ClearVue 350/550

User Manual

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PHILIPS

Manufactured by Philips Ultrasound

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CE 0086

This Medical Device meets the provisions of the transposition of the Medical Device Directive 93/42/EEC within the country of origin of the Notified Body concerned with the device.

Made by Philips in Bothell, Washington, USA, or in Suzhou, China.

European Union Representative

Philips Medical Systems Nederland B.V.
Quality & Regulatory Affairs
Veenpluis 4-6
5684PC Best
The Netherlands

WARNING

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

Contents

1 Read This First

This manual is intended to assist you with the safe and effective operation of your Philips product. Before attempting to operate the product, read this manual and strictly observe all warnings and cautions. Pay special attention to the information in the "Safety" section.

The user information for your Philips product describes the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may be unavailable on your product's configuration.

Intended Audience

Before you use your user information, you need to be familiar with ultrasound techniques. Sonography training and clinical procedures are not included here.

This document is intended for sonographers, physicians, and biomedical engineers who operate and maintain your Philips product.

Intended Use

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. For indications for use, see "Indications for Use and Supporting Transducers" on page 161. However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

Installation, use, and operation of this product is subject to the law in the jurisdictions in which the product is used. Install, use, and operate the product *only* in such ways that do not conflict with applicable laws or regulations, which have the force of law.

Use of the product for purposes other than those intended and expressly stated by Philips, as well as incorrect use or operation, may relieve Philips or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

WARNING

System users are responsible for image quality and diagnosis.

Warnings

Before using the system, read these warnings and the "Safety" section.

WARNINGS

- Do not remove the protective covers on the system; hazardous voltages are present inside. Cabinet panels must be in place while the system is in use. All internal adjustments and replacements must be made by a qualified Philips Ultrasound field service engineer.
- To avoid electrical shock, use only supplied power cords and connect only to properly grounded wall (wall/mains) outlets.
- Do not operate the system in the presence of flammable anesthetics or other flammable gases or liquids. Explosion can result.
- Medical equipment must be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in the "Safety" section.
- The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.

Warning Symbols

The system may use the following warning symbols. For additional symbols used on the system, see the "Safety" section.

Symbol	Description
	Identifies a safety note.
	Dangerous voltages: Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	Indicates that the user should see the instructions for use for safety information.

User Information Components

The user information provided with your product includes the following components:

- ***Compact Disc (CD)***: Includes all of the user information, except the *Operating Notes*. The instructions for using the CD are included with the CD.
- ***Operating Notes***: Contains information that clarifies certain product responses that might be misunderstood or cause user difficulty.
- ***User Manual***: Provided with the product and included on the CD. The *User Manual* introduces you to features and concepts, helps you set up your system, and includes important safety information. This manual also includes

procedures for basic operation. For detailed operating instructions, see the Help.

- ***Help***: Available on the system in some languages and included on the CD, the Help contains comprehensive instructions for using the system. The Help also provides reference information and descriptions of all controls and display elements. To display the Help, press **Help** on the system keyboard.
- ***Acoustic Output Tables***: Included on the CD, it contains information about acoustic output and patient-applied part temperatures.
- ***Medical Ultrasound Safety***: Included on the CD, it contains information on bioeffects and biophysics, prudent use, and implementing ALARA (as low as reasonably achievable).
- ***Shared Roles for System and Data Security***: Included on the CD, it contains guidelines to help you understand how the security of your Philips product could be compromised and information on Philips' efforts to help you prevent security breaches.
- ***Media Compatibility***: Included on the CD, it contains current information on media that are compatible with your system.

Product Conventions

Your Philips product uses certain conventions throughout the interface to make it easy for you to learn and use:

- Two unlabeled buttons, referred to as "trackball buttons," are used with the trackball. Those controls, located on either side of the trackball, operate somewhat similarly to PC mouse buttons. Both trackball buttons function identically.
- The middle trackball button is located above the trackball and is used in certain procedures along with the trackball and trackball buttons.
- In the system setups, tabs along the top of the monitor display let you choose additional sets of setup options.

- To type text into a text field, click in the field and use the keyboard.
- To display a list, click the down arrow  . To scroll through a list, click the arrows at either end of the scroll bar or drag the scroll box up or down.
- Controls on the control panel include buttons, knobs, slide controls, and a trackball. Press a button to activate or deactivate its function. Turn a knob to change the selected setting. Move a slide control to change its setting. Roll the trackball in the direction that you want to move an object.
- Controls across the top of the control panel, called quick keys, function as both buttons and knobs. To select one of the functions displayed above the control, simply press the control. To select a setting for the function, also displayed above the control, turn the control.

User Information Conventions

The user information for your product uses the following typographical conventions to assist you in finding and understanding information:

- All procedures are numbered, and all subprocedures are lettered. You must complete steps in the sequence they are presented to ensure success.
- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- Control names and menu items or titles are spelled as they are on the system, and they appear in bold text. The only exceptions are the trackball and the buttons adjacent to it, which are unlabeled.
- Symbols appear as they appear on the system.
- The *pointer* is the cursor used to select elements on the display. Use the **Pointer** control to display the pointer.
- *Point* means to position the tip of the pointer or cursor on an item on the display.
- *Click* means to move the pointer to an object and press the left trackball button.
- *Select* means to click a check box to put a check mark in it. *Deselect* means clicking the check box to remove the check mark.
- *Double-click* means to quickly click twice to select an object or text.

- *Right-click* means to point at an item and then press and immediately release the right trackball button.
- ***Shift****+click* means to press and hold the **Shift** key while clicking an item on the display.
- ***Ctrl****+click* means to press and hold the **Ctrl** key while clicking an item on the display.
- *Hover* means to pause the pointer over an item on the display.
- *Drag* means to place the pointer over an object and then press and hold the left trackball button while moving the trackball. Use this method to move an object on the display.
- *Highlight* means to change the color of a display selection (such as an item in a list) or overlay it with a colored bar, usually by clicking.
- The left side of the system is to your left as you stand in front of the system, facing the system. The front of the system is nearest to you as you operate it.

Information that is essential for the safe and effective use of your product appears throughout your user information as follows:

WARNING

Warnings highlight information vital to the safety of you, the operator, and the patient.

CAUTION

Cautions highlight ways that you could damage the product and consequently void your warranty or service contract or ways that you could lose patient or system data.

NOTE

Notes bring your attention to important information that will help you operate the product more effectively.

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.

Customer Comments

If you have questions about the user information, or you discover an error in the user information, in the USA, please call Philips at 800-722-9377; outside the USA, please call your local customer service representative.

Supplies and Accessories

To order ECG trunk cables, lead sets, and electrodes; transducer covers; biopsy guides; and other supplies and accessories, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52247-9589
Telephone: 800-445-6741 (USA and Canada), +1 319-656-4447 (International)
Fax: 877-329-2482 (USA and Canada), +1 319-656-4451 (International)
E-mail: info@civco.com
Internet: www.civco.com

NOTE

Model or part numbers in the following tables are subject to change.

System Accessories

Accessory	Model/Part Number	Description
ECG cable lead set (AAMI)	453561365771	ECG three-lead cable lead set (AAMI)
ECG cable lead set (IEC)	453561365781	ECG three-lead cable lead set (IEC)
ECG electrode	40420A	Pre-gelled snap electrode
Transducer covers	610-010	Covers for C9-4v transducer
Cables	–	See "Approved Cables for Electromagnetic Compliance" on page 66
Transducers	–	See "Clinical Options and Transducers" on page 161
Removable media	–	See "Media Compatibility" on page 133

Biopsy Guides

Transducer	Compatible Biopsy Guide Starter Kit
C5-2	989605398931
C9-4v	989605398941
L12-4	989605398951
S4-1	989605398411

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 Healthcare "Contact Us" website:

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

Philips Ultrasound Headquarters

22100 Bothell-Everett Highway, 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 information is provided in a Philips Healthcare Recycling Passport. Such recycling passports for Philips Ultrasound systems are available on this website:

www.healthcare.philips.com/main/about/sustainability/recycling/ultrasound.wpd

Recycling, reuse, and disposal information in this document is directed mainly at the entity with legal authority over the equipment. Operators are usually uninvolved in disposal, except in the case of certain batteries.

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 Healthcare 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 Healthcare about the new user, so that Philips Healthcare 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.

WARNING

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.

Philips Healthcare gives support for the following:

- Recovery of useful parts
- Recycling of useful materials by competent disposal companies
- Safe and effective disposal of equipment

For advice and information, contact your Philips service organization, or see the following website:

www.philips.com/about/sustainability/recycling/productrecyclingservices/index.page

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

2 Safety

Please read this information before using your ultrasound system. It applies to the ultrasound system, transducers, recording devices, and any optional equipment. This section covers general safety information only. Safety information that applies only to a specific task is included in the procedure for that task.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

A WARNING describes precautions necessary to prevent injury or loss of life.

A CAUTION describes precautions necessary to protect the equipment and patient or system data.

Basic Safety

WARNINGS

- 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 "Safety" section. Operating the system without a proper awareness of safe use could lead to fatal or other serious personal injury.
- Do not use this system for any application until you are sure that the system's periodic maintenance is current. If *any* part of the system is known or suspected to be defective or incorrectly adjusted, *do not use* the system until it is repaired. Operating the system with defective or incorrectly adjusted components could expose you and the patient to safety hazards.
- Do not use the system for any application until you are adequately and properly trained on its safe and effective operation. If you are unsure of your ability to operate the system safely and effectively, do not use it.

Operation of the system without proper and adequate training could lead to fatal or other serious personal injury.

- Do not operate the system with patients unless you have an adequate understanding of its capabilities and functions. Using the system without such understanding may compromise the system's effectiveness and the safety of the patient, you, and others.
- Never attempt to remove, modify, override, or frustrate any safety device on the system. Interfering with safety devices could lead to fatal or other serious personal injury.
- Use the system only for its intended purposes. Do not use the system with any product that Philips does not recognize as compatible with the system. Operation of the product for unintended purposes, or with incompatible products, could lead to fatal or other serious injury.

Electrical Safety

This equipment has been verified by a recognized third-party testing agency as a Class I device with Type BF isolated patient-applied parts, and Type B non-isolated patient-applied parts. (The safety standards met by this system are included in the "Specifications" section.) For maximum safety observe these warnings and cautions:

WARNINGS

- Shock hazards may exist if this system, including all externally mounted recording and monitoring devices, is not properly grounded. Protection against electrical shock is provided by grounding the chassis with a three-wire cable and plug. The system must be plugged into a grounded outlet. The grounding wire must not be removed or defeated.
- To avoid the risk of electrical shock, never connect the system power cord to a power strip or an extension cord. When using the power cord, always connect it directly to a grounded wall outlet.
- Do not remove the protective covers on the system; hazardous voltages are present inside. Cabinet panels must be in place while the system is in use. All internal adjustments and replacements must be made by a qualified Philips Ultrasound field service engineer.

- Do not operate this 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.
- 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.
- To avoid risk of electrical shock hazards, always turn off the system and disconnect it from the wall outlet before cleaning the system.
- All patient-contact devices, such as transducers, pencil probes, and ECG leads not specifically indicated as defibrillation-proof must be removed from patient contact before application of a high-voltage defibrillation pulse. See "Defibrillators" on page 27.
- Ultrasound equipment in normal operation, as with other medical electronic diagnostic equipment, uses high-frequency electrical signals that can interfere with pacemaker operation. Though the possibility of interference is slight, be alert to this potential hazard and stop system operation immediately if you note interference with a pacemaker.
- 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 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1-1.
- 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.
- Connection of optional devices not supplied by Philips Ultrasound could result in electrical shock. When such optional devices are connected to your ultrasound system, ensure that the total system earth leakage current does not exceed 500 µA, or in the United States, 300 µA.

- To avoid risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level.
- To avoid risks of electrical shock and fire hazards, inspect the system power cord and plug regularly. Ensure that they are not damaged in any way.
- Operating the system with physio input signals that are below the specified minimum levels may cause inaccurate results. See the "Specifications" section.
- Electrosurgical units (ESUs) and other devices intentionally introduce radio frequency electromagnetic fields or currents into patients. Because imaging ultrasound frequencies are coincidentally in the radio frequency range, ultrasound transducer circuits are susceptible to radio frequency interference. While an ESU is in use, severe noise interferes with the black-and-white image and completely obliterates the color image.
- To avoid risk of a burn hazard, do not use transducers with high-frequency surgical equipment. A burn hazard may result from a defect in the high-frequency surgical neutral electrode connection.
- 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.

CAUTIONS

- Although your system has been manufactured in compliance with existing EMI/EMC requirements, use of this system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image. When interference is present or intermittent, use caution when continuing to use the system. If interference occurs often, review the environment in which the system is being used, to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radio, TV, or microwave transmission equipment located nearby can cause emissions. In cases where EMI is causing disturbances, it may be necessary to relocate your system.
- For information on electromagnetic emissions and immunity as it applies to the system, see "Electromagnetic Compatibility" on page 62. Ensure that the operating environment of your system meets the conditions specified

in the referenced information. Operating the system in an environment that does not meet those conditions may degrade system performance.

Defibrillators

Observe the following warnings when a defibrillation is required while using the ultrasound system.

WARNINGS

- Before defibrillation, always remove all patient-applied parts from the patient.
- Before defibrillation, always disconnect invasive transducers from the system.
- A disposable transducer cover provides no protective electrical insulation against defibrillation.
- A small hole in the outer layer of the transducer opens a conductive path to grounded metal parts of the transducer. The secondary arcing that could occur during defibrillation could cause patient burns. The risk of burns is reduced, but not eliminated, by using an ungrounded defibrillator.

Use defibrillators that do not have grounded patient circuits. To determine whether a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

Fire Safety

WARNING

On electrical or chemical fires, use only extinguishers that are specifically labeled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury. Before attempting to fight a fire, if it is safe to do so, attempt to isolate the product from electrical and other supplies, to reduce the risk of electrical shock.

Use of electrical products in an environment for which they were not designed can lead to fire or explosion. Fire regulations for the type of medical area being used should be fully applied, observed, and enforced. Fire extinguishers should be available for both electrical and nonelectrical fires.

Mechanical Safety

A list of precautions related to mechanical safety follows; observe these precautions when using the system:

WARNINGS

- Be aware of the wheels on the system cart, especially when moving the system. The system could cause injury to you or others if it rolls over feet or into shins. Use caution when going up or down ramps.
- When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.
- Position external hardcopy devices away from the system. Ensure that they are secure. Do not stack them on the system.
- When positioning the monitor, move it carefully to avoid pinching hands or extremities against other objects, such as a bed rail.
- Never park the system on an incline.
- The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.
- If system operation is abnormal after you move or transport the system, contact Philips Ultrasound Customer Service immediately. System components are installed securely and can withstand considerable shock, but excessive shock can cause a system failure.
- To avoid injury, Philips recommends against lifting the system cart.

CAUTIONS

- Before moving the system, ensure that the system is secured for transport. On some systems, that may include ensuring that the monitor is latched, to prevent monitor damage during transport.
- Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management system to ensure that transducer cables are protected from damage.
- Do not roll the system over transducer cables or power cables.

Equipment Protection

Follow these precautions to protect your system:

CAUTIONS

- 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.
- Improper cleaning or sterilization of a patient-applied part may cause permanent damage.
- Do not submerge the transducer connector in solution. The cables and transducer bodies are liquid-tight, but the connectors are not.
- Do not use solvents, such as thinner or acetone, or abrasive cleaners on the system, transducers, or any hardcopy device.
- For optimal performance, connect your ultrasound system to a circuit dedicated solely for the system. Do not connect life-support devices to the same circuit as the ultrasound system.
- If systems, transducers, and peripherals have been in an environment below 10°C (50°F), allow them to reach room temperature before connecting or turning them on. Philips recommends allowing 24 hours for complete normalization. Otherwise, condensation inside the devices could cause damage. If the device was only briefly exposed to temperatures below 10°C (50°F), then the time required for the device to return to room temperature could be significantly less than 24 hours.
- To avoid damaging the flat-panel display in the monitor, do not store the system where the ambient temperature exceeds 65°C (149°F).

Product Compatibility

Do not use your system in combination with other products or components, unless Philips expressly recognizes those other products or components as compatible. For information about such products and components, contact your Philips representative.

Changes and additions to the system should be made only by Philips or by third parties expressly authorized by Philips to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and best engineering practices.

WARNING

System changes and additions that are made without the appropriate training or by using unapproved spare parts may void the Philips warranty. As with all complex technical products, maintenance by unqualified persons or using unapproved spare parts carries serious risks of system damage and personal injury.

Symbols

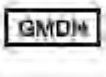
The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. Of those symbols, the following may be used on your Philips product and its accessories and packaging.

	Isolated patient connection (Type BF applied part).
	Defibrillation-proof patient connection (Type BF applied part).

	Non-isolated patient connection (Type B applied part).
	Isolated patient connection for applied part intended for intraoperative use, including direct cardiac application and contact with major vessels (Type CF applied part).
	Defibrillation-proof patient connection (Type CF applied part).
	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	Identifies an On/Off control.
	On a two-position power switch, represents On and Off.
	Identifies a safety note.
	Indicates that the user should see the instructions for use for safety information.

	Identifies equipotential ground.
	Identifies earth ground.
	Identifies protective earth ground.
	Nonionizing electromagnetic radiation. Indicates that interference may occur in the vicinity of equipment marked with this symbol.
	The radio component contained in this device is compliant to Council Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive).
	Indicates conformance with European Council Directive 93/42/EEC.
	Class 2 radio equipment identifier per Directive 1999/5/EC. European Union member states may apply restrictions on putting this device into service or placing it on the market. This device is intended to be connected to the Publicly Available Interfaces for use throughout the European Economic Area.
IPX1	Indicates that the device is protected against the effects of vertically falling water. This degree of protection can apply to transducers or foot-operated devices.

IPX4	Indicates that the device is protected against the effects of splashing liquids. This degree of protection can apply to foot-operated devices.
IPX7	Indicates that the device is protected against the effects of immersion. This degree of protection can apply to transducers and foot-operated devices.
IPX8	Indicates that the device is protected against the effects of immersion for up to 60 minutes. This degree of protection can apply to foot-operated devices.
	Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by Pb or Hg, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD system monitor contain mercury.
	Do not throw away. Dispose of in accordance with local, state, or federal laws.
	Do not reuse.

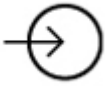
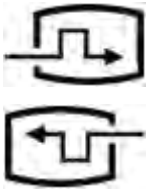
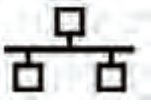
	Use-by date.
	Global Medical Device Nomenclature Code.
	Indicates a possible crushing hazard to hands.
	Warns that the system should not be used stacked with other equipment. If the system is used stacked with or adjacent to other equipment, verify normal operation before use.
	Indicates the temperature range (noncondensing) for transport and storage. (Does not apply to media.)
	Indicates the atmospheric pressure range for transport and storage.
	Indicates the relative humidity range (noncondensing) for transport and storage.
	Indicates that a connector receives alternating current.

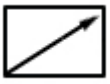
	Identifies fuse boxes or their locations. For continued protection from fire and shock, replace fuses only with fuses of the same type and rating.
	Identifies the date of manufacture.
	Identifies the legal manufacturer.
	This side up: Points toward the side of the shipping crate that should be kept facing up.
	Indicates that the device should be kept dry.
	Indicates that the device is fragile; handle with care.
	Do not use if damaged.
	Warns of system over-balance due to external force. (Do not push on the monitor or the transducer holders to move the system.)
	Keep away from sunlight.
	Non-sterile.
	Sterilized using ethylene oxide.

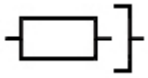
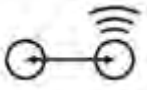
REF	Catalog number.
LOT	Batch code.
SN	Serial number.
UPN	Universal part number.

The following symbols may also be used on the system and its accessories and packaging:

	Connection for a pencil probe
	Connection for a pencil probe
	Connection for a transducer
	Connection for ECG leads
	Connection for ECG leads
	Print remote output

	Input port for audio left/right, VHS/S-VHS, microphone, CD, or DVD
	Output port for audio left/right, VHS/S-VHS, video patient monitor, black-and-white printer, or interlaced RGB output port
	Input port
	VGA or parallel output port
	DVI video output receptacle
	USB input/output port
	FireWire (IEEE 1394) input/output port
	Ethernet connection
	System microphone

AUX POWER ISOLATE OUTPUT	Isolated auxiliary power provided for connection of Philips-approved remote accessories.
	Foot switch
	Indicates the atmospheric pressure range for transport and storage.
	SVGA connection.
	S-Video connection
	B/W Composite video output connection
	Color composite video output connection
	Video print trigger connection
	Russian approval (GOST)

	Identifies the port for the PercuNav tool connector unit.
	Identifies the port for the PercuNav field generator.
	Chinese Environmentally Friendly Use Period symbol.
	UL (Underwriters Laboratories) classification symbol.
	CSA (CSA International) classification symbol.
	Indicates a possible pinch hazard when positioning the monitor.

The following symbols may be used inside the system:

	Dangerous voltages: Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	Identifies equipotential ground.

Biological Safety

This section contains information about biological safety and a discussion of the prudent use of the system.

A list of precautions related to biological safety follows; observe these precautions when using the system. For more information refer to *Medical Ultrasound Safety* on your user information CD.

WARNINGS

- Do not use the system if an error message on the video display indicates that a hazardous condition exists. Note the error code, turn off power to the system, and call your customer service representative.
- Do not use a system that exhibits erratic or inconsistent image updating. Discontinuities in the scanning sequence indicate a hardware failure that must be corrected before use.
- Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.
- Use only acoustic standoffs that have been approved by Philips Ultrasound. For information on ordering approved accessories, see "Supplies and Accessories" on page 17.
- Verify the alignment of the biopsy guide before use.
- Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.
- Transducer covers may contain natural rubber latex. Those covers may cause allergic reactions in some individuals. See "FDA Medical Alert on Latex" on page 41.
- 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.
- If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your Philips service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

- The backlight lamps in the system displays contain mercury and must be recycled or disposed of according to local, state, or federal laws.
- Select the correct application when starting an exam, and remain in that application throughout the exam. Some applications are for parts of the body that require lower limits for acoustic output. One example is an ophthalmic application activated by selecting an orbital transcranial Doppler preset; when performing an ophthalmic exam, use only an ophthalmic preset.

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, call the FDA Problem Reporting Program, operated through the U.S. Pharmacopoeia toll-free number: 800-638-6725. (In Maryland, call collect 301-881-0256.)

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

NOTE

The ultrasound system and transducers described in this document do not contain natural rubber latex that contacts humans. Natural rubber latex is not

used on any Philips ultrasound transducer. It also is not used on Philips ECG cables for the products described in this document.

ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the "as low as reasonably achievable" (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, it is the sonographer's responsibility to control total energy transmitted into the patient. The sonographer must reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, an ultrasound system provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound, not only in the technology but in the applications of that technology, have resulted in the need for more and better information to guide the user. The output display indices are designed to provide that important information.

There are a number of variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include index values, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the user. The ability to limit the index values over time supports the ALARA principle.

Applying ALARA

The system imaging mode used depends upon the information needed. 2D and M-mode imaging provide anatomical information, while Doppler, Color Power

Angio (CPA), and Color imaging provide information about blood flow. A scanned mode, like 2D or Color, disperses or scatters the ultrasonic energy over an area, while an unscanned mode, like M-mode or Doppler, concentrates ultrasonic energy. Understanding the nature of the imaging mode being used allows the sonographer to apply the ALARA principle with informed judgment. Additionally, the transducer frequency, system setup values, scanning techniques, and operator experience allow the sonographer to meet the definition of the ALARA principle.

The decision as to the amount of acoustic output is, in the final analysis, up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to transducer surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading. Limiting exposure time is an effective way to accomplish this goal.

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

Acoustic Output Limits

This ultrasound system maintains acoustic output below the appropriate limits for each application, as listed here. The significant difference in magnitude emphasizes the need to select the correct application and remain in that application, so the correct application limits are in use for the appropriate application.

Limits for Non-Ophthalmic Applications

- $I_{spta.3} \leq 720$ mW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

Limits for Ophthalmic Applications

- $I_{spta.3} \leq 50$ mW/cm^2
- MI ≤ 0.23
- TI ≤ 1.0

Direct Controls

Application selection and the output-power control directly affect acoustic intensity. There are different ranges of allowable intensity or output based on your selection. Selecting the correct range of acoustic intensity for the application is one of the first things that occurs in any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular application, while others require manual selection. Ultimately, the user has the responsibility for proper clinical use. The ultrasound system provides both automatic (default) settings and manual (user-selectable) settings.

Output power has direct impact on acoustic intensity. Once the application has been established, the power control can be used to increase or decrease the intensity output. The power control allows you to select intensity levels less than the established maximum. Prudent use dictates that you select the lowest output intensity that is consistent with good image quality.

Indirect Controls

The indirect controls are those that have an indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency, focus depth, pulse length, and transducer selection.

The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode; Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy in a single location. A moving or scanned ultrasound beam disperses the energy over an area and the beam is concentrated on the same area for a fraction of the time as that of an unscanned mode.

Pulse repetition frequency or rate refers to the number of ultrasound bursts of energy over a specific period of time. The higher the pulse repetition frequency, the more pulses of energy in a period of time. Several controls affect pulse

repetition frequency: focal depth, display depth, sample volume depth, flow optimization, scale, number of focal zones, and sector-width controls.

Focus of the ultrasound beam affects the image resolution. To maintain or increase resolution at a different focus requires a variation in output over the focal zone. This variation of output is a function of system optimization. Different exams require different focal depths. Setting the focus at the proper depth improves the resolution of the structure of interest.

Pulse length is the time during which the ultrasonic burst is turned on. The longer the pulse, the greater the time-average intensity value. The greater the time-average intensity, the greater the likelihood of temperature increase and cavitation. Pulse length, burst length, or pulse duration is the output pulse duration in PW Doppler. Increasing the Doppler sample-volume size increases the pulse length.

Transducer selection indirectly affects intensity. Tissue attenuation changes with frequency. The higher the transducer operating frequency, the greater the attenuation of the ultrasonic energy. A higher transducer operating frequency requires more output intensity to scan at a deeper depth. To scan deeper at the same output intensity, a lower transducer frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency transducer is needed.

Receiver Controls

Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, TGC, dynamic range, and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before output is increased. For example, before increasing output, optimize gain to improve image quality.

An Example of Applying the ALARA Principle

An ultrasound scan of a patient's liver begins with selecting the appropriate transducer frequency. After selecting the transducer and the application, which are based on patient anatomy, adjustments to output power should be made to

ensure that the lowest possible setting is used to acquire an image. After the image is acquired, adjusting the focus of the transducer, and then increasing the receiver gain to produce a uniform representation of the tissue follows. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should you increase output to the next level.

Having acquired the 2D display of the liver, Color can be used to localize blood flow. As with the 2D image display, gain and image processing controls must be optimized before increasing output.

Having localized the blood flow, use the Doppler controls to position the sample volume over the vessel. Before increasing output, adjust velocity range or scale and Doppler gain to obtain an optimal Doppler trace. Only if maximum Doppler gain does not create an acceptable image do you increase output.

In summary: Select the correct transducer frequency and application for the job; start with a low output level; and optimize the image by using focus, receiver gain, and other imaging controls. If the image is not diagnostically useful at this point, then increase output.

Additional Considerations

Ensure that scanning time is kept to a minimum, and ensure that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam may require a follow-up, which ultimately increases exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it should be used efficiently and effectively.

Output Display

The system output display comprises two basic indices: a mechanical index and a thermal index. The thermal index further consists of the following indices: soft tissue (TIS), bone (TIB), and cranial bone (TIC). One of these three thermal indices will be displayed at all times. Which one depends upon the system preset or user choice, depending upon the application at hand.

The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

The thermal index comprises three indices, and only one of these is displayed at any one time. Each transducer application has a default selection that is appropriate for that combination. The TIB, TIS, or TIC is continuously displayed over the range of 0.0 to maximum output, based on the transducer and application, in increments of 0.1. For the location of the output display, see "Imaging Display" on page 124.

The application-specific nature of the default setting is also an important factor of index behavior. A default setting is a system control state that is preset by the manufacturer or the operator. The system has default index settings for the transducer application. The default settings are invoked automatically by the ultrasound system when power is turned on, when new patient data is entered into the system database, or when an application change occurs.

The decision as to which of the three thermal indices to display should be based on the following criteria:

- Appropriate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface, as in a cranial exam.
- Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays?
- Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.
- Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

Mechanical Index (MI) Display

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

Thermal Index (TI) Displays

The TI informs the user about the conditions that exist that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI informs the user of the potential for temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation, and others. The TI should be used as a guide for implementing the ALARA principle.

The bone thermal index (TIB) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid; for example, at or near second- or third-trimester fetal bone.

The cranial bone thermal index (TIC) informs the user about the potential heating of bone at or near the surface; for example, cranial bone.

The soft tissue thermal index (TIS) informs the user about the potential for heating within soft homogeneous tissue.

You can choose to display TIS, TIC, or TIB. (For details on changing the TI display, see the system Help.) On systems with transcranial applications, TIC is displayed when you select a transcranial preset.

Mechanical and Thermal Indices Display Precision and Accuracy

The MI and TI precision is 0.1 unit on the system.

The MI and TI display accuracy estimates for the system are given in *Acoustic Output Tables*, on your user information CD. Those accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability, as discussed in this section.

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values in interrogated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the American Institute of Ultrasound in Medicine (AIUM) measurement standard. The measurements are then put into algorithms for calculating the displayed output values.

Many of the assumptions used in the process of measurement and calculation are conservative in nature. Overestimation of actual *in situ* intensity exposure, for the vast majority of tissue paths, is built into the measurement and calculation process. For example:

- The measured water tank values are derated using a conservative, industry standard, attenuation coefficient of 0.3 dB/cm-MHz.
- Conservative values for tissue characteristics were selected for use in the TI models. Conservative values for tissue or bone absorption rates, blood perfusion rates, blood heat capacity, and tissue thermal conductivity were selected.
- Steady State temperature rise is assumed in the industry standard TI models, and the assumption is made that the ultrasound transducer is held steady in one position long enough for steady state to be reached.

A number of factors are considered when estimating the accuracy of the displayed values: hardware variations, estimation algorithm accuracy, and measurement variability. Variability among transducers and systems is a significant factor. Transducer variability results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations. Differences in system pulser voltage control and efficiencies is also a contributor to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages. Inaccuracies in laboratory measurements are related to, among others, differences in hydrophone calibration and performance,

positioning, alignment, and digitization tolerances, and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3 dB/cm-MHz attenuative medium is not considered in the accuracy estimate for the display. Neither linear propagation, nor uniform attenuation at the 0.3 dB/cm-MHz rate, occur in water tank measurements or in most tissue paths in the body. In the body, different tissues and organs have dissimilar attenuation characteristics. In water, there is almost no attenuation. In the body, and in particular, in water tank measurements, nonlinear propagation and saturation losses occur as pulser voltages increase.

Therefore, the display accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by measuring according to, the AIUM measurement standards, or the effects of nonlinear loss on the measured values.

Control Effects

Controls Affecting the Indices

As various system controls are adjusted, the TI and MI values may change. This will be most apparent as the output power control is adjusted; but other system controls affect the on-screen output values.

Power

The output power control affects the system acoustic output. Two real-time output values are on the display: TI and MI. They change as the system responds to power-control adjustments.

In combined modes, such as simultaneous Color, 2D, and PW Doppler, the individual modes each add to the total TI. One mode will be the dominant contributor to this total. The displayed MI will be from the mode with the largest MI value.

2D Controls

- **Sector Width:** Narrowing the sector angle may increase frame rate. This action will increase the TI. Pulser voltage may be automatically adjusted down with software controls to keep the TI below the system maximums. A decrease in pulser voltage will decrease MI.
- **Zoom:** Increasing the zoom magnification by pressing **Zoom** may increase frame rate. This action will increase the TI. The number of focal zones may also increase automatically to improve resolution. This action may change the MI, because the peak MI can occur at a different depth.
- **Number of Focal Zones:** More focal zones may change both the TI and MI by changing frame rate or focal depth automatically. Lower frame rates decrease the TI. MI displayed will correspond to the zone with the largest MI value.
- **Focus:** Changing the focal depth will change MI. Generally, higher MI values will occur when the focal depth is near the natural focus of the transducer.

Color and Power Controls

- **Color Optimization:** Increasing the color sensitivity with the color optimization control may increase the TI. More time is spent scanning the color image. Color pulses are the dominant pulse type in this mode.
- **Color Sector Width:** Narrower color sector width will increase color frame rate and the TI will increase. The system may automatically decrease pulser voltage to stay below the system maximum. A decrease in pulser voltage will decrease the MI. If PW Doppler is also enabled, then PW Doppler will remain the dominant mode and the TI change will be small.
- **Color Sector Depth:** Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, the TI will decrease with increased color sector depth. MI will correspond to the MI of the dominant pulse type which is a color pulse. However, if PW Doppler is also enabled then PW Doppler will remain the dominant mode and the TI change will be small.
- **Scale:** Using the scale control to increase the color velocity range may increase the TI. The system may automatically adjust pulser voltage to stay

below the system maximums. A decrease in pulser voltage will also decrease MI.

- **Sector Width:** A narrower 2D sector width in Color imaging will increase color frame rate. The TI will increase. MI will change little, if at all. If PW Doppler is also enabled, then PW Doppler will remain the dominant mode and the TI change will be small.

M-Mode and Doppler Controls

- **Simultaneous and Update Methods:** Use of combination modes affects both the TI and MI through the combination of pulse types. During simultaneous mode, the TI is additive. During Duplex, the TI will display the dominant pulse type. The displayed MI will be from the mode with the largest MI value.
- **Sample Volume Depth:** When Doppler sample volume depth is increased, the Doppler PRF may automatically decrease. An increase in PRF will increase the TI. The system may also automatically decrease the pulser voltage to remain below the system maximum. A decrease in pulser voltage will decrease MI.

Other Control Effects

- **Imaging Mode Controls:** When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.
- **Transducer:** Each transducer type has unique specifications for contact area, beam shape, and center frequency. Defaults are initialized when you select a transducer. Factory defaults vary with transducer, application, and selected mode. Defaults have been chosen below the FDA limits for intended use.
- **2D Depth:** An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease the TI. The system may also automatically

choose a deeper 2D focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.

- **Application:** Acoustic output defaults are set when you select an application. Factory defaults vary with transducer, application, and mode. Defaults have been chosen below the FDA limits for intended use.

Related Guidance Documents

For more information about ultrasonic bioeffects and related topics, see the following:

- "Bioeffects and Safety of Diagnostic Ultrasound." AIUM Report, January 28, 1993.
- "American Institute of Ultrasound in Medicine Bioeffects Consensus Report." *Journal of Ultrasound in Medicine*, Vol. 27, Issue 4, April 2008.
- Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. (AIUM, NEMA, 2004)
- Second Edition of the AIUM Medical Ultrasound Safety brochure, 2009. (A copy of this document is provided with each system.)
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. FDA, September 2008.
- Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. (AIUM, NEMA, 2004)
- WFUMB. "Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-Thermal Mechanisms for Biological Effects of Ultrasound." *Ultrasound in Medicine and Biology*, 1998: Vol. 24, Supplement 1.

Acoustic Output and Measurement

Since the initial use of diagnostic ultrasound, the possible human bioeffects from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee ("Bioeffects Considerations for the Safety of Diagnostic Ultrasound." *Journal of Ultrasound in Medicine*, Vol. 7, No. 9 Supplement, September 1988), sometimes referred to as

the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report, "Bioeffects and Safety of Diagnostic Ultrasound," dated January 28, 1993, provides more-current information.

The acoustic output for this system has been measured and calculated in accordance with the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (Revision 3, AIUM, NEMA, 2004), the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" (Revision 2, AIUM, NEMA, 2004), and the September 2008 FDA document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water absorbs very little acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, *In Situ*, has been estimated by using the following formula:

$$In\ Situ = Water\ [e^{-0.23alf}]$$

Where:

In Situ	=	*In Situ* intensity value
Water	=	Water value intensity
e	=	2.7183
a	=	Attenuation factor
Tissue	=	a(dB/cm-MHz)
Amniotic Fluid	=	0.006

Brain = 0.53

Heart = 0.66

Kidney = 0.79

Liver = 0.43

Muscle = 0.55

l = Skin line to measurement depth (cm)

f = Center frequency of the transducer/system/mode combination (MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *in situ* intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the *In Situ* value which is commonly reported uses the formula:

In Situ derated = Water $[e^{-0.069lf}]$

Since this value is not the true *in situ* intensity, the term "derated" is used.

Mathematical derating of water based measurements using the 0.3 dB/cm-MHz coefficient, may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/cm-MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present all along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and derated values may not be related by the *in situ* (derated) formula. For example: A multi-zone array transducer that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its shallowest focal zones.

Conclusions Regarding Tissue Models and Equipment Survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels *in situ* from measurements of acoustic output made in water. Presently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in acoustical properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm-MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the *in situ* acoustic exposure when the path between the transducer and the site of interest is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3 dB/cm-MHz. When the path contains significant amounts of fluid, as in many first- and second-trimester pregnancies scanned transabdominally, this model may underestimate the *in situ* acoustical exposure. The amount of underestimation depends on each specific situation. For example, when the beam path is longer than 3 cm and the propagation medium is predominantly fluid (conditions that may exist during transabdominal OB scans), a more accurate value for the derating term is 0.1 dB/cm-MHz.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate *in situ* acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/MHz may be used during all trimesters.

The maximum acoustic output levels of diagnostic ultrasound devices extend over a broad range of values:

- A survey of 1990-equipment models yielded mechanical index (MI) values between 0.1 and 1 at their highest output settings. Maximum MI values of approximately 2 are known to occur for currently available equipment.

Maximum MI values are similar for real-time 2D, M-mode, PW Doppler, and Color flow imaging.

- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 PW Doppler equipment. The vast majority of models yielded upper limits less than 1°C and 4°C for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C for first-trimester fetal tissue and 7°C for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a "fixed-path" tissue model and are for devices having Ispta (derated) values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM Report, January 28, 1993).

Acoustic Output Tables

Acoustic output tables are in *Acoustic Output Tables*, on your user information CD.

Acoustic Measurement Precision and Uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables. Measurement precision and uncertainty for power, pressure, intensity, and center frequency are listed in the following tables.

NOTE

Per Section 6.4 of the Output Display Standard, measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

Acoustic Measurement Precision

Quantity	Precision (Percentage Standard Deviation)
Pr is the underated peak rarefactional pressure measured in MPa.	Pr: 5.4%
Wo is the ultrasonic power in mW.	6.2%
f_c is the center frequency in MHz (NEMA UD-2 definition).	<1%
PII.3 is the derated spatial-peak pulse intensity integral in J/cm^2.	P11.3: 3.2%

Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in MegaPascals.	Pr: ±11.3%
Wo is the ultrasonic power in milliWatts.	±10%
f_c is the center frequency in MHz (NEMA UD-2 definition).	±4.7%
PII.3 is the derated spatial-peak pulse intensity integral in Joules/cm^2.	PII.3: +18% to -23%

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.

Foot Switch Warning

WARNING

The foot switch is not intended for use in wet locations, such as emergency rooms and operating theaters.

Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. See "Clinical Options and Transducers" on page 161 for a list of the transducers that are compatible with your ultrasound system.

In the United States, the FDA 510(k) regulatory clearance for use of the product is applicable only when Philips-manufactured transducers are connected to the system.

Glutaraldehyde Exposure

The United States Occupational Safety and Health Administration (OSHA) has issued a regulation covering levels of acceptable glutaraldehyde exposure in the working environment. Philips does not sell glutaraldehyde-based disinfectants with its products, but this type of disinfectant is recommended for the disinfection of transducers used in TEE, intraoperative, endocavity, and biopsy procedures.

To reduce the presence of glutaraldehyde fumes in the air, be sure to use a covered or ventilated soaking basin. Such systems are commercially available. The most-current information about disinfection products and Philips transducers can be found on the Philips Transducer Care website:

www.healthcare.philips.com/us/products/ultrasound/transducers/transducer_care/

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.

Handling Contaminated Transducers

The primary area of concern is the handling of transducers that have contacted infected patients. Always wear gloves when you handle transducers used in TEE, endocavity, intraoperative, and biopsy procedures that have not been previously disinfected.

Removing Blood and Infectious Material from the System

CAUTION

Do not wipe the transducer housing joint, strain relief, or cable with isopropyl alcohol. Isopropyl alcohol can damage these parts of the transducer. This damage is not covered by the warranty or your service contract.

Use a gauze pad moistened with soap and water to remove blood on the system and the transducer connectors and cables. Then dry the equipment with a soft cloth to prevent corrosion. You can use a 70% solution of isopropyl alcohol on the system and only on certain parts of some transducers. Additional cleaning agents are available for transducers.

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.

CAUTION

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

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is defined as the ability of a product, a device, or a system to function satisfactorily in the presence of the electromagnetic phenomena that exists in the location of the product, the device, or the system being used; and, in addition, to not introduce intolerable electromagnetic disturbances to anything in that same environment.

Electromagnetic immunity is the ability of a product, a device, or a system to function satisfactorily in the presence of electromagnetic interference (EMI).

Electromagnetic emissions is the ability of a product, a device, or a system to introduce intolerable electromagnetic disturbances into the use environment.

Your system has been manufactured in compliance with existing electromagnetic compatibility requirements. Use of this system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image. If this occurs often, review the environment in which the system is being used to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room, or from portable and mobile RF communications equipment such as cellular phones and pagers, or from the existence of radio, TV, or microwave transmission equipment located nearby. In cases where electromagnetic interference (EMI) is causing disturbances, it may be necessary to relocate your system.

The system complies with International Standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard allows the system to be used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

WARNING

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.

CAUTION

Medical equipment has special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the system's accompanying documents.

This section includes information on electromagnetic emissions and immunity as it applies to the system. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet these conditions may degrade system performance.

The information and warnings contained in this and other sections should be observed when installing and using the system to ensure its EMC.

NOTE

See the other electrical-safety warnings and cautions in this section.

If the system is operated within the electromagnetic environment described in "Electromagnetic Immunity" on page 68, the system will remain safe and will provide the following essential performance:

- Imaging
- Doppler audio and spectral display
- Measurements
- Acoustic output
- ECG triggering
- Printing using system printers
- Patient information
- Date and time information

ECG Signal

WARNING

Operation of your system with ECG signals below 0.25 mV may cause inaccurate results.

The amplitude of the electrocardiogram (ECG) signal is critical for reliable frame triggering. Frame triggering should be used only when a clean, noise-free ECG waveform is observed on the ECG display. The ECG signal should be at least 0.25 mV to ensure reliable triggering when the system is used in the presence of the electromagnetic phenomena described in this section and elsewhere in your system user information.

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon that results in the flow of an electrical charge from a higher charged object or person to a lower charged object or person. ESD is most prevalent during conditions of low humidity, which can be caused

by heating or air-conditioning. During low humidity conditions, electrical charges naturally build up on individuals and objects and can create static discharges.

The following cautions can help to reduce ESD effect:

CAUTIONS

- Do not touch transducer connector pins or the system's transducer receptacle.
- Handle the transducer by the metal connector shell.
- Make contact with a metal surface of the system before connecting a transducer to the system.
- The following precautions can help to reduce ESD: anti-static spray on carpets; anti-static spray on linoleum; anti-static mats; or a ground wire connection between the system and the patient table or bed.
- On connectors labeled with the ESD sensitivity symbol  , do not touch the connector pins, and always observe the preceding ESD precautions when handling or connecting transducers.

NOTE

Electrostatic discharges (ESDs) may cause the ECG heart rate display to increase by 10% to 15% for a few seconds after the discharge. However, the ECG heart rate display will return to normal within 4 seconds.

Electromagnetic Emissions

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

Electromagnetic Emissions: Environment Guidance

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 establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class B	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

Approved Cables for Electromagnetic Compliance

Cables connected to the system may affect its emissions. Use only the cable types and lengths listed here.

WARNING

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.

Approved Cables

Cable	Type	Length
ECG 3-lead safety connector patient trunk cable, AAMI	Shielded	2.7 m (9 ft)
ECG 3-lead safety connector patient trunk cable, IEC	Shielded	2.7 m (9 ft)
ECG Aux input	Shielded	<3 m (<9.8 ft)
Video output	Shielded	Any
LAN	Twisted pair	Any
USB	Shielded	<3 m (<9.8 ft)

Approved Transducers for Electromagnetic Compliance

The imaging transducers used with the system may affect its emissions. The transducers listed in "Clinical Options and Transducers" on page 161, when used with the system, have been tested to comply with the Group 1, Class B emissions, as required by International Standard CISPR 11. Use only those transducers.

WARNING

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.

Approved Accessories for Electromagnetic Compliance

Accessories used with the system may affect its emissions. The accessories listed here, when used with the system, have been tested to comply with the Group 1, Class B emissions as required by International Standard CISPR 11. Use only the accessories listed here.

When connecting other accessories to the system, such as a remote video monitor or computer, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Use only CISPR 11 or CISPR 22, Class B-compliant devices, unless otherwise noted.

WARNING

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.

CAUTION

Use only Class-B USB storage devices with the system. Some plastic-cased unshielded USB devices may cause RF emissions that exceed Class-B limits. See the device's documentation to determine whether it is Class-B compliant.

Approved Accessories

Accessory	Manufacturer	Model Number
Ultrasonic imaging transducer	Philips	Use only Philips transducers
Printers	For information on approved printers, see "External Printers" on page 96.	

Electromagnetic Immunity

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

NOTES

- The guidelines specified here may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- U_T is the AC power voltage before application of the test level.
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Electromagnetic Immunity: Environment Guidance

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD), IEC 61000-4-2	± 6 kV contact, ± 8 kV air	Same as IEC 60601 test level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst, IEC 61000-4-4	± 2 kV for power supply lines, ± 8-18 kV for input/output lines	Same as IEC 60601 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	± 1 kV differential mode, ±2 kV common mode	Same as IEC 60601 test level	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_T >95% dip in U_T for 0.5 cycle 40% U_T 60% dip in U_T for 5 cycles 70% U_T 30% dip in U_T for 25 cycles <5% U_T >95% in U_T for 5 seconds	Same as IEC 60601 test level	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, Philips recommends that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	Same as IEC 60691 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF, IEC 61000-4-6	3 VRMS 150 kHz to 80 MHz	0.08 V	For recommended separation distances, see "Recommended Separation Distance" on page 74.
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	For recommended separation distances, see "Recommended Separation Distance" on page 74.

Cables, transducers, and accessories connected to the system may affect its immunity to the electromagnetic phenomena listed in the preceding table. Use only approved accessories, cables, and transducers to minimize the chance of performance degradation of the system due to those types of electromagnetic phenomena.

CAUTION

If the system is connected to other customer-supplied equipment, such as a local area network (LAN) or a remote printer, Philips cannot guarantee that the remote equipment will work correctly in the presence of electromagnetic phenomena.

Although most remote devices comply with their applicable standards for immunity, those device requirements may not be as stringent as those required for medical equipment. It is the responsibility of the installer and the user of this remote customer-supplied equipment to ensure that it functions properly in the electromagnetic environment where the system is installed. Philips suggests that the installer or the user of such a system consult with experts in the field of electromagnetic compatibility and safety for guidance to ensure the safe and effective use of the created system.

Electromagnetic Interference

Electromagnetic interference may appear in many ways on the system and depends on the mode the equipment is operating in, the imaging control settings, the type of transducer being used, the type of electromagnetic phenomena, and the intensity level of the phenomena.

CAUTION

When interference is present or intermittent, use caution when continuing to use the system.

NOTES

- Electromagnetic phenomena are not always present and may be transitory in nature. It may be extremely difficult to identify the source of the interference.
- The following table describes a few typical interferences seen in imaging systems. It is impossible to describe all manifestations of interference, because it depends on many parameters of the transmitting device, such as the type of modulation used by the signal carrier, the source type, and the transmitted level. It is also possible for the interference to degrade the imaging system's performance and not be visible in the image. If the diagnostic results are suspicious, other means should be used to confirm the diagnosis.

Typical Interference on Ultrasonic Imaging Systems

Imaging Mode	ESD[1]	RF[2]	Power Line[3]
2D or 3D	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	For sector imaging transducers, white radial bands or flashes in the center lines of the image. For linear imaging transducers, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes, or diagonal lines near the center of the image.
Color	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Color flashes, radial or vertical bands, increase in background noise, or changes in image color.	Color flashes, dots, dashes, or changes in the color noise level.
Doppler	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Horizontal lines in the spectral display or tones, abnormal noise in the audio, or both.	Vertical lines in the spectral display, "popping" noise in the audio, or both.

Imaging Mode	ESD[1]	RF[2]	Power Line[3]
M-mode	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Increase in the image background noise or white M-mode lines.	White dots, dashes, diagonal lines, or increase in image background noise.

1. Electrostatic discharge (ESD) caused by discharging of electric charge buildup on insulated surfaces or persons.
2. Radio frequency (RF) energy from RF transmitting equipment such as portable phones, handheld radios, wireless devices, commercial radio and TV stations, and so on.
3. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.

Recommended Separation Distance

The following table provides recommended separation distances, which are guidelines on the distances that any RF transmitting equipment should be kept away from the ultrasound system to reduce the risk of interference with the system. 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. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range as noted in the table. Interference may occur in the vicinity of equipment marked with the following symbol:  .

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 in the table, 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.

NOTES

- For transmitters rated at a maximum output power not listed in the following table, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The information provided here, in conjunction with "Electromagnetic Interference" on page 71, provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz $d = 43.8\sqrt{P}$	80 to 800 MHz $d_T = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.4\sqrt{P}$
0.01	4.4 m	0.12 m	0.24 m
0.1	13.8 m	0.38 m	0.76 m
1	43.8 m	1.2 m	2.4 m
10	138 m	3.8 m	7.6 m
100	438 m	12 m	24 m

The conducted RF test level is 3 V, and the system has a compliance level of 0.08 V. For the system, this means that the imaging system is extremely sensitive to RF interference in the transducer passband. For example, for a 5-MHz imaging transducer, the frequency range of interference from a 3-V/m field may be from 2 to 10 MHz and manifest itself as described in "Electromagnetic Interference" on page 71.

The 0.08-V level is where the interference becomes acceptable to some clinical specialists.

Sensitivity to interference is dependent on operating mode and imaging control settings. The order of increasing sensitivity to interference as a function of operating mode is 2D mode, 3D mode, M-mode, Color mode, PW Doppler mode, and CW Doppler mode. The system is more sensitive to interference in the CW Doppler or PW Doppler operating modes, but the probability of interference is lower than in 2D mode or Color mode, because the susceptible frequency range is lower. Therefore, you are more likely to see interference in 2D or Color modes.

As an example, if a portable transmitter has maximum radiated power of 1 W and an operating frequency of 156 MHz, it should only be operated at distances greater than 1.2 m (3.9 ft) from the system. Likewise, a 0.01-W Bluetooth wireless LAN device operating at 2.4 GHz should be placed no closer than 0.24 m (9.5 in) from any part of the system.

Avoiding Electromagnetic Interference

A medical device can either generate or receive electromagnetic interference. The EMC standards describe tests for both emitted and received interference. Emission tests deal with interference generated by the device being tested. Philips ultrasound systems do not generate interference based on the tests described in the referenced standards.

An ultrasound system is designed to receive signals at radio frequencies and is therefore susceptible to interference generated by RF energy sources. Examples of other sources of interference are medical devices, information technology products, and radio and television transmission towers. Tracing the source of

radiated interference can be a difficult task. Customers should consider the following in an attempt to locate the source:

- Is the interference intermittent or constant?
- Does the interference show up only with one transducer or with several transducers?
- Do two different transducers operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?
- Can the EMC coupling path be attenuated? For example, placement of a transducer or printer close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the location of the transducer or printer can result in reduced electromagnetic interference.

The answers to these questions will help determine if the problem resides with the system or the scanning environment. After you answer the questions, contact your Philips service representative.

Use Restrictions Due to Interference

The physician needs to determine if an artifact caused by radiated interference will have a negative impact on image quality and the subsequent diagnosis.

3 System Overview

Use this section to acquaint yourself with the ultrasound system and its components.

System Capabilities

The ClearVue 350/550 ultrasound systems are intended for cardiac applications and general imaging and analysis. The cart is ergonomically designed to be both highly mobile and adjustable for a range of users and operating conditions. You can use the system for 2D, 3D, freehand 3D, Panoramic, M-mode, Doppler, and Color imaging. You can also perform Duplex imaging and Triplex imaging depending upon the features included in your version. General-imaging exam protocols are system options. The system supports a wide range of transducers. The system provides measurement tools, analysis options, and DICOM network capabilities.

Measurements

The system provides tools for measuring the size, speed, or duration of image data. In calculations, the following application-specific tools are available:

- 2D Depth
- 3D Volume
- Continuous Trace
- Distance
- Ellipse
- Heart Rate
- High Q automatic Doppler analysis
- Hip Angle
- Physio 2 Point
- Time/Slope
- Volume

After you perform measurements, the system makes the pertinent calculations and organizes the measurements, calculations, and patient information into a patient report. For information, see the Help. To display the Help, press **Help** on the keyboard. To close the Help, press **Help** again.

Transducer Types

Available transducers include sector, linear, curved array, and endocavity. Applications for specific transducers are listed in "Clinical Options and Transducers" on page 161.

Image Acquisition and Review

You can acquire and save a single frame or a cineloop sequence. The frame or cineloop sequence is saved in the patient study, and a thumbnail of it is available in the live imaging display and the Review display. You can also acquire and save 3D volumes and MPR views. Images and cineloop sequences are stored on the system hard drive, and they also can be stored on CDs, DVDs, and USB devices, or sent over a network to a DICOM-compatible PACS or a printer.

Peripheral devices are available for recording images and study data. You can connect a black-and-white image printer, a color image printer, or a report printer.

Patient Data Protection

The data security feature, if enabled on your system, limits access to previously stored patient data and images. To gain access to such data, you must first log on to the system using a password. When you are finished using the system, you can log off manually, or you can simply shut down the system, which logs you off automatically.

This data protection feature can be used to help meet the requirements of the U.S. Health Insurance Portability and Accountability Act (HIPAA), which became effective April 2003.

For more information on protecting patient data, see "System Security" on page 121.

System Options

In addition to the standard features available in the system, other features are available as purchasable options. The types of options available include clinical options, imaging capabilities, and connectivity capabilities.

Configurations

The ClearVue ultrasound system is available in two configurations: the ClearVue 350 and the ClearVue 550. The following table describes the available features in each configuration.

Feature	ClearVue 350	ClearVue 550
Monitor	43.2 cm (17-inch) LCD with tilt/swivel mount	43.2 cm (17-inch) LCD with articulating arm mount
Control panel	Fixed	Fixed
Number of transducer receptacles	3	4
Transducers	C5-2, L12-4, C9-4v, S4-1	C5-2, L12-4, C9-4v, S4-1
Purchasable options	4 Clinical Applications, iSCAN 2D, Freehand 3D, DICOM Networking, Structured Reporting, Anatomical M-Mode, XRES image processing	4 Clinical Applications, iSCAN 2D, Freehand 3D, DICOM Networking, Structured Reporting, Anatomical M-Mode, XRES image processing, SonoCT Real-time Compound Imaging, High Q Automatic Doppler, Doppler iSCAN, Exam Protocols, Panoramic Imaging

Imaging Options

Once purchased, the imaging options listed here are available as supported by the current transducer and application:

- 2D iSCAN Intelligent Optimization
- Anatomical M-Mode
- Continuous-Wave Doppler
- Exam Protocols
- Freehand 3D
- High Q Automatic Doppler Analysis
- iSCAN Color/Doppler
- Panoramic Imaging
- Physio
- Pulsed-Wave Doppler
- Sector Probe
- SonoCT Real-time Compound Imaging
- XRES Image Processing

Connectivity Options

The following connectivity capabilities are available as purchasable options on your system:

- DICOM Networking
- DICOM Structured Reporting

Clinical/Analysis Options

Clinical options are available on the system as separate purchasable options. Clinical options include corresponding analysis packages. The following clinical options are available:

- Abdominal
- Adult Echo
- Cerebrovascular

- Musculoskeletal
- OB/GYN
- Pediatric Echo
- Pediatric Radiology
- Peripheral Vascular
- Small Parts
- Urology

Calculations

Calculations are organized in collections for the applications included in the system. The system uses measurement values to make calculations and create a patient report. For more information on using calculations, see the Help on your system.

The calculations in the system are based on medical references, which are listed in the "References" section of the Help.

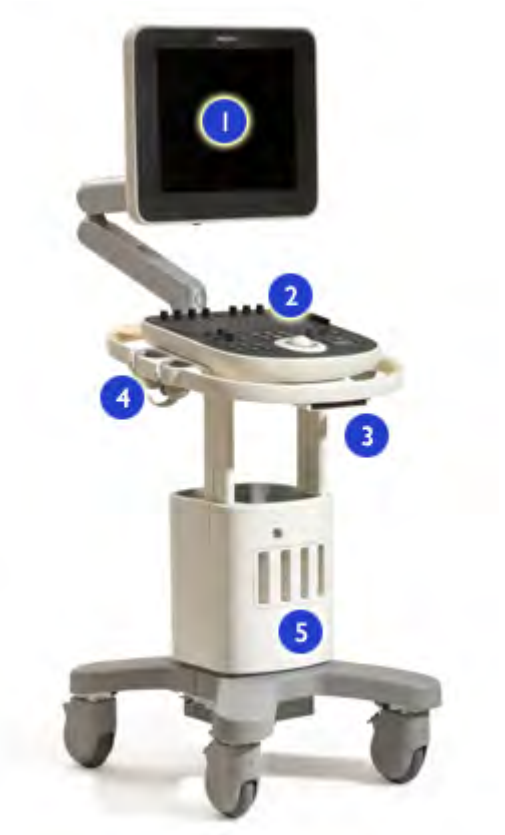
Data Security

A data security feature is available to help maintain the confidentiality of archived patient files. For more information, see "Patient Data Protection" on page 80.

System Components

The components include the monitor, control panel, DVD drive, transducer receptacles, and ECG/physio receptacle. The monitor position is adjustable to accommodate a range of operator heights and operating positions.

System Components



1.	Monitor
2.	Control panel
3.	DVD drive
4.	Transducer storage
5.	Transducer receptacles

Video Monitor

The system video monitor is a 43.2 cm (17-in) LCD display with tilt and adjustment capabilities dependent upon the version of your unit. LEDs located along the lower edge of the display aid in illuminating the control panel.

Control Panel

The control panel contains the imaging controls. These controls include buttons, knobs, TGC slide controls, and a trackball. The control panel also allows you to select transducers, enter patient data, review and annotate images, perform measurements and calculations, and change setups.

Eight quick key controls are located along the top of the control panel. Each control corresponds to a display above it on the monitor, which may contain one or two functions. Quick key controls are specific to the current operating mode.

The keyboard is used to enter patient data, comments, and text annotations on images.

Control Panel

On/Off (Power) Control

The ⏻ (On/Off) control is located on the control panel. When the system is off, pushing this control brings the system into a fully operational state. Pushing this control again turns off the system.

Data Storage

You can store study data and images onto removable media using the DVD drive. The system hard drive is located inside the system. You can also store study data, system setup data, and images onto USB devices connected to the USB port on the system. For more information, see "DVD, CD, and USB Devices" on page 132.

DVD Drive

Peripherals

Peripheral devices are available for printing images and studies. You can connect a black-and-white video printer, a color video printer, or a report printer.

External peripheral devices cannot be placed on the system cart, and they must be disconnected before moving the cart.

Transducer Receptacles and Cable Management

The system includes either three or four receptacles for imaging transducers, depending upon the system configuration. All receptacles can be occupied simultaneously, but only one transducer at a time can be active.

Transducer Receptacles

Description	Receptacles
Three imaging transducer receptacles	
Four imaging transducer receptacles	

When a transducer is not in use, store it in one of the transducer holders on the system cart. Always loop transducer cables over the cable hangers to prevent cables from being stepped on or run over by the cart wheels.

Transducer Holders and Cable Hangers

1	Transducer holders
2	Cable hangers

ECG Panel

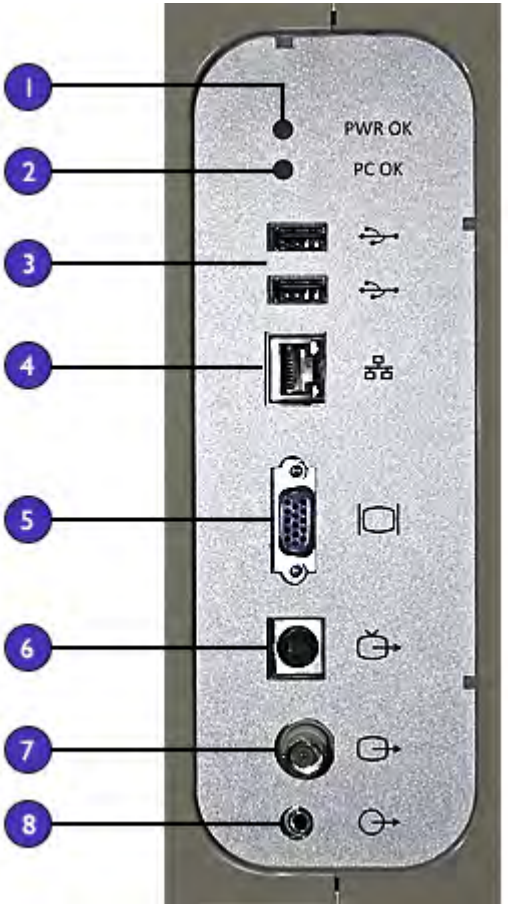
The ECG panel includes a receptacle for connecting an ECG cable. The panel is located on the front of the system.

ECG Panel

Rear Panel

The rear panel of the system contains the receptacles for the peripheral devices and network devices. The receptacles are identified by symbols on the rear panel. Those symbols are described in the "Safety" section.

Rear Panel



1	System power indicator
2	PC power indicator
3	USB receptacles

4	Network receptacle
5	VGA receptacle
6	SVG out receptacle
7	Video out receptacle
8	Audio out receptacle

Wheel Controls

All four wheels on the system cart swivel to aid in maneuvering the system. The front wheels have wheel controls that you can engage and disengage independently. Brakes help keep the cart stationary while in use.

For more information, see "Using the Wheel Controls" on page 114.

Wheel Controls

4 *Preparing the System*

The information and procedures in this section will help you prepare the system for use. Preparations include connecting external devices, setting up for moving, and ensuring that system operating requirements are met.

Connecting Devices

In addition to the devices installed in the system cart, the system supports external devices. These devices include printers, a foot switch, a black-and-white monitor, and a color monitor.

WARNINGS

- 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 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1-1.
- Philips ultrasound systems are tested to the requirements of IEC 60601-1, with on-cart peripherals that are powered by the built-in isolation transformer. The system peripherals meet general electrical safety usage requirements, but not necessarily medical device standards.
- Off-cart devices connecting to the ultrasound system must comply with the applicable IEC or national standards, such as IEC 60601-1, IEC 60950, or the equivalent.

CAUTIONS

- Using accessories, transducers, peripherals, or cables not supplied with the ultrasound system or recommended by Philips can affect the system

in the form of increased emissions or decreased immunity to external EMI/EMC occurrences.

- If systems, transducers, and peripherals have been in an environment below 10°C (50°F), allow them to reach room temperature before connecting or turning them on. Philips recommends allowing 24 hours for complete normalization. Otherwise, condensation inside the devices could cause damage. If the device was only briefly exposed to temperatures below 10°C (50°F), then the time required for the device to return to room temperature could be significantly less than 24 hours.

NOTE

Any device that is not purchased from Philips and that is not installed by Philips personnel is not covered under a Philips service agreement or warranty, and it will not be serviced by Philips.

External Printers

You can connect the following external printers to your system:

NOTE

The system uses the HP Universal Print Driver and the Epson Universal Print Driver, which support additional printers not listed here. For the supported printers, see the manufacturer's website and search for "universal print driver."

- Black-and-white image printer
  - Sony UP-D897
- Black-and-white report printer
  - HP LaserJet P2035
- Color report printers
  - Epson Artisan 810
  - Epson Stylus NX400
  - Epson WorkForce 310
  - HP Color LaserJet CP1518ni
  - HP Color LaserJet CP2025n

WARNING

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

NOTES

- Use only the printers listed here with your ultrasound system.
- To print the entire screen image on a video printer, select the **Full Screen (1680 x 1050) Local Printing Area** option under **Peripherals** in the setups. To slightly enlarge the ultrasound image on the video printer, select **Video Out (1024 x 768)**.

For additional information, see "Configuring Local Printers" on page 98 and the "Printing" section in the Help.

Connecting an External Printer

WARNINGS

- 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 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1-1.

1. Turn off the system and unplug the power cord from the power source.
2. Connect a standard USB cable between the USB port on the printer and a USB  port on the system.
3. Connect the printer's power cord into the back of the printer, and plug the other end into an appropriate power source (see "Warnings" on page 12).
4. Plug the system's power cord into an appropriate power source.

5. Turn on the printer, and then turn on the system. The system installs the printer drivers automatically.
6. After the system installs the new printer drivers, restart the system.

Configuring Local Printers

You can add a local printer to the system and then associate it either with the **Print** control or with the **Acquire** control in the setups. You can print only to a printer that has been selected. You can also change other printing parameters.

NOTE

Before adding a local printer, connect the printer to the ultrasound system as described in "Connecting an External Printer" on page 97.

1. Press the **Setup** key.
2. Click the **Peripherals** tab.
3. Select a printer from the **Print** menu in the **Peripheral Selection** area.
4. To assign a printer to the **Acquire** control, select a printer from the **Acquire** menu.
5. If you have assigned a printer to the **Acquire** control, click **Auto Print**, and then click one of the following:
   - **Batch Mode**, to print all images at the end of the study
   - **Send As You Go**, to print each image as it is acquired
6. Click **OK**.
7. Click **Config** and change the printer configuration as needed.
8. Click **OK**.
9. To print multiple images per sheet, select a key from the **Key** menu.

WARNING

Multi-image prints made on small-size paper are intended only for reference and should not be used for diagnostic purposes. Text annotation and scaling markers may not be visible on such prints.

10. To specify a layout for multiple images per sheet, click **Layout** and select options in the **Print Page Layout** dialog box.
11. Click **OK**.
12. Click **Apply** to apply your changes to this session only, or click **Save** to save your changes to a preset.

Connecting the Optional Foot Switch

Insert the connector on the foot switch cable into a USB  port on the system.

Configuring the Foot Switch

You can change the configuration of the foot switch in the **Peripherals** setups.

1. Press the **Setup** key.
2. Click the **Peripherals** tab.
3. In the **Footswitch Selection** area, select functions for the **Left** and **Right** foot switches.
4. Click **Close**.

Connecting an External Monitor

You can connect a compatible external color monitor or a compatible external black-and-white monitor to the connectors on the rear panel of the system. The color monitor connects to either the VGA video output connector  or the S-Video output connector  . The black-and-white monitor connects to the B/W composite output connector  .

WARNINGS

- 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 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.

- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1-1.

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1. Set the **Auxiliary Monitor Enabled** setting in the setups for the type of output that you are using on the system rear panel.
   a. Press the **Setup** key.
   b. Click the **System** tab.
   c. Do one of the following:
      - If you are using the VGA connector  , select **Auxiliary Monitor Enabled**.
      - If you are using the S-Video  or B/W composite  connector, deselect **Auxiliary Monitor Enabled**.
   d. Click **Close**.
2. Turn off the system and unplug the power cord from the power source.
3. Connect the data cable from the monitor to the video output connector on the system rear panel.
4. Connect the monitor's power cord and the system's power cord to an appropriate power source (see "Warnings" on page 12).
5. Turn on the monitor, and then turn on the system.

Connecting the System to a Network

For information on changing the network configuration for the system, see "System Administration" in the *Help*. To display the *Help*, press **Help** on the keyboard. To close the Help, press **Help** again.

1. Turn off system power.

2. Connect one end of the provided network connection cable to the wall receptacle for your network.
3. Connect the other end of the cable to the network receptacle on the rear panel of the system.
4. Turn on the system.

System Configuration

The ultrasound system is configured using the **System** setups. 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 must be configured before you use either the standard network support or the capabilities available through the DICOM Networking option.

To configure the system, information must be typed into the corresponding fields in the **System** setups display.

Standard Network Support

The system supports standard wired network functions, which include printing to local printers and report printers. Additional network capabilities are available in the DICOM Networking option.

DICOM Networking Option

The DICOM Networking option permits network transfer of image and report information to a DICOM storage server or PACS. The system conforms to the Digital Imaging and Communications in Medicine (DICOM) standard, version 3.0. Centralized printers, print servers, network file servers, and review workstations that comply with the DICOM standard can take advantage of the DICOM Networking option.

With the DICOM Networking option, you can store ultrasound images on DICOM-compatible file servers or storage devices and review them using a workstation. You can also print studies directly to a DICOM printer. Capabilities include support for DICOM services such as Modality Worklist, Performed

Procedure Step, and Storage Commit. The DICOM Structured Reporting option allows you to transfer tagged report data to a DICOM storage server or PACS.

The DICOM Networking option is initially set up by your Philips Ultrasound field service engineer or the system administrator. The **DICOM** setups are available from the **System** setups display or by clicking  . After you select **DICOM**, the options available to you depend upon the configuration of your system. The DICOM Networking option requires additional levels of setup.

Once the ultrasound system is configured, it remains that way through power cycles until you reconfigure it.

Configuration Information

Before you can use either the standard network support or the capabilities provided by the DICOM Networking option, the system must be configured to communicate on the network. The system configuration information must contain the correct AE title, port number, and IP address for each device on the network, including the system and its subnet mask.

The following list describes configuration information:

Name	Description
AE (Application Entity) Title	(1) The exact name of a device on the network, which is required for DICOM configuration. (2) In the **DICOM** setups, a field into which you enter the AE title.
Gateway	(1) A device or system that connects two networks together. (2) In the **DICOM** setups, a field into which you enter the gateway address of the ultrasound system. This field requires a four-byte IP address with each byte separated by a dot and in the range of 0 to 255.
IP Address	(1) A four-byte IP address with each byte separated by a dot and in the range of 0 to 255. A required field for DICOM configuration of the ultrasound system or device. (2) In the **DICOM** setups, a field into which you enter the IP address.

Name	Description
Port	(1) A number in the range of 0 to 65,535, found in the DICOM Conformance Specification for the ultrasound system or device. A required field for DICOM configuration of the ultrasound system or any device configured for DICOM operation. (2) In the **DICOM** setups, a field into which you enter the port number.
Subnet Mask	(1) A four-byte IP address with each byte separated by a dot and in the range of 0 to 255. A required field for DICOM configuration of the ultrasound system. (2) In the **DICOM** setups, a field into which you enter the subnet mask of the ultrasound system.

Entering System Network Settings

You must enter settings for your system before you connect your system to the network. If you have questions, see your network administrator.

NOTES

- You cannot make DICOM setup changes if you have a study open or if any DICOM jobs are pending. Close the open study and complete or delete pending DICOM jobs first. A message is displayed if you have pending jobs.
- If you change DICOM presets, the new preset's network settings are not applied immediately. You must first apply the network settings before trying to ping or create a new DICOM device in the new preset.

1. Do not connect the LAN cable to the system. If it is already connected, disconnect it.
2. Press the **Setup** key.
3. On the **System** tab, click **DICOM**.
4. Click the **DICOM Preset** tab.
5. On the **Change DICOM Preset** menu, select the preset that you want to change.

6. Click **Change Settings For Current Preset**.
7. Click the **This System** tab.
8. In the **System Name** area, change the **PC Name** to that specified by your network administrator and enter the **AE Title** for your system specified by your network administrator.

NOTES

- The AE title for each device on the network must be unique.
- AE titles are case sensitive. (That is, PACS1 is different from Pacs1.)
- In many institutions, the AE title is derived from the **PC Name**, which must be unique across the institution's network.

9. In the **System Port Number** area, type, or click the arrows to change, the port number specified by your network administrator.

NOTES

- The default port number, 104, is assigned to ultrasound systems at most institutions.
- If the network is configured for DHCP, then the network administrator may need to know the system's MAC address, which is displayed in the **Network Settings** area.

10. To apply the same AE title and port number to all DICOM presets that you create, in the **Common Settings** area, click **Press To Apply the Same AE Title and Port Number to All DICOM Presets**.
11. In the **Network Settings** area, click **TCP/IP Properties**.
12. In the **Internet Protocol (TCP/IP) Properties** dialog box, enter the **IP Address**, the **Subnet Mask**, and any other network parameters specified by your network administrator.
13. Click **OK**.
14. Connect the LAN cable to the system. After about 10 to 20 seconds, click **Network Administration**, verify that the TCP/IP properties that you entered are displayed in the **Information Window**, and verify that the **Network Status** is **Connected**.

NOTES

- To refresh the window, click **ipconfig** for summary information or **ipconfig/all** for detailed information.
- If DHCP is configured, you may need to release the connection and then renew the connection to obtain a DHCP lease. To do this, click **ipconfig/release** and then click **ipconfig/renew**.
- To verify that a particular server is on the network, in the **TCP/IP Ping a Networked Server** area, type the server's IP address or DNS name and click **Ping**. The system then performs a TCP/IP ping and displays the results in the **Information Window**.

15. Click **Close**, and then click **Close** again.
16. Click **OK** and then click **Close**.

Changing the PC Name

1. Press the **Setup** key.
2. On the **System** tab, click **DICOM**.
3. Click the **DICOM Preset** tab.
4. Select a preset from the **Change DICOM Preset** menu.
5. Click **Change Settings for Current Preset**.
6. Click the **This System** tab.
7. In the **System Name** area, click **Change** next to the **PC Name** field.
8. Enter the new computer name in the **Change Computer Name** dialog box.
9. Click **OK**.
10. In the **Computer Name Changed** dialog box, click **OK**.
11. Shut down the system and restart it.

NOTE

After you change the **PC Name**, the system disables all DICOM options until you restart the system. After you restart the system, all installed DICOM options are available again.

Remote Access

You can configure the system to enable remote service by a Philips field service representative. For example, a Philips representative could remotely operate the system to perform diagnostic tests.

During a remote-access session, the system displays the  (remote user logged in) icon.

To enable remote service, the system must be:

- Connected to the Philips Remote Services (PRS) network
- Configured to enable remote access

For more information on remote service, contact your Philips representative.

Enabling a Remote Access Session

NOTE

After a remote service session, you can choose to disable the remote session.

1. Press the **Setup** key.
2. Click the **Service** tab.
3. Click **Service**.
4. Click the **Remote Services** tab.
5. Click **Access / Status**.
6. In the **Remote Desktop** area, select one of the following:
   - **Enable Permanently**
   - **Enable Until** and select an end date

NOTE

If you click the  (remote user) icon on the display at any time during a remote session, you can choose to disconnect the remote session.

7. Click **OK**.
8. Click **Close**.

Repairing Network Connections

If the system's network connection is not functioning, as indicated by the  (Network Disconnected) icon on the display, you can attempt to repair the network connection.

When you repair the network connection, the system locates and selects the network adapter, renews the IP address, refreshes all DHCP leases, and reregisters DNS names. If the DICOM Networking option is installed, the system also updates the current DICOM preset with the TCP/IP settings.

1. Press **Pointer**.
2. Click  .
3. Click the **Diagnostics** tab in the **DICOM Setup** dialog box.
4. In the **Repair Network Connection** area, click **Repairs**.
5. In the **Repair Network Connection** dialog box, click **Repair**. The system displays information about the repair.
6. Click **Close**.
7. Click **OK**.

Moving the System

Observe the following warnings and cautions before moving the system.

WARNINGS

- Be aware of the wheels, especially when moving the system. The system could cause injury to you or others if it rolls over feet or into shins. Exercise caution when going up or down ramps.
- When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.
- Position external hardcopy devices away from the system. Ensure that they are secure. Do not stack them on the system.
- When positioning the articulated monitor, move it carefully to avoid pinching hands or extremities against other objects, such as a bed rail.
- Never park the system on an incline.
- The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.
- Before moving a system that has a monitor with an articulating arm mount, ensure that the arm is locked in the down position.
- When moving a system with the monitor in the folded-down position, do not place any objects on the monitor because it cannot support any added weight. Added weight could damage the monitor or the monitor arm, and any items placed on top could fall and cause injury to you or others.
- To avoid injury, Philips recommends against lifting the system cart.

CAUTIONS

- Do not move the system with the front handle. Doing so could damage the DVD drive. Use the front handle for close quarters maneuvering only.
- Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management system to ensure that transducer cables are protected from damage.
- Do not roll the system over transducer cables or power cables.
- When transporting the system in a vehicle, avoid exposing the monitor to direct sunlight and do not let the inside temperature of the vehicle exceed 65°C (149°F). Either of these conditions can permanently damage the monitor.

Preparing and Moving

1. Press the (On/Off) control to turn off the system.
2. Disconnect all external cables, including those to power, network, and external devices.
3. Secure all cables, transducers, and accessories so that they do not interfere with the wheels.
4. Lower and fold down the monitor to improve visibility.
5. Lock the monitor articulating arm mount in the down position.
6. Release the wheel brakes.
7. Move the cart, using the handle at the rear of the cart.

Positioning the System in Confined Spaces

Follow this procedure when positioning the system in a confined space.

1. Release the wheel brakes.
2. Move the system in any direction using the front handle or the rear handle.
3. When the system is in position, set the wheel brakes.

Setting Up After Moving

CAUTION

If the system behaves abnormally after moving contact Philips Ultrasound Customer Service immediately. The components are installed securely and can withstand considerable shock; however, excessive shock can cause a system failure.

1. With the system in position, connect the power, network, and other cables from the system to the appropriate wall receptacles.
2. Position the monitor where you want it.
3. Press the (On/Off) control to turn on the system.

5 *Using the System*

The topics that follow will help you understand and use the features of the system.

Turning the System On and Off

The ⏻ (On/Off) control is located on the upper left section of the control panel. When the system is on, the ⏻ (On/Off) control is lit.

CAUTIONS

- Do not unplug the system from the wall outlet until the system is completely off. If you unplug your system before the shutdown message appears, you will have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data.
- Pressing and holding the ⏻ (On/Off) control to force the system to shut down can cause the same problems as prematurely unplugging the system. Wait 90 seconds (or 3 minutes if DICOM activity is occurring) before assuming that the system has failed to shut down normally.

NOTES

- Always close all dialog boxes by clicking **OK** or **Cancel** before turning off the system.
- To break the connection from the main power supply, remove the ultrasound system plug from the wall outlet.

1. Do any of the following:
   - When the system is off, press the ⏻ (On/Off) control to turn it on.

- When the system is on, press the (On/Off) control to turn it off. A confirmation message appears briefly on the display immediately before the system turns off.

2. If the system does not turn off after 90 seconds (or 3 minutes if DICOM activity is occurring), press and hold the (On/Off) control for 7 to 10 seconds to force the system to turn off.

Setting the System Time and Date

The system includes a clock/calendar function, which maintains accurate time and date even when the system is turned off and disconnected from power. The system uses the clock/calendar function to display the time and date on the imaging display, and to provide a time stamp on patient studies and acquired images. The system automatically adjusts the date for leap years but does not automatically update for daylight saving time.

1. Press the **Setup** key.
2. Click the **System** tab.
3. Click **Date/Time**.
4. Under **Time**, highlight the hours, minutes, or seconds, and then click or .
5. Under **Date**, do any of the following:
   - To change the day, click it in the calendar.
   - To change the month, click a month in the menu.
   - To change the year, highlight it and then click or .
6. To save your changes, click **OK** and then click **Close**.

Positioning the Monitor

The monitor can be moved to suit different operating positions.

1. If the monitor is mounted on an articulated arm, press the release to unlatch the articulated arm.
2. Grasp the monitor by the sides and tilt or swivel it into position.

Articulated Arm Release

Monitor Settings

You can change the monitor brightness and tint in the setups or by using a keyboard shortcut.

Changing the Monitor Tint

You can change the tint of the monitor image. The tint setting affects only the appearances of images on the monitor; it does not affect saved or exported images. The following settings are available:

- **sRGB** (For routine use, Philips recommends this setting.)
- **1-4**

Do one of the following:

- Press **Ctrl+T** repeatedly to cycle through the tint settings.
- On the **System** tab in the setups, click a setting for **Monitor Tint**, click **Apply**, and then click **Close**.

Changing the Monitor Brightness

You can change the brightness of the monitor display. The brightness setting affects only the brightness of the monitor display; it does not affect saved or exported images.

On the **System** tab in the setups, click a setting for **Monitor Brightness**, click **Apply**, and then click **Close**.

Using the Wheel Controls

WARNINGS

- Never park the system on an incline.
- The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.

All four wheels on the system cart swivel to aid in maneuvering the system. The front wheels have wheel controls that you can engage and disengage independently. Brakes help keep the cart stationary while in use.

- To engage the brake, press the gray **ON** lever.
- To release the brake, press the gray **OFF** lever.

Wheel Controls

System Controls

The system includes a variety of controls, all of which are located on the control panel. These controls include imaging controls, quick keys, and the keyboard.

Control Panel

The control panel contains the imaging controls. These controls include buttons, knobs, TGC slide controls, and a trackball. The control panel also allows you to select transducers, enter patient data, review and annotate images, perform measurements and calculations, and change setups.

Eight quick key controls are located along the top of the control panel. Each control corresponds to a display above it on the monitor, which may contain one or two functions. Quick key controls are specific to the current operating mode.

The keyboard is used to enter patient data, comments, and text annotations on images.

Control Panel

Control Status

Some lighted controls and their labels indicate the availability of the controls and the status of modes.

Definitions of Control Backlight Colors and States

Backlight Color or State	Control Status
Off	Control is unavailable
White	Control is available
Amber	Control or mode is active or on (only on mode controls and certain other controls)

Changing Control Panel Brightness

You can change the brightness of the lit controls on the control panel.

On the **System** tab in the setups, click a new setting for **Panel Brightness** and then click **Apply**.

Quick Key Controls

Quick key controls are located along the top of the control panel. Two rows of labels for quick key functions and settings appear along the bottom of the display. Each column of labels corresponds to a quick key control below it on the control panel. Those quick key controls are used to select imaging features and settings. The functions of the quick key controls change depending on the mode, the application, the preset, and the transducer.

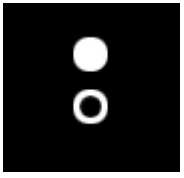
Two labels appear for each quick key control. The top label is the function that is invoked by *pressing* the control. The bottom label is the function that is invoked by *turning* the control.

In some cases, two rotary functions are available for a quick key. Only one of the two functions can be active at any time. When two rotary functions are available, the top label shows both functions that are available. The bottom label shows which function is currently selected. Pressing the quick key control selects which function is active. Turning the control changes the settings for the active function.

In most modes, there are two or more pages of quick key functions available. Use the **Next** control to display the next available page of quick key functions.

An indicator above the **Next** control shows how many pages of functions are available and which one is selected. For example, in this figure, the first of two available quick key pages is selected.

Quick Key Page Indicator



Using Quick Key Controls

- To change the setting of the top function, press the quick key control.
- To change the setting of the bottom function, turn the quick key control.
- If two rotary functions are available for a quick key control, press the control to select which function is active. Then turn the control to change the setting of the active function.
- To display the next page of quick key functions, press **Next**.

System Keyboard

You can use the keyboard to enter patient data, study comments, image annotation, and your logon password. The function keys along the top of the keyboard are used to perform various functions, such as entering patient data, reviewing images, ending an exam, changing setups, and displaying the system Help.

Typing Special Characters

The World keys are labeled with a globe. They appear on either side of the spacebar. Use a World key to type the characters that appear on the right side of some keys on the keyboard.

NOTE

Ensure that the Caps Lock is off (the Caps Lock indicator  should *not* appear on the left side of the status line on the display).

Do any of the following:

- To type a character that appears on the bottom right corner of a keyboard key, press the World key and the special character key simultaneously.
- To type a character that appears on the top right corner of a special character key, press the World key, the **Shift** key, and the special character key simultaneously.
- To type the lower case version of a character that appears on the top right corner of a special character key, press the World key and the special character key simultaneously.

Typing Accented Characters

You can type a letter with a diacritical mark that does not appear on your keyboard (for example, Â).

NOTE

Ensure that the Caps Lock is off (the Caps Lock indicator  should *not* appear on the left side of the status line on the display).

1. Press the key for the diacritical mark you want to type. If the diacritical mark is at the top of the key, press **Shift** while pressing the key (for example, **Shift+^**). The diacritical mark does not appear until you press the actual letter key.

2. Press the letter key. For an uppercase letter, press **Shift** and the letter key (for example, **Shift**+**A**).

Status Icons

Icon	Description
	Displayed when the **Caps Lock** key is on.
	Displayed when the SonoCT feature is on and in Survey mode.
	Displayed when the SonoCT feature is on and in Target mode.
	Displayed when the XRES feature is on.
	Displayed when the iSCAN Intelligent Optimization feature is on.
	Displayed when the Color iSCAN optimization feature is on.
	Displayed when the system is ready for acquisition. When the system is busy acquiring an image, the icon is hidden.
	Displayed when remote access is enabled, but there is no active remote session.

Icon	Description
	Displayed when a remote session is active.
	Displayed when the Network Packet Capture is enabled but not running.
	Displayed when the Network Packet Capture is enabled and running.
	Indicates the status of the network: • Green dot: Connected • Red X: Disconnected or error Click the icon to open the **DICOM Setup** dialog box. This icon appears only if the DICOM licensed options are installed.
	Indicates that no user is logged onto the system. Click the icon to log on.
	Indicates that a user is logged onto the system. Click the icon to log off.
	Indicates the status of the current print job: • When a print job is being sent, the icon is displayed. • When the print job has been sent, the icon is hidden.

System Security

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 on to the system using a password. When you are finished using the system, you can log off manually or simply shut down the system, which logs you off automatically.

The data security feature is set up by your system administrator. For information, see "System Administration" in the Help. To display the Help, press **Help** on the keyboard.

Logging On to the System

When data security is enabled by your system administrator, you must log on to the system before you can view or load patient files or start a new study. (For information on starting a study in an emergency, see "Temporary ID" on page 123.) To log on, use the user ID provided by your system administrator.

1. Do one of the following:
   - If you are beginning a study, press the **Patient** key.
   - If the system has automatically logged you off, press **Review** and then click  .
2. For **Password**, type your password and click **OK**.

Logging Off of the System

If you do not log off manually, the system will automatically log you off when you shut down the system. If the automatic log-off function is enabled, you are logged off automatically after the system has been inactive for a predetermined length of time. Logging off of the system does not change the current patient, but it does deny further access to protected patient data.

1. Click  .
2. Click **OK** to log off, or click **Cancel** to remain logged on.

Emergency Studies

If the system administrator has enabled the data security feature on your system, it is important to understand how to start a study in an emergency situation.

Temporary ID

Use the temporary ID feature to start a study quickly. This feature allows you to log on without a password and perform a study without first entering patient data. When you select this feature, the system enters unique, temporary placeholders for the patient's last name and ID. Using the temporary ID feature allows you to perform a study as you would normally, except that access to prior patient data is not available if the data security feature is implemented.

NOTE

If another study is active when you use the temporary ID feature, the active study is saved and closed without notification.

Patient data can be entered at the end of the study or later, depending on the export configuration:

- If your system is configured with **Manual Print Only**, you can change the patient data for up to 24 hours as long as you do not export the study from the system.
- If your system is configured with **Batch Mode** enabled (batch export), you cannot change the patient data after the study is ended. Once you export the study from the system, you can no longer change the patient data.
- If your system is configured with **Send As You Go** enabled (send each image as it is acquired), you cannot change the patient data after you acquire the image. Once you acquire an image, it is exported from the system and you can no longer edit the patient data.

Images can be printed before entering patient data, if the system is configured to print images as you scan, but those images are labeled only with the temporary ID.

Starting Emergency Studies

In an emergency, you can use the temporary ID feature to start a study without first having to enter patient data.

1. Do one of the following:

- If no study is active, press **Acquire**, and then click **Temporary ID**.
- If a study is active, press the **Patient** key and then click **Temporary ID**.

2. When the study is finished, press the **Patient** key and edit the emergency patient data.

NOTE

In studies with a temporary ID, three different scenarios are possible depending your system's configuration. If your system is configured with **Manual Print Only**, you can change the patient data for up to 24 hours as long as you do not export the study from the system. If your system is configured with **Batch Mode** enabled (batch export), you cannot change the patient data after the study is ended. Once you export the study from the system, you can no longer change the patient data. If your system is configured with **Send As You Go** enabled (send each image as it is acquired), you cannot change the patient data after you acquire the image. Once you acquire an image, it is exported from the system and you can no longer edit the patient data.

Imaging Display

The imaging display contains an ultrasound image, study and image information, quick key labels, and indicators.

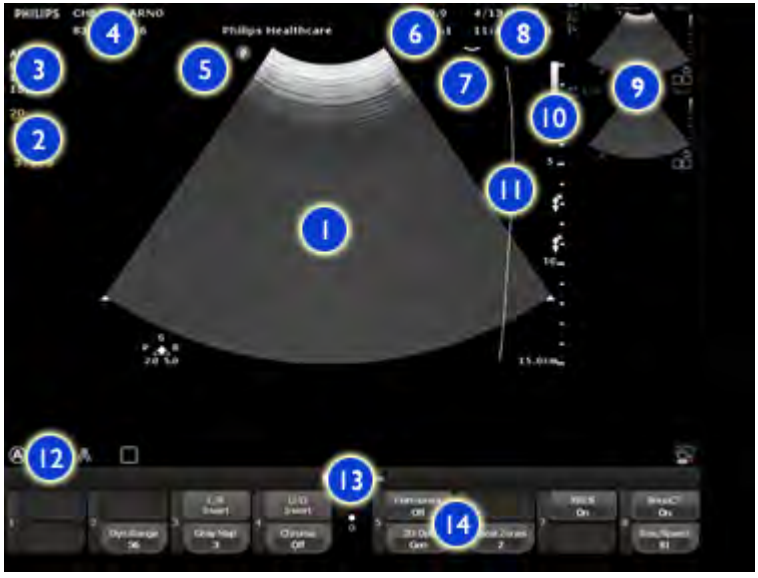
The image area is approximately in the center of the display. The image area includes scales indicating the depth and focus settings, curves representing the TGC and LGC settings, a color or grayscale bar, and, in M-mode and Doppler, the sweeping display. A scan plan orientation marker appears at the top left of the image. This marker corresponds to the orientation marker on the transducer.

The study information includes the patient data, the current time and date, the institution name, and the TI and MI values. The system does not display patient data until you start a study. You can use the **Hide ID** key to prevent the system from displaying the patient data in the exam information. The TI values appear as TIS, TIB, or TIC, depending on the selection for **Thermal Index** in the system

setups. Each application provides a default TI display that is used when the **Thermal Index** selection is **Normal**.

Image information is displayed to the left of the image. This includes the transducer and preset in use. In modes such as Duplex or Triplex, additional image information is also displayed. At the bottom of this area, icons indicating active features appear. These icons include active imaging features, printer status, and acquire states.

Imaging Display



1.	Imaging area
2.	Imaging settings
3.	Preset and transducer

4.	Patient and study information
5.	Scan plane orientation marker
6.	MI and TI values
7.	LGC curve
8.	Time and date
9.	Thumbnail images
10.	Grayscale or color bar
11.	TGC curve
12.	Status icons
13.	Select menu
14.	Quick key labels

Setting the Auto Freeze Function

The **Auto Freeze** function stops imaging and freezes the image, if a control is not manipulated within the **Wait** time that you specify. The default time is 5 minutes. After Auto Freeze has been invoked, press any control to restart imaging.

1. Press the **Setup** key.
2. Click the **System** tab.
3. Under **Auto Freeze**, select **On**, and then select the **Wait** time.
4. Click **Apply** and then click **Close**.

Transducer Receptacles and Cable Management

The system includes either three or four receptacles for imaging transducers, depending upon the system configuration. All receptacles can be occupied simultaneously, but only one transducer at a time can be active.

Transducer Receptacles

Description	Receptacles
Three imaging transducer receptacles	
Four imaging transducer receptacles	

When a transducer is not in use, store it in one of the transducer holders on the system cart. Always loop transducer cables over the cable hangers to prevent cables from being stepped on or run over by the cart wheels.

Transducer Holders and Cable Hangers

1	Transducer holders
2	Cable hangers

Connecting Transducers

Depending on your system configuration, the system has three or four imaging transducer receptacles located on the front of the system.

To connect an imaging transducer, insert its connector into the receptacle until it latches.

NOTE

If the **Unsupported Transducer** message appears, disconnect and reconnect the transducer.

Connecting a Transducer to the System

Selecting a Transducer

NOTE

If the system displays an **Unsupported Transducer** message, ensure that all connected transducers are compatible with your system configuration.

If multiple transducers are connected when the system is turned on, the system selects the transducer that was in use when the system shut down. You can select among the connected transducers during system operation.

You can connect or disconnect a transducer during live imaging without damaging the transducer or the system.

Press **Transducer** to select a transducer. The selected transducer is indicated on the display.

Selecting a Preset

When the system is turned on, the system selects the same preset that was in use when the system shut down, unless it is incompatible with the initially selected transducer. In this case, the system activates the autoselect preset for that transducer.

During system operation, you can select a clinical option preset for the selected transducer.

1. Press **Preset**.
2. On the **Presets** menu, select a preset.

Using Presets

These tips can help you understand presets and use them effectively.

- When a study moves to another part of the anatomy, you can select a different preset that is appropriate for that application.
- If you want to return the system to the default settings of the current preset, either with the current transducer or after selecting a different one, simply select the current preset again.
- When you select a different transducer that is not compatible with the current preset, the system selects the default preset.

Physio Feature

The system can display two physio traces that represent low-level ECG and respiration signals, which come from low-level ECG leads connected to the patient. Heart rate, derived from the ECG signal, is displayed whenever ECG is connected and displayed.

ECG Receptacle

For information on using ECG, see the Help. To display the Help, press **Help** on the keyboard. To close the Help, press **Help** again.

DVD, CD, and USB Devices

Removable media compatible with the system include DVD, CD, and USB storage devices. Use removable media to store and transfer patient files, including full studies, 3D data sets, and reports. Also, you can save, restore, and distribute setups data, including presets.

The system includes a DVD drive on the front of the system under the control module. You can use this drive to store and transfer patient files, including full studies, 3D data sets, and reports. Also, you can save, restore, and distribute setups data, including presets.

For additional information on specific applications of the DVD drive, see the Help. To display the Help, press **Help** on the keyboard. To close the Help, press **Help** again.

For details about USB devices, see "USB Devices" on page 134.

Media Compatibility

CD media capacity is approximately 700 MB; single-layer DVD media capacity is approximately 4.7 GB. Rewritable media types (indicated by the RW suffix) can be erased and used again, but you cannot erase media that has the R suffix. The system does not support dual-layer DVD media.

DVD and CD media are available in a number of types. Not all media types are fully compatible with the system DVD drive. To ensure consistent performance, use only high-quality CD or DVD media in the system DVD drive. For more information, see *Media Compatibility* on the *User Information* CD.

NOTE

For information regarding USB media, see "USB Devices" on page 134.

The following disc types can be used in the system DVD drive:

- CD-R
- DVD-R
- DVD+R
- DVD+RW

With certain disc types, multiple studies can be written to a disc, up to the limit of its capacity. This includes moving a single DVD or CD between different ClearVue 350/550 ultrasound systems and writing studies from each system to the disc. You can have multiple sessions on CD-R, DVD-R, and DVD+R media. Multiple-session writing is unsupported on DVD+RW media.

NOTE

The DVD drive allows writing data to a disc only in a single session. This means that the disc is finalized at the end of the session and no further data can be added to it later.

Loading and Ejecting a Disc

Do one of the following:

- To load a disc, gently guide a disc into the drive slot, until the disc is pulled into the drive.
- To eject a disc, press the Eject button on the drive.

USB Devices

The system provides USB ports that can be used to connect USB storage devices. Such devices include USB memory devices and USB hard disk drives. USB ports are on the right front corner of the control module and on the rear panel. Read the following information before using USB storage devices.

The system supports the following USB devices:

- Single-partition USB flash memory drives
- USB flash memory drives that do not use or contain any antivirus or other executable software
- USB hard disk devices that require 500 mA or less per USB port
- USB 2.0 compliant devices

WARNING

Connecting externally powered USB hard disk drives to the system involves electrical safety risks. If you connect such drives to the system, you must observe the electrical safety warnings in the "Safety" section. Philips recommends that you use only USB hard disk drives powered from the USB connector, or use USB flash memory devices.

CAUTIONS

- When transferring data to or from a USB device, be sure the transfer is complete before removing the USB device. For USB devices that have an indicator, be sure the indicator is no longer flashing before removing the device.
- Ultrasound systems may become vulnerable to security breaches when they accept removable media. Removable USB storage devices may contain viruses. Philips recommends that you use the system to format USB storage devices before working with them.
- Philips does not recommend that you use USB storage devices for long-term storage. Follow your IT department's recommended practices for intended

use of USB storage devices. For more information about security on the ultrasound system, see *Shared Roles for System and Data Security*, included on your *User Information CD*.

- Some USB flash memory drives are sold with "U3" smart technology installed. When a USB device with U3 technology is plugged into the system, the system does not allow reading from, or writing to, the U3 portion of the USB flash memory drive.
- Use only Class-B-compliant USB storage devices with the system. USB devices that are not Class-B compliant may cause RF emissions that exceed Class B limits. See the device's documentation to determine whether it is Class-B compliant.

Erasing a DVD or USB Device

Erasing a rewriteable disc (indicated by the RW suffix) or USB device erases all data on it and prepares it for reuse. After a disc or USB device is erased, the entire capacity of the disc or device is again available. Write-once media types (indicated by the R suffix) cannot be erased and used again.

CAUTION

You cannot restore data after it is erased from a disc or USB device.

1. Load the disc into the drive, or connect the USB device to a USB port on the system.
2. Press **Setup**.
3. Click the **Removable Media** tab.
4. In the **Select Media** menu, select the DVD drive or USB device.
5. To see the contents of the disc or device before erasing, click **Browse Media**.
6. Click **Erase Media**.
7. In the **Erase Media** dialog box, click **Yes** to erase.
8. When the dialog box indicates that erasing is complete, click **OK**.
9. Click **Close**.

6 *Customizing the System*

You can customize your system to increase efficiency and streamline your workflow. You can do the following:

- Create presets designed specifically for the exams you perform
- Change system settings to reflect your needs
- Add options to enhance your imaging abilities

Presets

A preset is a group of settings that optimizes the system for a specific type of exam. Presets establish many initial imaging settings, such as gain value, color map, filter, and which quick keys, annotations, and body markers are available.

When the system is turned on, the system selects the same preset that was in use when the system shut down, unless it is incompatible with the initially selected transducer. In this case, the system activates the autoselect preset for that transducer.

In addition to the presets provided with the clinical options, the system lets you create and use custom presets. The available presets are determined by the selected transducer.

NOTE

Presets are available only if you purchased a corresponding clinical option.

Custom Presets

Custom presets provide a quick way to set imaging parameters to the values you prefer for a specific exam type. Using the custom preset feature, you can define presets for specific clinical options and transducers. A custom preset stores the imaging settings that are active when you create the custom preset.

A custom preset can include certain settings found in the setups. Settings that affect the imaging display or imaging functions can be saved in a custom preset.

For example, you could change the gain and set the number of focal zones, and then save these changes to a custom preset. Neither factory presets nor custom presets store settings that affect the system as a whole, such as date and time, system options, and DICOM settings.

A custom preset is based on the factory preset or custom preset that is active when you create the custom preset. Thus, the custom preset will be compatible with the same set of transducers as the active preset. After you create a custom preset, it appears as an item on the **Presets** menu if a compatible transducer is active. When you select the custom preset, the system automatically invokes the settings in the preset. You can modify or delete existing custom presets; copy them onto a CD, a DVD, or a USB device; and load them into another system.

Creating Custom Presets

You can create a custom preset that is based on an existing preset. You can do this even during a study, while using the preset.

1. Press **Preset**.
2. On the **Presets** menu, click the preset on which you want to base your custom preset.
3. Adjust the imaging controls to create the settings for your preset. You can select an imaging mode, change the gain, set the number of focal zones, and so on.
4. Press **Preset**.
5. Press the **Save Preset** quick key.
6. In the **Save Preset** dialog box, click **Create New**.
7. In the **Create New Preset** dialog box, type a name for the new preset.
8. Click **Save**.

NOTE

You cannot change or save the default imaging mode with the preset. The default imaging mode is 2D mode or the last active mode from another preset.

Modifying Custom Presets

You can modify existing custom presets and save your changes. You can do this even during a study, while using the preset.

1. Press **Preset**.
2. On the **Presets** menu, click the custom preset you want to modify.
3. Adjust the imaging controls. You can select an imaging mode, change the gain, set the number of focal zones, and so on.
4. To include changes made in the setups into a custom preset, do the following:
   a. Press the **Setup** key.
   b. Make changes to settings that affect the imaging display or imaging functions.
   c. Click **Apply**, and then click **Close**.
5. Press **Preset**.
6. Press the **Save Preset** quick key.
7. In the **Save Preset** dialog box, click **Modify Current**.
8. If you want to change the name of the existing preset, change it in the **Modify Current Preset** dialog box and click **OK**.

Deleting Custom Presets

You can delete any custom presets on the system, including the current preset. Factory defaults cannot be deleted, but you can hide them on the **Presets** menu.

1. Press **Preset**.
2. Move the cursor over the preset you want to delete.
3. Press the **Delete Preset** quick key.
4. In the **Delete Preset** dialog box, click **OK**.

Presets Menu

The **Presets** menu can display items in two ways: **Show All** or **Show Exam Type**.

- In **Show All**, the **Presets** menu contains a list with exam types and presets together, with presets indented under the relevant exam type.
- In **Show Exam Type**, the **Presets** menu contains either the presets in a single exam type or a list of exam types.

When you press **Preset**, the system shows the menu in the state in which it last appeared.

In the setups, presets available with a specific transducer are designated either primary or secondary for that transducer. By default, the **Presets** menu shows only the primary presets.

Using the Presets Menu

Press **Preset** and do any of the following:

- Click **Show Exam Type** to show the presets in a single exam type.
- Click the exam type to display only the available exam types without the presets.
- Click **Show All** to show all exam types and their associated presets.

Modifying the Presets Menu

In the setups, you can select which presets appear in the **Presets** menu, change the order of the presets, and assign which preset will be automatically selected when a transducer is selected and the current preset is incompatible with the selected transducer.

1. Press the **Setup** key.
2. Click the **Preset Menu** tab.
3. Highlight a transducer in the **Supported Transducers** list.

4. In the **Preset Menu** list, do any of the following:
   - To change the location of a preset in the **Preset Menu** tab, highlight it and click **Move Up** or **Move Down**.
   - To change the location of an exam type and its presets, highlight the exam and click **Move Up** or **Move Down**.
   - To make a preset secondary, so that it is hidden in the default **Presets** menu, deselect it (the check mark disappears).
   - To make a preset primary, so that it is included in the default **Presets** menu, select it (the check mark appears).
5. To set a preset as the one to be automatically selected when the current preset is incompatible with the selected transducer, highlight the preset and click **Assign Autoselect**.
6. To reset all settings in the **Preset Menu** tab to factory-provided default values, click **Clear Preferences** and do one of the following:
   - To reset preferences for all transducers, click **All**.
   - To reset preferences for only the transducer that is highlighted in the **Supported Transducer** list, click **Current**.
7. To save your changes, click **Apply**.
8. Click **Close**.

Copying Custom Presets

You can copy custom presets to a CD, a DVD, or a USB device. This function is useful for archiving presets and for sharing presets among other ClearVue 350/550 ultrasound systems. For more information on copying custom presets to and from removable media, see the "System Administration" section in the Help.

System Setups

Setups provide control over system parameters that you can change. In the setups, you can customize the system to meet your operating preferences. The

setups are organized into categories by tabs located along the top of the **Setup** display. Most changes in the setups take effect when you apply or save the changes. Some changes, however, take effect when you click **OK** in a dialog box within the **Setup** dialog box; examples include the settings in the **Dual** and **Date/Time** dialog boxes.

There are two types of information controlled by the setups:

- System information can be applied but cannot be saved to presets. Changes applied to this type of information remain in effect until you change them again or load setup information from a CD, a DVD, or a USB device. These changes remain in effect even after the system has been turned off and on again.
- Preset information can be applied to the current study or can be saved to custom presets. Changes *applied* to this type of information remain in effect until you change them again, start a new study, or load setup information from a CD, a DVD, or a USB device. Changes to this type of information *saved* to a custom preset remain in effect until you change them again, switch to another preset, or load custom presets from a CD, a DVD, or a USB device. Preset information is updated each time you switch to another preset.

NOTE

The institution name exported with DICOM data always reflects the name shown in the setups at the time the study ended. When you change the institution name in the setups, Philips recommends restarting the system after changing the institution name.

Procedures for using setup options and descriptions of settings are included throughout the *Help*.

Changing Setups

1. Press the **Setup** key.
2. Click a tab to select a setup category.
3. Enter text or make selections necessary to set up your system.
4. To apply your changes to system or preset information types, click **Apply**.

5. To save your changes to preset information, click **Save** and then do one of the following:
   - To save changes to the current custom preset, click **Modify Current**.
   - To save your changes to a new custom preset, click **Create New**, type a name for the preset, and click **Save**.

Options

In addition to the standard features available in the system, other features are available as purchasable licensed options. The types of options available include clinical options, protocols, imaging capabilities, and connectivity capabilities.

Installing Temporary Options

The system lets you temporarily install licensed options. You can then evaluate these options for a fixed length of time, which is set by Philips. Before you can install temporary options, you must request and receive an access code for each option you want to install. The installation process requires restarting the system, so be sure that the last study has been closed before installing options.

1. Press the **Setup** key and click the **Options** tab.
2. On the **Options** tab, click **Options**.
3. In the options list, note the names of the options you want to install.
4. Contact your Philips representative and request an access code for each option you want to install.
5. When you receive your access codes, display the options list as described in step 1 and step 2.
6. In the options list, select an option to install.
7. Click **Install**.
8. In the **Access Code Required** dialog box, type the access code for the option you selected, and then click **OK**.
9. To install additional options, repeat step 5 through step 7.

10. To complete installation, click **OK** and then click **Close**.
11. Turn the system off, and when it has fully shut down, turn it on again. The temporary options you installed are now available.

7 *Performing a Study*

This section guides you through procedures commonly used in performing patient studies with the system. These procedures include entering patient data; acquiring, annotating, and reviewing images; and making measurements and calculations.

For detailed information on the controls, features, and tasks mentioned here, see the Help. To display the Help, press **Help** on the keyboard. To close the Help, press **Help** again.

New Patient Studies

You must create or restart a patient study before you begin acquiring images. If you do not, you cannot acquire, print, or save images. The way you create a patient study depends on whether you are using the Modality Worklist feature.

WARNING

Failing to end the current study before starting a new study can result in data being acquired and stored under the wrong patient name. If you turn off the system without ending the study, the system automatically ends the study before shutting down.

You start a study by entering patient data into the system. (But you can also create a study with a temporary ID without first entering patient data). There are two ways to enter patient data.

- If the Modality Worklist feature is not enabled or used on your system, you enter patient data into the **Patient Identification** display.
- If your system is connected to a DICOM network with the Modality Worklist feature enabled, you can select a study from the **Patient Selection** display to load patient data instead of entering that information manually.

The system uses a unique medical record number (MRN) to identify each patient. You can enter an MRN, or you can have the system create one automatically. Stored images, fetal growth graphs, and reports are stored based on the MRN. An accession number is an optional entry that an institution can assign to each patient file, for internal information-management purposes.

The system sets the study date when you first acquire an image during the study.

Entering Patient Data Manually (Without Worklist)

If you are not using the worklist option, you start a study by entering patient data into the ultrasound system.

NOTES

- Before entering patient data, verify that the date and time displayed on the system are accurate.
- Entering a new patient closes the previous study and clears all current images and report information.

1. Ensure that the previous study has ended by pressing **End Exam**, or by pressing **Review** and clicking  .
2. Press the **Patient** key.
3. In the **Patient Identification** display, do one of the following:
   - Type an MRN and press the **Tab** key. The system searches for a matching MRN, and if it locates one, it automatically populates the patient information.
   - Type the patient information. (Press the **Tab** key to move the cursor from field to field.)

NOTES

- The patient's last name must be entered to start a study, except when creating a temporary ID.
- If you enter a last name, but not an MRN, the system automatically generates an MRN based on the current time and date. Philips recommends that you enter the MRN.
- The same MRN is used for a single patient folder.
- If you create two studies with different patient names but with the same MRN, the system prompts you to enter a new MRN or to use the same MRN and change the patient name.

4. Click the **Additional** tab.
5. For **Additional Data Types**, select the study you will be performing.
6. Enter the pertinent study information for the patient.

NOTE

If you enter an **LMP** date for an obstetric study, the system automatically calculates and displays the **EDC (LMP)**.

7. When you are finished, click **OK**.

Using Modality Worklist

Before you use Modality Worklist, you must specify the Modality Worklist server. Modality Worklist is a component of the DICOM Networking option.

1. Press the **Patient** key to open the **Patient Selection** display. The **Modality Worklist** displays scheduled patients.
2. In the **Patient Selection** display, click a column header to sort the worklist by last name, exam time, or another category.
3. Search for the patient, if necessary:
   - Enter one or more letters or numbers in the **Find** field, and select a column from the **In Column** menu. As you type, the list changes to show only the patients that match your criteria.

- To find a subset of the results, type a value for a different column in the **And** field, and select the column from the **In Column** menu.
- To store the current filter settings as the default, click **Save Filter**.
- To start a new search, click **Clear Filter**.

4. Do one of the following:

   - Select the patient. Click the name of the patient and click **OK**, or double-click the highlighted patient name. The **Patient Identification** display opens and is populated with the patient's information. You can edit and save.
   - If the patient's name does not appear in the **Patient Selection** display, click **Manual Entry** to open a blank **Patient Identification** display.

Selecting a Transducer

NOTE

If the system displays an **Unsupported Transducer** message, ensure that all connected transducers are compatible with your system configuration.

If multiple transducers are connected when the system is turned on, the system selects the transducer that was in use when the system shut down. You can select among the connected transducers during system operation.

You can connect or disconnect a transducer during live imaging without damaging the transducer or the system.

Press **Transducer** to select a transducer. The selected transducer is indicated on the display.

Imaging Modes

Your ultrasound system offers a set of imaging modes to accommodate a variety of imaging applications. Some modes display a live grayscale image. Others are Doppler modes to evaluate the amplitude or the direction of the blood flow and

the spectral information. Special modes are also available for 3D and Panoramic imaging.

NOTE

Some modes are available on your system only if the corresponding option has been purchased and installed.

Using 2D Mode

NOTES

- With sector transducers, the top of the image does not correspond to the skin line.
- The color and state of the backlight on the controls and their labels indicates the status of controls and modes. When a control's backlight is white, the control is available but inactive. When the control's backlight is amber, the control is active. For multi-use controls, such as **Depth** or **Focus**, press the control to change the active function.

Before beginning an exam, you must enter patient information.

1. Press **2D** to start 2D imaging, if necessary.
2. Optimize the image using any of the following methods:
   - To automatically optimize the TGC, dynamic range, and gain settings for the current image, press **iSCAN**.
   - To control the image brightness, adjust **Gain**.
   - To increase or decrease the distance from the face of the transducer to the deepest point in the displayed image, use **Depth**.
   - To select the area where the image will be most clearly focused, adjust **Focus**.
   - To optimize the transmit and receive frequencies and penetration and resolution for the image, use **2D Opt**.
   - To compensate for signal attenuation, use the **TGC** and **LGC** controls. Use **TGC** to increase or decrease the amplification of the signal to adjust the brightness of the image at different depths, and use **LGC** to adjust the

amplification at the edges of the sector. You can use the **TGC** and **LGC** controls during live imaging, after freezing the image, or post-acquisition from the cineloop buffer.

- To enhance the image, use XRES image processing, which for many presets is on by default.
- To compare an acquired (or review) image with a live image, use the **Compare** control.

3. To enter another imaging mode, press the control for that imaging mode.
4. To return to 2D-only imaging from any other imaging mode, press **2D**.

Annotation

You can place text labels and arrows on an image to identify anatomical structures and locations. You can also annotate an image with a body marker graphic that indicates the part of the anatomy that you are scanning.

NOTE

You can add, modify, or delete annotation labels and body markers on an image in Review only if the image contains active native data. Changes to annotation labels and body markers in Review are not retained with the image unless you acquire the image in Review.

Placing a System-Defined Label on the Display

You can place system-defined labels on the display by pressing **Label**.

1. If annotation mode is not currently active, press **Label**.
2. Do one of the following:
   - Press the left or right trackball button to highlight **Cursor** on the display. Use the trackball to position the cursor, and then press the left or right trackball button to highlight **Menu** on the display. Highlight a label in the label menu and press the middle trackball button to place it on the display.

- Press the **Menu** quick key to hide the label menu. Position the cursor where you want to place the label, and then press the **List** quick key for the list that contains the label you want. For example, to select a label from the top list in the label menu, press **List 1**. To cycle through all the labels in the list, press the **List** quick key repeatedly.

3. Press **Label** to exit annotation mode.

Typing a Label on the Display

Do one of the following:

- Use the arrow keys (**PgUp**, **PgDn**, **Home**, and **End**) to position the cursor where you want to place the label, and then type the label text. If you do not position the cursor, the text is placed at the home position. When you are finished typing, press the **Enter** key.
- Press **Label**, and then press the **Menu** quick key to hide the label menu. Use the trackball to position the cursor. Type the label text, and then press the **Enter** key.
- Press **Label**, and then press the left or right trackball button to highlight **Cursor** on the display. Use the trackball to position the cursor. Type the label text, and then press **Label** to exit annotation mode.

Placing a Body Marker on the Display

Body marker sets are organized by exam type.

1. Press **Marker**.
2. Do one of the following:

   - Use the quick key below the **View All** quick key to select the set of body markers that includes the marker you want. Use the leftmost quick key to select the body marker you want. Press the left or right trackball button to highlight **Icon** on the display, and then drag the body marker to the location where you want it and click.

- Press the **View All** quick key. On the **Select Body Marker** dialog box, click the tab for the exam type you want, and then click the body marker you want.

Printing

You can print single-frame images and reports to a local printer, usually installed in the system, or to DICOM printers on a network. The printer can be a color image printer, a black-and-white image printer, or a report printer.

The **Print** control is available for printing images.The **Acquire** control also has print capabilities associated with it.

In the setups, you can assign those controls separately to image printers. **Print** and **Acquire** can print to local and network printers. Report printing is assigned to a single dedicated report printer.

WARNING

Multi-image prints made on small-size paper are intended only for reference and should not be used for diagnostic purposes. Text annotation and scaling markers may not be visible on such prints.

Review

During or after a study, you can use Review to examine and compare still-frame images and loops acquired in the study. You can view images, delete images from the study, edit loops, and end the study.

You can export images and studies from Review to a CD, a DVD, a USB removable-storage device, or DICOM-compatible devices on a network.

You can make measurements and annotations in the image view. Measurements made in Review on the current study can be saved in the report. Measurements made in Review on prior studies cannot be saved.

If your image supports active native data, the system saves raw image data with the image, which enables you to perform most of the same adjustments to an image in Review as you can in live imaging.

Use the compare feature in Review to compare live images with previously acquired images.

Starting Review

1. Press the **Review** key.
2. To return to live imaging, press the **Review** key again.

Navigating Thumbnails and Images

In Review, you can switch between thumbnail view and image view.

1. To switch to thumbnail view from full-screen image view, click  .
2. To switch to full-screen image or loop from thumbnail view, double-click the thumbnail image, or click the thumbnail image and then click **Play**.

NOTE

If you have selected an *n*-up option from the **Image Selection** menu, *n* number of images or loops appear when you enter image view.

3. To view a different thumbnail as a full-screen image or loop in image view, do one of the following:
   - Double-click the thumbnail.
   - Turn **Page**. For example, turn **Page** to **3** to view the third thumbnail.

Acquiring Images and Loops

NOTES

- Acquisition during live imaging saves prospective or retrospective frames, as specified in the **Acquisition** settings.
- Acquisition while reviewing a cineloop sequence saves all frames within the start and end markers in the cineloop sequence.
- When you acquire an image, the system beeps to confirm that acquisition is complete, if you have selected **Beep After Acquire Completes** in your **Acquisition** setups. When the image is saved to the patient study, a thumbnail appears. Do not press **Review** until you see the thumbnail of the acquisition.

You can acquire and save a single frame or a cineloop sequence. The frame or cineloop sequence is saved in the patient study, and a thumbnail of it is available in the live imaging display and the Review display.

Use the **Freeze** control to stop and start system image acquisition and update. Pressing **Freeze** results in the system entering cineloop pause and assigning the trackball to manual cineloop review (frame-by-frame).

When the acquisition is complete, a thumbnail of the image is displayed.

- To acquire a single image, press **Freeze** and then press **Acquire**.
- To acquire a cineloop sequence, press **Acquire** in live imaging or while reviewing a cineloop sequence.

Measurement and Analysis

The ultrasound system supports a number of measurement and quantification methods. The basic measurements report the size, speed, or duration of image data. The image data may be contained in a 2D ultrasound image, a Physio region, an M-mode trace, or a Doppler spectral trace. The accuracy of the measurement depends, in part, on the ability of the operator.

Measurements require scaling information. This prevents measurements in instances where Doppler or M-mode still images in Review do not include scaling information in the trace data or where imported image loops use different scaling parameters. Freehand 3D image data is not calibrated and does not include scaling information.

There are two basic methods for quantifying the image data for reporting. You can "measure then label," using the **Measure** and **Trace** tools and then associate the measurement with a label. You can also "label then measure," using the analysis tools to select a labeled measurement. Measurements must be labeled for the results to appear in patient reports. Unlabeled measurements appear in the results but are not retained, unless they are associated with a labeled measurement or included in an acquisition.

Labeled measurements and calculations are stored in the patient data and report. The information is labeled according to the measurement or calculation label. Within the report, the information is organized by the calculations package. The values displayed can be the results of multiple measurements. The report displays the method used to select the viewable result. You can also select a specific instance of the measurement using the **Use in Calcs** option. You can edit the data in the report.

Calculations packages are system options that are associated with transducers and presets. A calculations package contains one or more collections that organize measurements and calculations into a coherent tool for diagnostic analysis. The **Calc** control provides access to the various measurements and calculations in the available calculations packages.

The measurements and their derived calculations included with the calculations packages are based on medical references. See the "References" section in the *Help*.

NOTE

Ensure that you follow current medical practices when identifying specific measurement points on an image.

Performing a 2D Distance Measurement

A 2D distance measurement uses two calipers to measure the length of a straight line between the two points. You can set the display of the line in the setups.

NOTE

The left and right trackball buttons can each be set to one of three measurement operations: **End Measurement**, **Toggle**, or **Next Measurement**.

1. Obtain the 2D image you want to measure and press **Freeze**.
2. Press **Measure**.
3. Use the trackball to position the caliper for the first end point and click to anchor it.
4. Use the trackball to position the caliper for the second end point. The results update as the distance between the calipers changes.
5. To end the measurement, press the middle trackball button.

Obtaining a Typical Labeled Measurement

This general procedure describes how to measure by using a typical labeled measurement tool. Guided or complex tools require specialized procedures, found in the Help.

1. Obtain the image you want to measure and press **Freeze**.
2. Press **Calc**.
3. Do one or more of the following:
   - Select an analysis collection to display calculation and measurement labels. For more information on selecting a collection, see the *Help*.
   - Select the calculation label you want to use to display the measurement labels required to complete the calculation. For each measurement label within a group, select a label and make the measurement.
   - To display the **Measure** or **Trace** tool, select the label for the calculation or measurement. As you make the measurement, the results and derived

calculations appear in the results and are simultaneously added to the patient report.

4. To complete the measurement, press the middle trackball button.

Obtaining a Calculation Result

Calculations use one or more measurements. The required measurements are grouped under the calculation. If a measurement has already been made, a measurement result appears next to the measurement label.

1. Obtain the image you want to measure and press **Freeze**.
2. Press **Calc**.
3. Select the calculation you want to add. The measurements required for the calculation appear in a menu.
4. Select and make each measurement. The measurement result appears beside the measurement label.

Ending a Study

Each time you finish a study, you must end the study to save images, reports, and other study data.

Ending a study stores all study data, clears the **Patient Identification** display, and prepares the system for the next study.

WARNING

Failing to end the current study before starting a new study can result in data being acquired and stored under the wrong patient name. If you turn off the system without ending the study, the system automatically ends the study before shutting down.

When the study is complete, do either of the following:

- Press the **End Exam** key.
- Press the **Review** key, then click  .

NOTE

If you've configured a modality performed procedure step (MPPS) server, or if you have configured the system to print all images at the end of the study, the system prompts you to either end or cancel the study when you press the **End Exam** key or click  in Review.

8 *Transducers*

The transducer that you select 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.

A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the transducer is shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

WARNING

To limit potential harm when scanning neonatal, pediatric, and medicated patients, minimize the time spent imaging at temperatures above 41°C (106°F).

NOTES

- When the system is not in use, press **Freeze** to stop ultrasound transmission.
- This system introduces Active Array technology with a new type of transducer that integrates imaging circuitry from the system into the transducer handle. During normal scanning operation this circuitry creates a small rise in handle temperature. A warm transducer handle is normal and does not indicate that the transducer is defective. The handle temperature varies by transducer, imaging mode, and scanning conditions. The maximum handle temperature and patient-contact temperature are within FDA-approved limits.

It is important to understand how to connect, disconnect, and select transducers, and how to use the cable management system on the system cart.

The system includes receptacles for imaging transducers. All receptacles can be occupied at the same time, but only one transducer at a time can be active. When a transducer is not in use, store it in one of the transducer holders on

the system cart. Always use the cable management system to prevent cables from being stepped on or run over by the cart wheels.

Selecting a Transducer

NOTE

If the system displays an **Unsupported Transducer** message, ensure that all connected transducers are compatible with your system configuration.

If multiple transducers are connected when the system is turned on, the system selects the transducer that was in use when the system shut down. You can select among the connected transducers during system operation.

You can connect or disconnect a transducer during live imaging without damaging the transducer or the system.

Press **Transducer** to select a transducer. The selected transducer is indicated on the display.

Selecting a Preset

When the system is turned on, the system selects the same preset that was in use when the system shut down, unless it is incompatible with the initially selected transducer. In this case, the system activates the autoselect preset for that transducer. (You can select an autoselect preset for each transducer on the **Preset Menu** tab in the setups.)

During system operation, you can select a clinical option preset for the selected transducer. For more information on exams, see "Presets" on page 137.

1. Press **Preset**.
2. On the **Presets** menu, select a preset.

Clinical Options and Transducers

A clinical option, available for one or more transducers, optimizes the system for a specific application.

The clinical options, or applications, for each transducer available for the system are listed here.

Use only transducers that are approved by Philips for use with your Philips ultrasound 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.

The following table lists the transducers that are compatible with your ultrasound system.

System Transducers and Supported Clinical Options

Transducer	Clinical Options
C5-2	Abdominal, OB/GYN, Pediatric Radiology, Urology
C9-4v	OB/GYN, Urology, EC Prostate
L12-4	Musculoskeletal, Pediatric Radiology, Peripheral Vascular, Small Parts
S4-1	Abdominal, Adult Echo, OB/GYN, Cerebrovascular, Pediatric Echo, Pediatric Radiology

Indications for Use and Supporting Transducers

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

System Indications for Use and Supporting Transducers

Indication for Use	S4-1	C5-2	L12-4	C9-4v
Abdominal	O	X		
Cardiac Adult	X			
Cardiac other (Fetal)	O	X		
Cardiac Pediatric	O			
Cephalic (Adult)	O			
Cephalic (Neonatal)	O			
Fetal/Obstetric	O	X		X
Gynecological	O	X		X
Musculoskeletal (Conventional)			O	
Musculoskeletal (Superficial)			O	
Pediatric	O	O	O	
Peripheral Vessel			O	

Indication for Use	S4-1	C5-2	L12-4	C9-4v
Peripheral Vessel other (Carotid)			X	
Small Organ (Breast, Thyroid)			X	
Small Organ (Testicle)		O	O	
Transrectal				X
Transvaginal				X

For China only: X = Primary use, O = Secondary use

For all other countries: X or O = Indication for use

Transducer Maintenance

Transducers require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization, as necessary.

Inspect the transducer cable, case, and lens before each use. Check for cracks or other damage that jeopardizes the integrity of the transducer. Report any damage to your Philips Ultrasound customer service representative, and discontinue use of the transducer.

For all information on transducer cleaning and disinfection and the use of acoustic coupling gels, see the "Transducer Care" section.

CAUTION

Some ultrasound coupling gels, as well as some solutions for precleaning, disinfecting, and sterilizing can damage a transducer. Before using a gel or solution on a transducer, see "Transducer Care". You can also call Philips at 800-722-9377

(North America), or call your local Philips Ultrasound representative (outside North America).

Information on compatible disinfectants is available on the Philips Ultrasound Transducer Care website:
www.healthcare.philips.com/us/products/ultrasound/transducers/transducer_care/

If you encounter poor image quality or transducer problems, see "Troubleshooting" on page 220.

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.

Acoustic Artifacts in 3D Imaging

Resolution, attenuation, and propagation artifacts are all common to 3D imaging. Careful scrutiny of the original 2D images is necessary to identify and preclude these types of artifacts from the 3D volume image.

Color gain and directional artifacts can present themselves in 3D imaging. Gain artifacts are mainly related to the use of excessive gain resulting in patterns of noise in the 3D image that might be interpreted as diagnostically significant. Directional artifacts are due to aliasing or directional confusion: The velocity range must be set properly, and the relationship between the transducer orientation and the flow vector must be understood.

Acquisition, rendering, and editing artifacts are specific to 3D volume images. Acquisition artifacts are related to patient motion, organ motion, or position-sensing errors. Rendering artifacts include elimination of structures by limiting the region of interest boundaries, thresholding that eliminates structures, and adjacent structure artifacts that add additional information or hide structures. Editing artifacts result from data deleted from a rendered image.

Fetal limb deficit artifacts are specific to 3D volume images. Partially absent fetal limb bones have been demonstrated. One explanation for the missing limbs was shadowing caused by adjacent skeletal structures. Overcoming the limb

deficit artifact can be accomplished by changing the transducer position and the acquisition plane.

Pseudoclefting and pseudonarrowing artifacts may be related to limb deficit artifacts. Artifacts may be present in 3D imaging of the fetal face. Being aware of pseudoclefting of the fetal face and pseudonarrowing of the fetal spine can help the sonographer understand and identify these artifacts. As with 2D imaging, it is important to verify putative physical defects by using additional images and other modalities.

Dropout and shadowing are present in 3D imaging although they are more difficult to recognize due to different and unfamiliar displays. Acoustic shadowing and other artifacts look very different when displayed in 3D volumes and may be more difficult to recognize than on standard 2D imaging. Those artifacts may produce apparent defects, such as limb abnormalities or facial clefts, where they are not present. Acquiring data from multiple orientations may avoid artifacts of this type.

Color and Color Power Angio artifacts relating to gain may also be confusing in rendered images.

Motion artifacts in 3D volumes can be caused by patient motion, fetal movement, cardiac motion, and movement of adjacent structures. Patient motion can produce flash artifacts that are more obvious in 3D images than in 2D imaging.

Transducer Covers

To prevent blood-borne pathogens, sterile transducer covers are required for intraoperative and biopsy procedures; in China, sterile covers are also required for transrectal, intravaginal, and transesophageal procedures. Protective covers are recommended for transrectal, intravaginal, and transesophageal procedures; the protective covers are mandatory in China and Japan. Philips recommends the use of qualified covers.

For procedures for using transducer covers, see the instructions provided with the covers.

WARNINGS

- Latex and talc are commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications and during biopsies. 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 41.
- In neurosurgical applications, sterilized transducers should be used with sterile gel and a sterile pyrogen-free transducer cover.
- Inspect transducer covers before and after use.
- If the sterile transducer cover becomes compromised during an intraoperative application involving a patient with Creutzfeldt-Jakob disease, follow the recommendations described in "Transmissible Spongiform Encephalopathy" on page 188.
- Transducer covers are disposable and must not be reused.
- If an installed transducer cover is cut or contaminated before use, the probe should be cleaned and disinfected, and a new sterile cover installed.

Transducer Storage

Use the appropriate guidelines for storing transducers for transport, and daily and long-term storage.

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 pockets (bubble wrap), 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 the side of your system 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.
- When storing transducers, use the cable-management clips to secure the transducer cable.
- Before storing transducers, make sure they are thoroughly dry.

9 *Endocavity Transducers*

Endocavity transducers provide high-resolution endocavity imaging for OB/GYN and prostate applications. The system supports the C9-4v endocavity transducer.

Operators of Endocavity Transducers

Philips endocavity transducers are designed for use under the guidance of physicians who are properly trained in endocavity ultrasound imaging techniques, according to currently approved relevant medical practices. Philips recommends that physicians operating any Philips endocavity transducer have the following qualifications:

- Proficiency in recognizing and interpreting imaging patterns
- Thorough familiarity with the safe operation, care, and maintenance of the system and endocavity transducers
- Thorough familiarity with the latest endocavity methods through literature and seminars

Patient Safety During Endocavity Studies

To operate an endocavity transducer, you must be under the guidance of a physician who is properly trained in endocavity ultrasound imaging techniques, according to currently approved relevant medical practices. You also must be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound system used with the transducer, as well as proficient at interpreting the images generated.

To help ensure patient safety when using an endocavity transducer, observe the following guidelines:

- Scrutinize the entire transducer before each use.
- Operate the transducer properly.
- Do not allow water or other liquids to drip onto the transducer connector, the interior of the system, or the keyboard.
- Use sterile ultrasound transmission gel when performing all endocavity studies.
- Protective covers are recommended for endocavity procedures; the protective covers are mandatory in China and Japan.

WARNING

Always remove the transducer from the patient before defibrillation.

Preparing Transducers for Endocavity Use

1. Place 20 cc of sterile gel or saline into the transducer cover.
2. Carefully inspect each transducer cover before use, and discard it if you find tears or blemishes. Also inspect each transducer cover after use. If you find a tear, the patient or the transducer may have been contaminated.
3. Insert the transducer into the transducer cover and unfurl the transducer cover until it covers the transducer and its cable. The cover must be unfurled far enough to maintain the sterile field.
4. Use a sterile elastic band or clip to hold the proximal end of the transducer cover in place.
5. Ensure that wrinkles and bubbles over the face of the transducer are minimized. Check the transducer cover for tears or damage before proceeding.
6. When operating the transducer, make sure that proper orientation is maintained to avoid interpretation confusion.

NOTES

- To achieve good acoustic contact, make sure that the imaging surface is moist.
- Imaging improves with adequate coupling between the patient surface and the transducer-cover surface. Sterile water is a good acoustic-coupling agent during surgery.

C9-4v Description

The C9-4v transducer is described here. For more information on connecting, activating, caring for, and maintaining transducers, see the "Transducers" and "Transducer Care" sections.

C9-4v Endocavity Transducer

Features of the C9-4v Transducer

Features	Curved array transducer designed to be easy to hold and manipulate and to provide maximum clinician and patient comfort. Enables high-resolution imaging for gynecological and obstetrical studies, and for urological procedures.
Frequency	Operating range: 4.0 to 9.0 MHz
Biopsy capable?	Yes
Specifications	• Length (transducer, cable, and connector): 2.09 m (8.2 ft) • Length (handle to tip): 30.5 cm (11.5 in) • Radius of curvature: 11 mm (0.4 in)

Patient-Contact Parts

Latex and talc are commonly used in transducer covers marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications and during biopsies. 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 on Latex" on page 41.

NOTE

The ultrasound system and transducers discussed here do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducers.

Biopsy with Endocavity Transducers

Endocavity transducers are biopsy capable.

For more information on the biopsy guide feature, see the "Biopsy Guides" section.

NOTE

CIVCO Medical Solutions supplies biopsy kits for Philips transducers that are biopsy capable. For information on proper attachment of a biopsy bracket, consult the manufacturer's instructions.

10 Biopsy Guides

The biopsy guide feature helps you position transducers with biopsy needle-guide attachments. The biopsy guide feature displays guidelines on the image that show the anticipated path of the needle. You can use those guidelines to ensure that the needle or instrument is following the correct path.

Starter kits, which include the biopsy guide or biopsy guide bracket and procedure kits, are available from CIVCO Medical Solutions; see "Supplies and Accessories" on page 17.

For detailed information about biopsy guides and brackets, see the instructions provided with the biopsy starter kits, guides, and brackets.

Attaching and Removing a Biopsy Guide

Detailed information about attachment and removal of biopsy guides is provided with the biopsy starter kits, guides, and brackets.

WARNINGS

- Do not attempt to use the biopsy guide until you have read the instructions for selecting the display, installing the sterile transducer cover, and verifying alignment of the biopsy guide.
- 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. Your Philips Ultrasound customer service representative can verify this information for you.
- Use only Philips-approved biopsy guides, transducers, covers, brackets, supplies, components, and accessories. Other brands may not properly fit Philips Ultrasound transducers. Improper installation may result in patient injury.

- Some biopsy guides must be installed over a sterile transducer cover.
- After each use, biopsy guides must be either sterilized or disposed of, depending upon the type. See the instructions included with the biopsy guide.
- Most transducers can only be disinfected; they cannot be sterilized. Only the transducer cover provides the sterile barrier.

Biopsy Guideline Display

WARNING

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

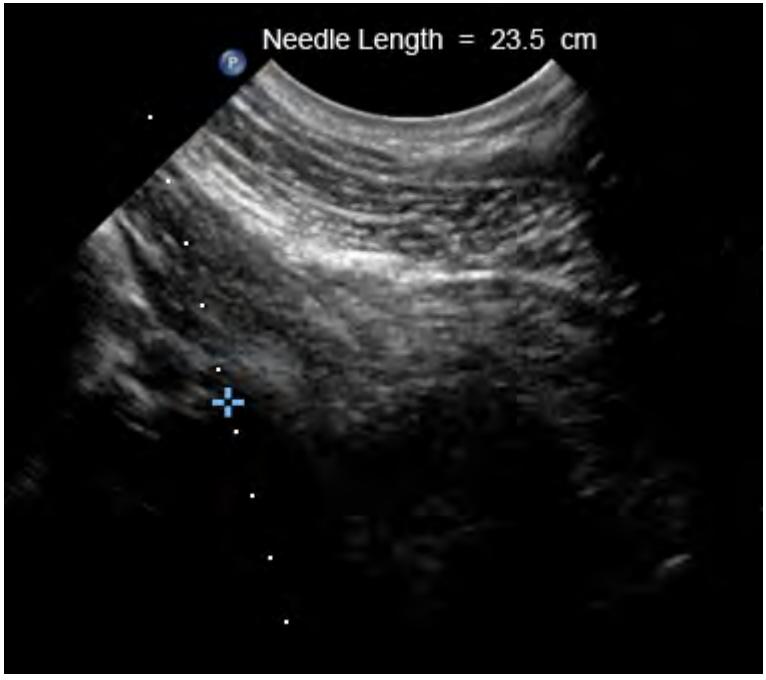
The system generates a biopsy guideline through the displayed real-time ultrasound image to indicate the anticipated path of the needle. You can use that guideline to ensure that the needle or instrument is following the correct path. You can select a guideline for use with either a biopsy gun or a biopsy needle. The gun guideline is a single dotted line, which illustrates the expected needle path. (The needle may not follow this path exactly.) The needle guideline is two dotted lines in a cone shape, which illustrate the maximum expected variance of the needle path from the most typical path.

When the biopsy display is active, a biopsy guideline is displayed on the left side of the display, during normal image presentation, or on the right side, when the image presentation is inverted. Image presentation is defined by the location of the scan plane orientation marker  . A needle-length crosshair also appears when the biopsy guideline display is active. The needle-length value is above the image.

When depth is changed, the biopsy display redraws to reflect the new relationships at the new depth setting. If the needle-length crosshair is no longer positioned in the boundaries of the image after depth is changed, the crosshair moves to the new edge of the image, and its value changes accordingly. (If you

revert to the original depth, the system returns the needle-length crosshair to its original position.)

Biopsy Guideline Display



Displaying the Biopsy Guideline

The **Biopsy** controls are available only when the selected transducer supports biopsy and when you are using a 2D noncardiac preset with HD Zoom off.

1. Press **Next**, and then use the **Biopsy** quick key as needed to display either the gun or the needle guideline.
2. If you are using a biopsy guide with multiple needle angles, use the **Biopsy** quick key to select a needle angle (for example, **A**, **B**, and so on) that corresponds to the setting you have chosen on the biopsy guide.

3. To hide the biopsy guideline, use the **Biopsy** quick key as needed to make the guideline disappear.

Moving the Needle Length Crosshair

When the biopsy guideline is displayed, you can use the trackball to display and control the needle-length crosshair, which is usually hidden.

1. Use the **Biopsy** quick key to select **Needle**.
2. Use the trackball to move the crosshair down onto the image and position it at the presumed final location of the needle tip. The **Needle Length** measurement value changes to reflect the distance from the top of the needle-guide stop to the crosshair position.

Biopsy Guideline Quick Keys

This topic describes the quick keys (virtual keys) associated with this mode. Some of the quick keys are visible immediately and others may be visible only when particular transducers or presets are active. Some systems display the quick keys on multiple pages.

To use a quick key function in the top row or to change its setting, press the corresponding knob; if the quick key function is in the bottom row, turn the knob. To display the next page of quick keys, press **Next**.

Name	Description
Biopsy Off/Needle/Gun	A control used to display or hide the biopsy guideline, and specify the type of guideline.
Biopsy A/B/C/D	A control used to select from predefined biopsy guideline angles.

Biopsy Guide Alignment

Perform the alignment verification before each use of the biopsy guide. The procedure verifies the system, transducer, and biopsy guide relationships.

WARNINGS

- Alignment verification is necessary before performing procedures with the biopsy guide.
- Do not use the biopsy guide if the needle is not following the intended path.
- The needle used for this alignment verification must not be used for the actual procedure. Always use a new, sterile needle for each biopsy procedure.
- To assist in an accurate projection of the needle, use a straight, new needle for each alignment procedure.

Do not use the biopsy guide if the needle is not following its indicated path. Contact a Philips Ultrasound customer service representative.

Preparation for Alignment Verification

Assemble the following items before performing the alignment verification:

- Transducer
- Biopsy guide or bracket (The bracket is not disposable. The type of bracket you use depends upon the transducer you are using. For the correct bracket, contact CIVCO Medical Solutions; see "Supplies and Accessories" on page 17.)
- Needle guide (Contact CIVCO for the needle guide that fits your biopsy guide bracket.)
- Sterile procedure kit (disposable)
- New, straight, biopsy needle
- Beaker of water (or water bath)

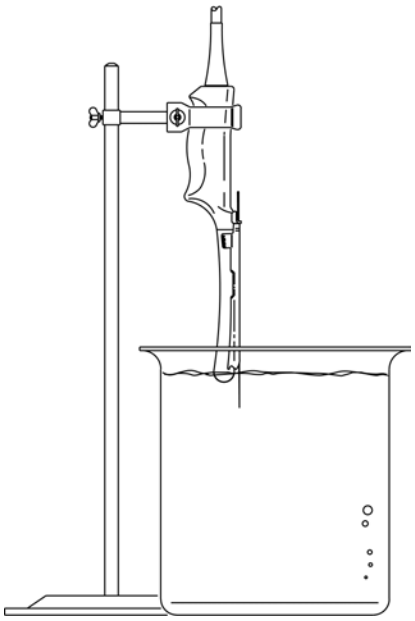
Verifying the Biopsy Guide Alignment

WARNING

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 your Philips Ultrasound customer service representative.

1. Attach the biopsy guide. Although some transducers require the use of a second transducer cover for biopsy procedures, a second transducer cover is unnecessary for this alignment verification.
2. Connect the transducer to the system, and select the appropriate preset.
3. Set the system depth for the procedure to be performed.
4. Display the biopsy guideline.
5. Use the trackball to position the needle length crosshair approximately in the middle of the image, and then note the needle length value displayed above the image.
6. Immerse the transducer no more than 6 mm (0.25 in) into the water bath.

Immersing the Transducer



7. Select a new, straight needle that matches the needle-gauge size on the biopsy guide clip you are using (if applicable), select the guide channel on the biopsy guide (**A**, **B**, and so on), and use the **Biopsy** quick key to select the matching biopsy angle setting.
8. Insert the straight, new needle into the biopsy guide.
9. Move the needle down into the water bath until its ultrasound image is visible on the video display.
10. Verify that the needle, as seen on the video display, falls along the guideline along the entire depth of the guideline display. The biopsy guideline is intended only to provide an indication of the expected path of the needle. Actual position must be verified by identifying the echoes from the needle.
11. Remove the needle from the biopsy guide.
12. From the tip of the needle, measure a distance equal to the needle length value noted in step 5. Mark this point on the needle.

13. Immerse the transducer no more than 6 mm (0.25 in) into the water bath.
14. Insert the needle back into the biopsy guide. 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.)
15. Move the needle length crosshair to the tip of the needle, as seen on the display, and verify that the displayed depth is within 1.5 cm (0.6 in) of the value noted in step 5.
16. Confirm that the needle is visible along its expected path. If so, then the biopsy guide is properly aligned.

Performing a Biopsy Procedure

WARNINGS

- Alignment verification should be performed at the selected depth prior to the biopsy procedure to ensure that the biopsy guide and the needle have been installed properly.
- Use a straight, new, sterile needle for each procedure.
- The biopsy guideline is intended only to provide an indication of the expected path of the needle. Actual position must be verified by identifying the echoes from the needle.
- If the needle is not following the expected path, discontinue the procedure and contact your Philips Ultrasound customer service representative.
- Thin needles can bend when entering tissue. Actual position must be verified by identifying the echoes from the needle.
- Reverberation or other tissue artifacts may produce false needle images, which can cause confusion in locating the actual needle image. Ensure the needle path is along the guideline, and that you are not using a false needle image to locate the needle.
- Philips Ultrasound does not recommend anatomical survey of the prostate with the biopsy guide attached.

1. Install the transducer cover and the biopsy guide according to the instructions provided with the biopsy guide.

2. Select a new, straight needle that matches the needle-gauge size on the biopsy guide clip you are using (if applicable), and select the guide channel on the biopsy guide.
3. Set the system imaging controls for the biopsy procedure.
4. Use the **Biopsy** quick key to display either the needle guideline or the gun guideline.
5. If you are using a biopsy guide with multiple needle angles, use the **Biopsy** quick key to select the angle that corresponds to the setting you have chosen on the biopsy guide (**A**, **B**, and so on).
6. Orient the transducer to match image presentation. Use the 2D scan plane orientation marker  .
7. If necessary, apply sterile acoustic coupling gel to the patient.
8. Begin scanning the patient. Position the transducer so that the puncture target is intersected by the guideline on the display.
9. Insert the needle into the needle-guide groove.
10. Perform the puncture by sliding the needle through the groove in the guide until the needle, as shown on the display, intercepts the target.
11. If you are using a biopsy guide bracket and procedure kit, you can remove the transducer from the patient while the needle is still inserted in the patient: Separate the needle from the biopsy guide by pulling the tab up so that the clip snaps out of the needle guide, allowing the clip (still attached to the needle) and needle to separate from the biopsy guide (still attached to the transducer).
12. Remove the biopsy guide after use.

Biopsy Guide Maintenance

WARNING

The biopsy procedure kit components are disposable and must not be reused.

NOTE

For information and instructions on cleaning, disinfecting and sterilizing transducers used in biopsy procedures, see the "Transducer Care" section.

For information and instructions on cleaning, disinfecting, and sterilizing the biopsy guide, see the instructions provided with the biopsy guide.

11 Transducer Care

This section contains information on cleaning, disinfecting, and sterilizing transducers compatible with your system, as well as cleaning and disinfecting system surfaces. This section also lists the ultrasound gels that are safe to use with the transducers compatible with your system.

These instructions are intended to assist in effective cleaning, disinfection, and sterilization. In addition, these instructions will help avoid damage, which could void your warranty, during cleaning, disinfection, sterilization, and gel use.

Transducer Care Safety

Observe the following warnings and cautions when using disinfectants and gels. More specific warnings and cautions are included within the various procedures in this section and on the labels of the cleaning or disinfection solutions.

WARNINGS

- Disinfectants listed in "Disinfectants and Cleaning Solutions Compatibility Table" on page 203 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 "Choosing a Disinfectant" on page 189. 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.
- Sterile transducer covers with sterile ultrasound transmission gel are required for intraoperative and biopsy procedures, and protective covers

are recommended for transrectal and intravaginal procedures, but in China and Japan, the covers are mandatory. Philips recommends the use of qualified covers.

- Do not apply the transducer cover and gel until you are ready to perform the procedure. Transducers should not be left soaking in gel.
- In neurosurgical applications, sterilized transducers should be used with sterile gel and a sterile pyrogen-free transducer cover.
- Transducer covers can contain natural rubber latex, which may cause allergic reactions in some individuals. See "Latex Product Alert" on page 188.

For information on ordering transducer covers, contact CIVCO Medical Solutions (see "Supplies and Accessories" on page 17).

Latex Product Alert

Philips ultrasound systems and transducers do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any ultrasound transducer, including transthoracic and intraoperative transducers. It also is not used on Philips ECG cables for the products in this manual.

For information on allergic reactions to latex-containing medical devices, see "FDA Medical Alert on Latex" on page 41.

Transmissible Spongiform Encephalopathy

WARNING

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.

Acoustic Coupling Medium

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.

CAUTION

Do not use mineral oil, oil-based couplants, gels with lotions or emollients of any kind, or other unapproved materials, because they might damage the transducer.

Choosing a Disinfectant

To choose an appropriate disinfectant, you first must determine the required level of disinfection, based on the device classification.

Levels of Disinfection by Device Classification

Classification	Definition	Level of Disinfection
Critical	Device enters otherwise sterile tissue (for example, intraoperative applications)	Sterilization
Semi-critical	Device contacts mucous membranes (for example, intracavity applications)	High
Noncritical	Device contacts intact skin	Intermediate or low

General Cleaning for All Transducers

These general cleaning instructions are indicated for all transducers. It is important that you clean the transducer and cable according to the following procedures.

WARNING

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

CAUTIONS

- Transducers *must* be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization. Be sure to follow the manufacturer's instructions when using disinfectants.
- Do not allow sharp objects, such as scalpels or cauterizing knives, to touch transducers or cables.
- When handling a transducer, do not bump the transducer on hard surfaces.
- Do *not* use paper products or products that are abrasive when cleaning the transducer. They will damage the soft lens of the transducer.
- Do *not* use a surgeon's brush when cleaning transducers. Even the use of soft brushes can damage transducers.
- During cleaning, disinfection, and sterilization, orient the parts of the transducer that must remain dry higher than the wet parts until all parts are dry. This will help keep liquid from entering unsealed areas of the transducer.
- Be sure to use the proper concentration of enzymatic cleaner and rinse thoroughly.
- Before storing transducers, make sure they are thoroughly dry. If it is necessary to dry the transducer's lens after cleaning, use a soft cloth and a blotting motion instead of a wiping motion.

Cleaning a Transducer

CAUTION

When cleaning the transducer, do not use paper products or products that are abrasive. They will damage the soft lens of the transducer.

1. After every patient study, use a moist cloth to remove the ultrasound transmission gel off of 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 should have a pH of 6.0 to 8.0. Those cleaners are further diluted during use. Follow the manufacturer's instructions for dilution. When cleaning the lens, use a blotting motion rather than a wiping motion.
4. To remove remaining particulate and cleaning residue, rinse thoroughly with water up to the immersion point shown in "Disinfecting Transducers by Immersion" on page 197.
5. Wipe with a dry cloth. To dry the lens, use a soft cloth and a blotting motion instead of a wiping motion.

Disinfecting Transducers Using a Wipe or Spray Method

To disinfect transducers, you can use either an immersion method or a wipe method with a disinfectant recommended by Philips Ultrasound. Use the method that is biologically appropriate, as described in "Choosing a Disinfectant" on page 189.

This topic provides instructions on using the wipe or spray method.

WARNING

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

CAUTIONS

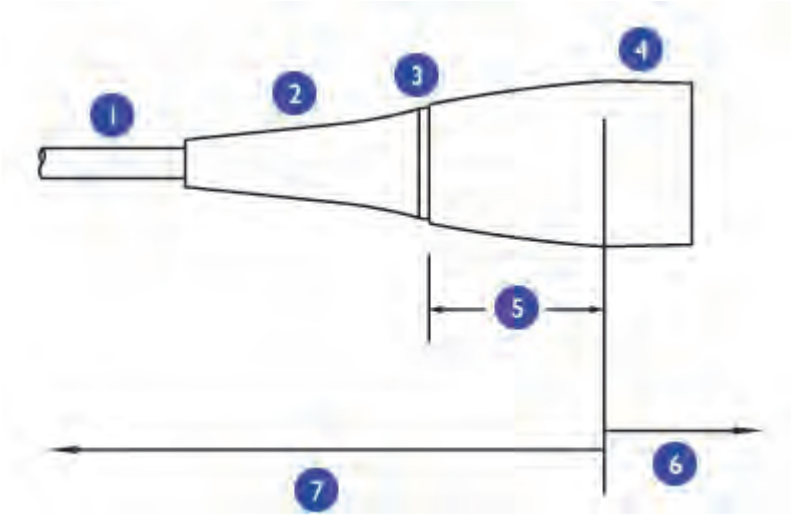
The use of 70% isopropyl alcohol (rubbing alcohol) and alcohol-based products on transducers is restricted. Isopropyl alcohol can cause damage to parts of the transducer. This damage is not covered by the warranty or your service contract.

- Wipe only the distal tip of the transducer up to 2.5 cm (1 in) from the strain relief/housing joint with an isopropyl alcohol solution.
- Do not use isopropyl alcohol on the strain relief/housing joint, the strain relief, or the cable.

NOTE

Transducers can be disinfected using the wipe method only if the product labeling of the compatible disinfectant you are using indicates it can be used with a wipe method.

Restricted Use of Isopropyl Alcohol to Clean Transducers



1	Cable
2	Strain relief
3	Strain relief/housing joint
4	Housing
5	2.5 cm (1 in) between housing and strain relief/housing joint
6	You can use alcohol in this area of non-TEE transducers
7	Do not use alcohol in this area

1. After cleaning the transducer and cable (see "General Cleaning for All Transducers" on page 189), wipe or spray the transducer and cable with a low-level disinfectant. Allow for the manufacturer's recommended contact time. For a list of compatible disinfectants, see "Disinfectants Compatibility" on page 201.
2. Remove any residue with a water-moistened soft cloth. Do not allow any solutions to air dry on the transducer.
3. 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 Ultrasound representative.

Cleaning and Disinfecting Cables and Connectors

The cables and connectors of all transducers can be disinfected using a recommended wipe or spray disinfectant.

WARNING

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

CAUTIONS

- Attempting to disinfect a cable or connector by using a method other than the one included here can damage the device and voids the warranty.
- Orient the parts that must remain dry higher than the wet parts until all parts are dry.
- Do not bend or crimp the gastroscope or cable.

1. Disconnect the device from the system.
2. Push the connector cover, if available, onto the connector to protect against fluid splashing onto the contacts.
3. Orient the device and the connector so they are both facing up.

CAUTIONS

- Do not allow any type of fluid to enter the connector. Be careful that fluid does not enter through the strain relief, through the connector, through

the electrical contacts, or through the areas surrounding the locking lever shaft and the strain relief. Fluid in the connector may void the transducer or device warranty.

- Do not use a brush on the connector label.

4. Use a soft cloth lightly dampened in a mild soap or detergent solution to clean the cable and the connector. A soft-bristled brush can be used to clean only the metal surfaces of the connector.

WARNING

If a premixed solution is used, be sure to observe the solution expiration date.

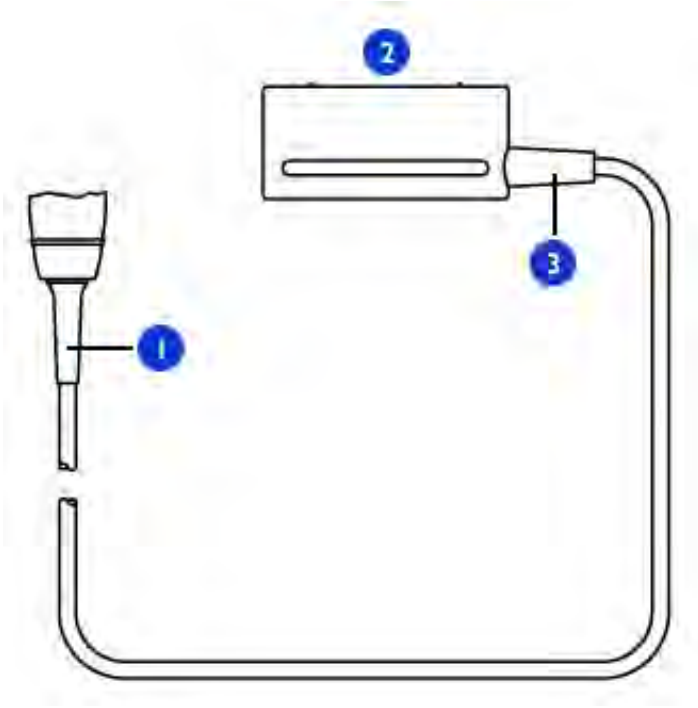
CAUTIONS

- You can use an alcohol solution for disinfection on the connector only. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.
- Do not use any alcohol or alcohol-based products on the cable or strain relief.
- Avoid disinfectant contact with the connector label.

5. Mix the disinfection solution compatible with your cable (see "Disinfectants and Cleaning Solutions Compatibility Table" on page 203) according to label instructions for solution strength.
6. Wipe or spray the cable and connector with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and duration of disinfectant contact with the cable. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Ensure that the disinfectant solution does not enter the device or the connector or come into contact with the connector label.
7. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.

8. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your Philips Ultrasound representative.

Disinfecting Cables and Connectors



NOTE

For cable disinfection, orient the device and the connector facing up (strain reliefs on the bottom). Wipe the strain reliefs, cable, and connector with a compatible disinfectant.

1	Transducer strain relief
2	Electrical contacts
3	Connector strain relief

Disinfection of Transducers by Immersion (High-Level Disinfection)

Observe the following warnings and cautions and then see "Disinfecting Transducers by Immersion" on page 197.

WARNINGS

- If a premixed disinfectant is used, be sure to observe the expiration date.
- If you use Cidex OPA Solution or other OPA-based disinfectants, residual solution may remain on your transducers if you do not carefully follow the manufacturer's instructions.
- To minimize the effects from residual OPA, or any other disinfectant, Philips recommends the following:
  - Follow the disinfectant manufacturer's instructions very carefully. For example, the manufacturer of Cidex OPA recommends soaking transducers three times in fresh water.
  - Use a protective transducer cover during endocavity and TEE studies.
  - Use a sterile protective transducer cover with sterile ultrasound transmission gel during intraoperative and biopsy studies.
  - Limit the time that transducers are soaked in the disinfectant solution to the minimum time recommended by the disinfectant manufacturer

(for example, the manufacturer of Cidex OPA recommends a minimum of 12 minutes).

CAUTIONS

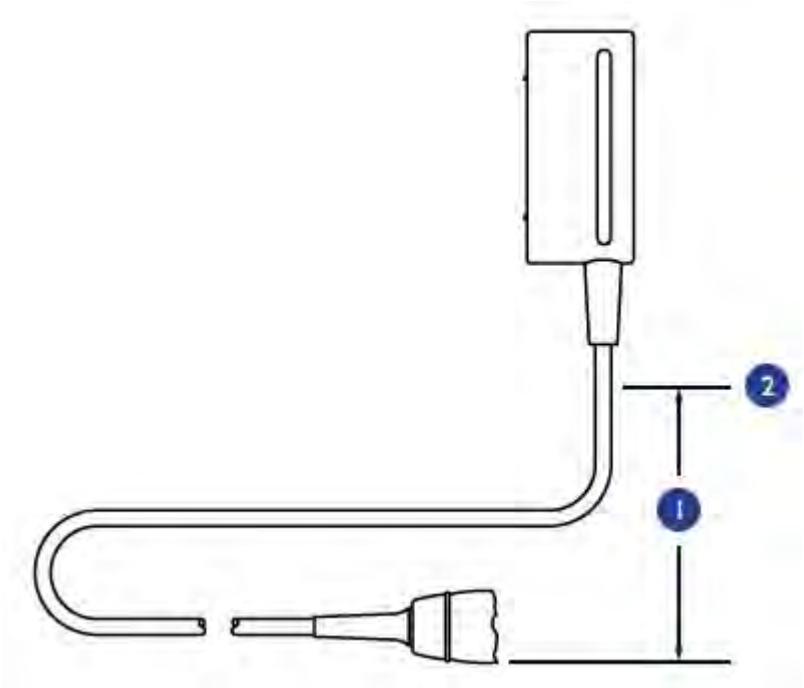
- Using non-recommended disinfectants, using incorrect solution strengths, or immersing a transducer deeper or longer than recommended can damage or discolor the transducer and voids the transducer warranty.
- Do not immerse transducers longer than the minimum time needed for your level of disinfection. For information on the levels of disinfection requirements, see "Choosing a Disinfectant" on page 189.

Disinfecting Transducers by Immersion

Before performing this procedure, read the warnings and cautions in "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 196.

1. Clean the transducer according to "General Cleaning for All Transducers" on page 189.
2. Mix the disinfection solution compatible with your transducer (see "Disinfectants and Cleaning Solutions Compatibility Table" on page 203) according to label instructions for solution strength.
3. Immerse the transducer into the appropriate disinfectant for your transducer as shown. 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.
4. Using the instructions on the disinfectant label, rinse the transducer up to the point of immersion, and then air dry or towel dry with a sterile cloth.
5. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your Philips Ultrasound representative.

Immersing Transducers



1	Immerse this section only, up to 5.1 cm (2 in) from the connector's strain relief.
2	This is the maximum allowable immersion depth; you are not required to immerse to this depth if it is not necessary.

Sterilizing Transducers

Sterilization is required if the device is classified as a critical device.

WARNINGS

- Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.
- In neurosurgical applications, sterilized transducers should be used with a pyrogen-free transducer cover.
- If a premixed solution is used, be sure to observe the solution expiration date.

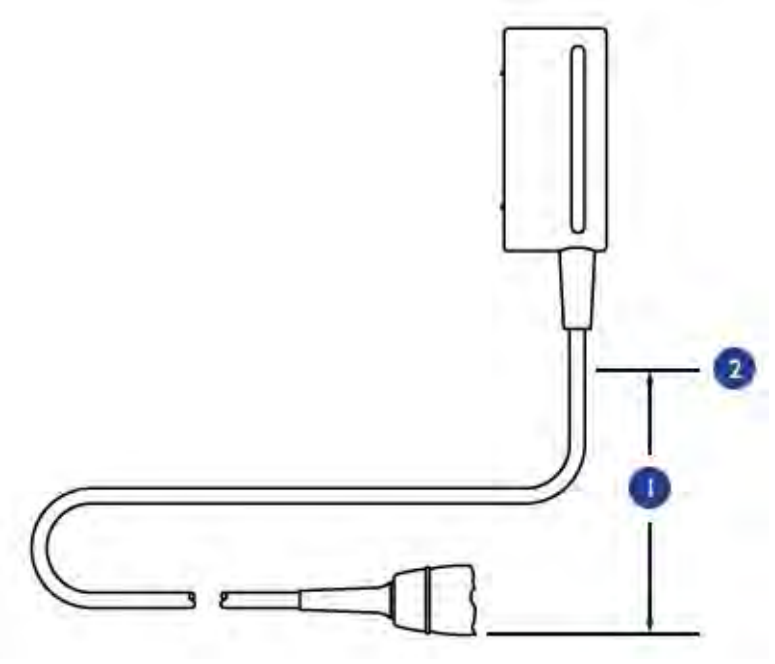
CAUTIONS

- Transducers must be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization. Be sure to follow the manufacturer's instructions when using disinfectants.
- Use only liquid solutions to sterilize transducers. Using autoclave, gas (EtO), or other methods not approved by Philips Ultrasound will damage your transducer and void your warranty.
- Do not allow sharp objects, such as scalpels and cauterizing knives, to touch transducers or cables.
- When handling a transducer, do not bump the transducer on hard surfaces.
- Ensure the solution strength and duration of contact are appropriate for sterilization. Be sure to follow the manufacturer's instructions.

1. Clean the transducer according to "General Cleaning for All Transducers" on page 189.
2. Mix the sterilization solution compatible with your transducer according to label instructions for solution strength.
3. Immerse the transducer in the sterilization solution as shown.
4. Follow the instructions on the sterilization label for the duration of transducer immersion required for sterilization.
5. Remove the transducer from the sterilization solution after the recommended sterilization time has elapsed.
6. Using the instructions on the sterilization label, rinse the transducer in sterile water up to the point of immersion, and then air dry or towel dry with a sterile cloth.

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 Ultrasound representative.

Immersing Transducers



1	Immerse this section only, up to 5.1 cm (2 in) from the connector's strain relief.
2	This is the maximum allowable immersion depth; you are not required to immerse to this depth if it is not necessary.

Disinfectants Compatibility

Read this information before performing disinfection and sterilization procedures. It discusses recommended disinfectants and choosing an appropriate disinfectant for the required level of disinfection. You must check "Disinfectants and Cleaning Solutions Compatibility Table" on page 203 for the chemical compatibility of disinfectants and cleaners with specific transducers. In addition, the table indicates if a device can be sprayed or wiped only, or if it can be soaked.

WARNINGS

- Not all disinfectants are effective against all types of contamination. Ensure the disinfectant type is appropriate for the type of transducer and that the solution strength and time of contact are appropriate for the intended clinical use.
- Disinfectants listed in this section 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 Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- If a premixed solution is used, be sure to observe the solution expiration date.
- Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTION

Using a non-recommended disinfection solution, using an incorrect solution strength, or immersing a transducer deeper or longer than recommended can damage the device and voids the warranty.

Disinfectant Types

WARNING

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the disinfectant type is appropriate for the type of transducer and the transducer application. For information on the levels of disinfection requirements, see "Choosing a Disinfectant" on page 189. For more information, 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.

CAUTION

If you use an isopropyl alcohol-based product for disinfection, ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage. Do not use alcohol on the transducer's strain relief or cable.

See "Disinfectants Compatibility" on page 201 for standard industry recommendations on disinfection, for information that can help you choose an appropriate disinfectant for the required level of disinfection, and for transducer-specific instructions.

Factors Affecting Disinfectant Efficiency

The following factors will affect the efficiency of a disinfectant solution:

- Duration of exposure
- Age of the solution
- Concentration and potency of the disinfectant
- Quantity and location of the contamination
- Resistance of the contaminant
- Organic matter on the item to be disinfected

Disinfectants and Cleaning Solutions Compatibility Table

The table that follows lists the disinfectants and cleaning solutions compatible with the transducers available for your system.

Other low- and intermediate-level disinfectants marketed for use on medical instruments and based on quaternary ammonium compounds (QUATS) or sodium hypochlorite (NaOCl), equal to or less than 0.6%, are approved for use.

NOTE

A 10% bleach solution typically provides a solution that is less than 0.6% NaOCl.

Additionally, products that contain 70% or less isopropyl alcohol (IPA) are acceptable for use on the transducer portion of the device only. Those disinfectant types must be used only in a spray or wipe application.

CAUTION

Do not use alcohol-based products on transducer cables and strain reliefs.

For more information:

- Philips Ultrasound Transducer Care Web site (www.healthcare.philips.com/us/products/ultrasound/transducers/transducer_care/)
- In North America, call Philips at 800-722-9377.
- Outside North America, contact your local Philips Ultrasound representative.

Disinfectants and Cleaning Solutions Compatibility

Solution	Origin	Qualified Use	Active Ingredients	C5-2	C9-4v	L12-4	S4-1
70% Isopropyl Alcohol	All	Spray/Wipe	Alcohol	T	T	T	T
AbcoCide	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
AbcoCide 28	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Accel Wipes	CA	Wipe	Hydrogen Peroxide	T,C	T,C	T,C	T,C
Aidal	AU	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Aidal Plus	AU	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Alkaspray	FR	Spray/Wipe	Alcohol, Alkylamine	T	T	T	T
Ampholysine Basique	FR	Spray/Wipe	Biguanide/Quat. Ammonia	T,C	T,C	T,C	T,C
Aniosept Activ	FR	Soak[1]	Peracetic Acid	T,C	T,C	T,C	T,C
Banicide	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Bleach (10% solution of 5.25% Bleach)	All	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T,C	T,C
CaviWipes	US	Wipe	Alcohol, Quat. Ammonia	T	T	T	T
Cidex	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Cidex 7	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Cidex OPA	US	Soak[1]	Ortho-phthalaldehyde	T,C	T,C	T,C	T,C
Cidex PAE 14J	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Cidex Plus	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Cleanisept Wipes	DE	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
Descoton Extra	DE	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Dispatch	US	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T,C	T,C
Endo FC	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C

Solution	Origin	Qualified Use	Active Ingredients	C5-2	C9-4v	L12-4	S4-1
Endosporine	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Enzol	US	Pre-cleaner	Enzymes	T,C	T,C	T,C	T,C
Epizyme Rapid	AU	Pre-cleaner	Enzymes	T,C	T,C	T,C	T,C
Gigasept FF	DE	Soak[1]	Succindialdehyde, dimethoxy tetrahydrofuran	T,C	T,C	T,C	T,C
Incidin	DE	Spray/Wipe	Alcohol	T	T	T	T
Incidur Spray	DE	Spray/Wipe	Alcohol, Quat. Aldehyde	T	T	T	T
Instruzyme	FR	Pre-cleaner	Enzymes, Quat. Ammonia, Biguanide	T,C	T,C	T,C	T,C
Klenzyme (unavailable)	US	Pre-cleaner	Enzymes	T,C	T,C	T,C	T,C
Kohrsolin	DE	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Korsolex Basic	FR	Soak[1]	Aldehyde Releasing	T,C	T,C	T,C	T,C
Korsolex PAE	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
MaxiCide Plus	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
MedDis	UK	Soak[1]	Quat. Ammonia, Sulfamic Acid	T,C	T,C	T,C	T,C
MetriCide	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
MetriCide 28	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
MetriCide OPA Plus	US	Soak[1]	Ortho-phthalaldehyde	T,C	T,C	T,C	T,C
MetriCide Plus 30	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
MetriZyme	US	Pre-cleaner	Enzymes	T,C	T,C	T,C	T,C
Mild Soap Solution	All	Pre-cleaner	Surfactants/Soap	T,C	T,C	T,C	T,C
Milton	AU	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T,C	T,C
Omnicide 14NS	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C

Solution	Origin	Qualified Use	Active Ingredients	C5-2	C9-4v	L12-4	S4-1
Omnicide 28	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Opticide3	US	Spray/Wipe	Alcohol, Quat. Ammonia	T	T	T	T
Peracetic Acid OCS	UK	Soak[1]	Peracetic Acid	T,C	T,C	T,C	T,C
PeraSafe Powder	UK	Soak[1]	Peracetic Acid	T,C	T,C	T,C	T,C
Perascope	UK	Soak[1]	Peracetic Acid	T,C	T,C	T,C	T,C
PerCept Wipes	CA	Wipe	Hydrogen Peroxide	T,C	T,C	T,C	T,C
Phagocide D	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Phagozyme ND	FR	Pre-cleaner	Enzymes, Quat. Ammonium	T,C	T,C	T,C	T,C
Pro-Cide	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Pro-Cide 14NS	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Pro-Cide 28	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Pro-Cide NS	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Pro-Cide Plus	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Prolystica 2X	US	Pre-cleaner	Enzymes	T,C	T,C	T,C	T,C
Protex Disinfectant Spray	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
PSS Select 14 Day	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
PSS Select 28 Day	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
PSS Select Plus	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Quaternary Ammonium	All	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
Rapicide	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Resert XL HLD	US	Soak[1]	Hydrogen Peroxide	T,C	T,C	T,C	T,C
Rivascop	FR	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
Salvanios pH 10	FR	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
Sani-Cloth AF	US	Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C

Solution	Origin	Qualified Use	Active Ingredients	C5-2	C9-4v	L12-4	S4-1
Sani-Cloth Plus	US	Wipe	Alcohol, Quat. Ammonia	T	T	T	T
SDS 14 NS	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
SDS 28	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Sekucid N	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Sekusept Aktiv	DE	Soak[1]	Peracetic Acid	T,C	T,C	T,C	T,C
Sekusept Easy	DE	Soak[1]	Peracetic Acid	T,C	T,C	T,C	T,C
Sekusept Plus	DE	Soak[1]	Glucoprotamin	T,C	T,C	T,C	T,C
Steranios 2%	FR	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
TD-5	US	TD-100 Reprocessor	Glutaraldehyde	N	N	N	N
Trophon EPR	AU	Trophon EPR Reprocessor	Hydrogen Peroxide	T,C	T,C	N	T,C
T-Spray	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
T-Spray II	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C
Vaposeptol	FR	Spray/Wipe	Alcohol, Biguanide	T	T	T	T
Vespore	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Virox 5 RTU	CA	Wipe	Hydrogen Peroxide	T,C	T,C	T,C	T,C
Wavicide -01	US	Soak[1]	Glutaraldehyde	T,C	T,C	T,C	T,C
Wip'Anios	FR	Wipe	Alcohol, Quat. Ammonia	T	T	T	T

C = Approved for use on the cable
T = Approved for use on the transducer
N = Not approved for use

AU = Australia
CA = Canada
DE = Germany
FR = France
UK = United Kingdom
US = United States

1. Soak or per product instructions

Gels Compatibility

Although most gels will provide suitable acoustic coupling, some gels are incompatible with certain transducer materials. Products that do not contain mineral oil are acceptable for use. Never use lotion-based products.

WARNING

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

CAUTIONS

- Do not use gels that contain mineral oil or lotion. Such products may damage the transducer and void the warranty.
- Gels listed in this section are recommended because of their chemical compatibility with product materials.

Some recommended gels include:

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

For additional compatibility information, call Philips at 800-722-9377 (North America) or your local Philips Ultrasound representative (outside North America).

12 System Maintenance

Maintenance should be performed regularly and as needed.

Because the system is a piece of medical equipment that contains several circuit boards, extensive service diagnostics, and complex operating software, Philips recommends that only trained personnel service the system.

Cleaning and Maintaining the System

It is important to clean and maintain the ultrasound system and peripherals. Thorough cleaning is particularly important for pieces of peripheral equipment because they contain electromechanical devices. If exposed to constant and excessive environmental dust and humidity, these devices will suffer in both performance and reliability.

NOTE

At a certain internal system temperature, the system displays a warning message and then turns off automatically 30 minutes later. Increased internal temperature can result from obstructed vents on the front and back of the system. Failure to keep the vents clean can result in the system becoming unavailable during critical use.

It is essential to clean the transducers used with your ultrasound system. The cleaning procedures vary for the different types of transducers and their uses.

For detailed instructions on how to clean and maintain each type of transducer used with the system, including disinfectant compatibility, see the "Transducer Care" section.

Cleaning the System and ECG Equipment

Use this method to clean the system, the optional cart, and the ECG cables, leads, and electrodes. You can use a mild soap solution. If the equipment has come in contact with blood or infectious material, clean the equipment with

a 70% solution of isopropyl alcohol. For instructions on disinfecting system surfaces, see "Disinfecting System Surfaces" on page 211.

WARNING

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

CAUTIONS

- Attempting to disinfect a cable or connector by using a method other than the one included here can damage the device and voids the warranty.
- Orient the parts that must remain dry higher than the wet parts until all parts are dry.

Use the following procedure to clean the display; the system control panel; all the external surfaces of the system and the optional cart; and the ECG trunk cables, leads, and electrodes.

1. Before cleaning, turn off the system and unplug the power cord from the power source.
2. Wipe with a soft cloth moistened with soap and water.

CAUTION

Do not spill or spray liquid on the controls, into the system cabinet, or into the transducer connection receptacle.

3. Remove any solid matter around the keys or the controls with a cotton swab or toothpick to ensure that solids are not pushed into the cabinet.
4. If blood or other infectious material comes in contact with the system or any cable other than a transducer cable, wipe with a 70% solution of isopropyl alcohol.

CAUTION

If blood or other infectious material comes in contact with a transducer or transducer cable, do not wipe with isopropyl alcohol until you have read the "Transducer Care" 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.

5. Remove any residue with a cloth moistened with sterile water.
6. Be sure to dry the equipment to prevent potential corrosion.

Disinfectants for System Surfaces

The exterior surfaces of the system can be disinfected using a compatible disinfectant with a wipe method. System surfaces include the monitor screen and plastic and painted surfaces. The following products can be used on system surfaces:

- Mild soap solution
- 70% isopropyl alcohol (IPA)
- T-Spray II (quaternary ammonium-based)
- Opti-Cide-3 (quaternary ammonium/isopropyl alcohol-based)
- Sani-Cloth HB (quaternary ammonium-based)
- Sani-Cloth Plus (quaternary ammonium/isopropyl alcohol-based)

Other products that are based on quaternary ammonium compounds (QUAT) or QUAT/isopropyl alcohol can also be used in disinfecting system surfaces.

Disinfecting System Surfaces

WARNING

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

CAUTIONS

- Use only compatible disinfectants on system surfaces.
- If you use an isopropyl alcohol solution for disinfection, ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.

Before performing this procedure, read "Disinfectants for System Surfaces" on page 211.

1. Turn off the system and disconnect the system power cord from the wall outlet.
2. Use a soft cloth lightly dampened in a mild soap or detergent solution to clean exterior surfaces on the system.
3. Mix the disinfection solution compatible with your system according to label instructions for solution strength.

CAUTION

Do not spray disinfectant directly on system surfaces. When wiping, do not allow disinfectant to pool or run on system surfaces. In either case, disinfectant may leak into the system, damaging the system and voiding the warranty. Wipe only with a cloth or applicator that is lightly dampened.

4. Wipe system surfaces with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and disinfectant contact duration. Ensure the solution strength and duration of contact are appropriate for the intended clinical application.
5. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.

Cleaning the Trackball

Cleaning the trackball regularly prolongs its useful life and prevents service calls.

1. With your fingers, unscrew the ring around the trackball.
2. Lift the trackball out of the mounting area.
3. Clean the trackball and the mounting area with a lint-free cloth or a small brush.
4. Place the ball back on the mounting area.
5. With your fingers, screw the ring back on.

Transducer Maintenance

Transducers require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization, as necessary.

Inspect the transducer cable, case, and lens before each use. Check for cracks or other damage that jeopardizes the integrity of the transducer. Report any damage to your Philips Ultrasound customer service representative, and discontinue use of the transducer.

For all information on transducer cleaning and disinfection and the use of acoustic coupling gels, see the "Transducer Care" section.

CAUTION

Some ultrasound coupling gels, as well as some solutions for precleaning, disinfecting, and sterilizing can damage a transducer. Before using a gel or solution on a transducer, see "Transducer Care". You can also call Philips at 800-722-9377 (North America), or call your local Philips Ultrasound representative (outside North America).

Information on compatible disinfectants is available on the Philips Ultrasound Transducer Care website:
www.healthcare.philips.com/us/products/ultrasound/transducers/transducer_care/

If you encounter poor image quality or transducer problems, see "Troubleshooting" on page 220.

Printer Maintenance

WARNINGS

Before performing any maintenance on a device, always disconnect it from the source of power by using either of the following methods:

- If the device is internal to the system, disconnect the system from the wall outlet.
- If the device is external to the system, disconnect the device from the wall outlet.

CAUTIONS

- Do not scratch the roller or allow dirt and dust to contact the roller of a printer.
- Do not use strong solvents such as thinner or acetone, or abrasive cleaners, because those will damage a device cabinet.

Periodically clean the external surfaces of a device with a soft cloth. Difficult stains may be removed with a cloth lightly dampened with a mild detergent solution.

Removing the Printer

You may need to remove the printer for repair or replacement.

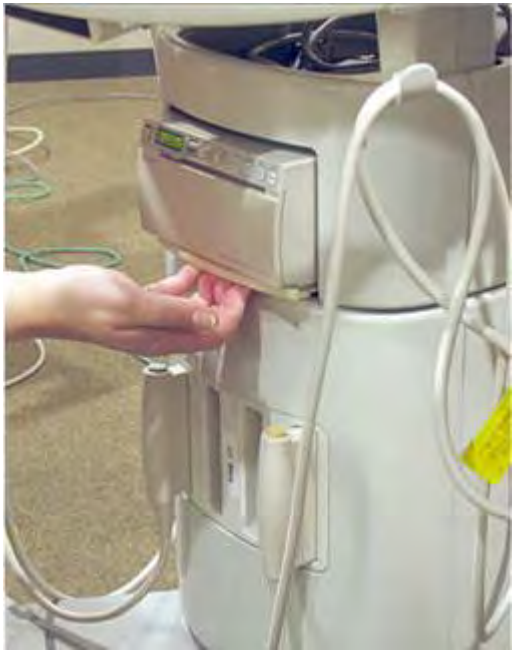
WARNING

Before removing the printer, always turn off the system and disconnect the system from the wall outlet.

CAUTION

Do not unplug the system from the wall outlet until the system is completely off. If you unplug your system before the shutdown message appears, you will have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data.

Removing the Printer



1. Set the brakes on the front casters.
2. If you cannot get a firm grip on the front of the printer tray, as shown, perform the following optional steps:
   a. Disconnect all connectors from the front panel.
   b. Holding the edges of the front panel near the top, pull the panel forward to release it from the cart frame. Holding the panel near the top rather than in the middle releases the ball studs in a series, rather than all at once. This eases removal of the front panel.
3. With one hand under the printer tray, lift the tray until you can pull it forward.
4. Pull the printer tray forward until you can remove it from the cart.
5. Disconnect the cables from the printer rear panel.
6. Set the removed printer and printer tray on a flat surface.

7. Release the printer support by pulling both support arms out and away from the printer tray.
8. Lift the printer support arms up and away from the printer.
9. Lift the printer off the printer tray.

Acquisition Module Maintenance

In the event of Acquisition Module (AM) failure, you can replace the AM. A replacement AM can be ordered from Philips Ultrasound Customer Service.

Troubleshooting the AM

If you suspect that one or more of the AM transducer connectors may be not be functioning properly, perform the following troubleshooting procedure.

1. Set the brakes on the front casters.
2. Check the two LEDs on the system back panel. When the system is fully powered up, they should both be green.
3. Disconnect all connectors from the front panel.
4. Holding the edges of the front panel near the top, pull the panel forward to release it from the cart frame. Holding the panel near the top rather than in the middle releases the ball studs in a series, rather than all at once. This eases removal of the front panel.
5. Set the front panel aside.
6. Check the LEDs below the transducer connectors. They should all be green.

AM Transducer Connector LEDs

7. If the LEDs are not all green, shut down the system and replace the AM.

Removing the AM

If it is necessary to replace the AM, you can remove it from the system. No tools are required.

WARNING

Before removing the AM, always turn off the system and disconnect the system from the wall outlet.

CAUTION

Do not unplug the system from the wall outlet until the system is completely off. If you unplug your system before the shutdown message appears, you will

have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data.

1. Set the brakes on the front casters.
2. Disconnect all connectors from the front panel.
3. Holding the edges of the front panel near the top, pull the panel forward to release it from the cart frame. Holding the panel near the top rather than in the middle releases the ball studs in a series, rather than all at once. This eases removal of the front panel.
4. Set the front panel aside.
5. With your fingers, turn the four captive fasteners counterclockwise to release the AM.

Acquisition Module Fasteners

6. Holding the AM by the bezel and the bottom edge, pull it straight forward and away from the cart frame.
7. Set the AM aside.
8. Holding the edges of the front panel, push the panel back into place on the cart frame to protect the AM connector until the AM is reinstalled.

Installing the AM

If you need to install the AM, follow this procedure. No tools are required.

WARNING

Before installing the AM, always turn off the system and disconnect the system from the wall outlet.

CAUTION

Do not unplug the system from the wall outlet until the system is completely off. If you unplug your system before the shutdown message appears, you will have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data.

1. Set the brakes on the front casters.
2. Holding the edges of the front panel near the top, pull the panel forward to release it from the cart frame. Holding the panel near the top rather than in the middle releases the ball studs in a series, rather than all at once. This eases removal of the front panel.
3. Set the front panel aside.
4. Hold the AM in a vertical position in front of the cart.
5. Position the AM guide rail into the guide bracket on the cart.
6. Slide the AM into the cart until the connectors meet.
7. With your fingers, turn the four captive fasteners clockwise to secure the AM in place.
8. After you have tightened all four captive fasteners, start with the upper-left fastener and proceed clockwise to tighten each one again. Failure to perform

this step may cause the fasteners to come loose due to system vibration during operation.

9. Holding the edges of the front panel, push the panel back into place on the cart frame.

Troubleshooting

If you encounter difficulty in the operation of the system, use the information here to help correct the problem. If the problem is not covered here, contact your Philips Ultrasound customer support representative.

The troubleshooting table contains a list of symptoms and the actions to take to correct the problems.

Troubleshooting

Symptoms	Corrective Action
The system does not power up. The monitor indicator light is off.	1. Verify the power connections. 2. Check the circuit breaker on the back of the system.
No image displays on the monitor.	1. After power up, the system takes about 20 seconds to initialize. During this time the monitor is blank. 2. After 20 seconds, adjust the **Monitor** brightness in **System** setups. 3. Check the monitor cables and connections.
Image quality is poor.	1. Run the system tests (see "Testing the System" on page 221). 2. If the system tests pass, run the transducer tests (see "Running the Transducer Tests" on page 222). 3. Contact your Philips service representative.

Symptoms	Corrective Action
No audio comes from the system speakers.	Use the **Volume** control to ensure the speakers are not muted.
An error message is displayed.	1. Run the system test (see "Testing the System" on page 221). 2. Note the error message and contact your Philips Ultrasound customer support representative.
An error message indicates that the system is above normal operating temperature.	1. Click **Continue**. The system will power down automatically in 30 minutes. 2. Note the error message and contact your Philips Ultrasound customer support representative.

Error Messages

The system displays error messages in response to operating or error conditions detected by the system.

The error messages must be noted and reported to your Philips Ultrasound customer support representative.

Testing the System

The system test is a comprehensive test of the system operational status. This test includes numerous subtests. If a subtest fails, the system completes the remaining subtests. The system test displays only a pass-fail result on the system monitor. If the system test fails, notify your Philips service representative.

Run the system test any time a system error is displayed, or if you suspect problems with the system. If an error message is displayed during the test, restart the system with the ⏻ (On/Off) control on the control panel.

NOTE

The system test can take several minutes to run.

1. Turn on the system.
2. Disconnect all transducers from the system.
3. Press the **Setup** key.
4. Click the **Service** tab.
5. In the **Maintenance Tools** section, click **Service**.
6. Click the **Test & Utilities** tab.
7. In the **System Test** area, click **Run**. The system displays a message when the test is complete, indicating whether the test passed or failed.
8. If the test fails, contact your Philips service representative for instructions about how to export the log files.
9. After the test is complete, do one of the following:
   - Run additional tests before restarting the system.
   - To restart the system immediately, click **Close**, and then click **Restart**.

Running the Transducer Tests

If you experience poor image quality, or if you suspect a problem with one or more of your transducers or transducer connectors, run the transducer tests.

NOTE

To run the transducer tests, the **Transducer Tests** service option must be enabled in the setups. This requires the service option access code. If you do not have this code, contact your Philips service representative.

1. Turn on the system.
2. Press the **Setup** key.
3. Click the **Service** tab.
4. In the **Maintenance Tools** section, click **Service**.
5. Click the **Test & Utilities** tab.

6. Click **Hardware Utilities**. If the transducer tests service option is enabled, **Transducer** appears in the **Interactive Tests** list.
7. If **Transducer** does not appear in the **Interactive Tests** list, do the following:
   a. Click the **Options** tab.
   b. Click **Enable** for the **Transducer Tests** option.
   c. In the **Service Options Access Code** dialog box, enter the code and then click **OK**.
   d. Click the **Test & Utilities** tab.
   e. Click **Hardware Utilities**.
8. Connect one transducer to the system. The transducer tests can only be run with one transducer at a time.
9. In the **Interactive Tests** list, click **Transducer** to highlight it.
10. Click **Run Test**.
11. On the **Transducer Element Utility** display, do one of the following:
    - If **Connected Transducers** displays an error indicating that the test is unable to identify the connected transducer, go to step 12.
    - If **Connected Transducers** displays the ID of the connected transducer, click **Run** to execute the transducer tests.

    The test runs, and then displays the result in the **Result** box.
12. If the test does not recognize the connected transducer, or if the test result is anything other than **Pass**, contact your Philips service representative for instructions about how to export the log files.
13. Click **Return** and then do one of the following:
    - Run additional tests before restarting the system.
    - To restart the system immediately, click **Close**, and then click **Restart**.

For Assistance

If you are unable to correct a problem, call your local Philips Ultrasound customer support representative.

13 Specifications

Philips reserves the right to change specifications contained herein or discontinue manufacture at any time without prior notice. Current specifications are supplied with each system purchased or are available from your Philips representative.

Dimensions

- Width: 51.8 cm (20.5 in)
- Control Panel Height: 83.8 cm (33 in)
- ClearVue 350 Height (including monitor): 138.4 cm (54.5 in)
- ClearVue 550 Height (including adjustable monitor): 135.6 cm (53.4 in) to 151.9 cm (59.8 in)
- Depth: 58.6 cm (23.0 in)
- Weight (excluding transducers): 55 kg (121 lb)

Gray Shades

255 in 2D, M-mode, and Doppler

Scan Lines

Up to 1,024 scan lines, depending on transducer and mode

Monitor

43.2-cm (17-in) LCD display

Input Signals

- Low-level ECG
- Three-port or four-port transducer receptacle

Output Signals

- Video: S-Video, VGA
- Video recorder audio (left and right)
- External printer
- USB serial data

Data Connections

- Ethernet network (Gigabit, 10Base-T, and 100Base-T)
- USB 2.0

Modality Interface

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

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

Physio

ECG range between 0.15 mV and 5.0 mV

Peripherals

The B/W image printer can be mounted on the cart. The other peripherals cannot be mounted on the cart but can be connected to the system.

- B/W image printer
- Color image printer
- Large format color image printer
- Report printer
- External monitor

Electrical Parameters

AC 100-240 V±10%

Power must be available through a grounded outlet.

In the United States, power must be available through a grounded, hospital-grade outlet.

Languages

Localized user interface (including international symbols on key caps) and Help:

- English
- French
- German
- Italian
- Japanese
- Portuguese (Brazilian)
- Russian
- Simplified Chinese
- Spanish

Localized documentation, other than Help:

- English
- Chinese, Traditional and Simplified
- Czech
- Danish
- Dutch
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Italian
- Japanese
- Norwegian
- Polish
- Portuguese (Brazilian)
- Romanian
- Russian
- Slovak
- Spanish
- Swedish
- Turkish

Pressure Limits

- Operating: 525 mmHg to 795 mmHg (700 hPa to 1,060 hPa)
- Storage: 375 mmHg to 795 mmHg (500 hPa to 1,060 hPa)

Humidity Limits

- Operating: 15% to 80%
- Storage: 15% to 95%

Temperature Limits

- Operating: 10°C to 40°C (50°F to 104°F)
- Storage: -34°C to 65°C (-29°F to 149°F)

Safety and Regulatory Requirements

Classification

- Class I equipment with Type BF applied parts
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

Electromechanical Safety Standards Met

- CAN/CSA 22.2 No. 60601.1, Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1, Medical Electrical Equipment, General Requirements for Safety
- IEC 60601-1-2, Collateral Standard, Electromagnetic Compatibility
- IEC 60601-2-37, Particular Requirements for Safety: Ultrasonic Medical Diagnostic and Monitoring Equipment
- UL 60601-1, Underwriters Laboratories Standard for Medical Electrical Equipment

Electromechanical Standards Met (EU Only)

EN60601-2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

Agency Approvals

- Canadian Standards Association (CSA)
- CE Mark in accordance with the European Community Medical Device Directive issued by British Standards Institute (BSI)

Compliance

Philips products comply with relevant international and national standards and laws. Information on compliance will be supplied by your local Philips representative, or the manufacturer, on request.

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