

# SIEMENS

## URGENT: MEDICAL DEVICE CUSTOMER SAFETY ADVISORY NOTICE

To: Radiation Oncology Department  
Subject: Motion Enable Switch for Therapy Simulator Systems

Dear Valued Siemens Customer:

This advisory letter is to inform you of a recently reported event concerning the motion enable switch that is used with the following systems:

- SIMVIEW 3000
- SIMVIEW NT
- MEVASIM S

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

It has been reported that an unintended motion of the X-ray arm may occur when the hand control is partially inserted in the new bracket as illustrated in Figure 1. This may cause the motion enable switches to depress and activate X-ray arm motion which could lead to potential patient injury.

Upon investigating the situation, we found that MecaSim (formerly know as Mecaserto) had introduced this newly designed storage bracket for the hand control.

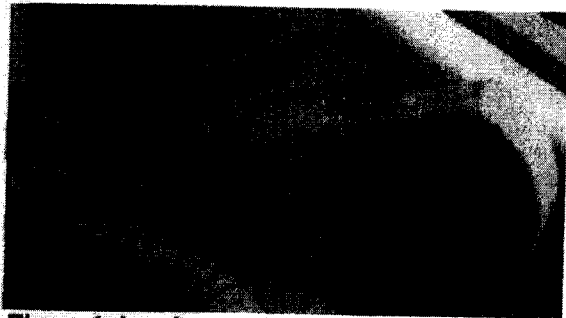


Figure 1: hand control partially inserted

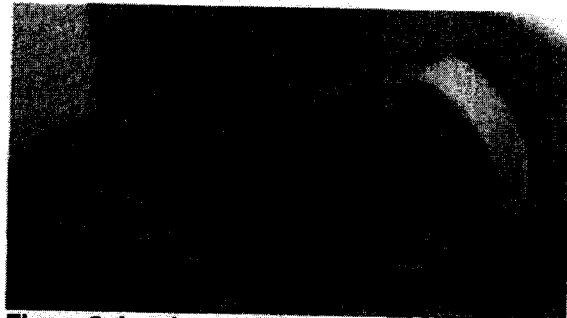


Figure 2: hand control fully inserted

### What can the user do?

To safely operate this device, it is important to ensure that the hand control is fully inserted in the bracket as illustrated in Figure 2. This will prevent activation of the motion enable switches.

Siemens Medical Solutions is working closely with MecaSim to improve the current hand control holder design.

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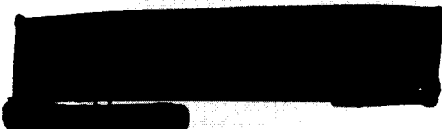
[www.siemensmedical.com/oncology](http://www.siemensmedical.com/oncology)

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Update TH021/08/S will be released, free of charge, to all affected systems.  
You will be contacted by your local service representative to schedule an appointment for implementing the improved hand control holder design.

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

Sincerely,  
Siemens Medical Solutions  
Oncology Care Systems



*CEO, Oncology Care Systems*



*VP, Quality Management / Regulatory  
Affairs*