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Your contact  
Fax extension  
E-Mail  
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	Serial Numbers
TruVidia™ Wireless Receiver	1940747	102584474 to 103214022

### 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](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

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.

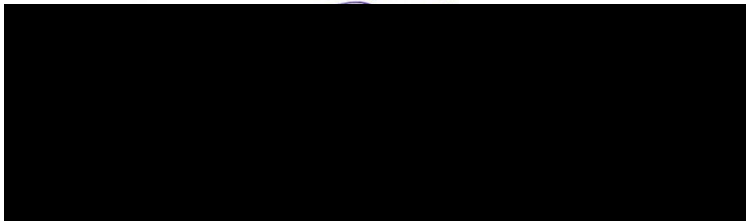
Please keep this notice at least until the action has been completed.

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,



### **Enclosures:**

Appendix 1      Confirmation of Receipt

# Appendix 1

Confirmation of Receipt and Questionnaire - MOD1273



## **Urgent Field Safety Notice - TruVidia™ Wireless Receiver**

Please return this confirmation within 2 weeks after receiving the safety notice to:

Fax                    fill in the Trumpf Medical Partner contact information                    or  
E-mail                fill in the Trumpf Medical Partner contact information                    **(Subject: "MOD1273")**

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Please enter your address here:

- Affected devices are in use at this facility
- None of the affected devices are in use at this facility
- Affected devices are no longer at this facility and were donated/resold (in this case, please provide any contact information available)

If any of the affected devices are in use, please complete pages 2 and 3.

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***With your signature, you acknowledge that you have received the Urgent Field Safety Notice with reference "MOD1273" and understand the outlined risks.***

Name in block capitals / position: \_\_\_\_\_

Tel.: \_\_\_\_\_ E-mail: \_\_\_\_\_

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

# Appendix 1

## Confirmation of Receipt and Questionnaire - MOD1273



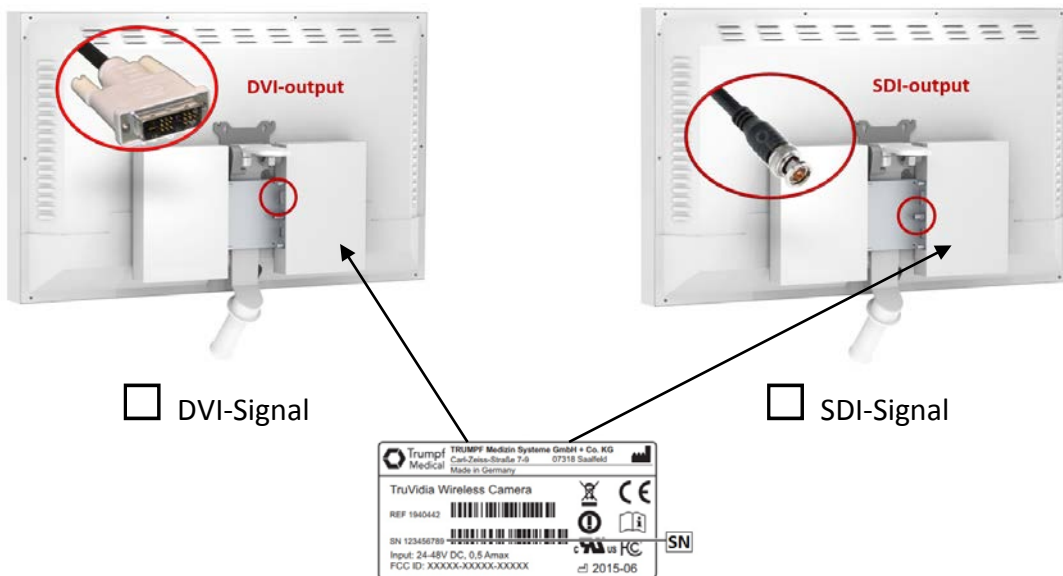
Dear customer,

Please complete the following checklist regarding your TruVidia™ Wireless Receiver installation. This helps us providing you a replacement kit as quickly as possible.

This questionnaire must be completed for each installed TruVidia™ Wireless Receiver.

**Serial Number TruVidia™ Wireless Receiver** \_\_\_\_\_

**Which video-signal output do you use? Please have a look at the rear side of your receiver / monitor:**



The Serial Number (SN) is located at the rear side of the TruVidia™ Wireless Receiver housing.

**Where is the receiver installed?**

- directly behind a monitor
- another location in the Operating Room

If the receiver is not mounted directly behind a monitor, please try to describe the location in as much detail as possible:

# Appendix 1

Confirmation of Receipt and Questionnaire - MOD1273



**How long is the cable between monitor and receiver?**

< 50 cm, as the receiver is directly behind a monitor

> 3 m, through the support arm system

Anything else you would like to mention:

**To which kind of monitor is the receiver connected?**

Monitor

Video routing system

Manufacturer \_\_\_\_\_

Type \_\_\_\_\_

Which signal inputs does the monitor  
or video routing system provide?

DVI-Signal

SDI-Signal

both