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URGENT Field Safety Notice

Wired Avalon Ultrasound Transducer (product number 867246)
Inaccurate Fetal Heart Rate (FHR) measurements when monitoring multiples

22-MAY-2024

To: Customer Name
Street Address
City, State, Zip Code

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 wired Avalon Ultrasound Transducer (867246) where inaccurate Fetal Heart Rate (FHR) measurements were produced when monitoring multiples (twins or triplets).

The ultrasound transducer directs a low-energy ultrasound beam toward the fetal heart and detects the reflected signal. Fetal monitors use the ultrasound Doppler method for externally monitoring the fetal heart rate. Using the Doppler method, the transducer sends sound waves and receives their echoes that are amplified, made audible, and sent to the monitor's speaker through which the fetal heart can be heard. The FHR is then determined and displayed as a number on the monitor's display and recorded as a graphical trace on paper, using the built-in recorder of the fetal monitor.

This *URGENT Field Safety Notice* is intended to inform you about:

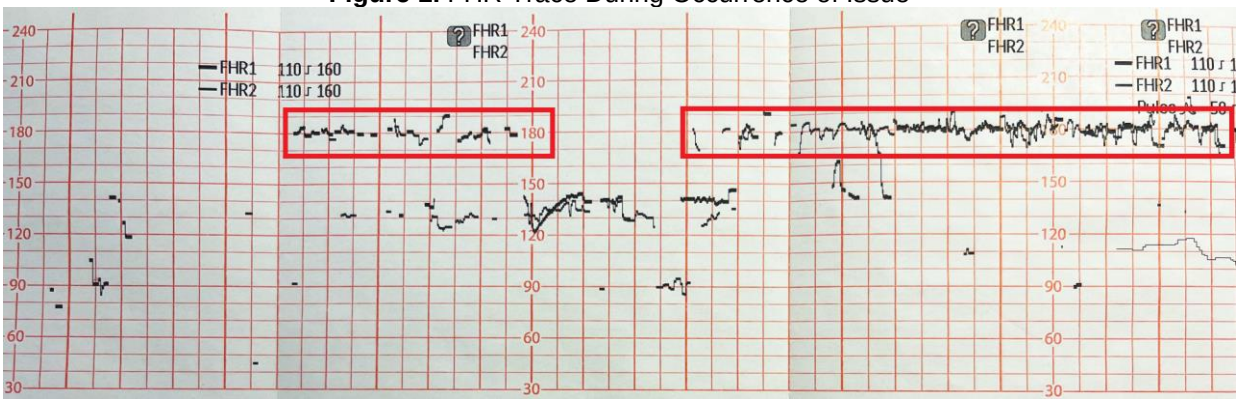
1. What the problem is and under what circumstances it can occur

It was found that the latest version of the wired Avalon Ultrasound Transducers (867246) may report inaccurate Fetal Heart Rate (FHR) measurements when monitoring multiples (twins or triplets): In situations where the physiological signal (echo from the fetal heart) is absent or very weak (e.g. in early weeks of pregnancy), there is a tendency of the wired Ultrasound transducers to interfere with each other and subsequently to produce an artificial FHR, mostly at approximately 180 bpm. The use cases affected by this issue are twin or triplet monitoring with wired Ultrasound Transducers including at least one transducer with software version L.01.04. The population at risk is women with multiple gestation (twins/triplets).

***Note: Wireless transducers and wired transducers with a different software revision than L.01.04 are not affected by this issue.**

Figure 1 below shows an example trace of FHR measurements when this issue occurs. Highlighted in red are the sections of the trace which show the issue as it would be present for the clinical user.

Figure 1. FHR Trace During Occurrence of Issue



2. Hazard/harm associated with the issue

Due to the issue identified with the wired Ultrasound Transducer (867246) it is possible for a mother with multiple fetuses to be exposed to the hazard of an unnecessary Caesarean section because the clinical users are unable to obtain reliable FHR data for the fetuses. The clinical users may be unaware that the measurements reported by the device are inaccurate and may cause incorrect/delayed treatment as a result (unplanned c-section). The issue does not pose a risk for monitoring with a single ultrasound transducer (singleton pregnancies).

3. Affected products and how to identify them

This issue is the result of a software (version L.01.04) defect therefore all devices with the impacted software have this defect. The affected patient population are women pregnant with twins or triplets and their fetuses who require monitoring of physiological parameters including uterine activity and fetal heart rates.

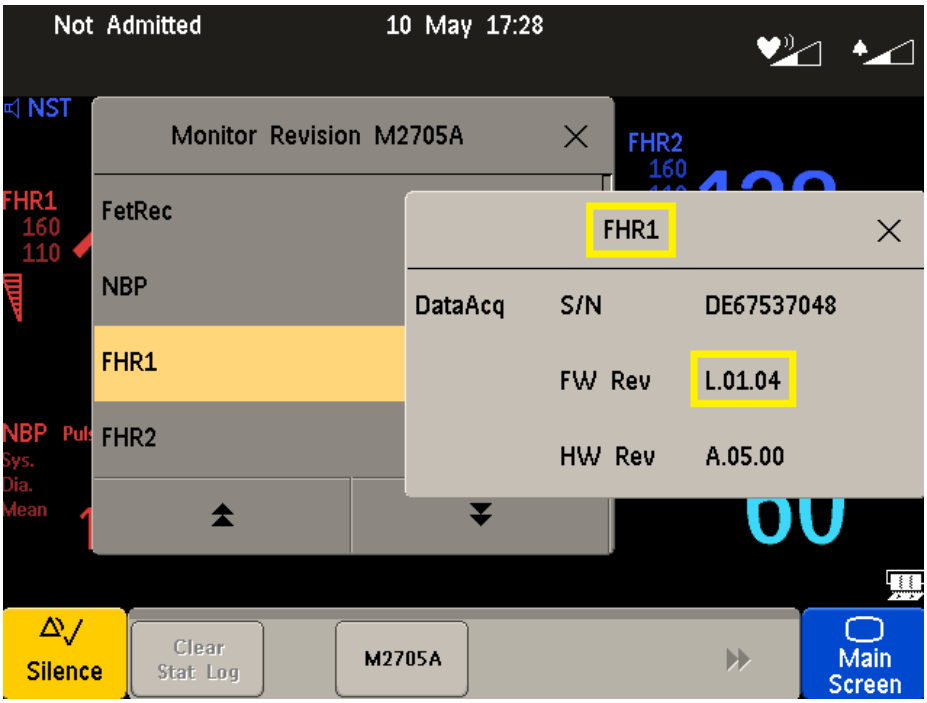
Affected device:

Product Number: 867246	**Device Brand Name:** Avalon Ultrasound Transducer
UDI: 00884838093195	**SW Version/Lot/Serial Numbers:** Software version L.01.04

How to determine software version of existing Transducer as a user:

1. Enter the Software Revisions screen in the fetal monitor graphical user interface: ***Main Setup > Revisions >*** *[FHR to check, e.g.* ***FHR1****]*

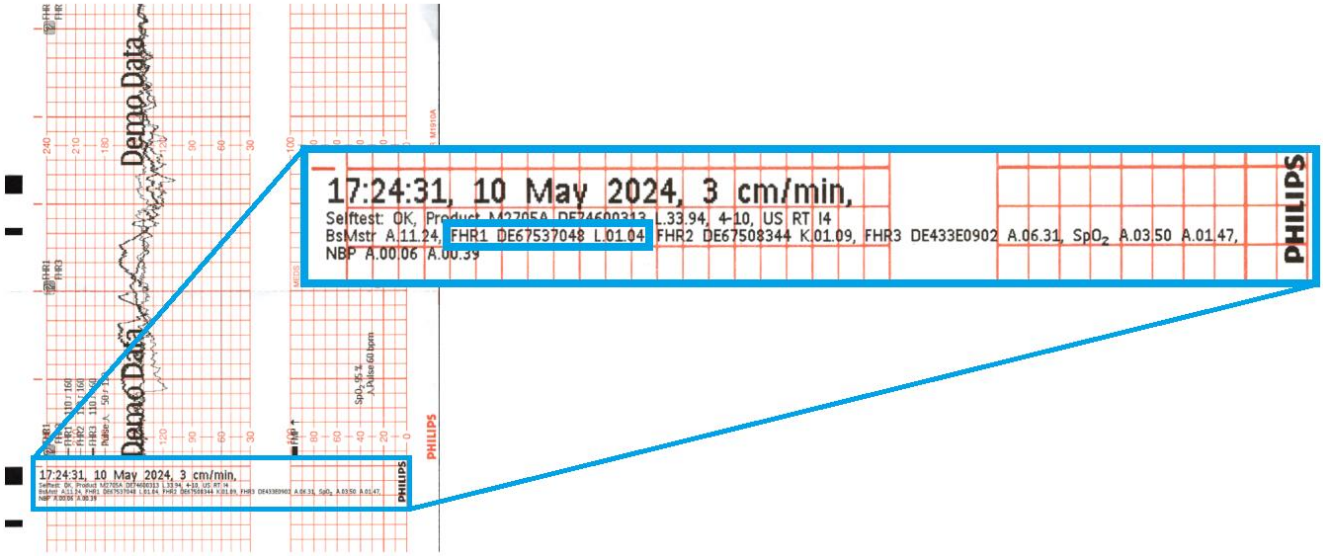
Figure 2. Checking the Transducer Software Revisions at the Avalon FM display



OR

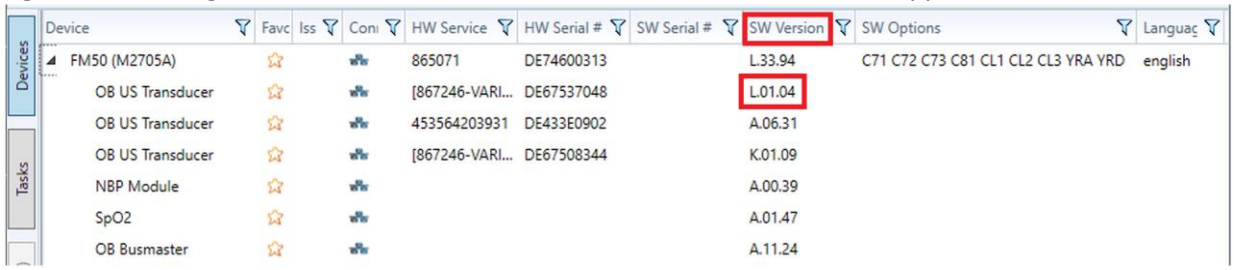
2. Review the recorder header of a printed trace

Figure 3. Checking the SW revisions of all connected transducers with the recorder header information



How to determine software version of device as a biomedical engineer or Field Service Engineer:

Figure 4. Checking the SW revisions of all connected transducers with the Support Tool



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

1. The affected Avalon wired transducer with software revision L.01.04 must not be used when monitoring multiples.
2. The Avalon wired Transducer 867246 can be safely used in the following cases:
    a. Monitoring the FHR of singletons (ca. 97% of all pregnancies) with any wired Avalon Ultrasound Transducers, including 867246 Ultrasound Transducer with software revision L.01.04.
    b. Monitoring also of twins or triplets with wired Ultrasound Transducers, as long as none of the involved transducers is an 867246 Ultrasound Transducer with software revision L.01.04.

    Current alternative to Avalon wired Transducer 867246:

    Monitoring the FHR of singletons, twins, or triplets with **wireless** Ultrasound Transducers (Avalon CL Ultrasound Transducer 866076).
3. Customers should complete the Urgent Medical Device Correction Response Form at the end of the notification to submit both their acknowledgment of this recall and confirm understanding of actions to be taken
4. This communication should be shared with all clinical staff to review and understand.
5. Place this Urgent Medical Device Correction notification with the documentation of the Avalon Ultrasound Transducer.

5. Actions planned by Philips to correct the problem

Philips is currently working on a solution. A Philips representative will contact you once the solution is available.

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/Business>

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 < Markets to insert to whom the customer should report>.

Philips regrets any inconvenience caused by this problem.
Sincerely,

Deborah Currlin
Head of Quality, HPM
Philips Healthcare

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URGENT Field Safety Notice Response Form

Reference: Wired Avalon Ultrasound Transducer (product number 867246)
Inaccurate Fetal Heart Rate (FHR) measurements when monitoring multiples

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:

1. The affected Avalon wired transducer with software revision L.01.04 must not be used when monitoring multiples.
2. The Avalon wired Transducer 867246 can be safely used in the following cases:

   - Monitoring the FHR of **singletons** (ca. 97% of all pregnancies) with <u>any</u> wired Avalon Ultrasound Transducers, including 867246 Ultrasound Transducer with software revision L.01.04.
   - Monitoring also of twins or triplets with wired Ultrasound Transducers, as long as <u>none</u> of the involved transducers is an 867246 Ultrasound Transducer with software revision L.01.04.

   Current alternative to Avalon wired Transducer 867246:

   - Monitoring the FHR of singletons, twins, or triplets with <u>wireless</u> Ultrasound Transducers (Avalon CL Ultrasound Transducer 866076).

3. Customers should complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both their acknowledgement of this recall and confirm understanding of actions to be taken.
4. This communication should be shared with all clinical staff to review and understand.
5. Place this URGENT Field Safety Notice notification with the documentation of the Avalon Ultrasound Transducer

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 wired Avalon Ultrasound Transducer.

Name of person completing this form:

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Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: <Reply form return details to be completed by the KM/ country>