

URGENT – Field Safety Notice

**CT Transcatheter Aortic Valve
Implantation (CT TAVI) Planning Application in
Intellispace Portal Software Version 6**

**Software may display incorrect measurements used to plan TAVI procedures and
select a Transcatheter heart valve**

Dear Customer,

The CT Transcatheter Aortic Valve Implantation (CT TAVI) planning application, supplied as an option to Intellispace Portal Software version 6, may display incorrect measurements of cardiac and aortic anatomy. Clinicians use this information to plan TAVI procedures and to select and size the Transcatheter heart valve (THV) to be used in the procedures.

Reliance on incorrect information could contribute to an unsuccessful THV implantation procedure; the potential consequences may be ineffective treatment and may require additional intervention.

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 customer or 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 or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate regulatory agencies.

Philips apologizes for any inconvenience caused by this problem.

Sincerely,

Danny Even Chen
Director, Quality and Regulatory



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AFFECTED PRODUCT	CT Transcatheter Aortic Valve Implantation (CT TAVI) planning application, supplied as an option to Intellispace Portal software version 6.
PROBLEM DESCRIPTION	<p>The CT TAVI planning application provides measurements of cardiac and aortic anatomy used to select and size the transcatheter heart valve (THV) to be implanted during the TAVI procedure. The application may display incorrect measurements in certain circumstances if the "Bookmark" function is used to save the clinician's work. If a cardiac study with multiple phases is reloaded using the "Bookmark" function, different measurements than those originally saved in the "Bookmark" may be displayed in the "Review Results" step and reported.</p> <p>In order for these incorrect measurements to be displayed, the user or users must have done all of the following:</p> <ol style="list-style-type: none"> 1. Loaded more than one phase to the CT TAVI planning application. 2. Saved "Bookmark" while in "Edit Planes" mode. 3. Loaded the "Bookmark" and switched to another phase that was not the active one when loading. 4. Activated the "Review Results" step.
HAZARD INVOLVED	<p>Reliance on incorrect measurements of the cardiac and aortic anatomy can contribute to the incorrect selection and sizing of a THV and result in an unsuccessful THV implantation procedure.</p> <p>Potential consequences may include paravalvular/or transvalvular leak, Valve regurgitation and Valve stenosis.</p> <p>Philips has not received any report of any patient harm associated with this issue.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>To identify the software version of Intellispace Portal and to determine if the CT TAVI planning application is enabled, please follow these steps:</p> <ul style="list-style-type: none"> - Click the "Help" button, - Select "About", and the software version is displayed. <p>The affected versions are 6.0.0, 6.0.1, 6.0.2 ,6.0.3</p> <p>If you have the affected software version mentioned above, please do the following:</p> <ul style="list-style-type: none"> - Click on "Preference" - Select "Licensing" - Scroll down and check the License Type for CT TAVI planning application. <p>If the License Type is "Permanent" and not "Disabled" then your system is affected.</p>



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ACTION TO BE TAKEN BY CUSTOMER / USER	Until corrected software becomes available, do not use the “Bookmark” function with the CT TAVI planning application. The “Save Results” function is not susceptible to this issue, and can be used to save your work.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is initiating a correction consisting of : <ul style="list-style-type: none"> • Distribution of this Field Safety Notice • Installation of software version 6.0.3.1, in which the above issue has been corrected and is available. A Philips Service Engineer will notify customers when the corrected software can be installed on the affected systems.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

