

# SIEMENS

## URGENT MEDICAL DEVICE CUSTOMER SAFETY LETTER

To: Radiation Oncology Department  
Subject: Customer Safety Advisory – **Applicable to ARTISTE™ with syngo® RT Therapist Version 4.1 build 67**

Dear Health Care Professional,

This advisory letter has been prepared to notify you about some recently reported issues in the use of the ARTISTE™ Digital linear accelerator in combination with syngo® RT Therapist Version 4.1 build 67 and **automatic Motion of Flat Panel**

The following page will provide you with a detailed description of the issue, the condition under which this issue may occur, as well as recommendation to avoid them.

Please read this information carefully and distribute this to the responsible persons in your radiotherapy department. Please include this CUSTOMER SAFETY LETTER in your syngo® RT Therapist Express manual where it should remain until the next release of software is installed. In the interests of safety, we ask that you perform the above preventive measures and inform all affected personnel immediately.

We appreciate your understanding and cooperation in this matter and apologize for any inconvenience.

Sincerely,  
Siemens Medical Solutions  
Oncology Care Systems



*President, OCS*



*Vice-President, QPI, OCS*

**Siemens Medical Solutions USA, Inc.**

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## **Automatic motion of the flat panel**

This advisory note is to update you about a recently reported issue concerning automatic motion of the flat panel. The result of this automatic motion of the flat panel is the possibility of an injury to a patient or damage to the treatment table or accessories.

To ensure the safety of your patients and to limit damage to the equipment, we recommend that you follow the instructions below carefully.

### **What is the issue and when does it occur?**

The auto-deploy check box in the Portal Imaging Options dialog box, if unchecked, prevents automatic deployment of the flat panel from the parked position only.

If the flat panel is at the standby position (SID 160cm), the flat panel will still move automatically to the prescribed SID.

This situation occurs if successive beams have Portal Imaging enabled and, therefore, the flat panel retracts only to the standby position during the gantry rotation and not to the parked position.

If the SID has been prescribed to be very close to the patient and/or table for example to enable imaging of a larger field size, the user may have purposefully not selected the auto-deploy to ensure that manual motion of the flat panel would be required and the user need to take special precaution that a collision would not occur. However, if the flat panel is already at standby position (rather than parked position) the motion will still be automatic and the possibility of collision with the patient and/or table may exist.

### **What preventive measures can the user take?**

We kindly request that when manual motion of the flat panel is required, users should in addition, add a manual pause to the treatment beam before the imaging segment, this will ensure that manual motion will be required at all times regardless as to whether the flat panel is in the parked or standby positions.

### **How will this issue be resolved?**

Update Instruction TH034/08/S or TH038/08/S will resolve this issue, depending on product configuration. The updates will be released free-of-charge to all affected ARTISTE™ systems.

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