

URGENT - Field Safety Notice

Medical Device Correction

Brilliance 6, Brilliance 10, Brilliance 16 & 16 Power, Brilliance 40, Brilliance 64

Front Gantry Cover Fall

Dear Customer,

Philips has identified an issue with the front gantry cover on certain Philips CT gantries used on Brilliance 6, Brilliance 10, Brilliance 16 and 16 Power, Brilliance 40, and Brilliance 64 systems that, if it were to re-occur, could pose a risk to patients, users, or bystanders. 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 minimize 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. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,


Holly Wright Lee
Sr. Manager, Quality & Regulatory



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| AFFECTED PRODUCTS | All systems of the following product name and model numbers are potentially affected: <table border="1"><thead><tr><th>Product Name</th><th>Model Number</th></tr></thead><tbody><tr><td>Brilliance 64</td><td>728231</td></tr><tr><td>Brilliance 40</td><td>728235</td></tr><tr><td>Brilliance 16 Power</td><td>728240</td></tr><tr><td>Brilliance 16-Slice</td><td>728246</td></tr><tr><td>Brilliance 10-Slice</td><td>728251</td></tr><tr><td>Brilliance 6-Slice</td><td>728256</td></tr></tbody></table> | Product Name | Model Number | Brilliance 64 | 728231 | Brilliance 40 | 728235 | Brilliance 16 Power | 728240 | Brilliance 16-Slice | 728246 | Brilliance 10-Slice | 728251 | Brilliance 6-Slice | 728256 |
|----------------------------|--|--------------|--------------|---------------|--------|---------------|--------|---------------------|--------|---------------------|--------|---------------------|--------|--------------------|--------|
| Product Name | Model Number | | | | | | | | | | | | | | |
| Brilliance 64 | 728231 | | | | | | | | | | | | | | |
| Brilliance 40 | 728235 | | | | | | | | | | | | | | |
| Brilliance 16 Power | 728240 | | | | | | | | | | | | | | |
| Brilliance 16-Slice | 728246 | | | | | | | | | | | | | | |
| Brilliance 10-Slice | 728251 | | | | | | | | | | | | | | |
| Brilliance 6-Slice | 728256 | | | | | | | | | | | | | | |
| PROBLEM DESCRIPTION | Philips has identified an issue with the front gantry cover from a particular supplier, which may impact the front gantry cover of your CT system. Some covers from this supplier may develop a problem where the fiberglass weakens at the connection point to the gantry frame, causing the front cover to separate from the gantry frame, allowing it to fall. | | | | | | | | | | | | | | |
| HAZARD INVOLVED | If the top of the gantry cover were to separate from the gantry during a patient scan, the scan would stop and a rescan of the patient may be required. Additionally, if this were to occur, it could result in the following: <ul style="list-style-type: none">• Upon separation, the cover could detach and fall directly on the patient. This would also expose the patient, operator, or bystander to the internal moving parts of the system and the internal electrical components. Contact with a falling cover, moving parts, or electrical components could lead to serious injury or death.• If the gantry cover becomes detached and falls, it may come in contact with internal moving parts of the system (gantry rotor), causing internal components to be dislodged and expelled. Any patient, operator, or bystander in the path of the expelled part could sustain injury. 0.2% of the potentially affected system population have reported this failure. | | | | | | | | | | | | | | |




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| <p>HOW TO IDENTIFY AFFECTED PRODUCTS</p> | <p>To identify if your system is affected look at the device name and model number on the back of the gantry in the bottom right corner as shown in the picture below:</p>  |
| <p>ACTION TO BE TAKEN BY CUSTOMER / USER</p> | <p>There is no predictable way to identify that a failure is imminent. However, cover separation may lead to an unusual noise – such as scratching or scraping sounds – as any change in the alignment of the cover may cause it to scrape against the gantry bore. If any unusual noise is heard, discontinue use of the system immediately and contact your Philips representative for support.</p> |
| <p>ACTIONS PLANNED BY PHILIPS</p> | <p>Field Change Order (FCO) 72800703 will be deployed to initiate an inspection of the front gantry cover. If the inspection finds evidence of weakening at this connection point, a temporary repair solution will be put in place to secure the cover for continued system use. Field Change Order 72800704 will then be deployed to replace the affected front cover. A Philips Field Service Engineer will contact you to schedule the inspection of your system.</p> |
| <p>FURTHER INFORMATION AND SUPPORT</p> | <p>If you need any further information or support concerning this issue, please contact your local Philips representative. For SUPPORT North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377, follow the prompts).</p> |

