V.05/07

Report Form
Field Safety Corrective Action

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 5)

1. Administrative information **Destination**
Name of national competent authority (NCA) See Unit affected list
Address of national competent authority
Date of this report
Reference number assigned by the manufacturer FCO72200269 / CAPA#: TW3509618
Incidence reference number and name of the co-ordinating national competent authority (if applicable)
Identify to what other national competent authorities this report was also sent See section 7

2 Information on submitter of the report
Status of submitter ☐ Manufacturer ☐ Authorised representative within EEA ☒ Others (identify the role):

3 Manufacturer information	
Manufacturer name Philips Medical Systems BV	
Manufacturer's contact person T. op het Veld	
Address Veenpluis 4-6, P.O. Box 10.000	
Postal code 5680 DA	City Best
Phone +31 6 10420792	Fax
E-mail Twan.op.het.veld@Philips.com	Country The Netherlands

4 Authorised representative information	
Name of the authorised representative	
The authorised representative's contact person	
Address	
Postal code	City
Phone	Fax

E-mail	Country

5 National contact point information	
National contact point name	
Name of the contact person	
Address	
Postal code	City
Phone	Fax
E-mail	Country

6 Medical device information

Class

☐ AIMD Active implants

☐ MDD Class III

☒ MDD Class IIb

☐ MDD Class IIa

☐ MDD Class I

☐ IVD Annex II List A

☐ IVD Annex II List B

☐ IVD Devices for self-testing

☐ IVD General

Nomenclature system (preferable GMDN)
GMDN

Nomenclature code
37621

Nomenclature text
X-Ray Imaging System

Commercial name/brand name/make
Allura Xper Systems

Model number
722003, 722010, 722011, 722012, 722013, 722017, 722121, 722122, 722123, 722124, 722133 and 722134

Serial number(s) and/or lot/batch number(s)
See UAL

Software version number (if applicable)
N/A

Manufacturing date/expiry date (if applicable)

Accessories/associated device (if applicable)

Notified body (NB) ID- number
344

7 Description of FSCA

Background information and reason for the FSCA

We have received a customer feedback where the Monitor Ceiling Suspension system fell to its lowest position. In this specific occasion it collided with the table top.
The investigation initiated concluded that the cause of the failure was an assembly error of the Actuator of the MCS.

Description and justification of the action (corrective/preventive)

- The investigation initiated concluded that the cause of the failure was an assembly error of the Actuator of the MCS. The MCS must be moved –manuel or motorically- before there is a chance that it drops to its lowest position and User, patient or bystander need to stand in a close position in relation to the MCS before a hazardous situation might occur.
- Philips will replace the actuator of all affected systems free of charge (Mandatory FCO72200269).
- It is expected that this corrective action will be available as of February 2015.
  In the meantime, as to mitigate the risk, Philips will secure the MCS actuator of the affected systems with straps (containment action Mandatory FCO72200274).
- Philips representatives will contact the involved customers as soon as possible in order to schedule the implementation of this action.

Advice on actions to be taken by the distributor and the user.

- Inform all possible system users.
- In order to avoid any risk for patients, users or bystanders we recommend the following until the containment action FCO72200274 or corrective action FCO72200269 has been implemented:
  When system in use, we recommend that the user does not:
  - Position or move the Monitor Ceiling Suspension above the patient.
  - Allow staff to stand under or close to the Monitor Ceiling Suspension.
- In addition, please avoid any unnecessary movement of the Monitor Ceiling Suspension and inform all possible System users.

Attached please find

☒ Field Safety Notice (FSN) in English
☐ FSN in national language
☒ Others (please specify): Unit Affected List. (UAL)

Time schedule for the implementation of the different actions

These countries within the EEA and Switzerland are affected by this FSCA

- EEA and Switzerland:

☒ Austria	☐ Belgium	☐ Bulgaria	☐ Cyprus	☐ Czech Republic
☒ Denmark	☐ Estonia	☐ Finland	☒ France	☒ Germany
☐ Greece	☐ Hungary	☐ Iceland	☐ Ireland	☒ Italy
☐ Latvia	☐ Liechtenstein	☐ Lithuania	☐ Luxemburg	☐ Malta
☒ Netherlands	☐ Norway	☐ Poland	☐ Portugal	☐ Romania
☐ Slovakia	☐ Slovenia	☒ Spain	☐ Sweden	☒ Switzerland
☒ United Kingdom				

- Candidate Countries

☐ Croatia ☐ Turkey

☐ All EEA, Candidate Countries and Switzerland.

- Others:

These countries outside the EEA and Switzerland are affected by this FSCA

AU, BR, CA, CL, CN, IN, JP, MX, US, ZA.

8 Comments

I affirm that the information given above is correct to the best of my knowledge.

Signature:

T. op het Veld	Best	
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.