
Computed Tomography

CIL CLE15-066

2016 APR 29

Customer Information

Philips Brilliance 64 and Ingenuity CT/Core/Core128

Issues with v4.1.3/4.1.4/4.1.5 software:

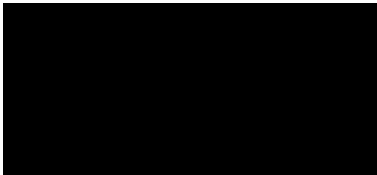
Dear Customer,

Philips has been made aware of issues found in software versions v4.1.3/4.1.4/4.1.5 in the Philips Brilliance 64 and Ingenuity CT products that, could affect the performance of the equipment. This Customer Information Letter is intended to inform you about:

- What the problems are and under what circumstances they may 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.

To correct these issues, a Philips field service representative will install a software update on the affected systems. Reference field change order (FCO) 72800652.

If you need any further information or support concerning these issues, 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).



Daniel R. Brown
Director, Quality & Regulatory

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<p>AFFECTED PRODUCTS</p>	<p>The following CT systems are potentially affected: Brilliance 64, Ingenuity Core, Ingenuity Core¹²⁸ , Ingenuity CT</p> <p>Running software versions: 4.1.3 4.1.4 4.1.5</p>
<p>PROBLEM DESCRIPTION</p>	<p>Philips became aware of certain issues with these products through its own testing and customer feedback. Philips is informing you that the correction for these issues will be provided to you our valued customer. Notable among these fixes are:</p> <p>IMR Cardiac - Irregular Appearance of Contrast in Vessels When reconstructing Coronary CTA images with IMR using any of the Cardiac specific settings (Image definition), an irregular appearance of contrast may be seen. This irregular vessel appearance has been reported to look like a calcified lesion or band artifacts in coronary arteries between 2 and 5mm's in diameter.</p> <p>Missing Image Annotation's in CCT During a volume Continuous CT (CCT) interventional procedure, in the acquisition viewer, when the scan is paused and the operator switches from overview layout to any other layout, the image orientation labels (L/R/A/P) are not displayed on the images.</p> <p>Halo Artifacts While performing brain scans using high resolution a dark halo or hypodense ring artifact may be seen at the bone-brain interface.</p> <p>Unable to Match Z Locations on Prescan and 4D CT Scan The system currently does not allow the user to type in an exact start or end location. Tumor tracking software requires that the pre-scan and the 4D CT scans have matching Z locations when loaded into the tracking software.</p> <p>Incorrect Z Annotation on Plan Box for Coronal/Sagittal Surviews When coronal or sagittal results are planned following axial results for a study with feet-first patient orientation, the start and end positions of the plan box (z-position values) displayed on the coronal/sagittal scan result are incorrect and reversed, relative to the values displayed on the axial scan result. Changes to the z-location for start of the scan made to the coronal/sagittal plan box results, may result in the scan being performed in the incorrect location, if not identified/corrected by the user prior to scan start.</p> <p>Unintended Change of Acquisition Timing on Scan Ruler If the user selects an Exam Card that falls in the same physical location on the screen as the scan ruler (in the background), and quickly double clicks and moves the mouse to the right at the same time, the scan ruler may be moved. This may cause the post injection delay time to be increased. If the user is unaware of the change to the post injection delay time, the acquired scan may have insufficient contrast enhancement, creating suboptimal images.</p>

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	<p>Bolus Tracker does not Trigger as Expected When the Bolus Tracker threshold value is changed using the "Show All" parameters page, instead of the Bolus Tracker Graph, the threshold value does not update appropriately and the scan is not triggered at the desired threshold value set under the "Show All" parameters page. If the bolus threshold is changed using the "Show All" page to a value lower than what is set from the BolusTracker Graph, the user may recognize that the trigger has not occurred at the expected value and manually trigger the scan. Alternatively, if the user changes the threshold using the "Show All" page to a higher value, the system would trigger at the previous lower value set, and initiate a scan prematurely. In both scenarios, there is potential for suboptimal images due to incorrect timing of the scan.</p> <p>System Unresponsive when Paused If the Pause button is pressed during a series of axial scans, the system may become unresponsive, and require that the host computer be restarted.</p> <p>System Becomes Unresponsive During Timed Scan Host computer may freeze near the end of a scan that utilizes a timed delay.</p> <p>Unplanned Results During Multi-Phase Pulmo Series, may Cause a System Crash While planning a Pulmo scan with multiple results, if the Plan Box on one of the results is dragged to the bottom of the surview, the additional result lengths may not update. When "GO" is pressed to initialize the scan, the system may become unresponsive.</p> <p>Communication Errors Between Host Computer & Gantry If the Host computer has been running for long periods of time without logging out and logging back in, acquisition of scans may be interrupted.</p> <p>Pin Wheel Artifact Using 0.67mm Slice Width In Cardiac Step & Shoot scans, a pin wheel artifact appears in images when using a 0.67mm slice width.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Determine your software version.</p> <p>To identify the software version of your product:</p> <ul style="list-style-type: none"> • Click the "Help" button • Select "About" and the software version is then displayed <p>The products affected will display one of the following software versions</p> <ul style="list-style-type: none"> • 4.1.3 • 4.1.4 • 4.1.5

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<p>ADVICE ON ACTIONS BY CUSTOMER / USER</p>	<p>IMR Cardiac - Irregular Appearance of Contrast in Vessels When reconstructing Cardiac studies with IMR use the "IMR Body Routine" setting as an alternative to the Cardiac specific IMR settings. This is similar to using the "CB" or "XCB" filter with iDose⁴ for coronary vessel visualization.</p> <p>Missing Image Annotation's in CCT During a volume Continuous CT (CCT) interventional procedure, it is recommended to remain in the volume display mode.</p> <p>Halo Artifacts If dark halo or hypodense ring artifacts are observed at the bone-brain interface changing the resolution from High to Standard can decrease their appearance.</p> <p>4D CT Exam Z Slice Location Does not Match CT Scan There is no recommended solution for this issue.</p> <p>Incorrect Z Annotation on Plan Box for Coronal/Sagittal Surviews For studies using axial with subsequent coronal/sagittal results, use the surviw to plan scans (versus typing-in z-locations on the plan box) or review the location of the plan box with respect to patient anatomy.</p> <p>Unintended Change of Acquisition Timing on Scan Ruler When adding scans to an existing study, select the exam card and confirm selection by clicking "OK", instead of double-clicking exam card.</p> <p>Bolus Tracker does not Trigger as Expected For desired changes to the contrast threshold trigger values, it is recommended to make the changes directly on the Bolus Tracker Graph and not under "Show All" parameters page.</p> <p>System Unresponsive when Paused It is essential to comply with the routine system shutdown recommendations outlined in the system's Instructions for Use.</p> <p>System Becomes Unresponsive During Timed Scan In situations where the system may freeze near the end of a scan, restart the system. After the restart, the results may be available under the patient directory and/or may be reconstructed from the raw data under the reconstruction folder. If the data is not present a rescan may be required.</p> <p>Unplanned Results During Multi-Phase Pulmo Series, may Cause a System Crash Ensure that all planned results in a Multi-Phase Pulmo series have the same length before pressing the GO button.</p> <p>Communication Errors Between Host Computer & Gantry Perform a shutdown and startup of the host computer, as recommended in the systems Instructions for Use. Perform a host computer shutdown at least once per day to avoid this issue.</p>
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	<p>Pin Wheel Artifact Using 0.67mm Slice Width Use a thicker slice thickness, such as 0.8 mm, for image reconstruction.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips Healthcare is notifying the affected users of these issues via this Customer Information Letter.</p> <p>Field Change Orders (FCO) involving installation of a software update will be released to correct the issue.</p> <p>A Philips Field Service Engineer will contact you to schedule the software update installation at your site.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>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).</p>

