

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**

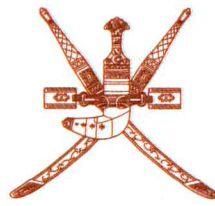
After Compliments,

Please find attached our Circular No 157 dated 24/7/2023 Regarding NCMDR  
FSCA of Computed Tomography, full-body from (mfr: 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





نتقدم بثقة  
Moving Forward  
with Confidence

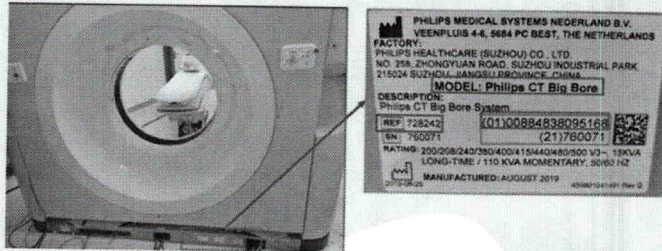
رؤية عمان  
2040  
Vision

Circular No. 157/2023

05 -01-1445 H

24 -07-2023

### Field Safety Corrective Action of Computed Tomography, full-body from Philips Healthcare

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19630">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19630</a>
Product	Big Bore RT and Upgrade Brilliance CT Big Bore systems.
Description	Computed Tomography, full-body.
Manufacturer	Philips Healthcare.
Local Agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Product Code REF (Device Identifier): 728242 ((01)00884838095168), 728244 ((01)00884838059450), 728243 ((01)00884838059450) Software version is 4.8.0.
Reason	Multiple software issues affecting above systems have been identified. Some of these issues may cause the system to shut down unexpectedly or to generate unsatisfactory images, which may result in the need to perform a rescan.
Action	1. You may continue to use your system(s) in accordance with the intended use. Please Refer to Appendix A in the attachment for specific details regarding the issue descriptions and recommendations on actions to be taken. 2. Customers will be contacted by Philips representative to schedule a site visit to install a software update to resolve the issues. 3. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General

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



Issue #	Issue Description	Impact to customer/patient	Recommendations
	Box Error will appear, stating <i>Please restart the Recon Box. Gantry is not ready.</i>		
11	After image reconstruction is completed, the offline ECG waves may not appear for the first result of a cardiac scan in View2.	You may not be able to see offline ECG waves in View2.	If you encounter this issue, alternate between the two results to see the offline ECG waves.
12	When the study in the directory for Therapy Planning System (TPS) simulation is selected, a series from a different study of the same patient from a scan completed at a different time may be combined into one study in the TPS system.	When selecting the study in the directory for TPS, there may be more series from scans from a different time appearing in that study.	Select the correct series for TPS planning before simulation. To avoid the issue, save the preferred EC before performing the surviiew scan in plan stage or after the clinical scans.
13	In View2, the status line message may display as <i>Reconstructing</i> even though the image reconstruction has been completed.	In View2, the status line message may display as <i>Reconstructing</i> even though the image reconstruction had been completed.	Navigate to the viewer displayed images to confirm that image reconstruction has been completed.
14	The exam application may crash immediately after the Exam Card is loaded. An error message stating, <i>System is still initializing and there seems to be a problem</i> error message may appear after the Exam Card is selected.	This issue occurs intermittently after exam card loading, prior to the scan beginning.	Reboot the Exam application to resolve the issue and allow scanning to begin.
15	When the injector parameters are changed, the window may become frozen and prevent exiting.	This issue occurs during the injection planning process before the scanning process begins.	End the Exam, then restart an Exam for the same patient by using the previous surviiew to complete the injection planning and the examination.
16	Automatic Image Quality test may fail with the harmonized phantom.	The image quality check is a regular test required to complete system calibration.	Contact service for repair
17	<i>Start Final Recon</i> button may be disabled after scanning is completed. An error message stating <i>CIRS cannot initialize</i> may appear.	All scanning and reconstructions can be completed successfully.	Perform offline reconstruction.
18	System may not be able to start scanning due to error <i>ACQ NOT OK</i> during initializing after CIRS Server1 restart.	You may not be able to start the scan.	Reboot CIRS and wait for five minutes to resolve the issue and allow scanning to begin.
19	After scanning and image reconstruction have been successfully completed, when transferring the coordinate axis from the console to the LAP system for therapy planning, the message <i>The deformation of the CT image is not allowed</i> may appear in the LAP system.	This Big Bore system may not work with the LAP laser system to support therapy planning.	Transfer the coordinate axis using the text file method or manually type in the coordinate values.
20	If an injection needs to be paused, the <i>Do you want to stop the injection</i> message may not appear, or the <i>Stop injection</i> and <i>Close</i> buttons may not appear when the trigger method <i>Manual</i> is selected.	The buttons to stop the injection may not be available if the injection needs to be paused.	Abort the injection from the injector device.

## Appendix A

The following table summarizes the issues identified, the impact to the customer/patient, and the and Philips recommendations for continued use where applicable.

Issue #	Issue Description	Impact to customer/patient	Recommendations
1	When a scan is planned close to 120sec and Go is selected, the application crashes.	The system could experience a loss of function due to a system error. This may result in the operator determining a patient rescan is required.	When planning a scan close to 120 seconds, click each phase result in the Series List before selecting Go, which will overcome the crash.
2	After selecting Go, an initialization error may occur and cause the scan to become disabled.	The system could experience a loss of function due to a system error. This may result in the operator determining a patient rescan is required.	In accordance with the Instructions for Use (IFU), <ul style="list-style-type: none"> <li>Perform a host computer restart daily.</li> <li>Perform a complete system shutdown and restart at least once per week.</li> </ul> The actions listed above may prevent occurrence of the issue.
3	After a surview has completed, the surview image may not appear immediately on the screen and an error message may be displayed.	The system could experience a loss of function due to a system error. This may result in the operator determining a patient rescan is required.	None.
4	After planning a dual surview and two-timed helical scans, the exam application may crash. Image reconstruction may fail.	The system could experience a loss of function due to a system error. This may result in the operator determining a patient rescan is required.	None.
5	After a surview scan is completed and CIRS (Common Image Reconstruction System) initializes, reconstructions which have been submitted may not start and will be lost.	The system could experience a loss of function due to a system error. This may result in the operator determining a patient rescan is required.	None.
6	When manually testing trauma scenarios, not all images are generated during the final reconstruction.	The system could experience a loss of function due to a system error. This may result in the operator determining a patient rescan is required.	Perform offline reconstruction for the missing images.
7	Bolus tracking images may not be displayed on the screen immediately. The operator may not be able to trigger the scan manually.	While using the exam card for Bolus tracking, the scanned images might not be satisfactory for clinical diagnosis. This may result in the operator determining a patient rescan is required.	None.
8	After selecting Go, the console is not able to trigger the clinical scan at the right time.	While using the exam card for Bolus tracking, the scanned images might not be satisfactory for clinical diagnosis. This may result in the operator determining a patient rescan is required.	None.
9	Exam summary page may fail to be created after scanning.	Only the exam summary page will be impacted. The scanning and image reconstruction will be completed.	The scan and reconstruction will complete successfully.
10	After the user loads the Exam Card before scanning, the Go button may be grayed out (unable to be selected) and a Recon	You may not be able to start the scan.	This issue occurs before scanning starts. To resolve the issue, reboot the system.