# URGENT - Field Safety Notice
# Brilliance CT 6, 10, 16, 40, 64 and Big Bore Configurations

## Potential leak in the Pulmonary Toolkit (Bellows Device accessory)

Dear Customer,

A problem has been detected in the Philips Brilliance CT 6, 10, 16, 40, 64 and Big Bore configurations 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
- 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.

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. If the system does not pass the attached Field Test Instructions you will be provided with a new toolkit 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 (4535 675 18621 Rev C) Philips recommends that you do not use the Bellows device and contact your local Customer Care Center to order your replacement.

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

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

John R. Miller
Senior Director Quality and Regulatory
Philips Healthcare

# URGENT - Field Safety Notice
# Brilliance CT 6, 10, 16, 40, 64 and Big Bore Configurations

## Potential leak in the Pulmonary Toolkit (Bellows Device accessory)

| | |
|---|---|
| **AFFECTED PRODUCTS** | Brilliance CT 6, 10, 16, 40, 64 and Big Bore 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. |
| **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 test (453567452861 Rev C). |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | The customer is asked to perform a functionality test (453567452861 Rev C) 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 system. 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 (MA FCO728000396) consisting of having a Philips Healthcare Field Service Engineer visit the site to test the bellows to ensure it is operating properly. If the system does not pass the attached test instructions (453567452861 Rev C) they will be provided with a new toolkit free of charge.<br>The action will start on 02-Jan-09. |
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative: Customer Care Center (1-800-722-9377, option 5: Diagnostic Imaging, option 5: Radiation Therapy, option 3: Oncology) or to your local Philips Healthcare office. |