



User Manual

English

Lumify Diagnostic Ultrasound System

PHILIPS

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1 Read This First

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

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

Transducers are available only in countries or regions where they are approved. For information specific to your region, contact your local Philips representative.

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CAUTION

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

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 healthcare professionals who operate and maintain your Philips product.

Intended Use/Indications for Use

The Intended Use of the product is to collect ultrasound image data that may be used by clinicians for diagnostic and procedural purposes. The product shall provide the ability for gathering clinically acceptable images and ultrasound data for the clinical presets and anatomies listed in [“Indications for Use and Supporting Transducers” on page 91](#).

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 Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), and M-mode. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac, Lung.

The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.



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.

Clinical Benefits

The expected clinical benefits of the Lumify Diagnostic Ultrasound System are related to the device's intended purpose to provide diagnostic ultrasound imaging and fluid flow analysis of the human body. These clinical benefits can be broadly classified as providing real-time noninvasive or minimally invasive visualization of the internal organs and anatomy to assist in providing a medical evaluation and diagnosis to direct patients' medical care. Because the Lumify Diagnostic Ultrasound System provides images of human anatomy without the use of ionizing radiation, the system can provide information about a patient's health status, without the risks of some other medical imaging modalities.

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.

**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. For more information, see [“Recommended Separation Distance” on page 84](#).

User Information Components

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

- *User Information* USB media: 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.
- *Care and Cleaning of Ultrasound Systems and Transducers*: Included on the USB media. Describes care and cleaning procedures for your ultrasound system and transducers.
- *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*: Included on the USB media. Provides information about compatible cleaning and disinfecting products for your ultrasound system and transducers.
- *User Manual*: Provided with the product and included on the USB media. 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.
- *User Information Update*: If required, contains updated information about the product.
- *Quick Guide*: Provided with the product and included on the USB media. The *Quick Guide* outlines basic features and step-by-step instructions for common functions.
- *Acoustic Output Tables*: Included on the USB media, it contains information about acoustic output and patient-applied part temperatures.
- *Medical Ultrasound Safety*: Included on the USB media, it contains information on bioeffects and biophysics, prudent use, and implementing ALARA (as low as reasonably achievable).

- *Shared Roles for System and Data Security*: Included on the USB media, it contains guidelines to help you understand security recommendations for your Philips product and information on Philips' efforts to help you prevent security breaches.
- *Using Ultrasound to Manage COVID-19 Related Lung and Cardiac Complications*: Included on the USB media, it contains imaging instructions and information pertinent to healthcare professionals engaged in the diagnosis and management of COVID-19 patients.

Some user information is also available on the **Support** section of the Lumify website:

www.philips.com/lumify

You can find user information here:

www.philips.com/IFU

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.
- *Select* means to touch an object on the display to "highlight" the object (such as an item in a list), or in the case of a check box or when selecting options, to fill the object. *Deselect* means touching the item to remove the highlight or fill.
- *System* and *ultrasound system* refer to the combination of a compatible Android or iOS device, a Philips transducer, the Philips Lumify app, and the Lumify Power Module (LPM) that is used with iOS devices only. Information that applies only to a specific device is marked.

- *Device* refers to Lumify-compatible mobile devices.
- *Operating system* refers to the Android and iOS operating systems.





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.
	Double-tap	Touch the screen briefly twice with the same finger.
	Pinch	Touch the screen with two fingers and move them toward each other.

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Gesture	Name	Description
	Touch	Touch a control with your finger.
	Touch and hold	Touch the screen for a short time without moving your finger.
	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.

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.

For more information, see [“Updating the Lumify App” on page 106](#).

Supplies and Accessories

For product and accessories information, visit the Lumify website:

www.philips.com/lumify

To order transducer covers and other supplies, 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 76.
Transducers	See “Presets and Transducers” on page 188.
Lumify Power Module (LPM)	(iOS devices only) See “Approved Accessories for Electromagnetic Compliance” on page 77.
Adhesive mounting plate	(iOS devices only) Philips part number: 453562010901.
Case with LPM mounts for iPad 10.2-inch mobile devices	Philips part number: 453562064171.
Case with LPM mounts for iPad 9.7-inch mobile devices	Philips part number: 453561999211.
Case with LPM mounts for iPad mini 5 mobile device	Philips part number: 453562064161.
Case with LPM mounts for iPhone 11 and iPhone XR mobile devices	Philips part number: 453562064151.
Case with LPM mounts for iPhone X and iPhone XS mobile devices	Philips part number: 453561999231.
Case with LPM mounts for iPhone 7 and iPhone 8 mobile devices	Philips part number: 453561999221.

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Customer Service

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

www.philips.com/lumify

Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431
USA

Regulatory Representatives

Australian Sponsor

Philips Electronics Australia Ltd
65 Epping Road
North Ryde NSW 2113
Australia

Brazilian Representative

Responsável Técnico
Thiago Medeiros de Abreu
CREA/SP: 5070149021
Detentor do Registro
Philips Medical Systems Ltda.
Av. Marcos Penteado de Ulhoa Rodrigues, 401 Setor Parte 39 – Tamboré
Barueri/SP, Brasil – CEP 06460-040
Registro: ANVISA 10216710372

Malaysian Authorized Representative

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Philips Malaysia Sdn. Berhad (3690-P)
Level 9, Menara Axis
2 Jalan 51A/223
46100 Petaling Jaya
Selangor Darul Ehsan, Malaysia
Telephone: 03-7965 7488
Lumify Registration No.: GB11274413717

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 and training. Philips designs and manufactures equipment in compliance with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

The European Union Directive on Waste Electrical and Electronic Equipment (WEEE) requires producers of electrical and electronic equipment to provide reuse and treatment information for each product. This information is provided in a Philips Recycling Passport. Such recycling passports for Philips ultrasound systems are available on this website:

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

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

Passing Your Transducer to Another User

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

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

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

Final Disposal of Your Device



If you are subscribing to the transducer, at the end of your Lumify subscription, you must return your transducer or transducers to Philips. Do not dispose of the transducers. For more information, see the **Support** section of the Lumify website:

www.philips.com/lumify

If you purchased the transducer outright, Philips gives support for the following:

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

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

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

Final disposal of your device is when you dispose of the device in such a way that it can no longer be used for its intended purpose.

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



WARNING

Do not dispose of the device (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The 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.

Discarding Batteries

Mobile device batteries are internal to the mobile device. Do not attempt to remove the batteries from a mobile device. Instead, discard the mobile device.

The Lumify Power Module (LPM) for iOS devices includes a removable battery. The LPM battery should be discarded at the end of its usable life or if there are visual signs of damage.

Batteries and mobile devices should be discarded in an environmentally safe manner. Properly dispose of batteries and mobile devices according to local regulations.



WARNING

Do not disassemble, puncture, or incinerate batteries. Be careful not to short the battery terminals, because that could result in a fire hazard.

**WARNING**

Use caution when handling, using, and testing the batteries. Do not short circuit, crush, drop, mutilate, puncture, apply reverse polarity, expose to high temperatures, or disassemble. Misuse or abuse could cause physical injury.

**WARNING**

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

Perchlorate Material

The device may contain perchlorate material in its batteries. Special handling may apply to the device batteries. For more information, see this website:

www.dtsc.ca.gov/hazardouswaste/perchlorate

2 Safety

Read this information before using your ultrasound system. It applies to the device, the transducers, and the software. This section covers only general safety information. 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 or a compatible iOS device with a Lumify Power Module 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.

Report any serious safety incident that occurs in relation to the ultrasound system to Philips and to the competent authority of the country in which the user and patient are established.



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 ultrasound systems without a proper awareness of safe use could lead to fatal or other serious personal injury.



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

The transducers have small, detachable parts that pose a choking hazard, and the transducer cable is a strangulation hazard. Do not leave children unattended with the system.



WARNING

Do not use the system for any application until you are adequately and properly trained on ultrasound techniques. Sonography training and clinical procedures are not included in the system user information. If you are unsure of your ability to use ultrasound techniques safely and effectively, do not use the system. Operating ultrasound systems 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 misuse the system. 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.

**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**

This ultrasound system is MR unsafe and presents a projectile hazard. Keep outside of the MRI scanner room.

Electrical Safety

The transducer and software, along with a representative device, have been verified as 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 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 34.](#)

**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**

All external devices and peripherals that you connect to the system must meet the safety standards defined by IEC 60601-1 or IEC 60950-1. This applies to all USB, HDMI, and serial input/output connections.

**WARNING**

Before you connect the system to a LAN, ensure that the LAN devices (for example, a router) are certified to IEC 60601-1 or IEC 60950-1.

**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 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 μ A.

**WARNING**

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

**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**

To avoid the risk of electrical shock, do not charge your Lumify system while scanning a patient.

**WARNING**

To avoid patient contact with the device while it is charging, do not charge the system while inside the patient environment.

**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.

**CAUTION**

For information on electromagnetic emissions and immunity as it applies to the system, see **“[Electromagnetic Compatibility](#)” on page 73**. 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; however, defibrillation-proof ECG leads may remain connected. The system will reestablish normal physio operation within 8 seconds after the application of a defibrillation pulse.

**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.

**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

Fire safety depends on fire prevention, isolating the cause, and extinguishing the fire. If you see evidence of smoke or fire, disconnect system power. Observe the following warnings when using the system.

**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.

**WARNING**

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.

**WARNING**

Damage to lithium-ion batteries may result in fire.

Equipment Protection

Follow these precautions to protect your system:

**WARNING**

To avoid improper operation, do not place the system adjacent to nor stacked with other equipment. If it becomes necessary to stack the system with or place it adjacent to other equipment, verify normal operation before use.

**WARNING**

If the system or transducers have been in an environment above 40°C (104°F), allow them to cool to operating temperature before turning on the system or connecting the transducers. Do not allow the transducer to contact the patient if the temperature of the transducer is higher than 43°C (109°F). Allow 25 minutes for the transducer to cool. If the transducers were only briefly exposed to temperatures above 40°C (104°F), then the time required for the devices to return to operating temperature could be less than 25 minutes.

**CAUTION**

If the system or transducers have been in an environment below 0°C (32°F), allow them to reach operating temperature before turning on the system or connecting the transducers. Allow 20 minutes for the transducers to warm to operating temperature. Otherwise, condensation inside the devices could cause damage. If the transducers were only briefly exposed to temperatures below 0°C (32°F), then the time required for the devices to return to operating temperature could be less than 20 minutes.

**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 immerse 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.

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 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. The following symbols may be used on your product, its accessories, or its packaging.








Symbol	Standards and Reference	Reference Description	Additional Information
Safety			
	ISO 15223-1, Symbol 5.4.4 ISO 7000-0434A	Caution (ISO 7000-0434A).	--



Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.4.3 ISO 7000-1641	Consult instructions for use.	--
	ISO 7010, Symbol M002	Refer to instruction manual/booklet.	--
	IEC 60417, Symbol 5019	Protective Earth; Protective ground.	--
	IEC 60417, Symbol 5017	Earth; ground.	--
	IEC 60417, Symbol 5021	Equipotentiality.	--
	IEC 60417, Symbol 5840	Type B applied part.	Non-isolated patient connection.
	IEC 60878, Symbol 5333 IEC 60417, Symbol 5333	Type BF applied part.	Isolated patient connection.
	IEC 60417, Symbol 5335	Type CF applied part.	Isolated patient connection for applied part intended for intraoperative use, including direct cardiac application and contact with major vessels.
	IEC 60417, Symbol 5334	Defibrillation-proof Type BF applied part.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417, Symbol 5336	Defibrillation-proof Type CF -- applied part.	--
	ISO 15223-1, Symbol 5.4.2 ISO 7000-1051	Do not reuse.	--
	ISO 7010, Symbol P017	No pushing.	Warns of system overbalance due to external force.
	IEC 60417, Symbol 5036	Dangerous Voltages.	Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	IEC 62570	MR Unsafe.	System is MR unsafe and presents a projectile hazard. Keep outside of the MRI scanner room.
Rx only	--	--	Rx Only. (USA federal law restricts this device to sale by or on the order of a physician.)
	--	--	Indicates a hazard to patients with pacemakers. Do not place field generator within 200 mm (8 in) of a patient with a pacemaker.
	--	--	Indicates a possible pinch hazard when positioning the monitor.

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Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 7010, Symbol W024	Warning: Crushing of hands.	--
	--	--	Warns that the system should not be used stacked with other equipment. If the system is used stacked with or adjacent to other equipment, verify normal operation before use.
	ISO 15223-1, Symbol 5.2.8 ISO 7000-2606	Do not use if package is damaged.	--
 www.philips.com/IFU	--	--	Consult the electronic instructions for use (eIFU).
	ISO 15223-1, Symbol 5.2.7 ISO 7000-2609	Non-sterile.	--
	ISO 15223-1, Symbol 5.2.3 ISO 7000-2501	Sterilized using ethylene oxide.	--
	ISO 15223-1, Symbol 5.1.4 ISO 7000-2607	Use-by date.	--











Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417, Symbol 5134	Electrostatic sensitive devices.	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	IEC 60417, Symbol 5140	Non-ionizing electromagnetic radiation.	Indicates that interference may occur in the vicinity of equipment marked with this symbol (IEC 60601-1-2).
Environmental			
IPX1	IEC 60529	Degrees of protection provided by enclosures (transducers).	Indicates that the device is protected against the effects of vertically falling water.
IPX4	IEC 60529	Degrees of protection provided by enclosures (foot-operated device).	Indicates that the device is protected against the effects of splashing liquids.
IPX7	IEC 60529	Degrees of protection provided by enclosures (foot-operated devices).	Indicates that the device is protected against the effects of immersion.
IPX8	IEC 60529	Degrees of protection provided by enclosures (foot-operated device or transducer).	Indicates that the device is protected against the effects of immersion for up to 60 minutes.








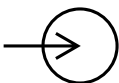

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Symbol	Standards and Reference	Reference Description	Additional Information
IP44	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of solid foreign objects having a diameter of 1.0 mm and greater. Indicates that water splashed against the enclosure from any direction shall have no harmful effect.
IP47	IEC 60529	Degrees of protection provided by enclosures (foot-operated device or transducer).	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 for up to 30 minutes at 1 m of submersion.
	IEC 60417, Symbol 5957	For indoor use only.	--
	ISO 15223-1, Symbol 5.3.7 ISO 7000-0632	Temperature limit.	Indicates the temperature range (noncondensing) for transport and storage. Does not apply to media.
	ISO 15223-1, Symbol 5.3.9 ISO 7000-2621	Atmospheric pressure limitation.	Atmospheric pressure range for transport and storage.
	IEC 15223-1, Symbol 5.3.8 ISO 7000-2620	Humidity limitation.	The relative humidity range (noncondensing) for transport and storage.
	ISO 7000, Symbol 0623	This way up.	Points toward the side of the shipping crate that should be kept facing up.







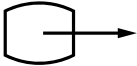
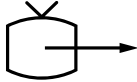
Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.3.4 ISO 7000-0626	Keep dry.	--
	ISO 15223-1, Symbol 5.3.1 ISO 7000-0621	Fragile, handle with care.	--
	ISO 15223-1, Symbol 5.3.2 ISO 7000-0624	Keep away from sunlight.	--
	EN 50419:2006 WEEE Directive 2002/96/EC	WEEE symbol. 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.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	--	Product contains hazardous material. Dispose of properly. (Required by WEEE Directive; see EN 50419.)	--
	IEC 60878, Symbol 1135 ISO 7000-1135	General symbol for recovery/recyclable.	Do not throw away. Dispose of in accordance with local, state, or federal laws.
Connectors and Ports			
	IEC 60417, Symbol 5032	Alternating current.	--
	IEC 60417, Symbol 5031	Direct current.	--
	IEC 60417, Symbol 5010	"ON"/"OFF" (Push-Push).	
	IEC 60417, Symbol 5009	Stand-by.	On/Off control with Stand-by.
	--	--	On a two-position power switch, represents On () and Off ().
	--	--	Connection for a pencil probe.

Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Connection for a pencil probe.
	--	--	Connection for a transducer.
	--	--	Connection for ECG and physio leads.
	--	--	Connection for ECG and physio leads.
	--	--	Print remote output.
	-	-	Input port for audio left/right, VHS/ S-VHS, microphone, CD, or DVD.
	--	--	Output port for audio left/right, VHS/ S-VHS, video patient monitor, black- and-white printer, or interlaced RGB output port.
	IEC 60417, Symbol 5034	Input.	--
	ISO 7000, Symbol 3650	USB Port.	--









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Symbol	Standards and Reference	Reference Description	Additional Information
	--	FireWire (IEEE 1394) input/ output port.	--
	IEC 60878 Symbol 5988	Computer Network.	Ethernet connection.
	IEC 60878, Symbol 5850	Serial Interface.	RS-232 serial port.
	--	--	System microphone.
AUX POWER ISOLATE OUTPUT	--	--	Isolated auxiliary power provided for connection of Philips-approved remote accessories.
	IEC 60417, Symbol 5114	Foot switch.	--
	IEC 60878, Symbol 5051	Television Monitor.	SVGA, DVI-I, DisplayPort, or HDMI connection.
	IEC 60878, Symbol 5529A	Video Output.	S-Video connection.
	--	--	Video output. S-Video connection.


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

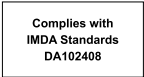




Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	B/W Composite video output connection.
	--	--	Color composite video output connection.
	IEC 60878, Symbol 0093	Remote Control.	Video print trigger connection.
	--	--	VGA or parallel output port.
 	--	--	DVI video output receptacle.
	IEC 60417, Symbol 5016	Fuse.	Identifies fuse boxes or their locations. For continued protection from fire and shock, replace fuses only with fuses of the same type and rating.
Product Data Identifiers			
	--	--	Identifies the total mass of the system, including its safe working load, in kilograms. Indicates compliance with IEC 60601-1, Cl. 7.2.21.








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Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60878, Symbol 2794 ISO 7000-2794	Packaging unit.	--
GMDN	--	--	Global Medical Device Nomenclature Code.
GTIN	--	--	Global Trade Item Number.
LOT	ISO 15223-1, Symbol 5.1.5 ISO 7000-2492	Batch code.	--
MD	--	--	Indicates that the item is a medical device.
MOD	--	--	Model name for the device.
REF	ISO 15223-1, Symbol 5.1.6 ISO 7000-2493	Catalog Number.	--
SH	--	--	System hardware.
SN	ISO 15223-1, Symbol 5.1.7 ISO 7000-2498	Serial Number.	--




Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Service part number / field-replaceable unit (FRU) number.
	--	--	Unique Device Identifier.
	--	--	Universal part number.
	--	--	Unique Device Identifier, 2D barcode.
	ISO 15223-1, Symbol 5.1.3 ISO 7000-2497	Date of Manufacture.	--
	ISO 15223-1, Symbol 5.1.1 ISO 7000-3082	Manufacturer.	--
	IEC 60417	Country of Manufacture.	--
	ISO 7000-3724	Distributor.	--
	ISO 7000-3725	Importer.	--
Regulatory Compliance			

Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60878, Symbol 5172	Class II Equipment.	--
	--	--	UL (Underwriters Laboratories) classification symbol.
	--	--	Indicates that the electrical and electronic equipment is in compliance with Infocomm Media Development Authority (IMDA) Standards.
	--	--	With an identification code (for example, 2AFNP-RIVNGFF525A), indicates that the system uses an embedded, FCC-approved Rivet Networks wireless adapter.
	--	--	With an identification code (for example CCAI15LP0780T9), indicates that the system uses an embedded NCC-approved (Taiwan) Rivet Networks wireless adapter.
	--	--	CSA (CSA Group) classification symbol.
	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE Mark of Conformity	--

Symbol	Standards and Reference	Reference Description	Additional Information
	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE0086 - CE Mark of Conformity	--
	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE2797 - CE Mark of Conformity	--
	ISO 15223-1, Symbol 5.1.2	Authorized Representative in the European community.	--
	--	--	Customs Union Mark of Conformity (EurAsian Conformity Mark).
	--	--	Chinese Environmentally Friendly Use Period symbol.
 UA.TR.116	--	--	Indicates that the system conforms with the Ukrainian Scientific Institute of Certification (UA.TR.116).
	--	--	Australian and New Zealand (RCM) Regulatory Compliance Mark indicates compliance with electrical safety, EMC, EME, and telecommunications requirements.

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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	KC (Korea Certification) mark for electrical and electronic equipment.
	--	--	INMETRO mark as issued by SGS. Indicates third-party approval in Brazil.
	--	--	INMETRO mark as issued by TUV. Indicates third-party approval in Brazil.

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* included on the *User Information* USB media.



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 authorized service representative.



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. For information on ordering approved accessories, see [“Supplies and Accessories” on page 19](#).

**WARNING**

Transducer covers may contain natural rubber latex and talc. Those covers may cause allergic reactions in some individuals. See [“FDA Medical Alert on Latex” on page 55](#).

**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.

**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.

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.

NOTE

The transducers described in this document do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducer.

ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the "as low as reasonably achievable" (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would

be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

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

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

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

Applying ALARA

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

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

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

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 manual selection. Ultimately, the user has the responsibility for proper clinical use. The ultrasound system provides both automatic (default) settings and manual (user-selectable) settings.

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

Indirect Controls

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

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

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

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

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

Receiver Controls

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

An Example of Applying the ALARA Principle

An ultrasound scan of a patient's liver begins with selecting the appropriate transducer frequency. After selecting the transducer and the application, which are based on patient anatomy, adjustments to output power should be made to ensure that the lowest possible setting is used to acquire an image. After the image is acquired, adjusting the focus of the transducer, and then increasing the receiver gain to produce a uniform representation of the tissue follows. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should you increase output to the next level.

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

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

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

Additional Considerations

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

Output Display

The system output display comprises two basic indices: a mechanical index and a thermal index. The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

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 109](#).

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

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

- Appropriate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface, as in a cranial exam.
- Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays?
- Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.

- Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

Mechanical Index (MI) Display

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

Thermal Index (TI) Displays

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

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

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

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

You can choose to display TIS, TIC, or TIB. For details on changing the TI display, see [“Setting the Thermal Index Display” on page 108](#).

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* USB media. Those accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability, as discussed in this section.

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values in interrogated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the measurement standards in IEC 62359: Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields. The measurements are then put into algorithms for calculating the displayed output values.

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

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

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

pulser voltages. Inaccuracies in laboratory measurements are related to, among others, differences in hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability among test operators.

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

Therefore, the display accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by measuring according to, the IEC 62359 measurement standards, or the effects of nonlinear loss on the measured values.

Control Effects

Controls Affecting the Indices

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

Power

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

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

2D Controls

- **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.

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. If PW Doppler is also enabled, then PW Doppler will remain the dominant mode and the TI change will be small.
- **Color Sector Depth:** Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, the TI will decrease with increased color sector depth. MI will correspond to the MI of the dominant pulse type which is a color pulse. However, if PW Doppler is also enabled then PW Doppler will remain the dominant mode and the TI change will be small.
- **Sector Width:** A narrower 2D sector width in Color imaging will increase color frame rate. The TI will increase. MI will change little, if at all. If PW Doppler is also enabled, then PW Doppler will remain the dominant mode and the TI change will be small.

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:

- "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.
- Third Edition of the AIUM "Medical Ultrasound Safety" document, 2014. (A copy of this document is provided with each system.)
- "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" FDA, June 2019.
- IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields.
- 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 IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields, and the June 2019 FDA document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

In Situ, Derated, and Water Value Intensities

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

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

Where:

Variable	Value
<i>In Situ</i>	<i>In Situ</i> intensity value
<i>Water</i>	Water value intensity
<i>e</i>	2.7183
<i>a</i>	Attenuation factor
<i>Tissue</i>	a(dB/cm-MHz)
<i>Amniotic Fluid</i>	0.006
<i>Brain</i>	0.53
<i>Heart</i>	0.66

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Variable	Value
Kidney	0.79
Liver	0.43
Muscle	0.55
<i>l</i>	Skin line to measurement depth (cm)
<i>f</i>	Center frequency of the transducer/system/mode combination (MHz)

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

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

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

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

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

Conclusions Regarding Tissue Models and Equipment Survey

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

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predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

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

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate *in situ* acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/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/cm². 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* USB media.

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 ISO/IEC Guide 98-3 (Uncertainty of Measurement - Part 3: Guide to the Expression of Uncertainty in Measurement), 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%
P is the ultrasonic power in milliwatts (mW).	6.2%
f _{awf} is the center frequency in megahertz (MHz).	<1%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm ²).	PII.3: 3.2%

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Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa).	Pr: ±11.3%
P is the ultrasonic power in milliwatts (mW).	±10%
f _{awf} is the center frequency in megahertz (MHz).	±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.

Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. For a list of the transducers that are compatible with your ultrasound system, see [“Presets and Transducers” on page 188](#).

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.

To reduce the presence of glutaraldehyde fumes in the air, be sure to use a covered or ventilated soaking basin. Such systems are commercially available.

Infection Control

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

Removing Blood and Infectious Material from the System

It is important to clean and maintain the ultrasound system and peripherals. If the equipment has come in contact with blood or infectious material, clean and disinfect the system and peripherals according to the instructions in the [“System Maintenance”](#) section.

Disposable Drape

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

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, the Lumify Power Module (if supplied), and the representative Android or iOS device are classified as Group 1, Class B 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, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

**WARNING**

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

**CAUTION**

Medical equipment has special precautions regarding EMC and 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:




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

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

Approved Cables

Cable	Length	Philips Part Number
(Android devices only) Transducer Cable, USB Type-B to Type-B (C5-2, L12-4, S4-1)	1.75 m (5.7 ft)	453561871782
Transducer Cable, USB Type-C to Type-B (C5-2, L12-4, S4-1)	1.75 m (5.7 ft)	453561854692
Transducer Cable, Glenair Mighty Mouse to USB Type-B (CS-2, L12-4, S4-1)	1.4 m (4.6 ft)	453561943061

Approved Transducers for Electromagnetic Compliance

The imaging transducers used with the system may affect its emissions. The transducers listed in [“Presets and Transducers” on page 188](#), when used with the system, have been tested to comply with the Group 1, Class B emissions, as required by international standard CISPR 11. Use only those transducers.

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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.

Approved Accessories for Electromagnetic Compliance

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

When connecting other accessories to the system, such as a 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 B-compliant devices, unless otherwise noted.



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.

Approved Accessories

Accessory	Manufacturer	Model Number or Part Number
Ultrasonic imaging transducer	Philips	Use only the transducers listed in “Presets and Transducers” on page 188.
Lumify Power Module (LPM)	Philips	Philips part number: 453561998451
Transducer Cable, USB Type-B to Type-B (C5-2, L12-4, S4-1)	Philips	453561871782

Electromagnetic Immunity

The system conforms to the professional healthcare environment intended use and the corresponding immunity test levels specified by IEC 60601-1-2 Edition 4, and is not intended for sale to the general public.



CAUTION

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

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

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

Electromagnetic Immunity: Environment Guidance

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD), IEC 61000-4-2	± 8 kV contact, ± 15 kV air	Same as IEC 60601-1-2 test level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst, IEC 61000-4-4	± 2 kV for power supply lines, ± 1 kV for input/output lines > 3 m	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	± 0.5, ± 1, ± 2 kV common mode ± 0.5, ± 1 kV differential mode on AC line	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on AC lines, IEC 61000-4-11	Dips: 100% for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° Dips: 100% for 1.0 cycle at 0° Dips: 30% for 30 cycles at 0° Interruption: 100% for 5 seconds	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, Philips recommends that the system be powered from an uninterruptible power supply or a battery.

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Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency magnetic fields, IEC 61000-4-8	30 A/m	Same as IEC 60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF, IEC 61000-4-6	3 VRMS (0.15–80 MHz) 6 VRMS (ISM bands) AM 80% depth 1 kHz tone on AC line and I/O cables	Same as IEC 60601-1-2 test level	See “Electromagnetic Interference” on page 82.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF, IEC 61000-4-3	3 V/m (80–2,700 MHz) AM 80% depth 1 kHz tone	Same as IEC 60601-1-2 test level	See “Electromagnetic Interference” on page 82.
Proximity fields from RF wireless communications, IEC 61000-4-3	385 MHz 27 V/m, 450 MHz 28 V/m, 710 MHz 9 V/m, 745 MHz 9 V/m, 780 MHz 9 V/m, 810 MHz 28 V/m, 870 MHz 28 V/m, 930 MHz 28 V/m, 1,720 MHz 28 V/m, 1,845 MHz 28 V/m, 1,970 MHz 28 V/m, 2,450 MHz 28 V/m, 5,240 MHz 9 V/m, 5,500 MHz 9 V/m, 5,785 MHz 9 V/m	Same as IEC 60601-1-2 test level	See “Electromagnetic Interference” on page 82.

Although most remote devices comply with their applicable standards for immunity, those device requirements may not be as stringent as those required for medical equipment. It is the responsibility of the installer and the user of this remote customer-supplied equipment to ensure that it functions properly in the electromagnetic environment where the system is installed. The installer or the user of such a system should 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.



WARNING

If electromagnetic 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.

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


Typical Interference on Ultrasonic Imaging Systems

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

1. Electrostatic discharge (ESD) caused by discharging of electric charge buildup on insulated surfaces or persons.
2. Radio frequency (RF) energy from RF transmitting equipment such as portable phones, handheld radios, wireless devices, commercial radio and TV stations, and so on.

3. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.

Recommended Separation Distance

The following table provides recommended separation distances, which are guidelines on the distances that any RF transmitting equipment should be kept away from the ultrasound system to reduce the risk of interference with the system. Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range as noted in the table. Interference may occur in the vicinity of equipment marked with the following symbol: .

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.



WARNING

To avoid degrading system performance, keep portable RF communications equipment (including peripherals such as antenna cables and external antennas) at least 30 cm (12 in) away from any part of the ultrasound system, including cables.

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 82](#), provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz	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 82](#).

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. The ultrasound system does not generate interference based on the tests described in the referenced standards.

An ultrasound system is designed to receive signals at radio frequencies and is therefore susceptible to interference generated by RF energy sources. Examples of other sources of interference are medical devices, information technology products, and radio and television transmission towers. Tracing the source of radiated interference can be a difficult task. Customers should consider the following in an attempt to locate the source:

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

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

Use Restrictions Due to Interference

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

3 System Overview

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

Device Requirements



WARNING

Using the Lumify app 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 website:

www.philips.com/Lumify-Compatible-Devices

Philips provides a list of minimum specifications for compatible devices, but cannot guarantee that the Lumify software application will perform equivalently across all platforms that meet the minimum requirements. Your device must meet all of the following specifications:

- Minimum 8 GB total storage. The software requires at least 200 MB of available space, plus additional space for patient data storage.
- Color display, minimum 12 cm (4.7 in)
- Touch interface
- Internally mounted speakers
- IEC 60950-1 or IEC 60601-1-compliant
- Date/time configuration
- Full compliance with USB On-The-Go standard¹
- 1280 x 800 resolution (minimum)

- Mobile device operating system if not using the Reacts collaboration tool:
 - Android devices: Android 5.0 or later operating system
 - iOS devices: iOS 11 or later operating system
- (Android devices only) Mobile device operating system if using the Reacts collaboration tool: Android 6.0 or later operating system
- Wireless or cellular networking capability
- Access to ports 80 and 443
- (Android devices only) Audio capability²
- Front- and rear-facing cameras²

¹Philips verifies that the devices listed in the Lumify Supported Devices table on the Lumify website (www.philips.com/Lumify-Compatible-Devices) comply with the USB On-The-Go standard.

²Required to use certain system features, such as the barcode scanner and Reacts live video and camera collaboration.

System Capabilities

The Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B + Color), M-mode, and PW Doppler. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal (including gallbladder and lung), Pediatric, Cephalic (neonatal and adult), Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, and Cardiac. The system provides 2D distance and ellipse area measurement tools. Measurements can be performed while using 2D and M-mode.

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 and for measuring the area and circumference of an ellipse.

After you perform measurements, you can save the measurements by acquiring an image that contains the measurements. The system displays a maximum of four distance measurements or one ellipse measurement at a time.

Transducer Types

Available transducer types are curved array, linear array, and sector array transducers. For a list of supported presets for specific transducers, see [“Presets and Transducers” on page 188](#).

Indications for Use and Supporting Transducers



WARNING

Unless the transducer used is indicated for ophthalmic use, the device is not intended for ophthalmic use or any application that causes the acoustic beam to pass through the eye.



WARNING

To avoid the risk of electrical shock, do not charge your Lumify system while scanning a patient.



WARNING

To avoid patient contact with the device while it is charging, do not charge the system while inside the patient environment.



CAUTION

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

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

Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

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	Supporting Transducers
Abdominal	C5-2, L12-4, S4-1
Cardiac Adult	S4-1
Cardiac Pediatric	S4-1
Carotid	L12-4
Cephalic (Adult)	S4-1
Cephalic (Neonatal)	S4-1
Fetal Echo	C5-2
Fetal/Obstetric	C5-2, S4-1
Gynecology	C5-2, S4-1
Musculoskeletal (Conventional)	L12-4
Musculoskeletal (Superficial)	L12-4
Pediatric	C5-2, L12-4, S4-1

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Indication for Use	Supporting Transducers
Peripheral Vessel	L12-4
Small Organ	L12-4
Urology	C5-2

Contraindications

None known.

Patient Data Protection



CAUTION
If you delete the Lumify app, patient data stored on the mobile device will be lost.

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.

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* USB media or in the **Support** section of the Lumify website:

www.philips.com/lumify

The Lumify Diagnostic Ultrasound System is not intended for long-term storage of patient data. Export exams frequently and delete them after they are exported. You can hide patient data on exported images and loops (see [“Exporting Exams” on page 174](#) and [“Showing or Hiding Patient Data on Exported Images and Loops” on page 175](#)). You can also delete all patient data from the Lumify system (see [“Deleting Patient Data and Lumify Settings” on page 117](#)).

Wireless Networking

For information about configuring your device for wireless or cellular networking, see the documentation that accompanies your device. For information about adding and configuring connectivity profiles, see [“Connectivity Profiles” on page 118](#).

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:

NOTE

Transducer subscription plans are available only to customers located in the USA.

- The Philips Lumify app
 - Android devices: You can download the Lumify app from the Google Play Store.
 - iOS devices: You can download the Lumify app from the Apple App Store.
- One or more Philips Lumify transducers

For subscription and purchasing options, contact your local Philips representative or visit the Lumify website:

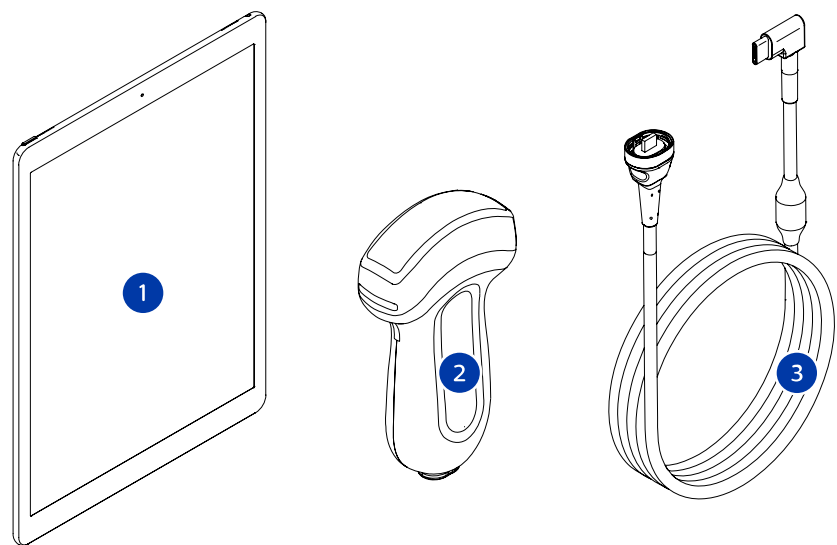
www.philips.com/lumify

- A compatible Android or iOS device

For a list of compatible devices, visit the Lumify website:

www.philips.com/Lumify-Compatible-Devices

- A carrying bag
- User information (see “User Information Components” on page 15)

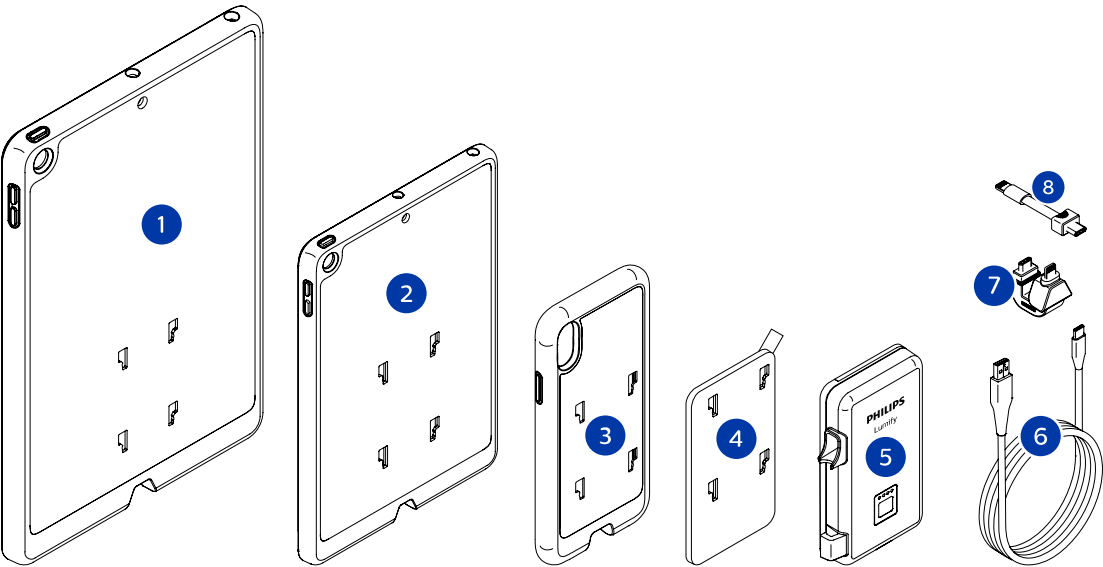


System Components

1	Android or iOS device
2	Transducer
3	USB transducer cable

System Components (iOS Devices)

In addition to the standard Lumify system components, there are additional hardware components available for iOS devices.



System Components (iOS Devices)

1	Cases with LPM mounts for 10.2-inch and 9.7-inch iPad mobile devices
2	Case with LPM mounts for 7.9-inch iPad mini 5 mobile device
3	Cases with LPM mounts for iPhone 7, iPhone 8, iPhone X, iPhone XS, iPhone XR, and iPhone 11 mobile devices
4	Adhesive mounting plate
5	Lumify Power Module (LPM)
6	Charging cable
7	Rigid connector
8	Flexible cable



Data Storage

You can export exams and images from the Lumify ultrasound system to the following:

- DICOM PACS
- (Android devices only) Network share
- Local directory

You can also send images by e-mail. For more information, see [“Exporting Exams” on page 174](#) and [“Exporting Images and Loops” on page 169](#).

System Settings

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

Android Devices

Lumify Settings for Android Devices

Setting Type	Settings
Device	WiFi Settings allows you to configure your device's wireless or cellular network settings.
Display	<ul style="list-style-type: none">• Control Orientation allows you to set the position of the imaging controls when your device is in landscape orientation.• Power Control displays a control that you can use to adjust the acoustic output power.• Thermal Index Display allows you to select the thermal index that you want to display.
Imaging	<ul style="list-style-type: none">• Cardiac Image Orientation allows you to reverse the left/right orientation of the image in the Cardiac preset.• Loop Duration displays a slider that you can drag to set the duration of acquired loops. For more information about acquiring loops, see “Acquiring Loops” on page 152.• 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.

Setting Type	Settings
Miscellaneous	<ul style="list-style-type: none">• 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 200.• Barcode Scanner allows you to add and rearrange barcode formats.• Customer Information allows you to edit or delete the contact information provided in the Contact Information form during registration of the connected transducer (see “Registration and Entitlement” on page 104).• Patient Database allows you to repair or reset the patient database. Repair Database removes corruption from the database. Reset Database deletes all patient data. Export Database archives the patient database to an encrypted file on your mobile device. Import Database restores the patient database from an archived file. For more information, see “Exporting and Importing the Patient Database” on page 201.• System Logs allows you to send logs to Philips in case of a system problem. For more information, see “Sending System Logs” on page 199.
Reacts Settings	<ul style="list-style-type: none">• Account and Login allows you to set up automatic login to Reacts and to clear your Reacts credentials from your device.• Call Settings allows you to set your device's audio preference and to specify whether to share your device's imaging stream with the collaborator upon starting a Reacts session.• Camera allows you to specify whether to share your device's video stream with the collaborator upon starting a Reacts session, and to set the default device camera for Reacts sessions.
Transducers	<ul style="list-style-type: none">• Registered Transducers displays a list of the transducers registered with Lumify.• 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 195.

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iOS Devices
Lumify Settings for iOS Devices

Setting Type	Settings
Customer Information	Edit Info allows you to edit or delete the contact information provided in the Contact Information form during registration of the connected transducer (see “Registration and Entitlement” on page 104).
Display	<ul style="list-style-type: none">• Loop Duration displays a slider that you can drag to set the duration of acquired loops. For more information about acquiring loops, see “Acquiring Loops” on page 152.• Power Control displays a control that you can use to adjust the acoustic output power.• Thermal Index Display allows you to select the thermal index that you want to display.
Device	Opens the iOS device settings options for Lumify.
Registered Transducers	<ul style="list-style-type: none">• Registered Transducers displays a list of the transducers registered with Lumify.• 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 195.
Imaging	<ul style="list-style-type: none">• Cardiac L/R Invert allows you to reverse the left/right orientation of the image in the Cardiac preset.• 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.
Logs	<ul style="list-style-type: none">• 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 200.• Auto-Send Logs automatically sends diagnostic logs to Philips whenever an error occurs.• System Logs allows you to send logs to Philips in case of a system problem. For more information, see “Sending System Logs” on page 199.

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Setting Type	Settings
Lumify Power Module	<ul style="list-style-type: none">• Charge Cycles displays the number of times the battery has been depleted and recharged.• Charge Level displays the percentage of the battery charge level. Philips recommends charging the LPM if the battery charge level is below 20%.• Design Capacity (DC) displays the rated capacity of the battery in milliampere-hours (mAh).• FCC to DC Ratio displays a percent comparison between the full charge capacity of the battery and its design capacity. Ratios below 100% show degradation of the battery capacity.• Full Charge Capacity (FCC) displays the current effective capacity of the battery in milliampere-hours (mAh).• Status displays the operational status of the LPM. A status of Normal indicates the LPM is ready for scanning.• Temperature displays the temperature of the battery in degrees Celsius (°C). Low temperatures can negatively affect battery life.• Voltage displays the battery voltage in millivolts (mV).
Patient Database	<ul style="list-style-type: none">• Import restores the patient database from an archived file.• Export archives the patient database to an encrypted file on your mobile device.• Repair removes corruption from the database.• Reset deletes all patient data. <p>For more information, see “Exporting and Importing the Patient Database” on page 201 and “Repairing the Patient Database” on page 200.</p>

System Information

System information is available in the **About** dialog box (touch , and then touch **About**).

Name	Description
Documents and Support	Provides access to legal documents, privacy information, the Lumify website, the <i>User Manual</i> and other documents, and open-source software licenses.
EU164	Allows Philips to identify and match your device with system logs, if you require assistance.
Lumify Power Module Firmware Version	(iOS devices only) Provides the firmware version currently installed on the Lumify Power Module (LPM). This information is only available when the LPM is connected.
Lumify Power Module Serial Number	(iOS devices only) Provides the serial number of the LPM. This information is only available when the LPM is connected.
Software Version	Provides the Lumify app version.
Tablet Identifier	Allows Philips to identify and match your device with system logs, if you require assistance.
Transducer Serial Number	Provides the connected transducer's serial number. The system automatically records the transducer serial number when you connect and register the transducer with the system.

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

Before you install the Lumify app, make sure that your device meets or exceeds the minimum specifications (see “[Device Requirements](#)” on page 89) and visit the Lumify website for a list of compatible devices:

www.philips.com/Lumify-Compatible-Devices

Android Devices

The Lumify app is available from the Google Play Store. The Google Play Store is a digital media store, operated by Google, from which you can download apps for the Android operating system.

1. On your Lumify-compatible Android device, open the Google Play Store  :
<https://play.google.com>
2. Search for the Lumify app. If you cannot find the Lumify app, your device may not meet the minimum specifications. For more information, visit the Lumify website for a list of compatible devices:
www.philips.com/Lumify-Compatible-Devices
3. Follow the displayed instructions to download and install the Lumify app.

iOS Devices

The Lumify app is available from the Apple App Store. The Apple App Store is a digital media store, operated by Apple, from which you can download apps for the iOS operating system.

1. On your Lumify-compatible iOS device, open the Apple App Store .

2. Search for the Lumify app. If you cannot find the Lumify app, your device may not meet the minimum specifications. For more information, visit the Lumify website for a list of compatible devices:
www.philips.com/Lumify-Compatible-Devices
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 connect your transducer and, if you purchased the transducer outright, provide your contact information.

If you are subscribing to a transducer, make sure that your device is connected to a wireless or cellular network. Your system automatically reregisters all previously registered transducers. If you receive notification that the transducer's registration has expired, connect your device to a wireless or cellular network and reconnect the transducer.

If you purchased the transducer outright, then you must register your transducer and provide your most up-to-date contact information the first time you install your Lumify software and initialize the transducer. Philips uses the contact information you provide to communicate important product information and updates to you. Unlike subscribed transducers, the system does not automatically reregister purchased transducers.

NOTE

If you upgrade the Lumify app, upgrade the operating system, or you purchased the transducer outright and have connected it into a new device, the system prompts you to reregister the next time you connect a transducer.

NOTE

The Lumify system preserves user settings when the Lumify app or the operating system is updated.

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.
4. (Android devices only) If you want the Lumify app to open automatically on startup whenever this transducer is connected, select **Use By Default For This USB Device**. Otherwise, continue to the next step.
5. Touch **OK**.
(Android devices only) The Lumify app performs a system check before starting the registration process.
6. If you are subscribing to the transducer, on the **Registration Complete** display, touch **Accept**.
7. If you purchased the transducer outright, touch **Continue** and, on the **Contact Information** form, do the following:
 - a. Type your information for **Institution** name, **Contact** name, **Zip/Postal Code**, **Country**, and **Email Address**. All information fields must be completed.
 - b. If you want to receive news of new products and promotions from Philips, select **Stay Informed of New Product Information**.
 - c. Touch **Submit**.
 - d. On the **Registration Complete** display, touch **Accept**.
8. (Android devices only) To redeem or share your Reacts access codes, if available, touch **Redeem or Share Codes**, and then see [“Redeeming or Sharing Your Reacts Access Codes” on page 127](#).

If registration fails, see [“Troubleshooting” on page 204](#), or visit the Lumify website for FAQs and troubleshooting tips:

www.philips.com/lumify

Giving Lumify Access to Shared Device Storage (Android Devices Only)

Some versions of the Android operating system require that you specify that an app is allowed access to shared device storage. If your device prompts you to allow Lumify to access photos, media, or files on your device, touch **Allow**. If you touch **Deny**, you cannot use the Lumify system until you give access to shared device storage in the Android **App Permissions** settings.

Updating the Lumify App



CAUTION

To avoid potential loss of patient data during update, export your patient database periodically, or whenever you update the Lumify app. For more information, see [“Exporting the Patient Database” on page 201](#).

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

If your Lumify-compatible mobile 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 mobile device is configured to update apps individually, you can obtain the latest update as follows:

- Android devices: You can download the Lumify app from the Google Play Store.
- iOS devices: You can download the Lumify app from the Apple App Store.



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.

At the end of the walkthrough, do one of the following:

- To begin an exam, touch **Start Scanning**.
- (Android devices only) To view the Reacts walkthrough, touch **Learn More**.

You can view the app walkthrough at any time.

Touch , and then touch **Walkthrough** .

Canceling Your Subscription

Transducer subscription plans are available only to customers in the United States. To cancel your subscription, contact your local Philips representative.

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.
- 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.

Touch , and then touch **Settings** , and then do one of the following:

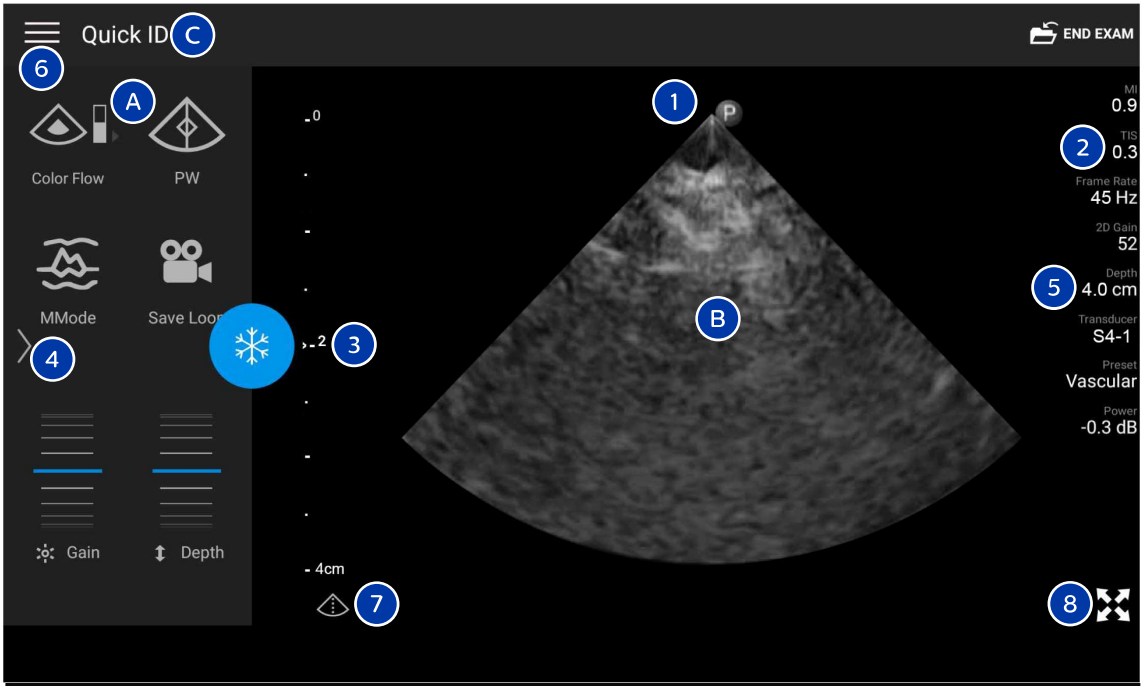
- Android devices: In **Thermal Index Display**, select the thermal index you want.
- iOS devices: Touch **Display**, touch **Thermal Index Display**, and then select the thermal index you want.

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.



Imaging Display (Landscape Orientation)

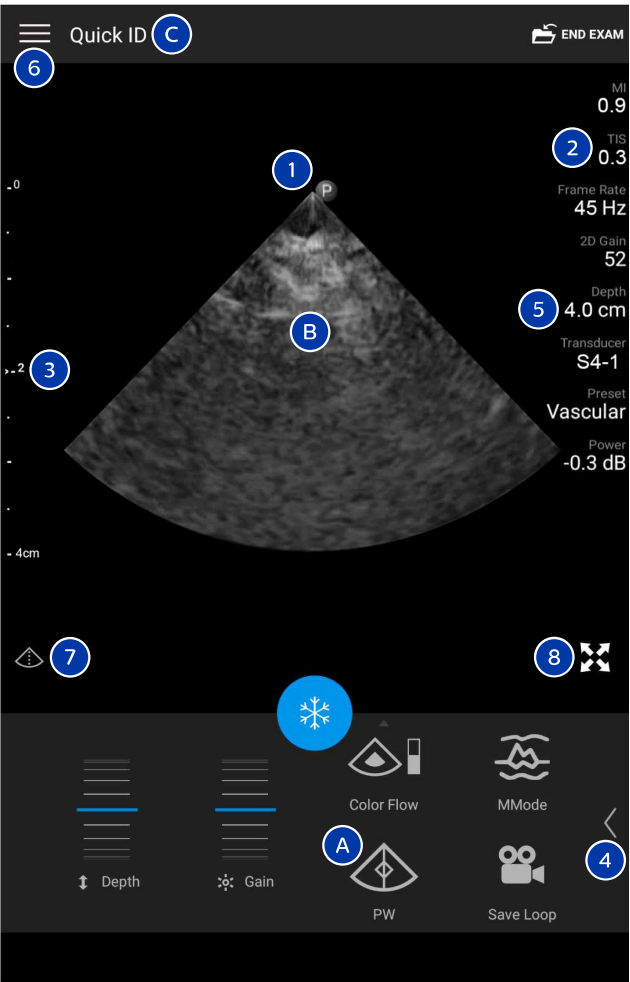
A	Controls area
B	Image area
C	Patient information
1	Scan plane orientation marker
2	MI and TI values
3	Focal indicator
4	Page indicator: Touch the indicator to go to the next page of controls, or swipe to move between pages.
5	Image information
6	Review and settings menu

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- | | |
|---|--------------------------|
| 7 | Centerline control |
| 8 | Full-screen view control |

In portrait orientation, the location of the controls area changes.



Imaging Display (Portrait 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
7	Centerline control
8	Full-screen view control

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.

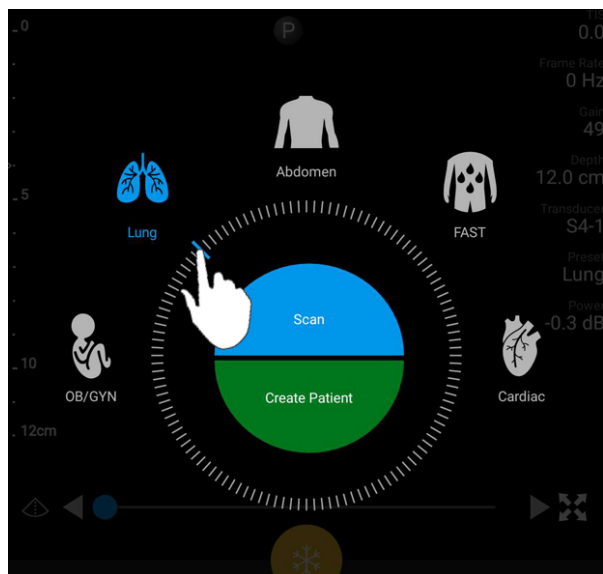
Starting Quick Exams



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, touch an exam preset or drag the selector on the preset selector wheel to the exam preset you want.



Drag the Wheel Selector to Select a 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, query a Modality Worklist (MWL), or scan a barcode (Android devices only). If you rotate the display while entering patient information, the active data field changes to the **Last Name** field. For more information, see [“Starting New Exams” on page 139](#).
 - c. Touch **Save and Return**.
 - d. Resume imaging.

Using Your Device's Camera as a Barcode Scanner (Android Devices Only)

You can use your mobile device's camera to scan barcodes and populate patient information fields.

If your mobile device prompts you to allow Lumify to access photos, media, or files on your mobile device, touch **Allow**.

You can save multiple barcode formats. See [“Saving Barcode Formats \(Android Devices Only\)” on page 115](#).


The first time you scan a barcode format, you must map the format to at least one patient information field. Lumify remembers this information for subsequent barcode scans of the same format.



The barcode you scan must meet the following conditions or Lumify will return an error:

- There is a delimiter between strings.
- The values must be unique.
- The delimiter is a non-alphanumeric, single character.

If you receive an error message, create a sample barcode where each field is a unique value and follow the steps in the following procedure to scan and map the format.




You can scan in either portrait or landscape orientation.




1. On the **Patient Info** display, touch **Scan Barcode** .
2. If prompted, touch **Allow** to allow Lumify to use your device's camera.
3. Use the viewfinder to place the horizontal red line across the barcode. Make sure that the entire barcode is included in the viewfinder, perpendicular to the red line. If sound is enabled on your device, it beeps when Lumify scans the code.
4. If this is the first time you have scanned this barcode format, do the following:
 - a. Type a name to describe the barcode configuration and touch **Continue**. Lumify displays the patient information fields from the barcode.

- b. In **Barcode Configuration**, drag the barcode text to the corresponding patient data entry field (to adjust your selection, drag  and ). Alternatively, type the patient information fields exactly as they appear in the displayed barcode result. Each field's value must be unique (for example, you cannot enter the same value for the **Last Name** and the **First Name**).
5. Touch **Save**.

Saving Barcode Formats (Android Devices Only)

You can save multiple barcode formats. When Lumify scans a barcode, it searches the formats for the best match.

1. Do either of the following:
 - In the barcode viewfinder, touch .
 - Touch , touch **Settings** , and then touch **Barcode Settings**.
2. In **Barcode Settings**, do any of the following:
 - To add a new barcode format, touch **Add New** and scan a barcode. Type a name for the barcode and touch **Continue**.

Lumify displays the patient information fields from the barcode result. In **Barcode Configuration**, drag the barcode text to the corresponding patient data entry field (to adjust your selection, drag  and ). Alternatively, type the patient information fields exactly as they appear in the displayed barcode result. Each field's value must be unique (for example, you cannot enter the same value for the **Last Name** and the **First Name**) and you must complete at least one field. Touch **Save and Return**.
 - To rearrange barcode formats, drag the entries.
 - To remove a barcode format, touch .

Supported Barcode Formats (Android Devices Only)

Lumify supports the following barcode formats:

Format	Symbologies
1D Product Barcodes	UPC-A, UPC-E, EAN-8, EAN-13
1D Industrial Barcodes	Code 39, Code 93, Code 128, Codabar, ITF-14, RSS-14, RSS-Expanded
Matrix (2D) Barcodes	QR Code, Data Matrix, Aztec, PDF 417

Connecting Transducers

If necessary, plug the transducer cable into the transducer:

1. Plug the straight connector of the USB transducer cable into the receptacle on the transducer. The USB cable is not reversible.
2. Slide the connector housing toward the transducer, until it fits snugly in place.

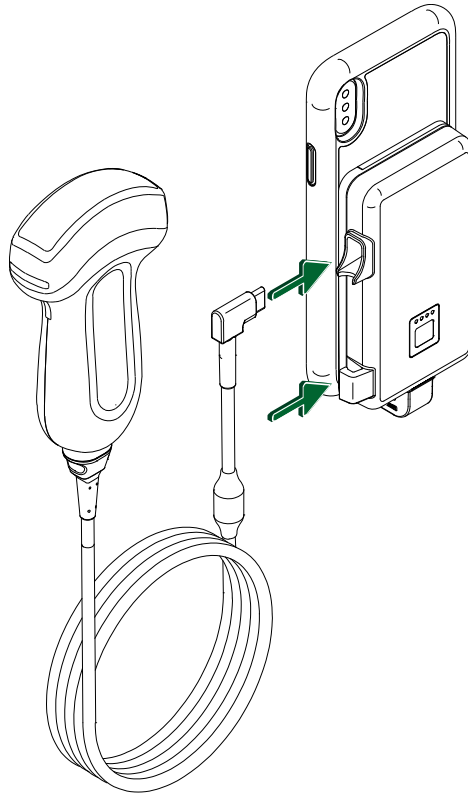
Android Devices

Plug the right-angle connector of the USB transducer cable into the USB port on the device. The USB cable is not reversible.

When you first connect a transducer, the 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.

iOS Devices

1. Plug the right-angle connector of the USB transducer cable into the USB port on the side of the Lumify Power Module (LPM). The USB cable is not reversible.



Connecting the Transducer Cable to the LPM

2. Press the transducer cable into the cable clip on the LPM.
3. If prompted, select **Use By Default for This USB Device**, and then touch **OK**.

When initialization is complete, the name of the transducer appears on the imaging display.





Deleting Patient Data and Lumify Settings

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

To delete patient data from exported images and loops, see [“Showing or Hiding Patient Data on Exported Images and Loops” on page 175](#).


Deleting Patient Data Only

To delete patient data only:

- Android devices: Touch , and then touch **Settings** . Touch **Reset Database**. Touch **Yes** to confirm.
- iOS devices: Touch , and then touch **Settings** . Touch **Patient Database**, and then, in the **Reset Database** area, touch **Reset**. Touch **Reset** to confirm.

Deleting Patient Data and All Settings

To delete all Lumify settings, including registration information, DICOM logs, and audit logs:

- Android devices: In the operating system, go to **Settings** . Touch **Apps**, touch **Lumify**, and then touch **Clear Data**.
- iOS devices: Uninstall the Lumify app.

Connectivity Profiles




Connectivity profiles let you define a set of storage destinations, export strategies, exam settings, and connection settings. You can create and configure multiple connectivity profiles and quickly switch among them. You must end the exam before you can switch connectivity profiles.

Adding a Connectivity Profile

NOTE



Ports less than or equal to 1024 cannot be used for inbound connections.

Android Devices

1. Touch , and then touch **Connectivity Profiles** .
2. Touch **Add New Profile**.
3. In the **Add New Profile** dialog box, type a name for the new connectivity profile, and then touch **Continue**.
4. Under **Profile Management**, to apply the connectivity profile, select **Set [connectivity profile] As The Current Profile**. A  indicates that the connectivity profile is applied. The active connectivity profile is indicated under **Connectivity Profile** in the review and settings menu.
5. Under **Servers & Roles**, do any of the following:
 - Select a primary storage destination. To add a new export destination, touch **Manage Options** and touch **Add New** (see [“Configuring Export Destinations” on page 179](#)).
 - Select a DICOM storage commitment server (available if a DICOM storage destination is the profile's primary storage destination). To add a new storage commitment server, select **Manage Options** and touch **Add New** (see [“Export Destination Settings” on page 180](#)).
 - Select a Modality Worklist (MWL) server. To add a new MWL server, select **+ Add New** and touch **Add New** (see [“Adding a Modality Worklist Server” on page 122](#)).
 - Select a Modality Performed Procedure Step (MPPS) server. To add a new MPPS server, select **Add New**, and then, in the **Setup MPPS Servers** dialog box, touch **Add New** (see [“Export Destination Settings” on page 180](#)).
6. Under **Export Strategy**, select how you want to export images.
7. Under **Exam Settings**, you can do the following:
 - To specify when exams automatically end, select a time from the **Automatically End Exams Older Than** menu.
 - If your primary storage destination is a DICOM destination, you can set the system to automatically delete exams after all of the images are committed to the storage destination.



8. Under **Inbound Connection Settings**, you can do the following:
 - To scan for a specific inbound port, touch the **Listen For Inbound Connections On Port** field, type a valid port higher than 1024, and then touch **Save**.
 - View the interface and IP address of your device's current inbound connections.
9. Touch **Save**.

iOS Devices

1. Touch , and then touch **Connectivity Profiles** .
2. Touch **Add**.
3. In the **New Profile** dialog box, type a name for the new connectivity profile.
4. To set your new profile as the current profile, select **Set as Current**. The active connectivity profile is indicated under **Connectivity Profile** in the review and settings menu.
5. Under **Servers & Roles**, do any of the following:
 - Select a primary storage destination: Touch **Primary Storage Destination**, and in the **Primary Storage Destination** dialog box, select a destination from the list. To add a new export destination, touch **Manage**, and then touch **+** (see [“Configuring Export Destinations” on page 179](#)).
 - Select a storage commitment server (available if a DICOM storage destination is the profile's primary storage destination): Touch **Storage Commitment Server**, and in the **Storage Commitment Server** dialog box, select a server from the list. To add a new storage commitment server, touch **Add** (see [“Export Destination Settings” on page 180](#)).
 - Select a Modality Worklist (MWL) server: Touch **MWL Server**, and in the **MWL Server** dialog box, select a server from the list. To add a new MWL server, touch **Add** (see [“Adding a Modality Worklist Server” on page 122](#)).
 - Select a Modality Performed Procedure Step (MPPS) server: Touch **MPPS Server**, and in the **MPPS Server** dialog box, select a server from the list. To add a new MPPS server, touch **Add** (see [“Export Destination Settings” on page 180](#)).
6. Under **Export**, touch **Export Strategy** and select how you want to export images.

7. Under **Exam Settings**, you can do the following:
 - To specify when exams automatically end, select a time from the **Auto-End Exams Older Than** menu.
 - If your primary storage destination is a DICOM destination, you can set the system to automatically delete exams after all of the images are committed to the storage destination.
8. Under **Inbound Connection Settings**, you can do the following:
 - To scan for a specific inbound port, touch the **Listening Port** field, type a valid port higher than 1024, and then touch **Done**.
 - To view the interface and IP address of your device's current inbound connections, touch **Current IP Address**.
9. Touch **Save**.


Editing Connectivity Profiles

1. Touch , and then touch **Connectivity Profiles** .
2. At the top of the display, touch the profile name to open it.
3. Make the profile changes you want.
4. Do one of the following:
 - To save the changes to the profile, touch **Save**.
 - To clear the changes to the profile, touch **Discard** (Android devices) or **Cancel** (iOS devices).

Switching Connectivity Profiles

The active connectivity profile is shown under **Connectivity Profile**  in the review and settings menu.

1. Touch , and then touch **Connectivity Profiles** .

2. At the top of the display, touch the profile name to open it.
3. Do one of the following:
 - Android devices: Under **Profile Management**, to apply the connectivity profile, select **Set [connectivity profile] As The Current Profile**. A  indicates that the connectivity profile is applied. Touch **Save**.
 - iOS devices: On the **Profile Information** page, select **Set as Current**.

Modality Worklist


You can load patient data and select a scheduled procedure from a DICOM Modality Worklist (MWL) server instead of entering the patient data manually.

Before you can use the modality worklist feature, you must add a DICOM MWL server.

Adding a Modality Worklist Server


You can add a new Modality Worklist (MWL) server from **Connectivity Profiles** in the review and settings menu. For information on **Connectivity Profiles**, see [“Connectivity Profiles” on page 118](#).

Android Devices

1. Touch , and then touch **Connectivity Profiles**.
2. With your preferred connectivity profile active, select **Add New** from the **Select a MWL Server for this Profile** menu.
3. On the **Setup Worklists** form, type or select values from the menus for the following:
 - **Server Nickname**
 - **Lumify AE Title:** The AE title for your device
 - **Remote AE Title:** The AE title for the MWL server
 - **Hostname or IP:** Use a DNS or a static IP address

- **Port:** The port number for the MWL server
- 4. Select **Query Options**.
- 5. To specify advanced connection settings, select **Show Advanced Options:**
 - **DNS Suffix:** The DNS name without the hostname
 - **Read Timeout (sec):** The network reply timeout
 - **Connection Timeout (sec):** The DICOM ARTIM timeout
 - **Max Packet Size (bytes):** The maximum size of a packet sent to the DICOM server.
- 6. To test the connection to the server, touch **Test**.
- 7. Touch **Save**.

iOS Devices

1. Touch , and then touch **Connectivity Profiles**.
2. Select the connectivity profile to which you want to add an MWL server.
3. Under **Servers and Roles**, touch **MWL Server**.
4. On the **MWL Server** page, touch **Manage**.
5. On the **Manage Servers** page, touch **Add**.
6. On the **Setup Worklists** form, type or select values from the menus for the following:
 - **Server Nickname**
 - **Lumify AE Title:** The AE title for your device
 - **Remote AE Title:** The AE title for the MWL server
 - **Hostname or IP:** Use a DNS or a static IP address
 - **Port:** The port number for the MWL server
7. Under **Query Options**, select your preferences for which exams to show.
8. To specify advanced connection settings, select **Show Advanced Options:**
 - **DNS Suffix:** The DNS name without the hostname
 - **Read Timeout (sec):** The network reply timeout


- **Connection Timeout (sec):** The DICOM ARTIM timeout
 - **Max Packet Size (bytes):** The maximum size of a packet sent to the DICOM server.
 - **Retry Interval (sec)**
 - **Max Retries**
9. To test the connection to the server, touch **Test**.
 10. Touch **Save**.

Modifying or Deleting a Modality Worklist Server




You can modify or delete a Modality Worklist (MWL) server from **Connectivity Profiles** in the review and settings menu. For information on **Connectivity Profiles**, see [“Connectivity Profiles” on page 118](#).

Android Devices

On the **Setup Worklists** form, type or select values from the menus for the following:

- To modify the MWL server, type settings or select options, and then touch **Save**.
- To delete the MWL server, touch .

iOS Devices

1. On the **MWL Server** page, touch **Manage**.
2. On the **Manage Servers** page, next to the server that you want to modify, touch .
3. Do one of the following:
 - To modify the MWL server, touch **Edit** , make the necessary changes to the server settings, and then touch **Save**.
 - To delete the MWL server, touch **Delete** , and then touch **Yes** to confirm.

5 Using Reacts (Android Devices Only)

Lumify integrated tele-ultrasound powered by Reacts collaboration platform (Lumify with Reacts) is available as a subscription-based option.

Reacts is interactive audio-video software developed by Innovative Imaging Technologies, Inc. (IIT), a subsidiary of Philips Ultrasound. The Reacts software is integrated into the Lumify app, providing live ultrasound collaboration.

With your device connected to the Internet, you can use Reacts to share your live Lumify ultrasound image with a remote Reacts user for training or collaboration. During the Reacts session, you can communicate with the remote Reacts user in a video chat.

When you share the Lumify ultrasound image with the remote Reacts user, the remote user is restricted to viewing only your camera's live feed and, in some instances, only the live ultrasound image. The remote Reacts user cannot see patient data or previously completed exams.

The Reacts instructions in this *User Manual* are intended for the Lumify with Reacts user. For instructions on using Reacts outside the Lumify app, IIT Reacts provides online training and tutorials at this website:

<https://reacts.zendesk.com/hc>

Before you can use Lumify with Reacts for the first time, you must be connected to the Internet and do the following:

1. Redeem or share your Reacts access codes (see [“Redeeming or Sharing Your Reacts Access Codes” on page 127](#)) to activate your free Reacts licenses.
2. Create a Reacts account (see [“Creating a Reacts Account” on page 128](#)). If you already have a Reacts account, you can use your Reacts credentials to log in to Reacts (see [“Logging In and Out of Reacts” on page 129](#)).
3. Add Reacts contacts (see [“Adding, Removing, and Searching Reacts Contacts” on page 130](#)).

NOTE

Remote Reacts users cannot modify or control the Lumify app.



NOTE

If you want to use Reacts on a workstation, see <https://www.iitreacts.com> for information about setting up a subscription and system requirements.

Viewing the Reacts Walkthrough

The first time you start the Lumify app, it displays the app walkthrough tutorial to familiarize you with the features of the system.

After you log in to the Lumify app, you can view the Reacts walkthrough by doing any of the following:

- After the Lumify app walkthrough ends, touch **Learn More**.
- After you have logged in to Reacts, touch , and then, in the Reacts area of the menu, touch **User Guide** .

Reacts Access Codes

With each Lumify transducer, Philips provides two access codes that, when redeemed or shared, provide free access to the Standard Plan of Reacts with the following terms and conditions, starting from the time that you register your transducer:

- If you are subscribing to the transducer, you can redeem or share your Reacts access codes at any time throughout your subscription; they do not expire. As long as your transducer subscription is active, each access code provides access to the Standard Plan of Reacts, which automatically renews every 12 months.

- If you purchase a transducer, upon registering of your transducer, you have 12 months to redeem or share your Reacts access codes before they expire. Each access code provides access to the Standard Plan of Reacts for a 6-month trial period. After the trial period, contact IIT Reacts to select a Reacts plan.



If you select **Remember Me** when you log in to Reacts, Lumify preserves redeemed Reacts access codes with other Lumify user settings during Lumify app upgrades or Android operating system upgrades.

If you prefer, you can redeem or share your access codes through the IIT Reacts website:


<https://reacts.com/philips/redeem>

Redeeming or Sharing Your Reacts Access Codes

Reacts access codes are unique and, when redeemed, create individual Reacts licenses. The access code recipient becomes the owner of the access code and the resulting license.





After you have registered your transducer (see [“Registering Your Transducers” on page 105](#)), touch , touch **Launch Reacts** , and then do any of the following from the Reacts login menu:

- To redeem or share your Reacts access codes, touch **Redeem or Share Codes** and do either of the following:
 - To redeem your Reacts access code, touch **Redeem**, type your Reacts login credentials, and then touch **Okay**.
 - To share your Reacts access code, touch **Share**, type the sender and recipient names and e-mail addresses, and then touch **Share**.
- For information about Reacts, touch **What is Reacts**.
- If you do not want the Reacts access code menu to appear the next time you register a transducer, select **Don't Ask Me Again**.
- To begin using the system and postpone redeeming or sharing your Reacts access code, touch **Skip**. For instructions on viewing your Reacts access codes, see [“Viewing Your Reacts Access Codes” on page 128](#).

- To return to the Lumify app, touch .

Viewing Your Reacts Access Codes

You can view any available Reacts access codes for the current connected transducer.

- Touch . The number of available access codes appear in green beside **Launch Reacts** .
- Touch , and then touch **Launch Reacts** . The available access codes and, if subscribed to the transducer, their expiration dates appear under **Sign In**.

For instructions on redeeming or sharing your Reacts access codes, see [“Redeeming or Sharing Your Reacts Access Codes” on page 127](#).

Creating a Reacts Account

NOTE



User e-mail systems may route Reacts e-mails to the Spam or Junk e-mail folders, depending upon the e-mail account settings.

Account management, including license redemption, account creation, activation, and deletion, is a collaborative effort among IIT Reacts, Philips, and the users of the Lumify app. In addition to the Reacts contacts within the Lumify app, IIT Reacts provides an Account Management Portal that allows you to manage user accounts and the list of approved contacts. For more information, see [“Adding, Removing, and Searching Reacts Contacts” on page 130](#).

Before you can use Reacts on your device, your device must be connected to the Internet, and you must create a Reacts account.

To set up a Reacts account on a PC workstation, a mobile device, or a web browser, see the Reacts website:

<https://reacts.com>





1. To create a Reacts account within the Lumify app, do the following:
 - a. Touch , and then touch **Launch Reacts** .
 - b. Touch **Create An Account**, and type your name and e-mail address.
 - c. Create a password. (The password must be a minimum of eight characters and include one uppercase letter, one lowercase letter, and one number.)
 - d. Touch **Create Account**. A verification e-mail is sent to the address that you provided in step b.
 - e. Follow the instructions in the verification e-mail to verify your Reacts account's e-mail address.
 - f. When the **You're Almost There** dialog box appears, touch **Okay**.
2. When you receive notification that your account is active, you can start using Reacts. If you do not receive a notification, do the following to verify your new account:
 - a. In your e-mail in-box, open the message with the subject line, "Please Verify Your Email."
 - b. Click **You're Almost There**.
 - c. Follow the prompts in the confirmation wizard.

Logging In and Out of Reacts

NOTE

If **Automatically Log In To Reacts** is enabled and you log out of Reacts, **Automatically Log In To Reacts** becomes disabled.






1. To log into Reacts, do the following:




- a. Touch , and then touch **Launch Reacts** .
 - b. If you want to redeem or share Reacts access codes, touch **Redeem or Share Codes** (see [“Redeeming or Sharing Your Reacts Access Codes” on page 127](#)).
 - c. Type the e-mail and password associated with your Reacts account.
 - d. If you want Reacts to remember your login information and automatically log in next time, select **Remember Me** and **Automatically Log In To Reacts**.
 - e. Touch **Log In**.
2. To log out of Reacts, touch , and then touch **Log Out** .

Managing Reacts Contacts

Your Reacts contacts sync with your Reacts license, so if you have Reacts installed on multiple Lumify devices, you can manage your Reacts contacts anywhere, using your same Reacts login credentials. For more information, see the IIT Reacts website.

Adding, Removing, and Searching Reacts Contacts





1. Touch , touch **Launch Reacts** , and then touch **Contacts** .
2. In the **Reacts Contacts** list, do any of the following:
 - To add a contact, check that your Lumify mobile device has access to the Internet, and then do any of the following:
 - If the contact does not have a Reacts account, touch , and then touch , in the **Invite New User To Reacts** dialog box, type the contact's e-mail address associated with their Reacts account and touch **Send**. A request to join Reacts is sent to the e-mail provided.

- If the contact has a Reacts account, touch , type the name of the contact you want to add in the **Search** field, and then touch the name you want from the search results that appear as you type. The contact appears in the **Reacts Contacts** list with **Pending**  status. For information on contact status, see [“Reacts Contact Status” on page 131](#).
 - To remove a contact, touch and hold the contact that you want to remove, and then touch **Yes**.
 - To search for a contact in your list, touch  and enter one of the following:
 - First name only
 - Last name only
 - E-mail address only
- Do not include spaces in your search text. Search results appear as you type. Users with expired Reacts licenses might not appear in search results.

Reacts Contact Status

The **Reacts Contacts** list includes a status description and indicator next to the contact's name.

Reacts Status Icons

Status	Description
Online 	The contact is available, and you can start a Reacts session with them.
Offline 	The contact is unavailable for a Reacts session.
Busy 	The contact is actively in a Reacts session, and is unavailable for a Reacts session with you.
Pending 	The contact has not accepted your contact request and is unavailable for a Reacts session.

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Responding to Reacts Contact Requests

The requests of other Reacts users to add you to their contacts list appear in your **Reacts Contacts** list. To respond, touch **Accept** or **Decline**.


If you touch **Accept**, the contact is added to your **Reacts Contacts** list, and you are added to theirs.

Starting a Reacts Session

1. Log in to Reacts (see [“Logging In and Out of Reacts” on page 129](#)).
2. Touch , and touch **Contacts** .
3. Touch  beside the active contact that you want to call. When the contact answers your call, the Reacts session is active.
4. If you want to end the call before the contact answers, touch **Cancel** .

Ending a Reacts Session

NOTE

Some controls are unavailable in full-screen view. To exit full-screen viewing, touch  in the lower right corner of the display.




To end a Reacts session, touch .

Using the Reacts Pointer

During a Reacts session, you can use the pointer to call attention to an area on the image.

NOTE

During a Reacts session between two Lumify devices, the pointer tool is unavailable.

1. To add a pointer, touch the streamed image, and then touch **Add a Pointer** .
2. Drag the pointer  to the preferred location on the streamed image.
3. To remove the pointer, touch the streamed image, and then touch **Remove Pointer** .

Reacts Session Views

A Reacts session can include the following views, which you can rearrange or hide:

- Your device's camera view
- The remote Reacts user's live video feed
- Lumify live ultrasound imaging


Rearranging Reacts Session Views





During a Reacts session, you can rearrange the views into three areas on the display: the main center view and smaller secondary views.

To move a session view, drag the view to the preferred area. The view previously in that area moves clockwise into the next position.

Showing and Hiding the Reacts Secondary Session Views


NOTE



Some controls are unavailable in full-screen view. To exit full-screen viewing, touch  in the lower right corner of the display.

- To hide the secondary views, in portrait orientation, touch . In landscape orientation, touch .
- To show the secondary views, in portrait orientation, touch . In landscape orientation, touch .

Muting the Microphone During a Reacts Session

NOTE

Some controls are unavailable in full-screen view. To exit full-screen viewing, touch  in the lower right corner of the display.



- To turn off your device's microphone and mute the session, touch .
- To restore your device's microphone and unmute the session, touch .

Sharing Your Device's Camera



WARNING

Images and loops viewed remotely through Reacts streaming are intended only for reference and must not be used for diagnostic purposes.

- To share your device's camera image with a remote Reacts user, touch the streamed image, and then touch **Share Camera** .
- To stop sharing your device's camera, touch the streamed image, and then touch **Stop Camera Sharing** .

NOTE

During a Reacts session between two Lumify devices, sharing your device's camera and simultaneously sharing your Lumify ultrasound image is unavailable.

NOTE



If a poor-connection message appears at the bottom of the imaging display, touch **Stop Camera Sharing** to improve session quality and responsiveness.

Sharing Your Lumify Ultrasound Image



WARNING

Images and loops viewed remotely through Reacts streaming are intended only for reference and must not be used for diagnostic purposes.

- To share your Lumify ultrasound image with a Reacts remote user, touch the ultrasound image, and then touch **Share Ultrasound** . The sharing status appears on the upper left corner of the imaging display.
- To stop sharing your Lumify ultrasound image, touch the ultrasound image, and then touch **Stop Ultrasound Sharing** .

NOTE

During a Reacts session between two Lumify devices, sharing your device's camera and simultaneously sharing your Lumify ultrasound image is unavailable.

NOTE

If a poor-connection message appears at the bottom of the imaging display, touch **Stop Camera Sharing** to improve session quality and responsiveness.

NOTE

Rotating your Lumify-compatible Android device during a Reacts session can cause a frozen 2D image to disappear from the display. To recover the image, adjust the loop time line or the device's scroll bar.

NOTE

To display the Reacts ultrasound share controls when imaging in M-mode during a Reacts session, touch a live M-mode image. Touching a frozen M-mode image does not display the Reacts ultrasound share controls.

NOTE

If the remote Reacts user requests to record the remotely streamed images, you must accept the request to enable recording.

6 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 and calculations.



WARNING

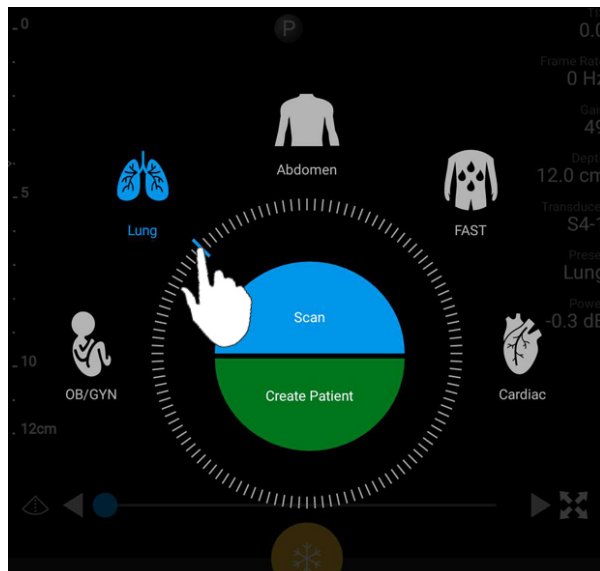
You are responsible for configuring your device in accordance with your institution's security policies. Notifications and alerts from third-party applications may interfere with an exam.

NOTE

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

Starting New Exams

1. On the **Scan/Create Patient** display, touch an exam preset or drag the selector on the preset selector wheel to the exam preset you want.





Drag the Wheel Selector to Select a 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 112](#).
- To manually enter patient information before you begin scanning, touch **Create Patient**. To show additional **Patient Info** fields, select **Show Detailed Form**. To begin scanning, touch **Start Exam**.

NOTE


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.

3. To search a Modality Worklist for a specific exam, touch **Create Patient**, and then touch **Query MWL**  (see [“Searching in the Worklist” on page 141](#)).
4. (Android devices only) To enter data into the system by scanning a patient's barcode, touch **Create Patient**, and then touch **Scan Barcode**  (see [“Using Your Device's Camera as a Barcode Scanner \(Android Devices Only\)” on page 114](#)).

Searching in the Worklist


You can search for a specific exam from a Modality Worklist (MWL) by using **Query MWL** on the **Patient Info** form. Before you can search for an MWL exam, you must configure a connection to an MWL server (see [“Adding a Modality Worklist Server” on page 122](#)).

Android Devices

1. Touch **Query MWL**  on the **Patient Info** form.
2. Select the MWL server you want to query.
3. In the **Enter Advanced Query Information** dialog box, do any of the following:
 - To search for a patient by **Patient Name**, **MRN**, **Accession #**, or **Requested Procedure ID**, type search criteria.
 - To search for all patients, leave all fields blank.
 - To insert a wildcard symbol (*) in the **Patient Name** or **MRN** field that allows the system to replace or represent one or more characters, touch **Insert Wildcard**. For example, type 45678 in the **MRN** field, and then touch **Insert Wildcard** to allow the system to return all MRNs that begin with 45678 (456781, 456782, 456783, and so on.)
4. Touch **Search**.
5. Do any of the following:
 - To see additional entries, swipe down.
 - To filter the **Query Results**, touch **Search All Fields** and type criteria. The system displays results that meet the criteria.

6. Select the patient from **Query Results**.

iOS Devices

1. Touch **Query MWL** on the **Patient Info** form.
2. Select the MWL server you want to query.
3. In the **Query Results** dialog box, do any of the following:
 - To scroll the patient list, swipe up.
 - To search the patient list, in the **Search** box, enter search criteria such as patient name, MRN, accession number, or requested procedure ID.
 - To refresh the patient list, touch .
4. Select the patient from **Query Results**.

Changing Presets During Exams

You can change presets during an active exam.


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 then touch **Edit Patient Info**.
2. Touch the field you want to edit and use the keyboard to replace, insert, or delete text. To show additional **Patient Info** fields, select **Show Detailed Form**.
3. Touch **Save and Return**.




Reviewing Saved Exams

You can review saved exams.

1. Touch .
2. Touch **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 delete images from a saved exam, see [“Deleting Images and Loops” on page 173](#).
 - To export images and loops from a saved exam, see [“Exporting Images and Loops” on page 169](#).
 - To export the exam, see [“Exporting Exams” on page 174](#).
5. To exit the **Review** display and return to the current exam, touch , and then touch **Current Exam** .

Resuming a Paused Exam

If you leave an exam or close the system, you can return to the open exam within 24 hours by doing any of the following:

- Touch , and then touch **Current Exam** .
- When  appears on the **Scan/Create Patient** display, swipe the screen from left to right.

Imaging Modes



CAUTION

Running multiple applications on your device while using the Lumify app increases your device's resource usage, causing decreased frame rate. To reduce device resource usage and increase frame rate, close all non-Lumify applications running on your device.

NOTE


When you adjust the depth to less than 3 cm while using the L12-4 transducer, the system zooms the image, and some portions of the image may not be visible. To view the entire image, pinch with your thumb and finger.





Available imaging modes are 2D, Color, M-Mode, and PW Doppler.

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.
 - 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 acoustic 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 148](#).
- To view the image in full-screen view, touch  in the lower right corner of the image. For more information, see [“Full-Screen View” on page 149](#).
- To display a centerline on the image, touch . For more information, see [“Displaying a Centerline” on page 149](#).






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 **Color Flow** .
3. Touch **Color Flow** , and then 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.)
6. To control the color gain, adjust the **Gain**  dial.
7. To view the image in full-screen view, touch  in the lower right corner of the image. For more information, see [“Full-Screen View” on page 149](#).
8. To display a centerline on the image, touch . For more information, see [“Displaying a Centerline” on page 149](#).
9. To exit Color imaging, touch **Fast Flow**  or **Slow Flow** .



M-Mode

In M-mode, you can learn about the movement of an area of anatomy. In M-mode, the tissue interface position or depth is displayed along the vertical axis, and time is displayed along the horizontal axis. First, you position the M-line in the 2D image on the anatomy of interest. Then you can display information about movement along that line in an M-mode trace. Over time, the movement of the anatomy along the M-line, which is displayed on the 2D image, creates a scrolling display.

Using M-Mode

1. In 2D mode, optimize the image.
2. Touch **MMode**  to display the M-line on the 2D image.
3. Drag the M-line to move it to the anatomy of interest. When you release the M-line, the M-mode trace begins.
4. Optimize the image, using any of the following methods:
 - 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 acoustic 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 148](#).
- To view the image in full-screen view, touch  in the lower right corner of the image. For more information, see [“Full-Screen View” on page 149](#).



5. To review the M-mode trace, touch , and drag the loop time line to scroll forward or backward.
6. To exit M-mode, touch **MMode** .

PW Doppler (Android Devices Only)

Pulsed-wave (PW) Doppler is a Doppler mode that measures velocity in a PW sample volume and displays that information in a spectral trace with audio output.

Using PW Doppler (Android Devices Only)

1. In 2D mode, optimize the image.
2. Touch **PW** .
3. Use your finger to position the sample-volume gate.
4. To adjust the sample-volume gate, do any of the following:
 - To adjust the size of the sample-volume gate, touch **+** or **-** in **SV Size**.
 - To adjust the angle of the sample-volume gate, touch **Steer** (linear transducers only).
 - To adjust the angle of flow, touch **SV Angle** to cycle between **60**, **0**, and **60**.
5. Touch  or **PW**  to display the spectral trace.
6. To hear the Doppler signal clearly, adjust the volume of your mobile device.
7. Optimize the image, using any of the following methods:

- To automatically optimize adjustments such as gain, scale, and baseline, touch **iSCAN** . For more information, see [“iSCAN Intelligent Optimization” on page 152](#).
 - To manually adjust the gain, use **Gain**.
 - To manually adjust the scale, use **Scale**.
 - To move the baseline, drag the baseline to the position you want.
 - To change sweep speed, touch **Sweep Speed**.
 - To invert the spectral trace, touch .
8. To review the Doppler trace, freeze the image, and then drag your finger left or right along the loop time line.
 9. To exit PW Doppler, touch **PW**.

Imaging Features

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



Full-Screen View

You can specify that Lumify display live or frozen images in full-screen view, including in **Review**.

1. To view an image in full-screen view, touch  in the lower right corner of the image.
2. To restore normal viewing, touch .

Displaying a Centerline

You can display a centerline in the imaging area during a scan or when the image is frozen. The centerline is included in acquired images or loops.

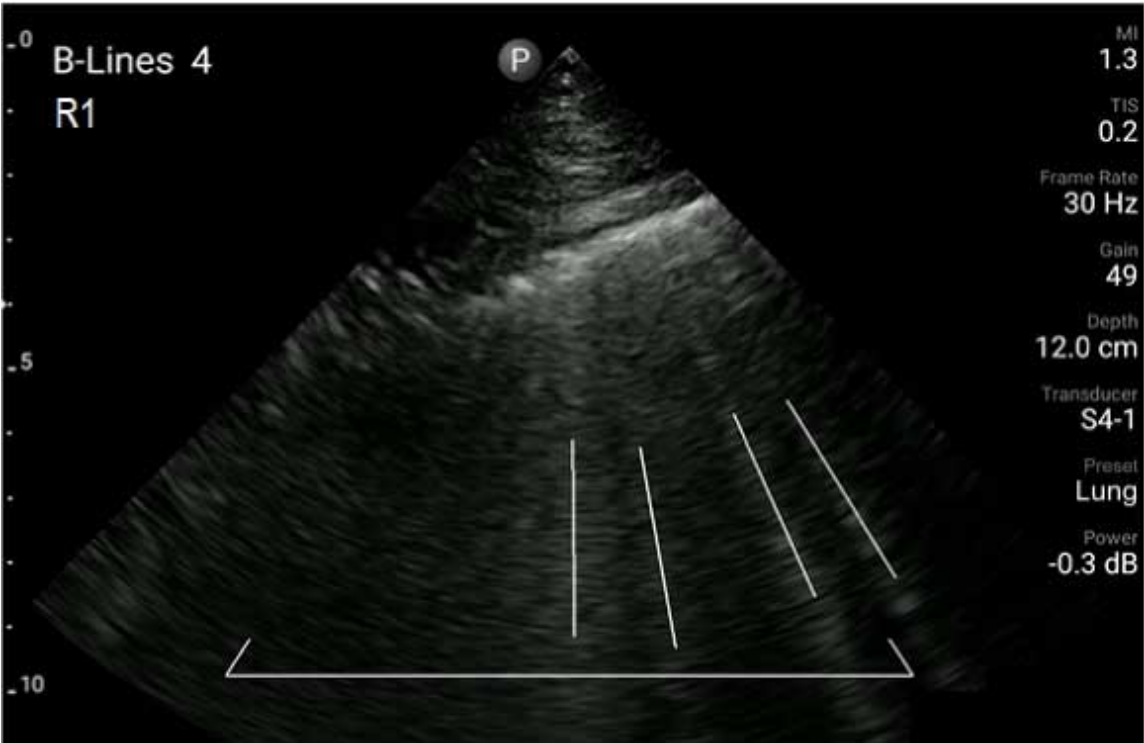
To display the centerline, touch  on the lower left corner of the imaging display. To hide the centerline, touch  again.

B-Lines and the Lumify B-Lines Feature (Android Devices Only)

This section describes B-lines and the Lumify B-Lines feature.

B-Lines Overview (Android Devices Only)

B-lines occur when sound waves encounter a mixture of air and water. They are hyperechoic imaging artifacts that appear in a lung exam as long bands of varying widths that originate at the pleural line and extend vertically the length of the ultrasound image. The presence of B-lines in a lung exam can indicate a wide variety of pulmonary conditions, such as pneumonia, pulmonary edema, lung contusion, and acute respiratory distress syndrome (ARDS).



B-Lines Example

Lumify B-Lines Feature

The Lumify B-Lines feature counts B-lines in each of up to 12 predefined segments of the chest and upper back (labeled **Front** and **Back** in the B-lines **Summary**). After selecting and scanning one or more segments, you can view a visual representation of the front and back with an overlay of the range of B-lines counted in each segment to help identify the most affected areas. For more information about the B-lines **Summary** display, see [“Viewing Results \(Android Devices Only\)”](#) on page 162.




Summary of Predefined Lung Segments with B-Line Results


Viewing the Lumify B-Lines Feature Walkthrough

The Lumify B-Lines feature walkthrough provides a basic tutorial of how to set up and perform B-line lung exams, including the following:

- Selecting lung segments to scan
- Acquiring loops and images
- Reviewing exam results

The first time you start the B-Lines feature, the walkthrough begins automatically. To view the walkthrough again at any time, touch .

iSCAN Intelligent Optimization


iSCAN Intelligent Optimization  is used to automatically optimize key imaging parameters during Doppler acquisition. Doppler iSCAN optimization adjusts the Doppler baseline and scale. In selected presets, Doppler iSCAN adjusts gain.

Acquiring Images

NOTE



All saved images and loops display the date and time of the time zone in which they were acquired.

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.

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.

- Android devices: Loops in Review have the  icon in the lower right corner of the thumbnail.
- iOS devices: Loops in Review have the  icon in the center of the thumbnail.

NOTE

All saved images and loops display the date and time of the time zone in which they were acquired.

The system captures loops prospectively. You can specify the loop length duration in **Settings**. For more information, see [“System Settings” on page 97](#).

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






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

Annotation (Android Devices Only)

The annotation feature is available in 2D and Color frozen mode.

Adding Labels (Android Devices Only)

You can place text labels on an image to identify anatomical structures and locations.

1. Obtain the image you want to annotate and touch .
2. If necessary, touch the page indicator ( or ) or swipe to display **Annotate** .
3. Touch **Annotate** .
4. Use the 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.
5. Drag the label into position in the imaging area.

6. To edit a label, do the following:
 - 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.
7. To delete a label, do either of the following:
 - Touch and hold the label. Touch **Delete Annotation** when it appears.
 - Touch the label and use your device's keyboard to delete the text.

Measurement and Analysis



The ultrasound system supports measurements. The measurement tools appear on the screen. Touching the tool label on the screen launches the tool.


The accuracy of the measurement depends, in part, on the ability of the operator.

Performing a 2D Distance Measurement

A 2D distance measurement uses two calipers to measure the length of a straight line between the two points. You can create a maximum of four distance measurements at a time. Each distance measurement uses a set of uniquely shaped calipers to help identify a measurement with their corresponding calipers.



While you are using the 2D distance measurement tool, double-tap to zoom the image. 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 152](#)).

1. Obtain the 2D image you want to measure and touch .
2. Touch **Measure** .

3. Touch **Distance**  from the menu. The word **Distance** and an initial value appear at the top of the image.
4. Touch the first caliper and drag to position it.
5. Touch the second caliper and drag to position it. The results update as the distance between the calipers changes.

NOTE



If you drag a measurement caliper out of the image area, the caliper may disappear. To restore the caliper position, touch **Measure**, touch **Clear All**, and then touch **Measure** and add the **Ellipse** or **Distance** measurement again.


6. To add additional distance measurements, repeat step 2 through step 5. A maximum of four distance measurements can be added to the image.
7. To save an image with the displayed measurements, touch **Save Image** .
8. To remove the measurements, touch **Clear All** .

Performing a 2D Ellipse Measurement

A 2D ellipse measurement uses an ellipse caliper to define the area and circumference of an ellipse.



While you are using the 2D ellipse measurement tool, double-tap to zoom the image. 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 152](#)).

1. Obtain the 2D image you want to measure and touch .
2. Touch **Measure** .

3. Touch **Ellipse**  from the menu. The word **Area** and **Circumference** with their initial values appear at the top of the image.
4. Using the control points, drag the ellipse into position in the imaging area. The results update as you move the ellipse into position.

NOTE

If you drag a measurement caliper out of the image area, the caliper may disappear. To restore the caliper position, touch **Measure**, touch **Clear All**, and then touch **Measure** and add the **Ellipse** or **Distance** measurement again.

5. To save an image with the displayed measurements, touch **Save Image** .
6. To remove the measurement, touch **Clear All** .

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.



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	0.001 to >30.0 cm
Lateral Distance	< ± 2.5% or 3 mm	0.001 to >40.0 cm
Diagonal Distance	< ± 2% or 2 mm	0.001 to >32.0 cm

M-Mode Measurement Range and Accuracy

Measurement	Accuracy	Range
Depth	< ± 2% or 1 mm	0.003 to >29.8 cm
Time	< ± 2% of time or 4 ms measurement	0.002 to >22.7 s
Slope	≤ ± 0.2 cm/sec or ± 1%	--

PW Doppler Measurement Range and Accuracy

Measurement	Accuracy	Range
Velocity Measurement	< ± 3% of full scale	0.1 cm/s to 350 cm/s
Time Difference	± 1% of total time scale	10 ms to > 8 s
















Performing Fetal Analysis (Android Devices Only)

You can perform fetal analysis from the current exam. The **Fetal Age Summary** is saved in the patient exam, and is available in the **Review** display (see [“Viewing the Fetal Age Summary \(Android Devices Only\)” on page 168](#)).






WARNING

You are solely responsible for custom measurements and calculations and the accuracy of elements entered into the equations.

1. If necessary, touch the page indicator ( or ) or swipe to display **Fetal Age** .
2. Touch **Fetal Age** .
3. Obtain the 2D image you want to measure and touch .
4. Touch a system-defined fetal age or growth measurement.
5. For **HC**  and **AC** , using the control points, drag the ellipse into position in the displayed image, and then touch **Confirm Measurement** .
6. For **FL** , **BPD** , and **CRL** , drag the calipers into position in the displayed image, and then touch **Confirm Measurement** .
7. For **Sac Diam** :
 - a. Touch **Sac Diam1**, drag the calipers into position in the displayed image, and then touch **Confirm Measurement**.
 - b. Touch **Sac Diam2**, drag the calipers into position in the displayed image, and then touch **Confirm Measurement**.
 - c. Touch , obtain the 2D image you want for the third measurement, and then touch .
 - d. Touch **Sac Diam3**, drag the calipers into position in the displayed image, and then touch **Confirm Measurement**.

NOTE

If you drag a measurement caliper out of the image area, the caliper may disappear. To restore the caliper position, touch **Measure**, touch **Clear All**, and then touch **Measure** and add the **Ellipse** or **Distance** measurement again.

8. For **LMP/EDD** , select the **EDD** date from the calendar. The **LMP(c)** date is automatically calculated based on your selection.
 - To switch to the next or previous weeks or months, swipe up or swipe down from the calendar.
 - To save the **LMP/EDD** measurement, touch **OK**.
 - To return to the **Fetal Age** menu without saving the **LMP/EDD** measurement, touch **Skip**.
9. To expand or collapse the **Fetal Age Summary**, in portrait orientation, touch  or .

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.

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

Using the Lumify B-Lines Feature (Android Devices Only)




This section guides you through the process of using the Lumify B-Lines feature to identify and assess areas of possible lung pathology in a patient.

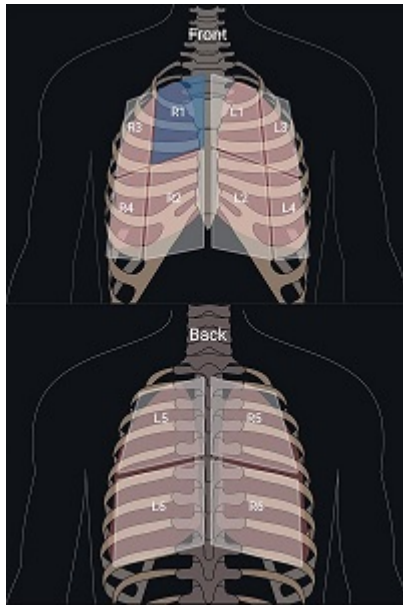
Performing a B-Lines Exam (Android Devices Only)

NOTE





The Lumify B-Lines feature is available for use only with the Lumify linear array (L12-4) and sector array (S4-1) transducers.


The default length of a loop in the B-Lines feature is 3 seconds (90 frames). The minimum length of a loop is 1 second (30 frames).

1. On the **Scan/Create Patient** display, touch the **Lung**  exam preset, or drag the selector on the preset selector wheel to **Lung** .
2. Touch **Scan**.
3. On the imaging display, touch **B-Lines** .
4. On the B-lines **Summary** display, using the **Front** and **Back** diagrams, touch the segment of the lungs (for example, **R1**) that you want to scan first.



Selecting a Lung Segment

5. Perform a scan of the lung in the area that corresponds to the segment that you selected, and then save a loop or an image of the scan. The loop or image is assigned to that segment. During scanning, B-lines indicators can sometimes extend below the reference line at the bottom of the image. Rotating your mobile device during scanning may cause the **Summary** display to appear.
6. To select another segment to scan, do one of the following:
 - For loops only, touch **Auto Advance** . After you save a loop, you will automatically advance to the next segment.
 - Touch **Summary** , and then select a new segment from the diagram.
 - Touch  to go to the next segment, or touch  to return to the previous segment.
7. To re-take a saved image or loop:

- a. On the B-lines **Summary** display, select the segment that contains the image or loop that you want to amend.
 - b. Touch the image or loop that you want to amend.
 - c. Touch **Re-Take** to return to the exam, scan the selected area, and save a new image or loop. The new image or loop replaces the one you selected.
8. To end the exam, touch **End Exam** . On the imaging display, the system prompts you to go to the B-lines **Summary** display to review your results.

Viewing Results (Android Devices Only)

To open the B-lines **Summary** display at any point during an exam or while in Review, touch

Summary .



B-Lines Summary

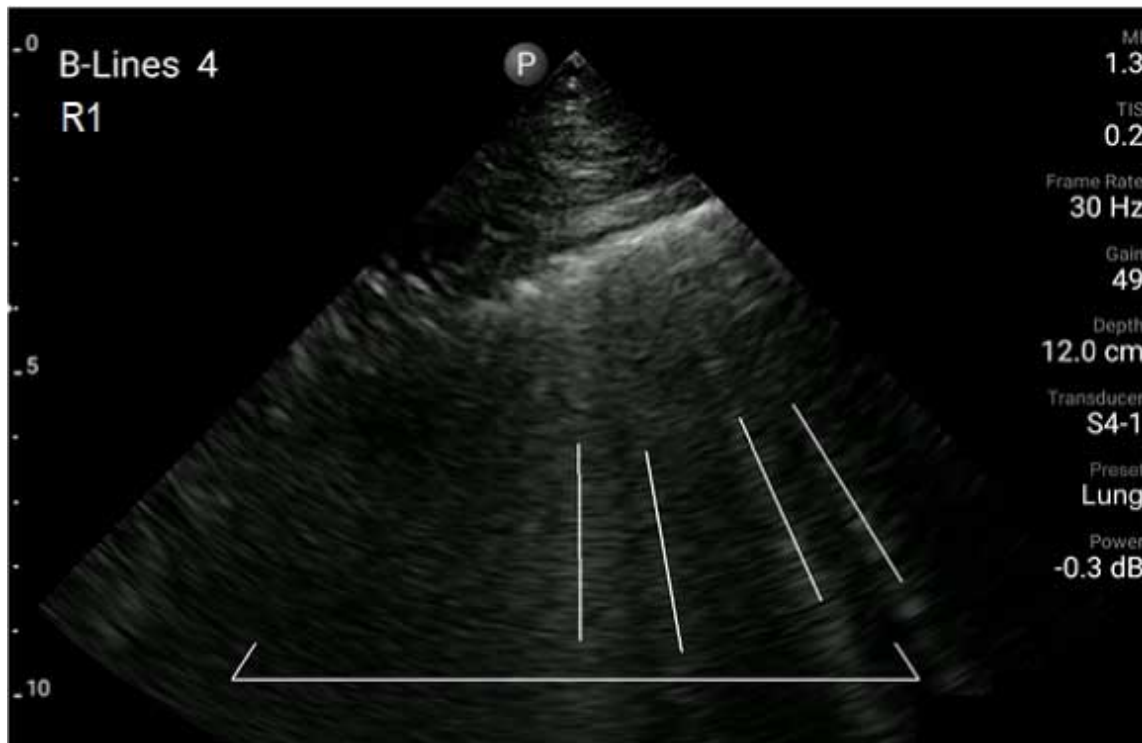
The B-lines **Summary** display shows the maximum number range of B-lines counted in each lung segment. More than three B-lines in any individual segment indicates an increased risk of lung pathology. The Lumify system assigns a color code to each segment based on the number of B-lines counted.

Color Codes for Number of B-Lines Counted in a Lung Segment

Color	Number of B-Lines
Green	0
Orange	1 to 2
Red	3 or more

Based on your own analysis, you can manually change the number of B-lines recorded for any segment. To change the maximum number of B-lines for a segment, see [“Revising a B-Line Exam \(Android Devices Only\)” on page 164](#).

For easier identification, B-line indicators on the display highlight the B-lines in each saved loop and image. The B-line indicators can be hidden on loops and images in Review. To hide B-line indicators on saved loops and images, see [“Revising a B-Line Exam \(Android Devices Only\)” on page 164](#).





B-Lines Example


Revising a B-Line Exam (Android Devices Only)

The Lumify B-Lines feature automatically indicates and counts the B-lines in each saved loop or image. You can manually identify and record the presence of B-lines in Review.

Hiding or Showing B-Line Indicators




While in Review, you can hide or show B-line indicators for all loops and images in an exam.

1. Touch , and then touch **Saved Exams** .
2. Select the B-line exam that you want to review.

3. Select or deselect **Show B-Lines**.
4. To exit review, touch .

Changing the B-Line Count

You can manually change the maximum number of B-lines shown on the **Summary** display for any lung segment. The changes are applied to the **Summary** image as well as the saved loops and images.

1. Touch , and then touch **Saved Exams** .
2. Select the B-line exam that you want to review.
3. Select a loop or an image that is associated with the segment you want to change.
4. Use the **Edit Max** control to raise or lower the number of B-lines counted in that segment.
5. Repeat this procedure for each segment you want to change.
6. To exit review, touch .

Exporting B-Line Exams (Android Devices Only)





When you export a B-line exam, the **Summary** display image is included with the exam. Each image and loop in the exam shows the lung segment being scanned.

7 Review

In the **Review** display, you can view and delete images and loops from the current exam or from saved exams. You can also export or e-mail images from Review. You must end the exam before you can export the exam or e-mail images from the exam. You cannot end an exam while in Review.





Starting Review During an Exam

To start Review during an exam:

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

Starting Review After an Exam

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

1. Touch , and then touch **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 then touch **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.
- To scroll through the available thumbnails, drag the thumbnails left or right, or up or down, depending on the screen orientation.

Viewing the Fetal Age Summary (Android Devices Only)

In **Review**, if you performed fetal analysis during an exam, **Summary** appears on the upper right corner of the **Review** display.

1. Touch **Summary**  to view the **Fetal Age Summary**.
2. Touch **Done** to close the **Fetal Age Summary** and return to the **Review** display.

Playing Loops

1. Touch the loop thumbnail.
 - Android devices: Loops are identified by the  icon located in the bottom right corner of the thumbnail.
 - iOS devices: Loops are identified by the  icon located in the center of the 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	Step back control. Touch to step a single frame backward.
3	Step forward control. Touch to step a single frame forward.
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.

Exporting Images and Loops

You must end the exam before you can export the exam or e-mail images from the exam. You can export any of the following to either a configured network destination or by using one of the supported e-mail clients on the device:

- Images
- Loops
- (Android devices only) **Fetal Age Summary**

E-mailing Images and Loops



WARNING

It is your responsibility to ensure that the security of your device and the protection of patient data meet your local security policies and regulatory requirements. Before e-mailing images and loops, 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* USB media or in the Support section of the Lumify website (www.philips.com/lumify).





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":

- Android devices: <https://support.google.com>
- iOS devices: <https://support.apple.com>

If several e-mail accounts are available on the device, the system prompts you to select from a list of the available accounts. You can select any e-mail account available to you regardless of which e-mail account is associated with your Reacts account. During e-mail export, the file may be omitted from the message without any notification if the file size exceeds the limit of the e-mail application.



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

Android Devices

1. Touch , and then touch **Saved Exams** .
2. Touch a saved exam to open it in **Review**.
3. In the **Review** display, do one of the following:
 - To e-mail all of the exam's images, touch **Export Exam** .
 - To e-mail select images and loops, touch and hold the thumbnail image. The border of the selected thumbnail changes to yellow. Touch additional images and loops to add them to the e-mail. Touch **Export Selected** .
4. Touch **Email**.
5. Read the privacy statement and touch **Continue**.
6. If the **Pick an Email Application to Use** dialog box appears, touch to select an e-mail application from the list, and then do any of the following:
 - Touch **Just Once** to only use the selected e-mail application during the current export. The **Pick an Email Application to Use** dialog box appears until **Always** is selected.
 - Touch **Always** to set the selected e-mail application as the default.
7. 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.

8. Add recipients and text to the e-mail and send the e-mail. The images, loops, and the **Fetal Age Summary** are automatically attached to the e-mail.

iOS Devices


1. Touch , and then touch **Saved Exams** .
2. Touch a saved exam to open it in **Review**.
3. In the **Review** display, touch **Select**, and then do one of the following:
 - To e-mail all of the exam's images, touch **Select All**.
 - To e-mail select images and loops, touch the thumbnail image. The border of the selected thumbnail changes to blue. Touch additional images and loops to add them to the e-mail.
4. Touch **Export**.
5. Under **Export To**, touch **App Share**.
6. Read the privacy statement and touch **Okay**.
7. Select an e-mail application from the list. A new e-mail message appears with your selected images attached.
8. Add recipients and text to the e-mail and send the e-mail. The images and loops you selected are automatically attached to the e-mail.




Exporting Images and Loops to a Network Destination

You can add, edit, copy, rename, or delete an export destination (see [“Configuring Export Destinations” on page 179](#) and [“Editing Export Destinations” on page 183](#)).


Android Devices

You can export images, loops, and the **Fetal Age Summary** to a DICOM PACS, to a network share, or to a local directory. The system exports still images and the **Fetal Age Summary** in **RLE (Lossless)** or **JPEG (Lossy)** format.

1. Touch , and then touch **Saved Exams** .



2. Touch a saved exam to open it in **Review**.
3. In the **Review** display, do one of the following:
 - To export all of the exam's images, touch **Export Exam** .
 - To export select images, touch and hold a thumbnail image. The border of the selected thumbnail changes to yellow. Touch additional images to add them to the export. Touch **Export Selected** .
4. If an export destination profile has previously been created, touch to select it from the **Export Selected**  menu, and the images, loops, and **Fetal Age Summary** export automatically.

NOTE

For information on creating a new export destination, see [“Configuring Export Destinations” on page 179](#). After you create a new export destination, it will be saved on the system and appear in the **Export Selected**  menu.

iOS Devices

You can export images and loops to a DICOM PACS or to a local directory. The system exports still images in **RLE (Lossless)** or **JPEG (Lossy)** format.

1. Touch , and then touch **Saved Exams** .
2. Touch a saved exam to open it in **Review**.
3. In the **Review** display, touch **Select**, and then do one of the following:
 - To e-mail all of the exam's images, touch **Select All**.
 - To e-mail select images and loops, touch the thumbnail image. The border of the selected thumbnail changes to blue. Touch additional images and loops to add them to the export.


4. Touch **Export**.
5. If an export destination profile has previously been created, touch to select it from the **Export To** menu, and the images and loops export automatically.

NOTE


For information on creating a new export destination, see [“Configuring Export Destinations” on page 179](#). After you create a new export destination, it will be saved on the system and appear in the **Export To** menu.

Deleting Images and Loops

Android Devices

1. In the **Review** display, touch and hold a thumbnail image. The border of the selected thumbnail changes to yellow. Touch additional images and loops to delete more than one image.
2. Touch **Delete** .
3. Touch **Yes** to confirm the deletion.

iOS Devices

1. In the **Review** display, touch and hold a thumbnail image. The border of the selected thumbnail changes to yellow. Touch additional images and loops to delete more than one image.
2. Touch .
3. Touch **Delete** to confirm the deletion.

Exporting Exams

You can export exams to a DICOM PACS, to a network share (Android devices only), or to a local directory. See [“Configuring Export Destinations” on page 179](#).

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








Android Devices

For exams exported to a DICOM PACS, the system uses the following formats:

- For still images and the **Fetal Age Summary**, JPG or RLE format
- For loops, JPG or RLE Ultrasound Multi-Frame Image format

For exams exported to a network share or to a local directory, the system uses the following formats:

- For still images and the **Fetal Age Summary**, PNG format
- For loops, MP4 format

1. Touch , and then touch **Saved Exams** .
2. Touch and hold an exam until **Selected Exams** appears.
3. Do one of the following:
 - 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 additional exams, and then touch **Export** .
 - To export all of the exams, touch **Select All** , and then touch **Export** .
4. Select a destination from the **Export**  menu. (To add a new destination, select **Add New**. For more information, see [“Configuring Export Destinations” on page 179](#).)

A confirmation message appears when the export is complete.





iOS Devices

For exams exported to a DICOM PACS, the system uses the following formats:

- For still images, JPG or RLE format
- For loops, JPG or RLE Ultrasound Multi-Frame Image format

For exams exported to a local directory, the system uses the following formats:



- For still images, PNG format
- For loops, MP4 format

1. Touch , and then touch **Saved Exams** .
2. Touch **Select**.
3. Do one of the following:
 - To export a single exam, touch it. A check mark  appears next to the exam you selected. Touch **Export**.
 - To export more exams, touch each additional exam. A check mark  appears next to each exam you select. Touch **Export**.
 - To export all of the exams, touch **Select All**, and then touch **Export**.
4. Select a destination from the **Export To** menu.




Showing or Hiding Patient Data on Exported Images and Loops

You can choose to show or hide patient information on images and loops that you export to a DICOM server, to a local directory, or to a network share (Android devices only). By default, the system includes patient data when you export to a network share or to a local directory, and hides the patient information at the top of the image when you export to a DICOM server.

Android Devices

1. Touch , and then touch **Export Destinations** .
2. Select the export destination for which you want to specify that patient data be shown or hidden (if you need to add an export destination, see [“Configuring Export Destinations” on page 179](#)).
3. Select **Show Advanced Options**.
4. Do one of the following:
 - To show patient information on exported images and loops, select **Include Patient Data on Each Image**.
 - To hide patient information on exported images and loops, deselect **Include Patient Data on Each Image**.



iOS Devices

1. Touch , and then touch **Export Destinations** .
2. On the **Export Destinations** page, next to the destination that you want to modify, touch .
3. Touch **Edit**.
4. Select **Show Advanced Options**.
5. Do one of the following:
 - To show patient information on exported images and loops, select **Include Patient Data on Each Image**.
 - To hide patient information on exported images and loops, deselect **Include Patient Data on Each Image**.




Showing or Hiding the Institution Name on Exported Images and Loops

You can choose to have the name of your institution appear on exported images and loops.

Android Devices

1. Touch , and then touch **Export Destinations** .
2. Select the export destination for which you want to specify that the institution name be shown or hidden (if you need to add an export destination, see [“Configuring Export Destinations” on page 179](#)).
3. Select **Show Advanced Options**.
4. Do one of the following:
 - To show the institution name on exported images and loops, select **Include the institution name on Each Image**.
 - To hide the institution name on exported images and loops, deselect **Include the institution name on Each Image**.

iOS Devices







1. Touch , and then touch **Export Destinations** .
2. On the **Export Destinations** page, next to the destination that you want to modify, touch .
3. Touch **Edit**.
4. Select **Show Advanced Options**.
5. Do one of the following:
 - To show the institution name on exported images and loops, select **Include the Institution Name on Each Image**.

- To hide the institution name on exported images and loops, deselect **Include the Institution Name on Each Image**.





Deleting Exams

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

Android Devices

1. Touch , and then touch **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 and hold to select additional exams and then touch **Delete** .
 - To delete all exams, touch **Select All**  and then touch **Delete** .
4. In the **Delete Confirmation** dialog box, touch **Yes**.

iOS Devices



1. Touch , and then touch **Saved Exams** .
2. Touch **Select**.
3. Do one of the following:
 - To delete a single exam, touch it. A check mark  appears next to the exam you selected. Touch **Delete**.
 - To delete multiple exams, touch each exam you want to delete. A check mark  appears next to each exam you select. Touch **Delete**.
 - To delete all of the exams, touch **Select All**, and then touch **Delete**.

4. In the **Delete Confirmation** dialog box, touch **Delete**.

Configuring Export Destinations

Android Devices

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

1. Touch , and then touch **Export Destinations** .
2. Touch **Add New**.
3. In the **Add New Destination** dialog box, type a **Destination Nickname** and select a **Destination Type**. Touch **Continue**.



NOTE

If you rotate your device while settings are selected in the **Add New Destination** dialog box or when you are editing an export destination, the system does not save your selections. To avoid this situation, do not rotate your device while adding or editing export destinations.

4. Configure destination settings (see [“Export Destination Settings” on page 180](#)).
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, on the **Connectivity Profiles** page, select an option from the **Upon Exam Completion, Automatically Export Loops and Images To** menu. For more information, see [“Editing Connectivity Profiles” on page 121](#).

iOS Devices

You can export exams to a DICOM PACS or to a local directory.

- 1. Touch , and then touch **Export Destinations** .
- 2. Touch **+**.
- 3. Select the type of export destination you want to create.
- 4. Type a **Destination Nickname**.

NOTE

The name entered for **Destination Nickname** appears in the **Export Destinations** list.

- 5. Configure destination settings (see [“Export Destination Settings” on page 180](#)).
- 6. To test the connection to the export destination, touch **Test**.
- 7. To save the export destination, touch **Save**.
- 8. To specify a default export destination, on the **Connectivity Profiles** page, select an option from the **Upon Exam Completion, Automatically Export Loops and Images To** menu. For more information, see [“Editing Connectivity Profiles” on page 121](#).

Export Destination Settings

DICOM Destination Settings

Setting	Description
Destination Nickname	The name that appears in the list of export destinations
Lumify AE Title	The AE title for the device
Remote AE Title	The AE title for the server
Hostname or IP Address	Use a DNS or a static IP address

Setting	Description
Port	The port number for the server
Export Format	RLE (Lossless) or JPEG (Lossy)
Advanced Options, Display Compensation	Brightness and Contrast
Advanced Options, Include Patient Data on Each Image	Adds patient information to exported images and loops (by default, this option is deselected).
Advanced Options, Include Institution Name on Each Image	Adds the institution name to exported images and loops (by default, this option is deselected).
Advanced Options, Advanced Connection Settings	<ul style="list-style-type: none">• DNS Suffix• Read Timeout (sec): The network reply timeout• Connection Timeout (sec): The DICOM ARTIM timeout• Max Packet Size (bytes): Restricts the size of data packets. Contact your network admin for packet limitations.• Retry Interval (sec): How much time the system will wait before retrying a job to the server• Max Retries: How many retries the system will perform before failing the job

Network Share Destination Settings (Android Devices Only)

Setting	Description
Hostname	The IP address 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

Setting	Description
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, Include Patient Data on Each Image	Deselect to remove patient information from exported images and loops (by default, this option is selected).
Advanced Options, Display Compensation	Brightness and Contrast
Advanced Options, Advanced Connection Settings	<ul style="list-style-type: none">• DNS Suffix• Retry Interval (sec): How much time the system will wait before retrying a job to the server• Max Retries: How many retries the system will perform before failing the job

Local Directory Destination Settings

Setting	Description
Destination Nickname	The name that appears in the list of export destinations
Directory	Type the path to the folder in which you want to store exams
Prompt each time when exporting to this location?	Select to require confirmation before exporting to this destination

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Setting	Description
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 .
File Type	Choose the file format you want to use to store the exam data
Advanced Options, Display Compensation	Brightness and Contrast
Advanced Options, Image Resolution	Choose a resolution that matches the display on which the exam will be viewed
Advanced Options, Include Patient Data on Each Image	Deselect to remove patient information from exported images and loops (by default, this option is selected)
Advanced Options, Include Institution Name on Each Image	Deselect to remove the institution name from exported images and loops (by default, this option is selected)

Editing Export Destinations







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

Android Devices

1. Touch , and then touch **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. Touch **Save**.



- To delete the export destination, touch and hold the export destination until the selection is highlighted. Touch **Delete** . Touch **Yes** to confirm the deletion.
- To rename the export destination, touch and hold the export destination until the selection is highlighted. Touch **Rename** . In the **Rename Destination** dialog box, type a new destination nickname for the destination and touch **Rename** .
- To copy an export destination, touch and hold the export destination until the selection is highlighted. Touch **Copy** . In the **Copy Destination** dialog box, type a name for the new destination and touch **Copy** .

iOS Devices

1. Touch , and then touch **Export Destinations** .
2. Touch  next to the export destination you want to modify, and then do any of the following:
 - To edit the export destination, touch **Edit**  and use the keyboard to modify fields and options. Touch **Save**.
 - To delete the export destination, touch **Delete** . In the **Delete Confirmation** dialog box, touch **Delete** again to confirm the deletion.
 - To copy the export destination, 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 180](#)).

1. Touch , and then touch **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 , touch **Export Queue** , and then, at the top of the page, touch  (Android devices) or  (iOS devices).
 - Touch , touch **Export Destinations** , and then, at the top of the page, touch  (Android devices) or  (iOS devices).
2. To start logging, touch **Start DICOM Logging**. To stop logging, touch **Stop DICOM Logging**.
3. To view logs, touch **View Logs From [Date and Time]**.
4. To delete logs, touch **Delete DICOM Logs**.

8 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.

For information on connecting transducers, see [“Connecting Transducers” on page 116](#). For more information on caring for and maintaining transducers, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

Transducer Safety



WARNING

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



WARNING

Always remove the transducer from the patient before defibrillation.



WARNING

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



CAUTION

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

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.

Presets and Transducers

These are the presets for the transducers that are compatible with your ultrasound system.

System Transducers and Supported Presets

Transducer	Presets
C5-2	Abdomen, Gallbladder, Lung, OB/GYN
L12-4	Lung, MSK, Soft Tissue, Superficial, Vascular
S4-1	Abdomen, Cardiac, FAST, Lung, OB/GYN

Transducer Maintenance

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 authorized service representative, and discontinue use of the transducer.

For all information on transducer cleaning and disinfection, including information on compatible disinfectants, see *Care and Cleaning of Ultrasound Systems and Transducers, Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*, and the Philips Transducer Care website:

www.philips.com/transducercare

If you encounter poor image quality or transducer problems, see “[Troubleshooting](#)” on [page 204](#).



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 193](#) and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers* or the Philips Transducer Care website: www.philips.com/transducercare. You can also contact your authorized service representative. For contact information, see “[Customer Service](#)” on [page 21](#).

Acoustic Artifacts

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

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

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

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

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

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

Enhancement is an increased relative amplitude of echoes caused by an intervening structure of low attenuation.

Focal enhancement, also known as **focal banding**, is the increased intensity in the focal region that appears as a brightening of the echoes on the display.

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

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

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

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

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

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

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

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

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

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

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

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

Transducer Covers

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



WARNING

High-level disinfected and sterilized transducers that are used in a sterile field should use be used with sterile ultrasound transmission gel and a legally marketed 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, mineral oil, or water-based gels that contain mineral oil. Such products may damage the transducer and void the warranty.



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
- EcoVue
- Scan
- Ultra Phonic

Transducer Transport

Transport used transducers in a spill-proof, closed container with appropriate contamination labeling. To avoid damage to the lens, ensure that the container holds the transducer in place. During transportation, prevent all patient-contact parts from contacting non-patient-contact parts.

When you transport cleaned and disinfected transducers, ensure that any containers used for transport are also cleaned and disinfected before you place the clean transducers in the containers.

For more information, see [“Storage for Transport” on page 195](#).

Transducer Storage

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

**CAUTION**

Before storing transducers, ensure that they are thoroughly dry. If it is necessary to dry the transducer lens (acoustic window) after cleaning, use a soft, dry, lint-free cloth and a gentle blotting motion. Aggressive wiping or scrubbing can damage the lens.

Storage for Transport

Always use the carrying bag that 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. If needed, start the Lumify app.

5. Touch , and then touch **Settings** .
6. Do one of the following:
 - Android devices: In **Transducer Tests**, touch **Run Tests**.
 - iOS devices: Touch **Registered Transducers**, and then, under **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 website:

www.philips.com/lumify

9 System Maintenance

You should perform system maintenance regularly and as needed.



WARNING

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



CAUTION

Follow all instructions provided to avoid damage during cleaning, disinfection, and sterilization. Failure to do so could void your warranty.

Transducer Care



CAUTION

Do not apply adhesive films, such as Tegaderm, to the transducer lens. Application of such films can damage the lens.

All Philips transducers require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization. Transducers must be cleaned and disinfected or sterilized after each use. You must also carefully inspect all parts of the transducer 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.

For detailed instructions on how to clean, disinfect, and maintain each type of transducer used with the system, including disinfectant compatibility, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*. Information on compatible disinfectants is also available at:

www.philips.com/transducercare

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 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

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 authorized service representative, and discontinue use of the transducer.

For all information on transducer cleaning and disinfection, including information on compatible disinfectants, see *Care and Cleaning of Ultrasound Systems and Transducers*, *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*, and the Philips Transducer Care website:

www.philips.com/transducercare


If you encounter poor image quality or transducer problems, see “[Troubleshooting](#)” on [page 204](#).





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 193](#) and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers* or the Philips Transducer Care website: www.philips.com/transducercare. You can also contact your authorized service representative. For contact information, see “[Customer Service](#)” on [page 21](#).

Sending System Logs

The Lumify app sends system logs to Philips periodically. System logs include Reacts errors. 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 then touch **Settings** .
2. Do one of the following:
 - Android devices: In **System Logs**, touch **Send Logs**.
 - iOS devices: Touch **Logs**. On the **Logs** page, under **System Logs**, touch **Send**.

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

Viewing Audit Logs

Audit logs record the following information about access to patient data:



- When exams began and ended
- When exams and images were viewed
- When exams and images were exported or deleted
- When images were sent by e-mail

1. Touch , and then touch **Settings** .
2. Do one of the following:
 - Android devices: In **Audit Logs**, touch **View Audit Logs**.
 - iOS devices: Touch **Logs**. On the **Logs** page, touch **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.



Repairing the Patient Database

Repair your patient database if you think it has been corrupted or if it is missing information. If **Repair Database** does not fix the problem, try importing the database from an archived export file. For more information about importing an archived patient database, see [“Importing a Patient Database” on page 203](#).

Android Devices

1. Touch , and then touch **Settings** .
2. Under **Patient Database**, touch **Repair Database**.
3. To confirm that you want to repair the patient database, touch **Yes**.

iOS Devices

1. Touch , and then touch **Settings** .
2. Touch **Patient Database**.
3. Under **Repair Database**, touch **Repair**.
4. To confirm that you want to repair the patient database, touch **Repair**.
5. After the operation is complete, touch **Okay**.

Exporting and Importing the Patient Database



CAUTION

If you delete the Lumify app, patient data stored on the mobile device will be lost.

NOTE



Depending on Android device backup settings, the local media export location can be duplicated after removing and reinstalling the Lumify application.

Exporting the Patient Database



Export can be used to archive your patient database or send it to another device. You should archive your patient database whenever you update the Lumify app or your mobile device operating system to guard against loss of data.

Be sure to note the name, location, and password of your exported database. The Lumify system has no password recall or reset function for lost or forgotten passwords.

Android Devices

1. Touch , and then touch **Settings** .
2. Under **Patient Database**, touch **Export Database**.
3. Type and confirm the password you want to assign to the export file, and then touch **Export**.
4. Select the location to which you want to save the export file.
5. Type the name you want to assign to the export file, and then touch **Save**.
6. When the patient database export is complete, touch **Done**.

iOS Devices

1. Touch , and then touch **Settings** .
2. Touch **Patient Database**.
3. Under **Export Database**, touch **Export**.
4. Do one of the following:
 - To overwrite an existing file, type the file name and password for the existing patient database export file.
 - To create a new patient database export file, type a new file name and a new password.
5. Retype the password to confirm it.
6. Touch **Export**.
7. Choose where to send your patient database export file.

Depending on your network access, device settings, and security policies, you can save or send the file to your choice of locations.

Receiving a Patient Database from Another Device

You can receive exported patient database files from another Lumify system and import them to your own. After receiving or downloading a patient database export file, save it to an appropriate location on your mobile device. To import the received patient database into your Lumify system, see [“Importing a Patient Database” on page 203](#).

Importing a Patient Database



CAUTION

The Lumify system has no password recall or reset function for lost or forgotten passwords.

To access a patient database export file, you must know the name of the file, the location on your mobile device where it is saved, and the password assigned to it when it was exported.

Android Devices

1. Touch , and then touch **Settings** .
2. Under **Patient Database**, touch **Import Database**.
3. Touch **Select**, and then navigate to and select the patient database file you want to import.
4. Type the password for the export file you want to import.
5. Touch **Import**, and then touch **Confirm**.
6. After the import process is complete, touch **Okay**.

iOS Devices

1. Touch , and then touch **Settings** .
2. Touch **Patient Database**.

- 3. Under **Import Database**, touch **Import**.
- 4. Under **Database File**, touch **Select a File**. Navigate to the location of the export file you want to import, and then touch the file to select it.
- 5. Type the password for the export file you want to import.
- 6. Touch **Import**, and then touch **Confirm**.
- 7. After the import process is complete, touch **Okay**.

Troubleshooting

If you encounter difficulty in the operation of the system, use the information provided in this topic and at the Lumify website:

www.philips.com/lumify

If you still have questions, contact your Philips representative.

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 Lumify application crashes.	Verify that the Lumify application is current. If not, upgrade to the most recent version.
The system spontaneously reverts to the Scan/Create Patient display.	Verify that the device is fully charged.

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. If you are still unable to register, see “Troubleshooting Connectivity Issues” on page 206 .
Image artifacts appear.	Run the transducer test. See “Testing Transducers” on page 195 .
Lumify or Reacts will not connect to your wireless or cellular network.	Verify that the system has access to your wireless or cellular network. If you are still not able to connect, see “Troubleshooting Connectivity Issues” on page 206 .
Audio echo or feedback occurs during a remote Reacts session.	<ul style="list-style-type: none">• Mute the microphone when not speaking.• Decrease the speaker volume.• Use a headset.

Troubleshooting Connectivity Issues

After you have verified that the system has access to your wireless or cellular network, contact your network administrator or IT representative to ensure that the following domains, IP addresses, and ports are whitelisted on your network.

Registration and Normal Use

DNS	IP Address	Port
api.lumify.philips-healthsuite.com	52.211.142.146	TCP 443
api.lumify.philips-healthsuite.com	52.211.142.146	

Sending Logs

IP Address	Port
162.13.31.14	TCP 443

Verifying Network Access to Reacts

To verify that your network allows access to Reacts, go to the following website:

<https://svc.iitreacts.com/api/echo>

If you see the message **{“Version”:””, “Body”:”Echo OK!”, “Type”:”System.String”, “Time”:”[28 digit time]”, “Id”:”[36 character ID]”}**, call your local Philips representative for assistance. Although receiving this message confirms that you are connected to the network and your institution allows access to Reacts, there continues to be a problem.

If you do not see the message, contact your network administrator or IT representative to ensure that the following domains, IP addresses, and ports are whitelisted on your network:

Domains	IP Addresses	Ports
*.iitreacts.com, *.reacts.com	69.90.8.45	TCP 443
	69.90.8.46	UDP 443
	69.90.8.36	
	69.90.8.43	
	69.90.9.87	
	69.90.8.44	
	80.94.74.78	
	80.94.74.77	
	80.94.74.74	
	80.94.74.73	
	69.90.8.42	
	80.94.74.72	
	80.94.74.76	
	80.94.74.75	
	52.242.34.249	
	52.242.38.88	
	52.242.38.188	
	52.242.25.169	
	52.235.47.123	
	52.242.28.128	
	52.242.21.129	
	52.235.43.213	
	52.235.44.190	
	52.235.42.129	

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Domains	IP Addresses	Ports
	52.235.42.238	
	52.235.44.47	

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, see the Lumify website:

<https://www.usa.philips.com/healthcare/resource-catalog/feature-detail/ultrasound-lumify-global-resources>

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

If you still have questions, call your Philips representative.

10 References

Area and Circumference from Ellipse

The formula for area and circumference from ellipse via Beyer, where d_1 and d_2 are the two axes of the ellipse, is

$$\pi * \frac{d_1}{2} * \frac{d_2}{2}$$

Area from Ellipse

$$2\pi \sqrt{\frac{d_1^2 + d_2^2}{2}}$$

Circumference from Ellipse

Beyer, W. H. *Standard Mathematical Tables*. 28th Edition. CRC Press, Boca Raton, Florida, 1987, p. 126.

Gestational Age (Fetal Age)

The formula for gestational age (wk+day) via Hadlock, using abdominal circumference (AC range: 4.93 to 38.0 cm) is

$$8.14 + 0.753(AC) + 0.0036(AC^2)$$

Given the head circumference (HC range: 5.41 to 35.8 cm), the formula for gestational age via Hadlock, GA(HC)Hadl (in weeks) is

$$8.96 + 0.540(HC) + 0.0003(HC^3)$$

The formula for gestational age (in weeks) via Hadlock, using biparietal diameter (cm) (BPD range: 1.4 to 10.17 cm) is

$$9.54 + 1.482(BPD) + 0.1676(BPD^2)$$

The formula for gestational age (in weeks) via Hadlock, using femur length (FL in cm, range: 0.616 to 8.2 cm) is

$$10.35 + 2.460(FL) + 0.170(FL^2)$$

Hadlock, F. P., Deter, R. L., Harrist, R. B., Park, S. K. "Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters." *Radiology*, Vol. 152, No. 2: 497-501, August 1984.

Hadlock, F. P., Shah, Y. P., Kanon, D. J., Lindsey, J. V. "Fetal crown-rump length: reevaluation of relation to menstrual age (5-18 weeks) with high-resolution real-time US." *Radiology*, Vol. 182, No. 2: 501-505, February 1992.

Nyberg, D. A., Hill, L. M., Bohm-Velez. M., et al. *Transvaginal Ultrasound*. Mosby Year Book, 1992, p.76.

Estimated Due Date (EDD)

The estimated due date given the last menstrual period (LMP) equation is calculated using the following formula:

$$LMP + 40 \text{ weeks}$$

Hagen-Ansert, Sandra L. *Textbook of Diagnostic Ultrasonography, Third Edition*. The C. V. Mosby Co., 1989, p. 408.

Last Menstrual Period (LMP)

The last menstrual period given the estimated due date (EDD) equation is calculated using the following formula:

$$EDD - 40 \text{ weeks}$$

Hagen-Ansert, Sandra L. *Textbook of Diagnostic Ultrasonography, Third Edition*. The C. V. Mosby Co., 1989, p. 408.

Estimated Fetal Weight (EFW(BPD, HC, AC, FL))

The formula for the estimated fetal weight (EFW) in grams, from biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC) and femur length (FL) all in centimeters via Hadlock is

$$10^{(1.3596 - (0.00386AC \times FL) + (0.0064HC) + (0.00061BPD \times AC) + (0.0424 \times AC) + (0.174 \times FL))}$$

Normal ranges are grouped by EFW as percent of EFW and a gram offset.

Hadlock, F. P., Harrist, R. B., Sharman R. S., Deter R. L., Park S. K. "Estimation of Fetal Weight with the Use of Head, Body, and Femur Measurements—A prospective study." *AM J OBSTET GYNECOL* Vol. 151, No. 3: 333-337, February 1985.

11 Specifications

The Lumify system conforms to the following specifications.

System Specifications

Gray Shades

256 in 2D and M-mode

Scan Lines

Up to 1,024 scan lines

Service Life

Service life is defined by IEC 60601-1 as the amount of time that a medical device is expected to remain safe for use. The service life for medical device components may be defined by hours of use or number of times used.

NOTE

Regular maintenance is necessary for a medical device or component to perform for its expected service life.

The Lumify system is designed to have a minimum of 3 years of service life. The service life of the Lumify system will vary depending on the usage and environmental conditions.

Pressure, Humidity, and Temperature Limits (Transducers)

These limits apply only to the Philips Lumify transducers, not to the mobile 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, Transient, and Storage Limits (Transducers)

Parameter	Operating Limits	Transient Operating Limits (Not to exceed 20 minutes)	Storage Limits
Pressure	620 hPa (465 mmHg) to 1,060 hPa (795 mmHg)	--	500 hPa (375 mmHg) to 1,060 hPa (795 mmHg)
Humidity	15% to 95% non-condensing	Up to 41% relative humidity	15% to 95% relative humidity
Temperature	0°C (32°F) to 40°C (104°F)	-20°C (-4°F) to 50°C (122°F)	-40°C (-40°F) to 70°C (158°F)

Safety and Regulatory Requirements

Classification

- Device with transducers: 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.

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Vehicle Standards Met

The Lumify system has been tested to standards required for use in road ambulances, fixed-wing aircraft or rotary-wing aircraft.

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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