

TRUMPF Medizin Systeme GmbH + Co. KG
Postfach 24 44 07318 Saalfeld Germany

TRUMPF Medizin Systeme GmbH + Co. KG

Carl-Zeiss-Straße 7-9
07318 Saalfeld

Phone +49 3671 586-0
Fax +49 3671 586-41105

info@trumpfmedical.com
www.trumpfmedical.com

Your contact Ms Julia Bielmeier
Fax extension +49 3671 586 41 175
E-Mail TM_FSCA_MOD@Hill-Rom.com
Date December 2017

Reference No.: MOD1273

Urgent Field Safety Notice
Corrective Action
concerning
TruVidia™ Wireless Receiver

Please forward this information to all affected users and the medical technical department!

Dear Customer,

We would like to inform you of an issue with the TruVidia™ Wireless Receivers, which could potentially result in harm to patients as described below. TruVidia™ Wireless Receiver is a part of the TruVidia™ Wireless camera system. The issue is limited to the model number and serial numbers listed below.

Product Name	Model Number	
TruVidia™ Wireless Receiver	1940747	

Description of the problem

During internal testing, Trumpf Medical discovered that the radiated emission from the TruVidia™ Wireless Receiver is above the normative accepted limits. It is unlikely, but possible, that the radiated emission may interact with other devices in the operating room, which may cause other devices to not function properly. The frequency of interference and associated risk will be dependent upon the immunity of the other devices for radiated emissions and nature of the failure mode of the operating room equipment being used at the time.

Trumpf Medical has not received any complaints or allegations of injury related to this issue.

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

Enhancing outcomes for
patients and their caregivers:

Hill-Rom

Actions to be taken by the Customer

Complete and return the "Confirmation of Receipt" attached to this letter; as this will allow us to determine the appropriate upgrade components for your equipment. The Trumpf Medical service organization or an authorized dealer will be contacting you to arrange an appointment for an authorized Service Engineer to upgrade your TruVidia™ Wireless Receiver.

If you suspect that the device may be interacting with other devices in the operating room, switch off the TruVidia™ Wireless Receiver* and contact Trumpf Medical.

*Please ensure the TruVidia™ Wireless Receiver is switched off, it is not sufficient to switch off the camera or any control unit.

Passing along this information

Please make sure that all users of the devices listed above as well as any other personnel who must be informed in your organization have been made aware of this **Urgent Field Safety Notice**. If you have provided devices to third parties, please forward them a copy of this notice, or inform your Trumpf Medical contact person.

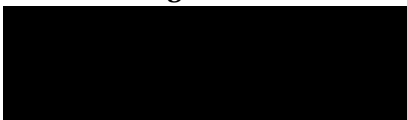
Please keep this notice at least until the action has been completed.

The appropriate Regulatory Agency has received a copy of this Urgent Field Safety Notice.

Confirmation of receipt

Please confirm that you have received this Urgent Field Safety Notice by sending back the completed form listed in Appendix 1 within two weeks after the receipt of this letter.

With best regards,



Florian Denk
Medical Device Safety Officer Trumpf Medical

Enclosures:

Appendix 1 Confirmation of Receipt