PHILIPS

URGENT - Field Safety Notice

Medical Device Correction

Ingenuity TF PET/CT running software version 4.0.2 (4.0.0.26645)

Software Issues

Dear Customer,

Philips is deploying a software update to correct issues detected with the Philips Ingenuity TF PET/CT software version 4.0.2. Field Change Order 88200515 is being released to implement software version 4.0.3. In some cases, these issues may require a patient rescan. There is a very low likelihood of any other risk to patients. This Field Safety Notice is intended to inform you about:

- what the issues are and under what circumstances they can occur
- the actions that should be taken by the user in order to prevent risk to patients
- the actions planned by Philips to correct the issues

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 these issues, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee

Holly Wright Lee
Sr. Manager, Post Market Surveillance
Quality & Regulatory

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AFFECTED PRODUCTS	Ingenuity TF PET/CT (model 882456) running software version 4.0.2 The Help screen will indicate "v4.0.0.26645".
PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER	1) If the "Admin Time" field in an exam card is populated and "Wait for Start" is checked, the system will use the Acquisition Start time as the Admin Time, which can lead to incorrect SUVs and a potential for incorrect examination results. **Actions to be taken by the User (1):** This issue can be detected by reviewing DICOM information or the images in the fusion viewer application. Correct the "Admin Time", if necessary, in retrospective reconstruction. Follow Instructions for Use, System Operation for Ingenuity TF PET/CT (459800079331), Chapter 7 Reconstructing PET Images, Administration Parameters Tab. 2) If the operator selects a patient name from the worklist using the mouse and then selects a different patient name using the keyboard (arrow keys then press enter) the patient name that populates the exam information page is the patient name selected with the mouse. **Actions to be taken by the User (2):** Select a patient name from the worklist using the mouse. Do not select a patient name from the worklist using the keyboard. 3) Contrast annotation "C" is missing from some CT images when manual contrast was administered. **Actions to be taken by the User (3):** Keep track of the contrast appearance in a sequence of CT scans when contrast has been introduced manually. 4) Dot artifact present intermittently after startup. **Actions to be taken by the User (4):** Review the CT image to screen for unusual image artifacts when the system is first turned on. If an artifact is suspected, then the user should run system IQ Check and restart the system if the artifact is present. 5) When an X rotation or a Y rotation is manually entered by the user in the PET/CT Alignment QC application on the Console to realign PET and CT images for a retrospective reconstruction, the PET reconstruction incorrectly updates the Z-axis position.

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PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER (continued)	**Actions to be taken by the User (5):** Use the alignment tools provided in the application; do not manually enter the values. Refer to Instructions for Use, Cardiac PET and CT Imaging and Analysis for Ingenuity TF PET/CT, 459800079371, Chapter 4, PET/CT Alignment QC. 6) When performing a patient acquisition, if the Requesting Physician or Referring Physician value includes the non-alphanumeric characters "<" or ">" (for example <DR TEST>), the acquisition data cannot be reconstructed. When the reconstruction starts, an error message appears: "ERROR: POSSIBLE_INVALID_INPUT POSSIBLE_PET_RECONSTRUCTION_ERROR" and reconstruction is not possible due to the incorrect input data. **Actions to be taken by the User (6):** Do not use "<" or ">" when inputting patient information. 7) When creating a custom exam card in the Exam Card Manager with one CT series to be used for attenuation correction and more than one PET series where CTAC Shared Planning is to be off for one of the PET series, the settings for CTAC Shared Planning may not be saved correctly. **Actions to be taken by the User (7):** When creating exam cards with multiple PET series in the Exam Card Manager, save the exam card and then open it to confirm that the CTAC Shared Planning settings were saved as intended. 8) If data is realigned and reconstructed via PET/CT Alignment QC, and the application is relaunched with the realinged data, the previous rotation values (if any) are not taken into account. **Actions to be taken by the User (8):** Always start with the original PET series when launching PET/CT Alignment QC. 9) Increasing the PET Field of View (FOV) after the CTAC is acquired will cause PET reconstruction to fail due to the CT FOV being smaller than the PET FOV. **Actions to be taken by the User (9):** Do not increase the PET FOV after the acquisition of the CT to be used for Attenuation Correction is completed.

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PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER (continued)	10) A variable used in the NMRS database is being filled incorrectly causing some adjacent memory to be overwritten, which could cause the database process to stop and make the system unusable. PET red will not allow the user to perform the PET acquisition, and this issue may cause PET reconstruction to fail. **Actions to be taken by the User (10):** If PET Red status occurs or PET reconstruction fails, contact your Philips Service Representative. 11) PET Red Status and corresponding error messages are not properly displayed when manually stopping and starting Watchdog. Watchdog is a service monitoring application for system communication. This is a background tool that is not available to customers. PET red will not allow the user to perform the PET acquisition. **Actions to be taken by the User (11):** If PET Red status occurs, contact your Philips Service Representative. 12) When the available disk space is less than 100MB on the Console, a disk full error may be displayed. As a result, scanning may not be possible and applications may not start. **Actions to be taken by the User (12):** Contact your local Field Service representative. 13) It was observed that the Watchdog service does not restart after shutting itself down due to an error. Watchdog is a service monitoring application for system communication. This is a background tool that is not available to customers. This cannot be anticipated, and if the issue occurs it could cause a PET red status indicator. **Actions to be taken by the User (13):** If PET Red status occurs, contact your Philips Service Representative. 14) When attempting to transfer PET raw data from the NMRS to the Console, all of the raw data may not transfer. Raw data that was incompletely transferred will be marked as archived and may have been deleted via the Auto Delete process. **Actions to be taken by the User (14):** If retrospective reconstruction of archived PET raw data fails, contact your local Field Service representative.

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PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER (continued)	15) When a Cardiac acquisition is set to "Acq Time" the acquisition does not correctly acquire during the specified window limits. The acquisition acquires as if "Clock Time" is set. Due to this, there may not be enough data acquired. This lack of data may result in substandard image quality. **Actions to be taken by the User (15):** Only use Clock Time for gated Cardiac scans. 16) An intermittent communication issue can cause an error to appear on the Console indicating that the Low Dose CT (LDCT) has not completely transferred to the NMRS. However, the user may see the LDCT on the NMRS even though the file did not transfer completely. Reconstruction fails in this scenario. **Actions to be taken by the User (16):** If the reconstruction fails and an error message is received indicating that the LDCT has not completely transferred, verify the total number of LDCT images in the NMRS match the number of LDCT images in the CT Host. If they do not match, perform a manual transfer of the LDCT data from the CT Host to the NMRS, followed by a retrospective reconstruction of the data. 17) When performing two successive high count rate studies, such as dynamic Oxygen-15 PET procedures, a failure may appear at the start of the second dynamic acquisition. There is a 20-second set time for the acquisition computer to respond to the Console. This time could be exceeded due to a very high count-rate study and result in an "acquisition failed" message following the start of the second acquisition. **Actions to be taken by the User (17):** Perform only one dynamic acquisition per exam card. 18) When displaying a dynamic scan in the Kinetic Analysis layout in the fusion viewer, the generated statistics displayed in the graph do not appear as expected. In this case, the graphical display of the timing of the scan will have the time intervals incorrectly marked. **Actions to be taken by the User (18):** Record the frame durations acquired and manually calculate by drawing regions of interest on each frame using fusion viewer.

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PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER (continued)	19) When performing a dynamic acquisition with 69 or more frames, the time for the 19th frame will be applied to the 69th frame. All other frames will be as expected. **Actions to be taken by the User (19):** Dynamic reconstructions should be performed with 68 frames or fewer. 20) If the PET and CT gantries are in the open position and the couch subpallet is in the CT position, a software fault does not disable the "In To Internal Marker" button on the PET Gantry Control Panels only. This allows the user to move the couch, possibly causing the PET scan to not be performed in the intended location. **Actions to be taken by the User (20):** To avoid potential image misalignment, do not use the "In To Internal Marker" button in this scenario. 21) A memory issue may cause the database to fault, potentially resulting in a loss of acquisition data that would be required for reconstruction. A user will not be aware that this is occurring until an error message is received. **Actions to be taken by the User (21):** If the fault occurs, a patient rescan or re-injection will be required. 22) Increasing the number of PET frames after the CTAC is acquired will produce a PET scan longer than the CT causing a portion of the PET image to not be corrected for attenuation. **Actions to be taken by the User (22):** Do not increase the number of PET frames after the acquisition of the CT to be used for Attenuation Correction is completed. 23) On initial install of the system, the CT scanner is configured with a commercial anti-virus scanning application (McAfee) which is set to run regularly during off-hours or during hours of low activity. It is during this time that the systems performance is affected. • It is possible to begin a normal clinical scan while the anti-virus scan is running. However, if the user is running a bolus tracking scan, typical real time information is not displayed to the user. The consequence is the user may initiate the clinical scan either earlier or later than desired resulting in a mistimed bolus. • If the operator is already running a bolus tracking scan at the time the anti-virus is scheduled to run and the operator ignores or is not

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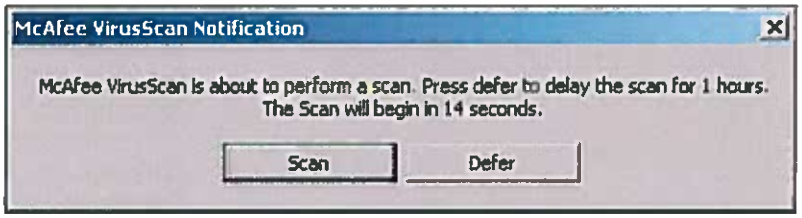
PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER (continued)	aware of the McAfee VirusScan Notification message displayed on the screen, typical real time information will not be displayed to the user. The consequence is the user may initiate the clinical scan either earlier or later than desired resulting in a mistimed bolus. **Actions to be taken by the User (23):** When the system is about to begin the anti-virus scan the user will receive the following Display Message.  Philips Healthcare advises the operator to defer the anti-virus scan during a scheduled bolus tracking exam by selecting "Defer" when the user is prompted by the following message displayed by the McAfee VirusScan Notification text message box. 24) Swirl-like ring artifacts may appear in reconstructed CT images impairing the diagnostic quality of the images. **Actions to be taken by the User (24):** If this issue occurs, contact your Philips Service Representative. 25) When executing two bolus scans, the system may freeze during the second tracker execution, impacting the countdown timer displayed to the user which indicates the start of the clinical CT scan. **Actions to be taken by the User (25):** If this issue occurs, contact your Philips Service Representative. 26) DoseRight is incorrectly enabled when the Exam Card specified disabling DoseRight. **Actions to be taken by the User (26):** The user should disregard the DoseRight feature results for Exam Cards that disallow DoseRight.

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PROBLEM DESCRIPTION & ACTIONS TO BE TAKEN BY CUSTOMER / USER (continued)	27) PET reconstructions fail intermittently due to a negative table position (-1 value is inserted) in the raw data list file, rather than the actual table position. This error has been found to occur in two scenarios: a. When the system user cancels an acquisition i. The error will occur every time a scan is cancelled by the user. b. Couch position requests within the software sequence were delayed i. The error occurs intermittently, but has been found to occur more frequently when the gantry's network is heavily loaded with multiple retrospective reconstructions running in parallel. ii. The error is evident to the technologist by an error message and Failed status on the Reconstruction Monitor and the error message "Result {0} failed to reconstruct" on the Acquisition Workflow window during reconstruction after the patient scan has been completed. In both scenarios, the acquisition data will not be able to be reconstructed and will therefore be unusable. **Actions to be taken by the User (27):** There is no way for the technologist to prevent this reconstruction failure or determine if the reconstruction failure was due specifically to this error. Please follow the Warning provided in the Instructions for Use - System Information for Ingenuity TF 459800079321 Rev B, Section 2 Safety Guidelines, pg 2-17 that states: ***Warning*** *Verify that all scans complete and that all data is acquired without error before allowing the patient to leave. If the patient leaves before valid data is acquired, the patient may need to return for another study.* It is further recommended that the patient remains in the original scan position until reconstructed images are verified. Following this guidance, only a PET emission rescan needs to occur, and additional radiation exposure for the Low Dose CT scan can be avoided. Always attempt a retrospective reconstruction before choosing whether or not to perform a CT rescan. This is defined in Section 7 Reconstructing PET Images of the Instructions for Use - System Operation for Ingenuity TF PET/CT 459801099841 Release 4 (Rev B).

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	Refer to Appendix B Error Messages and Bug Reporting of the Instructions for Use - System Information for Ingenuity TF 459800079321 Rev B, and follow the indicated actions: *"Result {0} failed to reconstruct"* *Possible Solution: Attempt Retrospective Reconstruction* To avoid this issue, do not cancel the acquisition and allow the scan to complete. If the technologist needs to cancel a scan, please be advised that the data reconstruction will fail. Also, it is not advised to run multiple retrospective reconstructions during patient scanning. If the technologist is running multiple retrospective reconstructions there may be a delay in recognizing there has been a reconstruction failure.
HAZARD INVOLVED	**Issues 1 - 4:** There is a potential for these issues to lead to incorrect examination results: • False-negative leading to disease progression • False positive or inconclusive outcome resulting in trauma from invasive procedure or minor deterministic radiation effect, e.g. skin reddening, hair loss, etc. **Issues 5 - 27:** There is a potential for these issues to lead to additional radiation exposure from either a Low Dose CT rescan and/or a PET radiopharmaceutical reinjection depending upon the circumstance as follows: • If the PET reconstruction fails and the raw data is unable to be reconstructed by the technologist, and if the patient is still in the original scan position, a PET emission rescan can be performed without the need to for an additional Low Dose CT rescan or PET reinjection. • If the PET reconstruction fails and the raw data is unable to be reconstructed by the technologist, and the patient has been removed from the original scan position, then: o A Low Dose CT rescan and PET emission rescan may be determined by the technologist or radiologist to be needed. o A PET radiopharmaceutical reinjection may also be needed depending on when the technologist identifies that the reconstruction has failed and the availability of the patient. The

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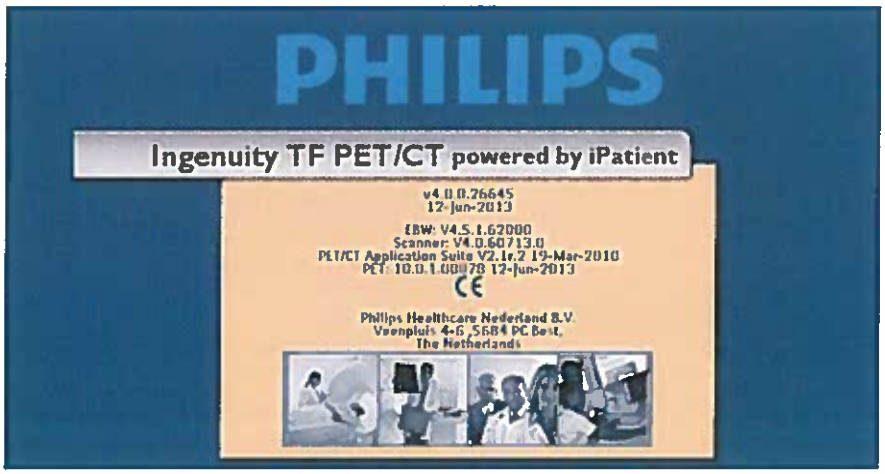
	need for radiopharmaceutical reinjection is also dependent on the half-life of the isotope being used.
HOW TO IDENTIFY AFFECTED PRODUCTS	The help screen will indicate "v4.0.0.26645" as pictured below: 
ACTIONS PLANNED BY PHILIPS	Philips will be releasing Proactive Field Change Order (FCO) 88200515 to deploy software version 4.0.3 to correct the issues described above. This update will include both hardware and software. Your Philips Field Service Engineer will contact you to schedule the update. The software and hardware installation will take approximately 3-4 days, followed by 3 days of onsite support from your local Philips clinical applications specialist. Because of the software change, your custom site-specific exam cards will not be available on the system after the upgrade. The CT parameters for all custom CT and PET/CT exam cards can be saved via the Print & Text Tool in the Exam Card Manager prior to the upgrade. However, the PET parameters (including reconstruction protocol names that are linked to the custom exam cards) will not be exported and recorded. Please work with your Clinical Applications Specialist prior to the upgrade to develop a plan for recording the PET parameters for all custom site-specific PET/CT exam cards.

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FURTHER INFORMATION AND SUPPORT	Please share this information with all Philips Ingenuity TF PET/CT users at your site. If you need any further information or support concerning these issues, please contact your local Philips representative. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377, follow the prompts).