

TRUMPF



TRUMPF Medizin Systeme GmbH + Co. KG
P.O Box 24 44 · 07310 Saalfeld · Germany

TRUMPF Medizin Systeme GmbH + Co. KG

Carl-Zeiss Strasse 7-9
07318 Saalfeld – Germany

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

med@trumpf.com
www.trumpf.com

Date 10.10.2012

Urgent Safety Information

Corrective action

concerning

TruSystem 5500 operating table system

Dear customer and user,

As part of our product observation in the field, we feel compelled to inform you about risks to patients and users that may arise with the use of the following products:

Name	Item no.	Serial no.
TruSystem 5500 SM operating table column	1607822	101353767 - 101674401
TruSystem 5500 SF operating table column	1607823	101255225 - 101676363

Description of the problem including the established cause:

Several users have informed us of availability problems with the TruSystem 5500 operating table system. In some tables this is characterized by the fact that certain functions are temporarily unavailable, up to system failure.

The causes of the failed system have been isolated to the system software (programming error), the column keypad (manufacturer's production error), and the motor controller (manufacturer's design error).

What measures should the user take?

In case of a failure, the system can usually be returned to a functioning state quickly by switching the operating table column off and then on (the "OFF" key has to be pressed at least 2 seconds) or through a reset (described in the user manual).

Management:
Dr.-Ing. Eckhard Meiners (Chairman)
Dr. rer. nat. Klaus Frank

TRUMPF Medizin Systeme GmbH + Co. KG, Saalfeld
Jena District Court Reg. 502248
VAT ID No. DE 813 231 480, Tax No. 117/178/51406
Part. TRUMPF Medizin Systeme Beteiligungs-GmbH, Puchheim HQ
Munich District Court Reg. 139265

To permanently correct the possible errors, TRUMPF will retrofit the hardware and software of all affected operating table systems. To this end, our Technical Customer Service or customer service partners will get in contact with you soon and arrange an appointment. Please designate a corresponding contact person for your site and enter that information in Appendix 1 to this letter.

Disclosure of the information contained herein

Please ensure that within your organisation, all users of the above-mentioned products and other relevant persons shall be informed about this **Urgent Safety Information**. If the products have been passed to third parties, please forward a copy of this information or inform the contact person mentioned below.

Please store this information at least until this measure has been completed.

The National Competent Authority has received a copy of this "Urgent Safety Information".

Confirmation of receipt

Please confirm the receipt of this Urgent Safety Information by sending us the completed form in Appendix 1.

TRUMPF contact:

TRUMPF Medizin Systeme GmbH + Co. KG

Ms. Madlen Fischer

Carl-Zeiss-Str. 7-9

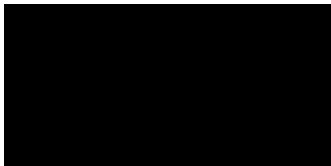
D-07318 Saalfeld

Tel. +49 3671 586 41423

Fax +49 3671 586 41175

med-service@de.trumpf.com

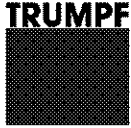
www.trumpf.com



Head of Quality Management

Attachments:

Appendix 1 Confirmation of User Receipt



TRUMPF Medizin Systeme GmbH + Co. KG
Carl-Zeiss-Str. 7-9
07318 Saalfeld Germany

Appendix 1

Confirmation of User Receipt

Urgent Safety Information TruSystem 5500 operating table system

Please return this confirmation within 1 week after receiving the safety information to:

Fax or
email (Subject: "TruSystem 5500")

Please enter your address here:

By signing, you are confirming receipt of the Urgent Safety Information for the TruSystem 5500 operating table system.

Name in block capitals / position:

Tel.: E-mail:

Place / Date: Signature: