

**Philips Healthcare  
Ultrasound**

FSN MA-FCO79500335 2015 MAY 15

## **URGENT - Field Safety Notice Philips Ultrasound Q-Station**

### **Q-STATION STRUCTURED REPORTING AND MEASUREMENTS**

Dear Customer,

A problem has been detected in the Philips Ultrasound Q-Station software that could pose a risk for patients or users. 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 / user in order to prevent risks for patients or users
- 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.

Philips Healthcare has discovered a problem in the Philips Ultrasound Q-Station version 3.0 or higher that could result in measurements from a study to be appended to subsequent studies for other patients.

If a healthcare provider makes a clinical decision on the sole basis of these measurements, without considering other available clinical data, misdiagnosis and/or delayed or incorrect therapy may result.

If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service at 1-800-722-9377.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Scott Zhang  
Senior Director, Quality and Regulatory  
Philips Healthcare – Ultrasound

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<b>AFFECTED PRODUCTS</b>	Q-Station version 3.0 or higher
<b>PROBLEM DESCRIPTION</b>	<p>If a user opens a study for review on Q-Station before its transfer from the Ultrasound system cart has completed, measurements from that study (Structured Report) may be appended to subsequent studies for other patients.</p> <p>The hazardous situation will exist only if all of the following events occur:</p> <ul style="list-style-type: none"> <li>• A user performs and completes a study (study A) on the Ultrasound system that includes SR (Structured Report) measurements and initiates the export of study A to Q-Station ('manual', 'auto' or 'send as you scan').</li> <li>• The user opens study A for review On Q-Station using view/report/export before the transfer of the SR is complete.</li> </ul> <p>At this point the initial condition for the issue to occur has been established. Then the user either</p> <ul style="list-style-type: none"> <li>• Repeats the same operation with a second study (Study B) for review on Q-Station prior to its complete transfer</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>• Opens study B after the transfer has completed and then performs a Wall Motion Scoring on study B.</li> </ul> <p>Study B would now contain SR measurements from both study A and study B. The report and the CLR (Calculation Label Region) will display measurements from both the study A and B.</p>
<b>HAZARD INVOLVED</b>	If a healthcare provider makes a clinical decision on the sole basis of these measurements, without considering other available clinical data, misdiagnosis and/or delayed or incorrect therapy may result
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>Q-Station version 3.0 or higher are affected.</p> <p>There are two ways to determine the version of Q-Station that is installed:</p> <ol style="list-style-type: none"> <li>1. When the Q-Station application is launched, the version is displayed in the 'splash screen'.</li> <li>2. Once in Q-Station, the version number can be displayed by selecting 'HELP' on the top left of the screen and then selecting 'ABOUT'.</li> </ol>

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<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>You can confirm whether your system is affected by checking the version of software on your system using the instructions above on How to Identify Affected Products. Philips has corrected this issue in version 3.3.2 and higher.</p> <p>Philips has corrected this issue, and is sending a CD with the latest version of Q-Station to affected customers, free of charge.</p> <p>Upon receipt from Philips of a CD with Q-Station version 3.3.2 which is being sent to you under separate cover, please uninstall previous versions of Q-Station and install version 3.3.2 on your system carefully following the installation instructions that accompany the CD. It is important that you register your Q-Station 3.3.2 installation as described in those instructions, so that Philips can confirm that you have completed this correction.</p> <p><b>Please complete the enclosed Customer Reply Form to confirm that you have (1) read and understood this important Field Safety Notice and (2) have either installed Q-Station version 3.3.2 or declare that this FCO does not apply to your institution. We ask that you return it to Philips Healthcare within 5 days of receipt of the replacement software.</b></p> <p>Until your software can be upgraded, the situation can be avoided by ensuring that studies are open for review in Q-Station only after their complete transfer from the Ultrasound System.</p> <p>This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.</p>
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<p>Philips has corrected this issue in version 3.3.2. This update will be provided to you, free of charge.</p> <p>Philips has corrected this issue, and is sending a CD with the latest version of Q-Station to affected customers, free of charge.</p>
<p><b>FURTHER INFORMATION AND SUPPORT</b></p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service at 1-800-722-9377</p>

