URGENT – Medical Device Correction

Brilliance CT Big Bore, Brilliance 64, Ingenuity CT and Brilliance iCT

DoseRight Feature for Pediatrics

Dear Customer,

A problem has been detected with the DoseRight feature for Pediatrics found in certain Philips Brilliance CT Big Bore, Brilliance 64, Ingenuity CT and Brilliance iCT systems that could pose a risk for patients. Only a small number of systems undergoing Philips external validation testing pursuant to a written agreement with Philips are affected.

This Field Safety Notice (FSN) 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, we have provided contact information on the last page of his notice.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

[redacted]
Senior Director
Quality & Regulatory, CT/NM

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AFFECTED PRODUCTS	The following CT system/software version combinations: Brilliance CT Big Bore: software version 3.5.17030 Brilliance 64: software version 3.5.21028 Ingenuity/eCT: software version 3.5.25028 Brilliance iCT: software version 3.2.0.19010 These devices were undergoing Philips external validation testing pursuant to a written agreement with Philips.	
AFFECTED PRODUCTS (Serial Numbers)	Brilliance iCT	100103, 100019, 100023, 100170, 200047, 200013 200005, 100087
	Brilliance 64	4003, 9745, 9875, 90135, 90169, 95414
	Brilliance CT Big Bore	7006, 7060, 7154, 7298, 7349
	Ingenuity CT	300003, 300004, 300005, 300010
PROBLEM DESCRIPTION	The DoseRight feature suggests a mAs based on the measured patient size, a reference size and a reference mAs. When scanning large children (50-90 kg), the suggested mAs may be higher than clinicians would expect. This may happen when: • The child protocols reference a 20 cm Water Equivalent Diameter (WED) reference, but the actual size of the child as detected by the Surview is greater than 25 cm. • An inappropriate reference mAs is specified in the protocol or; • When the user turns the DoseRight feature on with a non-DoseRight protocol while planning a scan.	
HAZARD INVOLVED	If a user accepts a mAs level suggested by DoseRight that is higher than necessary, the patient may be exposed to excess radiation.	
HOW TO IDENTIFY AFFECTED PRODUCTS	The following instructions can be executed in order to identify the serial number and the software version of the product: • Click the "Help" button, • Select "About", (NOTE: for iCT customers you do not need to select "About") and • Look at the software version, and/or look at the serial tag at the back of the gantry.	
ACTION TO BE TAKEN BY CUSTOMER / USER	The DoseRight feature for pediatrics should not be used on any system running one of the software versions identified above.	
ACTIONS PLANNED BY PHILIPS	Philips will provide a new software release to address this issue.	

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FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the Philips Product Manager: Peter Johnson, Brilliance iCT, Email: peter.c.johnson@philips.com Telephone: +1-440-483-6136 Jake Durgan, Brilliance 64 and Ingenuity CT Email: jacob.durgan@philips.com Telephone: +1-440-483-2153 Scott Smith, Brilliance CT Big Bore Email: scott.smith@philips.com Telephone: +1-440-483-2244