

Siemens Healthcare GmbH, HC CP XP MK, Allee am Röthelheimpark 2,  
91052 Erlangen

<To the person in charge of the unit where the SIEMENS product is operated, and the administrative head of organization>

Contact person of  
the Regional Unit  
Department

Telephone  
Fax  
E-Mail

Date

### **Field Safety Notice**

– To all users of the MODULARIS Variostar

Contact person of  
the Business Unit  
Department

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Date

### **Re: MODULARIS Variostar with display freeze on MODULARIS hand control**

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients:  
Display freeze of MODULARIS hand control results in information not being updated on the display.  
Current treatment data are not shown to the user.

#### **When does this malfunction occur and what are the potential risks?**

On rare occasions the display of the MODULARIS hand control freezes and the information on the display is not updated. Neither the number of applied shock waves nor other parameters which have been changed by the user on the hand control will be displayed. This might result in insufficient information for the treatment.

#### **What steps can the user take to avoid the potential risk of this issue?**

- Whenever parameter changes are performed on the MODULARIS hand control, please ensure that the display is showing the new updated values.
- If the display of the MODULARIS hand control freezes, interrupt the treatment immediately.
- Disconnect the MODULARIS hand control from the basic unit MODULARIS Variostar and reconnect it. The hand control will initialize automatically and will show the correct values. Then the treatment can be continued.

Unrestricted

**Siemens Healthcare GmbH**  
Management: Bernhard Montag, Chairman;  
Thomas Rathmann, Michael Reitermann

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Chairman of the Supervisory Board: Siegfried Russwurm  
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WEEE-Reg.-No. DE 64872105

Currently the potential malfunction of incorrect treatment data display can only be mitigated by the user checking that the hand control's display is showing the new updated values after parameters have been changed.

### **How will the issue finally be resolved?**

We are working intensely to provide a solution which permanently resolves the potential malfunction. As soon as this solution is available, all affected systems will be updated.

We appreciate your understanding and cooperation with this field safety notice and ask you to immediately instruct your personnel accordingly. Please ensure that this field safety notice is placed in the system's instructions for use. Your personnel should maintain awareness until the modification has been implemented.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this field safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely yours,



*Ronan Kirby*  
Head of Service Ireland



*Andrew Rennie*  
Service Supervisor AX/XP

**Acknowledgement of receipt**

Customer address:

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I hereby confirm as the owner / responsible operator of the **MODULARIS Variostar** with the Serial number \_\_\_\_\_(optional) that I received the following document:

**Field Safety Notice**

**MODULARIS Variostar with display freeze on MODULARIS hand control**

Place, Date \_\_\_\_\_

Name \_\_\_\_\_

Signature \_\_\_\_\_