

URGENT - Field Safety Notice Digital Diagnost family

Special attention with use of Autostitching functionality

Applicable to: 712 050/052/055/060/062

Dear Customer,

a problem has been detected in the use of the Auto stitching functionality with Philips products listed above, that, if it were to re-occur, could pose a risk for patients. 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 educate clinical user.

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.

1 PROBLEM DESCRIPTION

The auto stitching functionality implemented in above Philips products is a computerized mechanism, which joins individual images to a combined (stitched) overview. This computerized mechanism can not fully replace the experienced decision from a radiologist. It is advised by Philips and described within the existing product manual that stitched images and their manual manipulations need to be verified by the operator and radiologist before used for diagnosis and surgery.

2 ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

The system can be used as usual. Operators and radiologist might need to be re-trained on auto stitching. At least before surgery a radiologist need to be consulted before surgery.

3 ACTIONS PLANNED BY PHILIPS

Philips will update user manual for coming installations and train their own application force. For customers with the need of re-training special on-site trainings sessions will be offered.



4 FURTHER INFORMATION AND SUPPORT

If you need any further information or support concerning this issue, please contact your local Philips representative:

Switzerland German: 0800 80 3000

Switzerland French: 0800 80 3001

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

R. Schultz
Safety Manager for Medical Devices
Philips Medical Systems DMC GmbH