URGENT - Field Safety Notice
GEMINI GXL and GEMINI TF Configurations
Potential leak in the Pulmonary Toolkit (Bellows Device Accessory)

Dear Customer,

A problem has been detected in the CT sub-system of the Gemini GXL and Gemini TF PET/CT Systems, 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
- the actions planned by Philips to correct the problem.

+ - Please refer to page 2, *Hazard Involved* section for specific details.

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.

Philips has determined that some bellows may develop an air leak, which could result in being unable to produce the desired respiratory correlated images.

A Philips Healthcare Field Service Engineer will be visiting your site to test the Pulmo Toolkit to ensure it is operating properly. Then the FSE will replace certain parts of the pulmonary toolkit (bellows transducer, tubing, and pulmo digital assembly) free of charge.

In the future we recommend that the bellows be tested on each day of use. If a bellows device fails the attached test, Philips recommends that you do not use the Bellows device and contact your local Customer Care Center or to your local Philips Medical Systems office to direct any questions and to order your replacement as follows:

- North America:
  - United States: 1-800-722-9377, (option 5: Diagnostic Imaging, option 5: NM)
  - Canada: 1-800-467-1080 or 905 201 4351
- Europe:
  - +31 40 27 88700 (option 5)
  - E-mail: ECCC.NM@philips.com
- China :
  - Phone : 800 810 0038
  - FAX : 010-65181170

Philips apologizes for any inconveniences caused by this problem. We remain committed to your satisfaction and look forward to working with you now and in the future.

Sincerely,

[redacted]
Sr. Director – Quality, Regulatory, & Sustainability

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Philips Healthcare – Nuclear Medicine

AFFECTED PRODUCTS	GEMINI GXL and GEMINI TF Configurations
PROBLEM DESCRIPTION	Philips Healthcare decided to proactively recall the respiratory gating accessory due to the fact that there is a possible leak between the Tube Interface and the Outlet Tube of the transducer. This leak is caused by a manufacturing error. A system with the error will continue to function as expected, but may allow the scanner to produce images with incorrect labels. The physiology represented will still be true, however the label of each phase of breathing will no longer be correct with an error measured to be up to 10% from the true phase. For example, the inhalation image could be labeled up to 10% (in time) from actual inhalation. This is relatively insignificant compared to the natural variation in patients.
HAZARD INVOLVED	The error in the identication of the treatment area may be off by 1-3mm, however this error would be within the margin that is added to the tumor volume to account for various inaccuracies. Gemini GXL and TF systems currently have the functionality of prospective gating with a 20% window. Therefore, if this issue presents itself, the 20% window would cover the 10% phase shift. The correct anatomy is still displayed and the harm to the patient is considered negligible.
HOW TO IDENTIFY AFFECTED PRODUCTS	All products mentioned above could be affected when the bellows device is used. In order to determine if a system is affected the customer and/or field service engineer must perform the attached test procedure.
ACTION TO BE TAKEN BY CUSTOMER / USER	The customer is asked to perform a functionality test (refer to attached test procedure) each day the system is used for gating. If the device fails the test the customer is asked not to use the bellow system and to contact their local Philips office to request a free replacement of the bellows. If the device passes the test, the customer can use the bellows device. In addition, the customer is instructed to place the field test instructions with their Instructions for Use documentation.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare will start a corrective action (FCO 88200322) consisting of having a Philips Healthcare Field Service Engineer visit the site to test the bellows to ensure it is operating properly. Then the FSE will replace certain parts of the pulmonary toolkit (bellows transducer, tubing, and pulmo digital assembly) free of charge. The action is scheduled to start in April 2009.

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FURTHER INFORMATION AND SUPPORT	• If you need any further information or support concerning this issue, please contact your local Philips representative Customer Care Center as noted below: North America: ○ United States: 1-800-722-9377, (option 5: Diagnostic Imaging, option 5: NM) ○ Canada: 1-800-467-1080 or 905 201 4351 • Europe: ○ +31 40 27 88700 (option 5) ○ E-mail: ECCC.NM@philips.com • China : ○ Phone : 800 810 0038 ○ FAX : 010-65181170