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URGENT Field Safety Notice

AneurysmFlow

Potential Safety issue if MAFA ratio is used for clinical decision making

19-MAR-2026

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 identified a potential safety issue involving the Mean Aneurysm Flow Amplitude (MAFA) ratio of AneurysmFlow (Interventional Tool). This URGENT Field Safety Notice is intended to inform you about:

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

The MAFA ratio represents the volumetric flow rate quotient before and after neuro-interventional treatment in a cerebral aneurysm (e.g., Flow Diverter Stent (FDS) placement).

Philips has determined that the MAFA ratio does not provide reliable prognostic information regarding aneurysm occlusion following Flow Diverter Stent treatment.

The Instructions for Use (IFU) of AneurysmFlow state that the MAFA ratio should not be used for making clinical decisions (Section 9.2 Measuring Flow). In addition, when hovering over the MAFA ratio header within the software interface, an on-screen message states that the MAFA ratio is not to be used for clinical decision making.

Despite the existing cautions, the displayed MAFA ratio may still be considered during intra-procedural decision-making and could influence clinical judgment. This may potentially result in an incorrect clinical decision.

2. Hazard/harm associated with the issue

Clinical decisions that are influenced by the MAFA ratio may result in overtreatment of the aneurysm, such as the placement of an additional device when it is not clinically necessary, or undertreatment, such as withholding an additional embolization device when it would be warranted. Inadequate occlusion of the aneurysm increases the risk of delayed rupture, potentially leading to serious procedural complications and adverse patient outcomes.

To date, Philips has not received any complaints or reports of patient harm due to this issue.

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3. Affected products and how to identify them

AneurysmFlow is a software medical device (Interventional Tool) intended to be used in combination with a Philips interventional X-ray system and 3DRA data.

AneurysmFlow assists during endovascular procedures for treating saccular cerebral aneurysms, by:

- Visualization of blood flow patterns in the aneurysm and parent vessel, based on digital subtraction angiography.
- Quantification of the blood flow in the aneurysm parent vessel, based on digital subtraction angiography and 3D rotational angiography.
- Comparison of blood flow, both visual and quantified between two acquisitions.

This issue affects all software releases of AneurysmFlow. **Appendix A** explains how to verify if AneurysmFlow is installed on your Philips interventional X-ray system.

4. Actions that should be taken by the customer / user that are aimed at lowering risks for patients

- **Do not use the MAFA ratio for clinical decision making as described in the IFU** (Section 9.2).
- AneurysmFlow may continue to be used in accordance with the Instructions for Use (IFU).
- Circulate this Urgent Field Safety Notice to all users so that they are aware of the issue and keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- In case the Philips interventional X-ray system on which AneurysmFlow is installed has been transferred to another organization, please send a copy of this Urgent Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.
- Complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and actions required.

5. Actions planned by Philips IGT Systems to correct the issue

Philips is developing a software update to remove the MAFA ratio from AneurysmFlow. Philips expects to release this software update in December 2026. Your local Philips representative will contact you to schedule implementation of this software update once available.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this matter, please contact your local Philips representative.

Philips regrets any inconvenience caused by this matter.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

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Appendix A

To identify if AneurysmFlow is available on your Philips interventional X-ray system, follow the steps below:

1. Go to the Interventional Workspot.

2. Go to the Patient list screen and click on “Help” and then “About” (see red box in Figure 1).

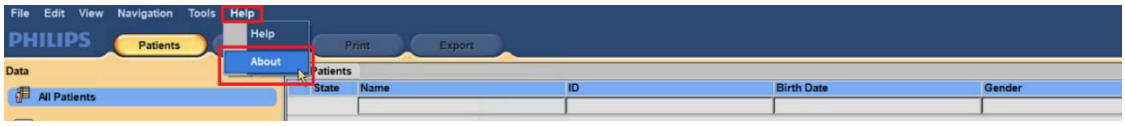

Figure 1

3. Click on EULA at the bottom of the page (see Figure 2).

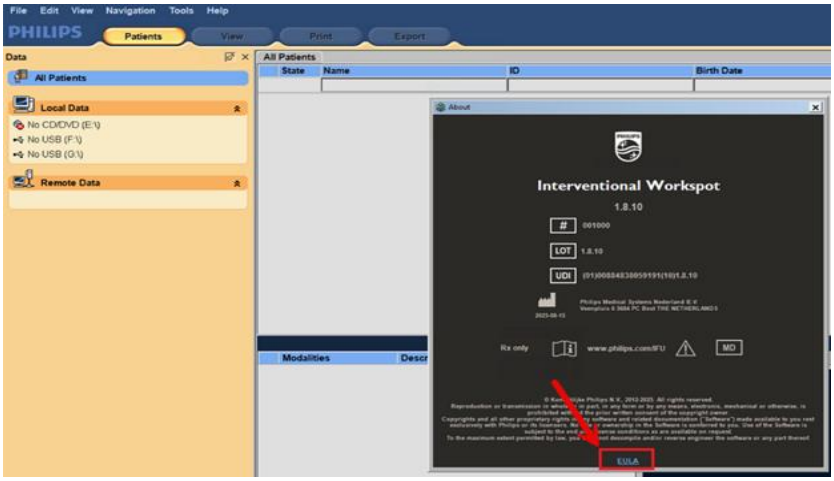

Figure 2

4. If AneurysmFlow is installed, AneurysmFlow will be listed together with the software release (see Figure 3).

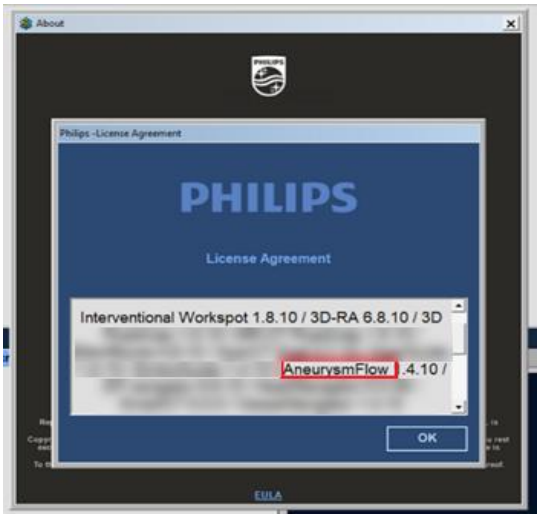

Figure 3

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URGENT Field Safety Notice Response Form

C&R 2025-IGT-BST-025 Reference: Potential Safety issue if MAFA ratio is used for Clinical Decision Making.

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:

- **Do not use the MAFA ratio for clinical decision making as described in the IFU** (Section 9.2).
- AneurysmFlow may continue to be used in accordance with the Instructions for Use (IFU).
- Circulate this Urgent Field Safety Notice Letter to all users so that they are aware of the issue and Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- In case the Philips Interventional X-ray system where AneurysmFlow is installed has been transferred to another organization, please send a copy of this Urgent Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.

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 affected system(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

It is important that your organization acknowledges receipt of this letter. Your organization's reply is evidence required to monitor the progress of this Urgent Field Safety Notice.