PHILIPS

URGENT Field Safety Notice

EPIQ Elite v14.0 Software Issue with C5-1 Transducer

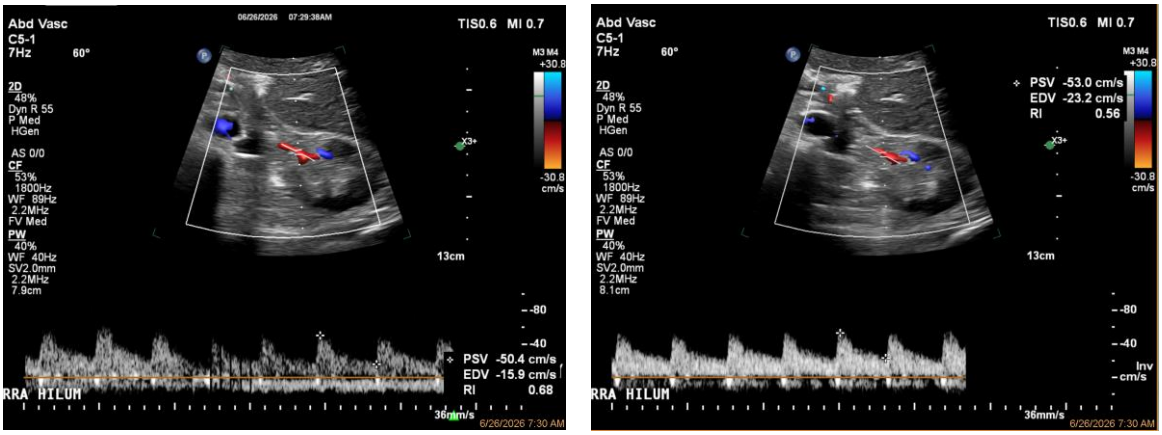
AUG-2026

Dear Customer,

Philips is aware of a potential safety issue impacting Philips EPIQ Elite Ultrasound Systems running software version 14.0, when utilizing the C5-1 transducer with a particular Tissue Specific Preset (TSP). Philips EPIQ Elite systems using a C5-1 transducer with Abd Vasc TSP may not accurately display the Pulsed Wave (PW) measurement which would result in an incorrect image, measurement, or content. This could lead to a delay in diagnosis or treatment. Inaccurate data may lead to misdiagnosis and incorrect treatment decisions if not identified or corroborated with other diagnostic tools. There have been no customer complaints or reports of harm for this issue.

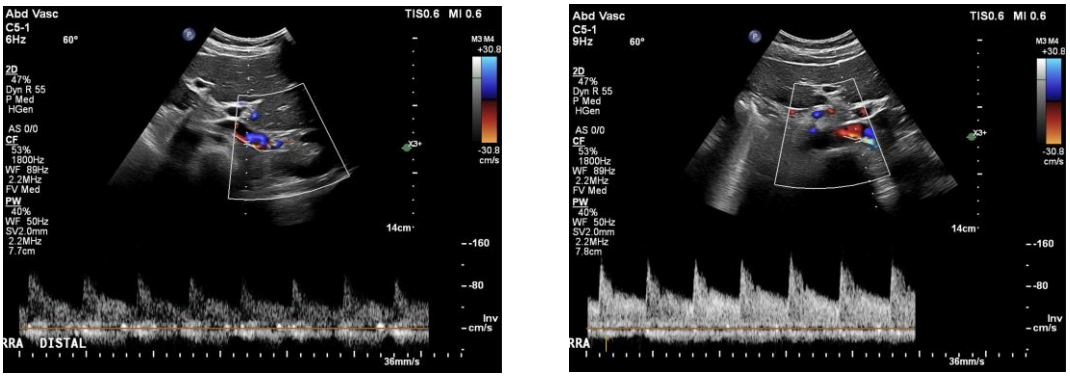
Issue Description

When using a Philips EPIQ Elite system with the C5-1 transducer with the Abd Vasc TSP in Pulsed Wave Doppler mode, the visual representation of the Pulsed Wave sample volume (SV) gate is slightly offset (shallower) to the actual location of the Pulsed Wave measurement. Under default conditions, it will result in an approximate 2mm offset. In larger vessels, the defect may result in reduced signal, which the user may compensate for by increasing PW Gain on the system. In smaller vessels or stenotic flow, the defect may result in underestimation in severity of stenosis. This issue could result in delayed diagnosis or treatment. Inaccurate data may lead to misdiagnosis and incorrect treatment decisions if not identified or corroborated with other diagnostic tools.



(a) (b)

Figure 1: Example with small vessels. (a) Ideal Positioning - SV placed near center of vessel lumen. Weaker amplitude signal with PSV of 50.4cm/s. (b) Positioning Offset - SV placed slightly posterior to the vessel resulting in a stronger PW Doppler trace. PSV of 53.0cm/s.



(a) (b)

Figure 2. Example with large vessels. (a) Ideal Positioning - SV volume placement in center of lumen. Signal is weak and is not what the user would expect to see given the normal color Doppler signal displayed (Typically gain would be increased by user). (b) Positioning Offset - SV is placed deep to the periphery of the vessel, and a normal PW trace is observed

User Instructions

Philips recommends the following actions be taken for safe use of the device:

- Due to possibility of a weak PW Doppler Signal on EPIQ Elite running 14.0 SW, customers are advised not to use C5-1 Abd Vasc Tissue Specific Preset (TSP). Please use a different TSP (e.g., Abd Gen, Abd Renal) within C5-1. Please note that this issue (i.e., Weak PW Doppler signal) is restricted to the Abd Vasc TSP with C5-1 on EPIQ Elite running SW 14.0 only.
- Otherwise, you may continue to use your device in accordance with the IFU.
- Circulate this notice to all users of the device so that they are aware of the product issue and associated hazard / harm.
- Post this notice near the affected unit(s) for ease of reference

Please return the completed response form at the end of this notice, indicating that information on this issue has been read and understood. Philips asks that you return the completed response form no later than 30 days from receipt of this letter.

Identification of Affected Product

To identify your software version:

EPIQ Elite Ultrasound Systems operating with software version 14.0 are impacted by this issue.

To determine if your EPIQ system is impacted, follow the steps below:

A. To determine if your EPIQ system is operating with version 14.0, utilize one of the following two methods:

1. The software version will be displayed on the splash screen during the system boot up as shown in Figure 3.

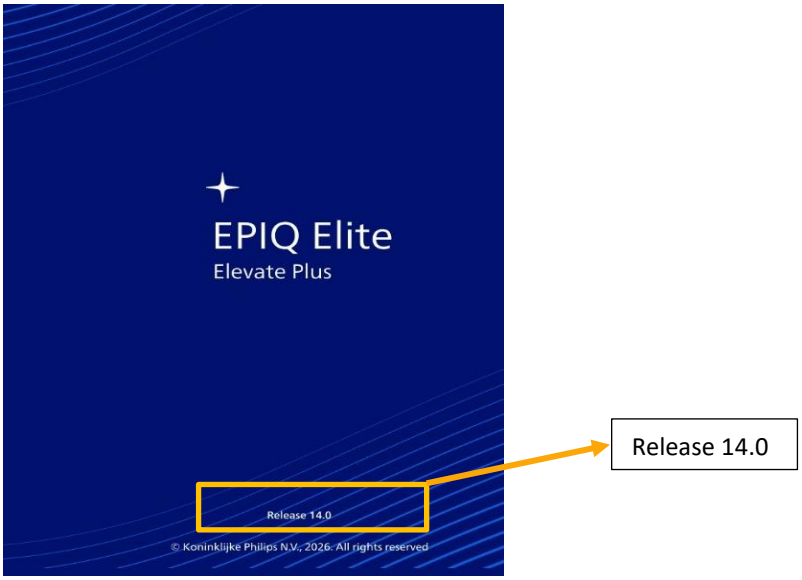


Figure 3 Software Version

2. Alternatively, after the system has started/completed its boot-up, follow the instructions below to locate the software version of your EPIQ Ultrasound System:
   1. **Power up** the system and allow it to complete the boot sequence,
   2. Press the **Support** button on the right side of the system control panel,
   3. Under **System Management,** click **System Information,**
   4. The software version is listed in the **Software Information** Section.

Intended Use:
The intended use of the EPIQ series diagnostic ultrasound systems is diagnostic ultrasound imaging and fluid flow analysis of the human body. The clinical environments where the ultrasound systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

Manufacturer Actions (*SRN: US-MF-000002237)*
Philips will be implementing a software correction free of charge to address the issue.
A Philips representative will contact you to schedule the correction (reference FCO79500580).

Please contact your local Philips representative with any additional questions.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Ondrea Bermudez
Head of Quality, Ultrasound, Philips

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URGENT Field Safety Notice Response Form

Reference: EPIQ Elite v14.0 Software Issue with C5-1 Transducer, 2026-PD-US-009, FCO79500850

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter, and confirm that the information from this Letter has been properly distributed to all users that handle the Philips EPIQ Elite Ultrasound System.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to Philips.