

User Manual

English

iOS Devices

Lumify Diagnostic Ultrasound Systems

PHILIPS

Contents

1 Read This First 11
Intended Audience 12
Indications for Use 12
Intended Use 13
Clinical Benefits 13
Use of the System 14
Warnings 14
User Information Components 15
User Information Conventions 16
Upgrades and Updates 20
Supplies and Accessories 20
Customer Service 21
Regulatory Representatives 22
Recycling, Reuse, and Disposal 23

2 Safety 27
Basic Safety 28
Electrical Safety 30
Defibrillators 33
Fire Safety 34
Equipment Protection 35
Product Compatibility 37
Symbols 38
Biological Safety 52
FDA Medical Alert on Latex 54

3000 135 93553_B/795 * NOV 2025

Philips

ALARA Education Program 56
Output Display 60
Control Effects 63
Related Guidance Documents 65
Acoustic Output and Measurement 66
Acoustic Output Tables 69
Acoustic Measurement Precision and Uncertainty 69

Operator Safety 70
Repetitive Strain Injury 71
Philips Transducers 71
Glutaraldehyde Exposure 71
Infection Control 72

Electromagnetic Compatibility 72
Electrostatic Discharge Precautions 74
Electromagnetic Emissions 75
Approved Cables for Electromagnetic Compliance 76
Approved Transducers for Electromagnetic Compliance 76
Approved Accessories for Electromagnetic Compliance 77
Electromagnetic Immunity 78
Electromagnetic Interference 82
Recommended Separation Distance 84
Avoiding Electromagnetic Interference 86
Use Restrictions Due to Interference 87

3 System Overview 89

Device Requirements 89

System Capabilities 90
Measurements 91
Transducer Types 91
Indications for Use and Supporting Transducers 91
Contraindications 93
Patient Data Protection 93
Wireless Networking 94

3000 135 93553_B/795 * NOV 2025

Philips

System Components 95
Data Storage 98
System Settings 98
System Information 100

4 Using the System 101

Downloading and Installing the Lumify App 101
Registration and Entitlement 101
Using the Lumify Power Module 102
Attaching the Lumify Power Module 102
Charging the Lumify Power Module Battery 108
Checking the Lumify Power Module Battery Charge 109
Turning On the Lumify Power Module 112
Registering Your Transducers 112
Updating the Lumify App 113
Viewing the App Walkthrough 114
Turning the System On and Off 114
Setting the System Time and Date 115
Setting the Thermal Index Display 115
Imaging Display 116
Quick Exams 120
Starting Quick Exams 120
Connecting Transducers 122
Type of Transducer connection 124
Direct Connection Workflow 125
Lumify Power Module Connection Workflow 127
Resetting the Transducer Connection 128
Deleting Patient Data and Lumify Settings 129
Connectivity Profiles 129

3000 135 93553_B/795 * NOV 2025

Philips

Adding a Connectivity Profile 129
Editing Connectivity Profiles 131
Switching Connectivity Profiles 131
Modality Worklist 132
Adding a Modality Worklist Server 132
Modifying or Deleting a Modality Worklist Server 133
5 Performing an Exam 135
Starting New Exams 135
Searching in the Worklist 137
Changing Presets During Exams 138
Editing Patient Data 138
Reviewing Saved Exams 138
Resuming a Paused Exam 139
Imaging Modes 139
2D Mode 140
Using 2D Mode 140
Color Mode 140
Using Color Mode 141
M-Mode 141
Using M-Mode 142
PW Doppler 142
Using PW Doppler 143
Imaging Features 144
AutoSCAN 144
Zoom Magnification 144
Full-Screen View 144
Displaying a Centerline 145
iSCAN Intelligent Optimization 145
Acquiring Images 145

3000 135 93553_B/795 * NOV 2025

Philips

Acquiring Loops 145
Annotation 146
Adding Labels 146
Deleting Labels 147
Measurement and Analysis 147
Performing a 2D Distance Measurement 147
Performing a 2D Ellipse Measurement 148
PW Doppler Measurements 149
Measurement Accuracy 152
Measurement Accuracy Tables 152
Performing Fetal Measurements 153
Ending an Exam 154

6 Review 155

Starting Review During an Exam 155
Starting Review After an Exam 155
Navigating Thumbnails and Images 155
Playing Loops 156
Exporting Images and Loops 156
Deleting Images and Loops 159
Exporting Exams 159
Showing or Hiding Patient Data on Exported Images and Loops 160
Showing or Hiding the Institution Name on Exported Images and Loops 161
Deleting Exams 161
Configuring Export Destinations 162
Export Destination Settings 163
Editing Export Destinations 165
Viewing the Export Queue 166

3000 135 93553_B/795 * NOV 2025

Philips

Enabling DICOM Logging 166

7 Transducers 167

Transducer Safety 167

Presets and Transducers 168

Transducer Maintenance 169

Acoustic Artifacts 170

Transducer Covers 173

Ultrasound Transmission Gels 173

Transducer Transport 175

Transducer Storage 175

Storage for Transport 176

Daily and Long-Term Storage 176

Testing Transducers 177

8 System Maintenance 179

Transducer Care 179

Device Maintenance 180

Transducer Maintenance 180

Sending System Logs 181

Viewing Audit Logs 181

Repairing the Patient Database 182

Exporting and Importing the Patient Database 183

Exporting the Patient Database 183

Receiving a Patient Database from Another Device 184

Importing a Patient Database 184

Troubleshooting 185

Troubleshooting Connectivity Issues 187

3000 135 93553_B/795 * NOV 2025

Philips

Error Messages 188
For Assistance 188
System Maintenance of LPM 188
Replacing the Lumify Power Module Battery 188
Cleaning and Disinfecting the Lumify System Components 190

9 Specifications 195

System Specifications 195
Dimensions 196
Environmental Limits 197
Connections 198
Safety and Regulatory Requirements 199
Safety and Regulatory Requirements 199

10 References 201
Adult Echocardiography References 201
Obstetric References 202
Vascular References 204

Index 207

3000 135 93553_B/795 * NOV 2025

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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”.

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 Philips representative.

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CAUTION

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

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Intended Audience

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

This document is intended for healthcare professionals who operate and maintain your Philips product.

Indications for Use

The Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), Pulsed Wave Doppler, and M-modes.

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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, Trans-vaginal, Ophthalmic.

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

For indications for use for transducers, see "Indications for Use and Supporting Transducers" on page 91.

Intended 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 the "Indications for Use" on page 12.

This product is intended to be installed, used, and operated only in accordance with 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 the user's responsibility for sound clinical judgement and best clinical procedure.

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.

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Use of the System

WARNING

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

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

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

WARNING

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

Warnings

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

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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 (Anaesthesia Proofed Gas) 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.

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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*: Provides information that clarifies certain product responses that might be misunderstood or can 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.

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- *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 as low as reasonably achievable (ALARA).
- *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.

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- 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 a compatible iOS device, a Philips transducer, the Philips Lumify app, and the Lumify Power Module (LPM). Information that applies only to a specific device is marked.
- *Device* refers to Lumify-compatible mobile devices.
- *Operating system* refers to the iOS operating systems.

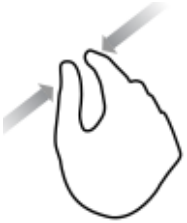
The following touch gestures are used to control your system.

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.

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Gesture	Name	Description
	Pinch	Touch the screen with two fingers and move them toward each other.
	Touch	Touch a control with your finger.
	Touch and hold	Touch the screen for a short time without moving your finger.
	Spread	Touch the screen with two fingers and move them apart.

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Gesture	Name	Description
	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.

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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 113.

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 168.
Lumify Power Module (LPM)	See “Approved Accessories for Electromagnetic Compliance” on page 77.
Adhesive mounting plate	Philips part number: 453562010901.

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Item	Additional Information
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.

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 LLC
22100 Bothell Everett Hwy
Bothell, WA 98021-8431
USA

The Philips Customer Services Portal provides an online platform that helps you manage your Philips products and services across all modalities:

https://www.philips.com/customer-services-portal

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Regulatory Representatives

Australian Sponsor

Philips Electronics Australia Ltd
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Australia

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CRF/SP 42230

Detentor do Registro:
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Guarulhos/SP, Brasil – CEP 07.251-500
CNPJ: 58.295.213/0001-78
AFE: 102.167-1

Registro: ANVISA 10216710372

Malaysian Authorized Representative

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Selangor Darul Ehsan, Malaysia

Telephone: 03-7965 7488

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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 pass the transducer 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.

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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



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
- Degauss all data on the device

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.

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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.

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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

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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 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.

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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.

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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.

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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 (Anaesthesia Proofed Gas) 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.

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WARNING

All patient-contact devices, such as transducers and pencil probes, must be removed from patient contact before application of a high-voltage defibrillation pulse. See “Defibrillators” on page 33.

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.

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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

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

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.

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WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased electromagnetic emissions from the system, and/or decreased electromagnetic 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 72. 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.

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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WARNING

For 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 non-electrical 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.

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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).	--
	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.

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	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.	--
	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. When color reproduction is not practical, the icon may be printed in black and white.

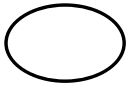
3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
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.
	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.	--

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.2.3 ISO 7000-2501	Sterilized using ethylene oxide.	--
	ISO 15223-1, Symbol 5.2.11	Single sterile barrier system.	--
	ISO 15223-1, Symbol 5.2.12	Double sterile barrier system.	--
	ISO 15223-1, Symbol 5.2.13	Single sterile barrier system with protective packaging inside.	--
	ISO 15223-1, Symbol 5.2.14	Single sterile barrier system with protective packaging outside.	--
	ISO 15223-1, Symbol 5.1.4 ISO 7000-2607	Use-by date.	--
	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			

3000 135 93553_B/795 * NOV 2025

Symbol	Standards and Reference	Reference Description	Additional Information
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.
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.

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
IP67	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of dust and 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.
	ISO 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.
	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.	--

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	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.	--
	--	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.	--

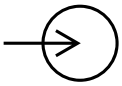
3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	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.
	--	--	Connection for a pencil probe.
	--	--	Connection for a transducer.
	--	--	Connection for ECG and physio leads.
	--	--	Connection for ECG and physio leads.
	--	--	Print remote output.

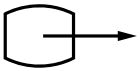
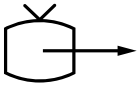
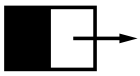
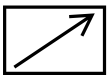
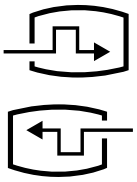
3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	-	-	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.	--
	--	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.

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	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.
	--	--	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.

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	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.
	IEC 60878, Symbol 2794 ISO 7000-2794	Packaging unit.	--
	--	--	Global Medical Device Nomenclature Code.
	--	--	Global Trade Item Number.
	ISO 15223-1, Symbol 5.1.5 ISO 7000-2492	Batch code.	--
	--	--	Indicates that the item is a medical device.
	--	--	Model name for the device.

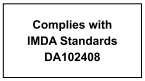
3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
#	--	--	Model number for the device and configurations.
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.	--
SVC	--	--	Service part number / field-replaceable unit (FRU) number.
UDI	--	--	Unique Device Identifier.
UPN	--	--	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.	--

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417	Country of Manufacture.	--
	ISO 7000-3724	Distributor.	--
	ISO 7000-3725	Importer.	--
Regulatory Compliance			
	IEC 60878, Symbol 5172	Class II Equipment.	--
 E173637	--	--	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, 2ATC9-PHC-11AC1), indicates that the system uses an embedded, FCC-approved wireless adapter.
	--	--	With an identification code (for example, CCAI15LP0780T9), indicates that the system uses an embedded NCC-approved (Taiwan) wireless adapter.

3000 135 93553_B/795 * NOV 2025

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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	CSA (CSA International) 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	--
	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.
	--	--	Indicates that the system conforms with the Ukrainian Scientific Institute of Certification (UA.TR.116).

3000 135 93553_B/795 * NOV 2025

Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Australian and New Zealand (RCM) Regulatory Compliance Mark indicates compliance with electrical safety, EMC, EME, and telecommunications requirements.
	--	--	KC (Korea Certification) mark for electrical and electronic equipment.
	--	--	INMETRO mark as issued by SGS. Indicates third-party approval in Brazil.
	--	--	INMETRO certification issued by TÜV SÜD. 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.

3000 135 93553_B/795 * NOV 2025

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WARNING

Do not use a system that exhibits erratic or inconsistent image updating. Discontinue use and contact your Philips service representative.

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 20.

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 54.

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/CSR/APH/2000.3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.

3000 135 93553_B/795 * NOV 2025

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WARNING

If the Lumify-compatible mobile device becomes contaminated internally with bodily fluids containing pathogens, you must immediately notify your Philips service representative. Components inside the device cannot be disinfected. In that case, the device 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 healthcare 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.

3000 135 93553_B/795 * NOV 2025

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Proteins in the latex itself appear to be the primary source of 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.

3000 135 93553_B/795 * NOV 2025

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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 the 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

3000 135 93553_B/795 * NOV 2025

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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 of acoustic output tables emphasizes the need to select the correct application and remain in that application, so the correct application limits are in use for the appropriate application.

Limits for Non-Ophthalmic Applications

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

Limits for Ophthalmic Applications

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

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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. 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.

The 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.

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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. Ensure receiver controls are optimized before increasing the output. 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, you should 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.

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In summary: Select the correct transducer frequency and application for the anatomy; 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 acceptable, then increase output.

Additional Considerations

Ensure that scanning time is kept to a minimum and ensure that only medically required scanning is performed. 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 116.

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.

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- 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 indicates 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.

3000 135 93553_B/795 * NOV 2025

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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 115.

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 a steady state to be reached.

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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, occurs 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 the most apparent as the output power control is adjusted; but other system controls affect the on-screen output values.

3000 135 93553_B/795 * NOV 2025

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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.

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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.
- Fourth Edition of the AIUM "Medical Ultrasound Safety" document, 2020. (A copy of this document is provided with each system.)
- "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" FDA, February 2023.
- IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields.

3000 135 93553_B/795 * NOV 2025

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- 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 2023 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
In Situ	*In Situ* intensity value
Water	Water value intensity

3000 135 93553_B/795 * NOV 2025

Variable	Value
e	2.7183
a	Attenuation factor
Tissue	a(dB/cm-MHz)
Amniotic Fluid	0.006
Brain	0.53
Heart	0.66
Kidney	0.79
Liver	0.43
Muscle	0.55
l	Skin line to measurement depth (cm)
f	Center frequency of the transducer/system/mode combination (MHz)

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

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

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

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

3000 135 93553_B/795 * NOV 2025

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

Conclusions Regarding Tissue Models and Equipment Survey

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

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

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

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

3000 135 93553_B/795 * NOV 2025

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- 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. The estimated maximum temperature elevations given here are for a “fixed-path” tissue model and are for devices having Ispta (derated) values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM Report, January 28, 1993).

Acoustic Output Tables

Acoustic output tables are in *Acoustic Output Tables*, on your *User Information* 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.

3000 135 93553_B/795 * NOV 2025

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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%

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.

3000 135 93553_B/795 * NOV 2025

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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 168.

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.

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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

3000 135 93553_B/795 * NOV 2025

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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 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.



CAUTION

Electrocautery, diathermy and electrosurgical units (ESUs) intentionally introduce radio frequency electromagnetic fields or currents into patients. Because imaging ultrasound frequencies are in the radio frequency range, ultrasound transducer circuits are susceptible to radio frequency interference from these devices. When one of these devices is in use the ultrasound image will be obscured with severe noise.



WARNING

Wireless battery charging or wireless power transfer (WPT) use frequencies that are in the pass band of ultrasound transducers. Therefore, it is recommended to avoid using these devices near the ultrasound system to avoid noise in the ultrasound image.



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.

3000 135 93553_B/795 * NOV 2025

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CAUTION

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

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

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

NOTE

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

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon that results in the flow of an electrical charge from a higher-charged object or person to a lower-charged object or person. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air-conditioning. During low humidity conditions, electrical charges naturally build up on individuals and objects and can create static discharges.

The following cautions can help to reduce ESD effect:

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CAUTION

The following precautions can help to reduce ESD: anti-static spray on carpets; anti-static spray on linoleum; anti-static mats; or a ground wire connection between the system and the patient table or bed.

CAUTION

On connectors labeled with the ESD sensitivity symbol , do not touch the connector pins, and always observe the preceding ESD precautions when handling or connecting transducers.

Electromagnetic Emissions

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

Electromagnetic Emissions: Environment Guidance

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions, CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

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Approved Cables for Electromagnetic Compliance

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

WARNING

Using cables, transducers, 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
Transducer Cable, USB Type-C to Micro-B (C5-2, L12-4, S4-1)	1.75 m (5.7 ft)	453561854693
Rigid Connector (Lightning to USB Type-C)	1.8 cm (0.7 in)	453561978092
Flexible Cable (Lightning to USB Type-C)	6.5 cm (2.6 in)	453562003951
Flexible Cable (USB Type-C to Type-C)	15 cm (5.9 in)	453562163821
Charging Cable (USB Type-C to Type-A)	1.7 m (5.6 ft)	453562174991

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 168, 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.

3000 135 93553_B/795 * NOV 2025

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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 168.
Lumify Power Module (LPM)	Philips	453561998453
Transducer Cable, USB Type-C to Micro-B (C5-2, L12-4, S4-1)	Philips	453561854693
Rigid Connector (Lightning to USB Type-C)	Philips	453561978092

3000 135 93553_B/795 * NOV 2025

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Accessory	Manufacturer	Model Number or Part Number
Flexible Cable (Lightning to USB Type-C)	Philips	453562003951
Flexible Cable (USB Type-C to Type-C)	Philips	453562163821
Charging Cable (USB Type-C to Type-A)	Philips	453562174991

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.

3000 135 93553_B/795 * NOV 2025

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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, ± 2, 4, 8, 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.

3000 135 93553_B/795 * NOV 2025

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.
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.

3000 135 93553_B/795 * NOV 2025

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Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
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.

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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.

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Typical Interference on Ultrasonic Imaging Systems

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

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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.

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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.

3000 135 93553_B/795 * NOV 2025

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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 standard[1]
- 1280 x 800 resolution (minimum)

3000 135 93553_B/795 * NOV 2025

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- Mobile device operating system: iOS 16 or later operating system.
- Wireless or cellular networking capability[3]
- Access to port 443
- Front- and rear-facing cameras[2]

[1]Philips 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.

[2]Required to use certain system features, such as the barcode scanner.

[3]While Lumify does not have minimum requirements related to network connectivity and throughput, Philips recommends that customers select a mobile device that is compatible with their local network requirements, configuration and any applicable device management solutions.

System Capabilities

The Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), Pulsed Wave Doppler, 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, Trans-vaginal, Ophthalmic. The system provides 2D, M-Mode, PW doppler measurement tools.

NOTE

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

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Measurements

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

- Trace
- Velocity
- Heart Rate
- Time
- Slope

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 168.

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.

3000 135 93553_B/795 * NOV 2025

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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 appropriately trained 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
Adult Cephalic	S4-1
Cardiac Adult	S4-1
Cardiac Pediatric	S4-1
Carotid	L12-4
Fetal Echo	C5-2
Fetal/Obstetric	C5-2, S4-1
Gynecological	C5-2, S4-1

3000 135 93553_B/795 * NOV 2025

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Indication for Use	Supporting Transducers
Lung	C5-2, L12-4, S4-1
Musculo-skeletal (Conventional)	L12-4
Musculo-skeletal (Superficial)	L12-4
Neonatal Cephalic	S4-1
Ophthalmic	L12-4
Pediatric	C5-2, L12-4, S4-1
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.

3000 135 93553_B/795 * NOV 2025

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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.

Secure DICOM can be configured to ensure the data in transit is encrypted. For more information, see “Adding a Connectivity Profile” on page 129 and “Adding a Modality Worklist Server” on page 132.

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 159 and “Showing or Hiding Patient Data on Exported Images and Loops” on page 160). You can also delete all patient data from the Lumify system (see “Deleting Patient Data and Lumify Settings” on page 129).

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 129.

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.

3000 135 93553_B/795 * NOV 2025

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Port Usage Category	Port Number	Protocol	Inbound	Outbound	Service Name	Description of Service	Optional	Configurable	Encrypted
Service	443	TCP	●		Registration	Lumify App/ Transducer Registration			● HTTPS
Clinical	11112	TCP	●	●	DICOM	DICOM connectivity	●	●	
Clinical	2762	TCP	●		Secure DICOM	DICOM connectivity	●	●	● TLS 1.2+

System Components

The system consists of the following:

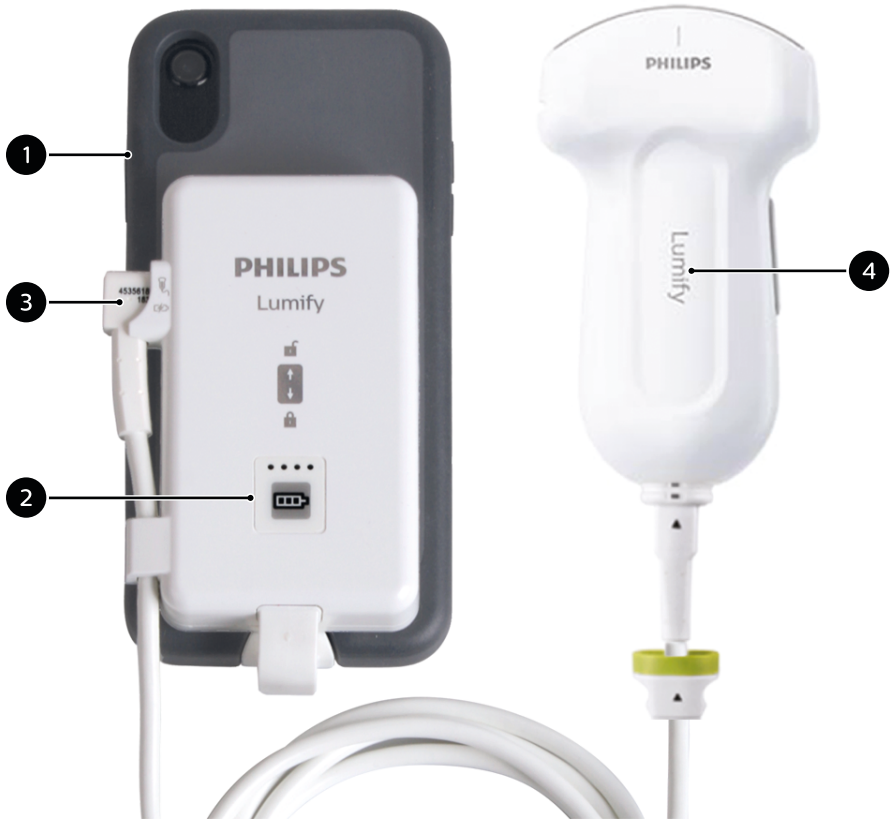
- The Philips Lumify app: You can download the Lumify app from the Apple App Store.
- One or more Philips Lumify transducers

  For purchasing options, contact your local Philips representative or visit the Lumify website: www.philips.com/lumify
- A compatible 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)

3000 135 93553_B/795 * NOV 2025

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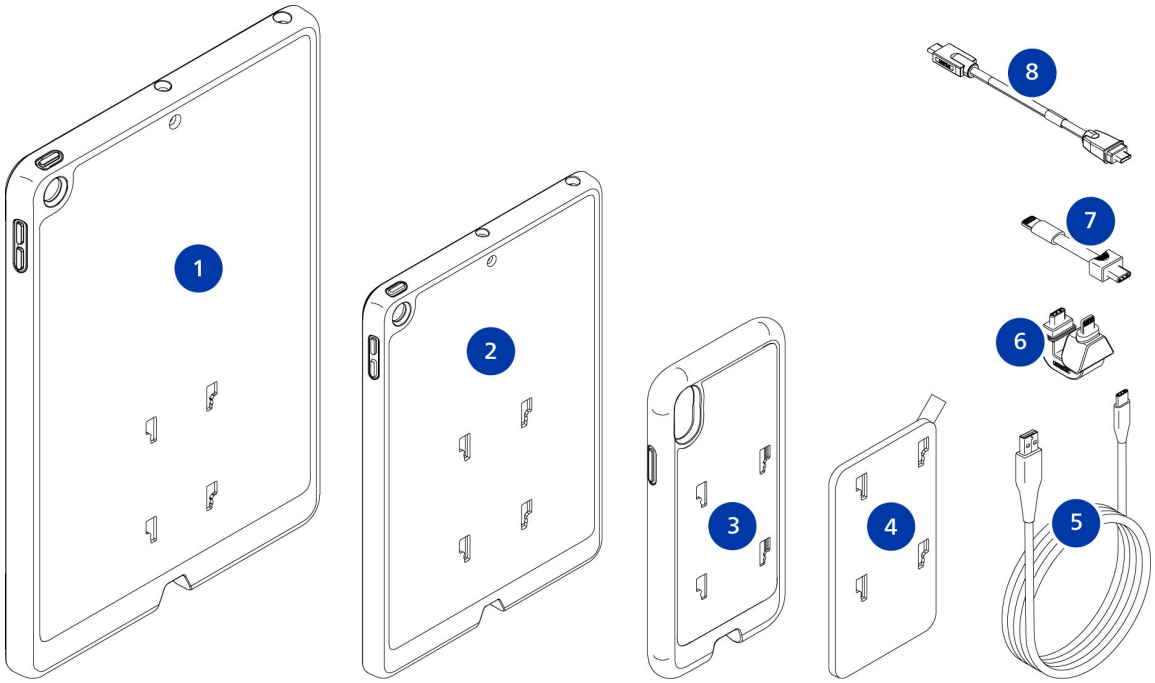


1	iOS device
2	LPM
3	USB transducer cable
4	Transducer

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

3000 135 93553_B/795 * NOV 2025

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1	Cases with LPM mounts for 10.2-inch iPad (7th, 8th and 9th generation) mobile devices Cases with LPM mounts for 9.7-inch iPad (6th generation) 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	Charging cable
6	Rigid connector (for use with Lumify mobile device cases for iPhone and iPad mobile devices)
7	Flexible Cable - Type-C to Lightening Port (device to be used with lightening socket)
8	Flexible USB - Type-C to Type-C (device to be used with Type-C socket)

3000 135 93553_B/795 * NOV 2025

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Data Storage

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

- DICOM PACS
- Local directory

You can also send images by e-mail. For more information, see “Exporting Exams” on page 159 and “Exporting Images and Loops” on page 156.

System Settings

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

Lumify Settings

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 101).
Display	• **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 145. • **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	• **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 177.

3000 135 93553_B/795 * NOV 2025

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Setting Type	Settings
Imaging	• **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	• **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 181. • **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 181.
Lumify Power Module	• **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**).

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Setting Type	Settings
Patient Database	• **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. For more information, see "Exporting and Importing the Patient Database" on page 183 and "Repairing the Patient Database" on page 182.

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 *User Manual* 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	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	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.

3000 135 93553_B/795 * NOV 2025

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4 Using the System

The topics that follow will help you to 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

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. Your device must be connected to the Internet to register your transducer. The Lumify app prompts you to connect your transducer and provide your contact information.

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. The system does not automatically reregister transducers.

3000 135 93553_B/795 * NOV 2025

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NOTE

If you upgrade the Lumify app, upgrade the operating system, or have connected a transducer to 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.

Using the Lumify Power Module

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

Attaching the Lumify Power Module

The Lumify mobile device case is the most secure method of attaching the Lumify Power Module (LPM) to your mobile device. The Lumify mobile device case is only compatible with certain iOS devices; it is not compatible with other holders or accessories. Philips provides Lumify mobile device cases that are designed to work with the following iOS devices:

- Cases with LPM mounts for 10.2-inch and 9.7-inch iPad mobile devices
- Case with LPM mounts for 7.9-inch iPad mini 5 mobile device
- Cases with LPM mounts for iPhone 7, iPhone 8, iPhone X, iPhone XS, iPhone XR, and iPhone 11 mobile devices

For iOS devices that cannot use one of the Lumify mobile device cases, an adhesive mounting plate is included for attaching the LPM to a case.

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Attaching the LPM to a Lumify Mobile Device Case

CAUTION

Always insert the mobile device into the Lumify mobile device case in a clean, dust-free, and low-humidity environment. Make sure the mobile device is clean and dry before inserting it into the case.

1. Gently insert the mobile device into the Lumify mobile device case. Make sure the mobile device seats fully in the case. Only gentle pressure is required to seat the mobile device. Do not force the mobile device into the case.

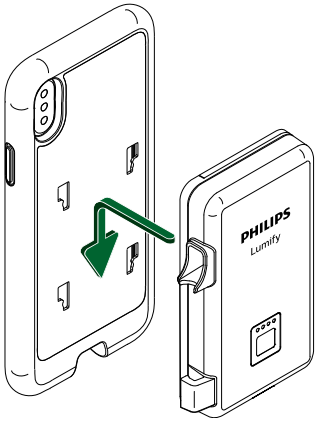


Inserting the Mobile Device into the Lumify Mobile Device Case

2. Insert the tabs of the LPM into the slots on the case and slide the LPM down to lock it in place.

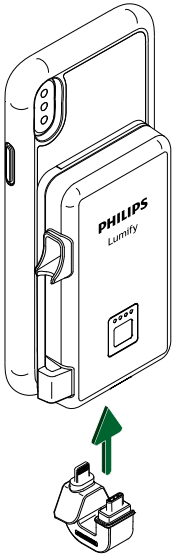
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Inserting the LPM Tabs into the Slots of the Lumify Mobile Device Case and Locking the LPM in Place

3. Use the rigid connector to connect the LPM to the mobile device.



Using the Rigid Connector to Connect the LPM to the Mobile Device

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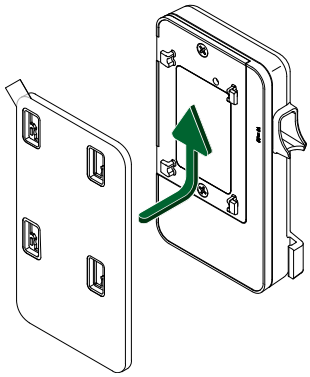
Attaching the LPM to a Lumify Adhesive Mounting Plate

For iOS devices that cannot use one of the Lumify mobile device cases, an adhesive mounting plate is included for attaching the LPM to a case.

NOTE

The mounting plate adhesive is not compatible with certain slick or non-stick surfaces. For best results, attach the mounting plate to a phone case or tablet case made of metal or hard plastic.

1. Make sure that the surface of the device or the case to which you are attaching the mounting plate is clean and dry.
2. Attach the mounting plate to the LPM.
   a. Insert the tabs on the LPM into the slots on the mounting plate.
   b. Slide the mounting plate toward the top of the LPM until it locks in place.

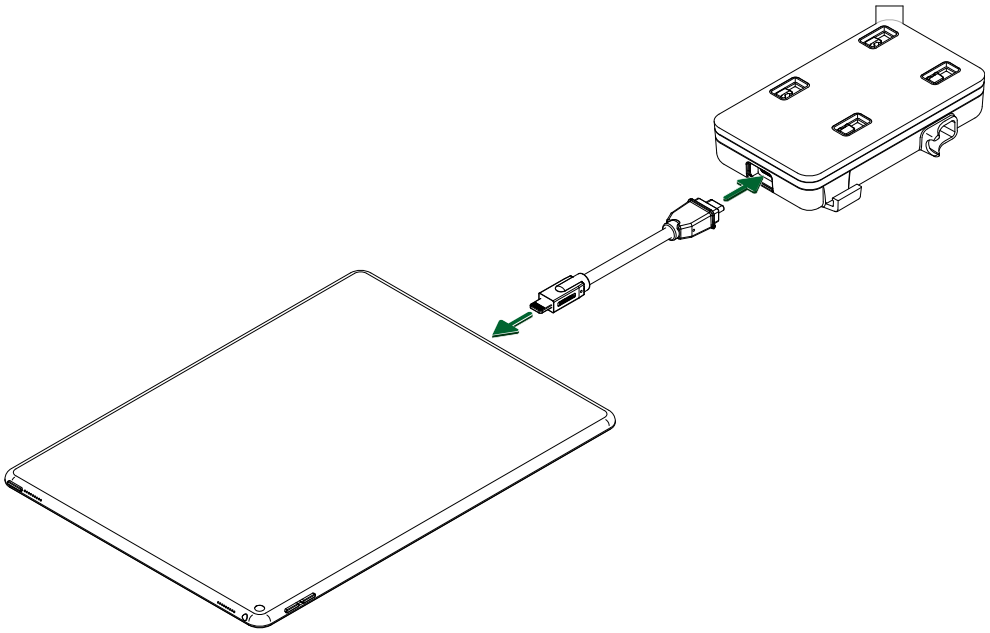


Inserting the Tabs on the LPM into the Mounting Plate Slots and Sliding the LPM into Place

3. Use the flexible cable to connect the LPM to the mobile device.

3000 135 93553_B/795 * NOV 2025

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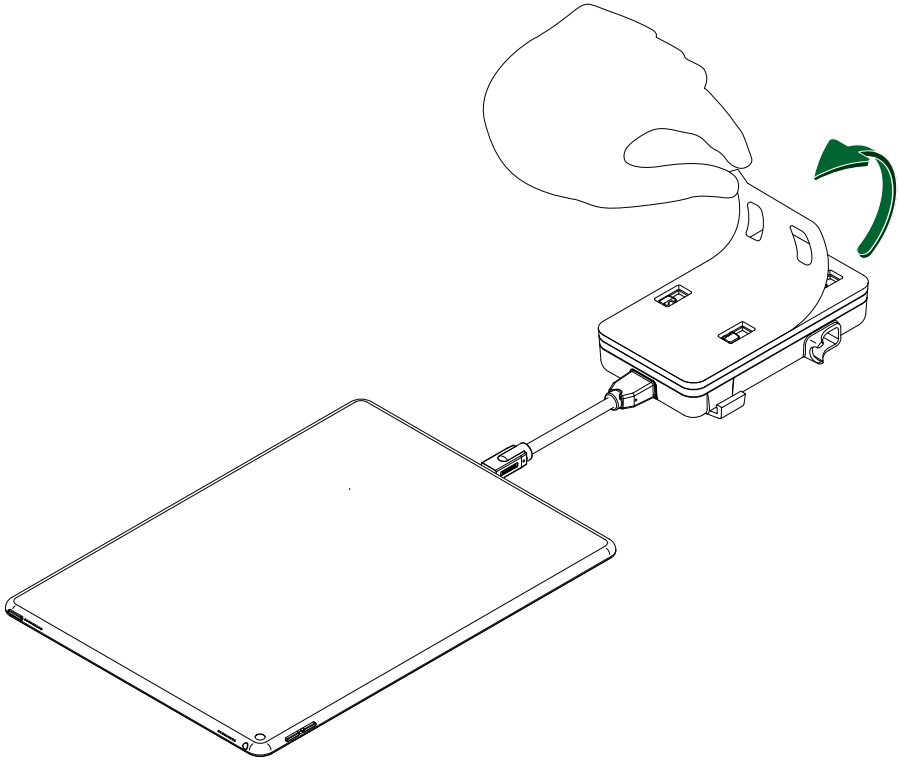


Using the Flexible Cable to Connect the LPM to the Mobile Device

4. Remove the adhesive backing from the mounting plate.

3000 135 93553_B/795 * NOV 2025

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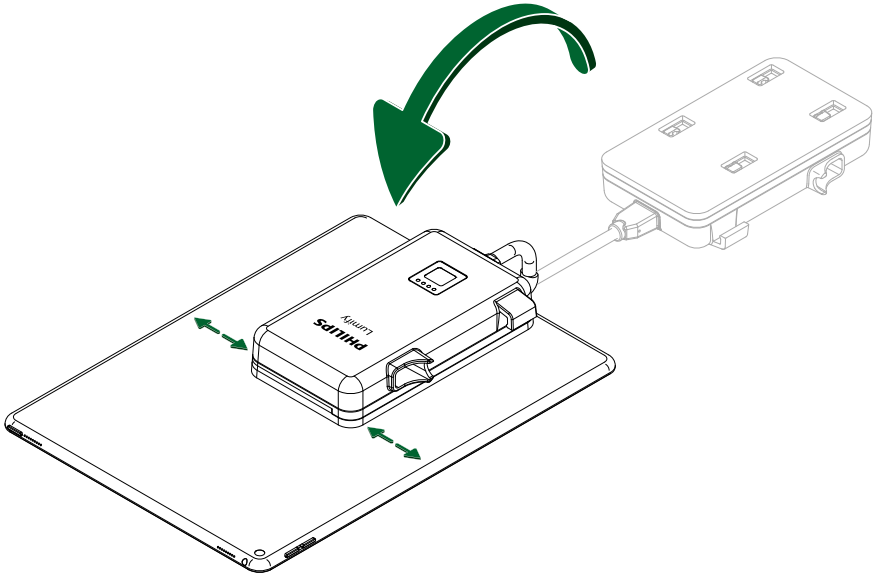


Removing the Adhesive Backing from the Lumify Mounting Plate

5. Press the mounting plate with the LPM onto the back of the mobile device or the case.
   - Make sure that the LPM is aligned with the bottom of the mobile device and is centered along the width of the device.
   - Make sure that the mounting plate is securely adhered to the surface.

3000 135 93553_B/795 * NOV 2025

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Pressing the Lumify Mounting Plate with the LPM onto the Back of the Mobile Device or the Case

Removing the LPM

1. Disconnect the LPM from the mobile device by removing the rigid connector or the flexible cable.
2. Slide the LPM toward the top of the mobile device to unlock it from the case.
3. Pull the LPM straight back and away from the mobile device.

Charging the Lumify Power Module Battery

WARNING

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

3000 135 93553_B/795 * NOV 2025

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WARNING

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

NOTE

Philips recommends using the charging cable supplied with your Lumify system to charge the LPM. Use a charger with a USB Type-A connector port to charge the LPM. Do not use a charger with USB Type-C connector port.

Charge the Lumify Power Module (LPM) fully before you use the system for the first time or when the LPM has been unused for extended periods.

You can charge the LPM separately. However, if your charger has an output of at least 2 A, you can charge the LPM while it is connected to your iPhone (both devices charge simultaneously).

Do not attempt to charge the LPM while it is connected to an iPad. The iPad draws too much current to enable simultaneous charging.

1. If a transducer is connected to the LPM, disconnect it.
2. Insert the USB Type-C connector of the charging cable into the power/transducer port on the LPM.
3. Insert the USB Type-A connector of the charging cable into a USB Type-A charger.
4. After the LPM battery is fully charged, disconnect the LPM from the charger:
   a. Unplug the charging cable from the LPM.
   b. Unplug the charging cable from the power source.

Checking the Lumify Power Module Battery Charge

Before starting an exam, check that the Lumify Power Module (LPM) has sufficient charge. You can check for the charge by using the Lumify app or by using the charge indicator button.

3000 135 93553_B/795 * NOV 2025

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Using the Lumify App to Check the LPM Battery Charge

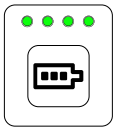
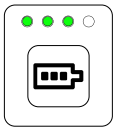
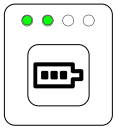
When you are scanning, an icon in the upper right of the imaging screen shows the approximate charge level of the LPM battery. For more detailed information about the state of the LPM battery, use the following procedure.

1. In the Lumify app, touch , and then touch **Settings** .
2. Under **Settings**, touch **Lumify Power Module**.
3. On the **Lumify Power Module** page, check that the battery **Status** is **Normal** and that the **Charge Level** is above 20%.
4. If the LPM does not have sufficient charge for your exam, charge the LPM battery or exchange it for a freshly charged LPM. See “Charging the Lumify Power Module Battery” on page 108.

Using the Charge Indicator Button to Check the LPM Battery Charge

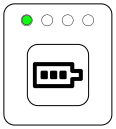
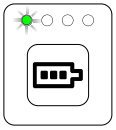
The charge indicator on the LPM has four LEDs to show the charge level.

Charge Level Indicator

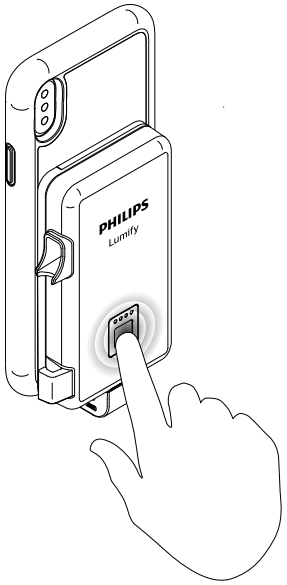
Indicator	Description
	75% to 100% charge
	50% to 75% charge
	25% to 50% charge

3000 135 93553_B/795 * NOV 2025

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Indicator	Description
	10% to 25% charge
	When blinking, less than 10% charge. Requires charging before use.

1. Press the button on the LPM and check that at least one charge indicator LED is lit.



Checking the LPM Battery Level

2. If the currently installed LPM does not have sufficient charge for your exam, charge the LPM battery or exchange it for a freshly charged LPM. See “Charging the Lumify Power Module Battery” on page 108.

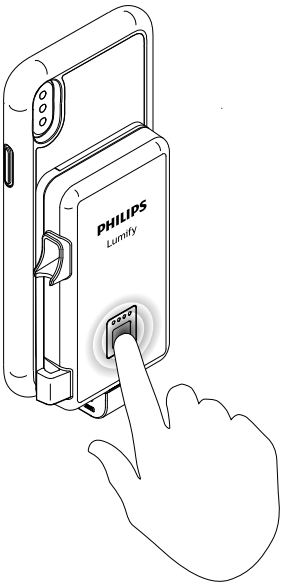
3000 135 93553_B/795 * NOV 2025

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Turning On the Lumify Power Module

Before you can begin scanning, you must turn on the Lumify Power Module (LPM). There are two ways to turn on the LPM:

- Connect a transducer. For information on connecting a transducer, see the *Lumify User Manual*.
- Press the button on the back of the LPM. The lights on the LPM will show the level of charge in the LPM battery. For information on battery charge levels, see "Checking the Lumify Power Module Battery Charge" on page 109. Allow several seconds for the LPM to turn on before starting a scan.



Turning on the LPM

Registering Your Transducers

1. Make sure that your device is connected to a wireless or cellular network.
2. Start the Lumify app.

3000 135 93553_B/795 * NOV 2025

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3. Connect your Philips transducer to your device.
4. Touch **OK**.
5. 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. Touch **Submit**.
   c. On the **Registration Complete** display, touch **Accept**.

If registration fails, see "Troubleshooting" on page 185, or visit the Lumify website for FAQs and troubleshooting tips:

www.philips.com/lumify

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 183.

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 by downloading the Lumify app from the Apple app store.

3000 135 93553_B/795 * NOV 2025

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NOTE

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

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 the following:

- To begin an exam, touch **Start Scanning**.

You can view the app walkthrough at any time.

Touch , and then touch **Walkthrough** .

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.

3000 135 93553_B/795 * NOV 2025

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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 the following:

- Touch **Display**, touch **Thermal Index Display**, and then select the thermal index you want.

3000 135 93553_B/795 * NOV 2025

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Imaging Display

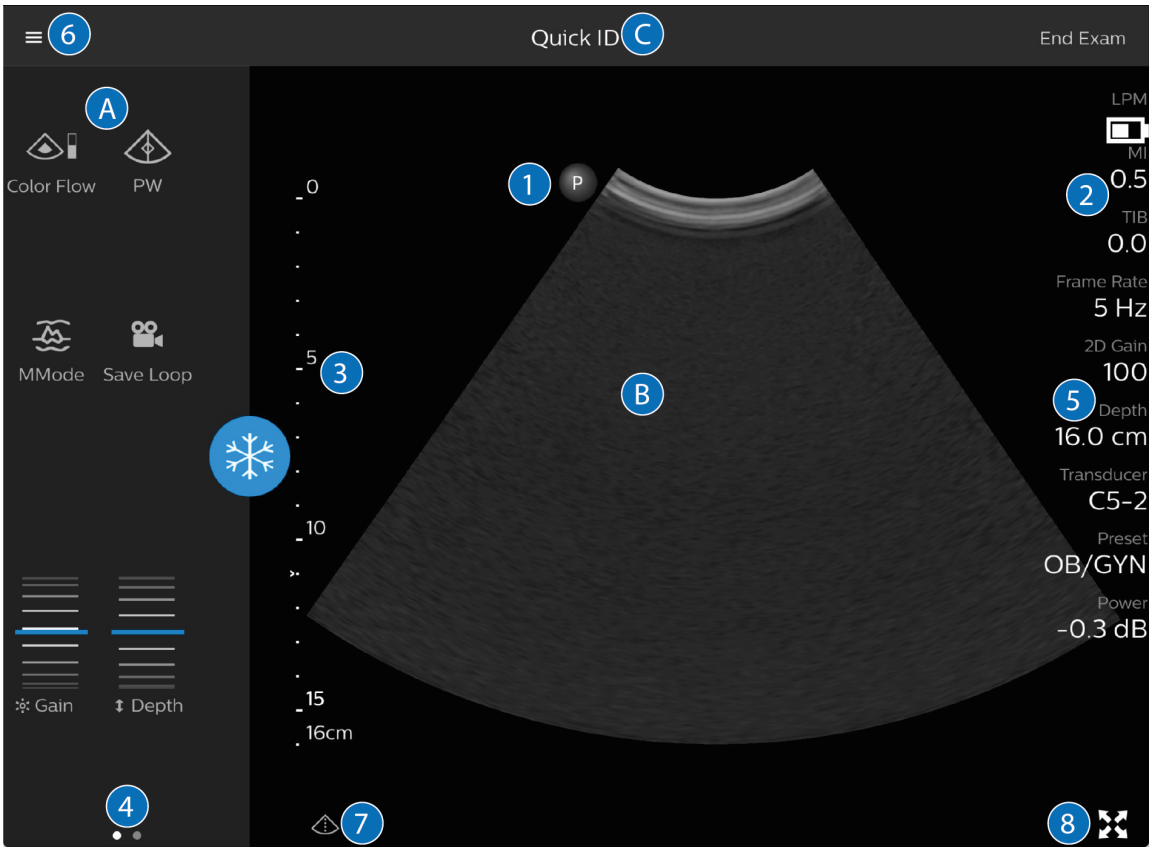
The imaging display contains an ultrasound image, exam and image information, indicators, and system controls.

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.

3000 135 93553_B/795 * NOV 2025

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Imaging Display (Landscape Orientation)

A	Controls area
B	Image area
C	Patient information
1	Scan plane orientation marker
2	MI and TI values
3	Focal indicator

3000 135 93553_B/795 * NOV 2025

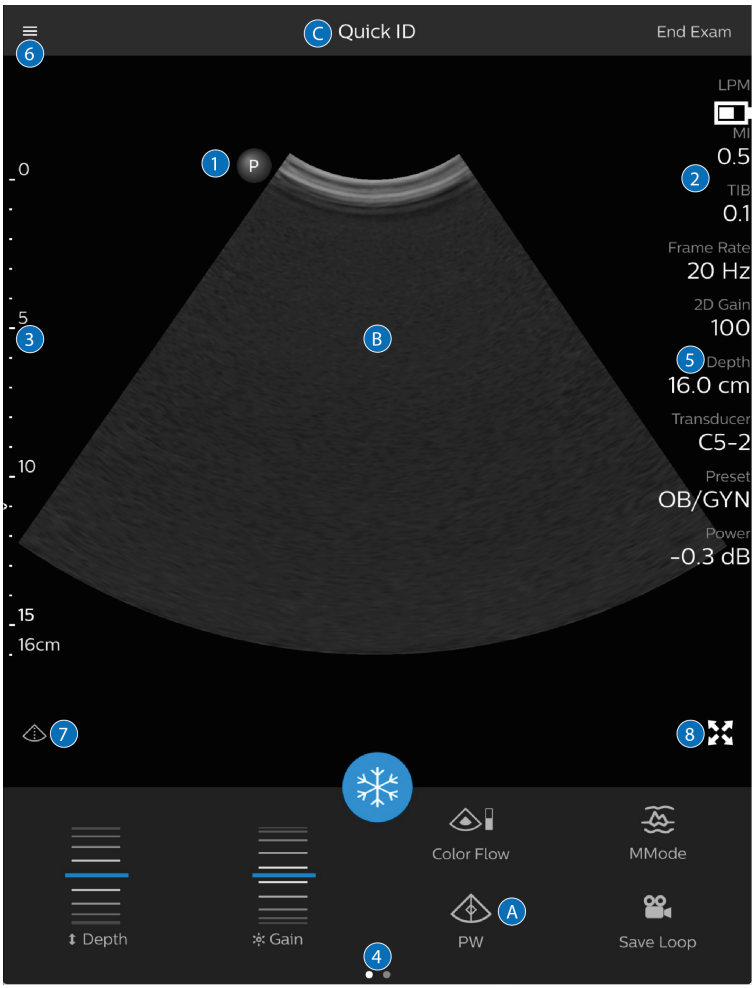
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4	Page indicator: Touch the indicator to go to the next page of controls, or swipe to move between pages.
5	Image information
6	Review and settings menu
7	Centerline control
8	Full-screen view control

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

3000 135 93553_B/795 * NOV 2025

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Imaging Display (Portrait Orientation)

A	Controls area
B	Image area
C	Patient information

3000 135 93553_B/795 * NOV 2025

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

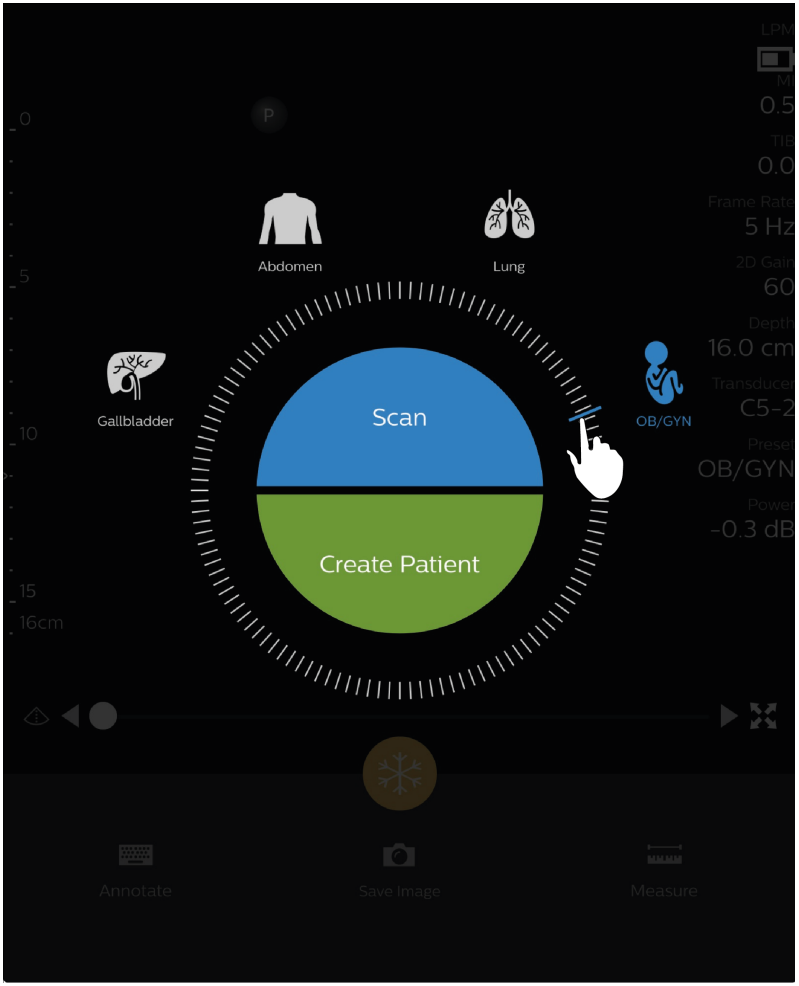
CAUTION

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.

3000 135 93553_B/795 * NOV 2025

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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**.

3000 135 93553_B/795 * NOV 2025

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b. On the **Patient Info** display, type the patient information or query a Modality Worklist (MWL). 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 135.

c. Touch **Save and Return**.

d. Resume imaging.

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.



WARNING

Always connect the transducer cable directly to the Lumify Power Module. Philips does not recommend using adapters. For approved cable options, contact your Philips representative.

NOTE

When switching transducers, disconnect the transducer cable from the device or Lumify Power Module. Do not switch transducers by leaving the cable in place and switching the transducer connected to the micro-B end of the cable. The micro-B connector is not as durable. Frequently disconnecting the transducer from the cable can lead to failure of the connection.

3000 135 93553_B/795 * NOV 2025

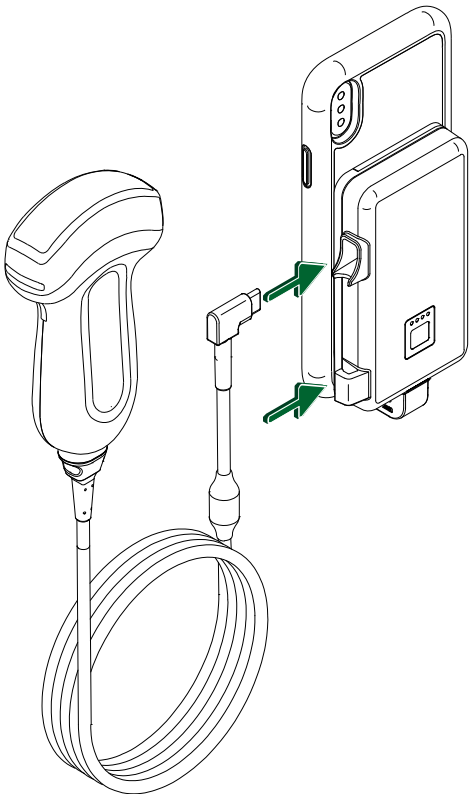
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3. Plug the right-angle connector of the USB transducer cable into the USB port on the device or the USB port on the side of the Lumify Power Module (LPM). The USB cable is not reversible.



Connecting the Transducer Cable to the Device

3000 135 93553_B/795 * NOV 2025



Connecting the Transducer Cable to the LPM

4. If required, press the transducer cable into the cable clip on the LPM.
5. 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.

Type of Transducer connection

The transducers can be connected through the Lumify Power Module (LPM) connection or Direct connection. When the Lumify app launches for the first time on the device, depending on the iOS device, the user can select any one of the transducer connection types (LPM or

3000 135 93553_B/795 * NOV 2025

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Direct connect) and need to complete the connection setup with the available transducer. The Lumify app will retain the same connection thereafter until the app is uninstalled or the user updates the connection settings.

Direct Connection Workflow

The following workflow demonstrates how to connect the transducer through direct connection.

1. Launch the Lumify app.
2. Touch **Register**.
3. Touch **USB-C**.
4. After selecting **USB-C**, connect the transducer via the USB-C port.

NOTE

If the user needs additional guidance for direct connection, touch **Confirm driver enable**.

5. Touch **HERE** to go to the iOS device settings page.
6. Turn on the **Lumify Driver** in the device settings and touch **Enable**.

NOTE

If the user is unable to locate the Lumify driver, see “Locating the Lumify Driver”.

7. Touch **Lumify** at the top right corner of the device to return to the Lumify app.
8. Touch **Continue**, and on the Contact Information form, do the following:
   – Type user information for **Institution** name, **Contact** name, **Zip/Postal Code**, **Country**, and **Email Address**. All information fields must be completed.

3000 135 93553_B/795 * NOV 2025

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– Touch **Submit**.
– On the **Registration Complete** window, touch **Accept**
– After the registration process is completed, reboot the iOS device. Then open the Lumify app.

NOTE

The following instructions will appear when the user connects the transducer without enabling the Lumify driver and tries to unfreeze the image.

1. Please ensure Lumify driver is enabled.

2. When driver is enabled, disconnect and reconnect transducer.

3. Should driver remain unavailable, please repeat connection configuration from the settings page.

NOTE

Do not connect the LPM while the device is in direct connection mode.

When the system is configured for Direct Connect and the LPM is attached, if the user tries to unfreeze, scanning will be prevented. A dialog box will appear , **A LPM is Not Required. This device is configured to not require a LPM for scanning. Please disconnect the LPM and connect the transducer directly.**

NOTE

When users uninstall and reinstall the app, they have to disconnect and reconnect the transducer while setting up the connection type again.

3000 135 93553_B/795 * NOV 2025

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Locating the Lumify Driver

If the user is unable to locate the Lumify driver by touching HERE (the hyperlink), follow the below steps to locate the driver,

1. Go to the iOS settings.
2. Select Lumify under the Apps, it will display the Lumify Driver.

Lumify Power Module Connection Workflow

The Lumify Power Module is compatible with iOS devices having Lightning and USB-C ports.

Lightning port LPM Connection

1. Launch the Lumify app.
2. Touch **Register**.
3. Touch **Lightning connection**.

See “Using the Lumify Power Module” on page 102 and “Registering Your Transducers” on page 112 for LPM installation and transducer registration.

USB-C Connection

1. Launch the Lumify app.
2. Touch **Register**.
3. Touch **USB-C**.
4. Touch **Power module instructions**.

NOTE

The user can also configure the LPM connection type by touching **Confirm driver enable**, and then touching the **Power module**.

See “Using the Lumify Power Module” on page 102 and “Registering Your Transducers” on page 112 for LPM installation and transducer registration.

3000 135 93553_B/795 * NOV 2025

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NOTE

The following instruction will appear when the user tries to unfreeze the image without connecting the LPM or the transducer is directly connected.

1. Connect the Lumify Power Module to the port on your device.
2. Connect transducer.
3. Press the battery icon button on the Lumify Power Module.

If there is still no response, change the Lumify Power Module and repeat.

NOTE

If user tries to unfreeze the screen without connecting the transducer when the device is connected to LPM, the following pop-up will appear on the screen “Please connect a transducer”.

Resetting the Transducer Connection

The user can manually change the transducer connection type at any time in Lumify app. Follow the below steps to go to the Connect Your Transducer screen.

1. Touch  .
2. Touch **Settings**.
3. Touch **Direct Connect**.
4. Touch **Start**.

After reaching the Connect Your Transducer screen, user can change the transducer connection type to LPM or Direct Connection.

3000 135 93553_B/795 * NOV 2025

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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 160.

Deleting Patient Data Only

To delete patient data only:

- 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:

- 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.

3000 135 93553_B/795 * NOV 2025

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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 162).
   - 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 163).
   - 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 132).
   - 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 163).
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:

3000 135 93553_B/795 * NOV 2025

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- 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**.
- Select **Enable Secure DICOM (TLS)**, to enable **Secure DICOM (TLS)**.
- To import security certificates from device storage, touch **Install CA certificate**, browse the certificate file path, and select the certificate file.

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 **Cancel**.

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. On the **Profile Information** page, select **Set as Current**.

3000 135 93553_B/795 * NOV 2025

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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 129.

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 (Application Entity) 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
   - **Enable Secure DICOM (TLS)**: Secure DICOM enables the encryption of data during network transfer.
   - **Certificate File**: Browse the certificate path and select the certificate file.
   - **Password (If applicable):** If the certificate file is password protected then you can enter the password.
7. Under **Query Options**, select your preferences for which exams to show.

3000 135 93553_B/795 * NOV 2025

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8. To specify advanced connection settings, select **Show Advanced Options**:
   - **DNS Suffix**: The DNS (Domain Name Server) 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 129.

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.

3000 135 93553_B/795 * NOV 2025

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5 Performing an Exam

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

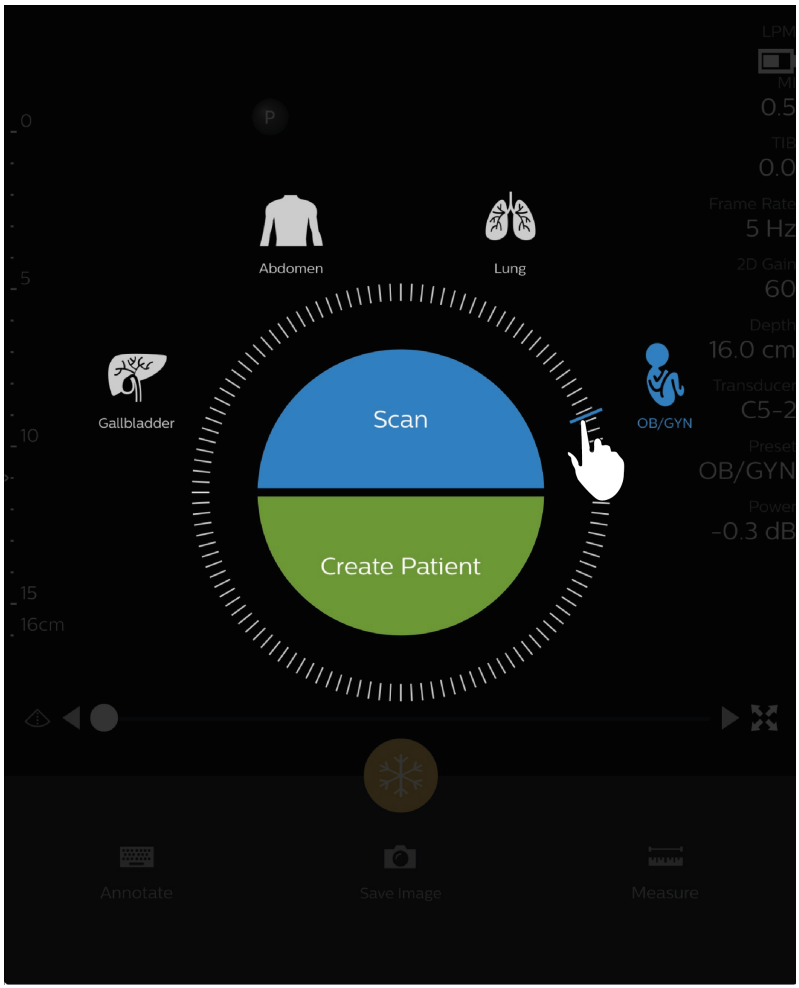
Have a backup system present during critical exams to ensure completion of the exam in the event that the primary system fails. If a backup system is unavailable, then address any patient-specific clinical symptoms according to standard patient-management protocols.

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.

3000 135 93553_B/795 * NOV 2025

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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 120.

3000 135 93553_B/795 * NOV 2025

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- 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 137).

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 132).

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**.

3000 135 93553_B/795 * NOV 2025

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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:

3000 135 93553_B/795 * NOV 2025

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- To delete images from a saved exam, see “Deleting Images and Loops” on page 159.
- To export images and loops from a saved exam, see “Exporting Images and Loops” on page 156.
- To export the exam, see “Exporting Exams” on page 159.

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.

3000 135 93553_B/795 * NOV 2025

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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 144.
   - 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 144.
   - To display a centerline on the image, touch . For more information, see “Displaying a Centerline” on page 145.

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.

3000 135 93553_B/795 * NOV 2025

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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. Do any of the following:
   - Touch **Color Flow** , and then touch **Fast Flow Fast Flow** or **Slow Flow** .
   - Touch **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 144.
8. To display a centerline on the image, touch . For more information, see “Displaying a Centerline” on page 145.
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

3000 135 93553_B/795 * NOV 2025

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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 144.
   - 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 144.
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

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.

3000 135 93553_B/795 * NOV 2025

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Using PW Doppler

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 145.
   - 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**.



3000 135 93553_B/795 * NOV 2025

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Imaging Features

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

AutoSCAN

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

Zoom Magnification

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

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

NOTE

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

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  .

3000 135 93553_B/795 * NOV 2025

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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.

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.

3000 135 93553_B/795 * NOV 2025

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- 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 98.

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

The annotation feature is available in both Live and Frozen states of 2D, Color mode, PW Doppler and M-Mode.

Adding Labels

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**  .

3000 135 93553_B/795 * NOV 2025

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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.

Deleting Labels

1. To delete a label, do either of the following:
   - Touch the label. Touch  when it appears.
   - Touch the label and use your device's keyboard to delete the text.
2. To delete all annotations, touch **Clear All**  .

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.

3000 135 93553_B/795 * NOV 2025

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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 145).

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.

3000 135 93553_B/795 * NOV 2025

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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 145).

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**  .

PW Doppler Measurements

Three PW Doppler sweep speeds are available in all presets. Sweeps speeds are faster in cardiac presets.

Sweep Speeds

Speed	Cardiac	Noncardiac
Fast	2 seconds	3 seconds

3000 135 93553_B/795 * NOV 2025

Speed	Cardiac	Noncardiac
Medium	3 seconds	5 seconds
Slow	5 seconds	8 seconds

PW Doppler measurements on the Lumify system fall into the following categories:

- Velocity measurements
- Distance measurements
- Trace measurements

Measurement Abbreviations and Acronyms

Measurement	Definition	Measurement	Definition
EDV	End-diastolic velocity	PSV	Peak systolic velocity
MaxPG	Maximum pressure gradient	RI	Resistivity index
MDV	Minimum diastolic velocity	S/D	Systolic to diastolic ratio
MeanPG	Mean pressure gradient	Vmax	Maximum velocity
P½t	Pressure half-time	VTI	Velocity time integral
PG	Peak pressure gradient		

The measurement data that appears after completing each measurement varies based on the exam preset, as shown in the following table:

PW Doppler Measurements Available for Each Exam Preset

Exam Preset	Velocity Measurements	Distance Measurements	Trace Measurements
Cardiac	Velocity, PG	Time, Slope, P½t	Vmax, MaxPG, MeanPG, VTI
OB/GYN	Velocity	PSV, EDV, S/D, RI	PSV, EDV, MDV, S/D, RI
Vascular	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI, VTI
FAST	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI

3000 135 93553_B/795 * NOV 2025

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Exam Preset	Velocity Measurements	Distance Measurements	Trace Measurements
Abdomen	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Lung	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
MSK	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Soft Tissue	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Superficial	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI

Performing Velocity Measurements

1. Obtain the Doppler trace image that you want to measure.
2. Touch **Measure**.
3. Touch **Velocity**, and then drag the caliper to the peak of the velocity you want to measure.
4. Repeat step 3 for up to four separate velocity measurements.
5. To save an image with the displayed measurements, touch **Save Image**.

Performing Distance Measurements

1. Obtain the Doppler trace image that you want to measure.
2. Touch **Measure**.
3. Touch **Distance**, and then drag the first caliper to the peak systolic velocity (PSV).
4. Drag the second caliper to the end-diastolic velocity (EDV).
5. To save an image with the displayed measurements, touch **Save Image**.

Performing Trace Measurements

1. Obtain the Doppler trace image that you want to measure.
2. Touch **Measure**.

3000 135 93553_B/795 * NOV 2025

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3. Touch **Trace**, and then drag the first caliper to the start of the waveform you want to measure.
4. Touch the start of the waveform again to create a second caliper, and then drag the new caliper over the shape of a single cycle.
5. To save an image with the displayed measurements, touch **Save Image**.

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

3000 135 93553_B/795 * NOV 2025

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Measurement	Accuracy	Maximum Range
Diagonal Distance	< ± 2% or 2 mm	0.001 to >32.0 cm

M-Mode Measurement Range and Accuracy

Measurement	Accuracy	Range
Distance	< ± 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%	--
FHR	--	30 to 300 bpm

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 Measurements

You can perform fetal measurements within OB/GYN preset from the current exam.

You can perform FHR measurement with M-Mode. Do the following:

NOTE

For MMode, the FHR is measured as a one beat peak to peak measurement.

1. Touch **MMode**  .
2. Position the cursor on the fetal heart and release.
3. Once the **MMode** completes the trace, touch **Freeze**  .

3000 135 93553_B/795 * NOV 2025

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4. Touch **Measure**.
5. Position the first caliper at the leading edge of the Cardiac activity.
6. Position the second caliper at the leading edge of the next Cardiac activity.
7. Displays **FHR** in **bpm** (beats per min) unit.
8. Touch **Save Image** .

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.

3000 135 93553_B/795 * NOV 2025

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6 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.

3000 135 93553_B/795 * NOV 2025

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- 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.

Playing Loops

1. Touch the loop thumbnail.
   - 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

3000 135 93553_B/795 * NOV 2025

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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":

- 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. 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.

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**.

3000 135 93553_B/795 * NOV 2025

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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 162 and "Editing Export Destinations" on page 165).

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 162. After you create a new export destination, it will be saved on the system and appear in the **Export To** menu.

3000 135 93553_B/795 * NOV 2025

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Deleting Images and Loops

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 or to a local directory. See “Configuring Export Destinations” on page 162.

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

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**.

3000 135 93553_B/795 * NOV 2025

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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. 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.

NOTE

When you do the network share, ensure that you have secure infrastructure as data is not encrypted.

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**.

3000 135 93553_B/795 * NOV 2025

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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.

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.

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**.

3000 135 93553_B/795 * NOV 2025
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4. In the **Delete Confirmation** dialog box, touch **Delete**.

Configuring Export Destinations

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 163).
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 131.

3000 135 93553_B/795 * NOV 2025

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Export Destination Settings

NOTE

While enabling Secure DICOM (TLS), configure with CA certificate in connectivity profile settings before adding servers. Use the active connectivity profile's TLS settings for successful connection.

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
Port	The port number for the server
Export Format	**RLE (Lossless)** or **JPEG (Lossy)**
Enable Secure DICOM (TLS)	Secure DICOM enables the encryption of data during network transfer.
Certificate File	Browse the certificate path and select the certificate file.
Password (If applicable)	If the certificate file is password protected then you can enter the password.
Advanced Options, **Display Compensation**	**Brightness** and **Contrast**

3000 135 93553_B/795 * NOV 2025

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Setting	Description
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**	• **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

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
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**.

3000 135 93553_B/795 * NOV 2025

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Setting	Description
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.

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**.

3000 135 93553_B/795 * NOV 2025

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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 163).

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 .
   - Touch , touch **Export Destinations** , and then, at the top of the page, touch .
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**.

3000 135 93553_B/795 * NOV 2025

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7 Transducers

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

For information on connecting transducers, see “Connecting Transducers” on page 122. 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*.

WARNING

Disinfect new transducers before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from pathogens. Establish and clearly post a cleaning procedure that includes the steps described in *Care and Cleaning of 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.

3000 135 93553_B/795 * NOV 2025

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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.

CAUTION

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

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, Lung, Gallbladder, OB/GYN
L12-4	Lung, MSK, Soft Tissue, Superficial, Vascular, Ocular

3000 135 93553_B/795 * NOV 2025

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Transducer	Presets
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 185.



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 173 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.

3000 135 93553_B/795 * NOV 2025

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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. The 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.

3000 135 93553_B/795 * NOV 2025

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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

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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

3000 135 93553_B/795 * NOV 2025

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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 176.

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, low linting cloth and a gentle blotting motion. Aggressive wiping or scrubbing can damage the lens.

3000 135 93553_B/795 * NOV 2025

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Storage for Transport

CAUTION

Take extreme care when handling and storing transducers. Do not drop or knock the transducer against other objects. Careless handling can result in damage to the transducer. Never use transducers with cracked or otherwise damaged external materials such as transducer housings, lenses (acoustic windows), cables, strain reliefs, and system connectors.

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, low linting cloth and a gentle blotting motion. Aggressive wiping or scrubbing can damage the lens.

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:

3000 135 93553_B/795 * NOV 2025

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WARNING

If the TEE transducers are not thoroughly dried, there is a risk of connecters getting corroded and causing the transducers getting defective.

NOTE

The carrying case used for transport purpose only. If the transducers are stored in carrying case, it may increase the risk of contamination.

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. 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

3000 135 93553_B/795 * NOV 2025

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3000 135 93553_B/795 * NOV 2025

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8 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. Disinfect new transducers before performing the first study. 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.

3000 135 93553_B/795 * NOV 2025

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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.

3000 135 93553_B/795 * NOV 2025

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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 185.

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 173 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. 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. 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:

3000 135 93553_B/795 * NOV 2025

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- 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. 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 184.

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**.

3000 135 93553_B/795 * NOV 2025

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Exporting and Importing the Patient Database

CAUTION

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

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.

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.

3000 135 93553_B/795 * NOV 2025

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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 184.

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.

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**.

3000 135 93553_B/795 * NOV 2025

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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.
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.

3000 135 93553_B/795 * NOV 2025

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Symptom	Corrective Action
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 187.
Image artifacts appear.	Run the transducer test. See “Testing Transducers” on page 177.
Lumify 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 187.
The Lumify Power Module (LPM) does not display a charge.	If no lights appear after pressing the button on the back of the LPM: • Charge the LPM. • Remove the LPM battery for 30 seconds, and then reinstall the LPM battery. • Change the LPM battery. For more information, see “Replacing the Lumify Power Module Battery” on page 188.

3000 135 93553_B/795 * NOV 2025

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Symptom	Corrective Action
The Lumify app displays "Connect Lumify Power Module."	• Press the button on the back of the LPM to make sure the LPM is turned on. • After pressing the button on the LPM, make sure the LPM battery has sufficient charge by verifying that at least one LED is lit. • Disconnect and reconnect the connector or cable between the LPM and the mobile device. • Remove the LPM battery for 30 seconds, and then reinstall the LPM battery. • Change the LPM battery. For more information, see “Replacing the Lumify Power Module Battery” on page 188. • If possible, connect a different LPM.

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

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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/sites/lumify-handheld-ultrasound/support

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.

System Maintenance of LPM

This section extends and enhances the information contained in the user information provided with your ultrasound system. No planned maintenance by Philips is required. The system owner is responsible for maintenance and cleaning.

Replacing the Lumify Power Module Battery

Batteries for the Lumify Power Module (LPM) have a 1-year warranty, and can be replaced.

You can order replacement batteries for the LPM from the following international suppliers:

Company Name	Company Location
Element14	New Zealand
Mouser Electronics	USA
Farnell	United Kingdom

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CAUTION

Use only RRC model 1120 batteries.

You need a Phillips-head screwdriver to perform this procedure.

1. Disconnect and remove the LPM from the back of the mobile device.
2. Place the LPM on a clean, flat surface with the battery cover facing up.
3. Use the Phillips-head screwdriver to remove the battery cover screws and open the battery compartment.
4. Invert the LPM and gently tap it against a hard surface to dislodge and remove the battery.
5. Place the new RRC model 1120 battery into the battery compartment, and carefully align the contacts on the battery with those on the LPM.
6. Replace the battery cover:
   a. Make sure that the battery cover orientation is correct.
   b. Secure the battery cover with the screws.
7. Reattach and connect the LPM to the mobile device. For more information, see “Attaching the Lumify Power Module” on page 102.

Discarding Batteries

WARNING

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

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

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Cleaning and Disinfecting the Lumify System Components

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.

It is important to clean the ultrasound system. If exposed to constant and excessive environmental dust and humidity, these devices will suffer in both performance and reliability.

The Lumify Diagnostic Ultrasound System is composed of several components that may have different cleaning and disinfection requirements:

- For your mobile device, it is your responsibility to appropriately clean and disinfect your mobile device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.
- For the Lumify system transducer and transducer cable, 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
- For the Lumify Power Module (LPM) and the Lumify mobile device cases supplied for use with certain iOS devices, see “Cleaning the Lumify Component Surfaces” on page 192 and “Disinfecting Lumify Component Surfaces” on page 193.

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Disinfectants and Cleaners for Lumify System Components

The compatibility of disinfection and cleaning solutions varies depending on the item on which they are used.

The products in the following table are compatible with the system surfaces for the following components:

- Lumify Power Module (LPM)
- Lumify case for certain iPhone and iPad mobile devices

Cleaning Solutions	Disinfectants
Mild soap solution (for example, 1% Liquinox)[1]	• 70% isopropyl alcohol (IPA) • Opti-Cide 3 (QUAT/IPA based) • Oxivir Tb (accelerated hydrogen peroxide based) • PI-Spray II (QUAT based) • Protex • Sani-Cloth HB (QUAT based) • Sani-Cloth Plus (QUAT/IPA based)

1. Mild soap solutions do not contain any harsh ingredients and are not irritating to the skin. They must not contain fragrance, oils, or alcohols. Hand sanitizers are not approved for use.

CAUTION

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

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CAUTION

Do not use Sani-Cloth AF3 or Super Sani-Cloth to disinfect the system.

CAUTION

Do not spill or spray liquid into any system seams, ports, or transducer receptacles.

Cleaning the Lumify Component Surfaces

Before cleaning the Lumify Power Module (LPM) and the Lumify mobile device case, read “Disinfectants and Cleaners for Lumify System Components” on page 191.

NOTE

The mobile device and any accessories not supplied with the Lumify system should be cleaned and disinfected separately according to the manufacturer's instructions and your institution's policies. The Lumify mounting plate, if used, should be cleaned and disinfected in the same manner as the device or accessory to which it is attached.

1. To ensure a thorough cleaning and disinfection for the Lumify Power Module (LPM) and the Lumify case:
   a. Disconnect the transducer. For detailed instructions on how to clean, disinfect, and maintain each type of transducer used with the Lumify system, including disinfectant compatibility, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.
   b. Disconnect the rigid connector or the flexible cable.
   c. Remove the LPM from the Lumify mobile device case or the mounting plate.

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d. If a Lumify mobile device case is used, remove the mobile device from the case. The mobile device should be cleaned separately according to the manufacturer's instructions and your institution's policies.

2. Wipe the external surfaces of the following system components with a soft cloth lightly moistened (damp; not dripping) with a mild soap solution and potable water.
   - Lumify Power Module
   - Lumify mobile device case
3. Gently remove any soap residue with a cloth lightly moistened with potable water.
4. Allow the system components to air dry.

If the equipment has come in contact with blood or infectious material, see “Disinfecting Lumify Component Surfaces” on page 193.

Disinfecting Lumify Component Surfaces

Before disinfecting the Lumify Power Module (LPM) and the Lumify mobile device case, read “Disinfectants and Cleaners for Lumify System Components” on page 191 and “Cleaning the Lumify Component Surfaces” on page 192.

1. Choose a compatible disinfectant and follow the label instructions for preparation, temperature, and solution strength. If a pre-mixed solution is used, be sure to observe the solution expiration date.
2. Wipe the surface of the Lumify Power Module (LPM) and the Lumify mobile device case with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and disinfectant contact duration.
3. Allow the system components to air dry.

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9 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 expected operational duration of medical device components under normal use conditions, ensuring continued safety and essential performance throughout that period.

NOTE

Regular service and maintenance are necessary for a medical device or component to perform for its expected service life. Expected service life is also contingent on proper care, cleaning and handling. Reasonable care includes inspection, cleaning, and disinfection, as necessary.

The Lumify system is designed to have a minimum of 5 years of service life. The service life of the Lumify system will vary depending on the usage and environmental conditions.

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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)	For C5-2, L12-4 and S4-1: -40°C (-40°F) to 70°C (158°F)

Specifications of Lumify Power Module

These specifications apply to the Lumify Power Module (LPM).

Dimensions

- Height: 107 mm (4.2 in)
- Width: 60 mm (2.4 in)
- Depth: 17 mm (0.7 in)
- Weight (with battery): 150 g (5.3 oz)

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Environmental Limits

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)	For C5-2, L12-4 and S4-1: -40°C (-40°F) to 70°C (158°F)

Pressure, Humidity, and Temperature Limits (LPM)

These limits apply only to Lumify system components supplied by Philips. For information about your mobile device's environmental specifications, consult the documentation that accompanies your mobile device.

Pressure, Humidity, and Temperature Limits for the Lumify Power Module

Parameter	Operating Limits	Storage Limits
Pressure	700 hPa (525 mmHg) to 1,060 hPa (795 mmHg)	500 hPa (375 mmHg) to 1,060 hPa (795 mmHg)
Humidity	0% to 95% non-condensing	15% to 95% relative humidity
Temperature	0°C (32°F) to 40°C (104°F)	-34°C (-29.2°F) to 70°C (158°F)

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Connections

Ports

The Lumify Power Module has the following ports:

- Power/Transducer port: USB 2.0, Type C
- Mobile device connection port: USB 2.0, Type C

Lumify transducers have one USB 2.0, Type B port.

The Lumify app needs USB connectivity for all transducers. If USB devices are disabled on the MDM Endpoint Security, the app won't connect to the probe.

For information about mobile device ports, see the documentation that accompanies the device.

Network

Network capability is supplied by the mobile device. For information about network connectivity, see the documentation supplied with the device.

The Lumify app needs access to port 443 for transducer registration.

Modality Interface

Lumify uses the DICOM standard. DICOM conformance statements for Philips products are available at this website:
www.healthcare.philips.com/main/about/connectivity/dicom_conformance_main.wpd

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Safety and Regulatory Requirements

Electromechanical Safety Standards Met

The Lumify Power Module (LPM) complies with the requirements of IEC 60601-1 General Requirements for Basic Safety and Essential Performance, 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.

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.

Vehicle Standards Met

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

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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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10 References

Adult Echocardiography References

Baumgartner, Helmut, et al. “Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice.” European Journal of Echocardiography, 10: 1-25, 2009.

Calafiore, P., Stewart, W.J. “Doppler Echocardiographic Quantitation of Volumetric Flow Rate,” Cardiology Clinics, Vol. 8, No. 2: 191-202, May 1990.

Rudski, Lawrence, et al. “Guidelines for the Echocardiographic Assessment of the Right Heart in Adult: A Report from the American Society of Echocardiography.” Journal of the American Society of Echocardiography, Vol. 23, No. 7: 685-713, 2010.

Zoghbi, William, et al. “Recommendations for Evaluation of Prosthetic Valves with Echocardiography and Doppler Ultrasound.” Journal of the American Society of Echocardiography, Vol. 22. No. 9: 975-1014, 2009.

Maximum Pressure Gradient (Simplified Bernoulli)

Silverman, N. H., Schmidt, K. G. “The Current Role of Doppler Echocardiography in the Diagnosis of Heart Disease in Children.” Cardiology Clinics, Vol. 7, No. 2: 265-96, May 1989.

Reynolds, T. The Echocardiographer’s Pocket Reference, Second Edition. Arizona Heart Institute Foundation, Phoenix, AZ, 2000, p. 382.

Maximum Pressure Gradient (Full Bernoulli)

Silverman, N. H., Schmidt, K. G. “The Current Role of Doppler Echocardiography in the Diagnosis of Heart Disease in Children.” Cardiology Clinics, Vol. 7, No. 2: 265-96, May 1989.

Mean Pressure Gradient

Reynolds, T. The Echocardiographer’s Pocket Reference, Second Edition. Arizona Heart Institute Foundation, Phoenix, AZ, 2000, p. 382.

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Pressure Half-Time

Hatle, L., Angelsen, B., Tromsal, A. “Noninvasive Assessment of Atrioventricular pressure half-time by Doppler Ultrasound” Circulation, Vol. 60, No. 5: 1096-104, November, 1979.

Velocity Time Integral (VTI)

Silverman, N. H., Schmidt, K. G. “The Current Role of Doppler Echocardiography in the Diagnosis of Heart Disease in Children.” Cardiology Clinics, Vol. 7, No. 2: 265-96, May 1989.

Obstetric 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)

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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 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 weeks

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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.

Vascular References

Doppler Velocity (VEL)

Krebs, C. A., Giyanani, V. L., Eisenberg, R. L. Ultrasound Atlas of Vascular Diseases, Appleton & Lange, Stamford, CT, 1999.

End-Diastolic Velocity (EDV)

Strandness, D. E., Jr. Duplex Scanning in Vascular Disorders. Lippincott, Williams & Wilkins, Philadelphia, PA, 2002.

Minimum Diastolic Velocity (MDV)

Evans, D. H., McDicken, W. N. Doppler Ultrasound Physics, Instrumentation, and Signal Processing, Second Edition. John Wiley & Sons, Ltd., 2000.

Peak Pressure Gradient (PG)

Powls, R., Schwartz, R. Practical Doppler Ultrasound for the Clinician. Williams & Wilkins, Baltimore, Maryland, 1991.

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Peak Systolic Velocity (PSV)

Krebs, C. A., Giyanani, V. L., Eisenberg, R. L. Ultrasound Atlas of Vascular Diseases, Appleton & Lange, Stamford, CT, 1999.

Resistivity Index (RI)

Zwiebel, W. J., ed. Introduction to Vascular Ultrasonography, Third Edition. W. B. Saunders Company, Philadelphia, PA 1992.

Systolic to Diastolic Ratio (S/D)

Zwiebel, W. J., ed. Introduction to Vascular Ultrasonography, Third Edition. W. B. Saunders Company, Philadelphia, PA 1992.

Velocity Time Integral (VTI)

Reynolds, T. The Echocardiographer's Pocket Reference, Second Edition. Arizona Heart Institute Foundation, Phoenix, AZ, 2000, p. 383.

3000 135 93553_B/795 * NOV 2025

Philips

3000 135 93553_B/795 * NOV 2025

Philips

Index

Numerics
2D
distance measurements 147
mode 140
2D ellipse measurements 148
2D mode
using 140

A
Accessories
electromagnetic compliance 77
Accuracy, measurement 152
Acoustic artifacts 170
Acoustic coupling medium 173
Acoustic output
limits 56
measurement 66, 69
Acoustic output tables 16, 60, 69
Acquiring
images 145
loops 145
Adding labels 146
Adult Echocardiography References 201
ALARA principle
applying 56
education program 56
example 56
related guidance documents 65
Allergic reactions to latex 54
Annotation 146
App updates 113
Artifacts 170
Assistance 21, 188
Audience, intended 12
Audit logs 98, 181
Auto detect 98
AutoSCAN 144

B
Batteries 25
Biological safety 52

C
Cables
approved for electromagnetic compliance 76
protecting from damage 35
Capabilities, system 90
Cautions, described 27
Centerline
displaying 145
Cleaning
device 180
transducers 169, 180
Clinical benefits 13
Color mode
about 140
using 141
Compatibility
gels 173
product 37

3000 135 93553_B/795 * NOV 2025

Philips

Compliance, electromagnetic
approved accessories 77
approved cables 76
approved transducers 76
Components, system 95
Condensation 35
Connecting transducers 122
Connectivity profiles 129
Contraindications 93
Controls affecting MI and TI
direct controls 56
indirect controls 56
receiver controls 56
Conventions
user information 16
Covers
transducer 173
COVID-19
using ultrasound to manage 16
Customer
service 21
Customer information 98
Customer Services Portal 21

D

Data storage 98
Date and time, setting 115
Defibrillation, electrical safety 31, 33
Deleting exams 161
Deleting images 159
Deleting loops 159
Deleting patient data 129
Deleting settings 129
Device class 30
Device requirements 89
Device reuse 23
DICOM
logging 166
DICOM export settings 163
Disinfecting
device 180
system surfaces 193
transducers 169, 180
Display
avoiding damage 35
Display orientation 98
Disposal of device 23
Distance measurements 147
Doppler iSCAN optimization 145
Doppler, pulsed wave 142
Downloading app 101

E

Editing
patient data 138
Electrical safety 30
Electromagnetic compatibility 72
Electromagnetic compliance
approved accessories 77
approved cables 76
approved transducers 76
Electromagnetic emissions
defined 72
environment 75

3000 135 93553_B/795 * NOV 2025

Philips

Electromagnetic immunity
defined 72
system environment 78
Electromagnetic interference
avoiding 86
distance to transmitters 84
types 82
Electrostatic discharge (ESD) 74
Electrosurgical units (ESUs) 73
Ellipse measurements 148
E-mailing Fetal Age Summary 156
E-mailing images 156
E-mailing loops 156
Ending exams 154
Entitlement 101
Equipment protection 35
Error messages 52, 188
ESD precautions 74
Estimated Due Date (EDD) 203
Estimated Fetal Weight 204
Exams
deleting 161
ending 154
exporting 159
quick 120
restarting paused 139
reviewing 138
starting new 135
Explosion hazard 15, 30
Export destinations
configuring 162
editing 165
settings 163
Export queue 166
Exporting exams 159
Exporting Fetal Age Summary 156
Exporting images 156
Exporting loops 156
Exporting patient data on images 160
Exporting patient database 183

F

FAQs 188
Fetal age 202
Fetal Age Summary
e-mailing 156
exporting 156
Fire safety 34
Full-screen view 144

G

Gels
compatibility 173
recommendations 173
Gestational age 202
Gestures
reference 17
Glutaraldehyde exposure 71

H

Hadlock
CRL 203
Hazards
electrical shock 30
explosion 15, 30
IEC symbols 38

3000 135 93553_B/795 * NOV 2025

I
Icons
imaging display 116
IEC symbols 38
Image review 155
Image updating, inconsistent 52
Images
acquiring 145
deleting 159
e-mailing 156
exporting 156
viewing full screen 144
Imaging
2D 140
acoustic artifacts 170
Color 141
Color mode 140
display 116
features 144
M-mode 141
PW Doppler 142
Imaging modes 139
Import Patient Database 184
Indications for use 91
Indices 60
Infection control 72
Installing app 101
Intended audience 12
Intended use 13
Interference 82, 86
iSCAN Intelligent Optimization 145

L
Labels 146
adding 146
Latex
allergic reactions 54
Local directory export settings 163
Logging, DICOM 166
Logs
audit 98, 181
system 98, 181
Loops
acquiring 145
deleting 159
duration 98
e-mailing 156
exporting 156
playing 156

M
Magnification, zoom 144
Maintenance
system 179, 180
transducers 169, 180
Measurement tools 91
Measurement tools references 202
Measurements
accuracy 152
acoustic 66
distance 147
ellipse 148
tools 91
types 91

3000 135 93553_B/795 * NOV 2025

Philips

Mechanical index (MI) 60
controls affecting 63
display 60
display precision and accuracy 60
on-screen 60
Medical Ultrasound Safety 16
Messages, error 52, 188
MI 60
MI and TI accuracy estimates 60
M-mode 141
using 142
Modality Worklist 132
searching for exams 137
Modality worklist server
adding 132
deleting 133
modifying 133

N

Navigating thumbnails and images 155
Network share export settings 163
Nyberg
GS 203

O

On/Off control, system power 45, 114
Operating notes 15
Operating temperature 35
Operator safety 70
Ordering supplies 20
Orientation, display 98
Output display 60
Output power 98
Output tables, acoustic 16, 60, 69
Overview, system 89

P

Pacemakers 31
Patient contact temperature 167
Patient data
deleting 129
editing 138
exporting on images 160
protecting 93
security 93
Patient database 98
exporting and importing 183
repair 182
Perchlorate information 26
Performing an exam 135
Performing fetal measurement
estimated fetal weight 153
fetal growth 153
OB meas 153
Philips contact information 21
Playing loops 156
Power (On/Off) control 114
Power saving 98
Power, output 98
Presets 168
Presets, changing 138
Problems, correcting 185
Product compatibility 37
Protection against system damage 35

3000 135 93553_B/795 * NOV 2025

PW Doppler
about 142
using 143

Q

Quick exams 120
Quick ID 120

R

Recycling the device 23
References
Adult Echocardiography References 201
Area and Circumference from Ellipse 202
Estimated Due Date (EDD) 202
Estimated Fetal Weight (EFW) 202
Gestational Age (Fetal Age) 202
Last Menstrual Period (LMP) 202
measurement tool 202
Vascular References 204
Registered transducers 98
Registration, transducers 101, 112
Regulatory requirements 199
Repairing patient database 182
Repetitive strain injury 71
Requirements, device 89
Restrictions for use 87
Resuming a paused exam 139
Retrying export jobs 166
Review
displaying images 155
overview 155
starting 155

S

Safety 27
acoustic output and measurement 66
ALARA principle 56
basic 28
biological 52
defibrillators 33
electrical 30
electromagnetic emissions and immunity 72
electrosurgical units 73
equipment protection 35
fire 34
general warnings 14
guidance documents 65
mechanical index 60
medical ultrasound 16
operator 70
output display 60
pacemakers 31
requirements 199
symbols 38
thermal index 60
Saved exams 138
Security
data 93
Separation distance 84
Serial number, transducer 100
Service, customer 21
Settings
deleting 129
export destinations 163
system 98
Setups 98

3000 135 93553_B/795 * NOV 2025

Philips

Software updates 20
Software version 100
Solvents 35
Specifications
  environmental 196, 197
  safety requirements 199
Starting new exams 135
Starting review 155
Static shock 74
Storage
  data 98
Storing transducers 175
  daily and long-term 176
  for transport 176
Supplies 20
Symbols
  definitions 38
System error messages 188
System Information 100
System logs 98, 181
System maintenance 179
System settings 98
System upgrades 20

T

Tables, acoustic output 16, 69
Tablet identifier 100
Technical support 188
Testing transducers 177
Tests
  transducer 98
Thermal index (TI) 60
  controls affecting 63
  display 98, 115
  display precision and accuracy 60
  displays 60
  modes of operation 60
  on-screen 60
  using appropriate for application 60
Thumbnails 155
TI 60
TI and MI values 63
Time and date, setting 115
Tools, measurement 91
Touch gestures 17
Transducer maintenance 169, 180

3000 135 93553_B/795 * NOV 2025

Philips

Transducers 167
affecting TI and MI values 63
care 169, 179, 180
cleaning 169, 180
connecting 122
covers 173
electromagnetic compliance 76
environmental limits 196, 197
gels compatibility 173
humidity limits 196, 197
indications for use 91
inspecting for damage 30
maintenance 169, 180
operating limits 196, 197
presets 168
pressure limits 196, 197
registered 98
registering 101, 112
safety 167
serial number 100
storage limits 196, 197
storage, daily and long-term 176
storage, for transport 176
storing 175
testing 98, 177
transporting 175
types 91
Troubleshooting 185
Turning the system on and off 114
Tutorial
Lumify app 114

U

Ultrasonic bioeffects, related documentation 65
Ultrasound transmission gel
compatibility 173
recommended 173
Updates, app 113
Upgrades, system 20
USB media
user information 15
User information
about 11
components 15
conventions 16
User Information USB media 15

V

Vascular References 204

W

Walkthrough
Lumify app 114
Warning symbols 38
Warnings
described 27
general 14, 28
Website 188
Website, Philips 21
Wi-Fi settings 98
Wireless networking
Wi-Fi settings 98
wireless power transfer (WPT) 73
Worklist 132
searching for exams 137

3000 135 93553_B/795 * NOV 2025

Philips

Z
Zoom 144

3000 135 93553_B/795 * NOV 2025

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