User Manual

English

Lumify Ultrasound System

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1 Read This First

CAUTION

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

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

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

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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 clinicians and biomedical engineers who operate and maintain your Philips product.

Intended Use

The intended use of the product is diagnostic ultrasound imaging and fluid flow analysis of the human body. The product shall provide the ability for gathering clinically acceptable images and ultrasound data for the clinical applications and anatomies listed in the table provided in “Clinical Applications and Transducers” on page 99. The clinical environments where the product can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

The Lumify Ultrasound System is intended for diagnostic ultrasound imaging in B- (2D) mode and in color Doppler (color flow). The system is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Urology, Gynecological, Cardiac Fetal, Small Organ, Musculoskeletal, Peripheral Vessel, and Carotid. Lumify is intended for use in environments where healthcare is provided by healthcare professionals, with the exception of home, ambulance, and air.

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WARNING

Do not use the system for purposes other than those intended and expressly stated by Philips. Do not misuse the system, and do not use or operate the system incorrectly.

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

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

WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis, and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

Warnings

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

WARNING

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.

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WARNING

Medical equipment must be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in the "Safety" section.

WARNING

The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.

Warning Symbols

The system uses various warning symbols. For symbols used on the system, see "Symbols" on page 28.

User Information Components

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

- *User Information CD*: Includes all of the user information, except the *Operating Notes*.
- *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, contains comprehensive instructions for using the system and includes important safety information.
- *Acoustic Output Tables*: Included on the CD, it contains information about acoustic output and patient-applied part temperatures.
- *Shared Roles for System and Data Security*: Included on the CD, it contains guidelines to help you understand security recommendations for your Philips product and information on Philips efforts to help you prevent security breaches.

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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.
- Symbols appear as they appear on the system.
- *System* and *ultrasound system* refer to the combination of a Philips transducer, the Philips Lumify app, and a compatible Android device.
- *Device* refers to a Lumify-compatible Android device.
- *Operating system* refers to the Android operating system.

The following touch gestures are used to control your system.

Touch Gestures

Gesture	Name	Description
	Drag	Touch the screen with a finger and move the finger across the screen without lifting the finger.

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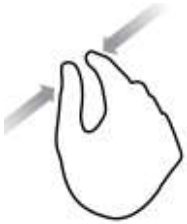
Gesture	Name	Description
	Double tap	Touch the screen briefly twice with the same finger.
	Pinch	Touch the screen with two fingers and move them toward each other.
	Touch	Touch a control with your finger.
	Touch and hold	Touch the screen for a short time without moving your finger.

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Gesture	Name	Description
	Spread	Touch the screen with two fingers and move them apart.
	Swipe	Touch the screen with your finger and move the finger in a quick motion right, left, up, or down.

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.

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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.

Supplies and Accessories

To order supplies and accessories, visit the Lumify portal (www.philips.com/lumify), or contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52247-9589

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

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

E-mail: info@civco.com

Internet: www.civco.com

System Accessories

Item	Additional Information
Cables	See “Approved Cables for Electromagnetic Compliance” on page 54.
Transducers	See “Clinical Applications and Transducers” on page 99.

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Customer Service

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

www.philips.com/lumify

Philips Ultrasound Headquarters

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

800-722-9377

Recycling, Reuse, and Disposal

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

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

Final Disposal of Your System

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Final disposal is when you dispose of the device and transducer in such a way that they can no longer be used for their intended purposes.

For information on proper disposal of your device, see the documentation that accompanies your device.

WARNING

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

Philips Healthcare gives support for the following:

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

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

www.healthcare.philips.com/us/about/sustainability/recycling

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2 Safety

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

The combination of a Philips transducer, the Philips Lumify app, and a compatible Android device is considered a medical device. 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.

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.

Basic Safety

WARNING

Do not use the system for any application until you have read, understood, and know all the safety information, safety procedures, and emergency procedures contained in this "Safety" section. Operating the system without a proper awareness of safe use could lead to fatal or other serious personal injury.

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WARNING

If *any* part of the system is known or suspected to be defective or incorrectly adjusted, *do not use* the system until it is repaired. Operating the system with defective or incorrectly adjusted components could expose you and the patient to safety hazards.

WARNING

Do not use the system for any application until you are adequately and properly trained on its safe and effective operation. If you are unsure of your ability to operate the system safely and effectively, do not use it. Operation of the system without proper and adequate training could lead to fatal or other serious personal injury.

WARNING

Do not operate the system with patients unless you have an adequate understanding of its capabilities and functions. Using the system without such understanding may compromise the system's effectiveness and the safety of the patient, you, and others.

WARNING

Never attempt to remove, modify, override, or frustrate any safety device on the system. Interfering with safety devices could lead to fatal or other serious personal injury.

WARNING

Use the system only for its intended purposes. Do not use the system with any product that Philips does not recognize as compatible with the system. Operation of the product for unintended purposes, or with incompatible products, could lead to fatal or other serious injury.

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WARNING

Stop use immediately if the system or the transducer appear to be malfunctioning. Contact your Philips representative immediately.

WARNING

You are responsible for configuring your device in accordance with your institution's security policies. Notifications and alerts from third-party applications may interfere with an exam.

WARNING

Thin needles can bend when entering tissue. Actual position must be verified by identifying the echoes from the needle.

WARNING

Do not perform a needle procedure if the needle is not visible.

WARNING

Reverberation or other tissue artifacts may produce false needle images, which can cause confusion in locating the actual needle image. Ensure that you are not using a false needle image to locate the needle.

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Electrical Safety

The transducer and software, along with a representative device, have been verified a compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device compliant with IEC 60950-1, the system meets IEC 60601-1 requirements for Class II/internally powered equipment. (The safety standards met by this system are included in the "Specifications" section.) For maximum safety, observe these warnings and cautions:

WARNING

Devices that are compliant with IEC 60950-1 have not been evaluated for compliance with the IEC 60601-1 temperature limits for patient contact. Therefore, only the operator is allowed to handle the device.

WARNING

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.

WARNING

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.

WARNING

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 25.

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WARNING

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.

WARNING

When using additional peripheral equipment that is to be interconnected by functional connection, the combination is considered to be a medical electrical 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.

WARNING

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.

WARNING

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.

WARNING

To avoid risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level.

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WARNING

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.

WARNING

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.

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 of the 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 disturbance, it may be necessary to relocate your system.

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CAUTION

For information on electromagnetic emissions and immunity as it applies to the system, see “Electromagnetic Compatibility ” on page 51. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet those conditions may degrade system performance.

Defibrillators

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

WARNING

Before defibrillation, always remove all patient-applied parts from the patient.

WARNING

Before defibrillation, always disconnect invasive transducers that remain in contact with the patient from the system.

WARNING

A disposable transducer cover provides no protective electrical insulation against defibrillation.

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WARNING

A small hole in the outer layer of the transducer opens a conductive path to grounded metal parts of the transducer. The secondary arcing that could occur during defibrillation could cause patient burns. The risk of burns is reduced, but not eliminated, by using an ungrounded defibrillator.

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

Fire Safety

WARNING

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

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

Equipment Protection

Follow these precautions to protect your system:

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CAUTION

Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system.

CAUTION

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.

CAUTION

Do not submerge the transducer connector in solution. The cables and transducer bodies are liquid-tight, but the connectors are not.

CAUTION

Do not use abrasive cleaners, or acetone, MEK, paint thinner, or other strong solvents on the system, peripherals, or transducers.

CAUTION

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.

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Product Compatibility

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

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

WARNING

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

Symbols

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

Symbol	Description
Rx only	USA federal law restricts this device to sale by or on the order of a physician.
	Isolated patient connection (Type BF applied part).

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Symbol	Description
	Identifies a caution.
	Indicates that the user should see the instructions for use for safety information.
CE 0086	Indicates conformance with European Council Directive 93/42/EEC.
EC REP	EU Authorized Representative
IP47	Indicates that the equipment inside the enclosure is protected against ingress of solid foreign objects having a diameter of 1.0 mm and greater. Indicates that the device is protected against the effects of immersion. This degree of protection can apply to transducers and 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.
GMDN	Global Medical Device Nomenclature Code

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Symbol	Description
	Global Trade Item Number
	Model name for the device.
	Identifies the date of manufacture.
	Identifies the legal manufacturer.
	This side up: Points toward the side of the shipping crate that should be kept facing up.
	Indicates that the device should be kept dry.
	Indicates that the device is fragile; handle with care.
	Do not use if damaged.
	Keep away from sunlight.

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Symbol	Description
	Non-sterile.
REF	Catalog number.
LOT	Batch code.
SN	Serial number.

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, see *Medical Ultrasound Safety* on your *User Information* CD.

WARNING

Do not use the system if an error message on the display indicates that a hazardous condition exists. Note the error code, turn off power to the system, and call your customer service representative.

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WARNING

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.

WARNING

Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.

WARNING

Use only acoustic standoffs that have been approved by Philips Ultrasound. For information on ordering approved accessories, see “Supplies and Accessories” on page 16.

WARNING

Transducer covers may contain natural rubber latex. Those covers may cause allergic reactions in some individuals. See “FDA Medical Alert on Latex” on page 33.

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.

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WARNING

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.

WARNING

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.

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.

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

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

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

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

www.fda.gov/Safety/MedWatch/

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

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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 imaging provides anatomical information, while Color imaging provides information about blood flow. 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.

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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

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

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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, focus depth, 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.

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.

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, time gain compensation (TGC), dynamic range, and image processing. The

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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.

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

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The thermal index further consists of the following indices: soft tissue (TIS), bone (TIB), and cranial bone (TIC). Only one of these is displayed at any 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 74.

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

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

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

Mechanical Index (MI) Display

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The potential for mechanical bioeffects varies with peak rarefactional pressure and ultrasound frequency. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of

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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.

but

You can choose to display TIS, TIC, or TIB. For details on changing the TI display, see “Setting the Thermal Index Display” on page 74.

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.

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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

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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 and 2D, the individual modes each add to the total TI. One mode will be the dominant contributor to this total. The displayed MI will be from the mode with the largest MI value.

2D Controls

- **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.
- **Zoom:** Increasing the zoom magnification by spreading the display 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.

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Color Controls

- **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.
- **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.

Other Control Effects

- **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.
- **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.

Related Guidance Documents

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

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- "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)
- Third Edition of the AIUM Medical Ultrasound Safety brochure, 2014. (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."

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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:

Variable	Value
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)

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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

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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/cm-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.

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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 megapascals (MPa).	Pr: 5.4%
Wo is the ultrasonic power in milliwatts (mW).	6.2%
f_c is the center frequency in megahertz (MHz) (NEMA UD-2 definition).	<1%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2).	PII.3: 3.2%

Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa).	Pr: ±11.3%
Wo is the ultrasonic power in milliwatts (mW).	±10%

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Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
f_c is the center frequency in megahertz (MHz) (NEMA UD-2 definition).	±4.7%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/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.

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Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. See “Clinical Applications and Transducers” on page 99 for a list of the transducers that are compatible with your ultrasound system.

Glutaraldehyde Exposure

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

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

www.Philips.com/transducercare

Infection Control

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

Disposable Drape

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

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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 image quality. 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 transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard allows the system to be used in all establishments except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. If the system is used in a residential environment (for which CISPR 11 Class B is normally required), you may need to relocate or reorient the system to offer adequate protection from radio frequency communication services.

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.

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CAUTION

Medical equipment has special precautions regarding EMC and must 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.

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:

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CAUTION

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.

CAUTION

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.

Electromagnetic Emissions

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

Electromagnetic Emissions: Environment Guidance

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions, CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	The system is suitable for use in all establishments, except 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 A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

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Approved Cables for Electromagnetic Compliance

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

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

Approved Cables

Cable	Type	Length	Philips Part Number
C5-2 Transducer Cable Kit	–	1.25 m (4 ft)	453561706781
L12-4 Transducer Cable Kit	–	1.25 m (4 ft)	453561806941

Approved Transducers for Electromagnetic Compliance

The imaging transducers used with the system may affect its emissions. The transducers listed in “Clinical Applications and Transducers” on page 99, when used with the system, have been tested to comply with the Group 1, Class A 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.

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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 A emissions as required by International Standard CISPR 11. Use only the accessories listed here.

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

Approved Accessories

Accessory	Manufacturer	Model Number
Ultrasonic imaging transducer	Philips	Use only the transducers listed in "Clinical Applications and Transducers" on page 99.

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.

NOTE

The guidelines specified here may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE

U_T is the AC power voltage before application of the test level.

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NOTE

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	8 kV air discharge, 6 kV contact discharge	8 kV air discharge, 6 kV contact discharge	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	Not applicable. The device does not function on AC power	- -	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	Not applicable. The device does not function on AC power	- -	Mains power quality should be that of a typical commercial or hospital environment.

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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	Not applicable. The device does not function on AC power	- -	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	3 A/m	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	3 Vrms	For recommended separation distances, see “Recommended Separation Distance” on page 59.
Radiated RF, IEC 61000-4-3	3 V/m	3 V/m	For recommended separation distances, see “Recommended Separation Distance” on page 59.

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

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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.

NOTE

Electromagnetic phenomena are not always present and may be transitory in nature. It may be extremely difficult to identify the source of the interference.

NOTE

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.

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Typical Interference on Ultrasonic Imaging Systems

Imaging Mode	ESD[1]	RF[2]	Power Line[3]
2D	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.

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

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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.

NOTE

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE

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 58, provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

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Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
0.01	0.35 m (13.8 in)	0.12 m (4.7 in)	0.23 m (9.1 in)
0.1	1.1 m (3.6 ft)	0.38 m (15 in)	0.73 m (28.7 in)
1	3.5 m (11.5 ft)	1.2 m (3.9 ft)	2.3 m (7.5 ft)
10	11 m (36.1 ft)	3.8 m (12.5 ft)	7.3 m (24 ft)
100	35 m (114.8 ft)	12 m (39.4 ft)	23 m (75.5 ft)

Ultrasound systems can be 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 58.

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:

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- 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 must determine if an artifact caused by radiated interference will have a negative impact on image quality and the subsequent diagnosis.

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3 System Overview

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

System Requirements

WARNING

Using the Lumify application on a device that does not meet the minimum specification may result in poor image quality, unexpected results, and possible misdiagnosis.

For a list of devices that Philips has tested and determined to be compatible with the Lumify app, visit the Lumify portal: www.philips.com/lumify.

Although Philips does not recommend other devices, these are minimum device specifications:

- Minimum 50 MB of storage space (plus more for patient data storage)
- Color display, minimum 15 cm (6 in)
- Touch interface
- Internally mounted speakers
- IEC 60950-1-compliant
- Date/time configuration
- Full compliance with USB On-The-Go standard
- 1280 x 800 resolution (minimum)
- Android 4.3 or later operating system
- NVIDIA Tegra3 Quad-Core CPU, 1.2 GHz (minimum)
- Wireless or cellular networking capability
- Access to ports 80 and 443

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System Capabilities

The Lumify Ultrasound System is intended for abdominal, gallbladder, general imaging, lung, musculoskeletal, OB/GYN, small parts, superficial, and vascular applications. It can be used for 2D and Color imaging. The system provides a 2D distance measurement tool.

NOTE

Voice-to-text capability depends upon your device's support for the feature and on your wireless or cellular connection.

Measurements

The system provides tools for measuring distance.

After you perform measurements, you can save the measurement by acquiring an image that contains the measurement. The system displays one measurement at a time.

Transducer Types

Available transducer types are curved array and linear array transducers. Applications for specific transducers are listed in “Clinical Applications and Transducers” on page 99.

Indications for Use and Supporting Transducers

CAUTION

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

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Ultrasound exams should be performed only for medical purposes with a prescription from a licensed physician.

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

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	Transducer
Abdominal	C5-2, L12-4
Carotid	L12-4
Cardiac Other (Fetal)	C5-2
Fetal/Obstetric	C5-2
Gynecological	C5-2
Musculoskeletal	L12-4
Small Parts	L12-4
Urology	C5-2
Peripheral Vessel	L12-4

Patient Data Protection

The Lumify app does not encrypt patient data. It is your responsibility to configure your device to meet your local security policies and regulatory requirements. Consult your healthcare-IT security department to ensure that your device is configured in accordance with your specific requirements for information security.

Philips recommends that you protect patient data by encrypting your device and setting a password or passcode as a screen lock for your device, in accordance with your institution's security policies and requirements. For instructions, see the documentation that accompanies your device.

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When you are finished using the system, you can briefly press the On/Off control on the device to lock the screen and prevent unauthorized access to patient data, or you can simply shut down the system, which logs you off automatically. For more information about patient data protection, see *Shared Roles for System and Data Security* on your *User Information* CD.

The Lumify Ultrasound System is not intended for long-term storage of patient data. Export exams frequently and delete them after they are exported. You can also delete all patient data from the Lumify system. For more information, see “Exporting Exams” on page 92 and “Deleting Patient Data and Lumify Settings” on page 78.

Wireless Networking

For information about configuring your device for wireless networking, see the documentation that accompanies your device.

It is your responsibility to configure the wireless network security mechanisms that are compatible with your network. Consult your healthcare IT security department to ensure that your device is configured in accordance with your specific requirements for information security.

System Components

The system consists of the following:

- The Philips Lumify app, available for download from the Google Play Store
- One or more Lumify Philips transducers, available with your Lumify subscription
- A compatible Android device (for a list of compatible devices, visit the Lumify portal: www.philips.com/lumify)
- A carrying bag
- User information (see “User Information Components” on page 12)

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System Components

1	Android device
2	Transducer

Data Storage

You can export exams and images to a DICOM PACS, to a network share, or to a local repository. You can also e-mail images. Supported e-mail applications include Gmail, K-9 Mail, Yahoo, Outlook, and Inbox. For more information, see “Exporting Exams” on page 92, “E-mailing Exams” on page 93 and “E-mailing Images” on page 91.

System Settings

To configure the settings for your system, touch and then select **Settings** .

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Name	Description
Audit Logs	Allows you to view audit logs, which contain actions such as exam start, exam end, and exam export or e-mail. For more information, see "Viewing Audit Logs" on page 135.
Control Orientation	Allows you to set the orientation of the display. To set the location of the imaging controls, touch **Left** or **Right**.
EU164	Philips uses this information to identify and to match your device with system logs if you require assistance.
Loop Duration	Allows you to control the duration of a loop. To set the loop length (in seconds), drag the slider. For more information about acquiring loops, see "Acquiring Loops" on page 86.
Patient Database	Allows you to repair or reset the patient database. To remove corruption in the system, touch **Repair Database**. To delete all patient data and reset the database, touch **Reset Database**. For more information, see "Deleting Patient Data and Lumify Settings" on page 78.
Power Control	Displays a control that you can use to adjust the output power.
Power Saving	Allows you to specify that the system reduce the frame rate while you are in the imaging display but not actively scanning a patient. Reducing the frame rate saves power and extends battery life.
Software Version	Provides the Lumify app version.
System Logs	Allows you to send logs to Philips in case of a system problem. For more information, see "Sending System Logs" on page 134.
Tablet Identifier	Philips uses this information to identify and to match your device with system logs if you require assistance.
Thermal Index Display	Allows you to select the thermal index that you want to display. For more information, see "Setting the Thermal Index Display" on page 74.
Transducer Serial Number	Provides the transducer serial number. The system automatically records the transducer serial number when you connect the transducer to the system.

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Name	Description
Transducer Tests	Allows you to run a series of tests to diagnose image quality issues, transducer recognition issues, or specific transducer error messages. For more information, see "Testing Transducers" on page 106.

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4 Using the System

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

Downloading and Installing the Lumify App

The Lumify app is available from the Google Play Store. The Google Play Store (https://play.google.com) is a digital media store, operated by Google, from which you can download apps for the Android operating system. Before you install the Lumify app, make sure that your device meets or exceeds the minimum specifications (see "System Requirements" on page 63) and visit the Lumify portal for a list of compatible devices:

www.philips.com/lumify

1. On your Lumify-compatible Android device, open the Google Play Store.
2. Search for Lumify. If you cannot find Lumify, your device may not meet the minimum specifications. For more information, see "System Requirements" on page 63.
3. Follow the displayed instructions to download and install the Lumify app.

Registration and Entitlement

Before you can use the Lumify app, you must register one or more transducers. The Lumify app prompts you to register when you first connect the transducer to your device.

At least once a month, make sure that your device is connected to a wireless or cellular network, with the Lumify app open and your transducers connected, so that the system can automatically reregister your transducers.

NOTE

If you upgrade the Lumify app or the Android operating system, the system prompts you to reregister the next time you connect a transducer.

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Registering Your Transducers

1. Make sure that your device is connected to a wireless or cellular network.
2. Start the Lumify App.
3. Connect your Philips transducer to your device. The first time you connect the transducer to your device, the device prompts you to **Open Lumify When This USB Device is Connected**. Select **Use By Default For This USB Device**, and then touch **OK**. The Lumify app performs a system check and registers your transducer.
4. On the **Registration Complete** display, touch **Accept** to begin using the system.

If registration fails, see “Troubleshooting” on page 135, or visit the Lumify portal for FAQs and troubleshooting tips:

www.philips.com/lumify

Updating the Lumify App

You can configure your device to update apps individually or allow them to be updated automatically.

If your Lumify-compatible device is configured to automatically update apps, the Lumify app updates automatically when an update is available, unless the update includes a permissions change. In that case, you are prompted to update the Lumify app.

If your device is configured to update apps individually, you can obtain the latest Lumify update from the Google Play Store. For more information, search for "update apps" in Google Play *Help*

Viewing the App Walkthrough

The first time you start the Lumify app, it displays a walkthrough tutorial to familiarize you with the features of the system. To begin an exam after the walkthrough ends, touch **Start Scanning**.

You can view the walkthrough at any time.

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Touch , and then touch **Walkthrough** .

Canceling Your Subscription

To cancel your subscription, visit the Lumify portal:

www.philips.com/lumify

Turning the System On and Off

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. If you close the Lumify app without ending the exam, the system pauses the exam.

NOTE

If battery power is unavailable, or if the battery charge level is critically low, disconnect the transducer and charge your device.

NOTE

Philips recommends that your device be fully charged before you start imaging. To avoid unexpected battery discharging, charge your device at regular intervals, or when the device displays the low-battery warning.

Before you turn on your device, disconnect the transducer and all peripheral devices.

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Before you turn off your device, end the current exam.

For instructions on turning the system on or off, see the documentation that accompanies your device.

Setting the System Time and Date

The Lumify app uses your device's clock and calendar function to display the time and date on the imaging display, and to provide a time stamp on patient exams and acquired images. If you change the time or date on your device, the Lumify app prompts you to restart.

For instructions on changing the time and date, see the documentation that accompanies your device.

Setting the Thermal Index Display

You can set which of the thermal indices to display depending on the type of tissue you are imaging.

1. Touch and select **Settings** .
2. In **Thermal Index Display**, select the thermal index you want.

Imaging Display

The imaging display contains an ultrasound image, exam and image information, indicators, and system controls.

The exam information includes the patient data, the current time and date, and the MI and TI values. The system does not display patient data until you start an exam.

Image information is displayed next to the image. This includes the transducer and selected preset. The controls area contains depth, gain, freeze, mode, and power controls. The location of the controls area changes depending on the orientation of your device.

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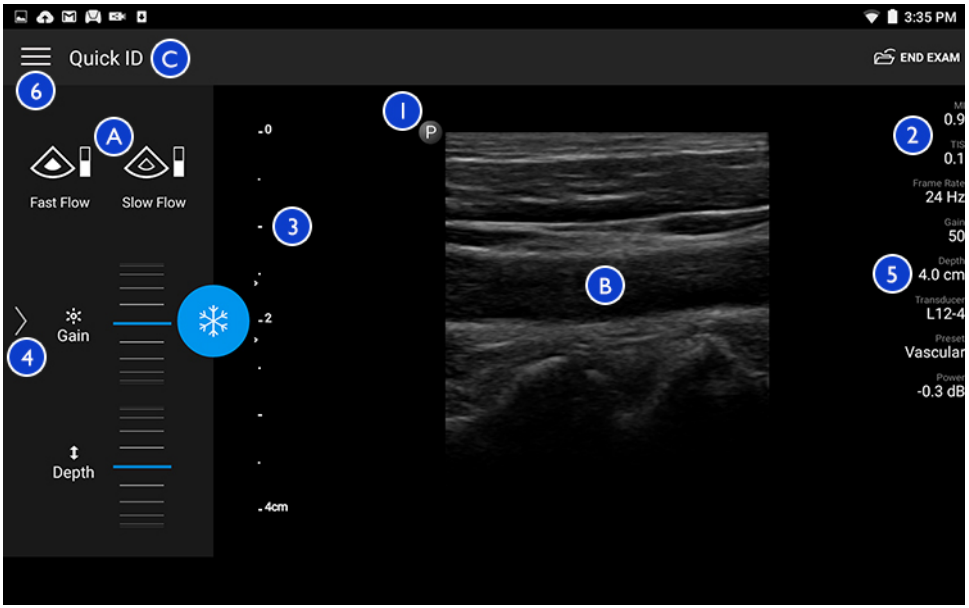

Imaging Display (Landscape Orientation)

A	Controls area
B	Image area
C	Patient information
1	Scan plane orientation marker
2	MI and TI values
3	Focal indicator
4	Page indicator: Touch the indicator to go to the next page of controls, or swipe to move between pages.
5	Image information
6	Review and settings menu

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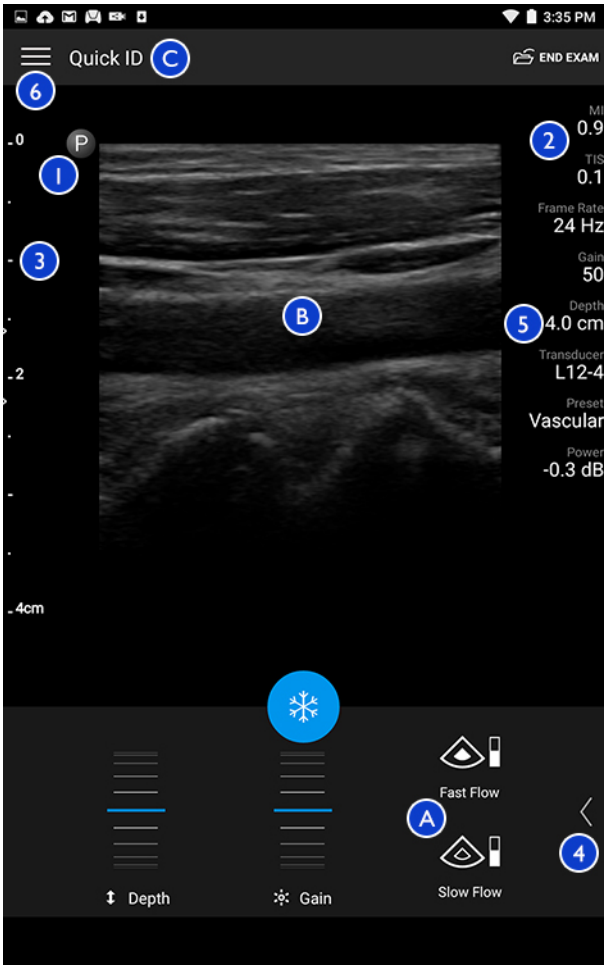

Imaging Display (Portrait Orientation)

A	Controls area
B	Image area
C	Patient information

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1	Scan plane orientation marker
2	MI and TI values
3	Focal indicator
4	Page indicator: Touch the indicator to go to the next page of controls, or swipe to move between pages.
5	Image information
6	Review and settings menu

Quick Exams

In an emergency, you can start an exam without entering patient data. This is called a quick exam. During a quick exam, the system provides a medical record number (MRN) and the words **Quick ID** appear as the patient's last name.

You can edit patient data until you end the exam.

Starting Quick Exams

CAUTION

You cannot edit patient information after you end the exam. After you end the exam, you can only view patient information. You cannot edit data for previous exams.

1. On the **Scan/Create Patient** display, select an exam preset .
2. Touch **Scan**. You can now begin imaging if you do not want to add any patient information.
3. To add patient information:
   a. On the imaging display, touch **Quick ID**.
   b. On the **Patient Info** display, type the patient information.

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c. Touch **Save and Return**.

d. Resume imaging.

Connecting Transducers

Plug the transducer into the USB port on the device. When initialization is complete, the name of the transducer appears on the imaging display.

When you first connect a transducer, the Android operating system prompts you to select whether the Lumify app should open when the transducer (USB device) is connected. If you select **Use By Default For This USB Device** and touch **OK**, the Lumify app opens whenever the transducer is connected, regardless of which app is currently open on the device.

Deleting Patient Data and Lumify Settings

You can delete all patient data and Lumify settings from the system, including data from the current exam.

Do one of the following:

- To delete only patient data, touch  and select **Settings**  . Touch **Reset Database**. Touch **Yes** to confirm.
- To delete patient data and all Lumify settings, including registration information, DICOM logs, and audit logs, in the Android operating system, go to **Settings**. Touch **Apps**, touch **Lumify**, and then touch **Clear Data**.

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5 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 and reviewing images, and making measurements.

Have a backup system present during critical exams to ensure completion of the exam in the event that the primary system fails.

NOTE

You are responsible for configuring your device in accordance with your institution's security policies. Notifications and alerts from third-party applications may interfere with an exam.

Starting New Exams

1. On the **Scan/Create Patient** display, select an exam preset.
2. Do one of the following:
   - To create a temporary Quick ID and start scanning immediately, touch **Scan**. The imaging display appears, and you can begin scanning. For more information, see “Starting Quick Exams” on page 77.
   - To enter patient information before you begin scanning, touch **Create Patient**. The last name is required. If you do not enter a medical record number (MRN), the system creates an MRN for the exam. If the system finds a matching MRN in the patient database, the system completes the remaining **Patient Info** fields. To begin scanning, touch **Start Exam**.

Changing Presets During Exams

You can change presets during an active exam.

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1. Touch .
2. Under **Current Exam** , touch a preset.

Editing Patient Data

CAUTION

You cannot edit patient information after you end the exam. After you end the exam, you can only view patient information. You cannot edit data for previous exams.

1. Touch and select **Edit Patient Info**.
2. Touch the field you want to edit and use the keyboard to replace, insert, or delete text.
3. Touch **Save and Return**.

Reviewing Saved Exams

You can review saved exams.

1. Touch .
2. Select **Saved Exams** .
3. Select an exam from the list. The exam opens in **Review**.
4. In the **Review** display, do any of the following:
   - To make a measurement on an image from a saved exam, see “Performing a 2D Distance Measurement” on page 83.
   - To delete images from a saved exam, see “Deleting Images and Loops” on page 92.

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- To e-mail images from a saved exam, see “E-mailing Images” on page 91.
- To export the exam, see “Exporting Exams” on page 92.

5. To exit the **Review** display and return to the current exam, touch and select **Current Exam** .

NOTE

You cannot add new measurements to an exam that started more than 24 hours earlier.

Restarting a Paused Exam

If you leave an exam or close the system, you can return to the open exam within 24 hours by touching and selecting **Current Exam** .

Imaging Modes

Available imaging modes are 2D and Color.

2D Mode

2D mode is the most commonly used imaging mode. In 2D mode, the image is displayed in grayscale.

Using 2D Mode

1. Start an exam. The system enters 2D mode.
2. Optimize the image, using the controls in the controls area. If necessary, touch the page indicator (or) or swipe to move between controls pages.

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- To control the image gain, adjust the **Gain**  dial.
- To increase or decrease the distance from the face of the transducer to the deepest point in the displayed image, use the **Depth**  dial.
- To increase or decrease the power output, use the **Power** dial.
- To view part of the image in more detail, spread your thumb and finger to zoom in on that area of the image. For more information, see "Zoom Magnification" on page 83.

Color Mode

In Color mode, a color box is overlaid on the 2D image; its size and position can be adjusted within the 2D image. The velocity and direction of flow in the color box are represented with different colors for direction and different shades for velocity. The colors being used appear in the color bar in the upper right corner of the imaging display.

Two color modes are available: **Fast Flow** (high color scale for arterial flow) and **Slow Flow** (low color scale for venous flow).

Using Color Mode

1. In 2D mode, optimize the image.
2. If necessary, touch the page indicator ( or ) or swipe to display **Fast Flow**  or **Slow Flow**  .
3. Touch **Fast Flow**  or **Slow Flow**  .
4. To position the color box on the anatomy of interest, drag the color box. (If you drag outside the color box, you pan the image.)
5. To change the size of the color box, pinch or spread inside the color box. (If you pinch or spread outside the color box, you zoom the image.)

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6. To control the color gain, adjust the **Gain**  dial.
7. To exit Color imaging, touch **Fast Flow**  or **Slow Flow**  .

Imaging Features

The system offers imaging features that provide improved imaging and greater flexibility when you are imaging a patient.

AutoSCAN

AutoSCAN automatically and continuously optimizes 2D image brightness at the default gain. AutoSCAN is always on.

Zoom Magnification

Using zoom magnification, you can magnify a region of interest in an image for closer examination.

With your thumb and finger, spread to expand or pinch to reduce the specific area of the image. Touch the image and move your finger to pan or move the magnified image.

NOTE

If you spread or pinch inside a color box, you resize the color box instead of zooming.

Performing a 2D Distance Measurement

A 2D distance measurement uses two calipers to measure the length of a straight line between the two points.

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You cannot zoom an image while you are using the 2D distance measurement tool. The system removes measurements from the image when it is unfrozen or when the exam ends. To retain the measurement on an image, acquire it (see “Acquiring Images” on page 85).

1. Obtain the 2D image you want to measure and touch  .
2. Touch **Measure**  . The word **Distance** and an initial value appear at the top of the image.
3. Touch the first caliper and drag to position it.
4. Touch the second caliper and drag to position it. The results update as the distance between the calipers changes.
5. To save an image with the distance shown, touch **Save Image**  .
6. To remove the measurement, touch **Measure**  .

Measurement Accuracy

You can use the ultrasound system to make measurements on ultrasound images. The measurements are then used with other clinical data to make a diagnosis.

Making a diagnosis based solely on measurements is not recommended. There are numerous factors to consider when using quantified data from any ultrasound imaging system. A careful analysis of those factors indicates that the accuracy of each measurement is highly dependent on image quality. Image quality in turn is highly dependent on system design, operator scanning technique, familiarity with system controls and, most important, patient echogenicity.

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WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

Measurement Accuracy Tables

2D Measurement Range and Accuracy

Measurement	Accuracy	Maximum Range
Axial Distance	≤ ± 2% or 2 mm	>30.0 cm
Lateral Distance	≤ ± 2.5% or 3 mm	>40.0 cm
Diagonal Distance	≤ ± 2% or 2 mm	>32.0 cm

Acquiring Images

You can acquire and save a still image from the current exam. The acquired image is saved in the patient exam, and a thumbnail of it is available in the **Review** display.

1. During live imaging, touch  .
2. To select a frame to acquire, drag the scroll bar or touch  or  to move through the images in the cineloop sequence to display the image that you want to acquire.
3. To make a measurement, touch **Measure**  . For more information, see “Performing a 2D Distance Measurement” on page 83.
4. To add a label, touch **Annotate**  . For more information, see “Adding Labels” on page 86.

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5. To save the image to the patient exam, touch **Save Image**  . The system beeps when the image acquisition is complete.

Acquiring Loops

You can acquire and save a loop from the current exam. The acquired loop is saved in the patient exam, and a thumbnail of it is available in the **Review** display. Loops in Review have the  icon in the lower right corner of the thumbnail.

The system captures loops prospectively. You can specify the loop length duration in **Settings**. For more information, see "System Settings" on page 67.

To acquire a loop during live imaging, touch **Save Loop**  .

The system beeps and a confirmation statement appears on the imaging display when the loop has been saved.

Annotation

You can place text labels on an image to identify anatomical structures and locations. The annotation feature is available in 2D and Color live and frozen modes.

Adding Labels

1. If necessary, touch the page indicator ( or ) or swipe to display **Annotate**  .
2. Touch **Annotate**  .
3. Use the on-screen keyboard to type a label. Auto-words appear to the left and right of the letters you are typing. You can touch an auto-word to add it to your label.

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4. Drag the label into position in the imaging area.
5. To edit a label:
   a. Touch the label. A line and the keyboard appear beneath it.
   b. Touch a starting point in the label and begin typing, or use the Backspace key to erase letters.
   c. Touch anywhere in the imaging area to exit annotation.
6. To delete a label, touch and hold the label. Touch **Delete Annotation** when it appears.

Ending an 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. If you turn off the system without ending the exam, the system pauses the exam before shutting down.

Each time you finish an exam, you must end the exam to save images and other exam data. You cannot end an exam while in Review.

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 acquire an image.) Ending an exam stores all exam data, clears the **Patient Info** form, and prepares for the next exam.

The system automatically ends an exam if it has been open for longer than 24 hours. You cannot append images to an ended exam.

When the exam is complete, touch **End Exam**  at the top of the imaging display.

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6 Review

In the **Review** display, you can view images and loops from the current exam or from saved exams. You can also export or e-mail images and exams from Review.

Starting Review During an Exam

To start Review during an exam:

1. Touch and select **Review Exam**.
2. To exit **Review** and return to the current exam, touch and select **Current Exam** .

Starting Review After an Exam

To start Review from the **Scan/Create Patient** display:

1. Touch and select **Saved Exams** .
2. To view an exam, select it from the list.
3. To exit **Review** and return to the **Scan/Create Patient** display, touch and select **Current Exam** .

Navigating Thumbnails and Images

In **Review**, small images, called *thumbnails*, appear on the side or bottom of the **Review** display, depending on the screen orientation. From these thumbnails, you can display one or more images and loops in their original format.

- To view a full-size image or loop, touch a thumbnail.

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- To scroll through the available thumbnails, drag the thumbnails left or right, or up or down, depending on the screen orientation.

Playing Loops

Loops are identified by the icon located in the bottom right corner of the thumbnail.

1. Touch the loop thumbnail.
2. Use the loop controls that appear beneath the loop.

Loop Controls

1	Play control. Touch to play the loop at normal speed or to pause the loop.
2	Rewind control. Touch to restart the loop from the beginning.
3	Fast Forward control. Touch to move to the end of the loop.
4	Loop time line. Drag to cycle through the loop at the specified loop speed. When the loop is paused, you can drag the line to a specific frame.

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E-mailing Images

WARNING

It is your responsibility to ensure the security of your device and of patient data to meet your local security policies and regulatory requirements. Before e-mailing images or exams, consult your healthcare IT security department to ensure that you are in compliance with your department's specific policies and regulations regarding the handling of patient information. For more information, see *Shared Roles for System and Data Security* on your *User Information* CD.

You must end the exam before you can export or e-mail images or the exam itself.

The system e-mails still images in PNG format and loops in MP4 format.

You may need to set up an e-mail client on the device before you can e-mail images. For setup instructions, see the following website and search for "configure email client":

https://support.google.com

If several e-mail accounts are available on the device, the system prompts you to select from a list of the available accounts. Possible e-mail accounts include:

- Inbox
- Gmail
- K-9 Mail
- Outlook
- Yahoo

1. In the **Review** display, touch and hold a thumbnail image. A check mark with **Done** appears in the upper left corner of the imaging display. Touch additional images to add them to the e-mail.
2. Touch **Email**  .

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3. Touch **Continue** to accept the content of the privacy notice. The device's default e-mail account opens and displays a new message with the images attached.
4. Add recipients and text to the e-mail and send the e-mail. The image is automatically attached to the e-mail.

Deleting Images and Loops

1. In the **Review** display, touch and hold a thumbnail image. A check mark with **Done** appears in the upper left corner of the imaging display. Touch additional images to delete more than one image.
2. Touch **Delete**  .
3. Touch **Yes** to confirm the deletion.

Exporting Exams

You can export exams to a DICOM PACS, to a network share, or to a local repository. See “Configuring Export Destinations” on page 95.

You must end the exam before you can export or e-mail images or the exam itself.

The system exports still images in PNG format and loops in MP4 format.

NOTE

The Lumify ultrasound system does not retain patient information in images exported to a DICOM PACS.

1. Touch  and select **Saved Exams**  .
2. Do one of the following:

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- To export a single exam, touch it to open it in **Review** and then touch **Export Exam**  .
- To export one or more exams, touch and hold an exam until **Selected Exams** appears. Touch additional exams to select them. Touch **Export**  .

3. Select a destination from the **Export Exam**  menu. (To add a new destination, select **Add New**. For more information, see “Configuring Export Destinations” on page 95.)

A confirmation message appears when the export is complete.

E-mailing Exams

WARNING

It is your responsibility to ensure the security of your device and of patient data to meet your local security policies and regulatory requirements. Before e-mailing images or exams, consult your healthcare IT security department to ensure that you are in compliance with your department's specific policies and regulations regarding the handling of patient information. For more information, see *Shared Roles for System and Data Security* on your *User Information* CD.

You must end the exam before you can export or e-mail images or the exam itself.

You may need to set up an e-mail client on the device before you can e-mail exams. For setup instructions, see the following website and search for "configure email client":

https://support.google.com

If several e-mail accounts are available on the device, the system prompts you to select from a list of the available accounts. Possible e-mail accounts include:

- Inbox
- Gmail

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- K-9 Mail
- Outlook
- Yahoo

1. Touch and select **Saved Exams**.
2. Select an exam and touch **Export Exam**.
3. On the **Export Exam** menu, select **Email**.
4. Touch **Continue** to accept the content of the privacy notice. The device's default e-mail account opens displaying a new message with the exam attached.
5. Add recipients and text to the e-mail and send the e-mail. The exam images and information are automatically attached to the e-mail.

Deleting Exams

After you have exported exams, you can delete them to save space on the system.

1. Touch and select **Saved Exams**.
2. Touch and hold an exam until **Selected Exams** appears.
3. Do one of the following:
   - To delete the selected exam, touch **Delete**.
   - To delete multiple exams, touch to select additional exams and then touch **Delete**.
   - To delete all exams, touch **Select All** and then touch **Delete**.
4. In the **Delete Confirmation** box, touch **Yes**.

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Configuring Export Destinations

You can export exams to a DICOM PACS, to a network share, or to a local repository.

1. Touch and select **Export Destinations** .
2. Touch **Add New**.
3. In the **Add New Destination** dialog box, type a **Destination Nickname** and select a **Destination Type**. Click **Continue**.
4. Configure destination settings (see “Export Destination Settings” on page 95).
5. To test the connection to the export destination, touch **Test**.
6. To save the export destination, touch **Save**.
7. To specify a default export destination, select an option from the **Automatically Export to [Option] When Exams Are Completed** menu.

Export Destination Settings

DICOM Destination Settings

Setting	Description
Device AE Title	The AE title for the device
Peer AE Title	The AE title for the server
Hostname or **IP Address**	Use a DNS or a static IP address
Port	The port number for the server
Export Format	**RLE (Lossless)**, or **JPEG (Lossy)**
Advanced Options, **Display Compensation**	**Brightness** and **Contrast**

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Setting	Description
Advanced Options, **Advanced Connection Settings**	• **DNS Suffix** • **Read Timeout (Sec)**: The network reply timeout • **Connection Timeout (sec)**: The DICOM ARTIM timeout • **Retry Interval (sec)** : How much time the system will wait before retrying a job to the server • **Maximum Retries**: How many retries the system will perform before failing the job

Network Share Destination Settings

Setting	Description
Hostname	The IP or computer name of the server hosting the network share
User	The domain and user name for the network share
Password	The password for the network share
Remote Directory	The path to the network share
Exported Filename Syntax	The order in which you select file name fields reflects the order that the field appears in the folder name for the exported content and is reflected in **Example Export Path**. For example, if you select **Last** and then **MRN**, the folder name will begin with the **Last** name, followed by the **MRN**.
Advanced Options, **Image Resolution**	Choose a resolution that matches the display on which the exam will be viewed
Advanced Options, **Display Compensation**	**Brightness** and **Contrast**
Advanced Options, **Advanced Connection Settings**	• **DNS Suffix** • **Retry Interval (sec)** : How much time the system will wait before retrying a job to the server • **Maximum Retries**: How many retries the system will perform before failing the job

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Local Directory Destination Settings

Setting	Description
Directory	Type the path to the directory in which you want to store exams
Exported Filename Syntax	The order in which you select file name fields reflects the order that the field appears in the folder name for the exported content and is reflected in **Example Export Path**. For example, if you select **Last** and then **MRN**, the folder name will begin with the **Last** name, followed by the **MRN**.
Advanced Options, **Image Resolution**	Choose a resolution that matches the display on which the exam will be viewed
Advanced Options, **Display Compensation**	**Brightness** and **Contrast**

Editing Export Destinations

You can edit, copy, rename, or delete export destinations when the system is not exporting images or exams.

1. Touch  and select **Export Destinations**  .
2. Do any of the following:
   - To edit the export destination, touch the export destination and use the keyboard to modify fields and options. Click **Save**.
   - To delete the export destination, touch and hold the export destination until **Done** appears. Touch **Delete**  . Touch **Yes** to confirm the deletion.
   - To rename the export destination, touch and hold the export destination until **Done** appears. Touch **Rename**  . In the **Rename Destination** dialog box, type a new name for the destination and touch **Rename**  .

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- To copy an export destination, touch and hold the export destination until **Done** appears. Touch **Copy**  . In the Copy Destination dialog box, type a name for the new destination and touch **Copy**  .

Viewing the Export Queue

The Export Queue displays the progress of exported exams and images. You can configure the number of export retries and the retry interval when you configure an export destination (see "Export Destination Settings" on page 95).

1. Touch  and select **Export Queue**  . If a job is in progress, the system displays it along with a status, the destination, and information about its progress.
2. If a job has failed or if you want to see details about the job while it is in progress, touch it. In the **Job Details** dialog box, do any of the following:
   - To view or edit the export destination, touch **View Destination Details**.
   - To retry the job, touch **Retry Job**.

Enabling DICOM Logging

You can enable DICOM logging to troubleshoot DICOM connectivity issues. DICOM logging is an advanced feature for IT professionals.

1. Do one of the following:
   - Touch  , select **Export Queue**  , and then touch  .
   - Touch  , select **Export Destinations**  , and then touch  .
2. To start logging, touch **Start DICOM Logging**. To stop logging, touch **Stop DICOM Logging**.
3. To view logs, touch **View DICOM Logs From [Date and Time]**.
4. To delete logs, touch **Delete DICOM Logs**.

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7 Transducers

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

The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the transducer is shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

WARNING

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

Clinical Applications and Transducers

A clinical application, available for one or more transducers, optimizes the system for a specific application. A clinical application consists of a preset for the transducer.

The clinical applications for the transducers that are compatible with your ultrasound system are listed here.

System Transducers and Supported Clinical Applications

Transducer	Clinical Applications
C5-2	Abdomen, GYN, OB, Fetal Echo, Urology
L12-4	Abdomen, Musculoskeletal, Small Parts, Vascular

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Transducer Maintenance

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

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

For all information on transducer cleaning and disinfection, see the "Transducer Care" section. For all information about the use of acoustic coupling gels, see "Ultrasound Transmission Gels" on page 104.

If you encounter poor image quality or transducer problems, see "Troubleshooting" on page 135.

CAUTION

Some ultrasound coupling gels, as well as some solutions for pre-cleaning, disinfecting, and sterilizing can damage a transducer. Before using a gel or solution on a transducer, see "Ultrasound Transmission Gels" on page 104 or the "Transducer Care" section. You can also contact your local Philips representative. For contact information, see "Customer Service" on page 17.

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.

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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.

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

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

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

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

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

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

Shadowing is the reduction in echo amplitude from reflectors that lie behind a strongly reflecting or attenuating structure. This phenomenon occurs when scanning a lesion or structure with an attenuation rate higher than that of the surrounding tissue. The lesion causes

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a decrease in beam intensity, which results in decreased echo signals from the structures beyond the lesion. Consequently, a dark cloud behind the lesion image forms on the display. This cloud, or shadow, is useful as a diagnostic clue.

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

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

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

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

Transducer Covers

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

WARNING

Latex and talc are commonly used in sheaths marketed to help with infection control during biopsies. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in “FDA Medical Alert on Latex” on page 33.

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WARNING

Sterilized transducers should be used with sterile gel and a sterile transducer cover.

WARNING

Inspect transducer covers before and after use.

WARNING

Do not apply the transducer cover until you are ready to perform the procedure.

WARNING

Sterile transducer covers are disposable and must not be reused.

Ultrasound Transmission Gels

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

CAUTION

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

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CAUTION

Do not use hand sanitizing gels.

CAUTION

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

CAUTION

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

Some recommended gels include:

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

Transducer Storage

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

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Storage for Transport

Always use the carrying bag is provided with your transducer 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 carrying bag to avoid contaminating the bag
- Place the transducer in the bag carefully to prevent kinking of the cable.

Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

- Avoid storing transducers in areas of temperature extremes or in direct sunlight.
- Store transducers separately from other instruments to avoid inadvertent transducer damage.
- Before storing transducers, make sure they are thoroughly dry.

Testing Transducers

You can run transducer tests to diagnose image quality and transducer issues.

1. Make sure that your device is connected to a wireless or cellular network.
2. Connect the transducer to your device.
3. Make sure that the transducer lens is clean, dry, and not touching anything.
4. Touch  and select **Settings**  .
5. In **Transducer Tests**, touch **Run Tests**.

The system runs a series of tests and then sends the logs to Philips Remote Services. If your device is not connected to a wireless or cellular network, the logs are queued until you have network connectivity. For more information, contact your Philips representative or visit the Lumify portal:

www.philips.com/lumify

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8 Transducer Care

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

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

The Lumify system does not support transesophageal echocardiographic (TEE) transducers, so the care and cleaning information provided is specific to non-TEE transducers.

For information on the gels that are compatible with your system's transducers, see “Ultrasound Transmission Gels” on page 104.

Transducer Care and Operator Safety

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

WARNING

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

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WARNING

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

WARNING

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

WARNING

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the disinfectant type is appropriate for the type of transducer and the transducer application. For information on the levels of disinfection requirements, see "Transducer Care Methods" on page 113. Also, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.

WARNING

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.

WARNING

When sterilizing a transducer, ensure that the sterilant solution's strength and duration of contact are appropriate for sterilization. Be sure to follow the manufacturer's instructions.

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WARNING

Follow the recommendations of the disinfectant manufacturer.

CAUTION

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

CAUTION

Do not allow sharp objects, such as scissors, scalpels, or cauterizing knives, to touch transducers or cables.

CAUTION

When handling a transducer, do not bump the transducer on hard surfaces.

CAUTION

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

CAUTION

Do not use a brush on the transducer label.

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CAUTION

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

CAUTION

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

CAUTION

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

CAUTION

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

CAUTION

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

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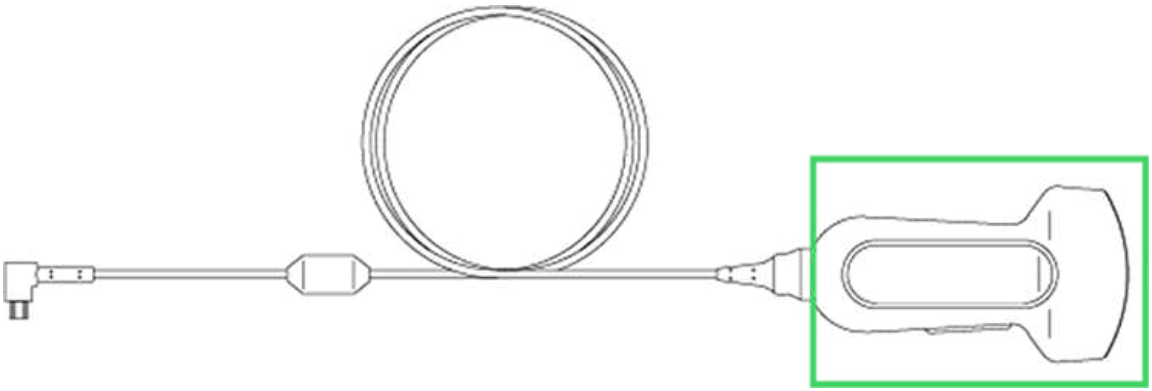
CAUTION

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

CAUTION

The only parts of the transducer that may be cleaned with isopropyl alcohol are the transducer housing and lens or acoustic window. Ensure that the solution is only 70% alcohol or less. Do not wipe any other part of a transducer with isopropyl alcohol (including cables, USB connectors, or strain reliefs), as it can damage those parts of the transducer. This damage is not covered by the warranty or your service contract.



Alcohol-Compatible Transducer Parts

The only part that can be wiped with 70% isopropyl alcohol or other alcohol-based disinfectant is the transducer housing and lens outlined above. Do not allow fluid to enter any unsealed area of the transducer.

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CAUTION

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.

CAUTION

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

CAUTION

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

Latex Product Alert

Philips ultrasound systems and transducers do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any ultrasound transducer, including transthoracic and intraoperative transducers.

WARNING

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

For information on allergic reactions to latex-containing medical devices, see “FDA Medical Alert on Latex” on page 33.

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Transducer Care Methods

Transducer care methods are based on the use of the transducer. For more information on transducer care, see the Philips "Transducer Care" website:

www.Philips.com/transducercare

Care Methods by Transducer Use

Transducer Use	Example	Classification	Care Method
Contacts intact skin	Curved, linear, and sector transducers	Noncritical	Low-level disinfection (see “Low-level Disinfecting of Transducers” on page 117)
Contacts mucous membranes	Endocavity and transesophageal (TEE) transducers	Semi-critical	High-level disinfection (see “High-level Disinfecting of Transducers” on page 118)
Enters otherwise sterile tissue	Intraoperative and laparoscopic transducers	Critical	Sterilization

The care method for your transducer determines the appropriate disinfectant for your transducer. For details about compatible disinfectants, see “Disinfectants Compatibility” on page 121.

Transducer and Cable Cleaning

These general cleaning instructions are indicated for all non-TEE transducers, cables, and connectors. It is important that you clean the transducer, cable, and USB connector according to the following procedures.

Before cleaning a transducer, read the “Safety” section and “Transducer Care and Operator Safety” on page 107.

After cleaning, you must disinfect or sterilize non-TEE transducers by following the appropriate procedures:

- “Low-level Disinfecting of Transducers” on page 117

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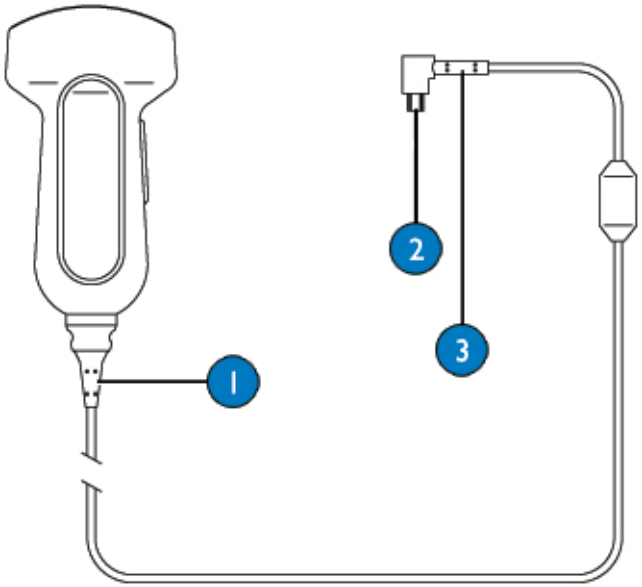
- “High-level Disinfecting of Transducers” on page 118

WARNING

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

CAUTION

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



Parts of a USB Transducer Cable

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1	Transducer strain relief
2	Electrical contacts
3	USB connector strain relief

Cleaning a Transducer

All transducers must be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization.

These general cleaning instructions must be followed for all non-TEE transducers and cables.

After cleaning, you must disinfect or sterilize non-TEE transducers by following the appropriate procedures:

- “Low-level Disinfecting of Transducers” on page 117
- “High-level Disinfecting of Transducers” on page 118

1. After every patient exam, use a moist cloth to remove the ultrasound transmission gel from the transducer.
2. Disconnect the transducer from the system, and remove any accessories attached to or covering the transducer.
3. To remove all organic matter and other residue, use a pre-cleaner or detergent to assist in removing protein residuals. Enzymatic cleaners must be diluted prior to use per the manufacturer’s instructions for dilution. Enzymatic cleaners are generically approved for use.
4. When cleaning the lens, use a blotting motion rather than a wiping motion.
5. To remove remaining particulate and cleaning residue, use cleaning wipes according to the manufacturer's instructions. You may rinse thoroughly with water up to the immersion point shown in the figure following the procedure. The transducer may be immersed up to the immersion point shown in the figure following the procedure. No other part of the transducer, cable, or USB connector can be soaked or immersed in fluids.
6. Wipe with a dry cloth if necessary. To dry the lens, use a soft cloth and a blotting motion instead of a wiping motion.

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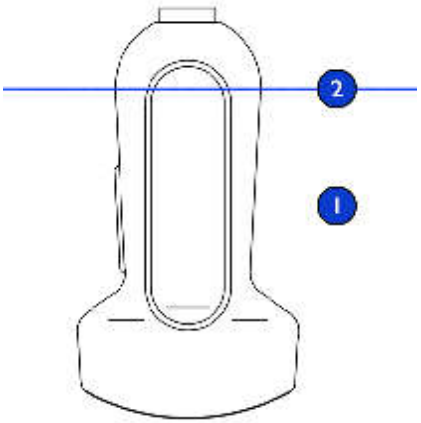
7. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your Philips representative.

NOTE

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



Immersion Point for USB Transducers

1	Immerse this portion only.
2	Maximum allowable immersion depth; you are not required to immerse to this depth if it is unnecessary.

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Low-level Disinfecting of Transducers

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

Before disinfecting a transducer, read the warnings and cautions in “Safety” and in “Transducer Care and Operator Safety” on page 107.

WARNING

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

WARNING

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

CAUTION

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

CAUTION

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

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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.

1. Clean the transducer and cable according to the procedures in “Transducer and Cable Cleaning” on page 113. Observe all warnings and cautions.
2. After cleaning, choose the low- or intermediate-level disinfection solutions compatible with your transducer, cable, and USB connector. For a list of disinfectants compatible with your transducer, see “Disinfectants Compatibility” on page 121. Follow the label instructions for preparation, temperature, solution strength and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. If a pre-mixed solution is used, be sure to observe the solution expiration date.
3. Wipe or spray the transducer, cable, strain relief, and USB connector with the disinfectant, following the disinfectant label instructions for temperature, wipe durations, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector. Do not allow any type of fluid to enter the connector. Ensure that fluid does not enter through the strain relief, through the connector, or through the electrical contacts. Fluid in the connector may void the device warranty.
4. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.
5. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your Philips representative.

High-level Disinfecting of Transducers

High-level disinfection of USB transducers typically uses an immersion method. Before disinfecting a transducer, read the warnings and cautions here and in “Safety” and “Transducer Care and Operator Safety” on page 107.

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WARNING

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

CAUTION

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

1. Clean the transducer and cable according to the procedures in “Transducer and Cable Cleaning” on page 113. Observe all warnings and cautions.
2. After cleaning, choose the high-level disinfection solutions compatible with your transducer, cable, and USB connector. For a list of disinfectants compatible with your transducer, see “Disinfectants Compatibility” on page 121. Follow the label instructions for preparation, temperature, solution strength and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. If a pre-mixed solution is used, be sure to observe the solution expiration date.
3. Using an appropriate disinfectant for the USB cable, wipe or spray the cable, strain relief, and USB connector, following disinfectant label instructions for temperature, wipe durations, solution strengths, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector. When disinfecting the USB cable, wipe or spray only the outer surfaces; do not allow any type of fluid to enter through the strain relief or electrical contacts.
4. Immerse the transducer into the appropriate disinfectant for your transducer as shown in the figure following the procedure. Follow the instructions on the disinfectant label for the duration of transducer immersion. Do not immerse transducers longer than the minimum time needed for your level of disinfection. The transducer may be immersed up to the immersion point shown in the figure following the procedure. No other part of the transducer or USB cable can be soaked or immersed in fluids.

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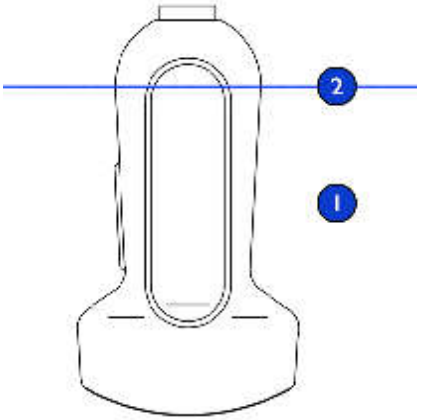
5. Using the instructions on the disinfectant label, rinse the transducer up to the point of immersion. Do not soak or immerse any other part of the transducer or USB cable.
6. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.
7. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your Philips representative.



Immersion Point for USB Transducers

1	Immerse this portion only.
2	Maximum allowable immersion depth; you are not required to immerse to this depth if it is unnecessary.

Minimizing the Effects of Residual Disinfectant

If you use an OPA-based disinfectant, residual solution may remain on your transducers if you do not carefully follow the manufacturer's instructions.

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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 rinsing transducers by immersing them three times in fresh water.
- 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.

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. For the chemical compatibility of disinfectants and cleaning solutions with specific transducers, see "Disinfectants and Cleaning Solutions for Transducers" on page 123.

Factors Affecting Disinfectant Efficacy

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

- Number and location of microorganisms
- Innate resistance of microorganisms
- Concentration and potency of disinfectants
- Physical and chemical factors
- Organic and inorganic matter
- Duration of exposure
- Biofilms

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WARNING

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 duration of contact are appropriate for the intended clinical use.

WARNING

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.

WARNING

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

WARNING

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

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WARNING

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the disinfectant type is appropriate for the type of transducer and the transducer application. For information on the levels of disinfection requirements, see "Transducer Care Methods" on page 113. 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

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.

CAUTION

The only parts of the transducer that may be cleaned with isopropyl alcohol are the transducer housing and lens or acoustic window. Ensure that the solution is only 70% alcohol or less. Do not wipe any other part of a transducer with isopropyl alcohol (including cables, USB connectors, or strain reliefs), as it can damage those parts of the transducer. This damage is not covered by the warranty or your service contract.

Disinfectants and Cleaning Solutions for Transducers

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

Based on material compatibility testing, product use profile, and active ingredients, Philips has approved for use the following types of low-level disinfectants used as a spray or wipe for surface (skin contact) and transvaginal or transrectal probes, according to the compatibility restrictions in the table:

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- Sodium hypochlorite based (for example 10% household bleach solution with active sodium hypochlorite at approximately 0.6%)
- Quaternary ammonium (QUAT) based (for example, products that contain n-alkyl (x)benzyl ammonium chloride solution where (x) can be any organic functional group such as ethyl and methyl, and so on; concentration at use should be less than 0.8% total for all QUATs listed)
- Accelerated hydrogen peroxide based (0.5% hydrogen peroxide maximum)
- Alcohol or alcohol plus QUAT based (product alcohol content cannot exceed 70%)
- You may also use products not specifically listed in the compatibility table but with similar active ingredients, as indicated in this list, and marketed for medical use

Always follow the manufacturer's instructions when using disinfectants and cleaning solutions.

Because of the large number of available cleaning and disinfection products, it is impossible to have an all-inclusive list. If you are unsure of the suitability of a particular product, please contact your Philips representative for more information:

- www.philips.com/transducercare
- In North America, call Philips at 800-722-9377.
- Outside North America, contact your local Philips representative.

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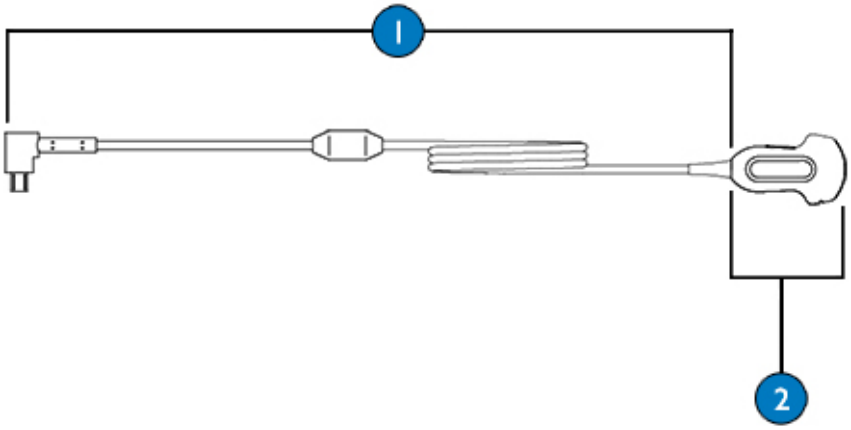
Disinfectants and Cleaning Solutions Compatibility Table Legend

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



Non-TEE Transducers (Micro-USB Connector)

1	C (Cable and connector)
2	T (Transducer)

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Disinfectants and Cleaning Solutions for Transducers

Solution	Origin	Qualified Use	Active Ingredients	Type	C5-2 L12-4
70% Isopropyl Alcohol	All	Spray/Wipe	Alcohol	LLD, ILD	T
AbcoCide	US	Soak[1]	Glutaraldehyde	HLD, S	T
AbcoCide 28	US	Soak[1]	Glutaraldehyde	HLD, S	T
Accel Wipes (all types)	CA	Wipe	Hydrogen Peroxide	LLD, ILD	T,C
Acecide	JP	Soak[1]	Peracetic acid	HLD	N
Aidal Plus	AU	Soak[1]	Glutaraldehyde	HLD, S	T
Alkaspray	FR	Spray/Wipe	Alcohol, Alkylamine	LLD, ILD	T
Ampholysine Basique	FR	Spray/Wipe	Biguanide/Quat. Ammonia	LLD, ILD	T,C
Aniosept Activ	FR	Soak[1]	Peracetic acid	HLD, S	T
ANIOXY DM	FR	Soak[1]	Peracetic acid	HLD, S	T
Anioxyde 1000	FR	Soak[1]	Peracetic acid	HLD	T
Antigermix E1	FR	E1 System	UV-C	HLD	N
Antigermix S1	FR	S1 System	UV-C	HLD	T,C
Banicide Plus	US	Soak[1]	Glutaraldehyde	HLD, S	T
Bleach (0.6% NaOCl Max)	All	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T,C
CaviWipes	US	Wipe	Alcohol, Quat. Ammonia	LLD, ILD	T
Cidex	US	Soak[1]	Glutaraldehyde	HLD, S	T
Cidex 7	US	Soak[1]	Glutaraldehyde	HLD, S	T
Cidex OPA	US	Soak[1]	Ortho-phthalaldehyde	HLD	T
Cidex PAE 14J	FR	Soak[1]	Glutaraldehyde	HLD, S	T

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Solution	Origin	Qualified Use	Active Ingredients	Type	C5-2 L12-4
Cidex Plus	US	Soak[1]	Glutaraldehyde	HLD, S	T
Cleanisept Wipes/forte	DE	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
Clorox Healthcare Bleach Germicidal Cleaner	US	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T,C
Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectants	US	Spray/Wipe	Hydrogen Peroxide	LLD, ILD	T,C
Combi-Instruments-N	FR	Soak[1]	Glutaraldehyde and formacetale blend	HLD	T
Descoton Extra	DE	Soak[1]	Glutaraldehyde	HLD, S	T
Dispatch	US	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T,C
Endosporine	FR	Soak[1]	Glutaraldehyde	HLD, S	T
Enzol	US	Pre-cleaner	Enzymes	CL	T
Epizyme Rapid	AU	Pre-cleaner	Enzymes	CL	T
Gigasept FF (neu)	DE	Soak[1]	Succinic dialdehyde	HLD	T
Gigasept PA	DE	Soak[1]	Peracetic acid	HLD	T
Gigasept PAA Concentrate	DE	Soak[1]	Peracetic acid	HLD	T
Incidin	DE	Spray/Wipe	Alcohol	LLD, ILD	T
Incidur Spray	DE	Spray/Wipe	Alcohol, Quat, Aldehyde	LLD, ILD	T
Instruzyme	FR	Pre-cleaner	Enzymes, Quat. Ammonia, Biguanide	CL	T
Klenzyme	US	Pre-cleaner	Enzymes	CL	T
Korsolex Basic	FR	Soak[1]	Aldehyde Releasing	HLD	T

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Solution	Origin	Qualified Use	Active Ingredients	Type	C5-2 L12-4
Korsolex Extra	FR	Soak[1]	aldehydes/Quaternary Ammonium	HLD	T
Korsolex PAE	FR	Soak[1]	Glutaraldehyde	HLD, S	T
MaxiCide Plus	US	Soak[1]	Glutaraldehyde	HLD, S	T
MedDis	UK	Soak[1]	Quat. Ammonia, Sulfamic Acid	HLD	T
Medistel	UK	Soak[1]	Quat. Ammonia, Sulfamic Acid	HLD	T
Medizyme	AU	Soak[1]	Enzymes	CL	T
MetriCide	US	Soak[1]	Glutaraldehyde	HLD, S	T
MetriCide 28	US	Soak[1]	Glutaraldehyde	HLD, S	T
MetriCide OPA Plus	US	Soak[1]	Ortho-phthalaldehyde	HLD	T
MetriCide Plus 30	US	Soak[1]	Glutaraldehyde	HLD, S	T
MetriZyme	US	Pre-cleaner	Enzymes	CL	T
Mikrozid PAA wipes	DE	Wipe	Peracetic acid	LLD, ILD	T,C
Mild Soap Solution	All	Pre-cleaner	Surfactants/Soap	CL	T
Milton	AU	Spray/Wipe	Sodium Hypochlorite	LLD, ILD	T,C
NDP Med Concentrated Plus	ES	Soak[1]	N-Duopropenide, Alkylamine	HLD	T
Neodisher endo CLEAN / Neodisher endo SEPT PAC	DE	AER	Peracetic acid	CL, HLD	N
Neodisher endo DIS active	DE	Soak[1]	Peracetic acid	HLD	T
Olympic Peracetic Acid	UK	AER	Peracetic acid	HLD	N

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Solution	Origin	Qualified Use	Active Ingredients	Type	C5-2 L12-4
Omnicide 14NS	US	Soak[1]	Glutaraldehyde	HLD, S	T
Omnicide 28	US	Soak[1]	Glutaraldehyde	HLD, S	T
OPAL	AU	Soak[1]	Ortho-phthalaldehyde	HLD	T
Opti-Cide 3	US	Spray/Wipe	Alcohol, Quat. Ammonia	LLD, ILD	T
Oxivir (all types)	US	Spray/Wipe	Hydrogen Peroxide	LLD, ILD	T,C
Oxygenon-I	FR	Soak[1]	Oxygen Generating	HLD	T
PeraSafe	UK	Soak[1]	Peracetic acid	HLD, S	T
Perascope	UK	Soak[1]	Peracetic acid	HLD	T
Perastel	UK	AER/Soak[1]	Peracetic acid	HLD	T
PerCept (all types)	CA	Spray/Wipe	Hydrogen Peroxide	LLD, ILD	T,C
Phagocide D	FR	Soak[1]	Glutaraldehyde	HLD, S	T
Phagozyme ND	FR	Pre-cleaner	Enzymes, Quaternary Ammonium	CL	T
PI-Spray	US	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
PI-Spray II	US	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
ProCide-D	US	Soak[1]	Glutaraldehyde	HLD, S	T
ProCide-D Plus	US	Soak[1]	Glutaraldehyde	HLD, S	T
Prolystica 2X	US	Pre-cleaner	Enzymes	CL	T
Protex Disinfectant Spray	US	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
Quaternary Ammonium (0.8% Active Max)	All	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
Rapicide	US	Soak[1]	Glutaraldehyde	HLD, S	T

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Solution	Origin	Qualified Use	Active Ingredients	Type	C5-2 L12-4
Rapicide OPA	US	Soak[1]	Ortho-phthalaldehyde	HLD	T
Rapicide PA	US	Soak[1]	Peracetic acid	HLD	N
Revital-Ox Resert XL HLD	US	Soak[1]	Hydrogen Peroxide	HLD	T
Rivascop	FR	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
Salvanios pH 10	FR	Spray/Wipe	Quat. Ammonia	LLD, ILD	T,C
Sani-Cloth Active	DE	Wipe	Quat. Ammonia	LLD, ILD	T,C
Sani-Cloth AF	US	Wipe	Quat. Ammonia	LLD, ILD	T,C
Sani-Cloth AF3	US	Wipe	Quat. Ammonia	LLD, ILD	T,C
Sani-Cloth HB	US	Wipe	Quat. Ammonia	LLD, ILD	T,C
Sani-Cloth Bleach	US	Wipe	Sodium Hypochlorite	LLD, ILD	T,C
Sani-Cloth Plus	US	Wipe	Alcohol, Quat. Ammonia	LLD, ILD	T
Sekucid N	FR	Soak[1]	Glutaraldehyde	HLD, S	T
Sekusept Aktiv	DE	Soak[1]	Peracetic acid	HLD	T
Sekusept Easy	DE	Soak[1]	Peracetic acid	HLD	T
Sekusept Plus	DE	Soak[1]	Glucoprotamine	HLD	T
Soluscope P	FR	AER	Peracetic acid	HLD	N
Steranios 2%	FR	Soak[1]	Glutaraldehyde	HLD, S	T
Sterrad 100S	US	Reprocessor (S)	Hydrogen Peroxide	S	N
TD-5	US	TD-100 Reprocessor	Glutaraldehyde	HLD, S	N
Tristel Duo	UK	Foam /Wipe	Chlorine Dioxide	HLD	T,C

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Solution	Origin	Qualified Use	Active Ingredients	Type	C5-2 L12-4
Tristel Fuse for Instruments	UK	Stella System	Chlorine Dioxide	HLD	T
Tristel Multi-Shot	UK	Stella System	Chlorine Dioxide	HLD	T
Tristel Sporicidal Wipes	UK	Wipe	Chlorine Dioxide	HLD	T,C
Tristel Trio Trace	UK	Pre-clean wipe, Sporicidal wipe, Rinse wipe	Enzymes, Chlorine Dioxide	HLD	T
Trophon EPR	AU	Trophon EPR Reprocessor	Hydrogen Peroxide	HLD	N
Vaposeptol	FR	Spray/Wipe	Alcohol, Biguanide	LLD, ILD	T
Virox 5 RTU	CA	Wipe	Hydrogen Peroxide	LLD, ILD	T,C
Wavicide -01	US	Soak[1]	Glutaraldehyde	HLD, S	T
Wip'Anios	FR	Wipe	Alcohol, Quat. Ammonia	LLD, ILD	T

[1] Never immerse or soak a connector.

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9 System Maintenance

Maintenance should be performed regularly and as needed.

Because the system is a piece of medical equipment, Philips recommends that only trained personnel service the system.

Device Maintenance

WARNING

If the system becomes contaminated internally with bodily fluids containing 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.

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 your responsibility to appropriately clean and disinfect your device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.

Transducer Maintenance

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

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

For all information on transducer cleaning and disinfection, see the "Transducer Care" section. For all information about the use of acoustic coupling gels, see "Ultrasound Transmission Gels" on page 104.

If you encounter poor image quality or transducer problems, see "Troubleshooting" on page 135.

CAUTION

Some ultrasound coupling gels, as well as some solutions for pre-cleaning, disinfecting, and sterilizing can damage a transducer. Before using a gel or solution on a transducer, see "Ultrasound Transmission Gels" on page 104 or the "Transducer Care" section. You can also contact your local Philips representative. For contact information, see "Customer Service" on page 17.

Sending System Logs

The Lumify app sends system logs to Philips periodically. You can explicitly send system logs to Philips in case of a system problem. For information about privacy, see the Lumify Privacy Notice (touch , touch **About**, and then touch **Privacy Notice**).

1. Touch and select Settings .
2. In **System Logs**, touch **Send Logs**.

The system uploads the logs and notifies you when the upload has completed.

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Viewing Audit Logs

Audit logs record information about access to patient data, including when exams began and ended, and when exams were exported, sent by e-mail, or deleted.

1. Touch and select **Settings**.
2. In **Audit Logs**, touch **View Audit Logs**.
3. Select an audit log from the list.
4. If prompted, choose an application that can display plain text files in which to view the log.

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 representative, or visit the Lumify portal:

www.philips.com/lumify

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

Troubleshooting

Symptom	Corrective Action
The system does not power up.	Verify that the device is fully charged.
The system spontaneously reverts to the **Scan/Create Patient** display.	Verify that the device is fully charged.

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Symptom	Corrective Action
The system does not recognize a connected transducer.	Disconnect the ultrasound USB cable from the transducer and connect a standard Type A to Micro B USB cable. Connect the temporary cable and the transducer to a Windows PC. Open the **Device Manager**. If the transducer is working properly, **PiUsb** appears in **Other Devices**. If you do not see **PiUsb**, contact your Philips representative for a replacement transducer or cable.
The system continuously reinitializes the transducer when attempting to image.	Verify that the device is fully charged.
Registration fails.	Make sure that you have constant wireless or cellular network connectivity throughout the registration process, and make sure that the transducer cable is firmly connected to your device.
Image artifacts appear.	Run the transducer test. See “Testing Transducers” on page 106.

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 representative.

For Assistance

If you are unable to correct a problem, call your local Philips representative or visit the Lumify portal:

www.philips.com/lumify

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The Lumify portal includes a list of frequently asked questions (FAQs) which can help you troubleshoot problems.

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10 Specifications

The Lumify system conforms to the following specifications:

System Specifications

Gray Shades

255 in 2D

Scan Lines

Up to 1,024 scan lines

Languages

User interface and documentation in English only.

Pressure, Humidity, and Temperature Limits

These limits apply only to the Philips Lumify transducers, not to the Android device on which you run the Lumify app. It is your responsibility to select a Lumify-compatible device that meets the needs of your clinical environment. For information about your device's environmental specifications, consult the documentation that accompanies your device.

	Operating Limits	Storage Limits
Pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa
Humidity	15 to 95%	0 to 95%
Temperature	5°C (41°F) to 40°C (104°F)	-34°C (-29°F) to 70°C (158°F)

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Safety and Regulatory Requirements

Classification

- Device with transducers: Class II/internally powered ME equipment. Transducers: Type BF applied parts, IP47
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

Electromechanical Safety Standards Met

The transducers and software comply with the requirements of IEC 60601-1 Medical Electrical Equipment, General Requirements for Safety, including all applicable collateral and particular standards, as well as all applicable deviations. System users are responsible for ensuring that the chosen device is compliant with the law in the jurisdiction in which the product is used.

Compliance

Philips products comply with relevant international and national standards and laws. Information on compliance will be supplied by your local Philips representative, or the manufacturer, on request.

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