-4v, 2D mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.115	0.2406		0.2406		N/A
Index component value			0.2406	0.2406	0.2406	0.2406	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.576					
	P (mW)		12.8		12.8		N/A
	$P_{1 \times 1}$ (mW)		8.7		8.7		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	2.16					
	$z_{pii,\alpha}$ (cm)	2.16					
	f_{awf} (MHz)	5.34	5.81		5.81		N/A
Other information	p_{rr} (Hz)	290					
	s_{rr} (Hz)	290					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	368					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	158.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	321					
	p_r at z_{pii} (MPa)	3.7					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: OB, THI On, 2D Focus 2, Density Low, FQBeam Off, 2D Depth 3, 2D Gain 58, 2D Size 94, Power 100, Freq Pen

Control 2: OB, THI On, 2D Focus 3, Density High, FQBeam Off, 2D Depth 3.5, 2D Gain 58, 2D Size 86, Power 100, Freq Gen

Transducer Model and Operating Mode: C9-4v, 2D+Color mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.158	0.79059		0.79059		N/A
Index component value			0.79059	0.79059	0.79059	0.79059	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.572					
	P (mW)		2D: 1 Color: 35.3		2D: 1 Color: 35.3		N/A
	$P_{1 \times 1}$ (mW)		2D: 0.2 Color: 33.4		2D: 0.2 Color: 33.4		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	2.19					
	$z_{pii,\alpha}$ (cm)	2.19					
	f_{awf} (MHz)	4.94	2D: 5.87 Color: 4.94		2D: 5.87 Color: 4.94		N/A
Other information	p_{rr} (Hz)	582					
	s_{rr} (Hz)	52.9					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	543					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	71.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	136.1					
	p_r at z_{pii} (MPa)	3.67					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: OB, Color mode, THI On, ROI box minimized @ max depth, Focus 2, 2D/Color Density Low, FQBeam Off, Depth 3, Gain 58, 2D Size 94, Power 100, 2D/Color Freq Res, Color Scale 38cm/s

Control 2: OB, Color mode, THI On, ROI box minimized @ max depth, Focus 4, 2D/Color Density High, FQBeam Off, 2D Depth 4.5, 2D Gain 58, 2D Size 94, Power 100, Freq 2D Gen/Color Res, Color Scale 8cm/s

Transducer Model and Operating Mode: C9-4v, 2D+CPA mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.153	0.84408		0.84408		N/A
Index component value			0.84408	0.84408	0.84408	0.84408	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.561					
	P (mW)		2D: 2.8 CPA: 39.2		2D: 2.8 CPA: 39.2		N/A
	P_{1x1} (mW)		2D: 0.5 CPA: 35.3		2D: 0.5 CPA: 35.3		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	2.21					
	$z_{pii,\alpha}$ (cm)	2.21					
	f_{awf} (MHz)	4.94	2D: 5.92 CPA: 4.94		2D: 5.92 CPA: 4.94		N/A
Other information	prr (Hz)	582					
	srr (Hz)	52.9					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	544					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	70.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	134.1					
	p_r at z_{pii} (MPa)	3.54					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: OB, CPA mode, THI On, ROI box minimized @ max depth, Focus 2, 2D/CPA Density Low, FQBeam Off, Depth 3, Gain 58, 2D Size 94, Power 100, 2D/CPA Freq Res, CPA Scale PRF 6

Control 2: OB, CPA mode, THI On, ROI box minimized @ max depth, Focus 4, 2D/CPA Density High, FQBeam Off, 2D Depth 4.5, 2D Gain 58, 2D Size 54, Power 100, Freq 2D Gen/CPA Res, CPA Scale PRF 1.2

Transducer Model and Operating Mode: C9-4v, 2D+M-Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.073	0.7291		0.8071		N/A
Index component value			0.7291	0.714	0.7291	0.8071	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.508					
	P (mW)		2D: 28.8 M: 4.6		2D: 28.8 M: 4.6		N/A
	P_{1x1} (mW)		2D: 22.9 M: 3.2		2D: 22.9 M: 3.2		
	z_s (cm)			1.291			
	z_b (cm)					2.01	
	z_{MI} (cm)	2.25					
	$z_{pii,\alpha}$ (cm)	2.25					
	f_{awf} (MHz)	5.47	2D: 5.84 M: 6.05		2D: 5.84 M: 6.05		N/A
Other information	prr (Hz)	250					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	507					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	71.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	165.6					
	p_r at z_{pii} (MPa)	3.64					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: OB, M-Mode, THI On, 2D Focus 2, Density Low, FQBeam Off, 2D Depth 3, 2D Gain 58, 2D Size 128, Power 100, Freq Pen

Control 2: OB, M-Mode, THI On, 2D Focus 3.5, Density High, FQBeam Off, 2D Depth 4, 2D Gain 58, 2D Size 62, Power 100, Freq Gen

Transducer Model and Operating Mode: C9-4v, PW mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.095	0.326		0.994		N/A
Index component value			0.326	0.2013	0.326	0.994	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.432					
	P (mW)		14.1		14.1		N/A
	P_{1x1} (mW)		13.8		13.8		
	z_s (cm)			1.464			
	z_b (cm)					1.91	
	z_{MI} (cm)	2.43					
	$z_{pii,\alpha}$ (cm)	2.43					
	f_{awf} (MHz)	4.93	4.96		4.96		N/A
Other information	prr (Hz)	1300					
	srr (Hz)	1300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	445					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	363					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	880					
	p_r at z_{pii} (MPa)	3.53					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: OB, PW mode, 2D Focus 2.5, Density Low, FQBeam Off, 2D Depth 3, 2D Gain 58, 2D Size 128, Power 100, Freq Res, PRF 1300

Control 2: OB, PW mode, 2D Focus 4.5, Density High, FQBeam Off, 2D Depth 5, 2D Gain 58, 2D Size 62, Power 100, Freq Res, PRF 3000

Transducer Model and Operating Mode: C9-4v, Triplex mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.023	1.1833		2.1203		N/A
Index component value			1.1833	1.1123	1.1833	2.1203	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.271					
	P (mW)		2D: 8.6 Color: 24.4 PW: 28		2D: 8.6 Color: 24.4 PW: 28		N/A
	P_{1x1} (mW)		2D: 6.5 Color: 22.1 PW: 20.5		2D: 6.5 Color: 22.1 PW: 20.5		
	z_s (cm)			2D/Color: 0 PW: 1.378			
	z_b (cm)					2D/Color: 0 PW: 1.91	
	z_{MI} (cm)	2.36					
	$z_{pii,\alpha}$ (cm)	2.36					
Other information	f_{awf} (MHz)	4.93	2D: 5.86 Color: 4.94 PW: 4.94		2D: 5.86 Color: 4.94 PW: 4.94		N/A
	prr (Hz)	1300					
	srr (Hz)	1300					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	350					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	284.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	704					
Operating control conditions	p_r at z_{pii} (MPa)	3.24					
	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: OB, Triplex mode, ROI box flat wide @ max depth, Focus 2, SV Depth 2, 2D/Color Density High, FQBeam Off, Depth 3, Gain 58, 2D Size 70, Power 100, 2D/Color/PW Freq Res, Color Scale 8cm/s, PRF 1300

Control 2: OB, Triplex mode, ROI box minimized @ max depth, Focus 4, SV Depth 4, 2D/Color Density High, FQBeam Off, 2D Depth 4.5, 2D Gain 58, 2D Size 78, Power 100, 2D/Color/PW Freq Gen/Res/Res, Color Scale 12cm/s, PRF 2000

Transducer Model and Operating Mode: C83B, 2D mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.232	0.363		0.363		N/A
Index component value			0.363	0.363	0.363	0.363	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.257					
	P (mW)		35.8		35.8		N/A
	P_{1x1} (mW)		15.5		15.5		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	1.88					
	$z_{pii,\alpha}$ (cm)	1.88					
	f_{awf} (MHz)	3.36	4.91		4.91		N/A
Other information	p_{rr} (Hz)	211.9					
	s_{rr} (Hz)	211.9					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	110.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	127.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	162					
	p_r at z_{pii} (MPa)	2.63					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen Res, THI On, 2D Focus 2, Density Low, SonoCT Off, 2D Depth 3, 2D Gain 56, 2D Size 128, Power 100, Freq Pen

Control 2: Abdomen Res, THI On, 2D Focus 4, Density Low, SonoCT Off, 2D Depth 4.5, 2D Gain 56, 2D Size 128, Power 100, Freq Res

Transducer Model and Operating Mode: C83B, 2D+Color mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.114	0.7008		0.7008		N/A
Index component value			0.7008	0.7008	0.7008	0.7008	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.134					
	P (mW)		2D: 1 Color: 36.4		2D: 1 Color: 36.4		N/A
	P_{1x1} (mW)		2D: 0.5 Color: 31.6		2D: 0.5 Color: 31.6		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	1.62					
	$z_{pii,\alpha}$ (cm)	1.62					
	f_{awf} (MHz)	3.67	2D: 4.96 Color: 4.58		2D: 4.96 Color: 4.58		N/A
Other information	pr (Hz)	1165					
	srr (Hz)	46.6					
	n_{pps}	25					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	152.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	56.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	73.1					
	p_r at z_{pii} (MPa)	2.633					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen Res, THI On, ROI box minimized @ max depth, 2D Focus 2, Density Low, FQBeam Off, SonoCT Off, 2D Depth 3, 2D Gain 56, 2D Size 128, Power 100, 2D/Color Freq Pen, Color Scale 33cm/s

Control 2: Abdomen Res, THI On, ROI box minimized @ max depth, Focus 4, Density Low, FQBeam Off, SonoCT Off, 2D Depth 5, 2D Gain 56, 2D Size 128, Power 100, 2D/Color Freq Res, Color Scale 38cm/s

Transducer Model and Operating Mode: C83B, 2D+CPA mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.101	0.41583		0.41583		N/A
Index component value			0.41583	0.41583	0.41583	0.41583	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.109					
	P (mW)		2D: 1.1 CPA: 21.8		2D: 1.1 CPA: 21.8		N/A
	P_{1x1} (mW)		2D: 0.8 CPA: 18.2		2D: 0.8 CPA: 18.2		
	z_s (cm)			0			
	z_b (cm)					0	
	z_{MI} (cm)	1.64					
	$z_{pii,\alpha}$ (cm)	1.64					
	f_{awf} (MHz)	3.67	2D: 4.94 CPA: 4.58		2D: 4.94 CPA: 4.58		N/A
Other information	prr (Hz)	1130					
	srr (Hz)	51.4					
	n_{pps}	22					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	147.5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	59.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	78					
	p_r at z_{pii} (MPa)	2.637					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen Res, THI On, ROI box minimized @ max depth, 2D Focus 2, Density Low, FQBeam Off, SonoCT Off, 2D Depth 3, 2D Gain 56, 2D Size 128, Power 100, 2D/CPA Freq Pen, CPA Scale PRF5

Control 2: Abdomen Res, THI On, ROI box minimized @ max depth, Focus 4, Density Low, FQBeam Off, SonoCT Off, 2D Depth 5, 2D Gain 56, 2D Size 128, Power 100, 2D/CPA Freq Res, CPA Scale PRF4.5

Transducer Model and Operating Mode: C83B, 2D+M-Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.249	0.10746		0.25736		N/A
Index component value			0.08936	0.10746	0.08936	0.25736	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.204					
	P (mW)		2D: 2.6 M: 5.2		2D: 2.6 M: 5.2		N/A
	P_{1x1} (mW)		2D: 1.2 M: 2.6		2D: 1.2 M: 2.6		
	z_s (cm)			1.263			
	z_b (cm)					1.27	
	z_{MI} (cm)	1.81					
	$z_{pii,\alpha}$ (cm)	1.81					
	f_{awf} (MHz)	3.114	2D: 4.93 M: 4.94		2D: 4.93 M: 4.94		N/A
Other information	pr (Hz)	250					
	srr (Hz)	250					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	120					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	38.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	55.6					
	p_r at z_{pii} (MPa)	2.519					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen Res, THI On, 2D Focus 2, Density Low, FQBeam Off, SonoCT Off, 2D Depth 3, 2D Gain 56, 2D Size 128, Power 100, Freq Pen

Control 2: Abdomen Res, THI On, 2D Focus 4, Density Low, FQBeam Off, SonoCT Off, 2D Depth 4.5, 2D Gain 56, 2D Size 128, Power 100, Freq Res

Transducer Model and Operating Mode: C83B, PW mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.096	0.33		1.353		N/A
Index component value			0.33	0.2714	0.33	1.353	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.1					
	P (mW)		20		20		N/A
	P_{1x1} (mW)		17		17		
	z_s (cm)			1.263			
	z_b (cm)					1.44	
	z_{MI} (cm)	1.68					
	$z_{pii,\alpha}$ (cm)	1.68					
	f_{awf} (MHz)	3.67	4.07		4.07		N/A
Other information	prr (Hz)	2000					
	srr (Hz)	2000					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	142.2					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	308.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	479					
	p_r at z_{pii} (MPa)	2.615					
Operating control conditions	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen Res, PW mode, 2D Focus 2, Density Low, FQBeam Off, SonoCT Off, 2D Depth 3, 2D Gain 56, 2D Size 128, Power 100, Freq Pen, PRF2000

Control 2: Abdomen Res, PW mode, 2D Focus 4, Density Low, FQBeam Off, SonoCT Off, 2D Depth 4.5, 2D Gain 56, 2D Size 128, Power 100, Freq Gen, PRF3000

Transducer Model and Operating Mode: C83B, Triplex mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.747	0.57583		1.55983		N/A
Index component value			0.57583	0.48183	0.57583	1.55983	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.51					
	P (mW)		2D: 1.5 Color: 18.1 PW: 24.9		2D: 1.5 Color: 18.1 PW: 24.9		N/A
	P_{1x1} (mW)		2D: 0.7 Color: 7.4 PW: 21.5		2D: 0.7 Color: 7.4 PW: 21.5		
	z_s (cm)			2D/Color: 0 PW: 1.415			
	z_b (cm)					2D/Color: 0 PW: 1.42	
	z_{MI} (cm)	2.72					
	$z_{pii,\alpha}$ (cm)	2.72					
Other information	f_{awf} (MHz)	4.09	2D: 4.57 Color: 4.05 PW: 4.08		2D: 4.57 Color: 4.05 PW: 4.08		N/A
	pr (Hz)	3000					
	sr (Hz)	3000					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	109.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	308.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	682					
Operating control conditions	p_r at z_{pii} (MPa)	2.201					
	Control 1	MI					
	Control 2		TIS		TIB		
	Control 3						
	Control 4						

Control 1: Abdomen Res, Triplex mode, ROI box minimized @ max depth, Focus 2, SV Depth 2, 2D/Color Density Low/High, FQBeam Off, SonoCT Off, Depth 3, 2D Gain 56, 2D Size 128, Power 100, 2D/Color/PW Freq Gen, Color Scale 9cm/s, PRF3000

Control 2: Abdomen Res, Triplex mode, ROI box minimized @ max depth, Focus 5, SV Depth 5, 2D/Color Density Low/High, FQBeam Off, SonoCT Off, Depth 6, 2D Gain 56, 2D Size 46, Power 100, 2D/Color/PW Freq Gen, Color Scale 9cm/s, PRF3000

Appendix E: 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 harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

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.

Appendix F: European Commission (CE) Statement

European Commission (CE) Statement

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.

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: EN55032, 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.



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