

URGENT – Medical Device Correction

TumorLOC in Brilliance CT Big Bore, Extended Brilliance Workspace (EBW), GEMINI GXL 16, GEMINI TF 16, GEMINI TF 64, GEMINI TF Big Bore

When a Single Contour is Saved in Edit Mode, TumorLOC Fails to Save Correct Contour

Dear Customer,

A problem has been detected in the Philips Brilliance CT Big Bore, EBW, GEMINI GXL 16, GEMINI TF 16, GEMINI TF 64, and GEMINI TF Big Bore that, if it were to re-occur, could affect the performance of the equipment. This Customer Information is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of 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 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,


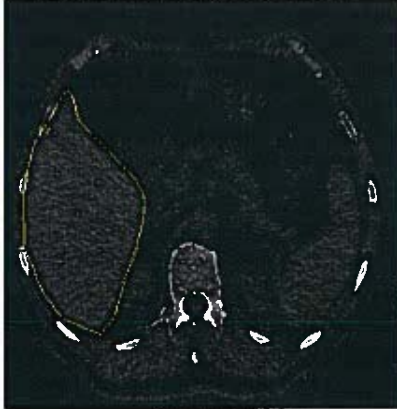
Senior Director
Quality & Regulatory, CT/NM



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<p>AFFECTED PRODUCTS</p>	<p>The following products are affected: TumorLOC in: Brilliance CT Big Bore EBW GEMINI GXL 16 GEMINI TF 16 GEMINI TF 64 GEMINI TF Big Bore</p>
<p>PROBLEM DESCRIPTION</p>	<p>TumorLOC will save the incorrect contour when the user saves the contour while in the edit mode, and the software does not force the user to exit the edit mode before saving. In TumorLOC, when saving while a contour is in edit mode, that contour will shift to the slice corresponding to the most recently drawn contour of the last organ in the Organ list.</p> <p>This occurs when using the Save button, Exit button or SendToLaser button</p> <div style="display: flex; justify-content: space-around;">   </div> <p style="text-align: center;"><i>Edit Mode</i> <i>Non-Edit Mode</i></p>
<p>HAZARD INVOLVED</p>	<p>There is a risk of unintended radiation to healthy tissue and failure to deliver radiation to target lesion. However, this is highly unlikely to occur because TumorLOC does not have the capability to create treatment plans that include dose information.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Brilliance CT Big Bore, GEMINI TF 16 and 64 Slice, GEMINI TF Big Bore, GEMINI GXL 16 Slice PET/CT Systems and Extended Brilliance Workspace (EBW) with licensed TumorLOC software application are affected. All versions of the TumorLOC application are affected.</p>



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ACTION TO BE TAKEN BY CUSTOMER / USER

Maintain a copy of this letter with the equipment Instructions for Use and follow these additional instructions.

Prior to saving, always ensure that no contour is in Edit mode. To exit from Edit mode:

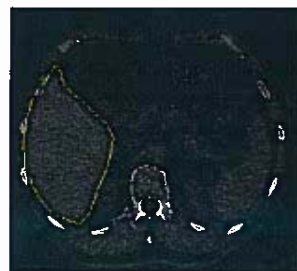
1. In the Organs workstep, navigate to the Draw/Edit Organ panel.
2. Select the Edit tool if it is not already selected:



3. Using the mouse, click on the viewer far from the edited contour:



4. The contour exits Edit mode:



The Save operation can now be safely completed.



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ACTIONS PLANNED BY PHILIPS	Philips is sending you this letter to inform you of the issue. Please maintain a copy with the equipment instructions for use.
FURTHER INFORMATION AND SUPPORT	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)

