Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

بتقدم بثقة
Moving Forward with Confidence
رؤية عمان 2040

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 57 dated 23/3/22 Regarding NCMDR FSCA of Philips Azurion R1.x System from (mrf: Philips Healthcare).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 57 / 2022

20-08-1443 H
23-03-2022

Field Safety Corrective Action of Philips Azurion R1.x System from Philips Healthcare.

Source	NCMDR- Nationa Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16061
Product	Philips Azurion R1.x System.
Description	Stationary general-purpose fluoroscopic x-ray system.
Manufacturer	Philips Healthcare.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Refer to section 3 in the attached FSN.
Reason	Inadvertent change of Patient Type when the study starts.
Action	1. Please refer to "actions should be taken by the customer / user" 2. This problem will be resolved by a software update, which will be available by March 2022. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

PHILIPS

Field Safety Notice

Philips Azurion R1.x System

Inadvertent change of Patient Type when the study starts

2022-Mar-04

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Customer,

A problem has been identified in the Philips Azurion R1.x system that could pose a risk for patients. This Field Safety Notice is intended to inform you about:

1. **What is the problem and under what circumstances it can occur**
   In the Azurion system, the user can add a new study to a patient by selecting the option "Add Study". The Add Study dialogue box is then displayed where the Patient Type is selected to perform the study. Due to a software defect, when the study is initiated by pressing "Start Procedure", the Patient Type changes inadvertently to a Patient Type different than the one selected as shown in the following Table:

Patient type selected on the "Add study" dialogue box	Patient type when the study starts
Auto (Normal Adult)	Neonate
Neonate	Infant
Infant	Child
Child	Small Adult
Small Adult	Normal Adult
Normal Adult	Large Adult
Large Adult	Very Large Adult
Very Large Adult	Unknown (default)

Table 1: Differences between the Patient Type selected and the Patient Type when the study starts

Philips has received 9 (nine) customer complaints related to this problem.

2. **What are the hazard/harm associated with this issue**
   A change in the patient type could lead to Image Quality Degradation (in case that the radiation dose is too low) or additional X-ray dose for the patient (when the radiation is higher than the one required). No harm is expected from the additional radiation dose.

   To date, Philips has not received any reports of harm associated with this problem.

3. What are the affected products and how to identify them

The following Philips Azurion systems, with a software R1.x, are affected.

Product name	Product number	Product name	Product number
Azurion 3 M12	722063	Azurion 7 B12	722067
Azurion 3 M15	722064	Azurion 7 B20	722068
Allura Xper R9 7 M12	722065	Azurion 7 M12	722078
Allura Xper R9 7 M20	722066	Azurion 7 M20	722079

The system product name and model number can be found in the System Identification Label located on the system stand (Fig. 1).

The software version of the Philips Azurion system is displayed during the start-up of the system (Fig. 2).

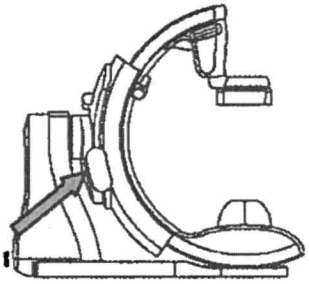

Fig. 1: System identification

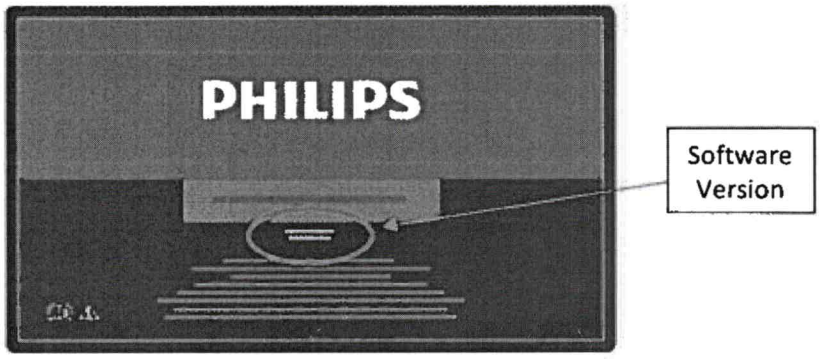

Fig. 2: Start-up screen

Philips is sending this notification directly to customers that have affected systems.

4. What actions should be taken by the customer / user in order to prevent risks for patients or users

- After pressing the "Start Procedure", always edit the "Study details" and change the Patient Type before starting the Study (Fig. 3).

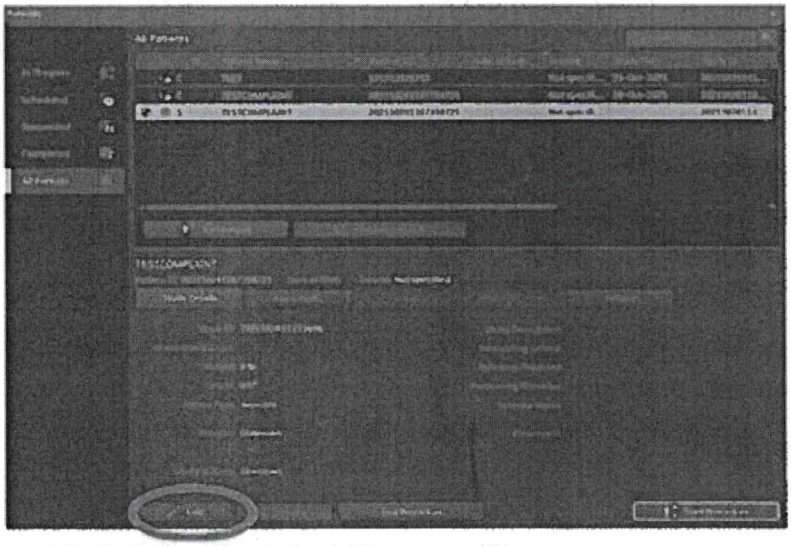

Fig. 3: Editing the Patient Type manually.

- Place this Field Safety Notice with the documentation of the system until Philips has installed a software update in your system.
- Circulate this notice to all users so they are aware of the product issue.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Field Safety Notice letter.

5. What are the actions planned by Philips IGT Systems to correct this problem

This problem will be resolved by a software update, which will be available by March 2022. You will be contacted by your local Philips representative to schedule the software update for your system.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information, please contact your local Philips representative (reference to FCO72200505).

Sincerely,

Rajesh Kathuria
Head of Quality – IGT-Systems

Philips' proprietary information. Unauthorized use is prohibited.

PHILIPS

FIELD SAFETY NOTICE RESPONSE FORM

Reference: 2021-IGT-BST-030

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

- After pressing the "Start Procedure", always edit the "Study details" and change the Patient Type before starting the Study.
- Circulate this letter to all users so they are aware of the product issue.
- Place this Field Safety Notice with the documentation of the system until the Philips has installed a software update in your system.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the Azurion R1.x system.

Name of person completing this response form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____