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URGENT Medical Device Correction

SmartPerfusion, release R1.0, R1.1, R1.1.1, R1.1.5, R1.1.5.1 and R1.1.6
2D Perfusion, release R1.0.x, R1.1.x, R1.2 and R1.2.1
Used with Philips Allura Xper and Azurion Systems

SmartPerfusion and 2d Perfusion May Inaccurately Present Time Density Curves and Images

20-February-2023

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 SmartPerfusion and 2D Perfusion, where the information provided by these software products might not be accurate.

SmartPerfusion and 2D Perfusion assist in the diagnosis of perfusion alterations of tissues, based on digital subtraction angiography (DSA), by providing color-coded images generated from the DSA series. It can visualize multiple functional parameters related to the time density function. It also provides a comparison between pre-, peri-, and post-procedural color-coded images.

Clinical diagnosis or treatment is not to be based on SmartPerfusion or 2D Perfusion results only. All findings, decisions, and diagnoses must be confirmed by the use of DSA.

This URGENT Medical Device Correction is intended to inform you about:

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

Philips has identified through an internal investigation that SmartPerfusion and 2D Perfusion have technical issues related to the way the perfusion signal is generated and processed, which may lead to inaccurate presentations of Time Density Curves and images.

No adverse events related to this issue have been reported to Philips as of 20 February 2023.

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2. Hazard/harm associated with the issue

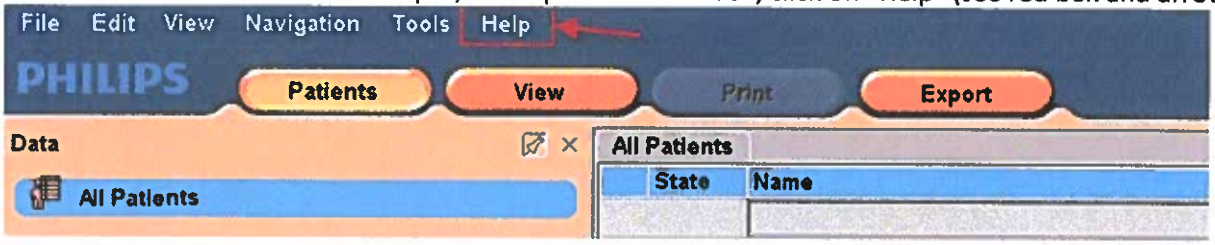
The identified issue may result in inaccurate presentations during clinical use, and/or poor image quality. When based on SmartPerfusion or 2D Perfusion only, subsequent clinical decisions could potentially result in overtreatment or undertreatment of patients in the Cathlab for peripheral artery disease (PAD).

3. Affected products and how to identify them

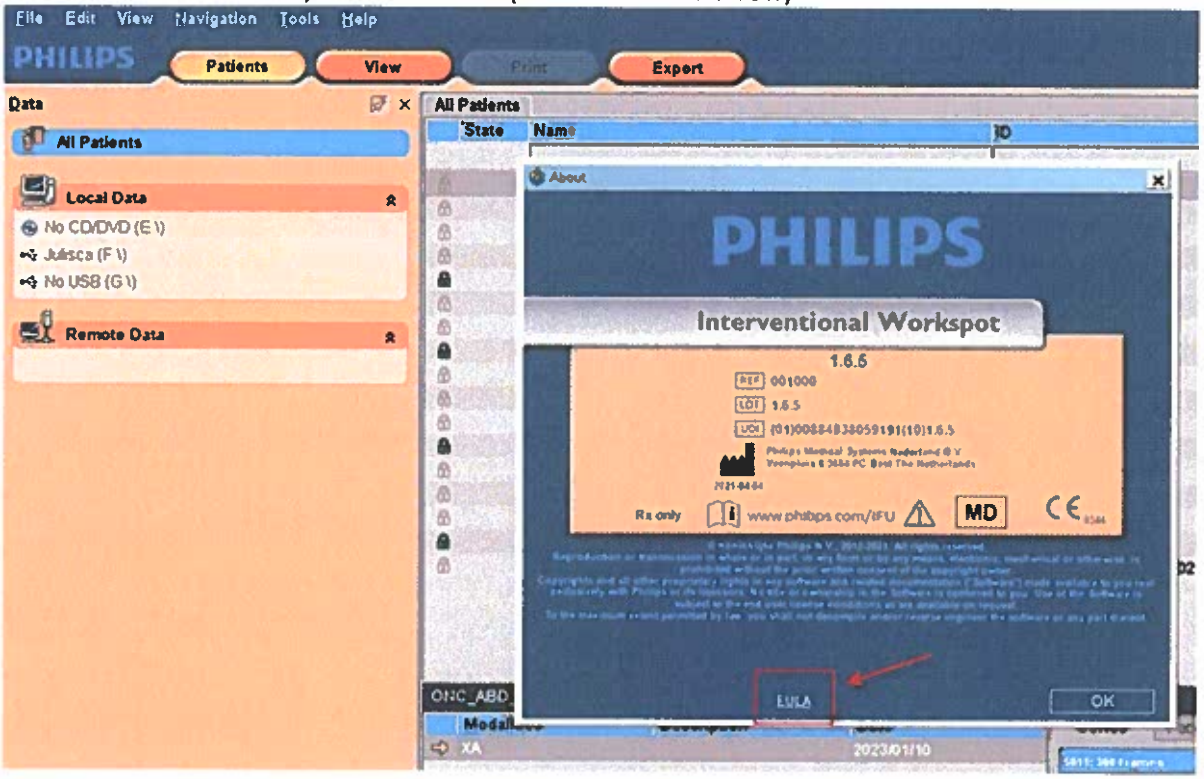
All software releases of SmartPerfusion and 2D Perfusion are affected by this issue. SmartPerfusion and 2D Perfusion are installed on the Interventional Workspot of the Philips Allura Xper or Azurion Systems.

To identify if SmartPerfusion or 2D Perfusion is available in your System, please follow the following steps on the Interventional Workspot:

Pic 1: On the Interventional Workspot, in the patient list screen, click on "Help" (see red box and arrow)



Pic 2: In the "About" box, click on "EULA" (see red box and arrow)



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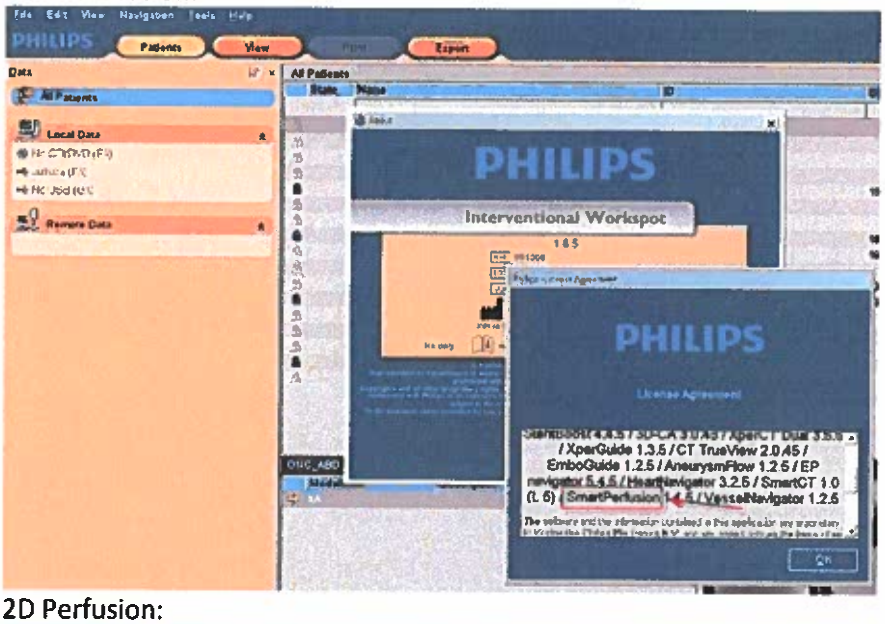
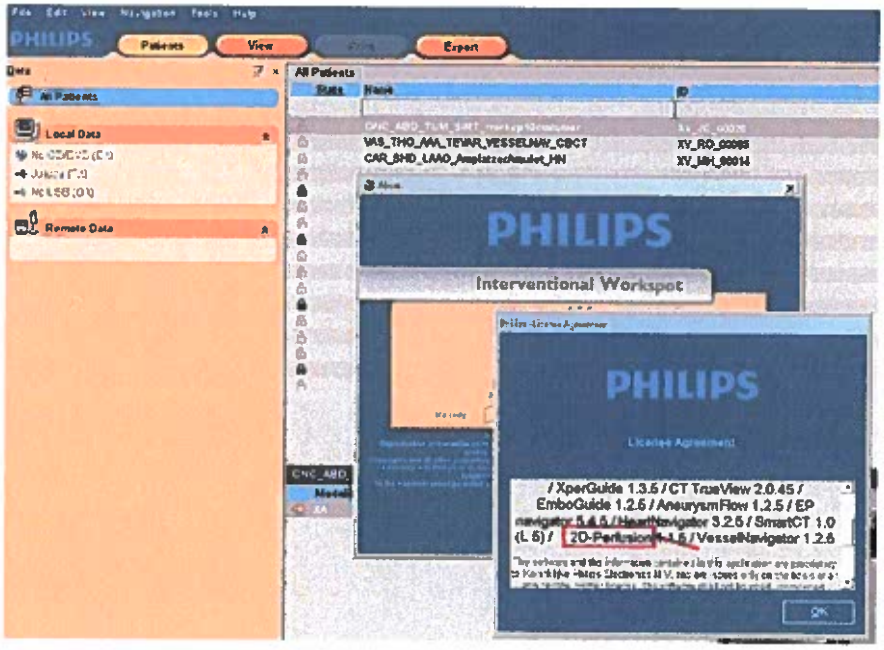
Pic 3: Check if a SmartPerfusion or 2D Perfusion license is available on the System (see red boxes and arrows)

SmartPerfusion:



2D Perfusion:



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

- Stop using SmartPerfusion and 2D Perfusion.
  - NOTE: This message does not impact (other parts of) the Philips Allura Xper or Azurion Systems or other tools within the Interventional Workspot. The Philips Allura Xper and Azurion Systems as well as other Interventional Workspot tools may continue to be used.
- Place this Urgent Medical Device Correction Letter with the documentation of the System.
- Circulate this notice to all users so that they are aware of the product issue.
- Return the attached reply form to Philips to confirm that the users of the System have reviewed and understood this Urgent Medical Device Correction letter.

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5. Actions planned by Philips to correct the problem

Philips will be disabling SmartPerfusion and 2D Perfusion from use. A Philips representative will be contacting you to schedule an appointment to disable the software (Ref: FCO72200524).

This notice has been reported to the appropriate Regulatory agencies.

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

Sincerely,

Marjan Vos
Senior Director Quality IGT Systems

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URGENT Medical Device Correction Response Form

Reference: IGT-S FCO72200524
SmartPerfusion and 2d Perfusion May Inaccurately Present Time Density Curves and Images

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 Medical Device Correction Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

Customer Actions:

- Stop using SmartPerfusion and 2D Perfusion.
- Place this Urgent Medical Device Correction Letter with the documentation of the System.
- Circulate this notice to all users so that they are aware of the product issue.
- Return the attached reply form to Philips to confirm that the users of the System have reviewed and understood this Urgent Medical Device Correction letter.

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Correction Letter and confirm that the information from this letter has been properly distributed to all users that handle the SmartPerfusion and/or 2D Perfusion software. We also acknowledge that we are no longer using the SmartPerfusion/2D Perfusion software as instructed in this communication.

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 the evidence required to monitor the progress of this Medical Device Correction.

Please return this signed form via email to: **IGT_Recalls@philips.com** or alternatively via regular mail to Philips at 222 Jacobs Street, Cambridge, MA 02141 for the attention of Mr. Roland Telson / 3rd Floor.