**Computed Tomography** CIL CLE15-066 2016 APR 29

# Customer Information

## Philips Brilliance iCT/iCT SP

### Issues with v4.1.3/4.1.5 software:

Dear Customer,

Philips has been made aware of issues found in software versions v4.1.3/4.1.5 in the Philips Brilliance iCT/ iCT SP 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 software update on the affected systems. Reference field change order (FCO) 72800644

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).

Sincerely,

[redacted]

Daniel R. Brown
Director, Quality & Regulatory

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### Issues with v4.1.3/4.1.5 software:

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| **AFFECTED PRODUCTS** | The following CT systems are potentially affected:<br>Philips Brilliance iCT and Brilliance iCT SP<br><br>Running software versions:<br>4.1.3<br>4.1.5 |
| **PROBLEM DESCRIPTION** | 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:<br>**IMR Cardiac - Irregular Appearance of Contrast in Vessels**<br>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.<br><br>**Missing Image Annotation's in CCT**<br>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.<br><br>**Halo Artifacts**<br>While performing brain scans using high resolution a dark halo or hypodense ring artifact may be seen at the bone-brain interface.<br><br>**Incorrect Z Annotation on Plan Box for Coronal/Sagittal Surviews**<br>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.<br><br>**Post Injection Delay Between Timed Scans may be Inaccurate**<br>When planning more than one contrast enhanced series using timed scans, the planned delay between the first and subsequent series may not be accurate. When the post injection delay of the subsequent series is modified by the user before pressing the "Go" button this delay may be recalculated once the "Go" button is pressed, causing the user defined delay time to be increased. This may lead to insufficient contrast enhancement in the second phase of the scan.<br><br>**Unintended Change of Acquisition Timing on Scan Ruler**<br>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.<br>**Gantry may not Initialize** |

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| | After planning a scan on a Surview and pressing "Go" to initiate the scan, it is possible that the scan may fail to start and a "Gantry cannot initialize. Please change scan parameters or restart the Gantry" message may display. Clicking "OK" on the dialog box should allow the scan to be completed.<br><br>**Incorrect Minimum Time Delay**<br>During a timed sequence, the minimum time delay is incorrect if an additional scan series is inserted or removed. This may result in a loss of bolus and/or suboptimal contrast enhancement in images.<br><br>**Bolus Tracker does not Trigger as Expected**<br>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.<br><br>**System Unresponsive when Paused**<br>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.<br><br>**System Becomes Unresponsive During Timed Scan**<br>Host computer may freeze near the end of a timed scan.<br><br>**Host Computer Becomes Unresponsive During Timed Scan**<br>Host computer may freeze near the end of a scan that utilizes a timed delay.<br><br>**Unplanned Results During Multi-Phase Pulmo Series, may Cause a System Crash**<br>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.<br><br>**Dynamic Myocardial Perfusion Acquisition Halted After First Shot**<br>During a Dynamic Myocardial Perfusion acquisition, the acquisition may stop during the second axial shot in the perfusion series. When this occurs, the operator must repeat the series and rescan the patient.<br><br>**Double Clicking ECG Phase Bar Crashes Exam Application**<br>Double clicking the "Phase" Bar of the ECG Viewer in the preview scene, to accept/reject irregularities, may cause the Application to crash. The scan is saved, but the operator may choose to repeat a surview.<br><br>**Incorrect Phase Tolerance for Cardiac S&S** |

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| | In some cases, the Phase Tolerance (padding around the targeted cardiac phase) for a Cardiac Step&Shoot scan may be incorrect potentially resulting in poor image quality or scan failure. The operator may need to rescan the patient.<br><br>**Communication Errors Between Host Computer & Gantry**<br>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.<br><br>**Ring Artifact's on High Resolution Images**<br>Concentric fine ring artifacts were observed on the start and end images of Hign resolution helical scans reconstructed with Standard (FBP) reconstruction.<br><br>**Ring Artifacts using iDose$^4$**<br>Concentric fine ring artifacts were observed on High and/or UltraHigh Resolution scans when using iDose$^4$ reconstruction technique.<br><br>**Ring Artifacts using IMR**<br>Concentric fine ring artifacts are observed on High Resolution scans when using IMR iterative reconstruction.<br><br>**Danish AutoVoice Not Working**<br>When the Danish autovoice is selected, there is no voice heard. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | Determine your software version.<br><br>To identify the software version of your product:<br>• Click the "Help" button<br>• Select "About" and the software version is then displayed<br>The products affected will display one of the following software versions<br>• 4.1.3<br>• 4.1.5 |

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### Issues with v4.1.3/4.1.5 software:

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| **ADVICE ON ACTIONS BY CUSTOMER / USER** | **IMR Cardiac - Irregular Appearance of Contrast in Vessels**<br>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 iDose$^4$ for coronary vessel visualization.<br><br>**Missing Image Annotation's in CCT**<br>During a volume Continuous CT (CCT) interventional procedure, it is recommended to remain in the volume display mode.<br><br>**Halo Artifacts**<br>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.<br><br>**Incorrect Z Annotation on Plan Box for Coronal/Sagittal Surviews**<br>For studies using axial with subsequent coronal/sagittal results, use the surview 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.<br><br>**Post Injection Delay Between Timed Scans may be Inaccurate**<br>For contrast studies, when making changes to the post threshold delays, after pressing "GO", confirm the injection timing before starting contrast injection.<br><br>**Unintended Change of Acquisition Timing on Scan Ruler**<br>When adding scans to an existing study, select the exam card and confirm selection by clicking "OK", instead of double-clicking exam card.<br><br>**Gantry may not Initialize**<br>It is essential to comply with the routine system shutdown recommendations outlined in the system's Instructions for Use.<br><br>**Incorrect Minimum Time Delay**<br>There is currently no recommended workaround for unintended changes to the minimum delay on timed studies when inserting/removing scan series.<br><br>**Bolus Tracker does not Trigger as Expected**<br>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.<br><br>**System Unresponsive when Paused**<br>It is essential to comply with the routine system shutdown recommendations outlined in the system's Instructions for Use.<br><br>**System Becomes Unresponsive During Timed Scan**<br>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.<br><br>**Unplanned Results During Multi-Phase Pulmo Series, may Cause a System Crash** |

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| | Ensure that all planned results in a Multi-Phase Pulmo series have the same length before pressing the GO button.<br><br>**Dynamic Myocardial Perfusion Acquisition Halted After First Shot**<br>There is no recommended solution for this issue.<br><br>**Double Clicking ECG Phase Bar Crashes Exam Application**<br>To accept or reject irregularities shown on the ECG Viewer, right click on "APB?" for the irregularity instead of the Phase Bar of the ECG Viewer.<br><br>**Incorrect Prediction Tolerance for Cardiac S&S**<br>There is no recommended solution for this issue.<br><br>**Communication Errors Between Host Computer & Gantry**<br>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.<br><br>**Ring Artifact's on High Resolution Images**<br>Use the following alternative parameter selections:<br>1. For High resolution mode YC filter can be used. Image enhancement can be applied if needed.<br>2. The standard resolution scan mode will not generate high frequency ring artifacts.<br><br>**Ring Artifacts using iDose$^4$**<br>Use the following alternative parameter selections for iDose$^4$:<br>1. For High resolution mode YC filter can be used. Image enhancement can be applied if needed.<br>2. For Ultrahigh resolution mode only Standard reconstruction technique should be used.<br><br>**Ring Artifacts Using IMR**<br>Use the following alternative parameter selections for IMR:<br>1. The standard reconstruction mode (non IMR) will not generate high frequency ring artifacts.<br>2. The standard resolution scan mode will not generate high frequency ring artifacts.<br><br>**Danish AutoVoice Not Working**<br>Record new Danish Audio files. |
| **ACTIONS PLANNED BY PHILIPS** | Philips Healthcare is notifying the affected users of these issues via this Customer Information Letter.<br><br>Field Change Orders (FCO) involving installation of a software update will be released to correct the issue.<br><br>A Philips Field Service Engineer will contact you to schedule the software update installation at your site. |

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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 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). |