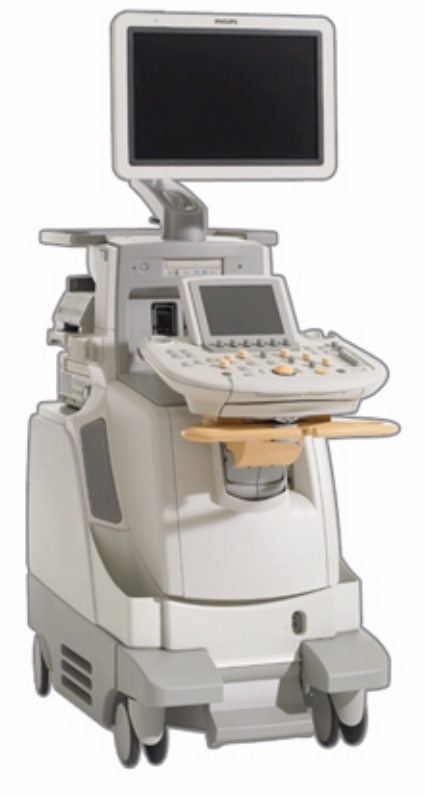
iU22 Ultrasound System

User Manual

4535 614 45861 Rev A
August 2010



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 2007/47/EC within the country of origin of the Notified Body concerned with the device.

European Union Representative

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

CAUTION

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

Contents

1 Read This First

This section contains important information about the user information for your product and about customer service.

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.

Warnings

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

WARNINGS

- Do not remove system covers; hazardous voltages are present inside the system. 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. Explosion can result.
- Medical equipment needs to 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. May also indicate that there is an impending loss of data that must be acknowledged.
	Warning: Indicates that there is a possibility of a system malfunction that might prevent the use of the ultrasound 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 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.
- ***PercuNav User Manual*** : Introduces you to PercuNav features and concepts, helps you set up your system, includes important safety information, and provides instructions for use specific to the PercuNav system when integrated with the ultrasound system. For information about using the ultrasound system, see the user information for your ultrasound system.
- ***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.
- ***Voice Control Quick Guide***: Provided with the system and included on the CD, the *Voice Control Quick Guide* contains procedures for using the voice control option and lists all commands used for voice control and voice annotation.

- ***PercuNav Quick Reference Guide***: Provides the most basic, procedural steps required to operate the PercuNav system.
- ***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 "Select controls," are used with the trackball. Those controls, located on either side of the trackball, operate somewhat similarly to PC mouse buttons. Both Select controls function identically.
- Tabs along the top of the monitor display let you choose additional sets of setup options. Tabs along the top of the touch screen let you choose additional pages of controls.
- 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. Press a knob-button to activate its function, or turn it 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.

The current trackball function is displayed in the trackball select menu at the bottom of the display.

- Controls on the touch screen include buttons and knobs. To use a touch screen button, simply touch it. To use a touch screen knob, adjust the corresponding knob below the knob display (located in the bottom row of the touch screen).
- Many tabs on the touch screen contain two pages of controls. Touch **Next** and **Previous** to display these pages.
- Controls on the touch screen use several methods to indicate their status. Buttons that are either on or off have an indicator in the upper corner that lights when it is on. Buttons that select a setting generally display the active setting either within the button or on the monitor display. An arrow in the lower right corner of a button indicates that the button displays or hides a group of related buttons. Where only one button in a group can be selected at a time, the selected button is indicated by a gold outline or background. For more information, see "Touch Screen Controls" on page 135.

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* or *select* means to move the pointer or cursor to an object and press one of the unlabeled Select buttons located on either side of the trackball.
- *Double-click* means to quickly click twice to select an object or text.
- *Drag* means to place the pointer over an object and then press and hold one of the Select buttons while moving the trackball. Use this method to move an object on the display.
- *Touch* means to press a button on the touch screen, located above the control panel.
- *Selecting* means to specify an image or thumbnail to be exported or deleted. To select an image, either click on the thumbnail or the thumbnail number.
- *Highlighting* means to mark an image you want to reject during a protocol exam or an image you want to post-process. To highlight an image, click inside the image (but not on the number).
- 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.
- Transducers and pencil probes both are referred to as transducers, unless the distinction is important to the meaning of the text.

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 Ultrasound Customer Service 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 cables and lead sets	–	See "Approved Cables for Electromagnetic Compliance" on page 71
ECG electrode	40420A	Pre-gelled snap electrode
Tip guards	610-748	Transducer tip protector for most TEE transducers
	610-945	Transducer tip protector for T6H and S7-2omni
Bite guard	M2203A	Bite guard for TEE transducers
Bite blocks	610-979	Pediatric bite block
	610-160	Bite block without strap
	610-749	Bite block with strap
Transducer covers	610-840 610-860 610-933	Protective sheath for TEE transducers
	610-836 610-843 610-010 610-214	Protective sheath for endocavity transducers
	610-797	Intraoperative protective sheath for L15-7io transducers
	610-833	Covers for noninvasive or noncavity transducers

Accessory	Model/Part Number	Description
Cables	–	See "Approved Cables for Electromagnetic Compliance" on page 71
Printers	–	See "External Printers" on page 108
Foot switch	989605344671	Optional foot switch
VCRs	–	See "Approved Accessories for Electromagnetic Compliance" on page 73
DVD recorders	–	See "Approved Accessories for Electromagnetic Compliance" on page 73
Biopsy guides	–	See the following table
Transducers	–	See "Clinical Options and Transducers" on page 196
Removable media	–	See "Media Compatibility" on page 166

Biopsy Guides

Transducer	Compatible Biopsy Guide Model
3D9-3v	989605351091
C5-1	989605369041
C5-2	989605341511

Transducer	Compatible Biopsy Guide Model
C8-4v	8500-8180-02
C8-5	989605341521
C9-4	8500-1290-01
C9-5ec	8500-1704-01
C10-3v	8500-8180-02
L12-5 50 mm	8500-9089-03
L17-5	989605341541
L9-3	989605352591
S4-1	989605341531
VL13-5	98960537771
X3-1	989605361851
X6-1	453561442341

Customer Service

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips Ultrasound representative for assistance. You can also contact one of the following offices for referral to a customer service representative, or visit the Philips Ultrasound Web site:

www.philips.com/ultrasound

Corporate and North American Headquarters

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

800-722-9377

Asia Pacific Headquarters

Level 9, Three Pacific Place, 1 Queen's Road East, Wanchai, Hong Kong

+852 2821 5888

European Headquarters (also serves Africa and the Middle East)

Philips Medizin Systeme Böblingen GmbH

Hewlett-Packard-Str. 2, 71034 Böblingen, Germany

+49 40 5078 4532

Latin American Headquarters

1550 Sawgrass Corporate Parkway, Suite 300, Sunrise, FL 33323, USA

+1 954-628-1000

WEEE Recycling Information

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 Web site:

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

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.

Electrical Safety

This equipment has been verified by a recognized third-party testing agency as a Class I device with Type BF and Type CF 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.
- Because Type B and BF transducers are not isolated and have a higher inherent leakage current, those transducers are not intended for invasive use.
- 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 32.
- During transesophageal echocardiographic (TEE) procedures, either remove the TEE transducer from the patient or disconnect the TEE transducer from the system immediately following image acquisition.
- 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 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.
- 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. See the "Transducer Care" section.
- 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. Concurrent failures in an ESU or other device and in the outer layer of the TEE transducer shaft can cause electrosurgical currents to return along the transducer conductors. This could burn the patient, and the ultrasound system and the transducer could also be damaged. Be aware that a disposable transducer cover provides no protective electrical insulation at ESU frequencies.

- 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 67. 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 using a transducer when a defibrillation is required.

WARNINGS

- Before defibrillation, always remove the transducer from the patient.
- Before defibrillation, always disconnect the transducer 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 or not a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

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.

- Before moving the system, ensure that the keyboard is retracted, the control panel is centered, and the monitor is locked (see "Positioning the Control Module" on page 134 and "Preparing and Moving" on page 117). When extended, the keyboard might be damaged if it hits another object, and the video monitor could swing out during transport, causing injury or equipment damage.

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. For cleaning and disinfection instructions, see the "Transducer Care" section.
- Do not submerge the cables of patient-applied parts in solution. The cables are not liquid-tight beyond the applied part/cable or cable/connector interfaces.

- In general, only the area of the transducer acoustic window is liquid-tight. Except where specified in specific transducer-cleaning instructions, do not immerse the remainder of a transducer in any liquid.
- Do not use solvents, such as thinner or benzine, 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).

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.
CE 0086 !	The radio component contained in this device is compliant to Council Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive).
!	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.

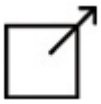
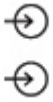
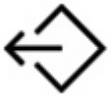
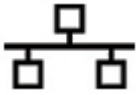
GMDN	Global Medical Device Nomenclature Code.
	Indicates a possible crushing hazard to hands.
	Warns that the system should not be used stacked with other equipment. If the system is used stacked with or adjacent to other equipment, verify normal operation before use.
	Indicates the temperature range (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.

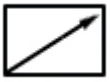
	Identifies the date of manufacture.
	Identifies the legal manufacturer.
	This side up: Points toward the side of the shipping crate that should be kept facing up.
	Indicates that the device should be kept dry.
	Indicates that the device is fragile; handle with care.
	Warns of system over-balance due to external force. (Do not push on the monitor 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
	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
	VGA or parallel output port
	DVI video output receptacle
	USB 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 Two video receptacles provide DVI-D digital video for flat-panel monitors.
	S-Video connection
	B/W Composite video output connection
	Color composite video output connection
	Video print trigger connection
	Russian approval (GOST)

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).
	Indicates 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 23.
- Verify the alignment of the biopsy guide before use. See the "Biopsy Guides" section.
- 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 45.
- In contrast studies using a high-MI acoustic field, capillary rupture, due to microbubble expansion within a capillary in an acoustic field, can cause extravasation. References: (1) Skyba, D.M., Price, R.J., Linka, A.Z., Skalak, T.C., Kaul, S. "Direct in vivo visualization of intravascular destruction of microbubbles by ultrasound and its local effects on tissue." *Circulation*, 1998; 98:290-293. (2) van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E.,

Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." *Journal of the American Society of Echocardiography*, 2000;13(4):288-94.

- Preventricular contractions can be caused by the oscillations of microbubbles when a high-MI acoustic field is triggered in the heart at the end of systole. In a very sick patient with certain risk factors, theoretically, this could lead to ventricular fibrillation. Reference: van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." *Journal of the American Society of Echocardiography*, 2000;13(4):288-94.
- 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 the ophthalmic application, which is activated by selecting a Tissue Specific preset such as **Orbital TCD**. 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 159.

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 data base, 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 peak pressure.

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

- **Flow Opt:** Increasing the color sensitivity with the flow opt 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 not change. 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 peak pressure.

- **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

Do not use the foot switch in the operating room. IEC 60601-1 specifies that foot-operated control devices used in the operating room must be of watertight construction. The foot switch supplied with the ultrasound system meets only drip-proof construction requirements.

Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. See "Clinical Options and Transducers" on page 196 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 Web site:

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.

For information on cleaning and disinfecting transducers, see the "Transducer Care" section.

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. Also, do not use isopropyl alcohol on TEE transducers (except for their handles).

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. For more information, see the "Transducer Care" section.

For more information about removing blood and other infectious material from the system, see "Disinfecting System Surfaces" on page 314.

ECG Cables and Lead Sets

For information on cleaning ECG cables and lead sets, see "Cleaning the System and ECG Equipment" on page 311.

Disposable Drape

If you believe contamination of the ultrasound 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 ultrasound 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 75, the system will remain safe and will provide the following essential performance:

- Imaging
- Doppler audio and spectral display
- Measurements
- Acoustic output
- ECG triggering
- Recording and playback on a VCR or DVD recorder
- 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 only RF energy 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.

iU22 Approved Cables

Cable	Type	Length	Philips Part Number
Adult and pediatric ECG three-lead patient trunk cable (for AAMI and IEC leadsets)	–	2.7 m (9 ft) with headset	453561227251
Adult ECG leadset, nondisposable (AAMI)	–	–	453561233291
Adult ECG leadset, nondisposable (IEC)	–	–	M1613A
Pediatric ECG leadset, nondisposable (AAMI)	–	–	M1609A
Pediatric ECG leadset, nondisposable (IEC)	–	–	M1619A
Pediatric ECG leadset, disposable (AAMI)	–	–	453561210001
Pediatric ECG leadset, disposable (IEC)	–	–	453561210121
Aux input	Shielded	<3 m (<9.8 ft)	–
Composite video	Shielded coaxial	Any	–
LAN	Twisted pair	Any	–
RS-232 interface	Shielded	2 m (6.5 ft)	–
USB	Shielded	Any	–

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 196, 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 the transducers listed in "Clinical Options and Transducers" on page 196.
VCR	Mitsubishi	HS-MD3000UA (NTSC) HS-MD3000EA (PAL)
DVD recorder	Sony	DVO-1000
Black and white printers	Sony	UP-D895MD UP-D897MD
Color printers	Sony	UP-D21MD UP-D23MD
	Mitsubishi	CP-30DW
Large-format multi-image color printer	Sony	UP-D55MD
Black and white LaserJet report printers	Hewlett-Packard	1300 1320
Color LaserJet printers	Hewlett-Packard	2550 3600

Accessory	Manufacturer	Model Number
Deskjet printers	Hewlett-Packard	5650 5940 6122
Officejet printers	Hewlett-Packard	K550 Officejet Pro

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	Drop out <40 msec	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	3.0 V	For recommended separation distances, see "Recommended Separation Distance" on page 80.
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 80.

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 78, 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 $d = \frac{3.5\sqrt{P}}{V}$	80 to 800 MHz $d = \frac{3.5\sqrt{P}}{E}$	800 MHz to 2.5 GHz $d = \frac{7.0\sqrt{P}}{E}$
0.01	0.12 m (4.7 in)	0.12 m (4.7 in)	0.24 m (9.5 in)
0.1	0.38 m (15 in)	0.38 m (15 in)	0.76 m (30 in)
1	1.2 m (3.9 ft)	1.2 m (3.9 ft)	2.4 m (7.9 ft)
10	3.8 m (12.5 ft)	3.8 m (12.5 ft)	7.6 m (25 ft)
100	12 m (39.4 ft)	12 m (39.4 ft)	24 m (78.7 ft)

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 78.

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 iU22 Ultrasound System is a high-resolution system intended for general imaging and shared services. The cart is ergonomically designed to be both highly mobile and adjustable for a range of users and operating conditions. You can use it for 2D, 3D, 4D, Live 3D, Volumetric, xPlane, M-mode, Doppler, Color, and Color Power Angio (CPA) imaging. You can also perform Duplex, Triplex, and Live xPlane imaging. Stress echocardiography is standard on the system, and QLAB Advanced Quantification Software plug-ins are available as options. The system supports a wide range of transducers. The system provides measurement tools, calculations options, and DICOM network capabilities.

Measurements

The system provides tools and controls for measuring distance, area, and volume. In calculations, the following application-specific tools are available:

- 2D Depth
- 3D Volume
- Distance
- Ellipse
- Convert to Ellipse
- Continuous Trace
- Trace by Points
- Curved Distance
- Volume

- Stacked Contours
- Hip Tools
- Volume Flow
- % Reduction
- Heart Rate
- Time/Slope

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.

Transducer Types

Available transducers include curved, sector, linear, compact linear, transesophageal, endocavity, intraoperative, CW, 3D, and for Live xPlane and 3D imaging, xMATRIX transducers.Applications for specific transducers are listed in "Clinical Options and Transducers" on page 196.

Image Capture and Review

You can capture and review single images and Philips Cineloop sequences. Images and Cineloop sequences can be stored on digital versatile discs (DVD RW) or sent over a network to an archive server or a printer.

Stress Echo capabilities also make use of the ability to capture and review image loops. Stress Echo protocols of up to eight stages are used to assess cardiac wall motion at various heart rates.

Peripheral devices are available for recording images and exams. You can add a VCR to the system and connect a black-and-white page printer or a color page printer. You can also connect 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. The system stores a record of each user logon.

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 155.

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, QLAB Advanced Quantification Software, protocols, imaging capabilities, and connectivity capabilities. A foot switch is available as an option.

Imaging Options

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

- 2D iSCAN Intelligent Optimization
- 3D freehand
- 3D/4D (mechanical transducers)
- Live 3D and xPlane (xMATRIX transducers)
- Fetal Spatio-temporal Image Correlation (STIC)
- iSTIC
- Doppler iSCAN Intelligent Optimization
- Elevation Compounding
- Panoramic Imaging
- Physio
- SonoCT Real-time Compound Imaging
- Voice control

- XRES Image Processing
- Volumetric Imaging
- Elastography

NOTE

The Elastography feature is only available in selected regions. For information specific to your region, contact your local Philips representative.

Voice Control Option

The voice control option allows you to operate the system using voice commands transmitted through a wireless headset. You can also use voice control to add text annotation to images. The voice control option can recognize commands in English, French, Italian, German, and Spanish.

Connectivity Options

The following features are standard:

- Image and waveform export to removable media
- Printing to DICOM printers
- Printing to local printers
- Printing report pages

In addition to those standard features, the Basic Connectivity purchasable option includes the following features:

- Image and waveform export to network storage servers
- DICOM worklist
- DICOM performed procedure step (PPS)
- DICOM storage commit (SC)
- DICOM Structured Reporting option

Clinical/Analysis Options

Clinical options are available on the system as separate purchasable options. The following clinical packages and their applications (for example, small parts superficial) are associated with specific transducers:

- Abdomen
- Adult Echo
- Contrast
- GYN
- Intervention
- Musculoskeletal
- OB
- Pediatric
- Small Parts
- Urology
- Vascular

Calculations Package Options

- Abdominal
- Adult Echo
- Fetal Echo
- General
- GYN
- OB
- Small Parts
- Vascular

QLAB Advanced Quantification Software Options

The following QLAB Advanced Quantification Software plug-ins are available as separate options:

- IMT (Intima-Media Thickness) measurement and quantification
- Cardiac 2DQ basic measurement and quantification
- Cardiac 3DQ basic measurement and quantification
- GI 3DQ basic measurement and quantification
- ROI (Region of Interest) quantification tools
- SQ (Strain Quantification) for Tissue Doppler Imaging
- MVI (MicroVascular Imaging) for assessing intensity changes over time

NOTES

- Instructions for using the QLAB plug-ins are included in QLAB Help, which is available by pressing the **Help** key while QLAB plug-ins are active.
- To ensure viewing compatibility of your QLAB Advanced Quantification files on a PC, ensure the QLAB software on your PC is the same version as that on your system.
- When acquiring images, do not have both black-and-white and color suppression enabled.

Stress Echocardiography

Stress Echocardiography (Stress Echo) is a protocol-driven study that allows a cardiologist to assess cardiac wall motion at various heart rates by acquiring views of the heart at different stages of the study. Stress Echo includes these Philips protocols:

- Exercise 2-Stage
- Exercise 3-Stage
- Pharmacological 4-Stage
- Wall Motion and Contrast
- Quantitative 4-Stage

You can create custom presets based on those protocols.

Data Security

A data security feature is available to help maintain the confidentiality of archived patient files. With this option, access to patient exam files is restricted to authorized personnel through user ID and password protection. For more information, see "Patient Data Protection" on page 86.

Technical Administration Option

The system includes many diagnostic capabilities as standard features, such as error handling and remote access for diagnosing the system. The technical administration option adds the following capabilities:

- Advanced tests and other diagnostic tools
- Automatic monitoring and logging of system operating parameters and usage; warnings when operating limits are exceeded
- Enhanced capabilities for self diagnosis
- Enhanced error handling and notification
- Preventive maintenance logging and notification
- Reporting of system and component configuration
- Secure technical administration interface

PercuNav Image Fusion and Navigation Device

You can use the PercuNav Image Fusion and Navigation Device to guide needles or probes using pre-procedure or intra-procedure images. By tracking the tip of flexible or rigid instruments using tiny sensors embedded in the tips of the instruments, the system provides real-time three-dimensional visualization and navigation during diagnosis and interventions.

Features include the following:

- Flexible instruments
- Multiple applications
- Multiple modalities

Instructions for using PercuNav are in the *PercuNav User Manual*.

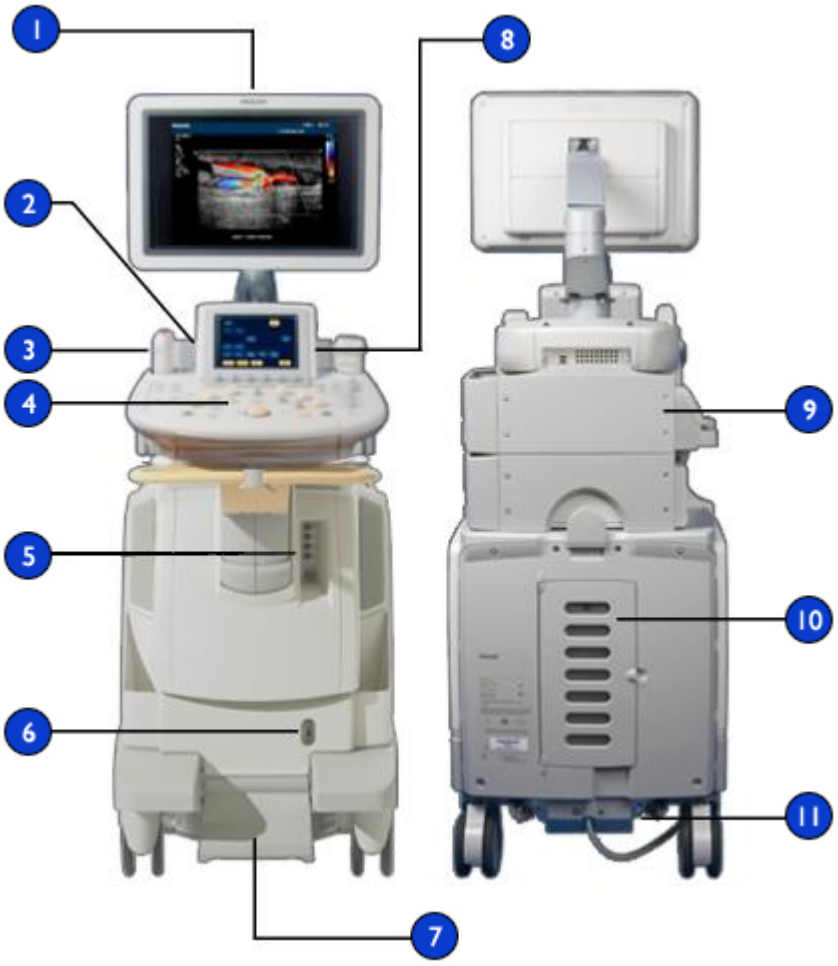
NOTE

PercuNav is a purchasable licensed option. Its user interface is available only when the PercuNav license is enabled.

System Components

The system is housed in an ergonomic cart. The cart is adjustable to accommodate a wide range of operator heights and operating positions. Adjustable components can be locked in place so the cart can be safely moved. The major components include the monitor, control module, On/Off switch, DVD RW drive, peripheral bay, transducer receptacles, ECG/physio receptacles, foot pedals, foot switch receptacle, and rear-panel power switch and audio/video receptacles.

System Components



1	Monitor
2	On/Off switch
3	Transducer receptacles

4	Control module
5	ECG/physio receptacles
6	Foot switch receptacle
7	Brake/steering lock foot pedal
8	DVD RW drive
9	Peripheral bay
10	Rear panel (audio, video, and network receptacles)
11	Power switch

Video Monitor

The system video monitor consists of a 43-cm (17-in) or 51-cm (20-in) flat-panel display on an articulated mounting arm. The monitor is adjustable to accommodate different operating positions and operator heights. The monitor can also be locked in position for moving the system (see "Moving the System" on page 116).

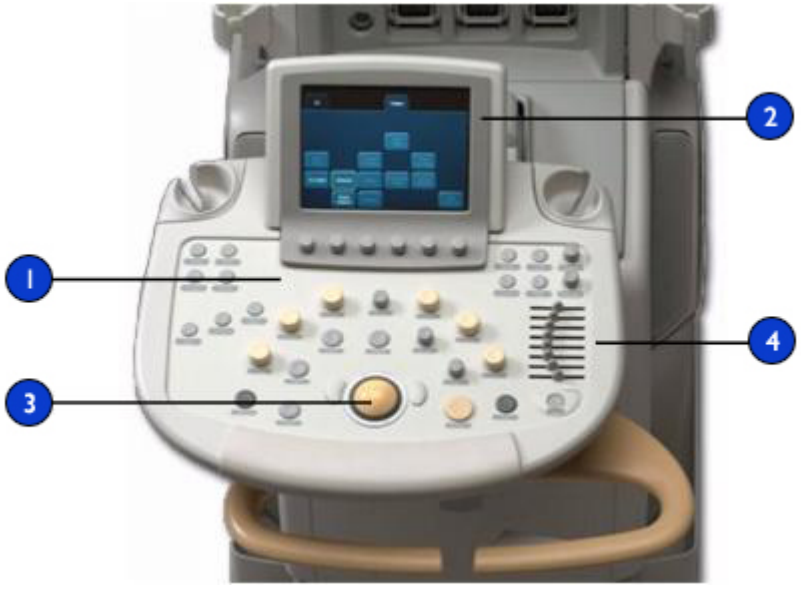
Control Module

The control module includes three main components: the control panel, the touch screen, and the keyboard. For more information on the control module, refer to "System Controls" on page 132.

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

The touch screen, located above the control panel, display controls used to select applications and imaging modes, as well as controls that are specific to the current operating mode. Touch screen controls include buttons and knob displays.

Control Module Components



1	Control panel
2	Touch screen
3	Trackball
4	TCG slide controls

You can adjust the position of the control module vertically and side-to-side. You can also swivel the control module.

Beneath the control panel is a retractable keyboard. The keyboard is used to enter patient data, comments, and text annotation on images. A light above the keyboard is switched on when the keyboard is pulled out.

Voice Control Headset

The optional voice control feature allows you to operate the system when the control module is out of reach or you need both hands for scanning. You can also use voice control to add text annotation to images. Voice control uses a wireless headset to send your voice commands to the system.

Voice Annotation Microphone

The voice annotation microphone allows you to record comments on a videotape or DVD. The microphone is in the monitor housing.

On/Off (Power) Control

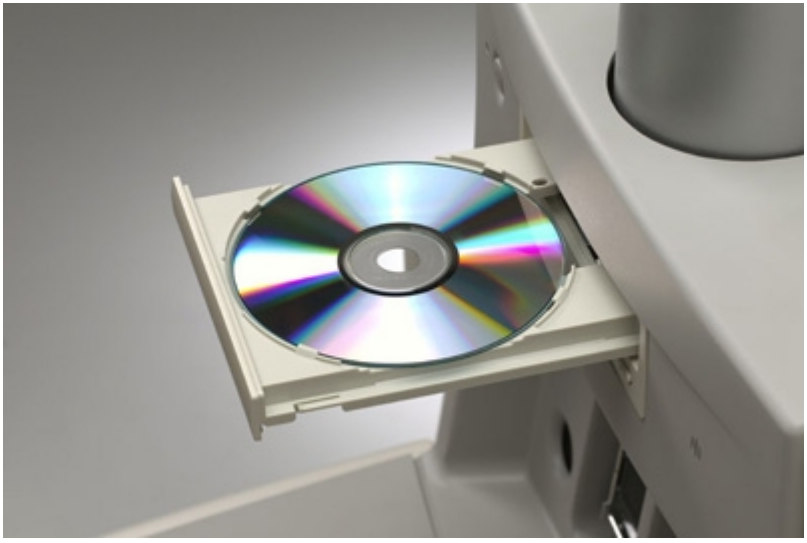
The **On/Off** switch is to the left of the DVD RW drive on the front of the system, above the control module. When the system is off, pushing this control brings the system into a fully operational state. Pushing this control again turns off the system.

On/Off Control

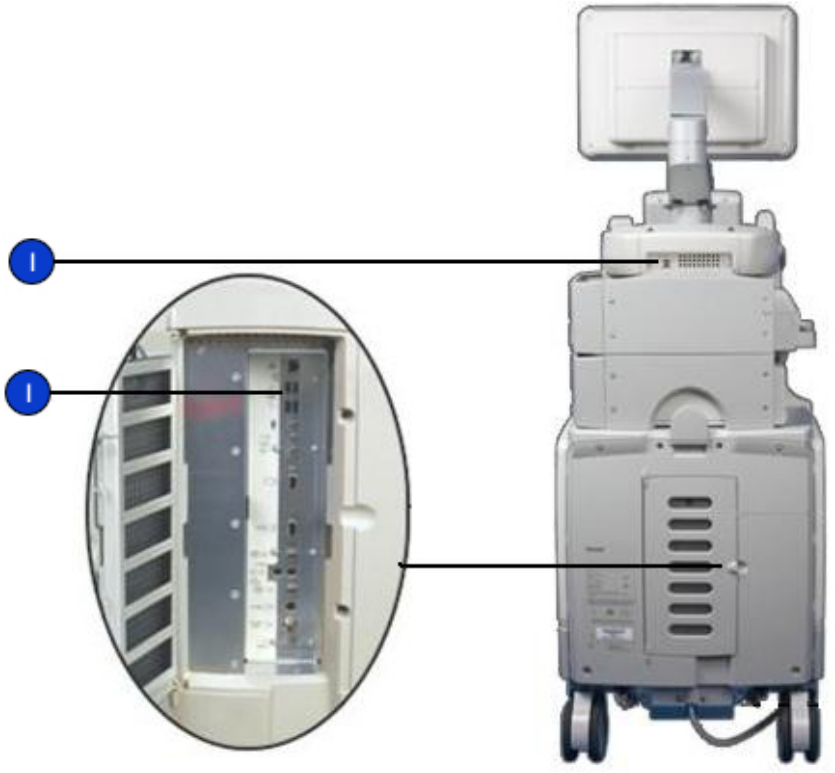
Data Storage

You can store exam data and images onto removable media. Removable media includes USB storage devices and the DVD RW drive, which is located above the control panel. The system hard drive is located inside the system.

DVD RW Drive



USB Port Location



1	USB port

Peripherals

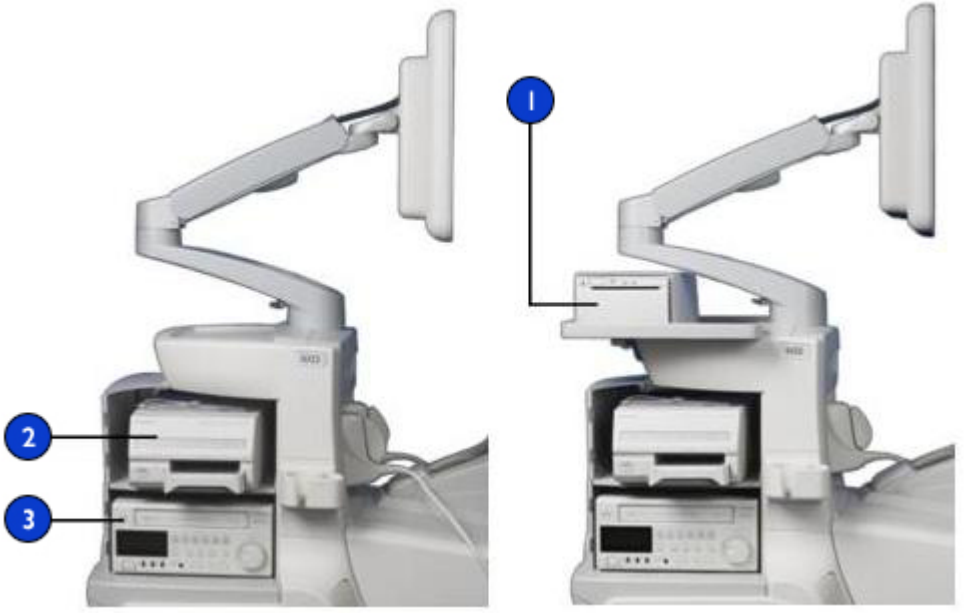
The peripheral bays at the back of the system provide space for up to three peripheral devices. Those devices can be any combination of the following devices: a black-and-white printer, a color printer, and a DVR or VCR. The third peripheral bay replaces the TEE transducer tray, so you can have either a third peripheral device or a TEE transducer tray, but not both. The devices can be

installed in the peripheral bay for access from either the right or left side of the system.

NOTE

If your system configuration includes the PercuNav Image Fusion and Navigation Device option, then the only other peripheral device that you can include on the back of the system is the black-and-white printer, which must be installed in the third peripheral bay.

Peripheral Bays



1	Black-and-white printer
2	Printer
3	DVR or VCR

Transducer Receptacles and Cable Management

The system includes three receptacles for array transducers and one receptacle for a pulsed- or continuous-wave Doppler probe. All four receptacles can be occupied at the same time, but only one transducer can be active at a time. When a transducer is not in use, store it in one of the transducer holders on the control module.

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

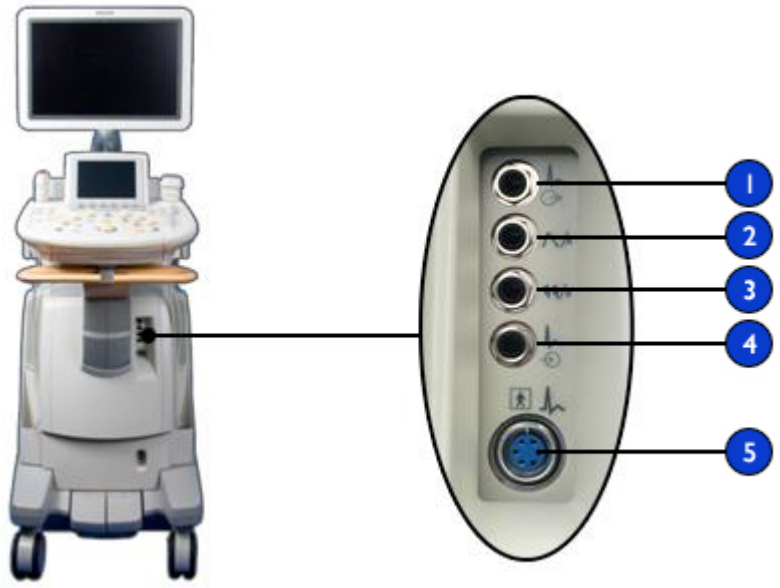
Transducer Receptacles, Holders, and Cable Management

1	Transducer holders
2	Array-transducer and pencil-probe receptacles
3	Cable hangers

Physio (ECG) Receptacles

For physio support, your system includes receptacles for both high-level and low-level ECG signals. In addition, there are receptacles for Analog Output (TTL-compatible trigger), Pulse/Aux1 (for physio channel 1), and Phono/Aux 2 (for physio channel 2). The ECG receptacles are on the front panel of the system below the control module.

ECG and Physio Receptacles



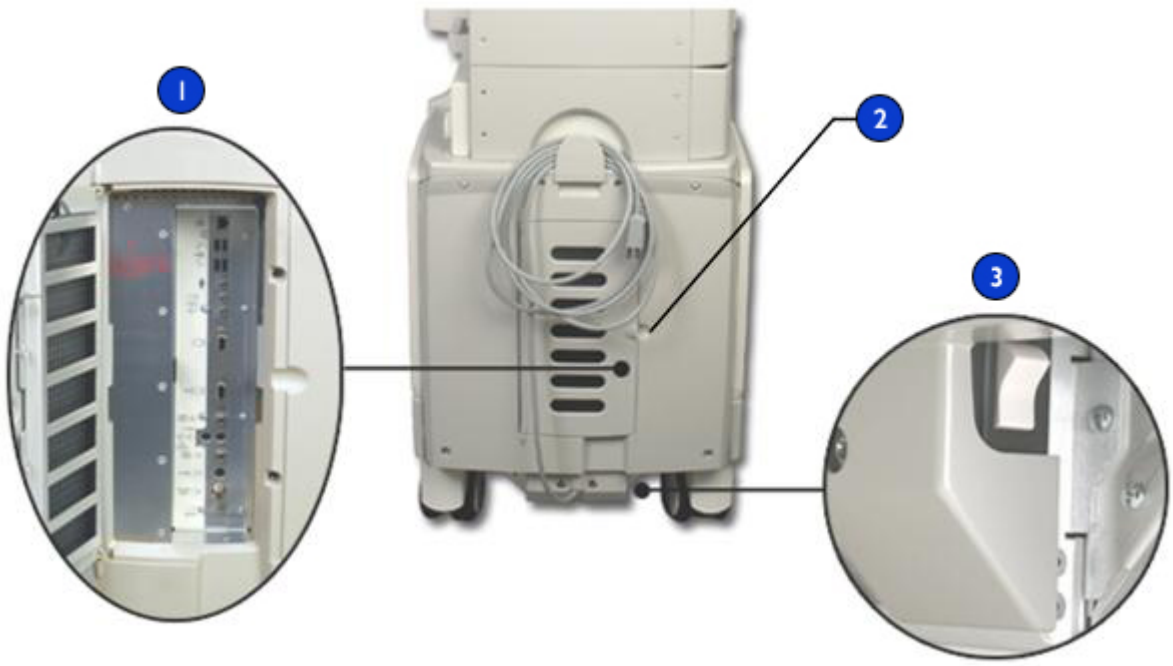
1	Analog output
2	Pulse/Aux 1 input
3	Phono/Aux 2 input

4	High-level ECG input
5	Low-level ECG input

Rear Panel and Power Switch

The rear panel of the system contains the receptacles for the peripheral devices, network devices, and power cords. Also located on the rear panel is the power switch.

Rear Panel



1	Audio, video, and network receptacles
2	Pull door to open
3	Power switch

Wheel Brakes and Steering Locks

The front wheels include brakes that you can engage to help keep the system in place during use. When you release the brakes, you can engage steering locks on the front wheels to aid in steering while moving the system. The brakes and steering locks are operated using the pedal located on the lower front of the

cart. To lock the brakes, press the pedal down completely. To engage only the steering lock, press the pedal again to release the pedal one notch.

For more information, see "Using the Brakes and Steering Locks" on page 128.

4 *Preparing the System*

The information and procedures in this section will help you prepare the system for use. Preparations include connecting transducers and external devices, locking articulated components 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 VCR, a foot switch, 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 and test the system to those requirements. For more information on peripheral devices, see the "Safety" section of the *User Manual*. 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.
- 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:

- Color image printers
  - UP-D21MD
  - UP-D23MD
  - CP-30DW
- Black-and-white image printers
  - UP-D895
  - UP-D897
- Large-format multi-image color printer
  - Sony UP-D55

- Black-and-white report printers
  - HP LaserJet 1300
  - HP LaserJet 1320
- Color report printers
  - Officejet Pro K550
  - HP Color LaserJet 2550
  - HP Color LaserJet 3600
  - Color Deskjet 5650
  - Color Deskjet 5940
  - Color Deskjet 6122
  - Officejet Pro K550

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.
- On some systems, the report printer must be connected to one of the two USB ports that are located in the printer bay.
- 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)**.

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

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.

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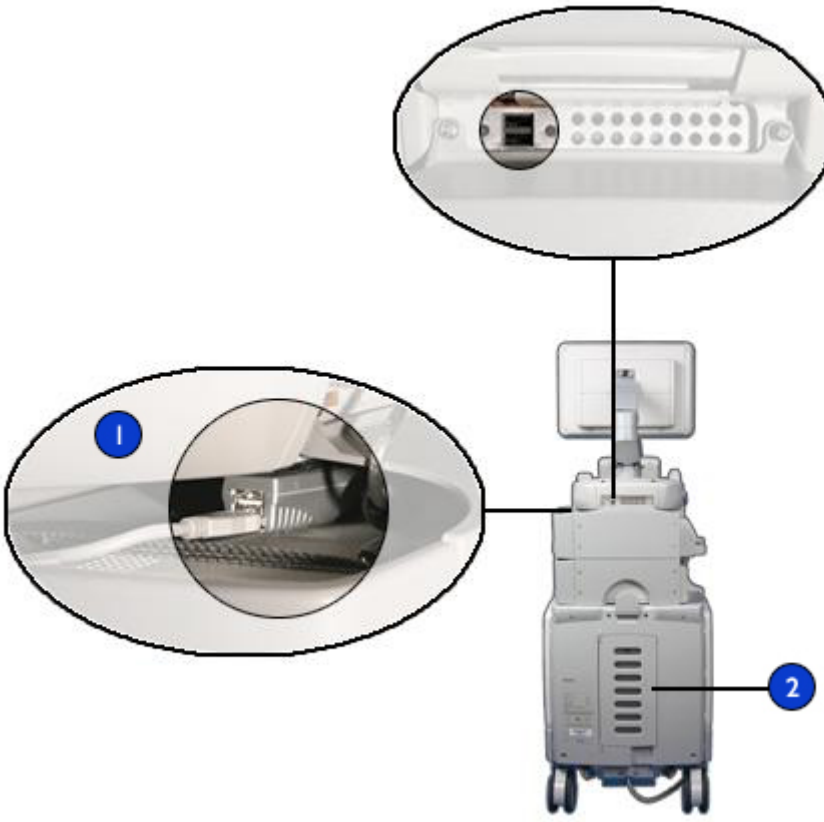
1. Turn off the system and unplug the power cord from the power source.
2. Connect a standard USB cable between the USB port on the printer and a USB  port on the system.
   - If your system has two USB ports on the back of the system behind the DVD drive, you can connect the printer cable to one of those ports or one of the USB ports on the lower rear of the system.
   - If your system has one USB port on the back of the system behind the DVD drive, you must connect the printer to one of the two ports on the USB hub located above the top peripheral bay.
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 17).
4. Turn on the printer, and then turn on the system.

   The system installs the printer drivers automatically.
5. After the system installs the new printer drivers, restart the system.

USB Port Location



1	On systems with a USB hub, connect a printer only to a USB port on the hub.
2	USB ports

Connecting the Foot Switch

The foot switch is available as an option.

1. Turn off the system
2. Insert the connector on the foot switch cable into the receptacle on the front of the system.
3. Secure the connector to the system by hand-tightening the retaining screws on the connector.

Foot Switch Receptacle

External VCRs

You can connect the Mitsubishi HS-MD3000UA (NTSC) or HS-MD3000EA (PAL) VCR to your ultrasound system as an external device. If your system has an internal VCR installed, an external VCR provides only recording from the system, and cannot support playback or be controlled from the system.

The system supports VCR control through the system control module only if this VCR is installed on the system using the Philips installation kit for that model.

(For availability of this kit, contact your Philips representative.) If you connect this VCR without the installation kit or connect any other VCR, you must control it from the front panel controls on the VCR.

Connecting an External VCR

1. Turn off the system and unplug the power cord from the power source.
2. Connect the audio cables between the **Audio** In on the VCR and the VCR **Audio** output on the ultrasound system.
3. Connect the audio cable between the **Audio** Out on the VCR and the VCR **Audio** input on the ultrasound system.
4. Connect an S-Video cable between the **S-Video** input on the VCR and the **S–Video** output on the ultrasound system. (This connector is available only if an internal VCR is not installed.)
5. Connect an S-Video cable between the **S-Video Out** on the VCR and the right **S–Video** input on the system; the left **S-Video** input is not functional.
6. Connect the 25-pin control cable from the system to **RS-232C** on the VCR.
7. Connect the VCR's power cord into the back of the VCR, and plug the other end into an appropriate power source.
8. Turn on the VCR, and then turn on the ultrasound system.

Configuring Print Functions

In the setups, you can associate a set of printers with each of the print controls. You cannot print to a printer unless it has been selected. A maximum of two DICOM printers, two local printers, and one report printer can be selected among the three lists. **Print** can print to local and network printers; **Alt Print** can print only to local printers. You can also change other printing parameters.

NOTE

During a study, **Print/Network** setups cannot be changed after you capture an image.

For information on configuring printers, see the *User Manual*.

1. Press the **Setup** key.
2. In the setups, click **Print/Network**.
3. Click the **Device Selection** tab and **Printer**.
   - To associate the **Print** control to a specific printer, select the printer under **Association to Print**.
   - To associate the **Alt Print** control to a specific printer, select the printer under **Association to Alt Print**.
   - To associate the **Report** control to a specific report printer, select the printer under **Association to Report**.
4. To modify the printer specific properties, select the printer, click **Edit**, and do any of the following:
   - To set the number of copies to be printed each time you use a print control, select the current setting and enter a number for **Number of Copies**.
   - Make additional configuration changes, such as **Film Orientation** or **Film Display Format**, as needed. If necessary, to revert to the default settings stored in the system, click **Reset Defaults**.
5. To apply and save your changes, click **OK**.
6. Click the **Printer/Capture** tab
   - To change the area printed, make selections for **Print** and **Alt Print** for **Print Format**.
   - To send report data to a computer or workstation, select **To Report Server** for **Send Report**. Otherwise, select **To Report Printer**.
7. To exit the setups, click **Done**.

Connecting an External Color Monitor

You can connect a compatible external color monitor to the **AUX** receptacle on the rear panel of the system. This receptacle provides standard DVI-D digital

output. You also can connect an external analog monitor to the **COMP VIDEO** receptacle, or for better image quality, to the **S-VIDEO** receptacle. A digital monitor connected to the DVI-D receptacle provides the best-quality image. The power cord for the external monitor plugs directly into a wall socket.

For analog monitors and video projectors requiring RGB video, a DVI-to-RGB converter is required. The Extron model DVI-RGB 100 converter has been tested with the system and verified to provide high-quality output that is compatible with many monitors and projectors.

The DVI-D output includes the entire screen. The aspect ratio of the screen is 16:10 (WSXGA+). To display this properly, select the 16:10 or 16:9 mode on the monitor or projector, if available. Also, you may be able to adjust the horizontal and vertical image size controls to create the correct aspect ratio. You can best judge the aspect ratio by displaying the circle test pattern on the system.

Connecting the System to a Network

To use connectivity features, the system must be connected to a network. The network receptacle on the system supports (10/100/1000 Mb/s) Ethernet LAN. The system is configured for network connectivity by a Philips field service engineer or your network administrator.

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.

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.

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 the system, ensure that the keyboard is retracted, the control panel is centered, and the monitor is locked. When extended, the keyboard might be damaged if it hits another object, and the video monitor could swing out during transport, causing injury or equipment damage.

CAUTIONS

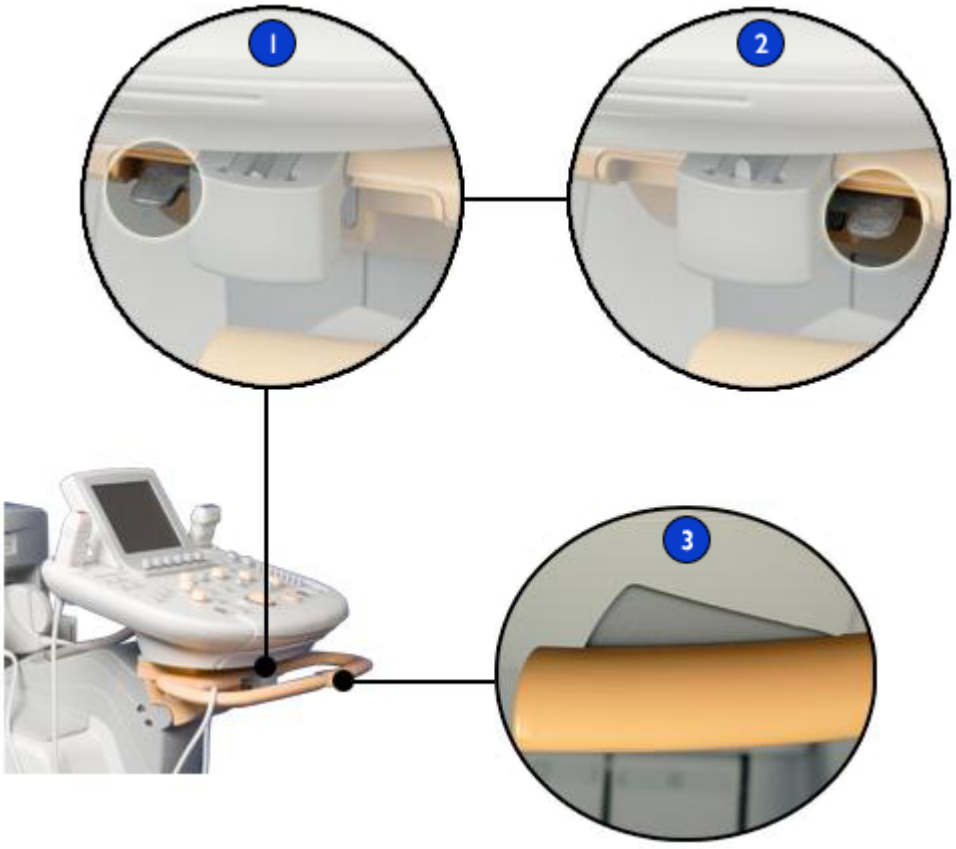
- Before moving the system, ensure that the brakes are completely released (by fully lifting the brake pedal). Otherwise, the engaged brake pad can damage the rubber casters on the wheels.
- Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management 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

Follow this procedure to move a system.

1. Press the power switch to turn off the system.
2. Disconnect all external cables, including those to power, network, telephone, and external devices. Secure all cables, transducers, and accessories so that they do not interfere with the wheels.
3. Squeeze the release lever on the front handle and use the handles to move the control module to its lowest position.

Control Module Locks



1	Unlocked position
2	Locked position
3	Release lever

4. Turn the locking lever beneath the control module to the right.
5. Grip the module by the sides, and center the module so that it latches.

6. Lock the monitor arm by pressing the articulating portions of the arm together.
7. Release the wheel brakes and set the steering locks by using the appropriate step:
   - On a one-pedal system, lift the foot pedal up fully.
   - On a two-pedal system, press the right foot pedal down fully.

WARNING

Do not move the system with the steering locked and wheels pointing in the direction you are moving the system. To avoid system instability while moving it, engage the steering lock only after you have moved the system a short distance in the intended direction. This means that when you push the system by using the front handles, the wheels are locked under the system, not protruding out from under the back of the system.

8. Move the cart using the front handles.

Positioning in Confined Spaces

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

1. Release the steering locks and wheel brakes by using the appropriate step:
   - On a one-pedal system, press the pedal to its middle position.
   - On a two-pedal system, Press the right foot pedal halfway down.
2. Move the system in any direction using the front handle.
3. When the system is in position, set the wheel brakes by using the appropriate step:
   - On a one-pedal system, press the foot pedal down fully.
   - On a two-pedal system, press the left foot pedal down fully.

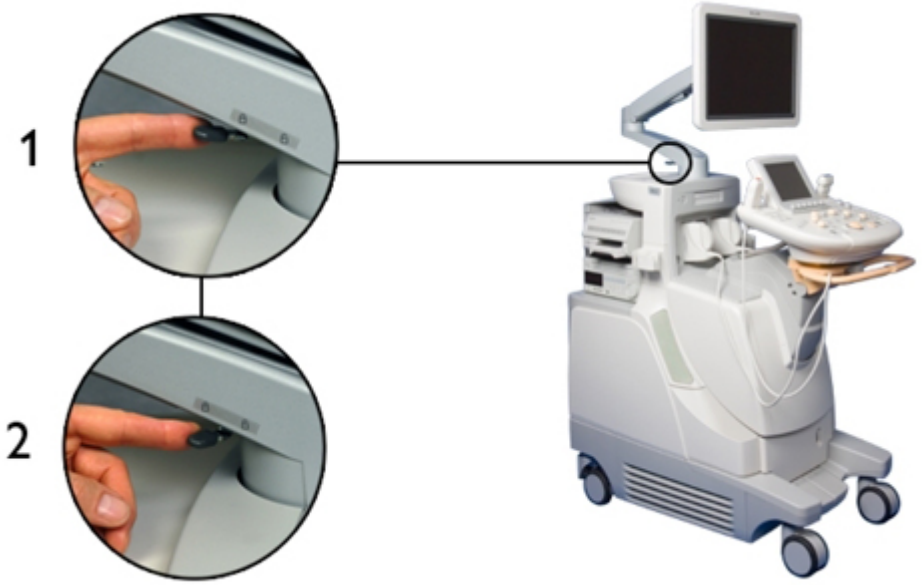
Setting Up After Moving

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.

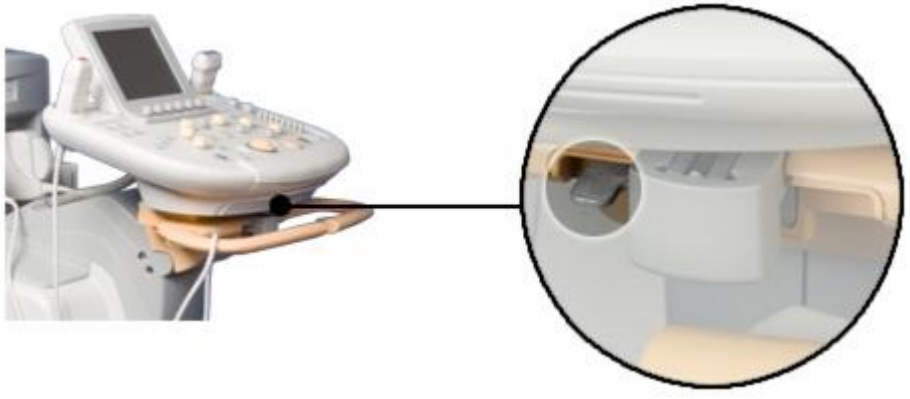
1. With the system in position and the brakes set, connect the power, network, modem and other cables from the system to the appropriate wall receptacles.
2. Unlock the monitor by moving the release lever to the unlocked position, and then position the monitor.

Unlocking the Monitor



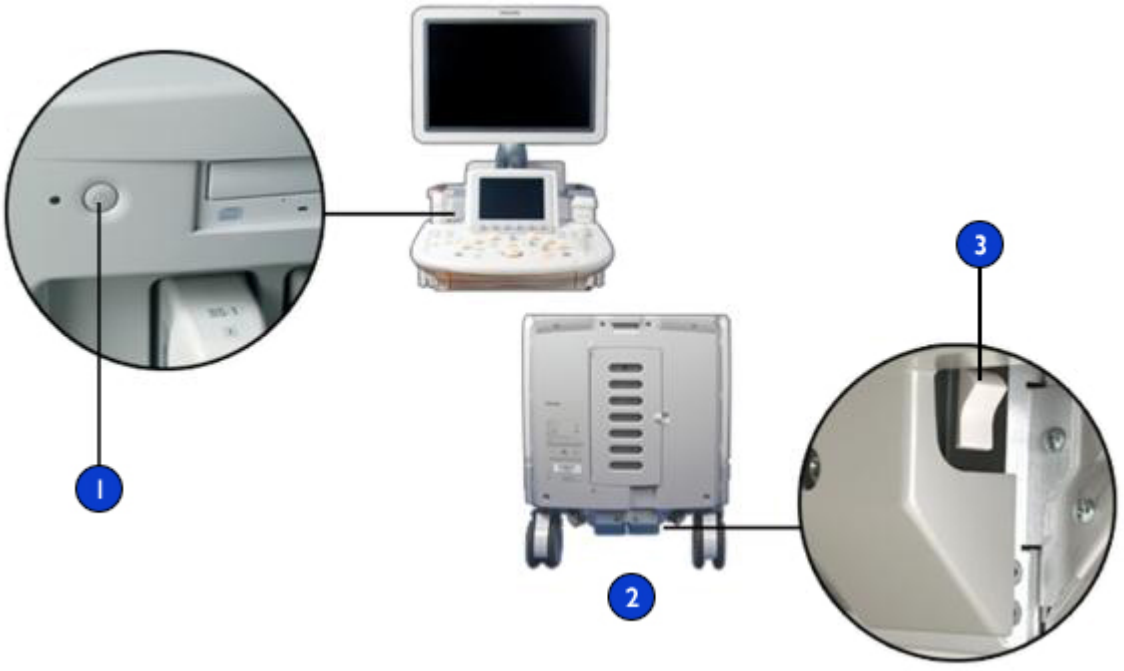
3. Unlock the control module by turning the locking lever below the module to the left.

Control Module Locks



4. Squeeze the release lever on the front handle and position the control module to the desired position.
5. Set the power switch to on **|** .
6. Press **On/Off** ⏻ to turn on the system.

On/Off Switch and Power Switch



1	On/Off switch
2	Rear of the system
3	Power switch

Transporting the System

Tie points are built into the system for anchoring it during transport in a vehicle. The system can be safely transported in a van if it is properly strapped down using the tie points.

1. Prepare the system as described in "Moving the System" on page 116.
2. Remove all transducers, cables, and accessories that are not attached to the system.
3. Using a lift gate or a secured ramp, load the system into the vehicle.
4. When the system is in position, set the wheel brakes by using the appropriate step:
   - On a one-pedal system, press the foot pedal down fully.
   - On a two-pedal system, press the left foot pedal down fully.
5. Place wheel chocks on the wheels to prevent the system from rolling.
6. Attach tie-down straps to the tie points on the lower rear of the system and to the handles. Secure the straps to anchor points in the vehicle.

Tie Points 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 system can be either on or off. When set to off, the system consumes no power. Follow these recommendations for when to turn your system on or off.

- If the system will not be used overnight, switch the system off at the end of the day.
- If the system will not be used for longer than overnight, power the system down. Press the On/Off switch above the control panel to turn the system off. When the monitor goes off, set the power switch on the back of the system to off ○.
- To power up the system, set the power switch on the back of the system to on | and then press the On/Off switch above the control panel.

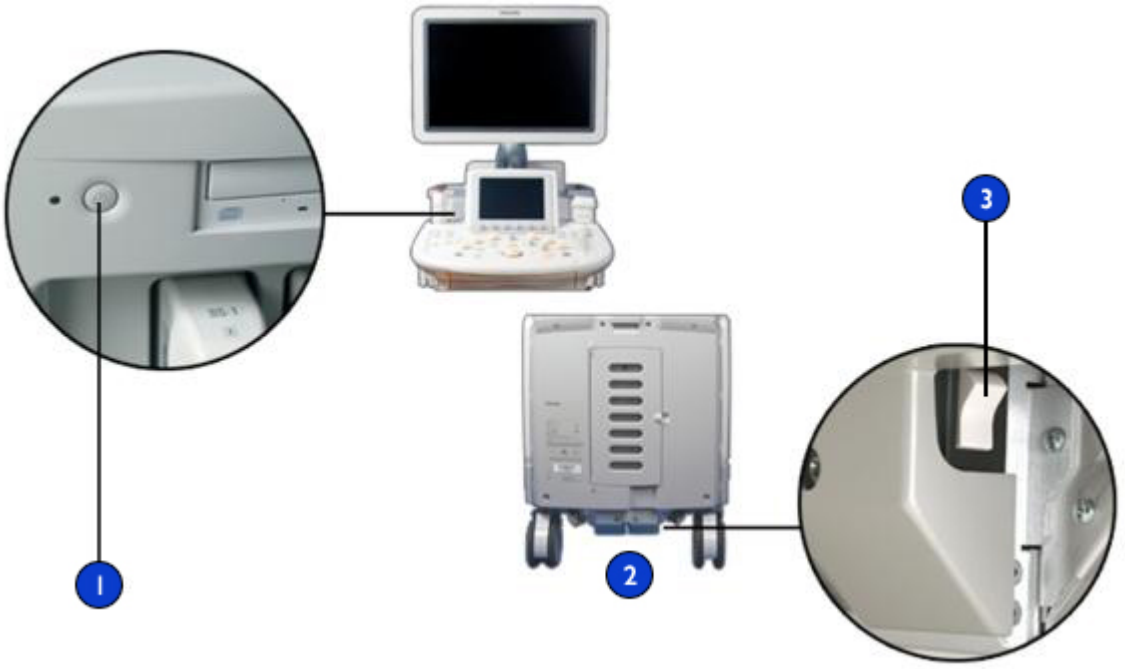
NOTES

- Never shut down the system while files are being transferred. File corruption or loss may result.
- Stop VCR activity (such as playback or rewind) before turning the system off.
- Stop DVR activity before turning off the system.
- Always use the procedures listed here for turning off the system, if possible. Turning off the system in any other way will result in longer initialization time when the system is turned on again, and may cause other problems.
- After you press the On/Off switch, as the system shuts down, the display blanks for a few seconds, returns briefly, and then blanks permanently. Turning off the Power switch on the back of the system or unplugging

the system before that shutdown sequence is complete can corrupt the hard drives. To ensure that the system is fully shut down, wait until the LED blinks or is off and the fans are not making any noise. A good practice is to wait 5 seconds in front of a black screen before setting the Power switch to off.

- Always end exams before powering down the system. If you power down the system with an exam open, the exam is paused, not closed.

On/Off Power Switches



1	On/Off switch
2	Rear of the system
3	Power switch

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.

NOTES

- The system time and date cannot be set when a study is active. It is recommended that you check the system time and date periodically before a study, and set the correct time and date, if necessary.
- If you change the system date while a study is paused, existing results for date-dependent calculations in the paused study are not recalculated by the system at any time.
- When you enter invalid characters in the time and date setups on the **Header** tab of **System Settings**, some characters are displayed and then erased, but others are not displayed at all. An invalid date may be displayed in the setups but not entered when you close the setups. After changing a date and exiting the setups, always check the date on the imaging display.

1. Press the **Setup** key. By default, **System Settings** is selected and the **Header** tab is displayed.
2. In **Set Time**, highlight the first digit in the **Time** box, and then use the number keys to enter the correct time (both hours and minutes). Select **Am** or **Pm**, if necessary.
3. In **Set Date**, highlight the first digit in the **Date** box to select it, and then use the number keys to enter the correct date. Repeat to set the other components of the date.
4. Click **Done**.

Using the Brakes and Steering Locks

All four wheels swivel to aid in maneuvering the system. You can engage steering locks to make steering easier when moving the cart. Brakes help keep the cart stationary while in use. The brakes and the steering locks are designed so that they cannot be engaged simultaneously.

Your system may have either a single foot pedal or two foot pedals at the lower front of the cart. Operate the brakes and the steering locks using the foot pedal or pedals using the appropriate procedure.

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.

On a One-Pedal System

Do any of the following:

- To engage the steering locks and release the brakes, lift the pedal fully.
- To release both the steering locks and the brakes, move the pedal to its middle position.
- To engage the brakes and release the steering locks, press the pedal fully.

Single Foot Pedal for Brakes and Steering Locks

		
Steering locks ON, wheel brakes OFF	Wheel brakes and steering locks OFF	Wheel brakes ON, steering locks OFF

On a Two-Pedal System

Do any of the following:

- To engage the steering locks and release the brakes, press the right pedal fully.
- To engage the brakes and release the steering locks, press the left pedal fully.
- To release both the steering locks and the brakes, press the higher pedal halfway down so that both pedals are even.

Two-Pedal System for Brakes and Steering Locks

		
Brake and steering lock OFF	Brake ON	Steering lock ON

Monitor Adjustments

The monitor is mounted on an articulated arm that permits it to be positioned vertically and in an arc from side to side. The monitor arm can also be locked for moving the system. You can adjust the brightness of the monitor image to compensate for ambient light. You can also change the default brightness setting for the monitor.

Positioning the Monitor

You can adjust the position of the monitor to suit different operating positions and operator heights.

CAUTION

To avoid damaging the flat-panel display in the monitor, do not operate it in direct sunlight. Also, do not operate or store the system where the ambient temperature exceeds 61°C (141.8°F).

1. Release the monitor from its locked transport position.
2. Grasp the monitor firmly and:
   - Tilt the monitor up and down
   - Swivel the monitor left and right

- Move the monitor side to side

Changing the Monitor Tint

In the setups, you can change the tint of the system display. The **Monitor Tint** setting affects only the appearance of images on the monitor; it does not affect saved or exported images. Three settings are available:

- **sRGB** provides the maximum dynamic range and most-balanced tint. Use it to match the look of the system display to a review station display that is set to the sRGB standard.
- **1** is balanced toward a blue tint, making the display look more like the display on a SONOS or HDI 5000 system.
- **2** is balanced toward a brown tint, making the display look more like the display on the 43-cm (17-in) analog monitor of an iU22 or iE33 system.

1. Press the **Setup** key.
2. With **System Settings** selected, click the **Display** tab.
3. Select the appropriate **Monitor Tint** setting. Philips recommends the **sRGB** setting for routine use.
4. Click **Close**.

NOTE

Rendered 3D volumes are particularly susceptible to changes in display tint. Some clinicians prefer the following settings for optimal viewing of 3D volumes: set **Monitor Tint** to **1** or **2** and set **Monitor** (brightness) to **1**.

Changing the Default Monitor Brightness

You can change the default brightness of the monitor image in the setups. The system uses this default value to set monitor brightness each time the system is turned on.

1. Press the **Setup** key.

2. With **System Settings** selected, click the **Display** tab.
3. Select a setting for **Default Monitor Brightness** from **1** (darkest) to **6** (lightest).
4. Click **Done**.

Adjusting for Ambient Light

The **Monitor** control on the **2D** touch screen allows you to adjust monitor brightness to compensate for changes in ambient light. Use this control to temporarily change the monitor brightness. When you cycle power, the system resets monitor brightness to the default value (see "Changing the Default Monitor Brightness" on page 131).

For maximum dynamic range, set **Monitor** to **3**. To match the look of the system display to earlier iU22 systems with the 43-cm (17-inch) monitor, set **Monitor** to **2**.

1. Touch **Next** on the **2D** tab.
2. Turn **Monitor** to select a setting from **1** (darkest) to **6** (lightest).

Automatic Display Dimming

To preserve monitor life and prevent burned-in display artifacts, the system automatically dims the display after more than 2 hours of operation with no control changes. The system restores full brightness as soon as you use any system control.

System Controls

System controls are located on the control panel, the touch screen, and the keyboard.

Control Panel

The control panel, located on the control module, contains the main imaging controls. These controls include knobs, buttons, TGC slide controls, and a trackball. Knobs that are indented on top act as both buttons and knobs. For example, when you press the **M-Mode** control, M-mode imaging begins; when you turn the **M-Mode** control, the 2D/M-mode gain changes.

A touch screen at the top of the control panel contains controls that assume different functions, depending on the system operating mode.

Control Panel

Positioning the Control Module

You can adjust the position of the control module vertically and side-to-side. In addition, you can also swivel the control module. For information on locking the control module, refer to "Moving the System" on page 116.

Do any of the following to position the control module:

- To move the control module up or down, squeeze the release lever on the front handle and use the handles to position the module.
- To swivel the control module, release the module by turning the locking lever to the left, then twist the module while gripping it by the sides.
- To move the control module side-to-side, release the module by turning the locking lever to the left, then slide it while gripping it by the sides.

Using the Retractable Keyboard

Beneath the control panel is a retractable keyboard. You can use the keyboard to enter patient data, exam comments, image annotation, and your logon password. The keyboard also includes function keys that access various features, such as setups and Help.

1. Pull out the keyboard. The keyboard illuminates after you pull it out completely.
2. Push the keyboard in completely when you are finished.

Touch Screen Brightness Controls

The touch screen brightness control is behind the touch screen at the top. Use it to adjust the brightness of the touch screen display when you need to compensate for changes in ambient light.

Touch Screen Brightness Control

Touch Screen Controls

The touch screen above the control panel provides controls that change function according to the current mode or function. The touch screen can contain several types of controls, depending on the function the control is to perform.

Types of Touch Screen Controls

For this type of button	Do this
	Touch a tab to display a different set of buttons. Touching the tab in this example displays buttons associated with pulsed wave (PW) Doppler mode but does not switch to PW mode.
	Touch **Next** or **Previous** to display the next or previous page of buttons associated with the current tab. For most tabs, there are two pages of buttons.
	Touch to perform or update a function. Touching the button in this example sends an image to the printer associated with it.
	Touch to turn a function on or off. The button is green when the function is on. In this example, SonoCT imaging is on.
	Touch to display a row of buttons used to select a mode or setting. Touching the button in this example displays five related buttons, one of which is shown below. Touching it when the associated buttons are displayed hides those buttons.
	Touch to select a mode or setting. This type of button is displayed only after you press the type of button shown above. Only one of the buttons in the row can be selected at one time. The button in this example is selected.

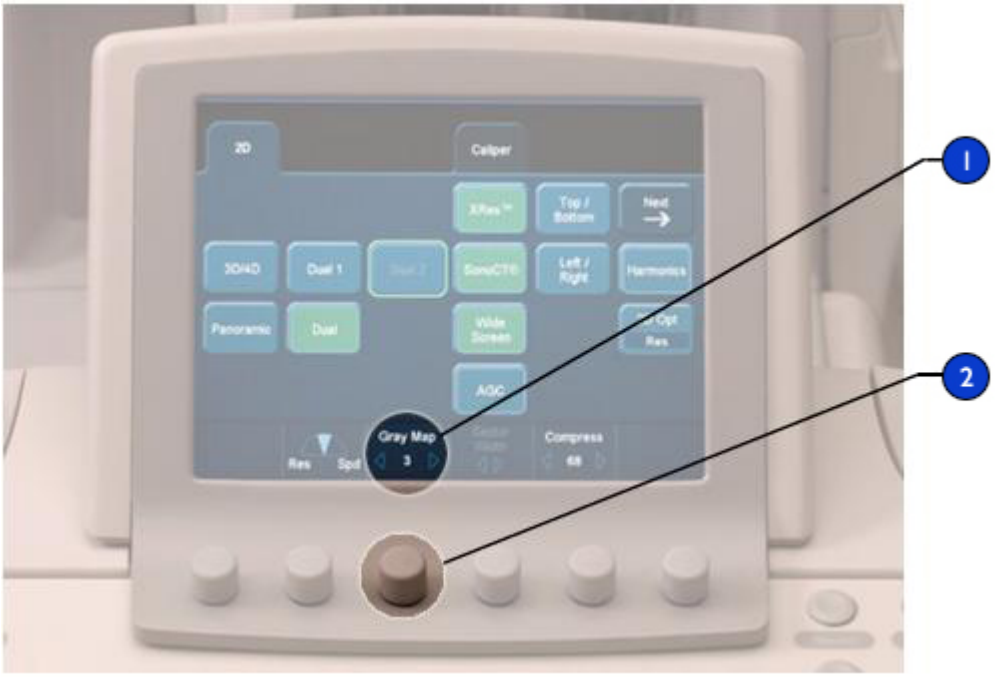
For this type of button	Do this
	Touch to change the value displayed on the button. Repeatedly pressing this type of button cycles through the range of available values. Do not confuse these buttons with rotary displays, which also display a value. Rotary displays appear only in the bottom row of the touch screen, and although they look like buttons, they are intended only to show a value for a function.

Touch Screen Knob Displays

Knob displays appear on the bottom row of the touch screen. Each knob display corresponds to a knob below it on the control panel. Like touch screen buttons, knob displays assume different functions based on the current imaging mode.

Turn the knob below a knob display to change the value for that function. For most functions, the value appears on the knob display. In a few instances, however, the value appears on the monitor display instead of on the knob display. One example of this is the **Gray Map** knob display.

Knob Displays



1	**Gray Map** knob display
2	Corresponding knob

Status Icons

The icons in a row on the bottom of the display provide feature-status indications and control . Status indicators include color combinations; graphic overlays, such as symbols and colored dots; lack of an overlay; and a non-displaying icon.

Icon	Description
	Indicates the status of the iSCAN Intelligent Optimization option: • No change (as shown): iSCAN optimization is available. • Green (for 3 seconds): iSCAN is optimizing the image. The iSCAN indicator is always present, even if iSCAN is not enabled in a Tissue Specific preset.
	Indicates the status of the media drive (DVD, CD, or USB storage device): • No dot: Available • Green dot: Writing data • Yellow dot: USB and DVD drives are empty; media is write-protected and the USB drive is empty; the DVD drive is malfunctioning and the USB drive is empty • Red dot: Failed Click the icon to open the **Media Status** dialog box. You can cancel, pause, or resume any data transfer job listed.

Icon	Description
	Indicates the presence of a remote services session. An exclamation point (as shown) in the lower right corner indicates that the patient name and ID are visible to the remote user. When the icon does not include the exclamation point, it indicates that the patient name and ID are not visible to the remote user. Click the icon to end the remote desktop session.
	Indicates the status of a local or network printer: • No dot: Available • Green dot: Active printing • Yellow dot: Printer not on the network • Red dot: Failed Click the icon to open the **Printer Status** dialog box. You can cancel, pause, or resume any print job listed.
	Indicates the status of a network communication: • No dot: No activity • Green dot: Active communication • Yellow dot: System or printer not on the network • Red dot: Failed Click the icon to open the **Network Status** dialog box. You can cancel, pause, or resume any network job listed.

Icon	Description
	Indicates the basic feature status of the voice control option: • Large X: Off • No change (as shown): On • Key overlay: On, with the keyword feature on • ABC overlay: On, with the voice annotation feature on
	Indicates the headset status of the voice control option: • Yellow on black: Not ready, not connected, out of range • Gray on black (as shown): Ready and listening • Black on yellow: Did not recognize, did not execute • Black on green: Heard and executed
	Indicates, when displayed, that the microphone is enabled. When the icon is not displayed, the microphone is disabled.

Voice Control

Voice control uses a wireless headset to send your voice commands to the system. You can use voice control to operate the system when the control panel is out of reach or you need both hands for scanning. You can also use voice control to add text annotation to images. When this feature is active, you can still use the controls on the control panel.

The voice control option can recognize commands in English, French, Italian, German, and Spanish.

Using voice control, you can operate the system controls that are most commonly used during an exam. For knobs and some controls on the touch screens, you can direct the system to adjust the control up or down. You can include a relative control setting, which specifies an increment or multiplier, depending on the command you use it with. For example, "2D gain up 5" corresponds to an increase

of 5 clicks of the 2D knob, while "Move color box up 5" moves the color box up 50 pixels (5 x 10, where 10 is the increment for this command).

When you first use voice control, try operating it without a voice profile. To do this, select **Guest** when enabling the feature. If you want to increase recognition accuracy, create a voice profile and train it to recognize your speech.

You can set voice control to listen only to commands that start with a keyword. The keyword feature reduces the possibility of erroneous commands caused by conversation or noise. When the keyword feature in voice control is on, you must start each full command with the word "Vox." For example, "Vox color." If you have created a user profile, you can set the default state of the keyword feature for your profile in the setups.

You can activate and deactivate voice control using one of the two voice control icons on the display. These icons also indicate the status of voice control and the keyword feature. For descriptions of these icons, see "Voice Control Icons" on page 143.

NOTES

- An AC adapter is included with your iCOMMAND headset and is intended only for use with the headset charging unit. Please check your local electrical device regulations prior to its use. For permanent use, Philips recommends that you obtain from your local wireless electronics dealer the Jabra FreeSpeak BT250v headset with Bluetooth v1.1 compliant technology that includes a charging unit compatible with local codes.
- Some system controls switch a function on and off or cycle through more than two states. For example, SonoCT switches between the on and off states of this feature, while Zoom cycles through Zoom standby, Zoom, and off. The voice commands that operate those system controls also switch between or cycle through states. The optional words for these voice commands, such as "on" or "off," are included as a convenience but do not change the action performed by these commands.
- The wireless headset emits radio waves in the ISM band at 2.4 GHz and complies with FCC regulations. It is your responsibility to determine the suitability of this wireless device in your environment.

Voice Control Icons

The state of voice control is indicated on the display by two icons. The first icon shows whether voice control and the keyword feature are on or off. The second icon shows whether or not the headset is connected. This icon also indicates when a command is recognized.

Icon	Description
On/Off/Feature Icon	
	Voice control is not active. Click to activate voice control.
	Voice control is active, and the keyword feature is off. Click to deactivate voice control.
	Voice control is active, and the keyword feature is on. Click to deactivate voice control.
	Voice control is active, and the voice annotation feature is on. Click to deactivate voice control.
Headset Status Icon	
	Voice control is not ready; headset is not connected.
	Voice control is active and listening.
	Voice control did not recognize a valid command and did nothing.

Icon	Description
	Voice control recognized and performed a command.

Turning Headsets On and Off

When a headset is on, the indicator on the headset lights as described in the headset documentation. To locate the controls on the headset, see the headset documentation. A headset may emit tones when you turn it on or turn it off. For information about the tones, see the headset documentation.

NOTE

Always wear the headset on the ear closest to the system. Wearing it on the other ear reduces the range of the headset.

1. To turn a headset on, press and hold the Call Handling button on the headset until you hear a tone.
2. To turn a headset off, press and hold the Call Handling button again until you hear a tone.

Pairing Headsets

The system recognizes only headsets that have been *paired* to it in the setups. You can pair up to seven headsets to a system. Until you assign a name to a headset, it will be identified on the **Headset Config** tab only by the model number. In this list, voice control headsets used with the system are identified by one of two model designations: for Sony Ericsson headsets, the model designation starts with **HBH**; for Jabra headsets, the model designation starts with the name **Jabra**. Ignore other nearby Bluetooth devices that may appear in the list on the **Headset Config** tab.

When using multiple headsets in one location, it is important to give each headset a unique name and to label each headset with its name. To locate the controls on the headset, see the documentation provided with the headset.

NOTE

When a new headset is paired to the system, it may be necessary to pair the headset twice. After you have paired it once, click **Unpair** to unpair it, turn the headset off and on again into pair mode, and then pair it a second time.

1. Press the **Setup** key.
2. Click **Voice Control**, and then click the **Headset Config** tab.
3. Wait until the message "Querying headsets" disappears from the bottom of the display, indicating that the system is finished querying headsets.
4. Ensure that the headset is off.
5. Press and hold the Call Handling button on the headset until the indicator lights as described in the headset documentation. The headset is now in pair mode.
6. Click **Refresh Current Status**.
7. Select the headset in the list:
   - For a Sony Ericsson headset, select the name that starts with **HBH**.
   - For a Jabra headset, select the name that starts with **Jabra**.
   - For a Plantronics headset, select the name that starts with **PLT**.
8. Click **Pair**.
9. At the prompt, type the passkey (0000) and click **Next**. If 0000 does not work, use the passkey shown in the headset documentation.
10. If the model number of the selected headset is listed under **Name**, rename the headset with a unique name by doing the following:
    a. Click **Change Name**.
    b. Type a unique name.
    c. Click **OK**.
11. Click **Done**.
12. Label the headset with the name you assigned to it in step 10.

Configuring Headsets

Once a headset has been paired to the system, you can configure the headset. Settings on the **Headset Config** tab allow you to delete or rename a headset and permit or prevent communications between a headset and the system. To locate the controls on the headset, see the documentation provided with the headset.

NOTE

Other nearby Bluetooth devices may appear in the list on the **Headset Config** tab of the **Voice Control** setups. In this list, voice control headsets used with the system are identified by one of three designations: for Sony Ericsson headsets, the designation starts with **HBH**; for Jabra headsets, the designation starts with the name **Jabra**; and for Plantronics headsets, the designation starts with **PLT**.

1. Ensure the headset is on.
2. Press the **Setup** key.
3. Click **Voice Control**, and then click the **Headset Config** tab.
4. Observe the message at the bottom of the display and wait until the system is finished querying headsets.
5. If your headset is not listed, perform the procedure in "Pairing Headsets" on page 144.
6. Select a headset and do one of the following:
   - To change the name of the headset, click **Change Name**, type a new name, and click **OK**.
   - To delete the selected headset from the list, click **Delete**, and when prompted, click **OK** to confirm the deletion.
   - To prevent the selected headset from communicating with the system, click **Unpair**.
   - To see any changes that are not reflected in the list, click **Refresh Current Status**.
7. Click **Done**.

Muting the Headset

When you want to talk with someone during an exam, it is a good idea to mute the headset to avoid sending unintended commands. This is especially important when the keyword feature is disabled. To locate the controls on the headset, see the documentation provided with the headset.

Do one of the following to control the mute function on the system:

- Say "Go to sleep" to mute the headset.
- Say "Wake up" to unmute the headset.

Enabling Voice Control

Before you can use voice control for the first time after powering up the system, you must enable it.

1. If the headset has been labeled, note the name or number on the label. Turn on the headset and put it on.
2. Click the voice control icon  .

NOTE

In some situations, you may need to press **Pointer** first, to activate the pointer.

3. For **User**, select your profile or select **Guest**, and then click **Next**.
4. For **Active Headsets**, select your headset and click **Next**.
5. When your headset rings, press the Call Handling button to connect to the system.

Voice Profiles

You can use voice control regardless of whether you have created and trained a voice profile. However, Philips recommends that you create and train a voice

profile before using voice control. Training voice control to recognize your speech significantly improves recognition accuracy. Minimally training a voice profile requires only about 2 minutes.

Training a voice profile involves reading text into the system using a voice control headset. The system lets you choose from among a number of books of text to read. Once you start the process, the system listens to your speech to associate each written word with your pronunciation of it. As you read the text, the system displays recognized text in green and unrecognized text in red.

If the system does not recognize one or more words, you can re-read some or all of the text on the page. When the system recognizes your reading of all text on a page, it displays the next page of text. It is not necessary that every word be recognized by the system during training. If a few words are not recognized after re-reading, you can skip to the next page by clicking **Next**.

If you need to stop the training before you are finished, you can click **Suspend** to save your input, mark your place, and close the training window. When you open the training window for your voice profile again, the system displays the text page you were working in when you suspended training.

Select a quiet location in which to train a voice profile. When reading during training, speak in your normal tone of voice at your normal rate.

Creating a Voice Profile

Before you begin creating a profile, read "Voice Profiles" on page 147.

You can use voice control regardless of whether you have created and trained a voice profile. However, Philips recommends that you create and train a voice profile before using voice control. Training voice control to recognize your speech significantly improves recognition accuracy. Minimally training a voice profile requires only about 2 minutes.

NOTE

When naming profiles, do not include single quotes or other special characters.

1. If the headset has been labeled, note the name or number on the label. Turn on the headset and put it on.

2. Press the **Setup** key.
3. Click **Voice Control**. On the **Voice Profiles** tab, click **New Voice Profile**.
4. Type a unique user name for your profile. Click **Next**.
5. Select the language you will be using for giving voice commands. Click **Next**.
6. Select the headset you are using from the list. Click **Next**.

NOTE

If the headset has not been paired to your system, follow the prompts.

7. Acknowledge the communication between the system and the headset by pressing the Call Handling button on the headset.
8. Click **Start** and read the paragraph in the dialog box. When you are done, click **Stop**. You have completed the creation of a new voice profile. For information regarding training the voice profile, see "Training Voice Profiles" on page 149.
9. Click **Done**.

Training Voice Profiles

You can use voice control regardless of whether you have created and trained a voice profile. However, Philips recommends that you create and train a voice profile before using voice control. Training voice control to recognize your speech significantly improves recognition accuracy. Minimally training a voice profile requires only about 2 minutes.

NOTE

After you have trained a voice profile to the minimum level, you can do further training at any time. Although additional training does improve recognition accuracy, the longer you train, the smaller the degree of improvement becomes.

1. If the headset has been labeled, note the name or number on the label. Turn on the headset and put it on.
2. Press the **Setup** key.
3. Click **Voice Control**.

4. On the **Voice Profiles** tab, select the profile you want to train.
5. Click **Training**.
6. In the **Training Topics** dialog box, select a book you would like to read to train voice control. Click **OK**.
7. Click **Microphone** and begin reading the text. Ignore text color for now and continue reading to the end of the displayed text. If all text is recognized, the next page of text is displayed.
8. Any text not recognized is marked in red. When you have finished reading and the text background changes to yellow, do one of the following:
   - To reread the entire page, click **Repeat** and begin reading.
   - To reread starting at the first unrecognized text, drag the text cursor to the beginning of the first red text. Then click **Microphone** and read from that point to the end of the page.

NOTE

If some text is still unrecognized after rereading it, click **Next** to display the next page.

Read at least until the prompt indicates that you have reached minimal training (2 minutes or more). To improve recognition accuracy, read further. If you need to stop the training temporarily before you are finished, click **Suspend**. When you resume training, the last uncompleted page will be displayed.

9. When you are finished reading, click **Start Processing** to apply the training to your profile.

NOTE

If **Start Processing** is not available, first click **Microphone**.

10. Click **Done** when the processing is complete.

Deleting Voice Profiles

You can delete voice profiles that are no longer needed. If you are not satisfied with the training you have done so far, you can delete that voice profile and start training a new profile from the beginning.

1. Press the **Setup** key.
2. Click **Voice Control**.
3. Select the profile that you want to delete, and then click **Delete Voice Profile**.
4. To delete other profiles, repeat step 3.
5. Click **Done**.

Background Noise

Background noise in the exam room can interfere with your use of voice control. Fans, patient monitors, voice paging, and even Doppler audio on the system can lower the accuracy of voice recognition. If you are going to be using voice control, it is helpful to reduce or eliminate noise by turning off loud equipment and by limiting the volume level of Doppler audio.

Communication Problems

The voice control feature uses Bluetooth wireless technology. This technology is also commonly used in cellular telephones and other wireless applications. To prevent other Bluetooth devices from sending unintended commands through voice control to the system, the system listens only to headsets that have been paired and connected to it.

On rare occasions, a nonstandard wireless device operating near the system may disrupt communications between the voice control headset and the system, but will not execute commands on the system.

If you cannot communicate with your system using the voice control headset, first perform the steps in "Troubleshooting Voice Controls" on page 152. If the

problem persists, move the ultrasound system to another room at least 30 m (100 feet) away and check communications again. Turning off all other wireless devices can help you locate the source of the interference.

Troubleshooting Voice Controls

If the error message "The system failed to communicate..." displays during the use of voice control, use the following procedure to correct the problem.

1. Ensure headset is turned on.
2. Ensure headset is paired to system.
3. Refresh the **Active Headsets** list and select your headset again.

NOTE

If the problem persists or is not covered here, contact your Philips Ultrasound customer support representative.

Using Voice Commands

You can use voice control regardless of whether you have created and trained a voice profile. However, Philips recommends that you create and train a voice profile before using voice control. Training voice control to recognize your speech significantly improves recognition accuracy. Minimally training a voice profile requires only about 2 minutes.

For a list of voice commands, see the *Voice Control Quick Guide*.

NOTE

Always wear the headset on the ear closest to the system. Wearing it on the other ear reduces the range of the headset.

1. If you have not used voice control since the system was powered up, perform the procedure in "Enabling Voice Control" on page 147.
2. Do any of the following to use voice control:

- Say a command. Most controls can be activated by more than one command. For example, to change the box size, you could say "Make" or "Make box" followed by "Wider" or "Taller" or "Larger," and so on.

- If voice control is set to use a keyword (indicated by ),start each full command with the word "Vox."
- To operate a button or key, say the name of the control. Some buttons have two possible commands; for example, "Freeze" and "Unfreeze."
- To operate a knob, say the name of the knob, followed by "Up" or "Down." You can also say "Decrease" or "Increase," followed by name of the knob. To state an increment of change, say a number (1-9). For example, to increase 2D gain, you can say "Increase 2D gain three" or "2D gain" followed by "Up three."
- To operate a touch screen control, say the name of the control. Controls on a touch screen page are available only when the tab for that page is displayed in the foreground and the control itself is not gray (unavailable based on the current mode).
- To display the next or previous touch screen, say "Next" or "Previous."
- To display a touch screen tab that is currently in the background, say the tab name followed by "Tab." For example, "Color tab."
- To click or select an object on the screen, say "Select."
- To repeat the last command, say "Repeat."
- To turn the keyword feature on or off, say "Keyword on" or "Vox keyword off."
- To turn on sleep mode, causing voice control to ignore commands, say "Go to sleep."
- To make voice control listen again, say "Wake up."

3. To disable voice control, click the voice control icon  or  .

Using the Keyword Feature

When the keyword feature is on, voice control performs only commands that start with the keyword "Vox." Using this feature helps prevent erroneous commands. In the setups, you can select whether the keyword feature will be on or off when you first activate voice control. Regardless of the default setting, you can turn the keyword feature on and off using a voice command.

1. Ensure that voice control is active.
2. Do one of the following:
   - To turn the keyword feature on, say "Keyword on."
   - To turn the keyword feature off, say "Vox keyword off."

Specifying Keyword Default Settings

In the setups, you can select whether the keyword feature will be on or off when you first activate voice control.

1. Press the **Setup** key.
2. Click **Voice Control**.
3. On the **Voice Profiles** tab, select the profile you want to set up.
4. Select or deselect **Use Keyword**.
5. Click **Done**.

Voice Annotation Commands

The voice control feature lets you add annotation to the screen from a list of terms. The list of terms that is displayed is dependent on which clinical option is selected.

For a full list of the terms, see the *Voice Control Quick Guide*.

The voice annotation feature is turned on and off with a voice command. "Erase all text" and "Erase last word" are the only other voice commands available when voice annotation is on.

NOTE

To simplify the annotation process, the keyword feature is not available when voice annotation is on.

Using Voice Annotation

NOTE

Always wear the headset on the ear closest to the system. Wearing it on the other ear reduces the range of the headset.

1. Say "Annotate" or "Vox annotate."
2. Say the annotation term. For example, "Lateral." Remember that the keyword feature is not used in voice annotation.
3. To erase specific annotations, position the annotation cursor to the right of the term using the arrow keys, then press the **Backspace** key until it is erased. You can also say "Erase last word" to remove one word at a time.
4. To erase all annotations, say "Erase all text."
5. To turn off voice annotation, say "Annotate off" or "Stop." You can add "Stop" to the end of a command to save time.

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, you must log on to the system before you will be able to view or load patient files.

1. Click the Log On icon  at the bottom of the imaging display.
2. In the **Logon** dialog box, type your user name.
3. Press the **Tab** key and type your password. (If you forget your system password, contact your system administrator.)
4. Select **OK** to log on to the system and start the valid access period.

NOTE

Logging off of the system does not change the current patient, but it does deny further access to protected patient data.

Logging Off of the System

If you do not log off, the system will automatically log you off when you shut down the system or after the system has been inactive for the length of time shown in Auto Log Off on the User Settings tab of the Data Security setups. Only the system administrator can change the **Auto Log Off** setting.

1. Click the Log Off icon  at the bottom of the imaging display.
2. In the **LogOff** dialog box, click **Yes**.

Changing Your Password

If the data security feature is implemented on your system, you must log on to the system to gain access to patient data and images.

Once the system administrator has given you a password for the system, you can change it as needed. A password must be 6 to 10 characters long and can contain only letters and numbers; punctuation marks and symbols are not allowed.

NOTE

The **Auto Log Off** time shown on the **User Settings** display indicates how long the system can be inactive before you are logged off automatically. Only the system administrator can change this setting.

1. Press the **Setup** key.
2. Click **Data Security**.
3. On the **User Settings** tab, click **Change Password**.
4. For **Old Password**, type your current password, and then press the **Tab** key.
5. For **New Password**, type the new password you want to use, and then press the **Tab** key.
6. For **Confirm Password**, type your new password again.
7. Click **OK**.
8. To exit setups, click **Done**.

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.

In an emergency, you can start a study without entering patient data. During an emergency study, the system provides a temporary ID for image acquisition and report editing. You should change the temporary ID to correct the patient data before you end the study. Otherwise, the temporary ID is the only identifier for that study.

Temporary ID

Use the temporary ID feature to start an exam quickly. This feature allows you to perform an exam 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 an exam as you would normally.

To use the temporary ID feature, the **Burn Patient Information Into Images** option in the **Print/Network** setups must be deselected.

When you use the temporary ID workflow, images can be sent to a PACS or to a DICOM printer before entering actual patient data, if the system is configured to send or print images as you scan.

NOTES

- For an exam started with a temporary ID, edit patient data before ending the exam. After the exam is ended, you cannot change patient data.
- If you have configured a DICOM performed-procedure-step-server, PPS messages are sent for the temporary ID.
- If you have configured a PPS server, PPS discontinue messages are sent for the temporary ID if you are in send-as-you-scan mode or if you have enabled send-on-demand.
- When the patient data is changed, all images are automatically resent to any local printers that they were previously sent to.

Starting Emergency Studies

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

You can create a temporary ID when starting a protocol, printing, capturing an image, or saving a volume.

1. Press **Patient Data**, **Capture**, **Protocol**, or **Print,** and then click **Temporary ID**.
2. When the exam is finished, do either of the following:
   - To replace the temporary ID with patient data, press **Patient Data**, click **Edit**, and edit the emergency patient data (either manually or by selecting

a Modality Worklist entry from the **Worklist** tab in the **Patient Data** form), and then click **End Exam**.

- To end the exam and use the temporary ID, press **End Exam** and click **End Exam** in the **Temporary Patient Study** dialog box.
- To end the exam without using a temporary ID, press **End Exam** and click **Cancel** in the **Temporary Patient Study** dialog box.

WARNING

If you use a temporary ID that you will replace with patient information, avoid using Send on Demand and avoid sending images or clips after each print or capture. Otherwise, one of the following occurs, which may result in the need to destroy incorrectly labeled data: If the **Send Images/Clips After Each Print/Capture** setting is selected, the system resends all images to archive servers and configured printers after updating the patient information; or if you use Send on Demand, the system marks all images as unsent, adds the new patient information, and will send them again, either at the end of the exam or when you use Send on Demand again. If data with incorrect patient information has been sent to a printer or server, destroy or remove that data.

Imaging Display

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

The image area is located approximately in the center of the imaging display. To the right of the image itself are a depth scale and a curve representing the TGC settings. To the right of the TGC curve is a list of values for the slide controls. A grayscale bar or color bar is displayed to the right of the TGC curve. In M-mode and Doppler, the sweeping display appears either below the 2D image or to the right of it, depending on the format you select.

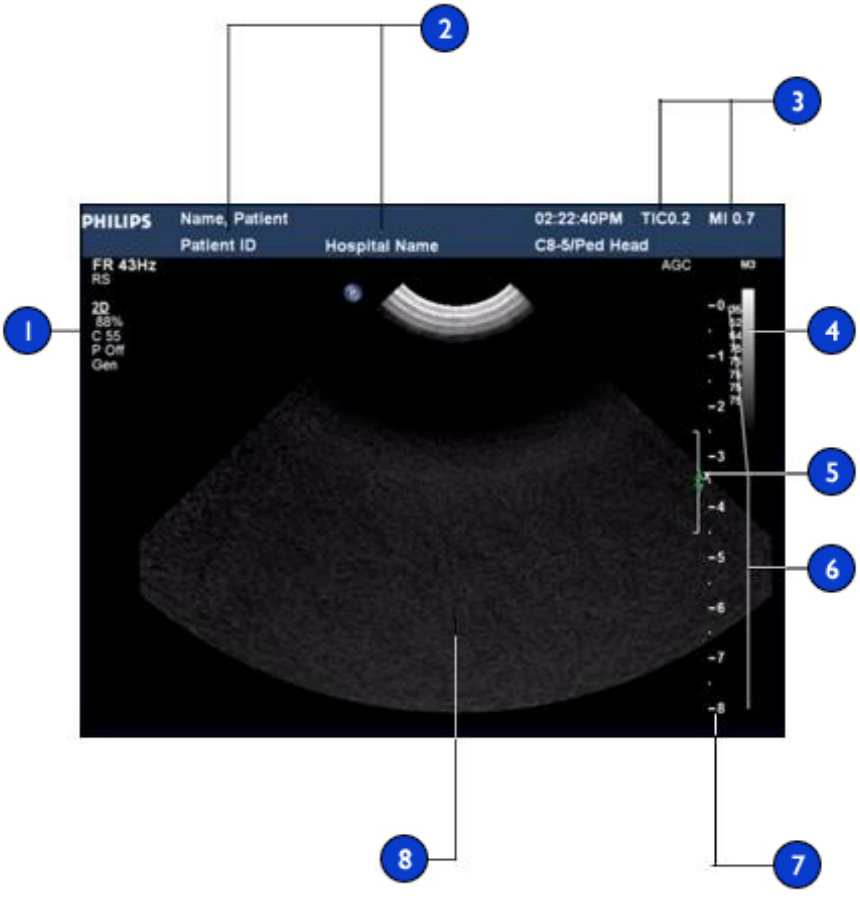
Patient and exam data are displayed in the area directly above the ultrasound image. The system does not display patient data in this area until you start an exam. This area also includes the current time and date, the institution name,

the selected transducer and clinical option, the thermal index (TI) setting and the TI and MI (mechanical index) values.

Image information is displayed to the left of the image. In modes such as Duplex or Triplex, additional image information is also displayed. Those additional parameter sets can be displayed below the initial set and to the right of the image.

Use the **Image Info** control to turn on or off the display of image information for the active imaging mode.

Imaging Display



1	2D image parameters
2	Patient and exam data
3	TI and MI values

4	Grayscale or color bar
5	Focal indicator
6	TGC curve
7	Depth
8	Image area

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 **System Settings**.
3. Click the **Display** tab.
4. Under **Auto Freeze**, select **On**, and then select the **Wait** time.
5. Click **Done**.

Transducer Receptacles and Cable Management

The system includes three receptacles for array transducers and one receptacle for a pulsed- or continuous-wave Doppler probe. All four receptacles can be occupied at the same time, but only one transducer can be active at a time. When a transducer is not in use, store it in one of the transducer holders on the control module.

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

Transducer Receptacles, Holders, and Cable Management

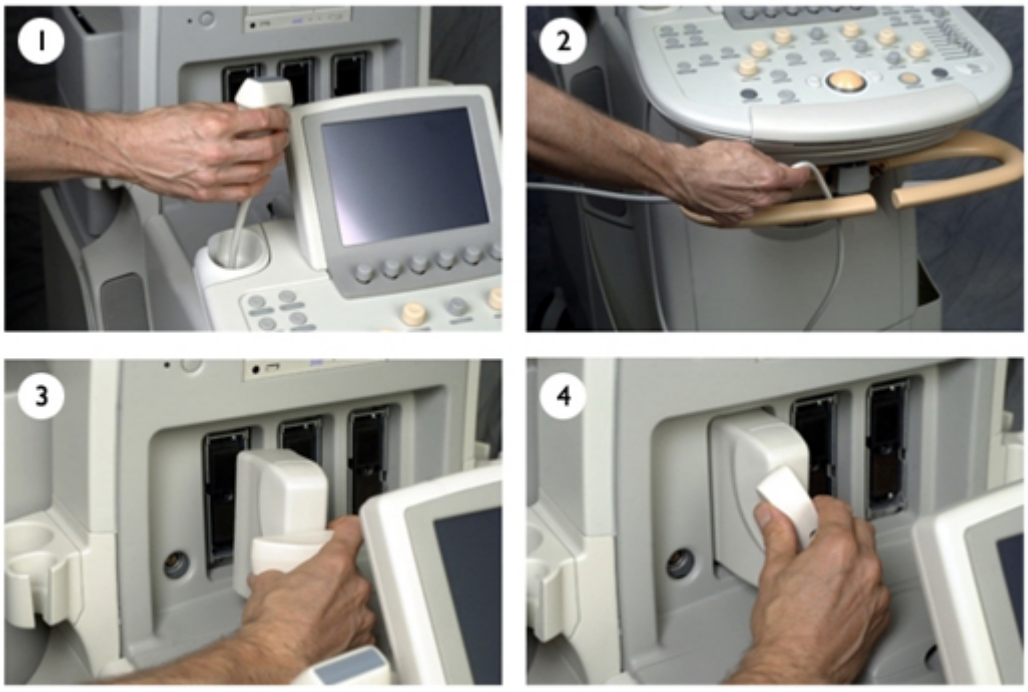
1	Transducer holders
2	Array-transducer and pencil-probe receptacles
3	Cable hangers

Connecting Transducers

The system includes three receptacles for array transducers and one receptacle for a pulsed- or continuous-wave Doppler probe.

1. Turn the locking lever counter-clockwise.
2. Set the transducer in one of the transducer holders on either side of the control module.
3. Hang the transducer cable on the cable management bracket below the control module.
4. Insert the transducer connector into one of the three receptacles on the front of the system.
5. Turn the locking lever clockwise.

Connecting a Transducer



Selecting a Transducer

When the system is turned on, the system defaults to the transducer connected to the left-most connector. You can select among the three connected transducers during system operation.

1. Press **Transducer**.
2. On the **Transducer** touch screen, touch a transducer button to select a transducer.
3. Touch the clinical option preset you want to use. The touch screen closes when you make your selection.

After you select the clinical option/preset, the system calibrates the transducer, enables the transducer for operation, and updates system status to reflect the transducer type and the preset you selected.

ECG Feature

The system can display a trace on the image representing an ECG signal. ECG input can be either a low-level signal (from leads connected to the patient) or a high-level signal (from a patient monitor). Separate receptacles are used to connect low-level ECG and high-level ECG signals to the system. Heart rate, derived from the ECG signal, is displayed on the screen whenever ECG is connected and displayed.

DVD, CD, and USB Devices

Removable media compatible with the system include DVD, CD, and USB storage devices.

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.

Media Compatibility

CD media capacity is approximately 700 MB; DVD media capacity is approximately 4.7 GB. Rewritable media types (indicated by the RW suffix) can be erased and used again.

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 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 169.

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 iU22 and iE33 ultrasound systems and writing studies from each system to the disc. To record multiple studies to a disc, you must end the exam you just recorded before removing the disc.

DICOM studies may only be written to new, blank, DVDs. Regardless of the type of DVD media used to store a DICOM study, once a DICOM study is written to a DVD, the DVD is flagged as read-only. Multiple studies can be written to a disc, up to the limit of its capacity and studies may be recorded across multiple DVDs using the Backup to Media feature. To record multiple studies to a disc, you must end the exam you just recorded before removing the disc.

Images and data stored as generic files may be written to DVD+RW discs multiple times and these discs may be reused.

DVD Drive

The system includes a digital versatile disc (DVD) drive, located next to the On/Off switch. You can use this drive to store and transfer patient files, including full exams, 3D data sets, and reports. In addition, you can save, restore, and distribute setups data, including Quick Save presets and voice profiles.

You do not need to format a disc before storing data on it.

NOTE

To provide improved storage capabilities, the current system software writes data to CDs and DVDs in a different format. As a result, CDs and DVDs that were used on an iU22 system with any previous version of system software can be read on your system but cannot be used to store data.

Loading and Ejecting a Disc

Do one of the following:

- To open the drive tray, press the Eject button on the drive.
- To load a disc, gently guide a disc into the drive slot until the disc is pulled into the drive.
- To close the drive tray, press the Eject button on the drive or gently push the tray in until it closes.

Erasing a DVD

Erasing a rewriteable disc (DVD+RW, DVD-RW, or CD-RW) erases all of the data on it and prepares it for reuse. After a disc is erased, the entire capacity of the disc is once again available. You can also erase a write-once disc (DVD+R, DVD-R, or CD-R) , but you will not be able to write files to the erased portion of the disc.

1. Display the Patient Directory by pressing **Review**, and if necessary, clicking **Patient Directory** in the **Review** display.
2. Load a disc into the drive.
3. In the Patient Directory, click **Erase**.
4. In the Erase Disc dialog box, click **OK** to erase the disc.
5. When the dialog box indicates that erasing is complete, click **OK**.

NOTE

If you receive an error message when exporting data to a DVD or when viewing exam data on a DVD, you may need to eject the DVD from the drive and re-insert it.

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. 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

There are a total of eight USB ports on the system and four are available for data storage; two are on the back of the drive bay at the rear of the system and two are behind the rear panel (ports 3 and 4). Although there are six USB ports behind the rear panel, four are dedicated to peripheral use. You can connect up to four USB storage devices at one time but you cannot export to or import from multiple devices or types of devices simultaneously. You must select the device and then perform the action. USB devices, when inserted into a USB port, are automatically assigned a drive letter.

Many portable USB hard drives require additional power and therefore include two USB connectors on the cable. When connecting USB hard drives to the system, Philips recommends that you connect both USB connectors to the USB ports on the back of the system.

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 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. USB storage devices are easily lost or damaged.
- 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. Having this application on the memory device should not interfere with the system. When these devices are plugged into a personal computer, they may launch utilities that could be confusing. The best way to avoid interference with these utilities is to format the USB device on your computer before plugging it into the system.
- 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.

NOTES

- Do not use USB hubs.
- Do not use USB storage devices that require additional power from an external source.
- Some offline viewers may not be able to load or view large images exported from the system to removable media.

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 settings, such as gain value, color map, filter, and items on the **Annotation** and **Measurement** touch screens.

When you turn on your system, the default preset is active. Before you begin an exam, be sure that the appropriate preset is active.

You can choose from several default presets. You cannot delete these default presets. However, they provide a starting point from which you can create your own presets. You can create and store up to 45 presets per transducer/application combination, depending on the number of buttons available on the **Transducer** touch screen. If you need to create more than 45 presets per transducer, you can save presets to a DVD or USB storage device and restore them when you need to use them.

In addition to the presets provided with the clinical options, the system lets you create and use custom presets.

NOTE

Presets are available only if you purchased the corresponding application-package option.

Clinical Options and Tissue Specific Presets

Clinical options are broad areas of medical study. Within each clinical option, there are Philips Tissue Specific presets for specific areas of study. For example, within the Small Parts clinical option, the Tissue Specific presets are Thyroid, Testicle, Breast, and Superficial. The **Transducer** touch screen lists the available clinical option/Tissue Specific preset combinations for the selected transducer.

You specify how the system will be set up for operation by selecting a clinical option/Tissue Specific preset. The more specific you are about your intended use of the system, the more you can benefit from Tissue Specific Imaging.

Quick Save Presets

Quick Save presets provide a quick way to set imaging parameters to the values you prefer for a specific exam type. Using the Quick Save feature, you can define presets for any combination of clinical option, preset, and transducer. A Quick Save preset stores the primary imaging mode and settings that are active when you create the Quick Save preset.

Once you create a Quick Save preset, it appears on the **Transducer** touch screen when the associated transducer is selected. When you select the Quick Save preset, the system automatically invokes the settings in the preset. You can delete existing Quick Save presets, copy them onto a DVD or USB storage device, and load them into another iU22 system.

The number of Quick Save presets you can store for a transducer/application combination is limited only by the number of buttons available on the corresponding **Transducer** touch screen. The number of buttons available, in turn, is dependent on which application is selected and how many Tissue Specific presets that application includes.

Creating Quick Save Presets

You can create a new Quick Save preset that is based on an existing preset. You can do this even during an exam, while using the preset.

1. Press **Transducer**.
2. On the touch screen, select the transducer and the preset on which you want to base your Quick Save preset.
3. Adjust the system controls to create the settings for your preset. (You can select an imaging mode, an image orientation, the number of focal zones, and so on.)
4. Press the **Quick Save** key.
   - For **Quick Save Label**, type the name of the new preset. (If you do not enter a name before saving a preset, the system will assign a name.)
   - For **Calculation Package**, select the desired calculations package.
   - For **Annotation/Body Marks**, select the annotations and body mark you want as the default.
5. Click **OK**.

Deleting Quick Save Presets

You can delete any Quick Save preset on the system except the active preset.

1. If a preset you want to copy is active, deactivate it by pressing **Transducer**, and then selecting the associated transducer and a different preset.
2. Press the **Setup** key.
3. In the setups, click **Service**, and then click **Test & Utilities**.
4. Click **Disk Maintenance**.
5. To delete specific presets, do the following:
   a. Select the presets you want to delete and click **Delete Presets**.
   b. Click **Yes** on the **Delete Presets** dialog box.
   c. Click **Close**.
   d. Click **Done**.
6. To delete all presets, do the following:
   a. Click **All Presets**, and click **Delete Presets**.
   b. Click **Yes** on the **Delete Presets** dialog box.
   c. Click **Close**.

d. Click **Done**.

Copying Quick Save Presets to Removable Media

You can copy Quick Save presets to a DVD or a USB storage device. This function is useful for archiving presets and for sharing presets among other iU22 systems.

NOTES

- When you load setups into the system from removable media, the contents of the source storage media are displayed; however, you cannot select specific items to load. When you load setups from removable media, all setups on that storage media are loaded onto the system. To load specific setups, copy only the required setups to removable media and then load them to the new location.
- If you receive an error message when exporting data to a DVD or when viewing exam data on a DVD, you may need to eject the DVD from the drive and re-insert it.

1. If a preset you want to copy is active, deactivate it by pressing **Transducer**, and then selecting the associated transducer and a different preset.
2. Press the **Setup** key.
3. In the setups, click **Service**, and then click **System Management**.
4. Click **Backup/Restore**.
5. Select presets to copy by doing one of the following:
   - To select all presets, click **Presets**.
   - To select specific Quick Save presets, expand the **Presets** list, and then select the presets you want to copy.
6. From the **Select the Media** menu, select the media type that you want to use.
7. Click **Backup**.

Loading Quick Save Presets from Removable Media

When you load setups into the system from removable media, the contents of the source storage media are displayed; however, you cannot select specific items to load. When you load setups from removable media, all setups on that storage media are loaded onto the system. To load specific setups, copy only the required setups to removable media and then load them to the new location.

1. Press the **Setup** key.
2. In the setups, click **Service**, and then click **System Management**.
3. Click **Backup/Restore**.
4. Insert the removable media containing the settings into the drive.
5. From the **Select the Media** menu, select the media type from which you are loading settings.
6. Click **Restore**.

System Setups

Setups are system parameters that you can change. By changing setups, you can customize the system to meet your operating preferences. Setups are organized into seven standard categories: **System Settings**, **Analysis Config** (configuration), **Annotate**, **Print/Network**, **Audio/Video**, **Protocols**, and **Service**. Additionally, two other categories appear only if the corresponding options are installed on the system. These optional categories are **Voice Control** and **Data Security**. **About** is not actually a setup category; it is used to display information about the system software. Changes in setups take effect immediately and remain in effect until you change them again or load setups from a DVD.

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 setup category on the left side of the setups display.
3. Click a sub-category tab at the top of the setups display.
4. Enter text or make selections necessary to set up your system.
5. Click **Done**.

Hiding the Doppler Velocity Minus Sign

You can choose to include only the numeric value of the Doppler velocity measurements. Doppler velocity is marked as negative (-) when the flow is moving away from the transducer. When reporting on the measurements, you may want only the value, not the direction of flow. When hidden, the negative sign does not appear on the displayed or printed patient reports; however, the sign is still part of the number and is visible when editing a patient report and is included in DICOM structured reports exported from the system.

The option to hide the doppler velocity minus sign is available in all calculation packages except **Adult Echo**.

NOTE

When **Hide Doppler Velocity Minus Sign** is enabled, avoid using the Doppler velocity value displayed in the results and report for manual calculations. The sign value, whether visible or not, affects any calculations performed with the reported value. The system includes the sign value in calculations.

To specify the display of the doppler velocity minus sign:

a. Press the **Setup** key.
b. Select **Analysis Config**.
c. Select calculations package tab you want to change, and then select **Tools & Results**.

d. Under **Hide Doppler Velocity Minus Sign**, select **On** or **Off**.

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, QLAB Advanced Quantification Software plug-ins, connectivity capabilities, and image-guided intervention.

For a list of options available for your system, see "System Options" on page 87.

Installing Temporary Options

The system lets you temporarily install up to five 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 activation key for each option you want to install. The installation process requires restarting the system, so be sure that the last exam has been closed before installing options.

1. Contact your Philips representative to obtain an activation key for each licensed option you want to evaluate.
2. Once you have received the activation keys, press **End Exam** to ensure that the last exam has been closed.
3. Press the **Setup** key.
4. Click **Service**.
5. Click **Options**.
6. Click **Temporary Options**.
7. For **Key**, type an activation key. Type each remaining key, one per line.
8. Click **Submit**.
9. Review the options installed, and then click **OK**.
10. Click **Done**.
11. In the **System Restart** dialog box, click **OK** to restart the system.

Purchasing Options

To add licensed options to your system, you purchase them from your Philips representative. Once purchased, they are installed in your system by a Philips field service engineer.

7 *Performing an Exam*

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

New Patient Exams

You start an exam by entering patient data into the system. There are three ways to enter patient data.

- If the worklist feature is not enabled or used on your system, you enter patient data into the **Patient Data** form.
- If your system is connected to a DICOM network with the modality worklist feature enabled, you can select an exam to load patient data instead of entering that information manually. See "Selecting in the Worklist" on page 181.
- If you want to start an exam without first entering patient data, you can use the Temporary ID feature.

The system uses a unique ID to identify each patient. You can enter an ID, or you can have the system create one automatically. Stored images, fetal growth graphs, and reports are stored based on the patient ID.

An accession number is an optional entry assigned to each patient file by an institution for internal information-management purposes.

The exam date is set by the system when you first acquire an image during the exam.

A study description is a definition providing the characteristics or representation of the study. If the worklist feature is enabled and contains a study description, when the Patient Data is downloaded, the Study Description is included in the information sent to the ultrasound system. If a worklist is not used, you can

manually enter a study description and it will be included in any patient data export.

Entering Patient Data

If you are not using the worklist option, you start an exam by entering patient data into the system.

NOTE

You can clear all patient data from the **Patient Data** form by clicking **Clear Patient Data**. Do not use this control unless you want to delete all of the patient data you have entered into the form.

1. Ensure that the previous exam ended by pressing **End Exam** or by clicking **End Exam** on the **Patient Data** form.
2. Press **Patient Data** on the control panel or press the **Patient Data** key.
3. On the **Patient Data** form, enter at least the patient name and ID. (Press the **Tab** key to move the cursor from field to field.)
4. Click the **Study Info** tab.
5. For **Study Type**, select the study you will be performing. It is important to select the correct study type at this time. Selecting a study type after you have entered patient data and exited the **Patient Data** form does not update the report with the correct study type.
6. Enter the pertinent study information for the patient.
7. When you are finished, click **Close**.

Starting Emergency Studies

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

You can create a temporary ID when starting a protocol, printing, capturing an image, or saving a volume.

1. Press **Patient Data**, **Capture**, **Protocol**, or **Print,** and then click **Temporary ID**.
2. When the exam is finished, do either of the following:
   - To replace the temporary ID with patient data, press **Patient Data**, click **Edit**, and edit the emergency patient data (either manually or by selecting a Modality Worklist entry from the **Worklist** tab in the **Patient Data** form), and then click **End Exam**.
   - To end the exam and use the temporary ID, press **End Exam** and click **End Exam** in the **Temporary Patient Study** dialog box.
   - To end the exam without using a temporary ID, press **End Exam** and click **Cancel** in the **Temporary Patient Study** dialog box.

WARNING

If you use a temporary ID that you will replace with patient information, avoid using Send on Demand and avoid sending images or clips after each print or capture. Otherwise, one of the following occurs, which may result in the need to destroy incorrectly labeled data: If the **Send Images/Clips After Each Print/Capture** setting is selected, the system resends all images to archive servers and configured printers after updating the patient information; or if you use Send on Demand, the system marks all images as unsent, adds the new patient information, and will send them again, either at the end of the exam or when you use Send on Demand again. If data with incorrect patient information has been sent to a printer or server, destroy or remove that data.

Selecting in the Worklist

1. Press **Patient Data**.
2. On the **Patient Data** form, click the **Worklist** tab.
3. On the worklist, select the exam you want, and click **Close**. The system loads the patient information, and you are ready to begin an exam for that patient.

Searching in the Worklist

If necessary, you can search for a specific exam by using **Patient Search** on the **Patient Data** form.

1. Press **Patient Data**, then click the **Worklist** tab.
2. If the downloaded patient information in the worklist is not current, click **Update Worklist** to download the patient information from the server.
3. To search for a patient by exam date, click **Patient Search**.
4. To further specify the date criteria, do one of the following:
   - Select the **Exam Date**.
   - Select **Today**; select **±** (plus or minus), **+**, or **–**; and then select the number of days. Select **1**, **2**, **3**, **5**, or **7 Days**.
5. Click **Search**.
6. Select the patient from the worklist.
7. Click **Close**.

Selecting a Transducer

When the system is turned on, the system defaults to the transducer connected to the left-most connector. You can select among the three connected transducers during system operation.

1. Press **Transducer**.
2. On the **Transducer** touch screen, touch a transducer button to select a transducer.
3. Touch the clinical option preset you want to use. The touch screen closes when you make your selection.

   After you select the clinical option/preset, the system calibrates the transducer, enables the transducer for operation, and updates system status to reflect the transducer type and the preset you selected.

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 imaging and Panoramic imaging.

Using 2D Mode

NOTE

With sector transducers, such as the S4-1, the top of the image does not correspond to the skin line.

1. Press **2D** to start 2D imaging, if necessary. The system turns on in 2D mode, unless a CW Doppler probe is the only transducer connected.
2. Use the following controls to optimize the image:
   - To automatically optimize the TGC, dynamic range, and gain settings for the current image, press **iSCAN**.
   - To adjust 2D gain, turn the**2D** knob.
   - 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, press**Focus** and adjust the focal range and position.
   - To compensate for signal attenuation, use the **TGC** control to increase or decrease the amplification of the signal to adjust the brightness of the image at different depths.
3. Use additional controls on the touch screen, as needed.
4. To enter other imaging modes, press the button for an imaging mode.
5. 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.

Adding Labels Using Annotate

1. Press **Annotate**.
2. Use the trackball to position the text cursor on the display, or touch **Home** to return it to the home location.
3. Do any of the following:
   - To add text, type the text that you want to appear on the display.
   - To display predefined labels, touch a label control to display its text.
   - To display an arrow, touch the Arrow control  , position the arrow with the trackball, and then click to fix the position.
   - To erase the last word typed, touch **Erase Last Word** to erase words one at a time.
   - To erase all text, press the **Erase Text** key or touch **Erase All Text**.
   - To erase all arrows, touch **Erase Arrow**.
   - To move the text cursor to the home position, touch **Home**.
   - To set a new home position, position the cursor and touch **Set Home**.
   - To exit annotation mode, touch **Close** or press **Annotate** again.
   - To use text replace, see Changing Labels Using Text Replace

Adding Labels Using the Keyboard

You can add labels using only the keyboard. You can manually format the annotation labels you add using the keyboard. Use spaces before and after the words you type to center the text or improve the word wrap format.

1. Press the **Text Cursor** key.

2. Use the trackball to position the text cursor on the display.
3. Type the text that you want to add. You can use spaces before and after the words to center the text or improve the text flow.
4. To erase text, press the **Backspace** key.
5. When finished, press Select or press the **Text Cursor** key again to remove the text cursor.
6. To remove all text, press the **Erase Text** key. You can also press **Annotate** and then touch **Erase Last Word** or **Erase All Text**.

Adding an Image Title

You can add a title to the image display.

1. Press the **Title Cursor** key.
2. Type the text that you want to add for the title.
3. To erase text, press the **Backspace** key.
4. When finished, press Select or press the **Title Cursor** key again.

Displaying Body Markers

NOTE

During Review, the **Body Markers** touch screen is available only when **1:1** is selected for **Layout**. You cannot add body markers to images in Review, although you can add them to clips in Review.

1. Press **Body Mark** to display the **Body Markers** touch screen for the current transducer and preset.
2. Touch a button to put the corresponding body marker on the display in the home location or to replace an existing body marker.
3. Use the trackball to position the transducer scan plane indicator on the body marker. Turn **Body Mark** to change the orientation of the transducer scan plane indicator.
4. Do any of the following:

- To move the marker, touch **Move Body Mark**, position the body marker using the trackball, and touch **Move Body Mark** again.
- To remove a body marker, touch **Erase Body Mark**.
- To close the **Body Markers** touch screen, touch **Close** or press **Body Mark** again.

Recording

You can record live imaging to a local VCR and simultaneously record comments. The installed VCR records and plays back standard S-VHS videocassettes. You can play back recordings on the system or on other VCRs. In addition, an optional DVD recorder can be used to record live imaging and play back the recording on the system.

NOTE

The microphone must be turned on (in the **Audio/Video** setups) before you can record comments.

Using the VCR

NOTE

Stop the VCR before suspending the system or turning the system off.

1. To record or play a recording, press **VCR** on the system control panel and use any of the following controls on either the **Video** touch screen or the VCR:

   - **Play**  to play back the video at normal speed
   - **Stop**  to stop the playback
   - **Record**  to start recording
   - **Pause**  to temporarily halt the recording or playback

- **Rewind**  to rewind the videotape
- **Fast Forward**  to advance the videotape
- **Eject** to stop the current recording or playback mode and eject the videocassette

2. To search for a location on the tape, touch **Search/Set Counter**, type a number in the format shown in the **Search/Set Counter** dialog box, and click **Search Media**.
3. To remove the counter from the display, touch **Hide Counter**. To display the counter, touch **Hide Counter** again.
4. To turn on or off the microphone, press the **Mic** key. The microphone is on when  appears in the icon list on the bottom of the display.

Using the DVD Recorder

1. To turn on the DVD recorder, ensure that **MAIN POWER** (on the rear panel) is set to **|**, and then press  on the front panel.
2. To insert a disc, press **OPEN/CLOSE** (on the recorder front panel), place a disc in the tray, and press **OPEN/CLOSE** again.
3. To record or play a recording, press **VCR** on the system control panel and use any of the following controls on either the **Video** touch screen or the DVD recorder:

- **Play**  to play back the video at normal speed
- **Stop**  to stop the playback
- **Record**  to start recording
- **Pause**  to temporarily halt the recording or playback
- **Rewind**  to rewind the recording
- **Fast Forward**  to advance the recording

- **Eject** to stop the current recording mode and eject the media

4. To search for a location on the tape, touch **Search/Set Counter**, type a number in the format shown in the **Search/Set Counter** dialog box, and click **Search Media**.
5. To remove the counter from the display, touch **Hide Counter**. To display the counter, touch **Hide Counter** again.
6. To turn on or off the microphone, press the **Mic** key. The microphone is on when  appears in the icon list on the bottom of the display.

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.

Three print controls are available for printing images, **Print**, **Alt Print**, and **Print Screen**. In the setups, you can assign **Print** and **Alt Print** to one or more printers. In addition, you can select whether these two print controls print the entire screen or just the image area. Report printing is also assigned to one or more printers.

NOTE

If you print a monochrome image while a Chroma map is selected, the system sends the image to the color printer. Also, if you export a monochrome image while a Chroma map is selected, the system sends the image as a color image. This is normal. To ensure that black-and-white images are sent to the black-and-white printer, set **Chroma** to **Off**.

Printing Images

1. Acquire the desired image.
2. Do one of the following:
   - Press **Print** on the system control panel.

- Press the print control on a video printer that is connected to the system.
- Touch **Print Screen** or **Alt Print** on the touch screen.

Review

During or after an exam, you can use Review to examine and compare images acquired in the exam. You can also review multiple exams for one patient.

In Review, you can look at the images or cineloop sequences that you stored. You can view, send, print, and back up your stored images. You can also perform analysis on images in Review. Images that are in image memory can be stored on the ultrasound system hard drive, on removable media, or on DICOM-compatible devices on a network. You can display images within an exam in several layouts, and you can display images from different exams.

Starting Review

1. Press **Review** to enter Review mode. You can also double-click a thumbnail image to open that image in Review.

   The display that appears depends on whether an exam is active on the system.

NOTES

- If an exam is in progress, pressing **Review** opens the **Review Exam** display.
- If no exam is in progress, pressing **Review** opens the Patient Directory display.

2. To return to live imaging, press **Review** again.

Navigating Thumbnails and Images

In **Review**, you can view small images, called *thumbnails*. Thumbnails are located on the right side of the **Review Exam** display.

NOTE

When reviewing images of an exam loaded from the Patient Directory, thumbnails will not be available in some circumstances. For example, exams copied from DVD to the hard drive may not have thumbnails if the images they contain are no longer in their native format.

1. For **Layout**, select the layout you want to use to display images.
2. Do any of the following:

   - Click  or  to move up or down through available thumbnails one or two images at a time.
   - Click  or  to move up or down through available thumbnails one page at a time.
   - Click  or  , or turn **Page**, to move backward or forward through the available images, one page at a time.
   - Touch **First Page** or **Last Page** to jump directly to the first or last page of images.
   - Click a thumbnail to jump to the page that contains the corresponding image.
   - To view a thumbnail full screen, double-click it. (If the image represents a 3D data set, it opens in 3D review mode.) To return to the review screen, double-click the full screen image or set **Layout** to **4:1**.

Capturing Images and Loops

You can capture and save a single frame or a Cineloop sequence. The captured 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. Images are automatically exported across the network either when you capture or print an image, or when you end an exam, depending on your selection for **Send Images/Clips** on the **Printer/Capture** tab in the **Print/Network** setups.

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).

During acquisition, a spinning hourglass icon displays at the bottom of the display. When the capture is complete, a thumbnail of the image is displayed.

To capture a single image:

- Press **Freeze** and then press **Print**.

To capture a Cineloop sequence:

- Press **Capture** in live imaging or while reviewing a Cineloop sequence. Capturing during live imaging saves prospective or retrospective frames, as specified in **Live Capture Type** in the setups. A prospective capture captures a specified acquired loop length. A retrospective capture captures a specified loop length that was acquired previously. A retrospective capture captures a loop that ends when **Acquire** is pressed. Capturing while reviewing a Cineloop sequence saves all retrospective frames in the Cineloop sequence.

NOTES

- When an image is captured, you will hear a beep to confirm that the loop or image was saved in the patient's study. Do not press **Review** until you hear the beep.
- If you press **Capture** in a non-simultaneous mode while a live M-mode or Doppler trace is active, you capture a Cineloop sequence. If you press **Capture** in a simultaneous mode, you capture a single image.
- If you attempt to capture a loop that was imported from media, only a frame of the loop is captured and displayed in the appending exam.

Measurement and Analysis

The measurement tools appear on the **Caliper** touch screen. Touching an active tool from the **Caliper** touch screen launches the tool. (The labels of inactive tools are gray.)

The **Calc** system control provides access to the collections, groups, measurements, and calculations that make up a calculations package. Calculations packages are system options that are associated with transducers and presets.

A calculations package contains one or more collections that organize groups, measurements, and calculations into a coherent tool for diagnostic analysis.

Measurement tools provide measurements and derived calculations. Various methods are available for generating results. The two primary methods allow you to "measure then label" or "label then measure." Either way, the results can appear on the display, on printed pages, and in patient reports, where they are available for your analysis.

In the setups is an analysis configuration capability that allows you to create your own calc lists including collections, groups, measurements, and calculations. In addition, the measurements and calculations can be associated with system and custom tables and equations.

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

NOTE

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

Measuring 2D Distance

1. Obtain the image that you want to measure and press **Freeze**.
2. Press **Caliper**.
3. Use the trackball to position the first caliper in the 2D image.
4. Press Select to anchor the first caliper and display the second caliper.
5. Use the trackball to position the second caliper. The Results box displays the results.
6. Touch **End Measure**, or press Select or **Enter** to complete the measurement.

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 elsewhere in the Help.

1. Obtain the image you want to measure and press **Freeze**.
2. Press **Calc**.
3. Click a collection label to display group and measurement labels.
4. Click a group label if a set of associated measurements are required. A group label opens to display multiple measurement labels.
5. Click a measurement label and make the measurement. First, the caliper or trace tool appears on the display. Then, as you make the measurement, the results and derived calculations appear in the Results box and are simultaneously added to the patient report.
6. For each measurement label within a group, click a label and make the measurement.
7. Touch **End Measure**.

NOTE

The measurement automatically completes if you unfreeze the image, change modes, or enter a report.

Obtaining a Calculation Result

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 regarding on using calculations, refer to Help on your system.

The calculations in the system are based on medical references, which are listed in the Help.

1. Press **Calc** to display the calcs list.

2. Click the **Calcs** icon 

, select a calc package from the menu, and click OK.
3. Click a tab at the top of the display to select a measurement list.
4. Obtain an image and press Freeze.
5. Press **Pointer**, click a measurement label, and make the measurement according to the prompts displayed at the bottom of the screen.
6. Press **End Measure**, if necessary, to complete the measurement. The measurement result appears below the measurement label.

Ending an Exam

Each time you finish an exam, you must end the exam to save images, reports, and other exam data. You can end an exam in the current exam display or with the current exam open in the Review display. You cannot end an exam while in the Patient Directory.

You will not be able to end the exam until the system has saved exam data for the current exam. (The system saves exam data when you capture an image.) Ending an exam stores all exam data, clears the **Patient Data** form, and prepares for the next exam.

WARNING

Failing to end the current exam before starting a new exam can result in data being acquired and stored under the wrong patient name.

When the exam is complete, do one of the following:

- Press **End Exam**.
- Click **End Exam** in the **Patient Data** display.

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.

The system limits patient contact temperature to 41 degrees Celsius for all transducers, and limits acoustic output values to their respective U.S. Food and Drug Administration limits for all transducers. 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

Use caution when scanning neonatal, pediatric, and medicated patients by minimizing the time spent imaging at temperatures above 41°C (106°F).

CAUTION

Mechanical transducers, such as the 3D6-2, should be operated only at normal operating temperatures (50°F to 104°F or 0°C to 40°C). Operating a mechanical transducer at lower temperatures can damage it.

NOTES

- Using excessive pressure when scanning with a motorized transducer can cause the acoustic lens to deform and impede the moving array, resulting in an error message. When pressure is reduced, the system recalibrates the transducer, and imaging resumes. Avoid excessive pressure when using a motorized transducer.
- If the L17-5 transducer is selected before using the C9-4 transducer, reducing the sector angle with SonoCT imaging on and then steering to the right results in corrupted display data and gain mismatch on the right side of the image.

Selecting a Transducer

When the system is turned on, the system defaults to the transducer connected to the left-most connector. You can select among the three connected transducers during system operation.

1. Press **Transducer**.
2. On the **Transducer** touch screen, touch a transducer button to select a transducer.
3. Touch the clinical option preset you want to use. The touch screen closes when you make your selection.

   After you select the clinical option/preset, the system calibrates the transducer, enables the transducer for operation, and updates system status to reflect the transducer type and the preset you selected.

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.

System Transducers and Supported Clinical Options

Transducer	Clinical Options
C5-1	Abdominal, Contrast, Fetal Echo, GYN, Intervention, OB, Pediatric, Urology, Nuchal Translucency, Vascular
C5-2	Abdominal, Contrast, Fetal Echo, GYN, Intervention, OB, Pediatric, Urology
C8-4v	Contrast, Fetal Echo, GYN, OB, Urology

Transducer	Clinical Options
C8-5	Abdominal, Pediatric, Vascular
C9-4	Abdominal, Fetal Echo, GYN, OB, Pediatric
C9-5ec	Fetal Echo, GYN, OB, Urology, Contrast
C10-3v	Contrast, Fetal Echo, GYN, OB, Urology
L8-4	Contrast, Musculoskeletal, Pediatric, Small Parts, Vascular
L9-3	Abdominal, Contrast, Musculoskeletal, Small Parts, Vascular
L12-5	Abdominal, Contrast, Musculoskeletal, OB, Pediatric, Small Parts, Vascular
L15-7io	Adult Cardiology, Small Parts, Vascular, Musculoskeletal Superficial
L17-5	Abdominal, Musculoskeletal, Pediatric, Small Parts, Vascular
S3-1	Adult Echo
S4-1	Abdominal, Contrast, Fetal Echo, GYN, Intervention, OB, Urology, Vascular
S5-1	Abdominal, Adult Echo, TCD, Urology, Vascular
S7-2omni	Adult Echo
T6H	Adult Echo
X3-1	Abdominal, Adult Echo, Contrast, Fetal Echo, Intervention, OB
X6-1	Abdominal, Contrast, Fetal Echo, Intervention, OB, GYN
X7-2	Pediatric
3D9-3v	Fetal Echo, GYN, OB, Urology

Transducer	Clinical Options
3D6-2/V6-2	Abdominal, Contrast, Fetal Echo, Intervention, OB, Urology
D2cwc	Adult Echo
D5cwc	Vascular
D2tcd	TCD
VL13-5	Small Parts Advanced Breast, Small Parts General, Small Parts Thyroid, Vascular Carotid

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	Supporting Transducers
Abdominal (includes Urology)	3D6-2, V6-2, 3D9-3v, C5-1, C5-2, C8-4v, C8-5, C9-4, C9-5ec, C10-3v, L8-4, L9-3, L12-5, L17-5, S4-1, S5-1, VL13-5, X3-1, X6-1, X7-2
Adult Head	D2cwc, D2tcd, S3-1, S5-1
Cardiac Adult	D2cwc, D5cwc, L15-7io, S3-1, S5-1, X3-1, X7-2

Indication for Use	Supporting Transducers
Cardiac Pediatric	D2cwc, D5cwc, S3-1, S5-1, X3-1, X7-2
Cerebral Vascular	3D9-3v, C8-5, D2tcd, L8-4, L9-3, L12-5, L15-7io, L17-5, VL13-5
Fetal (includes Echo)	3D6-2, V6-2, 3D9-3v, C5-1, C5-2, C8-4v, C8-5, C9-4, C9-5ec, C10-3v, L12-5, L17-5, S4-1, VL13-5, X3-1, X6-1, X7-2
Intraoperative (Abdominal, Cardiac, Spine, Vascular)	L15-7io, L17-5, X3-1
Intraoperative (Neurological)	C8-5
Musculoskeletal (Conventional)	L8-4, L9-3, L12-5, L15-7io, L17-5, VL13-5
Musculoskeletal (Superficial)	L8-4, L9-3, L12-5, L15-7io, L17-5, VL13-5
Neonatal Head	3D9-3v, C8-5, D2cwc, D2tcd, X7-2
Ophthalmic	L15-7io, L17-5, S5-1, VL13-5
Other: Fetal Echo	3D6-2, V6-2, 3D9-3v, S3-1, X6-1, X7-2
Other: Urology	C8-4v, C10-3v
Pediatric	C5-1, C5-2, C8-5, C9-4, L8-4, L9-3, L12-5, L17-5, VL13-5, X7-2

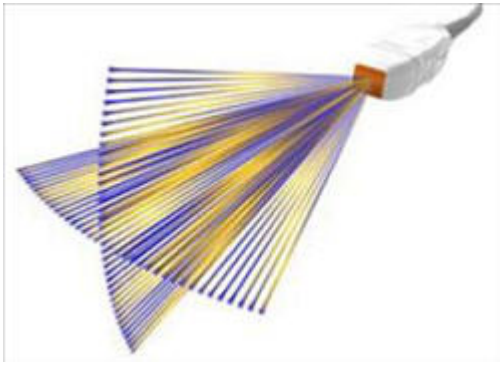
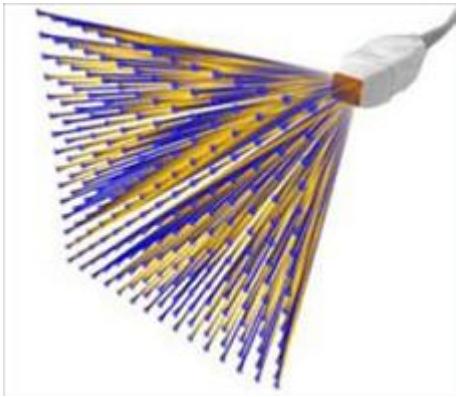
Indication for Use	Supporting Transducers
Peripheral Vessel	3D9-3v, C5-1, C5-2, C8-5, D2tcd, D5cwc, L8-4, L9-3, L12-5, L15-7io, L17-5, S4-1, VL13-5
Small Organ (Breast, Thyroid, Testicle)	L8-4, L9-3, L12-5, L15-7io, L17-5, VL13-5
Transesophageal (Cardiac)	S7-2omni
Transrectal	C9-5ec
Transvaginal	3D9-3v, C8-4v, C9-5ec, C10-3v

xMatrix Array Transducers

xMatrix array transducer technology provides volume acquisitions of the beating heart with remarkable image quality. You can use these transducers to acquire two planes simultaneously from the same heartbeat. The system's multi-directional beam steering lets you select unlimited planes in all directions, so you can get the precise view you want, with no degradation in image quality.

The following xMatrix array transducers are available with this system:

- X3-1
- X6-1
- X7-2

Use Live xPlane imaging to simultaneously create two full-resolution planes.	Use Live Volume imaging to acquire and render full volume data at true real-time frame rates.
	

X3-1 Description

Features of the X3-1 transducer include:

- Operating range: 1 to 3 MHz
- Biopsy capable
- 2D xMATRIX phased array with 2,400 elements
- 2D, Live xPlane, Live 3D, Color Doppler with 2D, xPlane and 3D, XRES image processing, Tissue Harmonic Imaging, LVO

X6-1 Description

Features of the X6-1 transducer include:

- Operating range: 1.5 to 5 MHz.
- Biopsy capable.
- 2D xMATRIX phased array with more than 9,000 elements.
- 2D imaging provides a 100-degree field of view, while volumetric imaging is 90 x 90 degrees.
- 2D imaging modes with Tissue Harmonic Imaging, M-mode, PW, Color, and CPA.
- 3D and 4D imaging modes with xPlane, Elevation Compounding, single-sweep 3D grayscale, Color, CPA, live 4D grayscale imaging, and iSTIC grayscale and color with automated heart rate estimation.

X7-2 Description

Features of the X7-2 transducer include:

- Operating range: 2 to 7 MHz
- 2D matrix array with 2,500 elements
- 2D, Live xPlane, Live 3D, color Doppler and PW Doppler with 2D, xPlane and 3D, XRES image processing, and Tissue Harmonic Imaging

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 the "Transducer Care" section of your system *User Manual*. You can also call Philips Ultrasound Customer Service at 800-722-9377 (North America), or call your local Philips Ultrasound representative (outside North America).

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 screen.

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 screen. 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, directional, and motion artifacts can present themselves in 3D imaging. Color and Color Power Angio gain artifacts are mainly related to the use of excessive gain resulting in random color patterns 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. Patient motion can produce flash artifacts that are less obvious in 3D images than in 2D imaging.

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 is 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 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 45.
- In neurosurgical applications, sterilized transducers should be used with sterile gel and a sterile pyrogen-free transducer cover.
- 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 286.
- 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.
- To avoid damaging the shaft or steering mechanism of TEE transducers, do not bend or coil the flexible shaft of the transducer in less than a 0.30-m (1-ft) diameter circle.

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 (see "Disinfecting System Surfaces" on page 314).
- 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.
- For TEE transducers, be sure the distal tip is straight and protected before storing the transducer.
- Never store a TEE transducer in the carrying case, except to transport it.

9 *Intraoperative Transducers*

An intraoperative transducer is used during surgery to help the surgeon locate and visualize anatomical structures, to visualize blood flow patterns and quantify velocities, and to image and measure anatomical and physiological parameters of interest to the surgeon.

The system supports the L15-7io transducer for use in intraoperative applications.

Operators of Intraoperative Transducers

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

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

Intended Uses for Intraoperative Transducers

Intraoperative studies are performed by surgeons, anesthesiologists, or sonographers to obtain images that can be used for the following purposes:

- Helping a surgeon locate and visualize anatomical structures before, during, or after a surgical procedure
- Helping a surgeon visualize blood flow patterns and quantify velocities before, during, or after a surgical procedure
- Imaging and measuring anatomic and physiologic parameters before, during, or after a surgical procedure

The L15-7io transducer can be used for adult cardiology applications.

WARNING

Intraoperative transducers used in animal studies should not be used on humans. Transducer disinfection procedures for cross-usage between animals and humans have not been validated.

Patient Safety During Intraoperative Studies

This section lists conditions that can adversely affect patients when you are using an intraoperative transducer.

To operate an intraoperative transducer, you must be under the guidance of a physician who is properly trained in intraoperative 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 intraoperative transducer, observe the following guidelines:

- Scrutinize the entire transducer before each use. (See the "Transducer Care" section.)
- Use mandatory protective equipment, including an approved sterile protective transducer cover, during intraoperative studies. For information about using transducer covers, see "Preparing Transducers for Intraoperative Use" on page 215.
- 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.

WARNINGS

- All intraoperative studies must be performed with a Type CF classified transducer. If your transducer is not labeled Type CF on the transducer connector, contact your Philips service representative.
- Be sure to use a market-approved sterile transducer cover and sterile ultrasound transmission gel when performing all intraoperative studies.
- Always remove the transducer from the patient before defibrillation.

Patient-Contact Parts

Latex is 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 content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See "FDA Medical Alert on Latex" on page 45.

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.

Preventing Intraoperative Transducer Problems

WARNING

If you find any signs of damage to the transducer, patient safety may be compromised. Do not use the transducer, and contact your Philips service representative.

Meticulous inspection and correct and careful operation of intraoperative transducers are imperative to patient safety. The situations listed here affect safe operation as well as the ability to service mechanical problems under the Philips warranty or service contract. Transducer repairs necessitated by misuse are not covered and can be very costly, often requiring complete disassembly and rebuilding of the transducer.

There are three primary areas of transducer misuse:

- Cuts and abrasions on the transducer insulation and lens from sharp instruments such as scalpels, scissors, and clamps
- Improper disinfection techniques, causing fluid to enter the transducer or damage transducer materials
- Damage caused by dropping the transducer on a hard surface

To minimize the chance of damage, Philips strongly recommends that you clearly post stringent protocols for the care of intraoperative transducers, based on the information provided here.

Intraoperative Transducer Description

L15-7io Transducer

L15-7io Transducer Features and Specifications

Features	• 15 to 7 MHz extended frequency range • Phased linear array with 128 elements • 8 degrees of trapezoidal imaging, 23 mm (0.9 in) effective aperture length • Explora connector • High-resolution intraoperative vascular applications • Steerable PW Doppler, Color Doppler, and Color Power Angio imaging, XRES processing, and Panoramic Imaging
Specifications	Lens footprint • Elevation: 10 mm (0.4 in) • Scan plane: 32 mm (1.25 in) Transducer length: 89 mm (3.5 in) Cable length: 2 m (80 in)

Preparing Transducers for Intraoperative 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.

Disposable Drapes

During studies in which you believe contamination of the ultraound system can occur, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

Accessories for Intraoperative Transducers

For information on ordering accessories, see "Supplies and Accessories" on page 23.

Electrical Safety and Intraoperative Transducers

All Philips ultrasound systems and transducers comply with common medical device electrical safety standards.

The L15-7io transducer is classified as a Type CF  isolated patient-applied part, as described in IEC 60601-1. There are no exposed conductive surfaces on the transducer head. To ensure safe operation of this transducer, read the cautions and warnings in the "Safety" section, especially those that address electrosurgical units, pacemakers, and defibrillators.

Leakage Current Testing for Intraoperative Transducers

Philips transducers approved for intraoperative use are labeled on the transducer connector as Type CF  in accordance with the IEC 60601-1. Type CF classification indicates that the degree of protection from electrical shock afforded by the transducer is suitable for all patient applications, including direct cardiac and intraoperative applications.

Leakage current tests should be performed by a technically qualified person any time that the transducer is dropped or if cracks or cuts are found on the transducer.

Normal leakage current testing frequency should be based on the procedures established by the hospital for operating-room-based equipment.

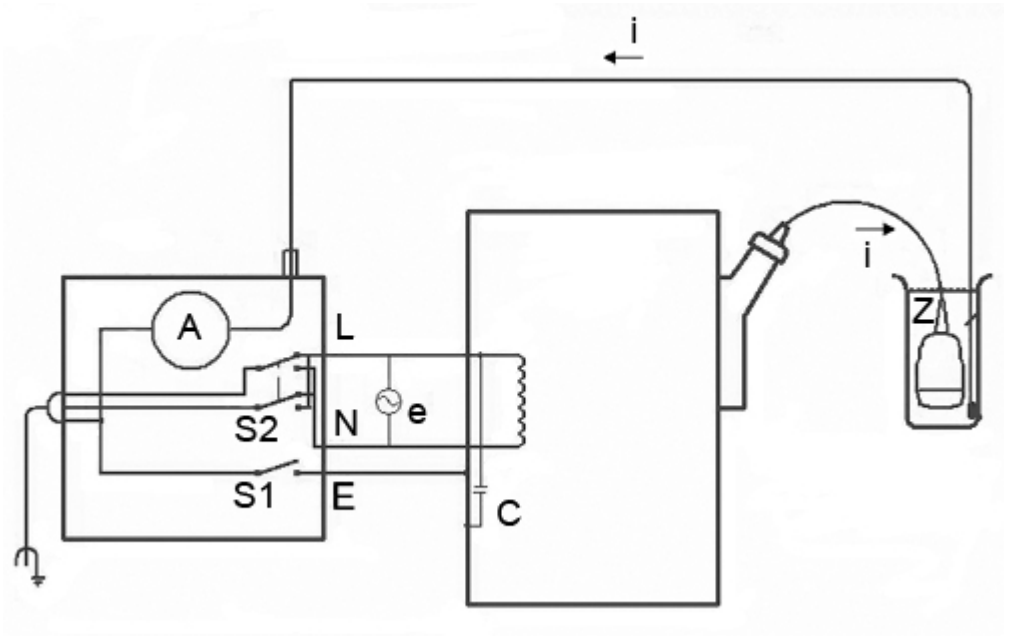
Regularly perform the electrical safety check to ensure that IEC 60601-1 Type CF leakage limits are not exceeded. You can perform this procedure with any commercially available safety analyzer that is designed for hospital use.

WARNING

Only a technically qualified person should perform the leakage current test procedure.

Test 1 tests the current leakage, using a Dynatech Nevada 232 Safety/ECG Analyzer. This procedure shows one example of a current leakage test (source and sink). The procedure for your safety analyzer may be very different.

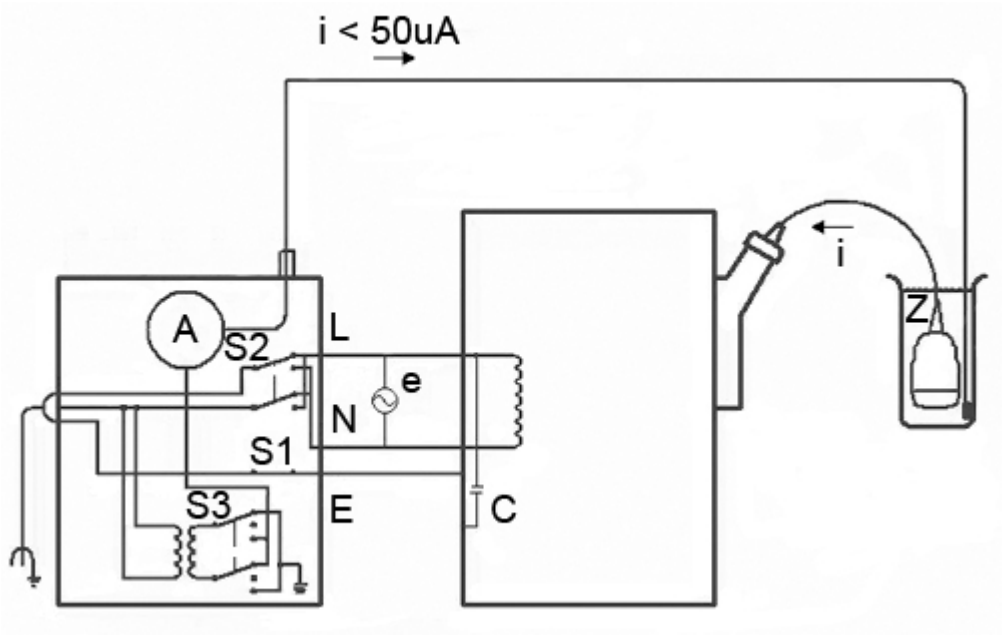
Test 1: Leakage Current Test with Mains Voltage Applied (Source) for Intraoperative Transducers



Key to Source Test Diagram

C	Stray capacitance from the ultrasound system power wiring to the system grounded metal chassis (1 to 3 MΩ reactance)
Z	Impedance between the metal parts of the transducer and a test electrode placed in the bucket of saline solution (about 850 kΩ with an intact outer insulating layer, 500 Ω with a hole in the layer)
A	Microammeter to measure leakage current from the transducer to the earth lift ground through Z to the test electrode
e	Line power source, either 110 Vac or 220 Vac
I	Current caused by e and stray capacitance, and optionally Z
S1	Open earth lift ground switch
S2	Line polarity switch
L	Line mains supply
N	Neutral mains supply
E	Earth ground

Test 2: Leakage Current Test with Mains Voltage Applied (Sink) for Intraoperative Transducers



Key to Test 2 Diagram

C	Stray capacitance from the ultrasound system power wiring to the system grounded metal chassis (1 to 3 MΩ reactance)
Z	Impedance between the metal parts of the transducer and a test electrode placed in the bucket of saline solution (about 850 kΩ with an intact outer insulating layer, 500 Ω with a hole in the layer)
A	Microammeter to measure leakage current from a line supply to the transducer and back to earth ground through electrode Z and the equipment chassis
e	Line power source, either 110 Vac or 220 Vac
I	Current caused by e and stray capacitance, and optionally Z
S1	Open earth lift ground switch
S2	Line polarity switch
S3	Isolation test button
L	Line mains supply
N	Neutral mains supply
E	Earth ground

Testing Intraoperative Transducer Leakage Current (Source)

This test checks leakage current without mains voltage applied. For a diagram of this test, Test 1, see "Leakage Current Testing for Intraoperative Transducers" on page 217.

WARNING

Electrical shock hazard: Do not touch the lead that you connect to the safety analyzer in step 7.

1. Plug the safety analyzer into the power source.
2. Plug the ultrasound system into the safety analyzer.
3. Connect the transducer being tested to the ultrasound system.
4. Immerse 5 cm (2 in) of the transducer in saline solution.
5. Set the safety analyzer **Mode** switch to the **ECG** position.
6. Set the safety analyzer **Leads** switch to the **ALL** (all ECG leads) position.
7. Connect a lead to any ECG terminal on the safety analyzer, and immerse the other end into the saline solution.
8. Set the safety analyzer **Line Polarity** switch to **Normal**.
9. Note the normal condition leakage reading.
10. Hold the safety analyzer **Ground Open** switch in the **Open** position (single fault condition), and note the leakage reading.
11. Repeat step 9 and step 10 with the **Polarity** switch in the **Reverse** position. These are the applicable limits:
    - 10 µA RMS (normal condition)
    - 50 µA RMS (single fault condition)

Testing Intraoperative Transducer Leakage Current (Sink)

WARNING

There is considerable hazard in performing this test. Use precautionary measures to avoid accidental contact with line voltage. In addition, any time that the ground

connection has been opened, do not touch the chassis or the patient cable during the test.

This test checks leakage current with mains voltage applied. For a diagram of this test, Test 2, see "Leakage Current Testing for Intraoperative Transducers" on page 217.

1. Plug the safety analyzer into the power source.
2. Plug the ultrasound system into the safety analyzer.
3. Connect the transducer being tested to the ultrasound system.
4. Immerse 5 cm (2 in) of the transducer in saline solution.
5. Set the safety analyzer **Mode** switch to the **ECG** position.
6. Set the safety analyzer **Leads** switch to the **Isolation Test** position.
7. Connect a lead to any ECG terminal on the safety analyzer. Leave the other end of the lead disconnected for now.
8. Press and hold the **Isolation Test** button and note the leakage reading. This is the correction factor that will be subtracted from the final reading.
9. Immerse the other end of the lead into the saline solution.
10. Press and hold the Isolation Test button and take the leakage reading again.
11. Subtract the correction factor found in step 8 to get the accurate leakage measurement. The leakage must be less than 50 µA RMS.

10 Transesophageal Transducers

A transesophageal echocardiography (TEE) study is performed with a transducer mounted in a gastroscope, which is positioned in the esophagus or stomach. TEE transducers offer images that are unobstructed by lungs and ribs, making them important diagnostic tools for conditions that transthoracic echocardiography cannot adequately image.

NOTE

Two Omni TEE transducers can be used with the iU22 Ultrasound System: the S7-2omni transducer and the T6H (Omni III) transducer, which requires a connector adapter to connect to the iU22 system. These transducers are functionally identical except for the connectors. Information that refers to the S7-2omni transducer also applies to the T6H (Omni III) transducer, except for connecting the transducer to the system.

Operators of TEE Transducers

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

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

Patient Safety During TEE Studies

Philips recommends that you practice using the TEE transducer controls before performing any procedure mentioned here. You must also be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound imaging

system used with the TEE transducer, as well as proficient at interpreting the images generated.

You can help ensure patient safety when using a TEE transducer by following these guidelines:

- Use informed judgement when selecting patients for TEE studies. (See "Patient Selection for TEE Transducer Use" on page 249)
- Verbally prepare each patient for the procedure before the study. See "Preparing Patients for TEE Studies" in the Help.
- Scrutinize the entire transducer and test all of the controls before each use. See "Checking the TEE Transducer" on page 247.
- Insert, remove, and operate the transducer properly.
- Ensure that the transducer handle does not rest on or touch the patient.
- Use protective equipment, such as a bite guard and a market-approved sterile transducer cover during a TEE study. See "TEE Accessories and Supplies" on page 258.
- Do not allow water or other liquids to come in contact with the interior of the system, the transducer connector, the inside of the transducer control handle, or to drip onto the keyboard.
- Minimize the possibility of transducer tip fold-over. This problem has occurred rarely, but its consequences can be serious. See "Tip Fold-Over" in the Help.

To prevent tissue damage such as pressure necrosis, gastroesophageal lacerations, bleeding, tearing of adhesions, ligament damage, and perforation, observe the following warnings and cautions.

WARNINGS

- Never apply excessive force when inserting or withdrawing a TEE transducer, or when operating the transducer deflection controls.
- Do not allow the transducer to remain at a maximum deflection for long periods of time.
- Lock medial/lateral movement of the TEE transducer during insertion.

- Whenever the TEE transducer is not being used during a procedure, ensure that it is in freewheeling mode and unplugged from the system.
- To prevent tissue damage, Philips recommends that the tip of the TEE transducer be straightened and both detent brakes released before you reposition the transducer or withdraw the transducer from the patient. In the neutral position, the tip is straight when the indicators on the control wheels are aligned and point toward the center of the array rotation button.
- Bite guards are mandatory; protective transducer covers are recommended for TEE transducers, but in China and Japan, the covers are mandatory. See "Electrical Safety and TEE Transducers" on page 233.

CAUTION

To avoid damaging gastroscope cables, be sure that the distal tip of the transducer is in the neutral (straight) position when inserting a transducer into, or removing it from, the transducer cover.

The TEE transducers are classified as Type BF isolated patient-applied parts, as described in IEC 60601-1. There are no exposed conductive surfaces distal to the transducer handle. To ensure safe operation of this transducer, read the cautions and warnings in the "Safety" section, especially those that address electrosurgical units, pacemakers, and defibrillators.

The following table summarizes patient safety problems, describes how to prevent them, and lists the sections in this manual where details are provided.

WARNING

If you encounter an irregularity not listed in the following table, do not use the transducer. Potentially serious consequences could result. Contact your Philips representative.

Ensuring Patient Safety During TEE Studies

Problem	Effect on Patient	Prevention	See
Mechanical damage	Severe trauma, cuts, bleeding, perforations	Inspect the transducer, using both sight and touch, before the study.	Checking the TEE Transducer
Electrical damage	Esophageal burns	Check the transducer for frayed insulation, kinks, or other abnormalities. Follow procedures for checking electrical safety.	"Electrical Safety and TEE Transducers" on page 233
Biting, scraping transducer	Tooth damage, esophageal burns	Always use a bite guard.	"Bite Guards" on page 258

Problem	Effect on Patient	Prevention	See
Insufficient cleaning protocol	Spread of illness or disease	Thoroughly clean and disinfect the transducer after each use. Cover the tip and shaft with a transducer cover. Cover the imaging system with a disposable drape if highly pathogenic organisms are known or suspected.	"Transducer Care" section
Improper insertion or withdrawal	Esophageal cuts, bleeding, ligament damage, perforations	To prevent improper insertion or withdrawal when using a TEE transducer, never use force when inserting, removing, or manipulating the transducer. During insertion, lock the medial/lateral controls. During withdrawal, release both brakes to place both steering knobs in the freewheeling position.	"TEE Study Guidelines" on page 250
Pressure necrosis	Death of esophageal lining tissue	Keep deflection controls in freewheeling mode and unplug the transducer from the system when not imaging. Minimize the pressure applied to deflection area and distal tip. Do not let the distal tip displace a tissue area for more than 5 consecutive minutes.	"TEE Study Guidelines" on page 250

Problem	Effect on Patient	Prevention	See
Increased transducer temperature	Esophageal burns	Use the TEE preset that has been established to minimize the effects of temperature. For febrile patients, use the Auto-Cool feature.	"Entering Patient Temperature" on page 256
Improper patient position	Transient unilateral vocal cord paralysis	Never use the transducer during any procedure requiring extreme neck flexion, such as sitting craniotomies.	"TEE Study Guidelines" on page 250
Nonisolated ESUs	Electrical burns	Only use isolated-output electrosurgical units (ESUs). The ESU label or service guide or your biomedical department should identify whether or not the ESU is isolated. Unplug transducer from the system when you are not imaging.	"Electrical Safety and TEE Transducers" on page 233
Defibrillation issues	Electrical burns	Remove the transducer from the patient before defibrillation.	"Electrical Safety and TEE Transducers" on page 233

Patient-Contact Parts

Latex is 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 content. Studies have shown

that patients can experience allergic reactions with natural rubber latex. See "FDA Medical Alert on Latex" on page 45.

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.

Preventing TEE Transducer Problems

Meticulous inspection and correct and careful operation of the TEE (transesophageal) transducer is imperative to patient safety. The situations listed here affect safe operation as well as the ability to service mechanical problems under the Philips one-year warranty or service contract. Transducer repairs necessitated by misuse of the transducer are not covered and can be very costly, often requiring complete disassembly and rebuilding of the transducer.

There are three primary areas of transducer misuse:

- Cuts and abrasions on the transducer and insulation from teeth or sharp instruments such as scalpels, scissors, and clamps
- Improper disinfection techniques, causing fluid to enter the control head assembly, transducer handle, and the rest of the transducer
- Consistently applying too much force to the control wheels of a TEE transducer, which can break the steering mechanism

Review the following table to familiarize yourself with specific problems, to learn how to avoid them, and to identify the sections in this manual where details are provided. Philips also strongly recommends that you clearly post stringent protocols for TEE transducer care, based on the information in this manual, to minimize the chance of damage.

WARNING

For any other irregularity not listed in the following table, do not use the transducer. Potentially serious consequences could result. Contact your Philips representative.

Preventing TEE Transducer Equipment Problems

Problem	Effect on Equipment	Prevention	See
Current leakage	Serious electrical hazards	Check the transducer for cuts, frayed insulation, kinks, or other abnormalities.	Checking the TEE Transducer
Biting transducer	Mechanical and electrical hazards	Cover the patient's teeth with a bite guard (mandatory). Cover the distal tip and flexible shaft with a transducer cover (recommended, but in China and Japan, mandatory).	"Bite Guards" on page 258
Forcing deflection controls	Steering mechanism broken	Operate the deflection controls gently.	TEE Deflection Controls
Incorrect storage	Possible damage to highly sensitive elements, cuts in flexible shaft	Suspend the transducer from a wall-mounted rack and the distal tip with a tip protector when not in use.	"Transducer Storage" on page 208
Internal exposure to liquids	Severe transducer damage that affects the image quality, the steering mechanism, and electrical safety	Never sterilize the transducer by using bleach, steam, heat, or ethylene oxide (EtO). Never immerse the steering mechanism in any disinfectant or liquid.	"Transducer Care" section

Electrical Safety and TEE Transducers

The ultrasound system and its transducers comply with common medical device electrical safety standards.

For electrical safety information about TEE transducers, see "Leakage Current and TEE Transducers" on page 233 and "Reducing Risks of Using TEE Transducers" on page 233.

For safety information on electrosurgical units, pacemakers, defibrillators, and related topics, see "Electrical Safety" on page 29.

Leakage Current and TEE Transducers

For the TEE transducers discussed in this document, the insertion tube and tip are Type BF  , as described in IEC 60601-1. There are no exposed conductive surfaces distal to the transducer handle. Within the flexible shaft, all active circuits and conductors are surrounded by a chassis-grounded shield that runs the length of the transducer.

If the outer layer of the shaft is punctured or cracked, a patient's esophagus could be exposed to chassis leakage current. This leakage current is not hazardous provided that the ground connector (third wire) in the ultrasound system power cable is intact and connected to a properly grounded wall outlet. Even if the ground connector breaks, leakage current is in compliance with the limits noted in IEC 60601-1.

Leakage hazards are further reduced when the ultrasound system is plugged into an isolated power outlet, which is standard in most operating rooms.

Reducing Risks of Using TEE Transducers

To reduce the possibility of electrical risks associated with use of TEE transducers, follow these recommendations:

- Visually and tactually inspect a TEE transducer for bumps, cracks, and cuts before each TEE exam. A small bump on the shaft surface could indicate

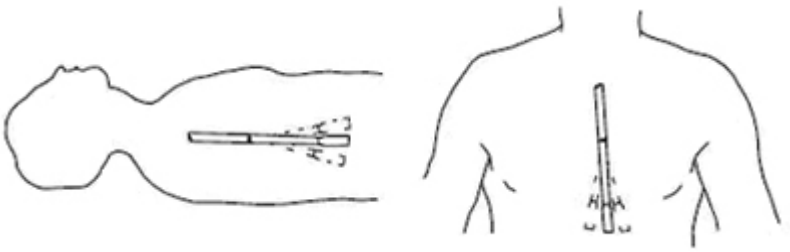
that a strand from the ground shield has broken and is beginning to puncture the outer layer. If you suspect a problem with the flexible shaft, perform the electrical safety check procedure. See "TEE Leakage Current Test" on page 259.

- Use electrosurgical units (ESUs) that have isolated outputs. Return fault/ground fault detection circuits provide additional protection. To determine if an ESU has an isolated output, read the label on the ESU, see the ESU service guide, or ask a biomedical engineer.
- Require periodic electrical safety checks to ensure that the grounding system in your area remains intact.
- If the transducer is left in a patient during periods when imaging is not taking place, unplug the transducer from the system to reduce the possibility of leakage current or ESU interaction. Also make sure that the deflection control brakes are off and that the transducer is in freewheeling mode.

TEE Deflection Control Basics

The deflection controls on the TEE transducer move the deflection area, located between the distal tip and flexible shaft. The deflection area bends when you operate the controls, permitting anterior, posterior, and lateral positioning..

Deflection Control Movement



To prevent tissue damage such as pressure necrosis, gastroesophageal lacerations, bleeding, tearing of adhesions, ligament damage, and perforation, observe the following warnings. See "TEE Transducer References" on page 263.

WARNINGS

- Never apply excessive force when inserting or withdrawing a TEE transducer, or when operating the transducer deflection controls.
- Lock medial/lateral movement of the TEE transducer during insertion.
- Whenever the TEE transducer is not being used during a procedure, ensure that it is in freewheeling mode and unplugged from the system.
- Do not allow the TEE transducer to remain at a maximum deflection for long periods of time.
- To prevent tissue damage, Philips recommends that the tip of the TEE transducer be straightened and both detent brakes released before you reposition the transducer or withdraw the transducer from the patient. In the neutral position, the tip is straight when the indicators on the control wheels are aligned and point toward the center of the array rotation button.
- Bite guards are mandatory; protective covers are recommended for TEE transducers, except in China and Japan, where protective transducer covers are mandatory for TEE transducers.
- To avoid damaging gastroscope cables, be sure that the distal tip of the transducer is in the neutral (straight) position when inserting a transducer into, or removing it from, the transducer cover.

Connecting an S7-2omni Transducer

NOTE

Before you connect the S7-2omni TEE transducer, be sure the tip and shaft are straight. When you connect the transducer, it automatically calibrates itself to the 0-degree (horizontal plane) position.

If the "Calibration failed" message appears, see "Calibrating the TEE Transducer" on page 246.

1. Plug the S7-2omni transducer into a transducer receptacle on the system.

2. Turn the latch 90 degrees clockwise to lock the transducer to the system.

Connecting a T6H Transducer

You can use a T6H (Omni III TEE) transducer with the system by using the Omni III adapter. This transducer can be identified by the label on the transducer connector and the transducer designation that appears on the display when the transducer is connected and selected.

The front of the adapter is the transducer connection. The back of the adapter is the system connection.

NOTE

Before you connect the T6H transducer, be sure the tip and shaft are straight. When you connect the transducer, it automatically calibrates itself to the 0-degree (horizontal plane) position. As with any array movement, the motor makes a humming sound while calibrating.

If the "Calibration failed" message appears, see "Calibrating the TEE Transducer" on page 246.

1. Plug the Omni III into the left transducer receptacle on the system, with the latch side facing out. (You can use the other transducer receptacles, but one additional receptacle will be blocked by the adapter if you do.)
2. Turn the latch on the adapter to lock the adapter to the system.
3. Orient the T6H connector so that the cord exits upward, and then plug it into the adapter.
4. Turn the latch 90 degrees clockwise to lock the transducer into the adapter.
5. To remove the T6H transducer from the adapter, turn the transducer latch to the unlocked position (90 degrees counterclockwise) and pull the connector toward you.
6. To remove the adapter from the system, turn the adapter latch to its unlocked position and pull it toward you.

Omni III Adapter

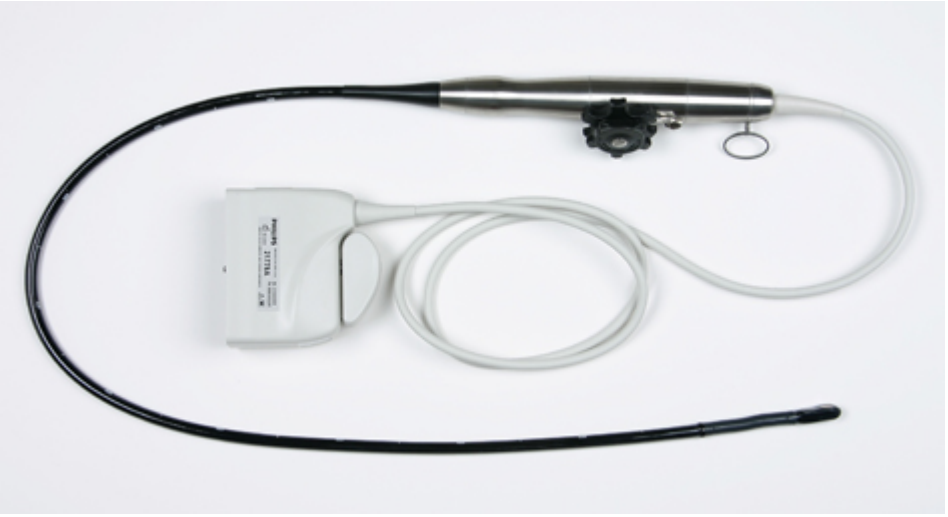
S7-2omni TEE Transducer Description

The S7-2omni TEE transducer is described below.

NOTE

The features and specifications are identical for the S7-2omni and T6H (Omni III) transducers.

S7-2omni TEE Transducer



NOTE

Philips recommends that you use the S7-2omni transducer only on patients weighing at least 25 kg (55 lb), to ensure the esophagus can comfortably accommodate the transducer.

Features

- Ultraband transducer technology sensor for Harmonic and Contrast imaging
- Enables high-resolution imaging and 360-degree views of the heart, unobstructed by lungs and ribs
- Capable of Harmonic imaging, contrast research, Tissue Doppler Imaging (TDI), Color imaging, steerable CW Doppler mode and PW Doppler mode, frequency agility, and electrocautery suppression
- Tip surface constantly monitored for patient safety
- Convenient hanging ring

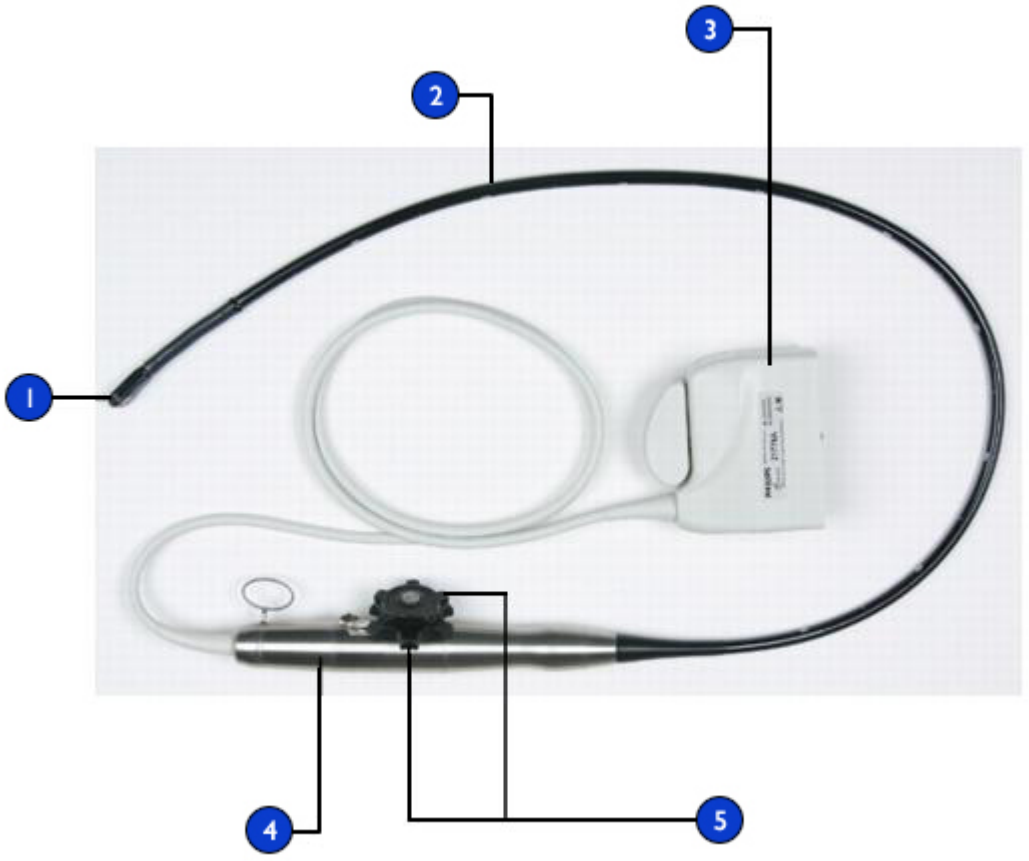
Specifications

- Tip width: 1.5 cm (0.6 in)
- Tip length: 3.5 cm (1.4 in)
- Shaft width: 1.0 cm (0.4 in)
- Shaft length: 1.0 m (3.3 ft)

Using the S7-2omni Transducer

Philips recommends familiarizing yourself with the controls and parts of the TEE transducer before using it in an exam. For more information on transducer controls, see "S7-2omni Deflection Controls" on page 241.

TEE Transducer Parts



1	Distal tip
2	Flexible shaft
3	Transducer connector

4	Transducer handle
5	Deflection controls

S7-2omni Deflection Controls

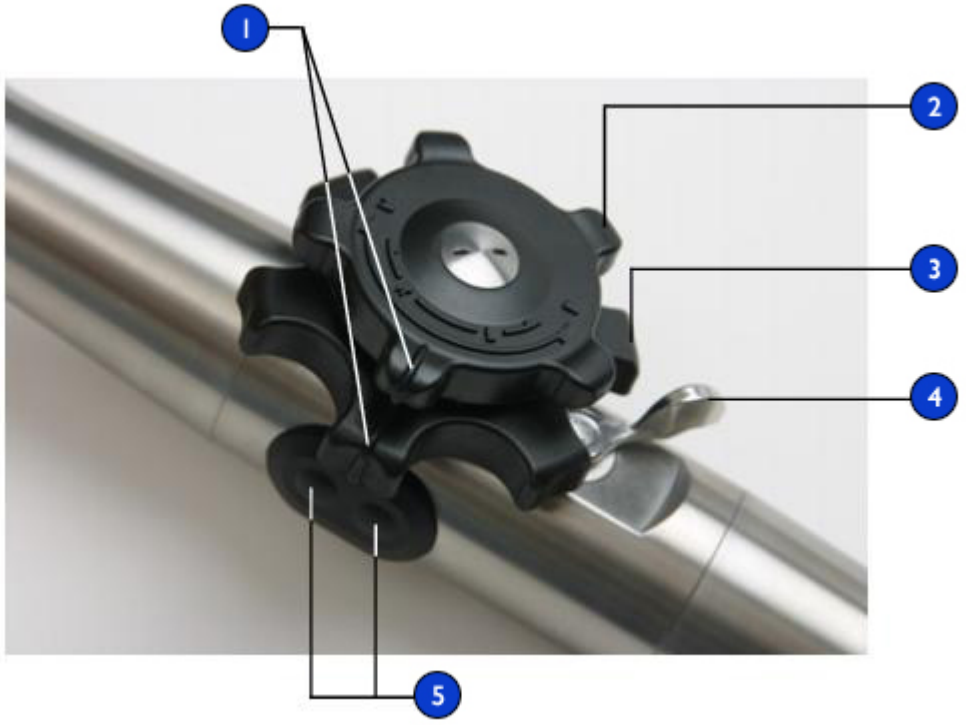
The S7-2omni controls and brake are shown below.

The larger inner knob controls anterior/posterior movement, while the smaller outer knob controls medial/lateral movement. To place the tip of the TEE transducer into the neutral position, align the ribs on each knob with the center of the array rotation buttons.

The knobs can be controlled by a detent brake that holds the tip position without locking it in place. This allows the tip to straighten if it meets additional resistance. When the detent brake actuator is rotated to the right (as shown) both knobs are in the freewheeling mode. When the detent brake actuator is centered, the small knob (medial/lateral movement) is in the detent mode, and when the actuator is rotated to the left, both knobs are in the detent mode.

During insertion, engage medial/lateral detent to limit movement or use freewheeling mode (no deflection and no brake resistance) to prevent patient injury.

Deflection and Brake Controls



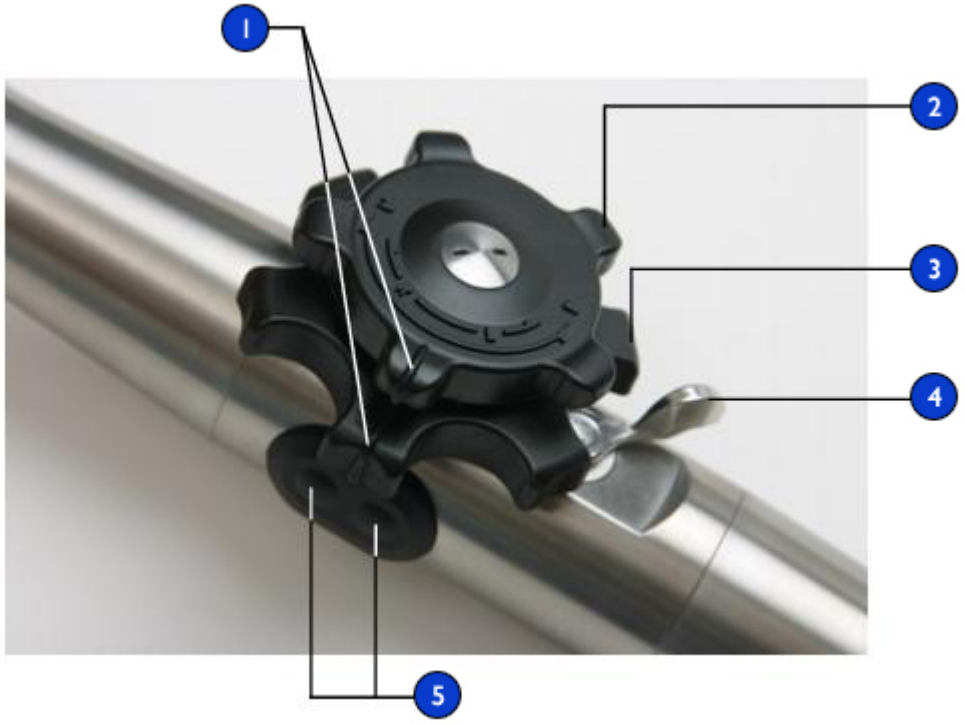
1	Neutral position indicators (no deflection)
2	Medial/lateral control
3	Anterior/posterior control
4	Detent brake actuator
5	Image plane rotation buttons

Manipulating the S7-2omni Tip

Review the warnings and caution in "Patient Safety During TEE Studies" on page 225 and "TEE Deflection Control Basics" on page 234 before using the transducer in a study.

1. Turn the detent brake actuator fully counter clockwise to put both knobs into freewheeling mode.
2. Turn the large knob to deflect the tip in the anterior/posterior plane.
3. Turn the small knob to deflect the tip in the medial/lateral plane.
4. Once the tip is positioned properly, do one of the following:
   - Turn the detent brake actuator fully clockwise to put both knobs in detent mode.
   - Center the detent brake actuator to put only the small knob (medial/lateral movement) in the detent mode.

Deflection and Brake Controls



1	Neutral position indicators (no deflection)
2	Medial/lateral control
3	Anterior/posterior control
4	Detent brake actuator
5	Image plane rotation buttons

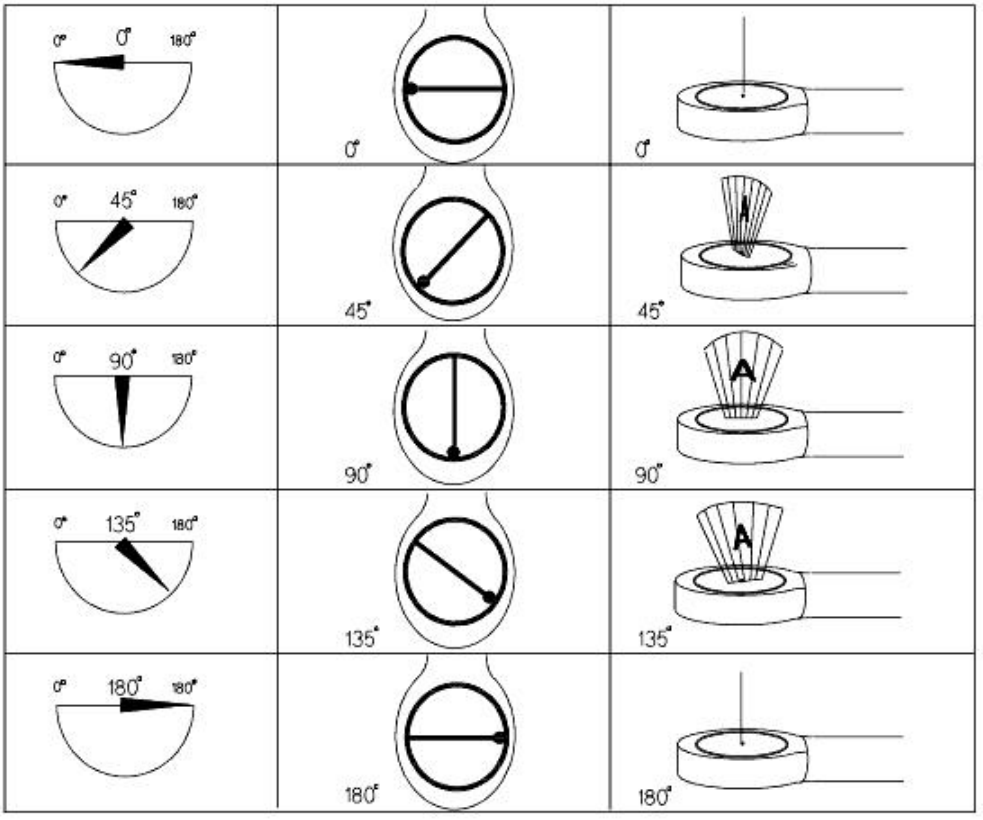
Rotating the S7-2omni Array

You can rotate the array on the TEE transducer to achieve a 360-degree view of the heart. You can use either the array rotation buttons on the transducer handle or the controls on the **TEE** touch screen. Rotation stops when you release either button.

An icon shows the current degree of rotation. Depending on image orientation, the icon appears in the upper or lower part of the display. Because the center of the array is the pivot point, you can achieve a 360-degree view

1. To rotate the TEE transducer array using the transducer controls , do one of the following:
   - Press the array rotation button that is distal to the system to rotate the imaging plane toward the 180-degree position.
   - Press the button that is proximal to the system to rotate the imaging plane toward the 0-degree position.
2. To rotate the TEE transducer array using system controls , go to the **TEE** touch screen and do any of the following:
   - Touch **Up** to rotate the imaging plane toward the 180-degree position.
   - Touch **Down** to rotate the imaging plane toward the 0-degree position.
   - Turn **Seek Angle** to set an angle and touch **Seek** to go directly to the specified angle.

TEE Transducer Array Rotation



Calibrating the TEE Transducer

Before connecting the TEE transducer, ensure that the tip and shaft are straight. When you lock the connector into the transducer receptacle, the TEE transducer calibrates the array to the 0-degree (horizontal plane) position. As with any array movement, the motor makes a humming sound while calibrating.

NOTE

Do not turn the TEE control knobs while calibration is in progress.

If a system message indicates a calibration failure, you will be unable to use the transducer until you perform the following procedure.

1. Ensure that the transducer shaft and tip are straight (the neutral position indicators must be aligned with the array rotation buttons).
2. Turn the locking lever on the transducer connector counterclockwise and pull the connector out of the receptacle.
3. Reseat the connector in the receptacle and turn the locking lever clockwise.
4. Select the transducer and preset.
5. If you still see the calibration-failure message, contact your Philips service representative.

Checking the TEE Transducer

Before each TEE exam, carefully inspect the transducer and try the controls, as described in the subordinate topics.

TEE Transducer Inspection

Carefully inspect the entire surface of the distal tip and flexible shaft for protrusions, holes, dents, abrasions, cuts, burrs, or cracks that could be extremely hazardous to both you and your patient.

Carefully feel the tip and shaft, and inspect the entire transducer. If you suspect an electrical problem, follow the electrical safety check procedure described in "Electrical Safety Check for TEE Transducers" in the "Transesophageal Transducers" section of the *User Manual*.

Also check for excessive flexibility in the tip, particularly in the medial/lateral direction. Do not use the transducer if the tip is extremely flexible. If you have any questions about tip flexibility, contact your Philips service representative.

TEE Transducer Controls Inspection

Use the deflection controls to position the tip in every possible direction, both to ensure that the controls work properly and to get used to the feel of the TEE

transducer. Make sure that the controls operate smoothly without binding, and that you can achieve all possible positions easily before introducing the TEE transducer into the patient.

Test the detent brakes and freewheeling mode. Remember that the controls must be in freewheeling mode (no deflection and no brake resistance) when repositioning or withdrawing the transducer, as well as whenever you are not imaging. See "Manipulating the S7-2omni Tip" on page 243.

Special Considerations for TEE Studies

Special considerations regarding TEE studies are advisable for patients with existing gastroesophageal abnormalities, such as esophageal varices, hiatal hernia, tumor, diverticula, esophageal webs and rings, fistulae, or peptic ulcers, as well as for patients who have had anti-reflux procedures. In addition, you should do the following:

- Consider the patient's size and ability to accommodate the transducer tip and shaft.
- Check the patient's history for gastroesophageal disease or difficulty swallowing.
- Evaluate the potential overall effects of any treatment that the patient is undergoing, such as mediastinal radiation, chemotherapy, anticoagulation, or steroid therapy.
- Be aware that you may discover unsuspected esophageal pathology during a study. Be alert for congenital problems with the esophagus or stomach, particularly with pediatric patients.
- When examining a patient with an above-normal temperature, use the Auto-Cool feature and enter the patient temperature. The Auto-Cool feature is described in "Entering Patient Temperature" on page 256.

This list is not comprehensive. Rather, it suggests areas to investigate when considering TEE for a particular patient.

Patient Selection for TEE Transducer Use

Although the TEE transducers can provide clinical data not available from other instruments, you should consider which patients can safely use the TEE transducers.

WARNINGS

- The ability of a patient to swallow or accommodate the transducer should be considered.
- You must consider any history of gastroesophageal diseases as well as the possible effects of other therapies that the patient is undergoing. You must also consider all gastroesophageal abnormalities or difficulty swallowing.

The table below lists the minimum patient weight recommendations when using TEE transducers.

TEE Transducer Minimum Patient Weight Recommendations

TEE Transducer	Minimum Patient Weight
S7-2omni	25 kg (55 lb)
T6H	25 kg (55 lb)

Preparing Patients for TEE Studies

These suggestions for pre-study patient preparation do not constitute an exhaustive list of all possible factors to explore before performing transesophageal echocardiography, nor do they imply medical protocols. Instead, they reflect basic guidelines resulting from extensive consultation with physicians throughout

the design, development, and clinical investigation periods of Philips TEE transducers.

- Besides gathering routine background information such as current medication and allergies, investigate any history of chronic obstructive lung disease, esophageal strictures, varices, or bleeding.
- Thoroughly explain the procedure to the patient before the study.
- Inform the patient not to eat or drink for at least 6 hours before the study.
- Advise the patient that he or she should not plan to drive after the study, because sedatives are often used.
- Follow institutional guidelines for obtaining patient consent for a transesophageal echocardiography (TEE) study.
- Be sure that a recent ECG, CBC, and SMA6 are available as a baselines.

TEE Study Guidelines

During a TEE study, an assistant can provide oral and pharyngeal suctioning of the patient and can monitor the patient's blood pressure and general responses. For unexpected occurrences, an emergency cart with basic life-support equipment should be ready. Throughout the study, it is important to carefully monitor the patient's reactions and to ensure that ventilation and vital signs are stable.

In the operating room, do not use TEE transducers during surgical procedures requiring extreme neck flexion, such as sitting craniotomies. The following are important guidelines for TEE studies. (See "TEE Transducer References" on page 263.)

- Minimize the possibility of transducer tip fold-over. This problem has occurred rarely, but its consequences can be serious. See "Tip Fold-Over" on page 251.
- Maintain a patent airway. For surgical patients, endotracheal intubation establishes a stable, patent airway before insertion of the transducer. For patients who are awake, carefully monitor the patient's breathing at all times.
- Minimize the possibility of pressure necrosis (tissue death). Do not let the distal tip displace any one segment of tissue for more than 5 consecutive minutes. Also make sure the deflection area and the distal tip are in the

position of least potential pressure. Be sure that the transducer is in a freewheeling mode and unplugged whenever you are not imaging.

- Prevent potential esophageal damage. Philips recommends that you stop TEE scanning and unplug the transducer from the system during periods of poor perfusion, circulatory arrest, or the hypothermic phase of open heart surgery. To discontinue scanning, unlock the transducer connector.
- Before each TEE study, carefully inspect the transducer, as described in "TEE Transducer Inspection" on page 247. A thorough inspection procedure is required for the safety of the patient and yourself, and to ensure the continued correct functioning of the transducer.
- Never use excessive force when inserting, operating, or withdrawing a transducer, and make sure the deflection area is straight during insertion and withdrawal. Forceful insertion, manipulation, or withdrawal of a transducer can result in lacerations, bleeding, perforation, tearing of adhesions, and ligament damage. Also be aware that the tip can fold over, causing similar damage.
- Refrain from handling the distal tip whenever possible. If you must handle the distal tip, grasp it on the sides. Do not touch the top or bottom. Support the transducer's proximal head, either by having an assistant hold the steering mechanism or by clamping the transducer at the steering mechanism. Ensure that the clamp does not interfere with steering, and do not clamp any part of the flexible shaft, as this will damage the transducer.

Tip Fold-Over

On rare occasions, the tip of a TEE transducer has folded over during insertion. The effects can be serious if the situation is handled incorrectly. The esophagus can be scraped, perforated, or otherwise damaged.

For more information on tip fold-over, see "Tip Fold-Over" in the Help.

Recognizing Tip Fold-Over

The TEE transducer tip might be folded over in the patient if you encounter any of the following:

- Resistance to advancing or removing the transducer
- An inability to turn the control knobs
- Fixation of the control knobs in the maximum flexion position
- Extreme difficulty in obtaining an image

Correcting Tip Fold-Over

If you suspect the transducer tip is folded over, Philips' physician consultants recommend that you gently try to manipulate the transducer. If the tip is neither locked nor jammed in a doubled-over position, and you can move it forward, advance the transducer into the stomach. Then straighten the tip and remove the transducer.

If you cannot move the tip in any direction, Philips's consultants recommend that you x-ray the patient to evaluate the situation. You might also want to involve a gastroenterologist or anesthesiologist.

Preventing Tip Fold-Over

The following steps can prevent the tip from folding over. This list is not exhaustive; other factors can also be involved.

Using Correct Insertion Technique

You may find transducer insertion easier if you guide the transducer into the patient's mouth with your fingers. You also may want to lock medial/lateral tip movement.

CAUTION

All patients should wear a bite guard during a TEE exam. A bite guard protects against dangerous transducer mechanical and electrical malfunction caused by involuntary biting. Even anesthetized patients require bite guards to prevent

damage to both their teeth and to the transducer. For information on bite guards available from Philips, see "Bite Guards" on page 258.

Avoid the following when inserting any TEE transducer into a patient:

- Any excessive flexion of the transducer tip, particularly in the medial/lateral direction
- Catching the tip in pharyngeal recesses
- Insertion when a patient is being uncooperative or is having a convulsion or spasm

Reviewing Patient Esophageal Pathology

Carefully review a patient's medical history for obstructing pathologies or anatomical irregularities before performing a TEE exam.

Ensuring Proper Transducer Maintenance

Thoroughly examine the transducer and test the controls before each exam. Be sure to check for excessive flexibility in the tip. See "TEE Transducer Inspection" on page 247.

TEE Temperature Sensing

The S7-2omni transducer contains built-in temperature sensors near the distal tip of the transducer. The sensor monitors the transducer's temperature to prevent potential burning of esophageal tissue.

The sensor is affected by patient core temperatures. The system assumes that the patient temperature is normal, and calculates the distal tip temperature accordingly. If the patient temperature is above 37°C (98.6°F), the Auto-Cool feature can miscalculate the temperature of the distal tip. This can expose patients to excessive temperatures or cause an unwarranted Auto-Cool condition in which the system stops scanning.

Ensuring Safe TEE Temperatures

To ensure patient safety and to avoid unnecessary interruption while scanning, follow these suggestions:

- Ensure distal-tip-temperature accuracy by entering an accurate patient core temperature.
- Decrease the transducer temperature by using the **Output Power** knob before introducing a TEE transducer to decrease acoustic output, and keep the control at the lowest possible setting during an exam.
- Use the TEE Manual Auto-Cool Safety feature to enter the patient temperature if it is above 37°C (98.6°F) as described in "Entering Patient Temperature" on page 256.

Manual Auto-Cool Feature

Use the TEE Manual Auto-Cool safety feature to enter above-normal patient temperatures. When the temperature display is enabled, you can see both the patient temperature and the distal tip temperature while scanning.

NOTE

The patient temperature displayed on the ultrasound screen is always either 37°C (98.6°F) or the temperature that you manually enter. The system does not monitor or report the actual patient temperature.

If the distal tip temperature reaches 41°C (105.8°F), a warning message appears and the transducer temperature is displayed in inverse video. If the temperature reaches 42.5°C (108.5°F), a warning appears with the patient and the transducer temperatures, and the system stops imaging until the distal tip cools to below 42°C (107.6°F). If the distal tip temperature reaches 43.5°C (110.3°F), the system shuts down. You may need to restart the system by turning it on.

WARNINGS

- To avoid the risk of esophageal burn for adult patients, minimize the time spent imaging at distal tip temperatures in excess of 42°C (107.6°F).

Exposure should be limited to 10 minutes or less at 42°C (107.6°F) or higher.

- Sufficient data on thermal tolerance of the esophagus in neonate and pediatric patients does not exist, but it is likely these patients are more vulnerable than adults. Minimize the time spent imaging at distal tip temperatures in excess of 41°C (105.8°F).

Using the Temperature Display

Both the patient temperature (assumed or entered) and the transducer temperature appear in the lower left corner of the display when enabled. On the display, the patient temperature is labeled **PAT T**, and the transducer temperature is labeled **TEE T**.

A less-than sign (<) after **TEE T** indicates that the transducer's distal tip temperature is below the patient temperature (**PAT T**) assumed by the system, which is either 37°C (98.6°F) or the temperature you entered.

You can customize the display of the TEE transducer temperature and the patient temperature from the **TEE** touch screen.

NOTE

If you want the temperature display enabled by default, turn on the temperature display and then create a preset as described in "Creating Quick Save Presets" on page 172.

1. Display the **TEE** touch screen by touching **TEE**.
2. Touch **Temp Display** to display or hide the temperature display.
3. Touch **Temp Units** to switch the temperature scale between Farenheit and Celsius.

Patient Temperature

Entering a patient's temperature enables the Auto-Cool feature to calculate tip temperature more accurately, which can prevent unnecessary interruptions while

scanning. If a patient's temperature is above normal, entering a temperature can avoid exposing the patient to excessive temperatures.

Always check the patient's temperature before inserting a TEE transducer. If it is above normal, whether from fever or therapeutic heating from a cardiac bypass heart-lung machine, perform the procedure in "Entering Patient Temperature" on page 256 before inserting the transducer. Also, follow that procedure if a patient's temperature rises during a study.

Measure the patient's core temperature, or more specifically, the actual temperature in the esophagus. For patients undergoing surgery, determine the temperature in the esophagus by direct measurement or by monitoring the temperature of blood returning from the bypass pump heat exchanger.

For closed-chest situations, rectal temperature is the best estimate of core temperature. You can also use oral temperatures, even though they can be one degree lower than the core temperature. If you measure an auxiliary temperature, which can be two degrees lower than the core temperature, add one or two degrees.

Entering Patient Temperature

1. If necessary, select the TEE transducer.
2. Display the **TEE** touch screen by touching **TEE**.
3. Turn **Pat Temp** to enter the patient's measured temperature.

NOTE

Each time you turn off or reset the system, or enter a new patient ID, the system assumes that the patient temperature is 37°C (98.6°F).

Resuming Imaging After Auto-Cool

If the distal tip temperature drops below 42.5°C (108.5°F), the system resumes imaging. If the Auto-Cool message persists longer than 1 minute or an error message appears, contact your Philips service representative.

If the distal tip temperature reaches 43.5°C (110.3°F), the system shuts down. You may need to restart it by pressing the On button.

WARNING

The **Reconnect the Transducer** error message is often caused by a poorly seated transducer connector, but it could be caused by a failure in the Auto-Cool safety logic. In the case of a logic failure, distal tip temperatures could reach 46.5°C (115.7°F) in hyperthermic patients (40°C to 41°C or 104°F to 106°F) before the error causes scanning to stop. At this temperature, esophageal burns may occur (see "TEE Transducer References" on page 263).

1. Turn the locking lever on the transducer connector counterclockwise, and pull the connector out of the receptacle.
2. Reseat the connector in the receptacle and turn the locking lever clockwise.
3. Select the transducer and preset.
4. If the system does not resume imaging after the transducer has initialized, shut down the system and then restart it.

Patient Care After a TEE Study

Follow your institutional guidelines for post-TEE studies. Additionally, you might want to include the following recommendations in your guidelines as part of your post-TEE study routine. These recommendations are neither exhaustive nor restrictive, but are steps you might want to incorporate into your post TEE exam routine.

- Inspect the patient's throat for any bleeding.
- Examine the patient for postural hypotension or difficulty walking.
- Instruct the patient to contact you immediately if he or she experiences any fever, chills, chest pain, or bleeding.
- Instruct the patient not to eat or drink for at least 2 hours or until swallowing returns to normal after anesthesia has worn off. It is especially important that the patient not ingest hot foods or fluids during this period.
- Follow up with a call to the patient the day after the a study to make sure there are no complications.

TEE Accessories and Supplies

Each TEE transducer comes with disposable bite guards and a disposable tip protector. Bite guards, TEE transducer covers, tip protectors, and disposable drapes are described here. For information on ordering TEE accessories, see "Supplies and Accessories" on page 23.

Bite Guards

WARNING

The M2203A bite guard strap contains natural rubber latex, which may cause allergic reactions. For more information, see "FDA Medical Alert on Latex" on page 45.

CAUTION

Damage caused when patients bite or scrape a TEE transducer is not covered in the transducer warranty or your service contract. Use bite guards to help prevent such accidents.

All patients must wear a bite guard during a TEE study. A bite guard prevents dangerous transducer mechanical and electrical malfunctions caused by involuntary biting. Even anesthetized patients require bite guards to prevent damage to their teeth and to the transducer. Philips supplies disposable bite guards that are suitable for both awake and anesthetized patients.

TEE Transducer Covers

WARNING

Transducer covers often contain natural rubber latex, which may cause allergic reactions. For more information, see "FDA Medical Alert on Latex" on page 45.

Philips recommends the use of a market-approved transducer cover during every TEE study.

For procedures on using transducer covers (protective sheaths), see the instructions provided with the covers.

Tip Protectors

When not using a carrying case to transport a TEE transducer, use a tip protector on its distal tip. The tip protector helps prevent serious damage to the transducer lens. Philips supplies tip protectors designed for each of its TEE transducers.

Disposable Drapes

During studies in which you believe contamination of the imaging system can occur, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

TEE Leakage Current Test

The electrical safety check described here should be performed regularly to determine if there is a hole in a transducer's outer insulating layer. This procedure detects liquid pathways to the interior parts of the transducer shaft and tip by measuring third-wire leakage current. This procedure can be performed with any commercially available safety analyzer that is designed for hospital use.

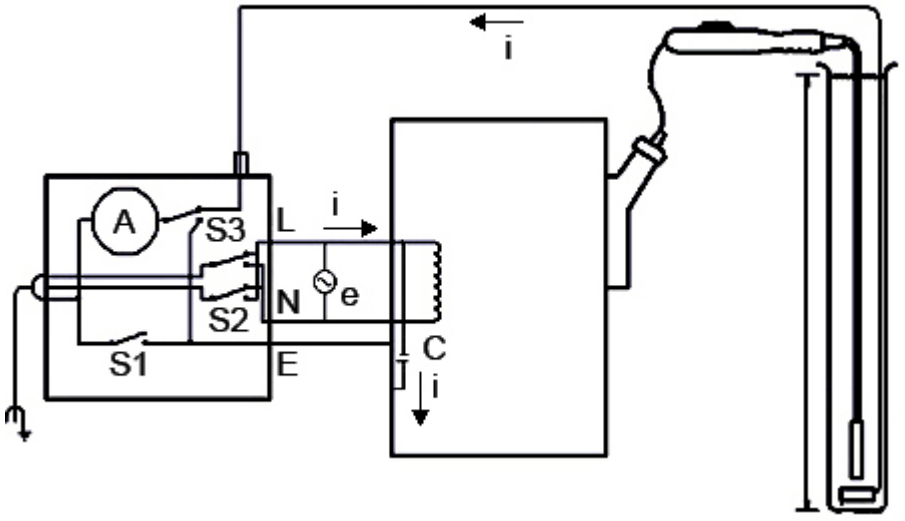
WARNING

Only a technically qualified person should perform the leakage-test procedure.

TEE Test Background

The test procedure (see figure) involves making an AC measurement of the ultrasound system current without a transducer. The results are then compared with the current measured when it is forced to flow through the insulating layer of the TEE transducer. If the two currents are nearly the same, it means there is a hole in the transducer's outer insulating layer that must be fixed before using the transducer.

Electrical Safety Check for TEE Transducers



TEE Leakage Current Test

Symbol	Definition
C	Stray capacitance from the ultrasound system power wiring to the system grounded metal chassis (1 to 3 MΩ reactance)
Z	Impedance between the metal parts of the TEE transducer and a test electrode placed in the bucket of saline solution (about 850 kΩ with an intact outer insulating layer, 500 Ω with a hole in the layer)
A	Microammeter to measure third-wire current, either directly from the chassis or through Z to the test electrode
e	Line power source, either 110 Vac or 220 Vac
I	Current caused by e and stray capacitance, and optionally Z
S1	Open earth lift ground switch

Symbol	Definition
S2	Line polarity switch
S3	Microammeter switch
L	Line mains supply
N	Neutral mains supply
E	Earth ground

Current I, driven by line supply e, flows through all stray capacitances between the primary wiring and the ultrasound system's metal chassis. Ordinarily, current then flows from the metal chassis through S3 and back to e through a third-wire ground. When S3 is thrown in the other position, current I is forced:

- From the chassis through the metal parts of the transducer
- Through impedance Z, produced by the insulating layer that covers the metal parts of the transducer and the saline solution
- Through the test electrode

Saline generally presents an impedance of about 500 Ω, so Z will vary between 850 kΩ and 500 Ω, depending on whether or not there is a conductive pathway caused by a hole in the transducer's insulating layer.

CAUTION

Do not make a DC measurement of impedance. This could set up a voltaic cell, with the metal of the transducer and a test electrode in the salt bath forming the two electrodes and an electrolyte. Such a voltaic cell produces inaccurate resistance measurements.

You need the following equipment to perform the electrical safety check procedure:

- Dempsey 432HD or 232D safety analyzer or equivalent
- Philips 2110A Disinfection Basin or equivalent
- Saline solution, 9 grams (0.3 oz) of salt to 1 liter (1 qt) of tap water, or one of the tested disinfectants listed in the "Transducer Care" section.

Testing TEE Transducer Leakage Current

For a list of the equipment needed to perform the electrical safety test procedure, see "TEE Test Background" on page 259.

WARNING

Only a technically qualified person should perform this procedure.

1. Gather the equipment in the preceding list.
2. Fill the basin to the fill line with saline solution.
3. Place the distal tip and shaft of the transducer into the basin.
4. Connect the transducer to the system.
5. Plug the ultrasound system's power cord into the test receptacle on the safety analyzer.
6. Attach a lead from the safety analyzer binding post labeled RL to a metal plate submerged in the basin.
7. On the safety analyzer, set the **Leads** switch to **RL**. Set the **Line Polarity** switch (S2) to **NORMAL**.
8. Turn on the safety analyzer and the ultrasound system.
9. Set the **Mode** switch (S3) on the safety analyzer to the **Case Leakage - Ground Conductor** position. Press the **Lift Ground** switch (S1) on the safety analyzer and record the chassis leakage current.
10. Set the **Mode** switch (S3) on the safety analyzer to the **ECG** position. Press the **Lift Ground** switch (S1) on the safety analyzer and record the patient leakage current.

The transducer fails the test if the patient leakage current recorded in step 10 is greater than 80% of the chassis leakage current recorded in step 9.

This failure indicates that there is a hole in the insulating layer of the TEE shaft. A hole enables a conductive pathway to internal metal parts of the transducer and presents a potentially hazardous condition to a patient undergoing external defibrillation or electrosurgery. A hole also allows invasion of organic material,

making it difficult to completely disinfect all portions of the transducer. For these reasons, the transducer must be repaired before it is used.

TEE Transducer References

Cucchiara, R.F., et al. "Air Embolism in Upright Neurosurgical Patients: Detection and Localization by Two-dimensional Transesophageal Echocardiography." *Anesthesiology*, 353-355, 1984.

Gussenhoven, Elma, et al. "Transesophageal Two-dimensional Echocardiography: Its Role in Solving Clinical Problems." *Journal of the American College of Cardiology*, 975-979, 1986.

Radwin, Martin, et al. "Transesophageal Echocardiography: Intubation Techniques." *Philips Application Note 5091-2804E*, 1992.

Urbanowitz, John H., et al. "Transesophageal Echocardiography and Its Potential for Esophageal Damage." *Anesthesiology*, Vol. 72, No. 1, 1990.

11 Endocavity Transducers

Endocavity transducers provide high-resolution endocavity imaging for OB, GYN, Contrast, and Urology applications. The system supports the following endocavity transducers:

- 3D9-3v
- C8-4v
- C9-5ec
- C10-3v

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 (see the "Transducer Care" section).
- 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.

WARNINGS

- All endocavity studies must be performed with a Type BF classified transducer. If your transducer is not labeled on the transducer connector with a Type BF symbol,  , contact your Philips service representative.
- 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.

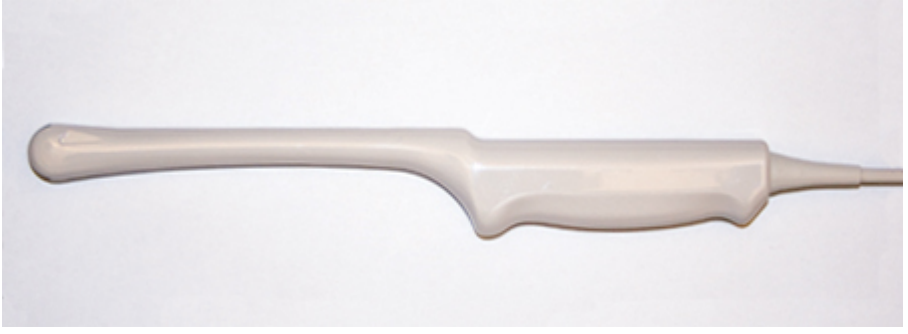
NOTES

- 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.

C8-4v Description

The C8-4v transducer is described here. For more information on connecting, activating, caring for, and maintaining transducers, see the "Transducers" and "Transducer Care" sections.

C8-4v Endocavity Transducer



Features of the C8-4v Transducer

Features	Curved array designed to be easy to hold and manipulate and to provide maximum clinician and patient comfort. Enables high-resolution imaging for obstetrical and gynecological studies.
Frequency	Operating range: 4 to 8 MHz
Biopsy capable?	Yes
Specifications	• Length (transducer, cable, and connector): 2.1 m (7 ft) • Length (handle to tip): 30 cm (12 in) • Radius of curvature: 11.0 mm (0.43 in)

C9-5ec Description

The C9-5ec transducer is described here. For more information on connecting, activating, caring for, and maintaining transducers, see the "Transducers" and "Transducer Care" sections.

C9-5ec Endocavity Transducer

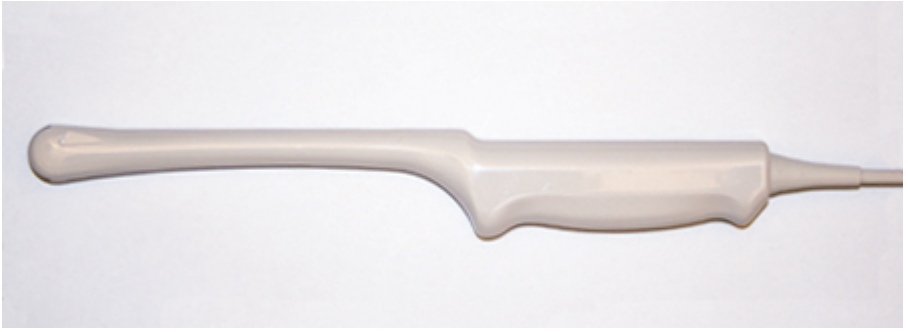
Features of the C9-5ec Transducer

Features	Curved array designed to be easy to hold and manipulate and to provide maximum clinician and patient comfort. Enables high-resolution imaging for gynecological, obstetrical, urological, and contrast studies.
Frequency	Operating range: 5 to 9 MHz
Biopsy capable?	Yes
Specifications	• Length (transducer, cable, and connector): 2.43 m (8.0 ft) • Length (handle to tip): 28.9 cm (11.4 in) • Radius of curvature: 8 mm (0.31 in)

C10-3v Description

The C10-3v transducer is described here. For more information on connecting, activating, caring for, and maintaining transducers, see the "Transducers" and "Transducer Care" sections.

C10-3v Endocavity Transducer



Features of the C10-3v Transducer

Features	Curved array designed to be easy to hold and manipulate and to provide maximum clinician and patient comfort. Enables high-resolution imaging for obstetrical, gynecological, urological, and contrast studies. Supported modes: 2D, M-mode, Color, CPA, Directional CPA, PW, and freehand 3D.
Frequency	Operating range: 3 to 10 MHz
Biopsy capable?	Yes

Specifications	• Length (transducer, cable, and connector): 2.5 m (8.17 ft) • Length (handle to tip): 30 cm (12 in) • Radius of curvature: 11.5 mm (0.45 in)

3D9-3v Description

The 3D9-3v transducer is described here. For more information on connecting, activating, caring for, and maintaining transducers, see the "Transducers" and "Transducer Care" sections.

3D9-3v Endocavity Transducer

Features of the 3D9-3v Transducer

Features	A curved array transducer with a 130-degree field of view that supports: high-resolution 2D imaging; high-resolution quantitative, single-sweep 3D volume acquisition; and 4D imaging up to 22 volumes per second for endovaginal obstetrical and gynecological applications.
Frequency	Operating range: 3 to 9 MHz
Sector angle	2D image plane: 130 degrees
Biopsy capable?	Yes
Specifications	Length (transducer and cable): approximately 2.38 m (7.8 ft) Length (handle to tip): 30 cm (12 in) Radius of curvature: 11.5 mm (0.45 in)

Patient-Contact Parts

Latex is 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 content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the "FDA Medical Alert on Latex" on page 45.

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.

12 Biopsy Guides

Biopsy guides are used to assist in the guidance of a biopsy needle. The system generates a guideline that represents the anticipated path of the biopsy needle. The echoes of the anatomical target and the tool are displayed on the video display and assist in guiding the biopsy needle to the target.

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 23.

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, 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.
- Most transducers can only be disinfected; they cannot be sterilized. Only the transducer cover provides the sterile barrier.

Biopsy Guideline Display

WARNING

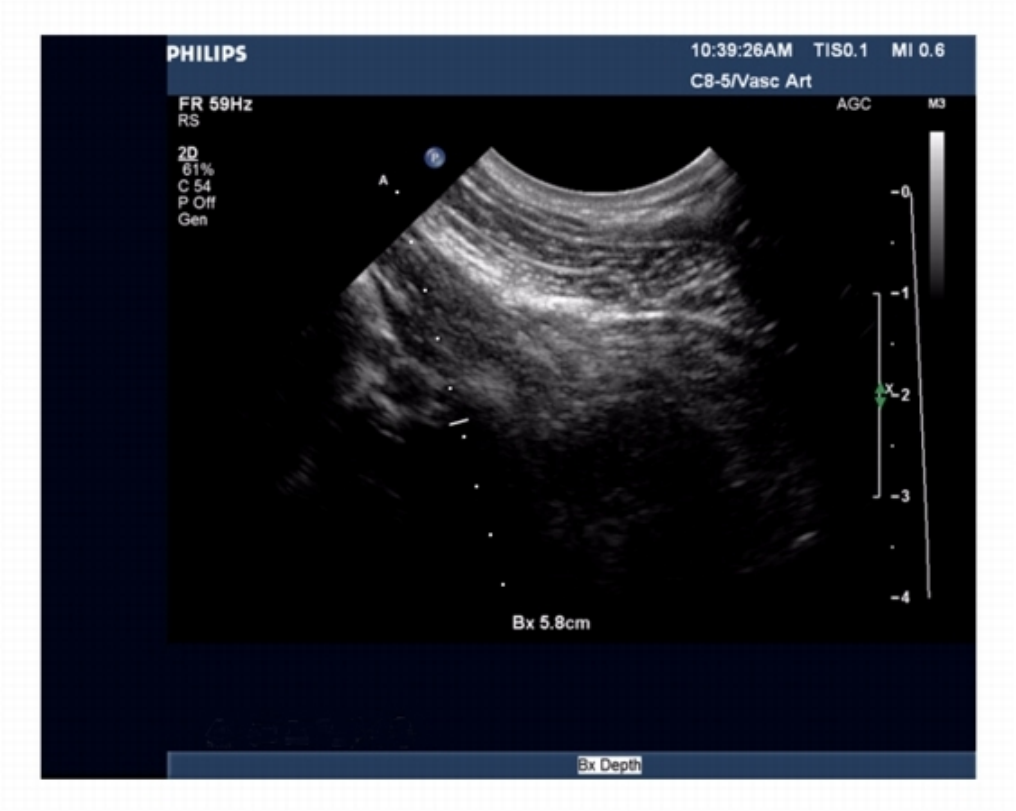
Do not attempt to use the biopsy guide until you have read the instructions for selecting the display, installing the sterile transducer cover, and verifying alignment of the biopsy guide.

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.

When the biopsy display is active, a biopsy guideline is displayed, entering from the left or right side of the screen, depending on the clinical application and image presentation you have selected. When you reverse the image presentation by touching **Left/Right**, the biopsy guideline moves to the opposite side. Image presentation is defined by the location of the orientation marker.

When depth is changed, the biopsy display redraws to reflect the new relationships at the new depth setting.

Biopsy Guideline Display



Displaying the Biopsy Guideline

The biopsy guideline can have a single, fixed path or multiple paths. The system determines which guideline to display based on the type of biopsy guide available for the transducer you have selected.

NOTE

The following procedure applies specifically to non-intervention applications.

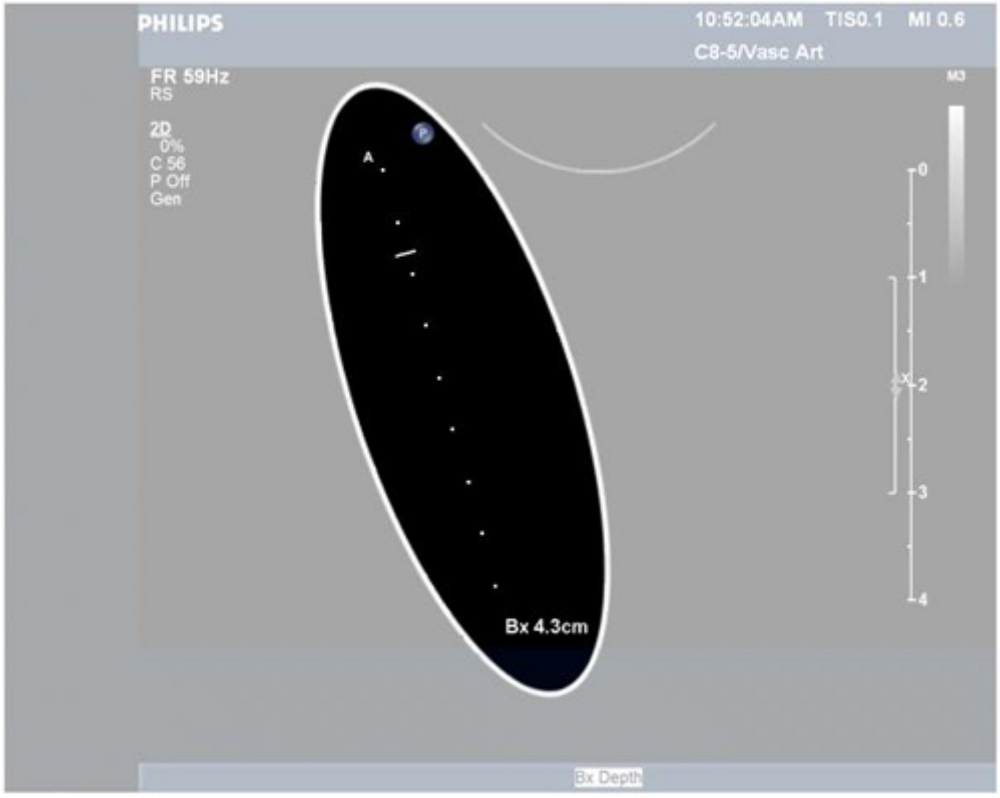
1. To turn the biopsy guideline on and off in non-intervention applications:
   a. Touch **Next** on the **2D** touch screen, and then touch **Biopsy**. The biopsy guideline appears
   b. If you are using a biopsy guide with multiple needle paths, touch the control (for example, **Angle A**, **Angle B**) that corresponds to the path you will be using.
   c. To turn the biopsy guideline off, touch **Biopsy** again.
2. To display or hide the biopsy guideline on a frozen image in non-intervention applications:
   a. With a biopsy guideline displayed and the image frozen, touch **Next** on the **2D Frozen** touch screen.
   b. Touch **Hide Guideline**. The biopsy guideline is hidden.
   c. To display the biopsy guide, touch **Hide Guideline** again.

Moving the Biopsy Depth Cursor

A depth cursor appears on the biopsy guideline. The distance from the skin line to the depth cursor appears at the bottom of the imaging screen.

Rotate the trackball to move the depth cursor along the guideline. The **Bx** measurement value changes to reflect the distance between the biopsy guide reference point origin and the depth cursor.

Biopsy Depth



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 23.)
- 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

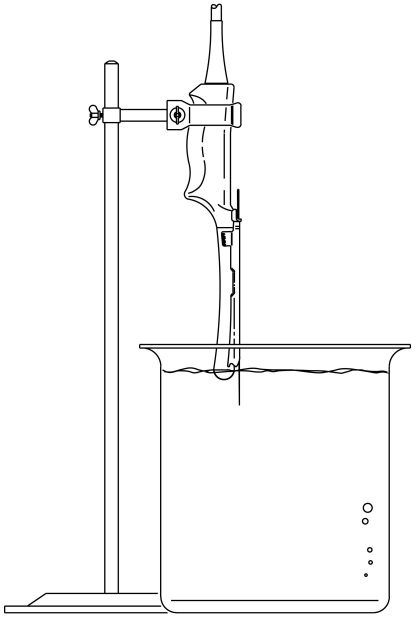
WARNING

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 clinical option and preset.
3. Set the system depth for the procedure to be performed.
4. Display the biopsy guideline.
5. Without changing the position of the biopsy depth cursor, note the default depth displayed at the bottom of the screen.
6. Immerse the transducer no more than 6 mm (0.25 in) into the water bath.

Immersing the Transducer



7. Insert the straight, new needle into the biopsy guide.

8. Move the needle down into the water bath until its ultrasound image is visible on the video display.
9. 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.
10. Remove the needle from the biopsy guide.
11. 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.
12. Immerse the transducer no more than 6 mm (0.25 in) into the water bath.
13. Insert the needle into a guide channel that corresponds to the size of the needle and the angle you selected. Continue sliding the needle in until the mark on the needle aligns with the origin on the biopsy guide. (The origin is the point at which the needle enters the biopsy guide.)
14. Move the biopsy depth cursor to the tip of the needle, as seen on the display, and verify that the displayed depth is within 0.4 cm (in) of the value noted in step 5.
15. 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 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.

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1. Install the transducer cover and the biopsy guide according to the instructions provided with the biopsy guide.
2. Set the system imaging controls for the biopsy procedure.
3. Touch **Next** on the **2D** touch screen, and then touch **Biopsy**.
4. If you are using a biopsy guide with multiple needle paths, touch the control that corresponds to the path you will be using (**Angle A**, **Angle B**, and so on).
5. Orient the transducer to match image presentation. Use the 2D scan plane orientation marker.
6. If necessary, apply sterile acoustic coupling gel to the patient.
7. Begin scanning the patient. Position the transducer so that the puncture target is intersected by the guideline displayed on the screen.
8. Do one of the following:
   - For guides with a single angle, insert the needle into the needle guide groove closest to the transducer.
   - For guides with multiple angles, insert the needle into the needle guide groove that corresponds to the angle you selected in step 4.
9. Perform the puncture by sliding the needle through the groove in the guide until the needle, as shown on the display, intercepts the target.
10. 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).

11. Remove the biopsy guide after use.

Biopsy Guide Maintenance

Observe the following warning and cautions when maintaining biopsy guides.

WARNING

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

CAUTION

Before cleaning, disinfecting, or sterilizing the biopsy guide or the transition wedge, see the "Transducer Care" section.

13 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.

Disinfectants and Gels 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 Compatibility Table" on page 304 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 287. 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, intravaginal, and transesophageal procedures, but in China and Japan, the covers are mandatory. Philips recommends the use of qualified covers.

- Bite guards are mandatory for TEE transducers. See "Electrical Safety and TEE Transducers" on page 233.
- 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 286.

For information on ordering transducer covers, contact CIVCO Medical Solutions (see "Supplies and Accessories" on page 23).

Latex Product Alert

For information on allergic reactions to latex-containing medical devices, see "FDA Medical Alert on Latex" on page 45.

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. The use of even 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 "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 293.
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 287.

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

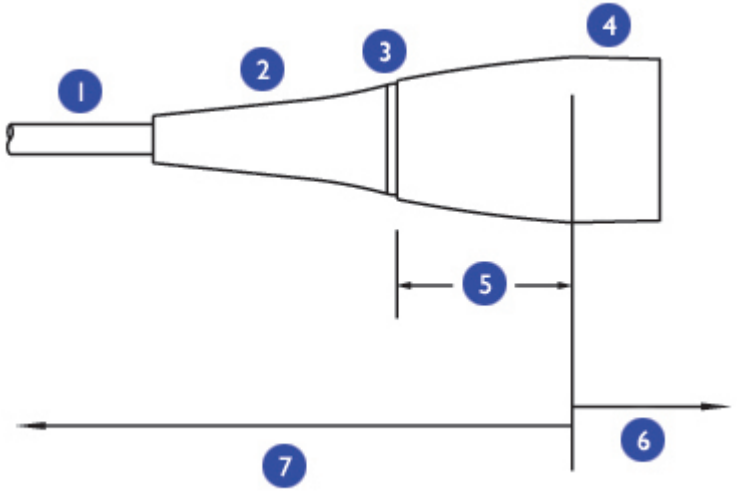
WARNING

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

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 inch)
6	You can use alcohol in this area
7	Do not use alcohol in this area

1. After cleaning the transducer and cable (see "General Cleaning for All Transducers" on page 287), 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 302.

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. To protect the electronics in the connector, Philips advises use of a Philips Connector Seal when you disinfect near the connector. Kits are available from CIVCO Medical Solutions (see "Supplies and Accessories" on page 23).

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 (provided with the transducer) 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. 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. Do not allow any type of fluid to enter the device. 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.

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.
- Avoid disinfectant contact with the connector label.

5. Mix the disinfection solution compatible with your cable (see "Disinfectants Compatibility Table" on page 304) 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.

Disinfection of Transducers by Immersion (High-Level Disinfection)

This topic provides information about using the immersion method to disinfect most transducers.

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. Residual OPA on TEE transducers may cause temporary staining of the mouth and lip area and irritation or chemical burns of the mouth, throat, esophagus, and stomach.
- 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

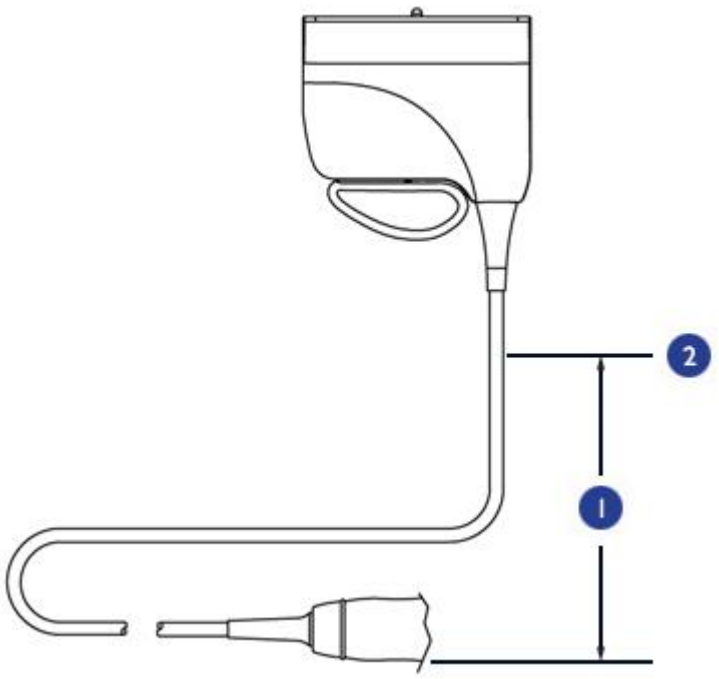
- Using non-recommended disinfectants, using incorrect solution strengths, or immersing a transducer deeper or longer than recommended can damage or discolor the transducer and voids the transducer warranty.
- Do not immerse transducers longer than the minimum time needed for your level of disinfection. For information on the levels of disinfection requirements, see "Choosing a Disinfectant" on page 287.

Disinfecting Transducers by Immersion

Before performing this procedure, read "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 293.

1. Clean the transducer according to "General Cleaning for All Transducers" on page 287.
2. Mix the disinfection solution compatible with your transducer (see "Disinfectants Compatibility Table" on page 304) according to label instructions for solution strength. A disinfectant listed in the table with the footnote “FDA 510(k) cleared” is recommended in the U.S.
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.

Disinfecting TEE Transducers by Immersion

WARNINGS

- 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. Residual OPA on TEE transducers may cause temporary staining of the mouth and lip area and irritation or chemical burns of the mouth, throat, esophagus, and stomach.

- 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).

Disinfection by immersion is the accepted method of infection control for transesophageal transducers. Philips recommends that a protective transducer cover be used during studies.

Upon receiving your new transducer, disinfect it before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from a variety of pathogens. Establish and clearly post a cleaning procedure that includes the following steps.

Before performing this procedure, read "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 293.

1. Disconnect the transducer from the system.
2. Use the following procedure 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.

- Alternatively, you may gently wipe the distal tip and flexible shaft up to the control housing (steering mechanism) with gauze pads soaked in mild, soapy water. Do not use iodine-based soaps.

3. Use water to rinse the distal tip and flexible shaft thoroughly.

CAUTIONS

- Do not bend the shaft into a circle with a diameter of less than 0.30 m (1 ft).
- Do not use bleach on the transducer and shaft.
- Do not use isopropyl alcohol-based products on the transducer and shaft.
- Do not soak the transducer for extended periods of time. Limit the time that transducers are soaked in disinfectant solution to the minimum time recommended by the disinfectant manufacturer.
- Do not rinse or immerse the connector or the portion of the cable near the connector.
- Do not immerse or rinse the steering mechanism.
- Follow the recommendations of the disinfectant manufacturer.

4. Disinfect the distal tip and flexible shaft by placing them in the appropriate disinfectant.
5. Remove the tip and shaft from the disinfectant and thoroughly rinse with water according to the instructions from the disinfectant manufacturer.
6. Check the transducer for any residual organic material. If any is present, remove it and disinfect the transducer again.
7. Gently dry the distal tip and flexible shaft with a sterile cloth or pad, or allow it to air dry.

CAUTION

The transducer steering mechanism is not sealed. If disinfectant or other fluid enters the steering mechanism, it will corrode the gears and electrical connections. Avoidable transducer damage is not covered by the warranty or service contract.

8. Lightly wipe only the steering mechanism and handle with a pad moistened with rubbing alcohol (70% isopropyl alcohol), or use approved cleaners as directed on the handle and steering mechanism.
9. Hang the transducer on a wall-mounted rack and let it air dry.

CAUTION

Never sterilize the transducer with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.

Disinfecting TEE Transducers in an Automated Disinfector

The TD-100 is an automated disinfector available from PCI Medical. For more information about this product, see www.pcimedical.com. Use this disinfector only for those transducers listed as compatible in "Disinfectants Compatibility Table" on page 304 or in the results of a compatible-solution search on the Transducer Care Web site:

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

1. Disconnect the transducer from the system.
2. Use the following procedure 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.
   - Alternatively, you may gently wipe the distal tip and flexible shaft up to the control housing (steering mechanism) with gauze pads soaked in mild, soapy water. Do not use iodine-based soaps.

CAUTION

Do not rinse or immerse the control housing, cable, or connector.

3. Use water to rinse the distal tip and flexible shaft thoroughly.
4. Disinfect the distal tip and flexible shaft in the TD-100 Automated TEE Disinfector. Follow the manufacturer's instructions for operation of the disinfector.
5. Check the transducer for any residual organic material. If any is present, remove it and disinfect the transducer again.
6. Gently dry the distal tip and flexible shaft with a sterile cloth or pad, or allow it to air dry.
7. Lightly wipe only the steering mechanism and handle with a pad moistened with rubbing alcohol (70% isopropyl alcohol), or use approved cleaners as directed on the handle and steering mechanism.
8. Hang the transducer on a wall-mounted rack and let it air dry.

CAUTIONS

- The transducer steering mechanism is not sealed. If disinfectant or other fluid enters the steering mechanism, it will corrode the gears and electrical connections. Avoidable transducer damage is not covered by the warranty or service contract.
- Never sterilize the transducer with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.

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.

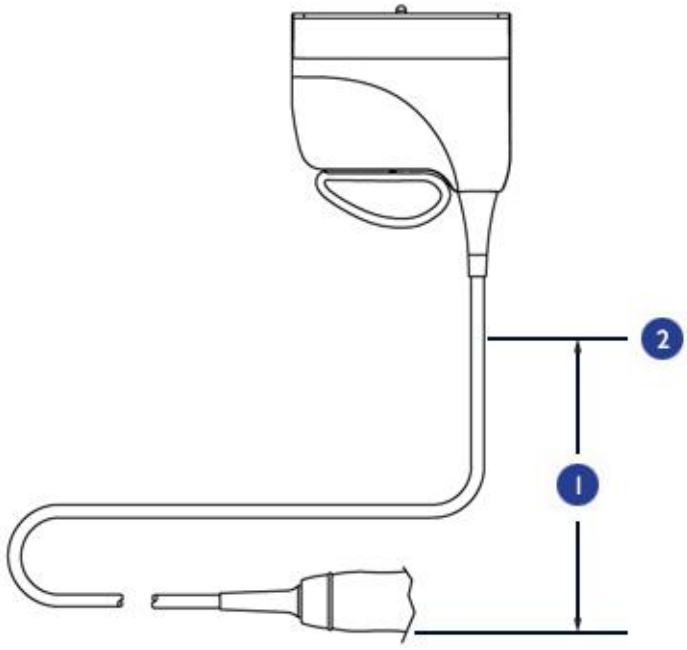
CAUTIONS

- 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 287.
2. Mix the sterilization solution compatible with your transducer according to label instructions for solution strength. A disinfectant listed in "Disinfectants Compatibility Table" on page 304 with the footnote "FDA 510(k) cleared" is recommended in the U.S.
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 Compatibility Table" on page 304 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 287. 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 solution 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, or on TEE transducers (except the handle).

See "Disinfectants Compatibility" on page 302 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 Compatibility Table

The table that follows lists the disinfectants 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.

CAUTION

The preceding recommendations do not apply to TEE transducers.

For more information:

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

Disinfectants Compatibility Table Legend

C = Approved for use on the cable N = Not approved for use T = Approved for use on the transducer H =Approved for use on the handle housing	1. FDA 510(k) cleared 2. Soak or per product instructions 3. Do not use on C8-4v transducers unless the transducer part number is 12 digits and ends with a number greater than 1. 4. Do not use on L15-7io transducers, unless the part number is 45356120781l or higher.	AU = Australia CA = Canada DE = Germany FR = France UK = United Kingdom US = United States

Disinfectants Compatibility

Solution	Origin	Qualified Use	Active Ingredients	C5-1 C5-2 C8-5 C9-4	D2cwc D5cwc D2tcd	L8-4 L9-3 L12-5 L17-5	3D6-2 3D9-3v C9-5ec V6-2 VL13-5	C8-4v C10-3v L15-7io X6-1	S3-1	S4-1	S5-1	S7-2 omni T6H	X3-1 X5-1 X7-2
70% Isopropyl Alcohol	All	Spray/Wipe	Alcohol	T	T	T	T	T	T	T	T	H	T
AbcoCide	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
AbcoCide 28	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Aidal	AU	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Aidal Plus	AU	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Alkaspray	FR	Spray/Wipe	Alcohol, Alkylamine	T	T	T	T	T	T	T	T	N	T
Ampholysine Basique	FR	Spray/Wipe	Biguanide/Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
Banicide	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Bleach (10% solution of 5.25% Bleach)	All	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
CaviWipes	US	Wipe	Alcohol, Quat. Ammonia	T	T	T	T	T	T	T	T	N	T
Cidex[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Cidex 7[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Cidex OPA[1]	US	Soak[2]	Ortho-phthal aldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Cidex PAE 14J	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Cidex Plus[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Cleanisept Wipes	DE	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
Descoton Extra	DE	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Dispatch	US	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C

Solution	Origin	Qualified Use	Active Ingredients	C5-1 C5-2 C8-5 C9-4	D2cwc D5cwc D2tcd	L8-4 L9-3 L12-5 L17-5	3D6-2 3D9-3v C9-5ec V6-2 VL13-5	C8-4v C10-3v L15-7io X6-1	S3-1	S4-1	S5-1	S7-2 omni T6H	X3-1 X5-1 X7-2
Endo FC	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Endosporine	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Enzol	US	Pre-cleaner	Enzymes	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Epizyme Rapid	AU	Pre-cleaner	Enzymes	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Gigasept FF	DE	Soak[2]	Succindialdehyde, dimethoxy tetrahydrofuran	T,C	N	T,C	T,C	T,C	N	T,C	N	N	N
Incidin	DE	Spray/Wipe	Alcohol	T	T	T	T	T	T	T	T	H	T
Incidur Spray	DE	Spray/Wipe	Alcohol, Quat. Aldehyde	T	T	T	T	T	T	T	T	N	T
Instruzyme	FR	Pre-cleaner	Enzymes, Quat. Ammonia, Biguanide	T,C	N	T,C	T,C	T,C	N	T,C	N	T	N
Kohrsolin	DE	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Korsolex PAE	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
MaxiCide Plus	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
MetriCide[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
MetriCide 28[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
MetriCide OPA Plus[1]	US	Soak[2]	Ortho-phthaldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	N	T,C
MetriCide Plus 30[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Metrizyme	US	Pre-cleaner	Enzymes	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Mild Soap Solution	All	Pre-cleaner	Surfactants/Soap	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C,H	T,C
Milton	AU	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C

Solution	Origin	Qualified Use	Active Ingredients	C5-1 C5-2 C8-5 C9-4	D2cwc D5cwc D2tcd	L8-4 L9-3 L12-5 L17-5	3D6-2 3D9-3v C9-5ec V6-2 VL13-5	C8-4v C10-3v L15-7io X6-1	S3-1	S4-1	S5-1	S7-2 omni T6H	X3-1 X5-1 X7-2
Omnicide 14NS	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Omnicide 28	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Opticide3	US	Spray/Wipe	Alcohol, Quat. Ammonia	T	T	T	T	T	T	T	T	N	T
PeraSafe Powder	UK	Soak[2]	Peracetic	N	N	N	N	T,C[3,4]	N	N	N	T	N
Perascope	UK	Soak[2]	Peracetic	N	N	N	N	T,C[3,4]	N	N	N	T	N
Phagocide D	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Phagozyme ND	FR	Pre-cleaner	Enzymes, Quat. Ammonium	T,C	N	T,C	T,C	T,C	N	T,C	N	T	N
Pro-Cide	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Pro-Cide 14NS[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Pro-Cide 28	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Pro-Cide NS	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Pro-Cide Plus	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Prolystica 2X	US	Pre-cleaner	Enzymes	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
PSS Select 14 Day	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
PSS Select 28 Day	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
PSS Select Plus	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Quaternary Ammonium	All	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
Rapicide	US	Soak	Glutaraldehyde	T,C	N	N	T,C	T,C	T,C	T,C	T,C	T	T,C

Solution	Origin	Qualified Use	Active Ingredients	C5-1 C5-2 C8-5 C9-4	D2cwc D5cwc D2tcd	L8-4 L9-3 L12-5 L17-5	3D6-2 3D9-3v C9-5ec V6-2 VL13-5	C8-4v C10-3v L15-7io X6-1	S3-1	S4-1	S5-1	S7-2 omni T6H	X3-1 X5-1 X7-2
Rivascop	FR	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
Salvanios pH 10	FR	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
Sanicloth HB	US	Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	T,C
Sanicloth Plus	US	Wipe	Alcohol, Quat. Ammonia	T	T	T	T	T	T	T	T	N	T
SDS 14 NS	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
SDS 28	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Sekucid N	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Sekusept Aktiv	DE	Soak[2]	Peracetic	N	N	T,C	N	T,C[3,4]	N	N	N	T	N
Sekusept Easy	DE	Soak[2]	Peracetic	N	N	T,C	N	T,C[3,4]	N	N	N	T	N
Sekusept Plus	DE	Soak[2]	Glucoprotamin	T,C	N	T,C	T,C	T,C	N	T,C	N	N	N
Steranios 2%	FR	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
TD-5	US	TD-100 Reprocessor	Glutaraldehyde	N	N	N	N	N	N	N	N	T	N
Trophon EPR	AU	Trophon EPR Reprocessor	Hydrogen Peroxide	T,C	N	T,C	T,C	T,C	N	T,C	T,C	N	T,C
T-Spray	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	C	TC
T-Spray II	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	T,C	T,C	T,C	T,C	T,C	T,C	H,C	TC
Vaposeptol	FR	Spray/Wipe	Alcohol, Biguanide	T	T	T	T	T	T	T	T	H	T
Vespore	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C
Virox 5 RTU	CA	Wipe	Hydrogen Peroxide	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	H,C	T,C
Wavicide -01[1]	US	Soak[2]	Glutaraldehyde	T,C	N	T,C	T,C	T,C	T,C	T,C	T,C	T	T,C

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 Ultrasound Customer Service at 800-722-9377 (North America) or your local Philips Ultrasound representative (outside North America).

14 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.

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 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 314.

WARNING

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

WARNING

Before performing maintenance or cleaning, always press the On/Off switch to turn the system off, set the power switch to off, and then disconnect the system from the wall outlet.

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; and all the external surfaces of the system and the cart; 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.

WARNING

Before performing maintenance or cleaning, always press the On/Off switch to turn the system off, set the power switch to off, and then disconnect the system from the wall outlet.

CAUTIONS

- 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.
- Do not use strong solvents, common cleaning products, or abrasive cleansers, which will damage the system surfaces.
- Do not touch the displays with sharp objects or use paper towels to clean them, which may damage them.

5. Periodically, clean all exterior surfaces of the system using a soft cloth moistened with a mild detergent solution. For disinfection information, see "Disinfectants for System Surfaces" on page 313.
6. Remove dust from the monitor screen and touch screen with a soft, lint-free cloth. A micro-fiber cloth is recommended. Clean the monitor screen and touch screen using a liquid screen cleaner specifically designed for LCDs. Spray the liquid onto the cleaning cloth or spray sparingly onto the displays. You can also use pre-moistened screen wipes. Dry the displays with a soft, lint-free cloth.

   When cleaning the system control panel, monitor screen, touch screen, and keyboard, take care not to get any solution inside the housings. Also take care not to scratch the face of the monitor while cleaning it.
7. Remove any residue with a cloth moistened with sterile water.
8. 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,

the touch 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 313.

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.
6. 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.

System Control Panel Maintenance

The system control panel and other outer surfaces are most likely to be affected by liquid spills and other materials such as excessive amounts of gel. These materials may seep into electrical components under the panel and cause intermittent failures. During preventive maintenance, look for such potential problems including loose knobs and worn controls.

Regularly clean the outside of the system as described in "Cleaning the System and ECG Equipment" on page 311.

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. Put your finger in the access hole underneath the trackball, and push the trackball up.

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.

Air Filter Cleaning

The system air filters should be inspected every week and cleaned as needed. The air filters are located in a slot at the bottom left side of the system and on the rear of the system. If you decide to clean the air filters with soap and water, you may want to install a set of spare filters while the other filters dry. Additional air filters can be ordered from Philips Ultrasound Customer Service.

You can specify the time period settings to remind you when to clean the air filter. The default setting is 365 days, but the time period for the air filter status reminder should be set according to the environmental conditions in which the system is located. For example, in an environment where a high concentration of dust is present you should select a shorter period of time (90 or 180 days). If you need assistance in determining which time period is best for your system, contact Philips Ultrasound Customer Service.

Cleaning System Air Filters

WARNINGS

- Before performing maintenance or cleaning, always press the On/Off switch to turn the system off, set the power switch to off ○, and then disconnect the system from the wall outlet.
- When a certain internal temperature is reached, the system displays a warning message and then shuts off automatically 30 minutes later. Increased internal temperature can be caused by a dirty air filter. Failure to keep the air filter clean can result in the system becoming unavailable during critical use.

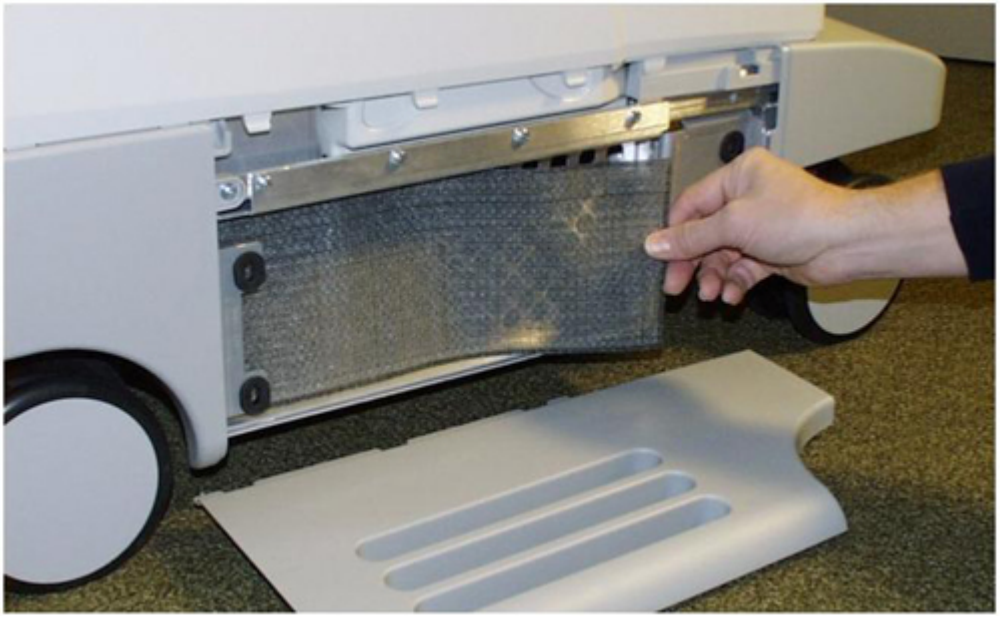
CAUTIONS

- Turn off power before you remove the air filter. Do not turn on power without the air filter installed.
- Ensure that air filter is dry before installing it. Installing a wet or damp air filter can damage the system.

1. Remove the air filter cover on the lower left side of the system by pulling the bottom of the cover toward you.

Removing the Lower Left Air Filter

2. Inspect the filter, and if it is dirty, replace it with a spare.



3. Open the air filter door on the rear of the system and lift the filter out for inspection.

Removing the Rear Air Filter

4. Inspect the filter, and if it is dirty, replace it with a spare.
5. Depending on the condition of the air filters, use either a vacuum cleaner or soap and water to clean them.

Specifying and Resetting the Air Filter Maintenance Status

1. Press the **Setup** key.
2. Click **Service**.
3. Click **Service Messages**.
4. In the **Filter Cleaning** section, select the number of days from the **Set Interval** menu and click **Done**.

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 the "Transducer Care" section of your system *User Manual*. You can also call Philips Ultrasound Customer Service at 800-722-9377 (North America), or call your local Philips Ultrasound representative (outside North America).

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 benzine, 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.

VCR and DVD Recorder Maintenance

WARNING

Before performing any maintenance on a device, always disconnect it from the source of power by either of the following: Disconnect the system from the wall outlet, if the device is internal to the system; or disconnect the device from the wall outlet, if it is external to the system.

CAUTIONS

- Do not insert a videotape into the VCR before the system has completed the initialization/warm-up phase.
- Do not move the ultrasound system with the videotape cassette in the VCR. Damage to the VCR may result.
- Do not use commercial head-cleaning products on the VCR. These products may damage the recording heads. All maintenance should be performed by a Philips Ultrasound field service engineer.
- Do not make adjustments to your VCR. Consult a Philips Ultrasound field service engineer for repair or maintenance of your VCR.
- Do not use strong solvents such as thinner or benzine, or abrasive cleaners, since these 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.

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 control. 3. Check the monitor cables and connections.
No audio comes from the system speakers.	Use the **Volume** control to ensure the speakers are not muted.

Symptoms	Corrective Action
The system failed to communicate... error message is displayed during use of voice control.	1. Ensure headset is turned on. 2. Ensure headset is paired to system. 3. Refresh the **Active Headsets** list and select your headset again.
An error message is displayed.	Run the system test (see "Testing the System" on page 325).
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. With power off, check for obstructed air filters (see "Cleaning System Air Filters" on page 316).

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, who may ask you to run the system test (see "Testing the System" on page 325).

Do not use the system if an error message is displayed.

Test Patterns

Two sets of test patterns are available for testing the image quality of the system, peripheral devices, review stations, or a PACS.

- The original set of test patterns (labeled **Test Patterns**) includes images intended for a variety of tests. Unlike the TG-18 test patterns, however, these test patterns are not tied to a unified standard.
- The newest set of test patterns was created by the American Association of Physicists in Medicine Task Group 18 (TG-18). The TG-18 test patterns on the system were adapted for the 1024 x 768 pixel image area of the 51-cm (20-in) system monitor. For information on using these test patterns, read IEC publication 61223-3-6 (62B/588/CD).

Transferring the Test Patterns

The test patterns are stored on a separate part of the system hard drive. You must transfer the test patterns to a different part of the hard drive before you can view them. The transferred test patterns remain unless you delete them.

1. Press **Review**.
2. Select **Test Imgs** from the **Drive** menu.
3. Select **TG18 Test Patterns** or **Test Patterns** from the exam selection list.
4. Click **Send to**.
5. Select **Hard Drive** and click **OK** to transfer the images.

NOTE

To view transfer progress, click the DVD drive status icon  .

Using the Test Patterns

1. Press **Review**.

2. Select **Hard Drive** from the **Drive** menu.
3. Select **TG18 Test Patterns** or **Test Patterns** from the exam selection list.
4. Click **Display Exams** and do any of the following:
   - To send a test pattern to a local printer, double-click a test pattern to display it full-screen, and press **Print** or **Alt Print**.
   - To send a test pattern to a DICOM printer or archive server, click a test pattern number to select it, click **Send To**, select a device, and click **OK**.

Testing the System

The system test is a comprehensive test of the system operational status. This test includes numerous sub-tests. If a sub-test fails, the system completes the remaining sub-tests. When run from the setups, the system test displays only a pass-fail result on the system monitor. The test can also be run from the Technical Administration application by qualified users, in which case error codes are displayed if faults are found. 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** switch.

NOTE

The system test takes approximately 15 minutes.

1. Turn on the system.
2. Disconnect all transducers from the system.
3. Press the **Setup** key.
4. Click **Service**.
5. Click the **Test and Utilities** tab.
6. In the **System Test** area, click **Run**. The system displays a message when the test is complete, indicating whether the test passed or failed.

7. Click **Cancel** or **Done** to exit the setups.

For Assistance

If you are unable to correct a problem, call your local Philips Ultrasound customer support representative.

15 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: 57.2 cm (22.5 in)
- Height: 166.4 cm (65.5 in), with monitor fully raised, to 139.7 cm (55 in) with monitor locked, depending on system configuration
- Depth: 113.0 cm (44.5 in), with control panel fully lowered
- Weight: 164.2 kg to 190.1 kg (362 to 419 lbs), depending on the peripheral devices installed

Gray Shades

255 in 2D, M-mode, and Doppler

Scan Lines

Up to 1,024 scan lines, depending on transducer and mode

Monitor

- 51-cm (20-in) flat-panel monitor on a tilt/swivel arm
- Vertical adjustment range of 120.7 to 144.8 cm (47.5 to 57 in) at the center of the screen
- 128 hues of color available

Input Signals

- S-Video with separate luma and chroma for VCR video in
- Three transducer receptacles
- Pencil probe receptacle

- High- and low-level ECG
- Physio pulse, phono, auxiliary 1, and auxiliary 2
- DVR and VCR audio (left and right)
- Microphone for DVR and VCR voice recording
- External peripheral device remote control

Output Signals

- Video: composite color, interlaced black-and-white, S-Video, and DVI-D
- VCR audio (left and right)
- External printer USB serial data
- Physio analog signal

Data Connections

- Ethernet network (10/100/1000 Mb/s)
- USB 2.0

Modality Interface

DICOM standard. DICOM conformance statements for Philips products are on this Web site:

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

Physio

- Lower Frequency Cut-off: 0.70 Hz ±10%
- Upper Frequency Cut-off: 17 Hz ±10%
- Nominal Input Amplitude: ±5 mV peak
- Minimum QRS Wave Amplitude: 0.05 mV

Peripherals

- S-VHS VCR
- DVR
- B/W video printer
- Color video printer
- Report printer

Electrical Parameters

In the United States, power must be available through a grounded, hospital-grade outlet.

The system contains a power supply designed to work with one of two voltage ranges: 100-127 Vac, 50/60 Hz, or 220-240 Vac, 50/60 Hz, both at 1,010 VA. Power must be available through a grounded, hospital-grade outlet.

Languages

Localized control panel, user interface, and documentation:

- English
- French
- German
- Italian
- Spanish

English control panel, localized keyboard and documentation:

- Danish
- Norwegian
- Swedish/Finnish

English control panel and localized documentation:

- Chinese, Traditional and Simplified
- Czech
- Dutch
- Greek
- Hungarian
- Japanese
- Polish
- Portuguese (Brazilian)
- Romanian
- Russian
- 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: 35% to 85% (with peripherals attached); 15% to 95% (without peripherals attached)
- 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 Requirements

Classification

- Class I equipment with Type B, Type BF, and Type CF applied parts
- Ordinary Equipment
- Non-AP/APG

Electromechanical Safety Standards Met

- CAN/CSA 22.2 No. 60601-1-08, Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1:2005, Medical Electrical Equipment, General Requirements for Safety
- EC 60601-1-2:2007, Collateral Standard, Electromagnetic Compatibility
- IEC 60601-2-37:2007, Particular Requirements for Safety: Ultrasonic Medical Diagnostic and Monitoring Equipment
- AMI/ANSI ES60601-1:2005, Medical Electrical Equipment, General Requirements for Safety

Index

Numbers

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

X