URGENT - Field Safety Notice
Philips Model EPIQ 7 Ultrasound System

Erroneous Velocities May Be Reported When Using High Pulse Repetition Frequency (HPRF)

Dear Customer,

A problem has been detected in the Philips Model EPIQ 7 Ultrasound System that, if it were to re-occur, could affect the performance of the equipment. 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.

You are being notified because our records indicate you have an EPIQ 7 Ultrasound System. All EPIQ 7 Ultrasound Systems shipped to date may experience this problem. Philips has corrected this issue in Version 1.1.2 of the EPIQ 7 Ultrasound System, which will begin shipping shortly. Within the next few weeks, a Philips Field Service Engineer will be contacting you to schedule the V1.1.2 upgrade to your system free of charge.

The EPIQ 7 will report incorrect Doppler velocities if you use High Pulse Repetition Frequency (HPRF) with multiple sample volume gates. To avoid this problem, do not use HPRF in PW Doppler mode.

While in High Pulse Repetition Frequency (HPRF) in ‘Display Zoom Velocity Scale’ using manual spectral Doppler trace, the velocities in the velocity results table may be overstated by 25-75%, depending on the scale value. The erroneous values are reported on the reports page and in DICOM SR if exported and include the following velocities and calculations:

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General Imaging, (GI)
- Peak Systolic Velocity, (PSV)
- End Diastolic Volume, (EDV)
- Minimum Diastolic Velocity, (MDV)
- Time Averaged Peak Velocity, (TAPV)
- Time Averaged Mean Velocity, (TAMV)

Affected GI Calculations:
- S/D, (Ratio of Peak Systolic Velocity / Peak diastolic Velocity)
- Resistivity Index, (RI)
- Pulsatility Index, (P1)

Please note that both the displayed scale within the spectral Doppler trace and distance measurements in the spectral Doppler trace are not affected by this issue and are accurate.

The issue can be reproduced as follows:
1. Press PW knob on the Control Panel then press the middle trackball key to 'Update' scrolling on PW.
2. Go to the second screen of the PW Touch Screen by swiping to the left.
3. Activate HPRF-by pressing the High PRF on the Touch Screen
4. Increase the Scale knob located on the Control Panel. The display is on the 1st screen of the PW Doppler Touch Screen. Increase scale until you get the first "Ghost" Doppler Range Gate. The first 3 Clicks to the right on the Scale knob after the Ghost Gate appears will reproduce the issue.
5. Freeze the Scrolling Trace
6. Press Measure Tab
   Press Continuous Trace and trace the Spectral Trace. The erroneous velocities will display in the velocity results value table.

Doppler velocities are used to assist in diagnosing the existence, location and severity of cardiac or vascular stenosis. Philips Healthcare has evaluated this issue and determined the overstated velocities do not pose a health risk to patients because high velocity measurements are confirmed by Continuous Wave Doppler (CW Doppler) before any invasive procedure might be performed to further diagnose or treat a stenosis. However, in order to avoid confusion when comparing velocities measured using HPRF and CW Doppler, avoid using HPRF in PW Doppler mode until your system is upgraded to version 1.1.2.

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If you need any further information or support concerning this issue, please contact your local Philips representative.

Philips apologizes for any inconvenience caused by this problem

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Paulin (Fred) Viaud
Sr. Director, Quality & Regulatory

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AFFECTED PRODUCTS	All Philips Model EPIQ 7 Ultrasound System at software version less than V1.1.2
PROBLEM DESCRIPTION	The EPIQ 7 will report incorrect Doppler velocities if you use High Pulse Repetition Frequency (HPRF) with multiple sample volume gates. To avoid this problem, do not use HPRF in PW Doppler mode. While in High Pulse Repetition Frequency (HPRF) in 'Display Zoom Velocity Scale' using manual spectral Doppler trace, the velocities in the velocity results table may be overstated by 25-75%, depending on the scale value.
HAZARD INVOLVED	Doppler velocities are used to assist in diagnosing the existence, location and severity of cardiac or vascular stenosis. Philips Healthcare has evaluated this issue and determined the overstated velocities do not pose a health risk to patients because high velocity measurements are confirmed by Continuous Wave Doppler (CW Doppler) before any invasive procedure might be performed to further diagnose or treat a stenosis.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Philips Model EPIQ 7 Ultrasound System at software version less than V1.1.2 The software version can be identified by selecting the 'Support' button on the control panel: Select the 'System Management' tab: Select 'System Information'. The software version is displayed
ACTION TO BE TAKEN BY CUSTOMER / USER	Do not use HPRF in PW Doppler mode until the system is upgraded to V1.1.2
ACTIONS PLANNED BY PHILIPS	Philips has corrected this issue in Version 1.1.2 of the EPIQ 7 Ultrasound System, which will begin shipping shortly. Within the next few weeks, a Philips Field Service Engineer will be contacting you to schedule the V1.1.2 upgrade to your system free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative