

**URGENT - Medical Device Correction  
IntelliSpace Portal R4.0.0**

**Incorrect values of diffusion/perfusion maps**

Dear Customer,

A problem has been detected in the Philips IntelliSpace Portal Release 4.0.0, that, if it were to re-occur, could pose a slight risk for patients or users. It concerns the following applications:

- MR Neuro Perfusion NICA209
- MR T1 Perfusion NICA212
- MR Diffusion NICA215

This Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur
- The actions that should be taken by the customer / user in order to prevent risks for patients or users
- The actions planned by Philips to correct the problem

**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 a copy with the equipment Instruction for Use.

Description of problem:

When maps are calculated using the option "Generate maps using registered data" within the perfusion package (Neuro Perfusion, T1 Perfusion) and diffusion package, there can be a problem with the outcome of maps generated in background. The found values in the maps may deviate from the true values by an unknown factor. A different color appearance in these generated maps may also occur.

This effect can be stronger in the case of perfusion scans based on PRESTO scans (Perfusion only).

NOTE: All the data available within the packages is correct, the problem only occurs when maps are generated in the background and does not occur for the previewed maps within the package (which are not registered).

Actions to be taken by the customer/user:

To generate maps with the correct values: turn off registration as the default within the application package (go to "More" option in the top of the left side bar and de-select the "Generate maps using registered data" option). Make sure that this setting is correct before using the generated data.



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Actions planned:

Philips will take appropriate corrective action and will solve the issue with a mandatory software update, via FCO78100386. This update will be implemented free of charge and you will be contacted by Philips for implementation of the corrective action.

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 KM / country>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>



## URGENT - Medical Device Correction IntelliSpace Portal R4.0.0

### Incorrect values of diffusion/perfusion maps

<b>AFFECTED PRODUCTS</b>	IntelliSpace Portal with release 4.0.0
<b>PROBLEM DESCRIPTION</b>	<p>When maps are calculated using the option "Generate maps using registered data" within the perfusion package (Neuro Perfusion, T1 Perfusion) and diffusion package, there can be a problem with the outcome of maps generated in background. The found values in the maps may deviate from the true values by an unknown factor. A different color appearance in these generated maps may also occur.</p> <p>This effect can be stronger in the case of scans based on PRESTO scans (perfusion only).</p> <p>All the data available within the packages is correct, the problem only occurs when maps are generated in the background and does not occur for the previewed maps within the package (which are not registered).</p>
<b>HAZARD INVOLVED</b>	Background maps calculated for perfusion and diffusion applications will have found values and color representations that vary from the real values. In particular, the MTT map can vary up to 100% on higher side. In the case of follow up scans for stroke patients, the MTT map is essential to evaluate how the affected areas in the brain are perfused. An incorrectly reported MTT value (on the high side) can result in a wrong interpretation of the progress of the patient and potential misdiagnosis.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	All IntelliSpace Portal with software release 4.0.0 are affected, that have the mentioned perfusion/diffusion packages installed.
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	To generate maps with the correct values: turn off registration as the default within the application package (go to "More" option in the top of the left side bar and de-select the "Generate maps using registered data" option). Make sure that this setting is correct before using the generated data.
<b>ACTIONS PLANNED BY PHILIPS</b>	Philips will take appropriate corrective action and will solve the issue with a mandatory software patch (V4.0.1), via FCO78100386. This patch will be implemented free of charge and you will be contacted by Philips for implementation of the corrective action.
<b>FURTHER INFORMATION AND SUPPORT</b>	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 KM / country>

