HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Allura Xper/Allura Centron/Allura Clarity/CV20

Priority 2 – Warning

HPRA Safety Notice: SN2015(30) **Issue Date: 04 December 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Medical Systems	V26149

ISSUE
The HPRA wish to inform you of a product defect which can occur on all systems within the Allura family. Philips has discovered that, in certain circumstances, the five minute fluoroscopy signal will not sound due to a software error. Although the error is known to occur intermittently, if it were to occur while the device is in use it could lead to a patient receiving more than the intended radiation dose. Philips will be providing a software upgrade to affected customers which will address the issue. There are no injuries attributed to this software error. Please refer to the attached FSN for additional details on the Allura systems which are affected and the actions proposed by the manufacturer.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Ensure that you have read and followed the instructions that were provided in the manufacturer's field safety notice (FSN).

2 Return the confirmation form to confirm receipt of the FSN to Philips through the FSN acknowledgement form if you have not already done so.

3 Forward this HPRA Safety Notice to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.

4 Ensure that relevant personnel receive a copy of the attached FSN.

TARGET GROUPS

HSE Hospital Staff Private Hospital Staff Clinical Engineers/Medical Physics	Risk Managers Purchasing Managers Supplies Managers

BACKGROUND

The error is known to occur in the following situation:

1) The user uses fluoroscopy in one or more multiple runs.

2) The user stops fluoroscopy at an accumulated radiation time of exactly five minutes +/- 0.1s.

3) System CPU is running at high load when fluoroscopy ends

This fault condition is reset when a new patient case is started or when the system is restarted.

Philips wish to advise users that they can observe real-time dose information and cumulative fluoro time provided by the Allura systems to monitor the amount of dose the patient is receiving.

The HPRA is communicating this Safety Notice at this time to ensure that all users of the device are aware of the issue.

MANUFACTURER CONTACT INFORMATION

Philips Healthcare UK
The Philips Centre,
Guildford Business Park,
Guildford,
GU2 8XH
United Kingdom

Contact: UK Philips Customer Care Service Centre

Telephone: +44 (0) 870 532 9741

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority	Telephone:	+353-1-6764971
Kevin O'Malley House	Fax:	+353-1-6344033
Earlsfort Centre	E-mail:	devicesafety@hpra.ie
Earlsfort Terrace	Website:	www.hpra.ie
Dublin 2		