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URGENT Field Safety Notice

Vue PACS – Perfusion Application
Potential for misdiagnosis due to incorrect ischemic map and tables values

09-Oct-2024

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,

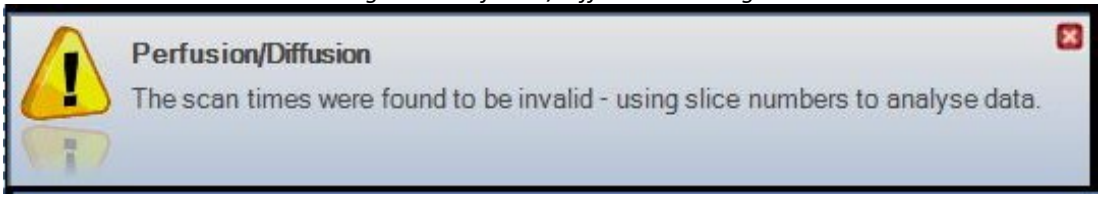
Philips has become aware of a potential safety issue with the Vue PACS image management system, Perfusion Application, that could pose a risk to patients. This URGENT Field Safety Notice is intended to inform you about:

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

A software issue affecting Philips Vue PACS may cause incorrect ischemic map and table value calculations when using the export function in the Perfusion Application for a Siemens CT perfusion study.

When a Siemens CT imaging study is initially loaded into the perfusion application and perfusion analysis is performed, the ischemic map calculation is correct. However, after an export action is performed and the study is reloaded in the Perfusion Application, the software issue may occur and the following warning message is generated.

Figure 1. Perfusion/Diffusion Warning



Specifically, for the software issue to occur, the following conditions must be true:

1. The Vue PACS Perfusion Application is used for clinical analysis
2. A Siemens CT study is selected for CT perfusion analysis
3. The Perfusion Application export function is used for the perfusion maps
4. The study is reloaded in the Perfusion Application and perfusion maps are recalculated

In such cases, the recalculated ischemic map and table values may be incorrect.

As of September 2024, there have been no reported adverse events related to this issue.

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2. Hazard/harm associated with the issue

Misdiagnosis due to incorrect ischemic map and table values. Misdiagnosis can subsequently impact treatment decisions which may lead to the potential for patient harm, including temporary or permanent stroke-related injury or impairment.

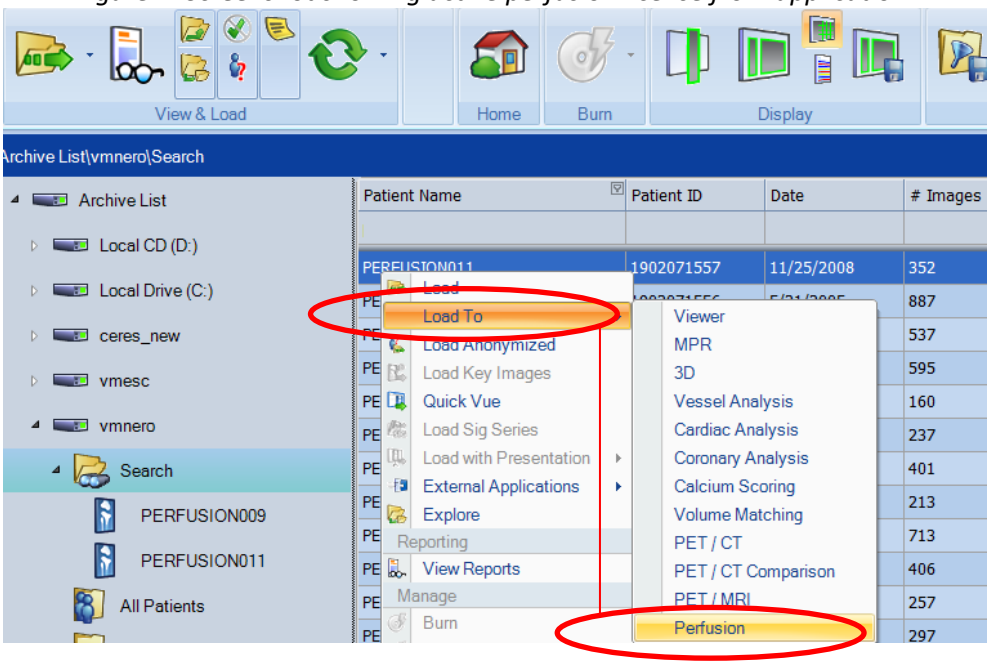
3. Affected products and how to identify them

Identification of affected products:
This issue affects all Philips Vue PACS image management systems which have the Perfusion Application license enabled. Use one of the following methods to confirm if your system has the Perfusion Application license enabled:

Method A (for clinical users)
To identify if your Vue PACS system has the perfusion license enabled:

1. Navigate to CT Perfusion Study
2. Select **Load To** from the right-click menu as shown in Figure 2.
3. If the **Perfusion** option is present in the menu, the perfusion license is enabled.
4. If the **Perfusion** option is not present, the license is not enabled, and your system is not affected.

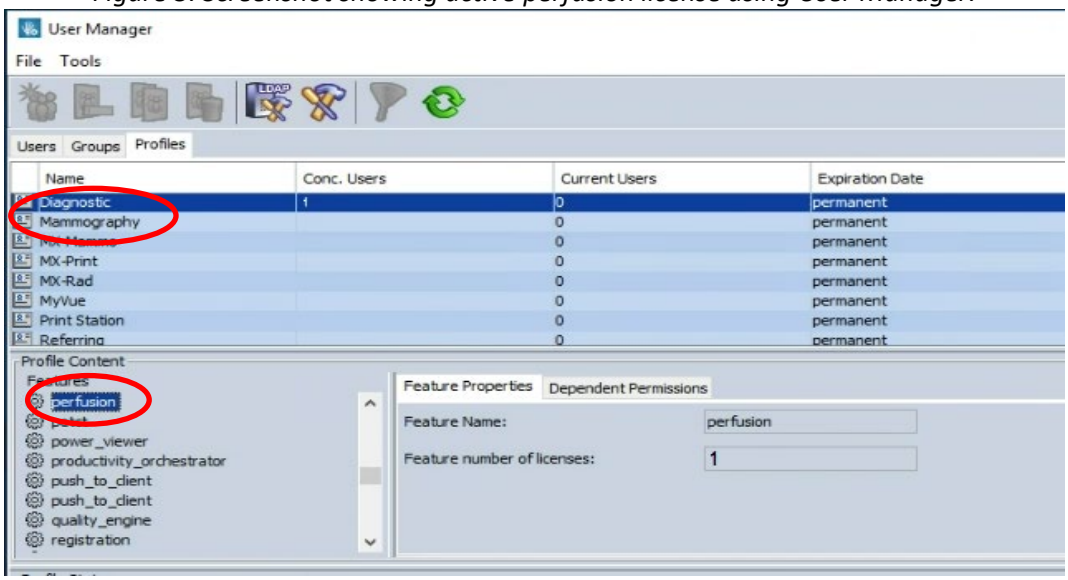
Figure 2. Screenshot showing active perfusion license from application.



Method B (for PACS administrators)
To identify if your Vue PACS system has the perfusion license enabled:

1. Log in to the **User Manager** tool
2. Go to the **Profile** tab as shown in Figure 3 and review the profiles named **Diagnostic** and **Mammography**
3. In the Profile Content list, if the **Perfusion** option is present the license is enabled
4. If the **Perfusion** option is not present in the Profile Content list, the license is not enabled.

Figure 3. Screenshot showing active perfusion license using User Manager.



Intended Use:
The Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS (Picture Archiving and Communication System) solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. 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.

The system contains a Perfusion module with interactive tools to analyze and compare Computed Tomography Perfusion (CTP) and MR Perfusion (MRP) images of adult patients. Blood perfusion parameters are automatically calculated and displayed as a set of perfusion maps and perfusion tables. The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

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

- To prevent the issue from occurring, Philips recommends that users not use the perfusion application **Export** function (as shown in Figure 4). When used without export functionality, the perfusion application performs as expected.

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Figure 4. Screenshot showing Perfusion Application export function.

- You may continue to use your system(s) in accordance with the intended use and by following the recommendation above.

- If a study is reloaded in the Perfusion Application after an export action is performed, and the *Perfusion/Diffusion Warning* message is observed (shown in Figure 1), the ischemic map and table value calculations should not be used for diagnostic purposes.

- 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.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a time to install a software solution on your system(s) to resolve the issue (reference FCO78000003). Philips plans to begin installing the solution on affected systems in October 2024.

Please be assured that maintaining the highest level of safety and quality is our greatest priority. If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

Edita Reznik-Shmueli
Quality Leader, Philips Radiology Informatics

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URGENT Field Safety Notice Response Form

Reference: Vue PACS Perfusion Application, incorrect ischemic map and table values, 2024-EI-RI-001 (FCO78000003)

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 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:

- 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.
- Until Philips has installed the solution, follow the instructions provided in Section 4 of the Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected Vue PACS image management systems.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed response form to your local Philips representative: *<Local Market to input contact information>.*