



mTRUMPF Medizin Systeme GmbH + Co. KG  
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## TRUMPF Medizin Systeme GmbH + Co. KG

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March 2020

**Reference No.: MOD1304**

# Urgent Field Safety Notice

## Field Safety Corrective Action

Concerning

## Charging Unit remote control TruSystem 7500

**Type of action:** On-Site Modification

**Date:** Marc 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
Charging Unit mounted T DC TS 7500	1537208	15 <sup>th</sup> September 2010 until 21 <sup>st</sup> February 2019	All serial numbers of this model are affected

Document Number: 103751

[www.trumpfmedical.com](http://www.trumpfmedical.com)

TRUMPF Medizin Systeme GmbH + Co. KG, Sitz Saalfeld, Amtsgericht Jena HRA 502248  
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/Trumpf Medical has become aware, since the standard IEC 60601-1-2:2014 has changed, that the Charging unit mounted T DC TS7500 may not comply with the EMC requirement (during charging) anymore. Therefore, it may not be safe for continued use, as it may have negative effects on other nearby electronic equipment. We have identified that our device may have radiated emissions exceeding the standard limit value of 40 dBµV/m by up to 8.39 dBµV/m. As indicated, it only exceeds the limits when charging.

**Actions to be taken:**

In the coming weeks, you will be contacted by one of our representatives who will ask you specific information about your installation and come with an adapted replacement solution. They will schedule a time for a Hillrom technician to come to your facility and change the affected charging unit. Until we are able to visit your facility, we ask that you not use the charging station during any medical procedures. It may be used once all clinical procedures are concluded. Please work with the representative to implement this action promptly with as little disruption to your facility as possible.

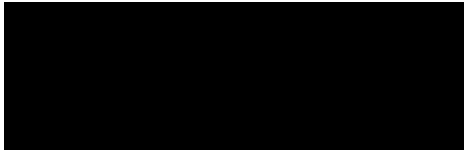
**Transmission of this information:**

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@hill-rom.com](mailto:MedicalDevicesEMEA@hill-rom.com) or your local Hillrom representative.

With best regards,



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