

Urgent: Medical Device Correction **Safety Advisory Notice**

Attention: Radiation Oncology Department
Subject: Customer Safety Advisory Notice – Applicable to ARTISTE™ digital linear accelerators with *syngo*® RT Therapist version 4.1 connected to LANTIS™

Dear ARTISTE customer,

This letter is intended to inform you about a potential safety issue related to patients intended for treatments on the ARTISTE digital linear accelerator as well as on other Siemens or non-Siemens branded linear accelerators. As a consequence of this issue, treatment plans might be inadvertently edited and patients may be mistreated.

What is the issue and when does it occur?

When a patient is loaded in the *syngo*® RT Therapist version 4.1 (RTT), all plans for this patient are included. This also includes plans intended for treatment on machines other than ARTISTE. When editing a beam of any plan on RTT the accessory information available in LANTIS can potentially be overwritten or removed. The result of this unintended update could be a mistreatment of a patient on the other linear accelerator as the accessories would be removed.

This problem can only occur if the block field in LANTIS is used to specify a block accessory which is not a valid Siemens block accessory (see Annex 1). Additionally RTT is showing incorrect accessory information for beams that contain those, a block tray and any physical accessory (wedge or applicator). Since the Artiste has only one accessory slot only either physical accessories or block trays can be supported. In case a TxField is defined in LANTIS which contains those, a physical accessory and a block tray, RTT will only show either the physical accessory or the block tray. In case such a beam is edited by the user on RTT the accessory/block tray which was not shown is also removed in LANTIS.

Annex 1 provides a list of valid block codes which can be used safely for a beam to be treated with Siemens ARTISTE.

In summary, the unintended update of accessory information occurs only under the following circumstances:

- A non-valid Block Accessory is specified in the LANTIS block field **OR** multiple physical accessories are specified in LANTIS (e.g. real wedge and block) **AND**
- The beam is edited in any way on RTT and saved

If these conditions are met the accessory information in LANTIS is updated unintentionally.

What preventive measures can the user take?

In order to avoid unintended changes to the accessories in treatment beams, we advise to strictly adhere to the following recommendations:

Recommendation 1:

Do not edit beams on the RTT for plans that are not intended for treatment on the ARTISTE.

Recommendation 2:

Please ensure to use only valid block codes (see Annex 1) in the block field of LANTIS for a beam intended to be delivered with ARTISTE.

Note:

Please note that the ARTISTE has only one accessory slot as depicted in Digital Linear Accelerator Operator Guide, Chapter 3, System Overview / Accessory Holder and therefore the plan must not include more than one physical accessory.

What will Siemens do to address this issue?

A SW update addressing this issue will be released as soon as possible.

Please include this Safety Advisory Notice in your *syngo* RT Therapist 4.1 System Owner Manual, chapter "Safety Advisory Letters", where it should remain until the measures defined above are performed. If you have any questions regarding the accessory codes or field attributes, please contact your responsible SIEMENS Service Engineer or Application Specialist.

In the interests of safety, we ask that you perform the above preventive measures and inform all affected personnel immediately.

The relevant National Competent Authority has been informed of this Safety Advisory Notice.

We regret any inconvenience that this may cause, and we thank you in advance for your understanding.

Sincerely,

Siemens Medical Solutions USA, Inc.
Oncology Care Systems



President, OCS



Vice-President, QM, OCS

Annex 1:**List of accessory codes, which are supported by Siemens MLC**

This list corresponds with the presently supported block codes on ARTISTE digital linear accelerators.

These values shown below can be decoded. Any other value will potentially lead to an error. **Please note that the format is case sensitive.**

Description	Code	Variables
Custom Beam Block Tray	BTxxxM	xxx – Numeric identifier (001 - 220)
Standard Holed Beam Block Tray	TRAYHM	
Standard Solid Beam Block Tray	TRAYSM	