

URGENT - Field Safety Notice

Digital Diagnost family, Bucky Diagnost family

Fixation problem of the Collimator

Applicable to: **704 031/032, 712 050/055/057**

Dear Customer,

A problem has been detected in the Philips products listed above, that, if it were to re-occur, could pose a risk for patients or users. 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.

1 PROBLEM DESCRIPTION

Under very special circumstances there will be a very small risk that the fixing screws for the collimator will become loose and the collimator may finally fell down. We found loose screws in our regular safety inspection. After investigation of the root causes Philips decided to start an inspection and a small modification for all collimators installed to eliminate any remaining risk.

2 ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

Due to the very low risk there are no special actions to be taken by the user. The system can be used as usual.

3 ACTIONS PLANNED BY PHILIPS

Philips will inspect all Collimators installed and take additional measures by introducing a new fixation flange to permanently assure the fixation.

4 FURTHER INFORMATION AND SUPPORT



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>

<Name>

<Function>