PHILIPS

[redacted]

30th Jan 2018

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the IQON Spectral CT due to FCO 72800689. Please note that the serial number of the units affected are stated below:

[redacted]

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number). This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:
Customer Name/Signature:
Company Name/Stamp:
Date:

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Reg. No 199705989C

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URGENT - Field Safety Notice
Medical Device Correction

IQon Spectral CT
Version 4.7.2 release related issues

Dear Customer,

A problem has been detected in the Philips IQon Spectral CT with software version 4.7.2 that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.

If you need any further information or support concerning these issues, please contact your local Philips representative. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377)

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

[redacted]

Sr. Manager, Quality & Regulatory

Philips Medical Systems (Cleveland), Inc.
595 Miner Road, Highland Heights, Ohio 44143 U.S.A

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AFFECTED PRODUCTS	IQon Spectral CT with software version 4.7.2
PROBLEM DESCRIPTION	Philips became aware of issues with IQon Spectral CT systems running software version 4.7.2. The most significant issues are: **Issue 1, Uric acid application for gout provides inconsistent results** When reviewing images using the Uric Acid Spectral Result type inconsistent results were provided on gout studies. The tendons would occasionally be displayed as containing Uric Acid even with no or normal uric acid blood levels. **Issue 2, Multi-phase Cardiac CTA Scans should include a planned conventional result for every planned spectral result** When planning a Cardiac multi-phase study, it is possible to create a phase that consists of only a Spectral Result. **Issue 3, O-MAR information is missing in DICOM when saving as original or Secondary Capture** When an SBI that was created with O-MAR enabled is used to create and save any Spectral result: • DICOM information about O-MAR is missing but the O-MAR label appears on a result saved as 'Original' • DICOM information and the O-MAR label are both missing on a result saved as 'Secondary Capture' **Issue 4, Attenuation plot presents incorrect HU values for MonoE** When comparing HU values of an ROI to the values in the attenuation plot graph when using the "Show spectral plots for this ROI" option, there is a difference of 10-20 HU values between the ROI HU value and the value shown on the graph **Issue 5, Windows Operating System Time Zone Updates** Microsoft Windows Daylight Savings Time Zone updates have not been applied since December 2014. This may cause the system time to be incorrect at the start and end of daylight savings time. **Issue 6, Sending Calcium Score findings to report using Mass Score protocol provides confusing information** The Heartbeat CS (Calcium Scoring) option provides confusing information in the "Impressions" section of the Calcium Scoring report. The report provides multiple analyses for the amount of plaque detected. The following is an example of typical output in the Impressions section: "There was definite but **mild plaque detected**. Patient is advised to actively engage in risk factor modification. Clinical follow up is recommended. There was **definite, moderate plaque detected**. Patient

URGENT - Field Safety Notice
Medical Device Correction

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	is advised to aggressively engage in risk factor modification. Clinical follow up is recommended…" The statement above indicates that the patient has both mild and moderate plaque. Only one of these should be present. Other plaque determinations add a third statement reflecting the correct level, but the output remains confusing due to the fact that the two cited in the example are present at all 5 possible scoring levels. **Issue 7, Host software doesn't have recent Microsoft security updates** Microsoft Security Updates released since June 2013 have not been part of the system software. This may make the system vulnerable to malicious software, computer viruses, or malware which could cause the system to react slowly to commands. **Issue 8, Z slice position in Spectral CT Viewer changes after scrolling through slices in slab preset** When loading an even number of images to the slab preset of the Spectral CT viewer the displayed Z-position of the images, may be incorrect when compared to the DICOM reported Z-position. **Issue 9, The system locked up during a reconstruction** The application locked up during the scout portion of the scan, the end exam button was disabled preventing the user from ending the exam. After host restart, the user was able to scan patients without any issues. **Issue 10, System crash** CT Host locked up after End Exam was clicked when an acquired Surview did not display as expected. **Issue 11, Scan failed** The system crashed while attempting to start the Tracker portion of a Bolus Tracking scan. **Issue 12, Tube too hot message** Due to a tube heat calculation error, a "Tube too Hot, wait or adjust kV or other scan parameters" message was displayed while attempting to start a timed scan sequence. **Issue 13, Reconstruction produces image block artifacts** Reliability issues within the CIRS hardware may cause images to be reconstructed with block or checker like artifacts. **Issue 14, System error trying to extend scan** When the user tries to extend a scan, a "System Error Trying to Extend Scan" may occur, the extend scan operation will fail.

URGENT - Field Safety Notice
Medical Device Correction

IQon Spectral CT
Version 4.7.2 release related issues

	Issue 15, Planning boxes on Surview remain orange when inactive If a system restart or shutdown is performed immediately after clicking the 'End Exam' option, inactive plan boxes may remain orange, instead of becoming transparent, while planning on the Surview. These overlapping boxes make scan planning difficult. **Issue 16, Scan started while the auto-voice was still playing** There are some cases where the Gantry can start X-rays before the PreVoice has finished playing. **Issue 17, When 'Extend' is performed near the scan boundary , the extended result's boundary overlaps the original result** If 'Extend' is used a second time on a scanner series, an overlap may occur with the previously scanned area. **Issue 18, Clinical scan fails to start after tracker scan is skipped** If the tracker scan is cancelled just as the X-ray shot is being initialized, there is a remote chance that the helical clinical scan will experience an error, and not be executed as planned. **Issue 19, Memory prediction errors for Spectral results may cause reconstructions to fail** After clicking 'Start Final Recon' and the system starts reconstruction of a Spectral Result, the system memory may become full and cause the reconstruction to fail. **Issue 20, Exam Application is crashing when the scan with spectral results is extended for the second time** On extending the scan with spectral results, console will update parent child relationship between the spectral results. When extending the scan is not possible, due to couch boundary limits, it will still try to update the relationship between the spectral results. Since no new step can be added, the system becomes unresponsive. **Issue 21, Continuous Link plans the clinical scan outside the Surview** When planning a Chest and Abd/Pelvis scan, the Chest scan is normally planned and acquired first. However, if the Abd/Pelvis scan is planned prior to the Chest, check the plan length of the Chest scan closely before starting the acquisition. The planned Chest may extend beyond the Surview boundary. **Issue 22, Collimator communication failure** The system may show a Gantry error after many high throughput scans due to collimator reliability issue. The system stops the ability to scan until the gantry power is cycled.

URGENT - Field Safety Notice
Medical Device Correction

IQon Spectral CT
Version 4.7.2 release related issues

	Issue 23, System error starting tracker scan The system reported a "System Error. Please end the exam and retry" message on the Host monitor after the user pressed GO to initiate the tracker scans (Locator and ROI placement completed).
HAZARD INVOLVED	The hazards are Incorrect or unnecessary treatment due to issue 1 ~ 8; CT rescan or over-scan due to issue 9 ~ 23.
HOW TO IDENTIFY AFFECTED PRODUCTS	Determine whether you have a potentially affected system, then determine your software version. To identify the software version of your product: • Click the "Help" button • Select "About" and the software version is then displayed The products affected will display the following software version start by V4.7.2.
ACTION TO BE TAKEN BY CUSTOMER / USER	We recommend the customer take the following respective actions with regard to these issues: **Issue 1, Uric acid application for gout provides inconsistent results** If the SBI (Spectral Based Image) is available, please examine the classified tissue using a MonoE-200 keV result to improve the detection of Uric-Acid. The tissue with Uric-Acid will have a Hounsfield value (HU) higher than 105 HU. It is recommended that you review conventional images prior to finalizing diagnosis. Spectral Images should not be used as the sole source for clinical diagnosis. **Issue 2, Multi-phase Cardiac CTA Scans should include a planned conventional result for every planned spectral result** When performing cardiac multi-phase studies, do not create any Spectral results. A Spectral Base Image (SBI) can be saved on a conventional result and any desired Spectral results created using off-line reconstruction and the saved SBI. Always insure that all reconstructed Spectral phases have a corresponding conventional phase. **Issue 3, O-MAR information is missing in DICOM when saving as original or Secondary Capture** When loading an SBI with O-MAR to the Spectral CT Viewer, do not create and save any Spectral result as a Secondary Capture.

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	Issue 4, Attenuation plot presents incorrect HU values for MonoE Do not use the ROI HU value of the attenuation plot graph for diagnosis, use the ROI value displayed on the image. **Issue 5, Windows Operating System Time Zone Updates** If the system time does not match the local daylight savings time start and end dates, adjust it manually. **Issue 6, Sending Calcium Score findings to report using Mass Score protocol provides confusing information** Revise the conflicting information in the automatically generated calcium scoring report and make it applicable to the patient diagnosis. **Issue 7, Host software doesn't have recent Microsoft security updates** While the system may become slow to react during any scans, it is most important to pay attention to the image arrival latency during CT interventional procedures. **Issue 8, Z slice position in sCTV changes after scrolling through slices in slab preset** When loading images to the slab preset in the Spectral CT Viewer, scroll through the data set to the start or end of the volume. This will correct the Z-positions of the images, and insure that measurements in the Z-direction are accurate. **Issue 9, The system locked up during a reconstruction** If this issue occurs, perform a restart of the host computer. **Issue 10, System crash** If this issue occurs, perform a restart of the host computer. **Issue 11, Scan failed** When the error occurs, acknowledge the error and try to start the tracker scan again. **Issue 12, Tube too hot message** When this message is displayed, you can either wait or lower the Dose Right Index (DRI). **Issue 13, Reconstruction produces image block artifacts** Perform an offline reconstruction of the raw data that produced the block or checker like artifacts. **Issue 14, System error trying to extend scan** After pressing End Exam, select 'Current Patient' then select 'Use previous surview' to plan the required area. **Issue 15, Planning boxes on Surview remain orange when inactive**

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Version 4.7.2 release related issues

	Do not perform a restart or system shutdown until the 'End Exam' application is properly closed. **Issue 16, Scan started while the auto-voice was still playing** No actions recommended. **Issue 17, When 'Extend' is performed near the scan boundary , the extended result's boundary overlaps the original result** Check the 'Extend' locations and adjust manually as needed. **Issue 18, Clinical scan fails to start after tracker scan is skipped** Re-plan the scan and attempt to continue scanning. **Issue 19, Memory prediction errors for Spectral results may cause reconstructions to fail** Restart the host computer once per day. Limit the number of Spectral Results or SBI's to only those that are clinically relevant and necessary. **Issue 20, Exam Application is crashing when the scan with spectral results is extended for the second time** Do not extend the scan near table boundary. If the error occurs, the raw data on previous scans before the second extension is available for offline recon. **Issue 21, Continuous Link plans the clinical scan outside the Surview** Use the zoom feature to reduce the size of the Surview to confirm the planned area is accurate. **Issue 22, Collimator communication failure** Cycle the gantry power to reset the collimator communications. **Issue 23, System error starting tracker scan** Click 'OK' to acknowledge the message and click 'GO' to attempt to reinitiate the tracker scan.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of these issues via this Field Safety Notice. Field Change Order (FCO) will be released to correct these issues. A Philips Field Service Engineer will contact you to schedule the FCO updates at your site. Reference Field Change Order (FCO) 72800689.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).

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