Philips Healthcare
Ultrasound

FSN MA-FCO79500321 2014 NOV 05

URGENT - Field Safety Notice
Philips Ultrasound Q-Station

Erroneous End-Systolic Volumes and Ejection Fraction May Be Reported When Using a2DQ & aCMQ

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.

When using the QLAB Auto 2D Quantification (a2DQ) and Auto Cardiac Motion Quantification (aCMQ) applications to calculate End-Systolic Volume (ESV), the reported ESV may be smaller than the ESV calculated by manual tracing without the use of QLAB. Correspondingly, the Left Ventricular Ejection Fraction (EF) calculated using these applications may be higher than the EF calculated by manual tracing. Philips' investigation has found that these differences may occur in cases where the EF is less than approximately 40%.

If a healthcare provider makes a clinical decision solely on the basis of an incorrect EF calculation 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,

[redacted]

Senior Director, Quality and Regulatory
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AFFECTED PRODUCTS	Q-Station 3.0 with a2DQ and/or aCMQ Q-Apps
PROBLEM DESCRIPTION	When using the QLAB Auto 2D Quantification (a2DQ) and Auto Cardiac Motion Quantification (aCMQ) applications to calculate End-Systolic Volume (ESV), the reported ESV may be smaller ESV calculated by manual tracing without the use of QLAB. Correspondingly, the Left Ventricular Ejection Fraction (EF) calculated using these applications may be higher than the EF calculated by manual tracing without the use of QLAB. Philips' investigation has found that this difference may occur in cases where the EF is less than approximately 40%.
HAZARD INVOLVED	An incorrect Ejection Fraction calculation could lead to misdiagnosis and/or delayed or incorrect therapy if healthcare providers make clinical decisions based solely on these measurements, without considering other available clinical data.
HOW TO IDENTIFY AFFECTED PRODUCTS	Q-Station 3.0 with a2DQ and/or aCMQ Q-Apps are affected. There are 2 ways to determine the version of Q-Station that is installed: 1. When you launch the Q-Station application the version is displayed in the splash screen. 2. Once in Q-Station, you can select HELP on the top left and then select ABOUT Q-Station to see the Q-Station version number. Q-Station version 3.0 is affected. Next you need to determine if you have one of the Plug-ins: 1. Launch Q-Assistant from the icon on the desktop. 2. Select the OPIONS TAB. 3. The Serial Number and Options (Q-Apps) are listed in this screen. Plug-ins affected: a2DQ and aCMQ

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ACTION TO BE TAKEN BY CUSTOMER / USER	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 Product. Philips has corrected this issue, and is sending a CD with the latest version of Q-Station to affected customers, free of charge. Upon receipt from Philips of a CD with Q-Station version 3.3, which is being sent to you under separate cover, please uninstall previous versions of Q-Station and install version 3.3 on your system carefully following the installation instructions that accompany the CD. It is important that you register your Q-Station 3.3 installation as described in those instructions, so that Philips can confirm that you have completed this correction. **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 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.** Until your software can be upgraded, you can avoid the situation by ensuring that you compute left ventricular volumes and ejection fraction by using either the on-cart manual analysis package or off-cart manual analysis package for your primary assessment.
ACTIONS PLANNED BY PHILIPS	Philips has corrected this issue, and is sending a CD with the latest version of Q-Station to affected customers, free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service at 1-866-767-7822.