Computed Tomography　　　　FSN 72800620　　　　2014 SEP 05

URGENT - Field Safety Notice
Medical Device Correction

Ingenuity CT, Ingenuity Core, Ingenuity Core[128]
With Continuous Computed Tomography
(CCT) Option and have been Upgraded from
Software Version 3.x to Version 4.0.0 / 4.0.1

Protocol Conversion Resulting in Delayed Images when using CCT Option

Dear Customer,

According to our information, you currently have one of the systems noted above. This Field Safety Notice is intended to inform you that when your software was upgraded from version 3.x to version 4.0.0 / 4.0.1, the protocol conversion can result in incorrect scan parameters, which in turn can result in delayed images, when using the CCT option.

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 or local Philips Healthcare office. For North America, contact the Customer Care Solutions Center (1-800-722-9377 and follow the prompts).

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Director, Quality and Regulatory

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AFFECTED PRODUCTS	The following CT systems may be affected: • Ingenuity CT • Ingenuity Core • Ingenuity Core[128]
PROBLEM DESCRIPTION	Philips became aware through a customer complaint that while performing a CCT examination on an Ingenuity CT system, the first image was marked as "last shot" rather than the actual "last shot" acquired. After the clinician pressed the pedal for first exposure, images were displayed as the "last shot". Subsequent pedal presses did not result in immediate image reconstruction and the first image remained on the screen labeled as the "last shot". Eventually all images appeared. The problem is caused by incorrect slice increment settings in the user set for CCT protocol resulting from the protocol to exam card conversion during the software upgrade from v3.x to v4.0.0 / v4.0.1. In normal CCT mode, images reconstruct without delay and the "last shot" is properly displayed with the last reconstructed result. To date, there have been no reported injuries resulting from this issue.
HAZARD INVOLVED	During an interventional procedure, there is a risk of serious injury to the patient if the clinician does not have real-time feedback of needle placement when the needle is near vital structures (major blood vessel, organ, etc).
HOW TO IDENTIFY AFFECTED PRODUCTS	If you have one of the above-listed systems **and** have been upgraded from software version 3.x to version 4.0.0 / 4.0.1, you are affected. To identify the software version of the product: • Click the "Help" button • Select "About" and the software version is then displayed
ACTION TO BE TAKEN BY CUSTOMER / USER	Affected users should check their CCT exam card and correct if the issue exists. Refer to the steps in the attached Addendum (See Instructions to Check for CCT Issue).

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying affected users who have been upgraded from software version 3.x to version 4.0.0 / 4.0.1 of this issue via this Field Safety Notice (FSN). The FSN also contains instructions to check for CCT issue and correct if necessary (See attached Addendum). In addition, a Field Change Order (FCO) will be released to correct the issue. A Philips Field Service Engineer will contact you to schedule the software installation at your site.
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, contact the Customer Care Solutions Center (1-800-722-9377 and follow the prompts).

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URGENT - Field Safety Notice
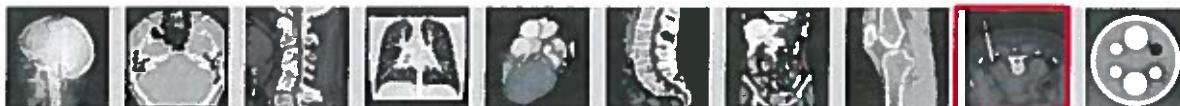## Medical Device Correction

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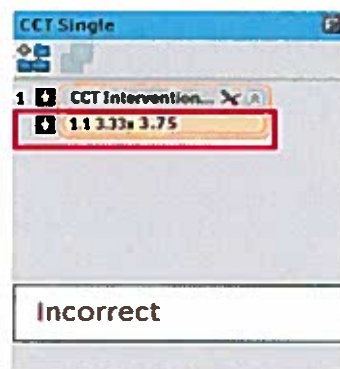**Protocol Conversion Resulting in Delayed Images when using CCT Option**

<u>ADDENDUM</u>
INSTRUCTIONS TO CHECK FOR CCT ISSUE AND
CORRECT IF NECESSARY

To check for this issue perform the following steps:

1. From the Utilities page select the **Exam Card Manager**.
2. In the **Password** field of the **Login** window, enter your password.
3. On the right side of the screen, select the **Exam Card set (User Set)**.
4. Click the Interventional Exam Card group or group containing CCT exam cards

5. Double-click to open the CCT **Exam Card**.
6. Exam cards having the issue will have slice thickness and increment that do not match when opening the exam card. Please see example below:
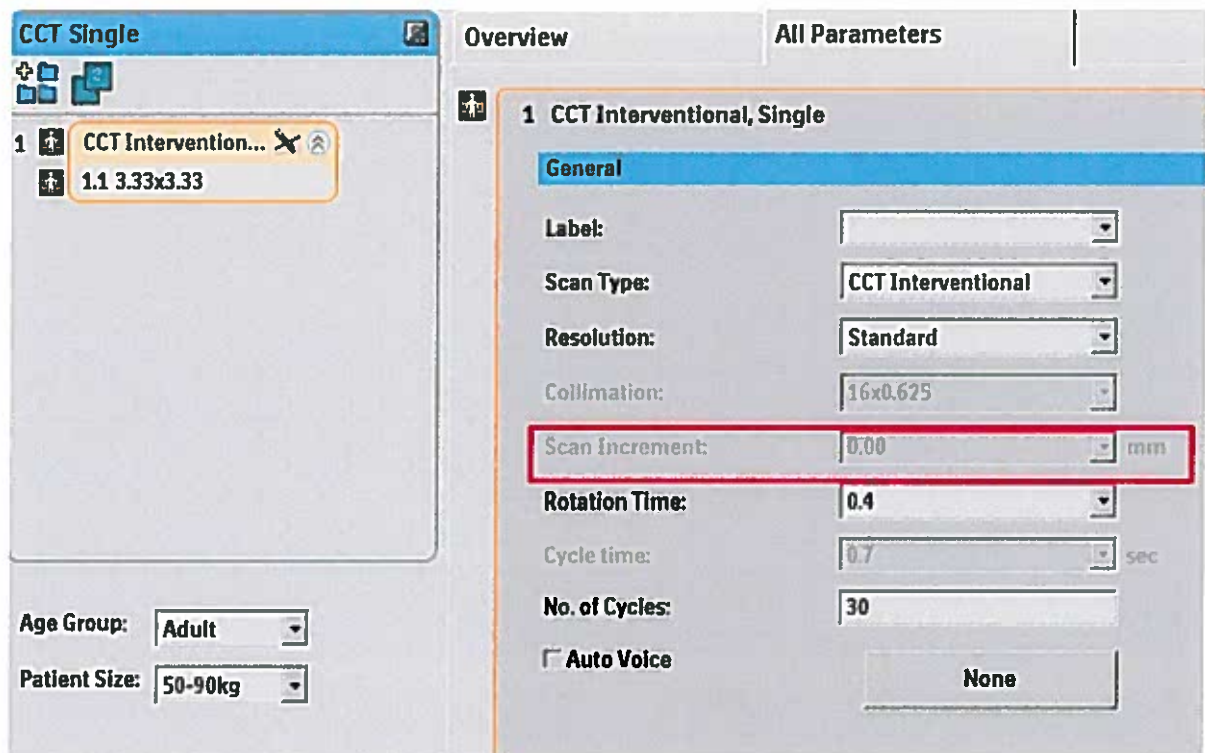

Correct

Incorrect

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7. Also note that when the acquisition step in the exam card is selected, the scan increment should be 0.00.

8. If the exam card has a mismatch, it is recommended to rebuild the CCT exam cards from the reference CCT exam cards.

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Rebuilding an Exam Card

1. Use Edit to change or create an Exam Card.

2. From the Utilities page click Exam Card Manager.

3. In the Password field of the Login window, enter your password.

4. On the right side of the screen, select the Exam Card Reference set

5. Click the Exam Card group.

6. Double-click to open the Exam Card.

7. Make necessary parameter changes

8. Save the Exam Card:

   o Save overrides the existing Exam Card.
   o Save As creates a new Exam Card with a new Exam Card name.