

HS DOMS GmbH, Langenschader Strasse 67, D-07318 Saalfeld

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Department: Quality Management
Contact person: Andy Ölsner
FSCA reference: C-101

date: 1. June 2021

Field Safety Corrective Action (FSCA) Urgent recall at a medical product: appendix to instructions of use of HSM 600

Dear Sir or Madam

Hereby we want to inform you about a Field Safety Corrective Action for the medical product HSM 600. This corrective action contains an appendix to the instruction of use for all devices from type HSM 600.

identification of concerned medical products:

You can find the name plate at the bottom side of the control panel. There is noted the product name **HSM 600** and one of the following reference numbers:

3320087
3320088
3320089
3320090

problem description

if the feet of the user or patient are placed on the base plate, they can be clamped when the table will be lowered in this situation. This could lead to an injury of user or patient. Until now we do not have some feedback about injuries.

Measures that the customer must execute

Before changing the height of the table, the user must ensure, that the path of movement is clear of obstruction. An appendix to the instruction of use is sent together with this letter. It includes a safety note for the further safe use of the HSM 600 instrument table. The user must pay attention to this safety note! Please add it to your existing instruction of use and keep both together.

Fill out the attached acknowledgement formular, please, and send it back to the specified address.

Forwarding this information

Please ensure in your organisation, that all users of the product above-mentioned and all other relevant persons will be informed about this Field Safety Corrective Action. If you delivered the product to others, please forward a copy of this information to them, or inform the contact person specified below.

Please keep this information at least until this Field Safety Corrective Action is finished.

The German federal Institute for Drugs and Medical Devices has received a copy of this Field Safety Corrective Action.

Amtsgericht Jena HRB 510890
Geschäftsführer:
Matthias Stahl

Commerzbank Saalfeld
IBAN: DE 16 8204 0000 0655 3259 00
SWIFT (BIC): COBADEFFXXX
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info@hs-doms.eu



Contact persons

If you have question about this Field Safety Corrective Action, you can contact one of the following persons:

Mr. Andy Ölsner
Tel. 03671 / 545018
E-Mail: oelsner@hs-doms.eu

Mr. Michael Koch
Tel. 03671 / 545017
E-Mail: koch@hs-doms.eu

We regret the inconvenience caused and want to apologize for that.

With best regards

HS DOMS GmbH

acknowledgement formular

Field Safety Corrective Action: C-101

date: 01/06/2021

concerning product: HSM 600

reference numbers: 3320087
3320088
3320089
3320090

<input type="checkbox"/>	I confirm the receipt of the Field Safety Corrective Action C-101 and that I read and understood the information
<input type="checkbox"/>	The information and corrective actions were forwarded to all relevant persons and organisations
<input type="checkbox"/>	The additional information in the sent appendix document was added to the instructions of use

signature: _____

surname, first name: _____

department: _____

place, date: _____

Please complete the formular, sign it and then send it per e-mail to oelsner@hs-doms.eu.