PHILIPS

URGENT Medical Device Recall (Correction)

Philips Ultrasound Lumify Systems
Lumify Systems Incompatible with iOS 18 Devices

November-2025

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

This letter supersedes the initial Field Safety Notice distributed for this issue, dated October-2025. The compatibility issue affecting Philips Lumify Ultrasound Systems with iOS 18 devices has been resolved in the recently released Lumify 5.1.2 software. As such, **Section 4 - Actions that should be taken by the customer / user in order to prevent risks for patients or users,** has been updated accordingly.

Dear Customer,

Philips has become aware that the Lumify System is incompatible with Apple devices that have USB-C connector and are running iOS 18, which will cause a failure to perform Live Imaging potentially resulting in the procedure needing to be redone or rescheduled. This *URGENT Medical Device Recall (Correction)* Letter is intended to inform you about:

Intended Use:
Philips Lumify Ultrasound system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals. 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 combination of a Philips transducer, the Philips Lumify app, and a compatible iOS device with a Lumify Power Module is considered a medical device.

1. What the problem is and under what circumstances it can occur

Philips is providing this URGENT Medical Device Correction Letter to inform you about the incompatibility issue with the Lumify System and Apple devices that have USB-C connector and are running iOS 18.

The Lumify software application has an intentional design component that restricts the ability to scan if the host device is charging. The Lumify Power Module (LPM) provides battery power to support the use of the transducer. It is not intended to provide charging capability to iOS devices.

With version 18.X of iOS, when the device's charge level drops below ~99%, it will attempt to charge from the LPM through the USB connection. This does not happen for Lightning port connected devices.

If the battery threshold is crossed while live scanning, the application will interrupt the live scan and display a dialog message requiring the user to charge the tablet. If the battery level is below the threshold prior to starting live scanning the application will prevent live scanning from starting and display a dialog message requiring the user to charge the tablet.

Philips received customer complaints regarding this issue. However, Philips has not received any reports of patient harm.

2. **Hazard/harm associated with the issue**

Philips' risk assessment determined that once Lumify is connected to an Apple device that has a USB-C connector and is running iOS 18.x, the incompatibility will be persistent with that device. This will cause a failure to perform Live Imaging potentially resulting in the procedure needing to be redone or rescheduled. Apple does not provide a provision for downgrading an iOS device from 18 to a lower iOS version.

3. **Affected products and how to identify them**

All Lumify devices utilizing an iOS based host product running iOS 18.X and have a USB-C port are affected by this issue. To check which OS software is installed on your device:

1. Click *Settings* app
2. Click *General*
3. Click *About*
4. Software version is displayed next to iOS Version



Figure 1. Lumify System – shown as an example

4. **Actions that should be taken by the customer / user in order to prevent risks for patients or users**

- **<u>For customers located in countries where Lumify 5.0 is not available (listed in Table 1 below):</u>**
  - Utilize an Android based device with your Lumify system.
  - Lightning port devices are not affected and may continue to be used as normal.
  - If you use an iOS based device, do not update your iOS device.

- Turn off iOS auto-updates on USB host devices for Lumify by following the below steps:
  - Click *Settings* application
  - Click *General*
  - Click *Software Update*
  - Click *Automatic Updates*
    - Under *Automatically Installed* – Turn off switch for iOS Updates
    - Under *Automatically Download* – Turn off switch for iOS Updates
  - Go back to *Software Update* and click *Beta Updates* to set to Off

Table 2. Countries Where Lumify 5.0 is Unavailable

Countries Where Lumify 5.0 is Unavailable		
Korea, Republic of	Australia	Saudi Arabia
Kosovo	Brazil	Serbia
Malaysia	Canada	Singapore
Mexico	Colombia	Taiwan
Moldova	Costa Rica	Thailand
Montenegro	Ecuador	Kazakhstan
New Zealand	El Salvador	Türkiye
Nicaragua	Eswatini	Ukraine
Peru	India	Vietnam
Philippines	Indonesia	Russia
Israel		

- **For customers located in countries where Lumify 5.0 is available (all countries not listed in Table 1 above):**
  - Verify the Lumify App version you are currently running
    - Click the *Lumify App*
    - Click *Demo Mode*
    - Click the three dash lines emblem in the upper left corner
    - Click *About*
    - If the software version displayed is *Software Version 5.1.2* you have the most recent software version, and the incompatibility issue will not occur
  - If you do not see *Software Version 5.1.2*, update the Lumify App to 5.1.2 by following the below steps, and the incompatibility issue will not occur
    - Open the *App Store* application
    - Search for *Lumify Handheld Ultrasound*
    - Click the *Update* button
    - After the update to Lumify 5.1.2, follow the prompts on your device to re-register your system

- **For customers in all countries:**
  - Place this Notice with the documentation of the affected Ultrasound system(s); ensure the notice is in a place likely to be viewed by device operators.
  - Circulate this Notice to all users of the affected device(s) so that they are aware of the issue.
  - Complete the Acknowledgment form indicating you have read and understand the recall.

Adverse health consequences experienced with the use of this product can be reported to the FDA's MedWatch Adverse Event Reporting program via:

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088 (1-800-332-1088)
- Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

5. Actions planned by Philips Ultrasound to correct the problem

Philips is issuing this letter as notification of the problem. Please follow instructions in section 4 as mitigation of the problem.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative: For North America, contact the Customer Care Solutions Center (1-800-722-9377).

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

Sincerely,



Ondrea Bermudez
Head of Quality, Ultrasound, Philips

PHILIPS

URGENT Medical Device Recall (Correction) Response Form

Reference: Lumify Systems Incompatible with iOS 18 Devices, 2025-PD-US-004

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Medical Device Recall (Correction) Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: Life-Assist Inc, 94310218

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

Refer to the instructions provided in Section 4 of the Urgent Medical Device Recall (Correction) letter.

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall (Correction) Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Philips Lumify Ultrasound system.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

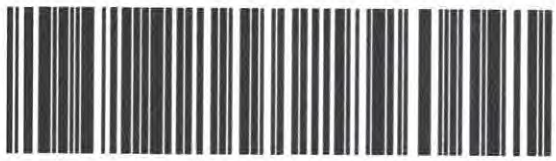
Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to Philips at: Philips.Recall@philips.com

930804X692X637XPRI
Philips Ultrasound Q&R
222 Jacobs St
Cambridge, MA 02141

USPS CERTIFIED MAIL™



PRESORTED
FIRST-CLASS MAIL
POSTAGE AND FEES PAID
C2M LLC
22202

9214 8901 3247 3400 2294 7662 49

Urgent Medical Device Recall (Correction)

7**********AUTO**MIXED ADC 480

2025-PD-US-004 94310218
ATTN: Director of Radiology
Life-Assist Inc
11277 Sunrise Park Dr
Rancho Cordova, CA 95742-6528



URGENT MEDICAL DEVICE CORRECTION

Philips
Lumify Systems Incompatible with iOS 18 Devices

Thursday, November 6, 2025

Dear Valued Life-Assist Customer,

According to our records you may have purchased a product that is affected by the attached manufacturer notification. Please examine your inventory to determine if you have the following product in your possession.

ALL Lumify Systems

Life-Assist Product Code	Manufacturer Product Code	Product Description
US6884	FUS6884	Lumify S4-1 (Critical Care) Broadband Sector Array
US0325	FUS0325	Lumify Ultrasound System iOS with S.A. S4-1 and power module
US6882	FUS6882	Lumify L12-4 Broadband Linear Array
US101983 / US1983	101983	Lumify Ultrasound System iOS with S.A. S4-1 and power module
US6884T	FUS6884-SPECIAL	Lumify S4-1 Broadband Sector Array w/ Rugged Tablet
US6884TC-SP	NUSH020-SP	Lumify S4-1 Transducer w/ Rugged Tablet & Rugged Case
DEMO_FUS0325	FUS0325	Demo Lumify Ultrasound Sector Array: S4-1 iOS
DEMO_LUMIFY	DEMO_LUMIFY	Lumify Ultrasound, Sector & Linear, w/ Tablet & Case (DEMO)
DEMO_LUMIFY3	DEMO_LUMIFY3	Lumify Portable Ultrasound, Sector & Linear w/ tablet (DEMO)

Reason:
Philips has become aware that the Lumify System is incompatible with Apple devices that have a USB-C connector and are running iOS 18, which will cause a failure to perform Live Imaging potentially resulting in the procedure needing to be redone or rescheduled.

Please reference the attached notice from the manufacturer for more information.

Action Required:

1. Read the attached **URGENT MEDICAL DEVICE CORRECTION** notice from the manufacturer.
2. Immediately forward this notification to any pertinent personnel, department, and/or location within your organization.
3. Identify affected product as described in Section 3 on page 2 of the manufacturer notification.
4. Follow instructions as outlined in Section 4 on pages 2-3 of the manufacturer notification.

If you need any further information or support concerning this issue, please contact your local Philips representative: For North America, contact the Customer Care Solutions Center (800-722-9377).

We apologize for any inconvenience.

PHILIPS

URGENT Medical Device Recall (Correction)

Philips Ultrasound Lumify Systems
Lumify Systems Incompatible with iOS 18 Devices

October-2025

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Ondrea Bermudez
Head of Quality, Ultrasound, Philips