

## URGENT Field Safety Notice

Vue PACS (Diagnostic) and Vue Motion version 12.2.8.600

Potential for misdiagnosis due to Bookmark not preserving the original measurement specified by the user upon subsequent access following version 12.2.8.600 upgrade.

17-Nov-2025

**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 this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with Vue PACS (Diagnostic) and Vue Motion version 12.2.8.600, that could pose a risk to patients. This URGENT Field Safety Notice is intended to inform you about:

### 1. What the problem is and under what circumstances it can occur

There is a software issue affecting Philips Vue PACS (Diagnostic) and Vue Motion version 12.2.8.600, where Bookmarks do not preserve the original measurement specified by the user upon subsequent access.

Bookmarks created prior to version 12.2.8.600 and accessed through Diagnostic Workstation or Vue Motion after upgrading to version 12.2.8.600 do not preserve the original measurement specified by the user upon subsequent access. The measurement graphic location (on the same image), size and values, as well as its representative bookmark might be changed. Upon closing the study, the updated bookmark graphic data is saved to the database, potentially affecting subsequent analyses.

The issue applies to 2D bookmarks measurements in oblique-based applications (e.g., MPR\*, Power View, PET-CT)

\* MPR-Multi-Planar Reformatting

Example:

Image #1: Bookmarks BM\_04 and BM\_05 created in MPR view, in a version prior to 12.2.8.600:

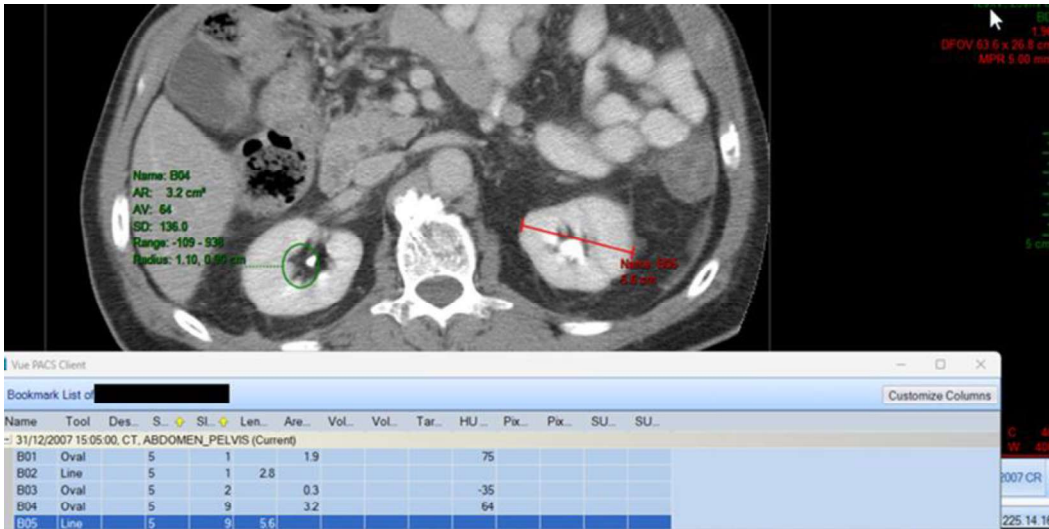
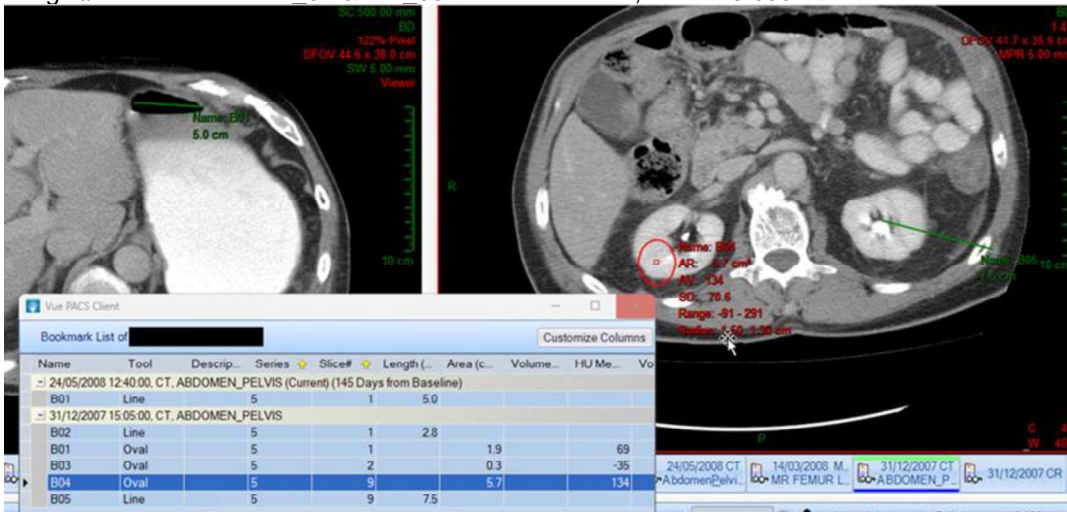


Image #2: Bookmarks BM 04 & BM 05 loaded to viewer, in 12.2.8.600 version



Note: In Image #2- The size, location and value of Bookmarks BM\_04 and BM\_05 were changed, not presenting the original user selection

Specifically, for the software issue to occur, the following sequence of the events must occur:

- Open Diagnostic viewer in a **version prior to 12.2.8.600**
- Load a volumetric study (e.g., MRI, CT, PET-CT) to oblique-based applications (e.g., MPR, Power View, PET-CT)
- Create 2D measurements (e.g., line, ROI, arrow, angle)
- Save graphic measurement(s) as bookmark (BM)
- Close the study
- Open the same study in Diagnostic viewer or Vue Motion, **version 12.2.8.600** (e.g., as a prior study after site was upgraded to the new version)
- Navigate to the same bookmark
- Graphic measurements (on the image and in the BM table) do not accurately preserve its original location, size and value.

Note: If a user opens a report signed in a version earlier than 12.2.8.600, the measurement data within the report remains unchanged. However, clicking the bookmark hyperlink will lead the user to the same incorrect graphic measurement.

There have been no reported adverse events related to this issue.

**2. Hazard/harm associated with the issue**

Misdiagnosis due to inaccurate size, location, and value of Bookmarks may subsequently impact treatment decisions which may lead to the potential for patient harm, including delay in recognizing disease progression resulting in missed therapeutic opportunity, worsened prognosis, and potentially life-threatening consequences or irreversible injury.

**3. Affected products and how to identify them**

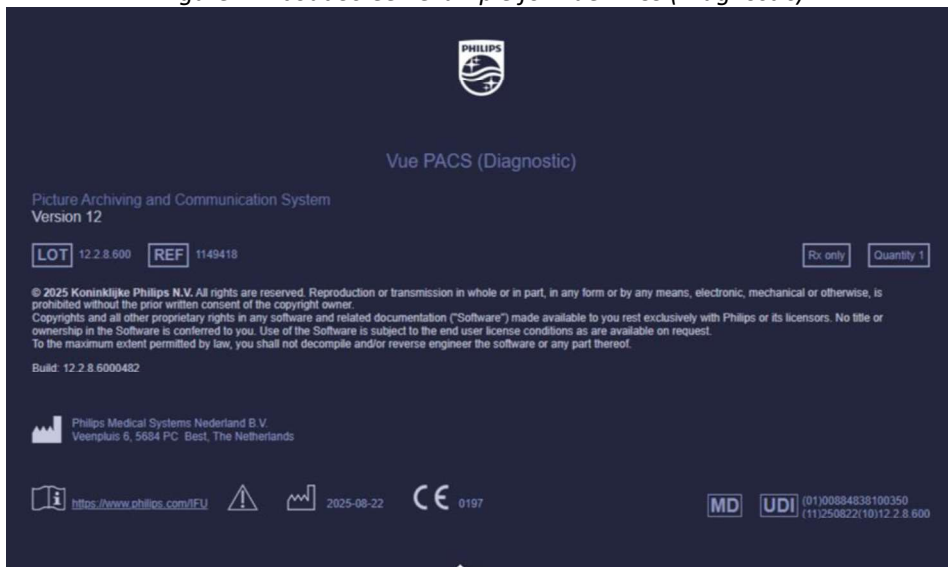
**Identification of impacted product:**

Impacted products are listed in Table 1 and can be identified by the product name, reference number, and lot number (represents the software version) which are located on the About Screen examples as shown in Figure 1 and Figure 2.

*Table 1. Impacted Product*

Product Name	Reference Number	Software Version
Vue PACS (Diagnostic) V12	1149418	12.2.8.600_0482
Vue Motion v12	1017979	12.2.8.600_0449

*Figure 1. About Screen example for Vue PACS (Diagnostic)*



*Figure 2. About Screen example for Vue Motion*



**Intended Use:**

The Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. This includes the display of structured reports from CAD systems with DICOM "for presentation" mammography images. The system is to be used by trained professionals including, but not limited to, physicians and medical technicians.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians.

**4. Actions that should be taken by the customer / user in order to prevent risks for patients or users**

- You may continue to use your system(s) in accordance with the intended use.
- Circulate this notice to all users of this device so that they are aware of the potential issue.
- Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt of this letter via email to: Philips.recall@Philips.com

**5. Actions planned by Philips Radiology Informatics to correct the problem**

To prevent the issue from occurring, Philips has temporarily disabled the Bookmark functionality in version 12.2.8.600 for Vue PACS (Diagnostic) and Vue Motion. A Philips representative will contact you to schedule a time to install a software solution on your system(s) to resolve the issue (reference FC083000225) and will then re-enable the Bookmark functionality upon implementation. Philips plans to begin installing the solution on affected systems in November 2025.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Electronically signed by: Edita Reznik Shmueli  
Reason: "I Approve"  
Date: Nov 17, 2025 14:24:16 GMT+2

*Edita Reznik Shmueli*  
Edita Reznik Shmueli

Quality Leader, Philips Radiology Informatics

**URGENT Field Safety Notice Response Form**

**Reference:** Bookmarks do not preserve the original intended measurement value and location specified by the user following 12.2.8.600 upgrade, 2025-EI-RI-004 (FCO83000225)

**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, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:	
Street Address:	
City/State/ZIP/Country:	

**Customer Actions:**

- You may continue to use your system(s) in accordance with the intended use.
- Circulate this notice to all users of this device so that they are aware of the potential issue.
- Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Vue PACS (Diagnostic) and Vue Motion version 12.2.8.600

**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 via email to: [<contact details to be completed by the Market/Business >](#)