

Urgent Safety Information

concerning
**Remote controls for
JUPITER, ARTIS and TruSystem 7500 operating tables**

Dear customer and user,

We are informing you of a potential risk for patients and users which could arise when using the below described devices.

Please note: The TruSystem 7500 operating tables are only affected by this action if they are used together with one of the mentioned remote controls. Other versions of remote controls are not affected.

Affected Remote Controls (to be replaced):

Remote control name	Material no.	Serial no.
Cable remote control JUPITER U	4500119	to (incl.) 102306915
Cable remote control JUPITER / TS7500	1601926	to (incl.) 101465919
Cable remote control JUPITER	4544119	to (incl.) 102284378
IR remote control JUPITER U	4500120	to (incl.) 102306940
IR remote control JUPITER / TS7500	1601927	to (incl.) 102222333
IR remote control JUPITER	4544120	to (incl.) 102006720
(R)IR remote control JUPITER	1219656	to (incl.) 102317869
(R)Cable remote control JUPITER	1219655	to (incl.) 101998119
Cable remote control JUX	1307315	to (incl.) 101287649
IR remote control JUX	1307314	to (incl.) 102338310
Cable remote control JUC, BUTTON	1239823	to (incl.) 100143048
IR remote control JUC, BUTTON	1239824	to (incl.) 100139854

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Operating tables which are operated with the affected remote controls:

Operating table name	Material no.	Serial no.
Mobile column JUPITER System U	4500113	all serial numbers
Mobile column JUPITER System Miyabi U	1574977	
Mobile column JUPITER System Miyabi	1591767	
Operating table column JUPITER SM 360 U	1389824	
Mobile column JUPITER System 360	1381431	
Mobile column JUPITER System	4544113	
Operating table column JUPITER SF U OCE	1622774	
Stationary column JUPITER System U	4500112	
Stationary column JUPITER Myiabi	1600198	
Stationary column JUPITER System 360	1225297	
Stationary column JUPITER System	4544112	
Floor mounting column JUPITER U	1276277	
Floor mounting column JUPITER 360 U	1389826	
Floor mounting column JUPITER	1271282	
LIFTING COLUMN	4544150	
BLANCOMATIC FOR JUPITER	4544471	
Operating table JUPITER UNIVERSAL U	4500170	
OR-Table JUPITER UNIVERSAL Carbon X-TRA	1302594	
OR-Table JUPITER UNIVERSAL CARBON U	1223188	
OR-Table JUPITER UNIVERSAL CARBON	1223187	
JUPITER UNIVERSAL Operating table	4544170	
Operating table JUPITER UNIVERSAL	4549170	
Stationary column ARTIS	1519807	
Floor mounting column ARTIS	1501878	
Floor mounting column TruSystem 7500	1501877	all serial numbers, but only in use with one of the affected remote controls
Floor mounting column TS 7500 U	1623698	
Stationary column TruSystem 7500	1454299	
Stationary column TruSystem 7500 NET	1583799	
Stationary column TruSystem 7500 U	1476269	
Mobile column TruSystem 7500	1454298	
Mobile column TruSystem 7500 U	1476268	

Description of the problem, including determined cause:

Trumpf Medical received reports stating that the affected operating tables sporadically moved independently and without the user deliberately pressing an operating element. No patients or users were injured. The reported incidents took place unexpectedly during preparation or a surgery. The individual investigations determined that the root cause was a button on a remote control which was mechanically damaged by external influences. The defective button correlates with each registered direction of motion. A damaged button can be caused by e.g., collision with other objects or even being jammed between two moving parts. As a result, specific vibrations or movements of the remote control can emit a valid movement command at any time, either continuously or sporadically. The operating table cannot differentiate this command from a wanted movement command.

Investigations carried out by Trumpf Medical determined that remote controls, which to some extent have considerable damages are being used and must therefore, no longer be used. Independent movements can be avoided with the appropriate tests prior to utilization.

What measures should be taken by the user?

Complete and return the attached Confirmation of Receipt (Attachment 1) to the stated contact. Trumpf Medical will then arrange the upgrade of your existing remote controls with a redesigned membrane keypad to eliminate the known mode of failure. The new membrane keypad is not visibly different from the previous version.

Affected TruSystem 7500 customers will get the original remote controls for this operating table system in the scope of this action.

Until we send you new remotes the following measures are necessary:

The remote control must be inspected for damages before each use. This significantly reduces the risk for the aforementioned possible errors. This can be executed as follows:

- Visual check - Inspect for visible damages, particularly on the membrane keypad. No visible damage is acceptable.
- Touch and functional check of keypad buttons – Check each button on the keypad as if you were initiating that function. There must be a concise key motion felt and the user must hear a distinct "clicking noise" during both the depression and the spring back of the button. In addition, ensure that the function of that button leads to the execution of the corresponding movement on the operating table, and when it is released ensure that the movement stops immediately. No damage to buttons is acceptable.
- Loose or damaged component check – If when handling the remote the user can hear a rattling noise indicating the possibility of loose or damaged components it should be assumed that there are damaged components. No loose or damaged components are acceptable

If the checks identify any unacceptable defects as described above then the remote control may not be used. Please contact Trumpf Medical prior to further use of the device. Care must be taken to ensure that the remote control is protected against damages and stored in a secure place when it is not being used.

If the remote control is undamaged then it can still be used. It is important to ensure that the remote control is protected from damage and stored properly at all times. If any event occurs

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during surgery or at any other point that may have caused damage to the remote then stop use of the remote until checks can be made again in a controlled manner without a patient on the table.

If an unintended movement occurs then it can be stopped as described in the attached Supplement to the User Manual (Attachment 2).

As additional alternatives to the above:

- The user can unplug the table from the main wall outlet and turn the table off from the column keypad during surgery
- The cable remote can be unplugged from the operating table during surgery.

Passing on this information

Please make sure that, in your organization, all users of the products listed above as well as any other personnel who must be informed, have been made aware of this safety information.

A copy of this safety information and the attached supplement must be stored together with the respective user manual of the operating table.

If you have provided products to third parties, please forward them a copy of this information, or inform the contact person listed below.

Confirmation of receipt

Please confirm to us that you have received this Safety Information by sending us back a completed form from Attachment 1. The on-time return will stop you from receiving further letters on this issue. We ask emphatically for executing these measures to guarantee patient security and we ask for your understanding.

Trumpf Medical contact person:

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Dr. Manfred Fehn

Head of Quality Management

Attachments:

Attachment 1 Confirmation of receipt

Attachment 2 Supplement to the User Manual

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