

URGENT Field Safety Notice

Philips Ultrasound Lumify Systems
Lumify Systems incompatible with iOS 18 devices

October-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.

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 Field Safety Notice* 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 Field Safety Notice 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

- 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
- 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.

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.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ondrea Bermudez', with a long horizontal flourish extending to the right.

Ondrea Bermudez
Head of Quality, Ultrasound, Philips

URGENT Field Safety Notice 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 Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

Refer to the instructions provided in Section 4 of the Urgent Field Safety Notice letter.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice 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.