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

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 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 75 **dated** 19/4/2023 **Regarding TGA Field Safety Corrective Action of Philips Spectral CT 7500 from (mfr: Philips Electronics Australia Ltd).**

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
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سلطنة عُمان
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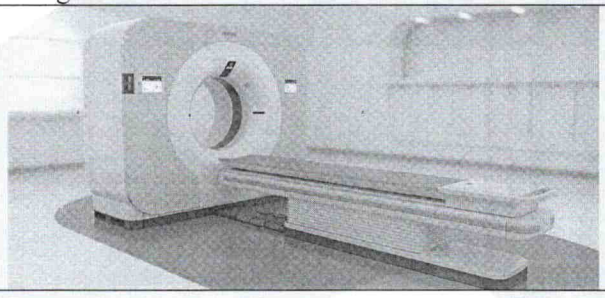
Circular No. 75 / 2023

28 -09-1444 H
19 -04-2023

Field Safety Corrective Action of Philips Spectral CT 7500 from Philips Electronics Australia Ltd

Source	TGA- Therapeutic Goods Administration https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2023-RN-00268-1
Product	Philips Spectral CT 7500.
Description	(Philips Electronics Australia Ltd - X-ray system, diagnostic, computed tomography, full-body)
Manufacturer	Philips Electronics Australia Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	ARTG 321687.
Reason	Philips has become aware of a potential safety issue when using the Unload Pedal of the foot switch on the Spectral CT 7500 system. Pressing the Unload Pedal of the foot switch to perform the unload function may cause entrapment of the operator's foot.
Action	1. Immediately stop using the Unload Pedal of the Foot Switch until Philips installs a solution on the system. 2. Instead of using the Unload Pedal, please use the Unload Patient function on the Gantry Control Panels, or use other Table In/Out, Up/Down functions on the Gantry Control Panels, CT Scan Control Box, or Hardware Interventional Controls to fulfill the normal patient unloading function, as instructed in the IFU. 3. Use of Load Pedal, and Free-Float Pedal of Foot Switch, can continue as they are not affected. 4. Contact the local agent for remedial action.
Product Image	
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 through the 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

ISO 9001:2015 CERTIFIED SYSTEMS

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

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2023-RN-00268-1
Product Name/Description[iii]	Philips Spectral CT 7500 ARTG 321687 (Philips Electronics Australia Ltd - X-ray system, diagnostic, computed tomography, full-body)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	28/03/2023
Responsible Entity[vii]	Philips Electronics Australia Ltd
Reason / Issue[viii]	Philips has become aware of a potential safety issue when using the Unload Pedal of the foot switch on the Spectral CT 7500 system. Pressing the Unload Pedal of the foot switch to perform the unload function may cause entrapment of the operator's foot.
Recall Action[ix]	Product Defect Correction
Recall Action Instructions[x]	Customers are advised to: - Immediately stop using the Unload Pedal of the Foot Switch until Philips installs a solution on the system. Instead of using the Unload Pedal, please use the Unload Patient function on the Gantry Control Panels, or use other Table In/Out, Up/Down functions on the Gantry Control Panels, CT Scan Control Box, or Hardware Interventional Controls to fulfill the normal patient unloading function, as instructed in the IFU. - Use of Load Pedal, and Free-Float Pedal of Foot Switch, can continue as they are not affected. - Philips will make contact to organise a Field Service Engineer to visit the site and install the solution to resolve the issue. - Complete acknowledgment form and return via email or fax within 3 business days, even if there is no affected stock.
Contact Information[xi]	1800 251 400 - Philips Service Delivery Team

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale /