

**URGENT - Field Safety Notice**  
**Medical Device Correction**  
**Ingenuity Core<sup>128</sup> with software version 3.5.5**

**A Software Issue May Result in Not All Images Being Reconstructed.**

Dear Customer,

According to our information, you currently have a Philips Ingenuity Core<sup>128</sup> system running software (SW) version 3.5.4 or 3.5.5. We have identified an issue with SW v3.5.5. Systems running SW v3.5.4 are currently planned to be updated to SW v3.5.5 under Field Change Order 72800597. Due to the issue identified in version 3.5.5, your system will be updated directly to SW v3.5.7 (Field Change Order 72800613). The issue identified in SW version 3.5.5 is described on the next page, including actions to be taken by the user.

**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:

*<Philips representative contact details to be completed by the FCO Executer>*

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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<b>AFFECTED PRODUCTS</b>	Ingenuity Core <sup>128</sup> running software version 3.5.5.
<b>PROBLEM DESCRIPTION</b>	If additional acquisitions/scans are requested prior to completion of the current reconstructions, not all planned images from the current reconstruction are displayed to the user. The information is not lost, as the raw data can be reconstructed off-line displaying all requested reconstructions. However, users may be unaware that the raw data is still available for offline reconstruction.
<b>HAZARD INVOLVED</b>	There is a potential that the user may choose to perform a rescan.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>If you have an Ingenuity Core<sup>128</sup> system running software (SW) version 3.5.5, then this issue affects your system.</p> <p>If you have an Ingenuity Core<sup>128</sup> system running software (SW) version 3.5.4, then your system will be updated directly to SW v3.5.7.</p> <p>To identify the software version of the product:</p> <ul style="list-style-type: none"> <li>• Click the "Help" button,</li> <li>• Select "About" and the software version is then displayed</li> </ul>
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>If your system is currently running software version 3.5.5, you are advised to:</p> <ol style="list-style-type: none"> <li>1. Verify that all planned image reconstructions are completed</li> <li>2. Perform off-line reconstructions if expected images are missing Refer to Section 15.3 Offline Reconstruction in your Instructions for Use.</li> </ol> <p>If your system is currently running software version 3.5.4, you are advised to:</p> <ol style="list-style-type: none"> <li>1. Refer to Field Safety Notice (FSN) 72800597</li> <li>2. Philips Field Service Engineer (FSE) will upgrade your system software from 3.5.4 to 3.5.5 (FCO 72800597) and then immediately upgrade from 3.5.5 to 3.5.7 (FCO 72800613). Therefore, the system will not be running 3.5.5 at any time.</li> </ol> <p>In the event both upgrades cannot be performed in immediate succession and the system is running software version 3.5.5, follow the above advice.</p>
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips is releasing Field Change Order (FCO) 72800613 to upgrade Ingenuity Core 128 systems running SW v3.5.5 to SW v3.5.7.</p> <p>Software versions 3.5.5 (if needed) and 3.5.7 will be installed on your system by the FSE during the same visit. Philips is releasing Field Change Order (FCO) 72800597 to upgrade systems with SW v3.5.4 to SW v3.5.5.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:  <a href="#">&lt;Philips representative contact details to be completed by the FCO Executer&gt;</a></p>