HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Philips Ear Thermometer (DL8740) and Philips AVENT Smart Ear Thermometer (SCH740)

Priority 2 – Warning

HPRA Safety Notice: SN2018(21)

Issue Date: 26th June 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Consumer Lifestyle B.V.	V34482

ISSUE
Philips Consumer Lifestyle B.V. has identified that due to inaccurate measurements associated with the Philips Ear Thermometer (DL8740) and Philips AVENT Smart Ear Thermometer (SCH740) there may be a risk of delay in treatment. Philips Consumer Lifestyle B.V. has determined that inaccurate temperature measurement may occur under different circumstances that are listed in the instructions for use for the device, for example improper cleaning of the devices. To date the maximum degree of error of unclean returned devices was found to be 3.4°C before cleaning.

Philips Consumer Lifestyle B.V. has issued a Field Safety Notice (FSN) to notify customers of the issue and to advise customers against using these devices as the sole basis of making a decision on whether to seek treatment and/or medical attention.

ACTION OR RECOMMENDATIONS

The HPRA is issuing the following advice to users:

1 Read the accompanying FSN carefully.

2 Do not rely on these devices as the sole basis for a decision seeking treatment and/or professional help as advised in the FSN.

3 Users who wish to return these devices based on the information provided in the FSN are advised to contact their local Philips product support representative using the information provided in the FSN.

4 Users who continue to use these devices should do so only as directed in the instructions for use and the additional advice contained in the FSN.

5 Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Members of the Public Practice Nurses	Carers Pharmacies

BACKGROUND

Philips Consumer Lifestyle B.V. received a number of reports of inaccurate measurements including one incident which resulted in hospitalisation.

There is the potential for a measurement to show a normal temperature when a patient actually has a fever. Inaccurate measurements such as these may lead to delayed or improper treatment of an underlying medical condition such as infection, which could result in patient injury. Philips Consumer Lifestyle B.V. has identified that the risk of delaying treatment can have serious consequences for new-borns, small children and other users that are unable to communicate for themselves.

Philips Consumer Lifestyle B.V. has issued an FSN to advise customers not to use these devices as the sole basis for making a decision on whether to seek treatment and/or medical attention. Philips Consumer Lifestyle B.V. is advising that these devices may continue to be used as long as the instructions for use and information contained in the FSN are followed.

The HPRA is issuing this safety notice to make users aware of this issue and as it has come to our attention that additional devices may have entered the Irish market through online sales.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Philips Healthcare UK,
The Philips Centre,
Guildford Business Park,
GU2 8XG

Telephone: +44 02079 490 240Fax: +44 01483 369 037
E-mail: devicevigilanceuki@phillips.com
Website: www.philips.co.uk

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie