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URGENT Field Safety Notice

5000 Compact Series Ultrasound Systems (Models 5500 and 5300)
Multiport adapter issue with a potential to cause a burn in the esophagus

March 20, 2024

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 of a potential safety issue with the Multiport adapter (available in Deluxe and Premium Cart Options on 5000 Compact Series Ultrasound Systems) that could pose a risk for patients. This URGENT Field Safety Notice is intended to inform you about:

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

The 5000 Compact Series Ultrasound Systems with Deluxe and Premium Cart options come with a Multiport adapter (MPA) as shown in Figure 1 below. This Multiport adapter enables connection of up to three transducers.

If, during a procedure where multiple transducers are connected to the Compact 5000, one of which is a transesophageal echocardiography (TEE) transducer and imaging is being performed with one of the other transducers, the TEE transducer may continue to receive power, which may cause the transducer head to exceed the established temperature limit (43°C/109.4°F). The fault condition is triggered by the vibrations caused by disconnecting and connecting/reconnecting of the transducer(s).

Specifically, for the fault condition to occur:

- A TEE transducer (X7-2t or X8-2t) is connected, but not selected, and
- One or two non-TEE transducers are also connected to the remaining ports, and
- One of the non-TEE transducers is selected for live imaging, and
- While leaving the TEE transducer connected, but not selected, the transducer which is selected or not selected for imaging, is removed and a new transducer is connected (or the same transducer is reconnected) and
- Imaging is continuing with any of the non-TEE connected transducer(s).

If the TEE probe remains unselected through all the steps outlined above, there is a possibility that the MPA will allow power to be directed to the TEE probe. Under these conditions, the temperature monitoring and control function for the TEE probe is circumvented which may result into the temperature of the TEE transducer head to exceed the established temperature limit.

Philips has not received any complaints or reports of patient harm associated with this issue.

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Figure 1. Multiport Adapter shown on a 5000 Compact Series Ultrasound System

2. Hazard/harm associated with the issue

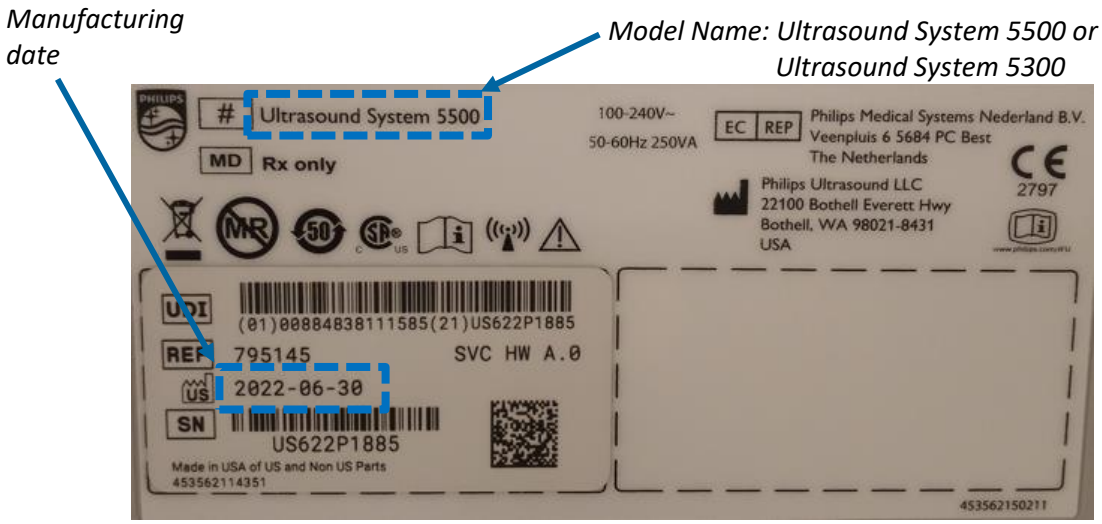
A transducer head which is exceeding the established temperature limit can cause a burn to a patient. In the worst case, if a patient is already intubated and the transducer head exceeds the established temperature limit, the user may not be aware of the condition, and a sedated patient may not be able to respond to a burn in the esophageal tract.

3. Affected products and how to identify them

All Compact 5000 series systems manufactured on or before 20-Dec-2023 and purchased with Deluxe and Premium Cart options may be affected by this issue if the conditions outlined in Section 1 take place. Follow the steps below to identify if your system is impacted with this issue.

1) Model Name indicated on the label (located at the bottom of the system) is “Ultrasound System 5500”, or “Ultrasound System 5300”. Figure 2 is shown as an example below. And:
2) The cart used with the system has a Multiport Adapter as shown in Figure 1 above.

Figure 2. Example System Label



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Intended Use:
Compact 5000 series ultrasound systems are intended for diagnostic ultrasound imaging and fluid flow analysis of the human body. The clinical environments where these diagnostic ultrasound systems can be used include physicians' offices, clinics, hospitals, surgical suites, and clinical point-of-care for diagnosis of patients.

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

There are two ways to avoid the condition.

Option 1: To prevent the issue from occurring, when using the TEE transducers, connect directly to the Compact 5000 system using the port on the side of the system as shown in Figure 3 below.

Figure 3. Port on the side for a directly connected transducer

The issue is associated with the MPA, therefore by using the port on the Compact 5000 directly, the issue is avoided.

Option 2: Whenever adding a transducer to, or removing a transducer from the MPA, disconnect and reconnect the MPA connector on the Compact 5000 system connector port, followed by a transducer selection on the touch screen. By performing this step when adding or removing a transducer, the monitoring and control systems are re-initialized.

Please complete and return the attached response 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.

Circulate this URGENT Field Safety Notice to all users of this device within your organization and forward to any organization where potentially affected devices have been transferred so that they are aware of the issue. Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.

5. Actions planned by Philips Ultrasound to correct the problem

A Philips representative will contact you to schedule a time for a Field Service Engineer to visit your site and implement the solution to resolve the issue (reference FCO79500569).

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.

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Sincerely,

Thuy Nguyen
Quality Leader – Philips Ultrasound

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URGENT Field Safety Notice Response Form

Reference: Multiport adapter issue with 5000 Compact Series Ultrasound Systems, 2024-PD-US-001 (FCO79500569)

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:

- Please retain this letter with your system(s) until a solution is installed on your system; ensure the notice is in a place likely to be seen/viewed.
- Circulate this notice to all users of this device within your organization and forward to any organization where potentially affected devices have been transferred so that they are aware of the issue.
- Until Philips has completed the system updates, follow the instructions provided in section 4 of the URGENT Field Safety Notice.

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 affected 5000 Compact Series Ultrasound Systems.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to your local Philips representative.