

URGENT Field Safety Notice

Vue PACS – Perfusion Stroke Application

Potential for misdiagnosis due to incorrect ischemic map and tables values

09-Oct-2024

Dear Distributor,

Philips is initiating a Field Safety Corrective Action due to a problem identified in the Philips Vue PACS image management system, Perfusion Application, that could pose a risk for patients.

It is imperative that all customers with affected products receive the attached Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- The actions that the customer/user should take to prevent risk for patients
- The actions planned by Philips to correct the problem.

Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

- Submit this Field Safety Corrective Action to the Regulatory Agency as applicable.
- Add your contact information in the Response Form attached to the Field Safety Notice.
- Send the attached Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible, together with the Response Form.
- Perform a good faith effort (e.g. follow-up phone call and/or email) to get the Response Form from the customer and inform Philips about the responses received.

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.

Sincerely,

Edita Reznik Shmueli

Edita Reznik-Shmueli
Quality Leader, Philips Radiology Informatics