

URGENT - Field Safety Notice

Medical Device Correction

Ingenuity TF PET/CT running software version 4.0.2 (4.0.0.26645) *PET Reconstruction Failure due to Negative Table Position*

Dear Customer,

A problem has been detected with the Philips Ingenuity TF PET/CT system running software version 4.0.2, that, if it were to reoccur, could pose a risk to patients. This Field Safety Notice 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 user in order to prevent risk to patients
- 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, please contact your local Philips representative:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

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



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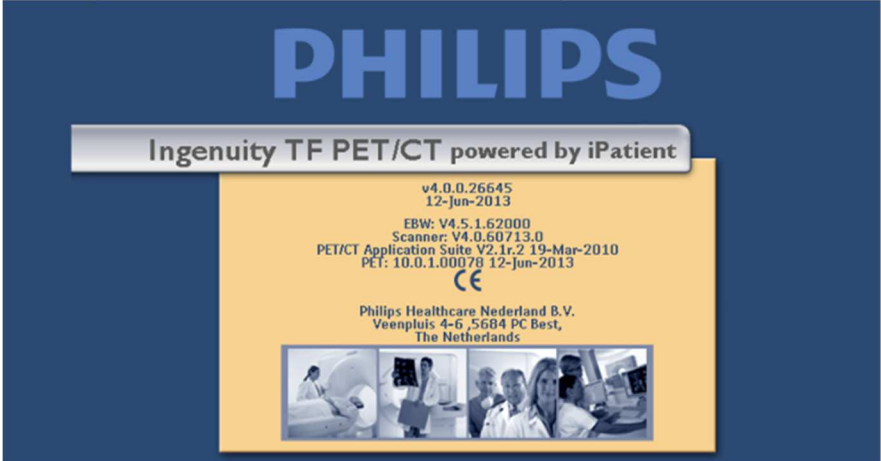
AFFECTED PRODUCTS	Ingenuity TF PET/CT (model 882442) running software version 4.0.2 The help screen will indicate "v4.0.0.26645".
PROBLEM DESCRIPTION	<p>Philips has identified a software issue that causes PET reconstructions to fail intermittently. It was determined that reconstructions fail due to a negative table position (-1 value is inserted) in the raw data list file, rather than the actual table position.</p> <p>This error has been found to occur in two scenarios:</p> <ol style="list-style-type: none"> 1) When the system operator cancels an acquisition <ol style="list-style-type: none"> a. The error will occur every time a scan is cancelled by the operator. 2) Couch position requests within the software sequence were delayed <ol style="list-style-type: none"> a. 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. b. The error manifests 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. <p>In both scenarios, the acquisition data will not be able to be reconstructed and will therefore be unusable.</p>
HAZARD INVOLVED	<p>There is a potential that a patient may incur additional radiation exposure from either a low dose CT rescan and/or a PET radiopharmaceutical reinjection depending upon the circumstance as follows:</p> <p>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.</p> <p>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 a low dose CT rescan and PET emission rescan may be determined by the technologist or radiologist to be needed.</p>



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	<p>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 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 need for radiopharmaceutical reinjection is also dependent on the half-life of the isotope being used.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>The help screen will indicate “v4.0.0.26645” as pictured below:</p> 
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>There is no way for the technologist to prevent this reconstruction failure or determine if the reconstruction failure was due to this error specifically.</p> <p>It is recommended that the technologist: 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:</p> <p style="text-align: center;">Warning</p> <p style="text-align: center;"><i>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.</i></p>



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	<p>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 would need to occur, and additional radiation exposure for the low dose CT scan can be avoided.</p> <p>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).</p> <p>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: <i>“Result {0} failed to reconstruct”</i> <i>Possible Solution: Attempt Retrospective Reconstruction</i></p> <p>Due to this issue, if the scan is expected to be used, complete the acquisition and do not cancel. If the technologist needs to cancel a scan, please be advised that the data reconstruction will not be supported and will not be reconstructed.</p> <p>Due to this issue, 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.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips will be releasing Mandatory Field Change Order (FCO) 88200515 to correct this issue as described above.</p> <p>A Philips Field Service Engineer will contact you to schedule the update.</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:</p> <p>0800 80 3000</p>

