

**URGENT – Medical Device Correction
Brilliance CT 6, 16, MX8000 v. EXP and GEMINI Dual**

Oil Accumulator within the Gantry may become detached

Dear Customer,

A problem has been detected in the Philips Brilliance CT 6, 16, MX8000 v. EXP and GEMINI Dual that if it were to recur, 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

If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office. For North America and Canada contact the Customer Care Solutions Center (1-800-722-9377, option 5: Enter Site ID or follow the prompts).

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Sr. Director, Quality and Regulatory

AFFECTED PRODUCTS	All Philips Brilliance CT 6, 16, MX8000 v. EXP and GEMINI Dual are affected.
PROBLEM DESCRIPTION	A bolt which attaches the oil accumulator within the gantry may fail, resulting in the oil accumulator detaching from the tube housing assembly within the gantry.
HAZARD INVOLVED	If the oil accumulator or other parts becomes detached, and if the gantry covers are open while the unit is in service mode, a field service engineer could be struck by an ejected oil accumulator and other parts.



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HOW TO IDENTIFY AFFECTED PRODUCTS	If you have received this notification your system is affected. We have also provided a list of serial numbers affected. Your serial number is located on the back of the gantry.
ACTION TO BE TAKEN BY CUSTOMER / USER	No action needs to be taken at this point by the customer or user.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying all affected customers of this issue via this Field Safety Notice, and a Philips Field Service Engineer will schedule a time to inspect and repair all the affected systems within approximately 6 months.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. In the United States and Canada, please contact the Philips Healthcare Customer Care Solutions Center at 1-800-722-9377 and follow the recorded menu options to reach a Customer Solutions Engineer; in all other countries please dial your local Philips Healthcare office.

Attachment A
Affected Brilliance 6 Air System Serial Numbers

System Code #, 728256, Serial #:
3695, 3703, 3718, 3719.



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Affected Brilliance 16 Air System Serial Numbers

System Code #, 728246, Serial #:

3463, 3508, 3519, 3548, 3552, 3591, 3592, 3593, 3603, 3637, 3648, 3654, 3659, 3661, 3675, 3679, 3687, 3692, 5415, 5543, 5567, 5583, 5586, 5658, 5664, 5675, 5697, 5707, 5749, 5752, 5774, 5807, 5813, 5815, 5845, 5846, 5852, 5866, 5872, 5910, 5963, 5968, 6028, 6036, 6045, 6071, 6126.

Affected MX8000 Dual V. Exp System Serial Numbers

System Code #, 728130, Serial #:

8128, 8158, 8369.

Affected GEMINI Dual System Serial Numbers

System Code #, 882160, Serial #:

97, 102, 103, 105, 106, 107, 109, 110, 111, 113, 114, 115, 116, 117, 118, 121, 122, 123, 124, 125, 126, 127, 131, 132, 133, 134, 135, 136, 137, 139, 140, 141, 143, 144, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 167, 1065, 6619.

