PHILIPS

CT/AMI FSN 72800720/88200522 Revision: 01 2019 JUN 24

URGENT - Field Safety Notice

Medical Device Correction

Ingenuity CT, IQon Spectral CT, iCT, Brilliance 64 CT, Ingenuity TF, Vereos

Step and Shoot Incorrect Image Phase Labeling

<Hospital/Clinic Name>
cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

A problem has been detected in the Philips Ingenuity CT, iCT, Brilliance 64, IQon Spectral CT, Ingenuity TF PET/CT, and Vereos PET/CT scanners, 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 this issue, please contact your local Philips representative: For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377 and follow the prompts).
Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

[redacted]

Holly Wright Lee
Sr. Manager, Post Market Corrections and Removals

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

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AFFECTED PRODUCTS	Ingenuity CT Ingenuity Core 128 Ingenuity Core iCT iCT SP Brilliance 64 IQon Spectral CT Ingenuity TF PET/CT Vereos PET/CT
PROBLEM DESCRIPTION	There are 3 scenarios users may experience which result in identical images that are incorrectly labeled as phase tolerance images: 1. When performing a Step and Shoot acquisition with phase tolerance selected, images may be reconstructed identically (a single phase), but are labeled as different phases. This occurs when “Start Final Recon” is selected prior to display of the ECG wave at the top of the acquisition window. 2. When performing a Step and Shoot acquisition with phase tolerance selected, images may be reconstructed identically (a single phase), but are labeled as different phases. This occurs if ECG leads become disconnected mid-acquisition or when the acquisition is halted prematurely due to an application crash. 3. By system design, in certain instances when a patient exhibits an arrhythmia or varying heart rate during a Step and Shoot acquisition, images from the acquisition following the heart rate variation, may be labeled in the incorrect phase.
HAZARD INVOLVED	1. If phase labeling is incorrect, and not noticed by the clinician, images could be misinterpreted, potentially leading to serious injury due to incorrect treatment. 2. For cases where the images are unable to be used for diagnosis a rescan may be required.

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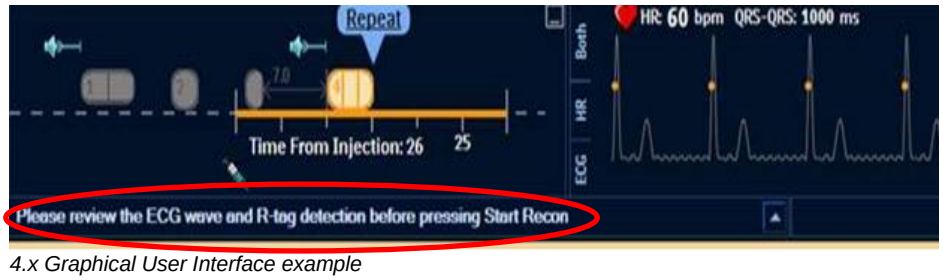
HOW TO IDENTIFY AFFECTED PRODUCTS	Determine whether you have a potentially affected system, then determine your AFFECTED PRODUCTS software version. To identify the software version of your product: Click the “Help” button Select “About” and the software version is then displayed Software versions 4.x, 3.x, and 2.x are potentially affected
ACTION TO BE TAKEN BY CUSTOMER / USER	1. When performing a Step and Shoot acquisition with phase tolerance selected, images may be reconstructed identically (a single phase), but are labeled as different phases. This occurs when “Start Final Recon” is selected prior to display of the ECG wave at the top of the acquisition window. • Reconstructed phases display as identical in online reconstruction, but reconstruct correctly during offline reconstruction. • This occurs when the user clicks ‘Start Final Recon’ prior to the Console/Host receiving the ECG wave.  *4.x Graphical User Interface example* • How to avoid in 4.x: Wait until the ECG strip is at the top of the acquisition window to starting the reconstruction.

URGENT - Field Safety Notice

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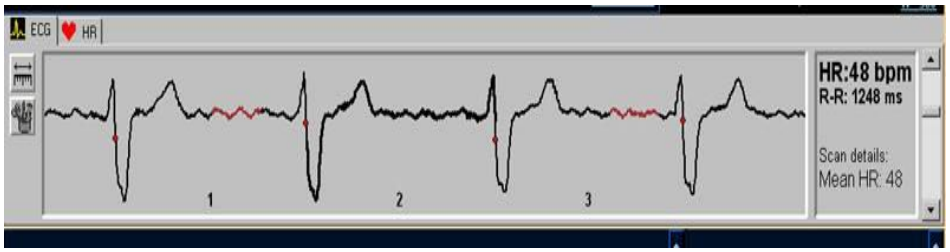

3.x Graphical User Interface example

- How to avoid in 3.x: Wait until the ECG strip is visible at the bottom of the acquisition window to starting the reconstruction.

  This issue affects all systems listed above (with the exception of Vereos) with 4.x software and all iCT systems with 3.x software. Images can be reconstructed with phase tolerance by performing an offline reconstruction of the raw data. No patient rescan is required.

2. When using software version 4.x only, if there is an ECG disturbance detected by the system (e.g., an ECG lead becomes disconnected or the application crashes resulting in the acquisition halting), reconstructed images for the phase tolerance reconstructions are identical to the scan phase acquired, however, the images are labeled as if phase tolerance was applied. This applies for both online and offline reconstruction of images. Software versions prior to 4.x are not affected.

URGENT - Field Safety Notice

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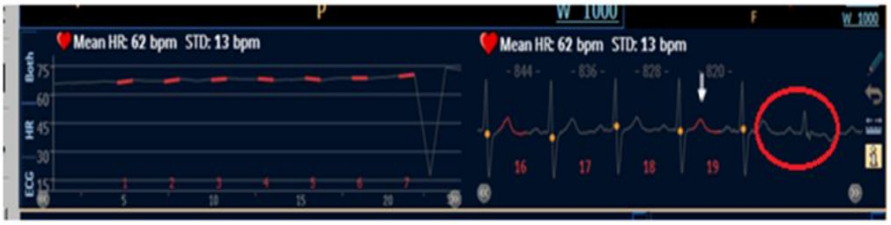
- This can occur with version 4.x software



- Should this occur, the user will receive the following console message:

- Images will be incorrectly labeled as if phase tolerance has been applied, however, the images will be reconstructed without phase tolerance.
- How to avoid: Ensure that the leads are securely attached to the patient prior to starting the acquisition and the length of table travel allows the leads to remain securely attached through acquisition completion. In the event of an application crash, there is no way to avoid the issue.
- When this issue occurs, images may still be used but are not labeled with the correct ECG phase. If images with phase tolerance are needed, a rescan may be required.

URGENT - Field Safety Notice

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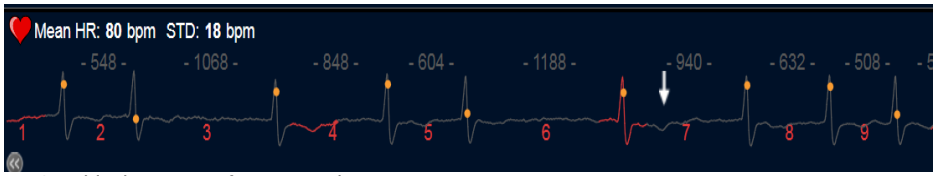
	3. In some instances, when a patient exhibits an arrhythmia or varying heart rate during a Step and Shoot acquisition, images from the acquisition following the heart rate variation, may be labeled in the incorrect phase. • This is by system design. In cases where the heart rate changes or an arrhythmia occurs, the white arrow/green line in the ECG display is not aligned on top of the acquisition.  *4.x Graphical User Interface example*

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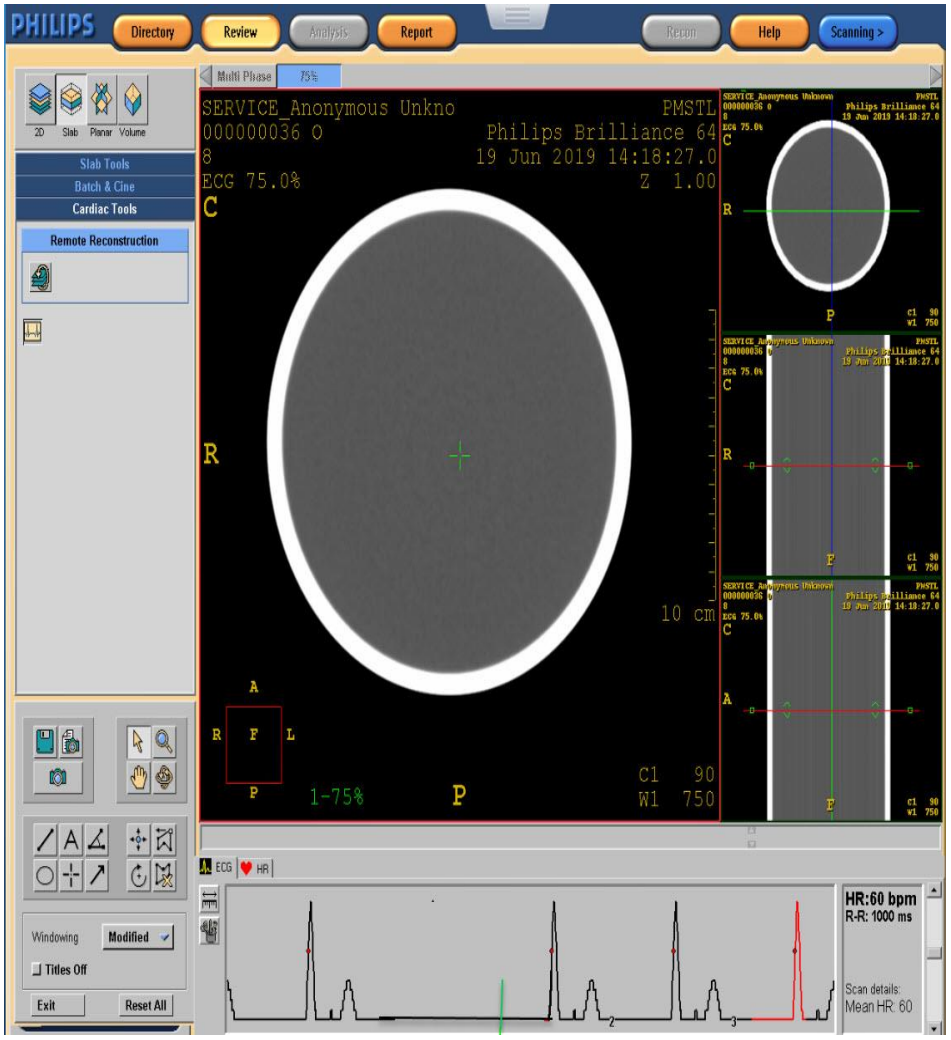

3.x/2.x Graphical User Interface example

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	• Arrhythmia Compensation Functionality Description: • After you start the Step & Shoot Cardiac scan, the planned scanning sequence proceeds normally until an arrhythmia/heart rate change is detected. • If X-rays are being generated during the arrhythmia, the irradiation is stopped. • The system waits for the heart to stabilize (approximately one heart cycle). • Radiation begins again on the next heart cycle. • How to avoid: Follow Philips Patient Qualification recommendations as listed in your Instructions for Use: **Patient Qualifications** Not all patients qualify for the Step & Shoot Cardiac scan. To acquire images with satisfactory image quality, it is recommend that the scanned patient: a. have a stable heart rate, with mean lower than 75 BPM for iCT/IQon b. have a stable heart rate, with mean lower than 65 BPM for Brilliance 64, Ingenuity, Ingenuity TF, Vereos c. have no severe known arrhythmias d. not be extremely obese
ACTIONS PLANNED BY PHILIPS	Philips investigation into a potential correction for this issue is still under way. At this time Philips is notifying customers of the issues and steps to take to avoid them while a solution is considered.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number) North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377 and follow the prompts).

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Customer Response Form

Please email completed form to: ***Philips***

By signing this form, you acknowledge having received, read, and understood the content of this letter and have taken appropriate actions.

_____ _____

Name (please print) Title

_____ _____

Signature Date

Contact information:

_____ _____

Phone Email