

**URGENT Field Safety Notice**

Philips Sparq Ultrasound Systems  
System Shutdown Issue

**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.

16-AUG-2021

Dear Customer,

A problem has been identified in the Philips Sparq Ultrasound Systems that could pose a risk for patients or users. This URGENT Field Safety Notice is intended to inform you about:

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

Philips identified a battery system data issue in the Philips Sparq Ultrasound Systems that can intermittently cause a system shutdown, regardless of actual battery state or application of AC (Alternating Current) power.

As of August 2021, there have been no reports of harm associated with this issue.

**2. Describe the hazard/harm associated with the issue**

Philips discovered the issue through internal testing. If the Sparq Ultrasound System shutdown occurs during clinical use, there is a potential for delay of therapy/treatment (due to restart of the system), and/or administration of unnecessary therapy/treatment to the patient (due to the need to use an alternative imaging method).

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

Our records indicate you have one or more of the potentially affected systems.

<b>Product Code</b>	<b>Product Description</b>	<b>Software Version</b>
795090	Sparq Ultrasound System	3.5

Instructions for how to determine the software version of your Ultrasound system:

1. Power up the system and allow it to complete the boot sequence,
2. Press the **Wrench** icon on the upper right side of the control panel,
3. Press the **Service** button on the bottom left corner,
4. Under **System Management**, Press **System Information**,
5. The software version is listed in the **Software Information Section**.

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

- If this shutdown occurs Philips recommends that the system be put back on AC power and restarted. The system will be fully functional upon restart. However, restarting the system will not prevent the possibility of the issue reoccurring.
- < Please complete and return the attached form to Philips promptly and no later than 30 days from receipt via email to:> < [Philips representative contact details to be completed by the Market](#) >

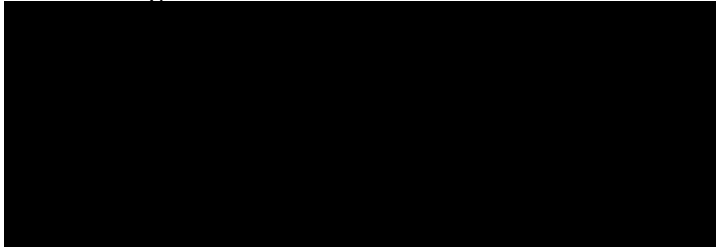
#### 5. Describe the actions planned by Philips Ultrasound to correct the problem

A Philips Field Service Engineer will contact you to schedule a software update to permanently resolve the issue (reference FCO79500550).

This notice has been reported to the appropriate Regulatory Agencies.

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 < [Philips representative contact details to be completed by the Market](#) > and reference FCO79500550.

Sincerely,



## URGENT FIELD SAFETY NOTICE RESPONSE FORM

**Reference:** Philips Sparq Ultrasound System Shutdown Issue FCO79500550

**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, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

### Customer Actions:

If the shutdown occurs Philips recommends that the system be put back on AC power and restarted. The system will be fully functional upon restart. However, restarting the system will not prevent the possibility of the issue reoccurring.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the Sparq Ultrasound Systems.

### Name of person completing this form:

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Date  
(DD/MM/YYYY): \_\_\_\_\_

Please send this completed form to [<Philips representative contact details to be completed by the Market>](#)