Philips Healthcare
Ultrasound

FSN MA-FCO79500317 2014 NOV 05

URGENT - Field Safety Notice
Philips Model EPIQ 5 Ultrasound System

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 EPIQ 5 Ultrasound System 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
Philips Healthcare - Ultrasound

Philips Healthcare
Ultrasound

FSN MA-FCO79500317 2014 NOV 05

URGENT - Field Safety Notice
Philips Model EPIQ 5 Ultrasound System

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

AFFECTED PRODUCTS	EPIQ 5 V1.0.x/1.1.x with QLAB a2DQ and/or aCMQ plug-ins
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	EPIQ 5 systems with software versions 1.0.x or 1.1.x are affected. The software version is displayed at boot up on the Philips 'Splash Screen' beneath the EPIQ 5 name. The system is affected by this issue if the Splash Screen displays a version lower than 1.2 (1.0.x or 1.1.x), and is therefore eligible to be upgraded. The software version can also be checked by doing the following: 1. Press the Support button on the control panel Under the System Management tab click the System Information button. In the Software Information box the first line is Application Software and will have a 12 digit number beginning with 4535, if the number immediately after that begins with a 1.0 or 1.1, the system is eligible to be upgraded.
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 Products. Philips has corrected this issue in version 1.2 and higher. If you have an affected version of software, please contact your local Philips representative to schedule an upgrade of your 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 in version 1.2. This update will be provided to you, free of charge. Please contact your local Philips representative to schedule the upgrade of your system.

Philips Healthcare
Ultrasound

FSN MA-FCO79500317 2014 NOV 05

URGENT - Field Safety Notice
Philips Model EPIQ 5 Ultrasound System

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

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.