Customer Information Letter

CNT-073105-04 Revision: 03 page 1 of 3

Computed Tomography

CIL CLE 15-052

2015 Oct 30

Customer Information

Ingenuity CT / Ingenuity Core / Ingenuity Core¹²⁸ Brilliance 64 CT / Brilliance iCT SP / Brilliance iCT

Issues with v4.1.2, v4.1.3 and v4.1.4 software: Unavailability of Perfusion Scan Feature

Dear Customer,

A problem has been detected with software versions v4.1.2, v4.1.3, and v4.1.4 in the Philips Brilliance 64, Ingenuity CT, Ingenuity Core, Ingenuity Core¹²⁸, Brilliance iCT SP, Brilliance iCT products that, if it were to reoccur, could affect the performance of the equipment. This Customer Information Letter is intended to inform you about:

- what the problem is and under what circumstances it can occur
- . the actions that you as a customer can take to minimize the effect of the problem
- · the actions planned by Philips to correct the problem.

Philips Healthcare has become aware of the issue on

unavailability of perfusion scan feature under specific conditions.

To correct this issue, Philips will release field change orders (FCO) 72800642 and 72800644 to install a software update on the affected systems.

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, Option 5: Enter Site ID or follow the prompts).

Philips apologizes for any inconveniences caused by this problem.

Sincerely

Daniel R. Brown
Director, Quality & Regulatory

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CNT-073105-04 Revision: 03 page 2 of 3

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Issues with v4.1.2, v4.1.3 and v4.1.4 software: Unavailability of Perfusion Scan Feature

AFFECTED PRODUCTS	This issue is software related. The following systems and an affected software version are affected: The following CT systems are potentially affected: Brilliance 64 Ingenuity CT Ingenuity Core Ingenuity Core Ingenuity Core128 Brilliance iCT SP Brilliance iCT Affected software versions: 4.1.2					
	4.1.3					
	4.1.4					
PROBLEM DESCRIPTION	On the affected CT systems and software versions, the perfusion scan feature may be unavailable.					
HOW TO IDENTIFY AFFECTED PRODUCTS	The following systems impacted: Brilliance 64 Ingenuity CT Ingenuity Core Ingenuity Core ¹²⁸ Brilliance iCT SP Brilliance iCT					
	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 one of the following software versions 4.1.2 4.1.3 4.1.4					

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CNT-073105-04 Revision: 03 page 3 of 3

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Issues with v4.1.2, v4.1.3 and v4.1.4 software: Unavailability of Perfusion Scan Feature

ADVICE ON ACTIONS BY CUSTOMER / USER	This information is to inform you the perfusion scan feature may not be available on your CT system. If you have further questions/concerns, Philips advises you to contact your local Philips representative regarding an update to your system.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of this issue via this Customer Information Letter.
	Field Change Orders (FCO) involving installation of a software update will be released to correct the issue.
	A Philips Field Service Engineer will contact you to schedule the software update 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 and Canada, contact the Customer Care Solutions Center (1-800-722-9377, Option 5: Enter Site ID or follow the prompts).