

URGENT - Field Safety Notice
Brilliance 6, 10, 16, 16P, 40, 64, Big Bore, iCT, iCT SP

Vertical Hub Brake Malfunction

Dear Customer,

A problem has been detected in the Philips Brilliance 6, 10, 16, 16P, 40, 64, Big Bore, iCT, iCT SP 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.

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,



Senior Director
Quality & Regulatory, CT/NM



URGENT - Field Safety Notice

Brilliance 6, 10, 16, 16P, 40, 64, Big Bore, iCT, iCT SP

Vertical Hub Brake Malfunction

AFFECTED PRODUCTS	Brilliance 6, 10, 16 ,16P, 40, 64, Big Bore, iCT, iCT SP
PROBLEM DESCRIPTION	Philips recently received a complaint that the patient table collapsed in the vertical direction with a patient on the table. Philips has determined that the root cause was a failure with the vertical brake hub of the patient support
HAZARD INVOLVED	If the vertical hub brake fails and the patient table is in an upright position when a patient is on the table, the patient could experience impact injuries (such as injuries to limbs, broken bones) due to the unexpected downward motion of the table.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Brilliance 6, 10, 16, 16P, 40, 64, Big Bore, iCT, iCT SP systems are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	If this failure does occur, stop using the system and immediately notify your Philips representative so Philips can arrange a time to install the field change as soon as possible.
ACTIONS PLANNED BY PHILIPS	A mandatory Field Change Order will be issued to repair the vertical brake hub on the patient table, free of charge. The Field Service Engineer will perform a brake hub rework on your system to solve the issue.
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: Customer Care Solutions Center, enter Site ID or follow the prompts), or to your local Philips Healthcare office.

