



TRUMPF Medizin Systeme GmbH + Co. KG

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Reference No.: MOD1307

Urgent Field Safety Notice

Subject: TruSystem®¹ 7500 Operating Table Column

Type of action: On-Site Modification

Date: May 2020

Legal Manufacturer: TRUMPF Medizin Systeme GmbH + Co. KG - Carl-Zeiss-Straße 7-9 –
07318 Saalfeld

Attention: Facility Administrator, Facility Engineer, Biomedical Engineering, Medical Device Liaison
Officer, User

Affected Devices:

Product Name	Model Number Trumpf Medical	Manufacturing date	Serial Numbers
Mobile column TruSystem® 7500	1717023	30-Aug-2013 and 26-Sep-2016	101632106; 101751483; 102004758; 102608651; 102678193; 102691232; 102715145; 102715192; 102722154; 102722169; 102806380; 102806382; 102816384; 102816385; 102816386; 102816387; 102816389; 102818920; 102818921; 102818923; 102818924; 102818925; 102818926; 102872177; 102872178; 102872179; 102872180; 102872181; 102872182; 102872183; 102897189; 102899488; 102921553; 102926555; 102932723; 102958280; 102958281; 102988599; 102988600; 102988845; 102988847; 102988848; 102988854; 102999976; 102999977
TruSystem® 7500 Hybrid (MC)	1773204	26 -Jan-2015	102457048

¹ TruSystem® is a registered trademark of TRUMPF GmbH+ Co. KG
QS10051 213839 REV 1

GD: QS14251

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Unlimited Liability Partner: TRUMPF Medizin Systeme Beteiligungs-GmbH, Puchheim,
Amtsgericht München HRB 139265
Managing Board: Francisco Canal Vega, Simone Faath, Josef Selinger

**Description of the problem:**

Hillrom has become aware that the table-top height adjustment mechanism may become damaged when the TruSystem® 7500 column is moved using the Shuttle during a non-patient transport procedure (the column is placed in the Shuttle). A specific version of software allows the column to move automatically to a reset position if the column is turned OFF [either manually or automatically (after four hours of no operation)] then turned back ON.

This reset movement can cause the base plate of the column to collide with the Shuttle frame. The collision may cause the spindle to break or fracture due to the high tensile force applied while it is trying to move to the reset position.

There is currently no inspection method to see if damage has occurred. If you suspect that your column may have been turned OFF and then back ON during non-patient transport while in the Shuttle, proceed to take the column out of service. If the column were to fail while in use, critical to catastrophic injury could be sustained by the user and/or patient as the table-top could without notice, lower to the lowest position suddenly. No reports of injury have been received

Actions to be taken:

To avoid any possible risk to patients or users, you should not use the above mentioned TruSystem® 7500 Operating Table columns if you are aware of any collision with the Shuttle frame.

Inform all users to not turn OFF or store the column within the shuttle for any length of time and to return it to the floor as soon as possible after relocation of the column.

Your Hillrom representative will contact you to arrange a time to perform the correction. Please work with the representative to implement this action promptly with as little disruption to your facility as possible.

Transmission of this information:

Please communicate this urgent field safety notice to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).

If you have any questions concerning this Medical Device Correction, please contact MedicalDevicesEMEA@hillrom.com or your local Hillrom representative.

With best regards,

Florian Denk
Director QA Trumpf Medical