



CL18001R/ FSN FCO #: PHS_Venice_Field_Action_012018

URGENT – MEDICAL DEVICE RECALL

Product: Philips AVENT Smart Ear Thermometer SCH740 sold through retailers online and in-store
Date: February 2, 2018
Subject: Important information regarding inaccurate measurements and the risk associated with relying on the Thermometer as the sole basis for a decision seeking treatment and/or professional help

Dear Customer,

A concern has been identified regarding the information provided with the Philips AVENT Smart Ear Thermometer (SCH740) ("**Device**"), that if it were to materialize, could pose risks for people being measured ("**Patient**").

This Field Safety Notice is intended to inform you about:

- what the concern is and under what circumstances these risks can occur;
- the actions that should be taken by the users of the Device in order to prevent risks to Patients;
- the actions planned by Philips to mitigate the risks.

This document contains important information for the continued safe and proper use of the Device.

Please review the following information and share with all the users of the Device. It is important to understand the implications of this communication. Please retain a copy of this Field Safety Notice with the instructions for use of the Device.

Philips has become aware of a number of complaints related to possible inaccurate measurements by the Device. Philips has identified that the risk of delaying treatment can have serious consequences for newborns (0-3 months), small children (4-36 months) and Patients of any age that may not be able to communicate and take care of themselves. In case a measurement shows a normal temperature value whereas the Patient actually has a fever, then that inaccurate measurement might lead to delayed or improper treatment of an underlying medical condition such as infection, which could result in Patient injury.

ACTIONS TO BE TAKEN BY USERS

- Philips advises users of the Device to only use the Device as directed in the instructions for use including the additional advice as per this Field Safety Notice
- **Philips advises users against relying on the Device as the sole basis for a decision seeking treatment and/or professional help**

Philips Healthcare

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- Users who wish to return the Devices based on the information provided in this Field Safety Notice can contact their local Philips product support representative

HOW TO IDENTIFY AFFECTED DEVICES

Users can identify the affected Devices by their model number. The model number can be found at the back of the Device as shown in the picture. The model number should always be SCH740.



LOCAL PHILIPS PRODUCT SUPPORT

If you need any further information or support concerning this issue or wish to return the Device based on this information for the continued safe and proper use of the Device, please contact your local Philips representative.

- For the Philips AVENT Smart Ear Thermometer (SCH740), you can contact the local support team via:
 - 1-844-531-6861

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused.