PHILIPS

URGENT Field Safety Notice

RE: Philips Avalon Fetal Monitor Incorrect Assembly of Speaker Connector

May 2026

To: Customer Name:
Attention To:
Customer 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 Philips Avalon Fetal Monitor having the incorrect assembly of the speaker connector. The incorrect assembly of the speaker connector can cause device cables to be pulled out of the housing and increase the risk of intermittent or permanent loss of speaker output.

The Philips Avalon Fetal Monitor FM20 (M2702A) offers non-invasive monitoring of fetal and maternal heart rates, maternal pulse rate, uterine activity and maternal non-invasive blood pressure (NIBP) during antepartum testing and labor and delivery. The Avalon FM20 provides the following external measurement parameters:

- Up to three Fetal Heart Rates (FHR) via ultrasound (US)
- Fetal Movement Profile
- Uterine activity via external Toco
- Maternal Pulse Rate via external Toco MP
- Maternal Heart Rate (MHR) via maternal ECG (MECG)
- Maternal NIBP

The Avalon Fetal Monitor Avalon FM30 (M2703A) shares all the features and capabilities of the Avalon FM20. In addition, the Avalon FM30 provides the following external and internal measurement parameters:

- Single Fetal Heart Rate via direct ECG (DECG)
- Uterine activity via intrauterine pressure (IUP)
- Pulse Oximetry (maternal SpO2).

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

What the problem is and under what circumstances it can occur

The Avalon Speaker Assembly cable contacts were inserted rotated 180° relative to the orientation specified. The reversed contacts in the Connector-Housing causes the locking nose to fail to engage the Connector Socket, which permits the cables to be pulled out of the housing and increases the risk of intermittent or permanent loss of speaker output.

If users do not routinely have fetal heart rate tones enabled, it may take longer for speaker malfunction to be identified prior to occurrence of harm. If audible fetal heart rate tones are enabled, this provides an opportunity to identify the issue promptly.

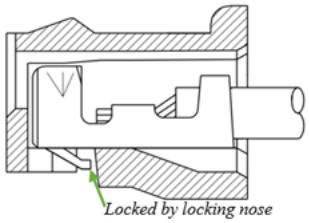

Figure 3:Contact and Housing (PASS schematic/assembled)

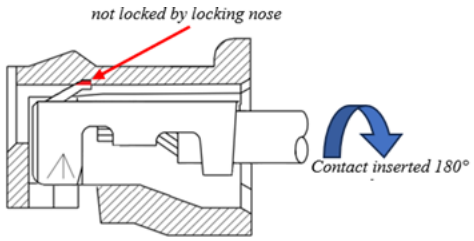

Figure 4: Contact and Housing (FAIL schematic/assembled)

Hazard/harm associated with the issue

When this issue occurs the highest potential severity could be a delay of treatment leading to death in the event there is a loss of audio that is not detected. In the case that the fetal heart rate tone is turned on continuously, it is most probable that no harm will occur as the loss of tone can be readily detected if it were to occur.

Please note: The use of this feature is based on tone preferences. If tone is not audible, the user may not recognize that there is a change in the patient's condition and go undetected as an alarm does not sound.

Sequence of Events required to result in Harm(s) identified in risk analysis:

1. A patient is being monitored using an Avalon FM20 or FM30 Fetal Monitor
2. The monitor in use was manufactured with incorrectly assembled Speaker Assembly
3. Device is powered on
4. Power-on speaker impedance test passes (internal speaker assembly cable not yet disconnected)
5. Internal speaker assembly cable/s is disconnected from the Connector Housing
6. Speaker functionality is lost
7. User is unaware of the loss of speaker functionality
8. Patient condition deteriorates
9. Visual alarms present, but fetal sounds and audible alarms do not annunciate
10. Treatment of patient is delayed

Affected products and how to identify them

The Philips Avalon Fetal Monitor are identified below:

Description	Part Number	UDI
Avalon FM20 Fetal Monitor	M2702A	00884838000407
Avalon FM30 Fetal Monitor	M2703A	00884838000414

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

- Ensure fetal heart rate tones are enabled on the Avalon Fetal Monitor until the planned fix/correction is implemented.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this Urgent Field Safety Notice with the documentation of the Philips Avalon Fetal Monitor and associated devices in a place where it is most likely to be seen and viewed.

Actions planned by Philips to correct the problem

A Philips representative will contact customers to arrange a part replacement to correct the issues listed.

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(s) 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, Hospital Patient Monitoring
Philips Healthcare

PHILIPS

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Reference: Philips Avalon Fetal Monitor Incorrect Assembly of Speaker Connector

Instructions: Please complete and return this Response Form to Philips promptly and no later than 30 days from receipt. Completing this Response 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:

- Ensure fetal heart rate tones are enabled on the Avalon Fetal Monitor until the planned fix/correction is implemented.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
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Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

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