HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Philips Efficia CM Monitors

Priority 2 – Warning

HPRA Safety Notice: SN2019(16) **Issue Date: 27th May 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Healthcare	V38566

ISSUE
Philips has received reports in which the lithium ion batteries in Efficia CM monitors overheated and ignited when batteries had exceeded their life expectancy and should have been replaced. Battery replacement should have occurred when the number of charge-discharge cycles first exceeded 300 cycles or when the battery capacity fell below 80% of that of a new battery. Philips is releasing a system software update for the Efficia CM monitors that will enhance users' ability to monitor battery condition over its lifetime and will alert users when it is time to replace the battery. The HPRA previously issued a safety notice relating to the same issue for Philips SureSigns VS VM & VSV patient monitors and viewing stations.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Read the manufacturer's field safety notice (FSN) carefully. 2 Promptly complete the software upgrade as detailed in the *Battery Management Software-Installation Instructions* that accompany the FSN, for each Efficia CM monitor in service and replace batteries as needed.

3 Download the *Instructions for Use Addendum* and *Service Guide Addendum* and review the information contained within with all staff members responsible for device management of the Efficia CM Monitors.

4 Acknowledge receipt of the FSN if you have not already done so.

5 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.

6 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS	
Hospitals	All departments
Clinics	All staff
A&E consultants	All wards
A&E nurses	A&E departments
Adult intensive care units	A&E directors
Cardiac consultants	Hospital IT managers
Patient Transport Managers	Clinical Engineers

BACKGROUND

Philips Healthcare issued a FSN to inform users about a software update relating to battery management and replacement for Efficia CM Monitor devices.
Overheating of the battery may cause the device exterior case to become excessively hot, causing the case to melt and/or the device to ignite, which can cause injury to a patient, nearby users, or cause damage to property.

The affected products are all Efficia CM Monitors manufactured before Oct 25, 2018 that are capable of operating under battery power.

Specifically, the following Efficia CM Monitors with software revisions up to and including A.01.10 (Worldwide, excluding USA)

Product	Description
863300	Efficia CM100
863301	Efficia CM10
863302	Efficia CM120
863303	Efficia CM12
863304	Efficia CM150

Please refer to the FSN for further instructions on how to identify affected products.

The HPRA is issuing this safety notice to raise awareness of this issue. The HPRA may issue further communications should additional field actions be undertaken by the manufacturer.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

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

Telephone: 0044 870 532 9741
E-mail: safetynoticeuki@philips.com

Website: www.philips.co.uk

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

Cardiac Services Ltd.
Unit 3
Northern Cross Business Park
Finglas
Dublin 11

Telephone: 01 830 7499
E-mail: recall@cardiac-services.com
Website: www.cardiac-services.com

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
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie