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URGENT Field Safety Notice

Philips Lumify Diagnostic Ultrasound System
Potential Loss or Delay of Scanning Functionality During Point-of-Care Use

November 2026

Do not use your Lumify system outside of areas with readily accessible Wi-Fi or Cellular connectivity due to the potential for unrecognized transducer registration.

Always have backup ultrasound devices and/or modalities available for care

Please review the following with all members of your staff who need to be aware of the contents of this communication.

Dear Customer,

Philips is aware of an issue that potentially impacts the Lumify Ultrasound System functionality at the point of use in clinical care.

Please return the completed response form at the end of this notice, indicating that information on this issue has been read and understood. Philips asks that you return the completed response form no later than 30 days from receipt of this letter.

Issue Description

Philips has identified the following potential issues with the Lumify Diagnostic Ultrasound System which may prevent or delay scanning functionality:

1. Due to a software issue, the Lumify application may not recognize a previously registered transducer and prompt for re-registration (outside of the defined criteria in the User Guide) without warning prior to point of care use. Scanning functionality is prevented until the registration step has been completed; registration requires Wi-Fi or cellular signal access.

   Lumify devices used outside the hospital, such as in ambulances, aircraft, or field settings, are at greater risk due to reduced access to Wi-Fi/cellular. Philips has received reports that these erroneous re-registration events have prevented scanning in pre-hospital environments and delayed care to patients. These pre-hospital events occurred outside of Wi-Fi or cellular access.

2. Additionally, Philips has identified that the connection between the Lumify transducer USB cable to a customer's tablet/ phone may disconnect or the cable may have an unstable connection during use which may disrupt continuous function of the device and result in a delay of care. Both USB connection scenarios described below may result in loss of device function, independent of the erroneous re-registration prompt issue as described above.

- A loose or unstable connection between the USB cable and the tablet/phone may result in intermittent imaging or loss of imaging.

- A loose or unstable connection between the transducer head and USB cable may result in the transducer not being recognised and the 'please connect a transducer' message being displayed.

Hazard/harm associated with the issue

Loss of functionality or system failure during a procedure may result in a delay in diagnosis and/or treatment. As Lumify is intended for Point-of-Care (PoC) use, where ultrasound imaging supports rapid diagnosis/treatment, real-time decision making, triage of unstable patients, and access to diagnostic capabilities in mobile, underserved, or remote settings, the consequences of loss of functionality/system failure may be greater than traditional Ultrasound devices. Depending on the clinical situation and patient condition, delays in diagnosis or treatment could lead to serious injury or death in the most severe cases.

Since the launch of Lumify in 2015, Philips Ultrasound has received four (4) reports of death and eight (8) reports of serious injury associated with the Lumify system not being available/ functional at the point of care.

User Instructions

Philips advises customers/ users to take the following actions to reduce risks for patients until an update is available and installed:

- Always have backup ultrasound devices and/or modalities available for care as advised in the User Guide to support continuity of care in the event that scanning is disrupted.
- Do not use the Lumify system outside of areas with readily accessible Wi-Fi/Cellular connectivity (e.g. pre-hospital transport (ambulance, helicopter) or use outside of a traditional healthcare setting (care in the field).
  - **Note**: Whilst Wi-Fi or cellular connectivity is not required for normal system operation, it is required to complete the registration process. This means that if a prompt for re-registration occurs when the device is in use in an area with poor Wi-Fi or cellular connectivity, the registration process would not be possible. This restriction is therefore intended to mitigate the risk of the system becoming unavailable for use that would arise from incomplete re-registration.
- For loss of imaging associated with a loose or unstable USB connection with the tablet or phone, users may consider manual stabilization of the cable, where practicable, to help maintain the connection. Note that manual stabilization does not replace the requirement to have a backup ultrasound device and/or alternative modality available for care, as issues with loose/unstable connection between transducer head and the USB cable may also result in the transducer not being recognized and may disrupt continuous function of the device.
- Circulate this notice to all users of the device so that they are aware of the product issue and associated hazard / harm.
- Post this notice near the affected unit(s) for ease of reference.
- Forward this notice to any area/facility that may have the device.

Please return the completed response form at the end of this notice, indicating that information on this issue has been read and understood. Philips asks that you return the completed response form no later than 30 days from receipt of this letter.

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Identification of Affected Product

Product Brand Name	UDI	Impacted Versions
Lumify Diagnostic Ultrasound System	Android: (01)00884838122116(21) iOS: (01)00884838124141(21)	**All Software is impacted:** Android Software versions: 1.X, 3.X, 4.X, 5.X iOS Software Versions: 2.X and 5.X

All Lumify Systems (Lumify application from Google Play Store or iOS store) are affected by this issue. All Lumify transducers will have "Lumify" printed on them as shown in Figure 1.

Figure 1



Intended Use:
The Philips Lumify Ultrasound system is a transportable ultrasound system consisting of the combination of a Philips transducer, the Philips Lumify application, and a compatible Android device or a compatible iOS device. 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.

Manufacturer Actions (SRN: US-MF-000002237)
The impacted Lumify application has been removed from Google Play Store and iOS store and is not available for new downloads to contain the identified software issue related to registration. Applications installed in portable devices remain operational. Philips is developing a software update to address the identified registration issue. Philips will communicate once the software update is available and provide instructions on any actions required.

Additionally, Philips is working diligently to fully assess the unstable cable connection issue and identify the appropriate solution. Updates will be communicated as soon as further information is available.

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Please contact your local Philips representative with any additional questions or to report any issue with your device.

Telephone: UKI: +448000260086
NI: +448000260430
ROI: +3531800832340

Email: UKFCO@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Tabitha Gibbs
Senior Director Quality, Ultrasound, Philips

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URGENT Field Safety Notice Response Form

Reference: Philips Lumify Diagnostic Ultrasound System, Potential Loss or Delay of Scanning Functionality During Point-of-Care Use, GB_2026-PD-US-010_FSN-RevB

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/Postcode: _____

_____

_____

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 Diagnostic Ultrasound System.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to **UKI_Quality_CR@philips.com**