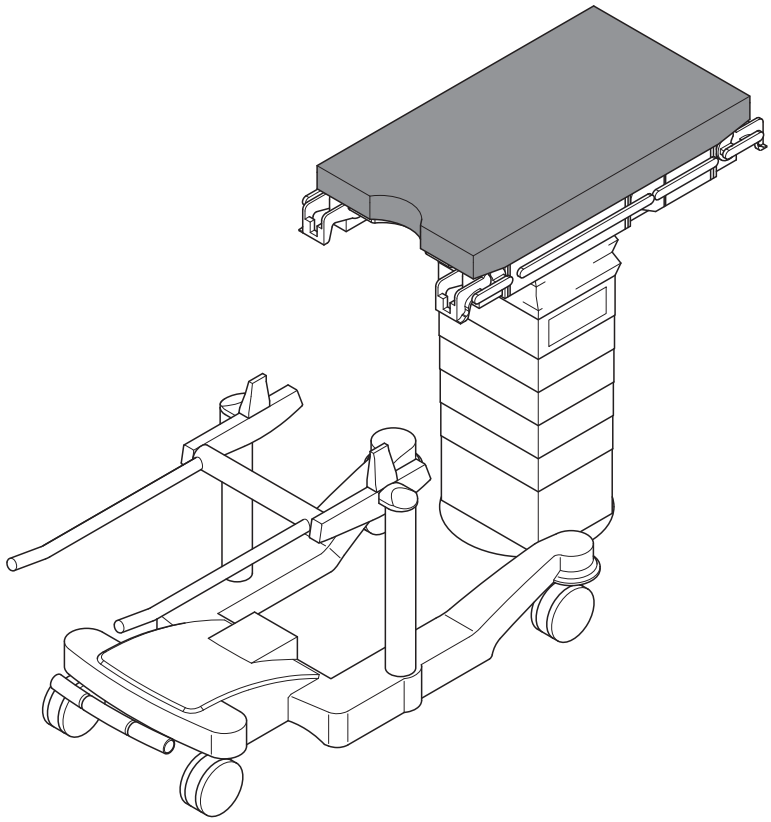
Instructions for use

TruSystem 7500

Surgical table, configurable



Read the instructions for use carefully before using the product and keep them safe for future reference.

ENGLISH
en-US

This page is intentionally blank.

Manufacturer

Baxter Medical Systems GmbH + Co. KG
Carl-Zeiss-Straße 7–9
07318 Saalfeld
Germany

Phone: +49 3671 586–0
Fax: +49 3671 586–41165

surgical@hillrom.com
hillrom.com

Baxter Medical Systems GmbH + Co. KG is a Baxter International Inc. company. The manufacturer is hereinafter referred to as Baxter.

Technical Customer Service

The contact details for the current Technical Customer Service hubs in the individual countries are listed on the Internet at www.hillrom.com.

Information about the document

Original instructions for use

Document number: 7990010
Language ID: 030
Version: 08
Part number: 2078288
Date of publication: 2023-01-19

These instructions for use are included in paper form in the scope of the product supply.

This document applies to the following sales units:

Product designation	Part number
Operating table	
TruSystem 7500	4091000

Supporting documents

The following additional documents are available online under ois.hillrom.com/ois:

Product designation	Document number
Compatibility matrix	7990090
Radio Information	7990101
SVHC list (Substances of Very High Concern)	–

This page is intentionally left blank.

Basic information

After purchase, the product is handed over to the operator in an appropriate and professional manner. Handover is performed by someone authorized by the manufacturer and is documented using a handover protocol.

Check the packaging on delivery for damage sustained during transport. If damage is noticed before unpacking, contact the Technical Customer Service.

Before using the product, familiarize yourself with the settings options and how to operate the product. Observe the information notices on the product.

About the instructions for use

- This instructions for use contain important information about the safe and effective use of this product.
- The instructions for use are part of the product and must be complied with.
- Read the instructions for use carefully and fully before using the product. The instructions for use must be thoroughly understood. In the event of uncertainty or questions about the product, please contact the manufacturer.
- The instructions for use must also be handed over in the event of a change of location or personnel.
- The instructions for use must be kept where the product is used.
- The instructions for use must be easily accessible in full to all users of the product at all times.
- The figures in the instructions for use are highly simplified and are intended to provide a basic understanding.
- Residual dangers that may occur while using the product are identified in the document with a signal word. The safety measures required and potential consequences of failing to take these are listed. A corresponding signal word provides information about the severity of the danger:

Signal word	Meaning
DANGER	The signal word indicates a dangerous situation that will immediately lead to death or serious injury if no precautionary measures are taken.
WARNING	The signal word indicates a dangerous situation that may lead to death or serious injury if no precautionary measures are taken.
CAUTION	The signal word indicates a dangerous situation that may lead to moderate to slight injury if no precautionary measures are taken.
NOTICE	The signal word indicates a dangerous situation that may lead to material damage or damage to the environment if no precautionary measures are taken.

This page is intentionally blank.

Contents

1 Usage specifications

1.1 Intended purpose

The operating table is intended for the following use:

- Patient positioning during surgical interventions including initiation and ending of anesthesia
- Application-related transfer of patients within operating rooms

1.2 Contraindication

Do not transport objects, devices, or materials on the operating table and its accessories. The products described in these instructions for use are for human medical use only.

Hazard to the patient. Changes to the medical product are prohibited. The manufacturer is not liable for changes made to the operating tabletop.

Risk of personal injury and damage to goods when the permitted loads are exceeded. Do not exceed the permitted load capacity for the operating table. If the permissible load is exceeded, the mobile operating table may tip over and cause serious injuries to the patient or staff. In general, overloading the operating table can lead to a failure of electrical functions and cause material damage to mechanical parts.

Hazard to the patient. The patient must only be positioned on the operating tabletop while lying down. Extremities must not extend beyond the end of the operating table in a longitudinal direction. Improper loading may damage the operating tabletop or cause the mobile operating table to tip over. When the operating tabletop is moved in a longitudinal direction, the patient must not climb onto or off the operating table over the side of the extended operating tabletop. Patients may only get on or off in the area of the support column. Do not sit, crouch or kneel on the end of the tabletop.

1.3 Patient definition

The surgeon basically decides whether the operating table (mostly depending on the tabletop) is positioned correctly for performing surgery on the patient. However, there are some restrictions with regard to the body weight and size of patients. The various patient groups that can be placed on the operating tabletop (in combination with the operating table column) are listed in the instructions for use.

1.4 User definition

The TruSystem 7500 operating table is to be operated by trained personnel only. Personnel training is carried out by the manufacturer, or by other persons accredited by the manufacturer.

The primary users are medically trained, specialized personnel. These include, for example:

- Anesthetists
- Operating room nurses
- Surgeons in various specialized fields

Cleaning staff are also included among the primary users. Cleaning personnel operate the mobile operating table, but only during cleaning. No patients are present during cleaning. The cleaning staff are trained to operate the operating table.

1.5 Usage environment

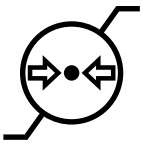
Temperature:	+10°C to +40°C/50 °F to 104 °F
Air humidity:	20% to 80%
Atmospheric pressure:	70 kPa to 106 kPa / 10 psi to 15 psi

The operating table must not be used in potentially explosive atmospheres.

1.6 Ambient conditions for storage and transport

Temperature: -15 °C to 55 °C / 5 °F to 131 °F

Air humidity: 10 % to 95 %



Atmospheric pressure: 70 kPa to 106 kPa / 10 psi to 15 psi

Fragile contents

Top

Keep dry

do not stack

Hazardous goods

Transport in a freight airplane (passenger airplane prohibited)

1.7 Service life

With normal use, the service life is 10 years.

2 Safety

2.1 Combination with other products from Baxter

Use of the operating table is permitted with other products from Baxter. The approved products are listed in the compatibility matrix [1)].

Baxter offers a number of products that can be combined with the operating table. Not all products are available in all countries. Detailed information can be obtained from the relevant representative offices of Baxter, which are represented worldwide. Contact details are available online at www.hillrom.com.

1) Document number 7990090

2.2 Combination with products from other manufacturers

The operating table is not designed for combination with products from other manufacturers (third-party products) and, accordingly, no compatibility tests have been carried out by Baxter. Baxter does not, however, exclude combination with third-party products. If the operator intends to combine the operating table with third-party products, the operator is responsible for this combination. Baxter accepts no responsibility for the combination of the operating table with third-party products. The guarantee/ warranty for products from Baxter may become void in the event of combination with third-party products.

2.3 Operator's responsibility

The operator is the natural or legal person who operates the product himself for commercial or economic purposes or who leaves its operation to a third party. The operator bears the legal product responsibility for protecting personnel or third parties.

The medical device may only be operated and applied according to its intended purpose and the general rules of technology. Medical devices may only be used by persons who have the training or knowledge required to do this.

Instruction regarding the proper handling of the medical device is required. However, training is not required when the medical device is self-explanatory or instructions for a product with the same design have already been provided.

Medical devices connected to each other as well as medical devices connected to accessories including software, or other objects, may only be operated and used when the specific combination is suitable with regard to its intended purpose and the safety of the patients, users, employees or third parties.

Before the medical device is applied, the user must ensure that the product is operational and in an appropriate state and the user must further have read the instructions for use as well as other, attached, safety-relevant information and maintenance instructions.

The instructions for use and the instructions provided with the medical device must be stored in a way that ensures that the user can access the information required for using the medical device at any time.

The user and/or patient must report any serious incidents related to the use of the medical device to the manufacturer and the relevant authorities of the member state of which the user and/or the patient is a resident.

2.4 Use of high-frequency (HF) surgical equipment

The operating table is electrically conductive in accordance with the applicable regulations and standards. The operating table is suitable for the use of high-frequency surgical equipment. Electrically motorized operating table functions may be interrupted if high-frequency surgical devices are used simultaneously.

There is a risk of burns to the patient when high-frequency surgical devices are used. The following safety measures must be followed in all cases:

- Follow the instructions for use provided by the equipment manufacturer.
- The patient must not come into contact with damp materials.
- Position the patient on the operating table so that he or she is insulated from metal parts (operating table, accessories) and conductive pads or tubes.

2.5 Use of defibrillators

The operating table is electrically conductive in accordance with the applicable regulations and standards. The operating table is suitable for the use of defibrillators and defibrillator monitors.

There is a risk of burns to the patient and the user when defibrillators are used. Staff are at risk of electric shock. The following safety measures must be followed in all cases:

- Follow the instructions for use provided by the equipment manufacturer.
- All accessories not specifically protected against defibrillation must be removed from the patient's body before defibrillation.
- Prior to defibrillation, all personnel must move clear of the operating table.

2.6 Malfunction caused by other devices

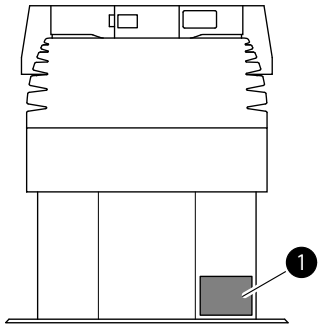
The medical or non-medical devices from other manufacturers may use the same frequency range as the operating table and infra-red remote control. If pieces of equipment with the same frequency range or a multiple of the frequency range is used in the same room, they can influence each other. This may therefore cause malfunctions of the operating table.

Examples of potential sources of interference:

- Electronic control gear (ECG) for fluorescent lamps
- HF surgical devices
- Wireless remote control for other devices (e.g. monitors)
- Very bright indoor lighting

Moreover, malfunctions will result while using the operating table in conjunction with the infrared remote control in the event that the TruSystem 7500 operating table is located in the same room as a TruSystem 7000 or PST500 operating table that is switched on.

2.7 Information notices



The information notices on the components are indicated in the instructions for use of the individual components.

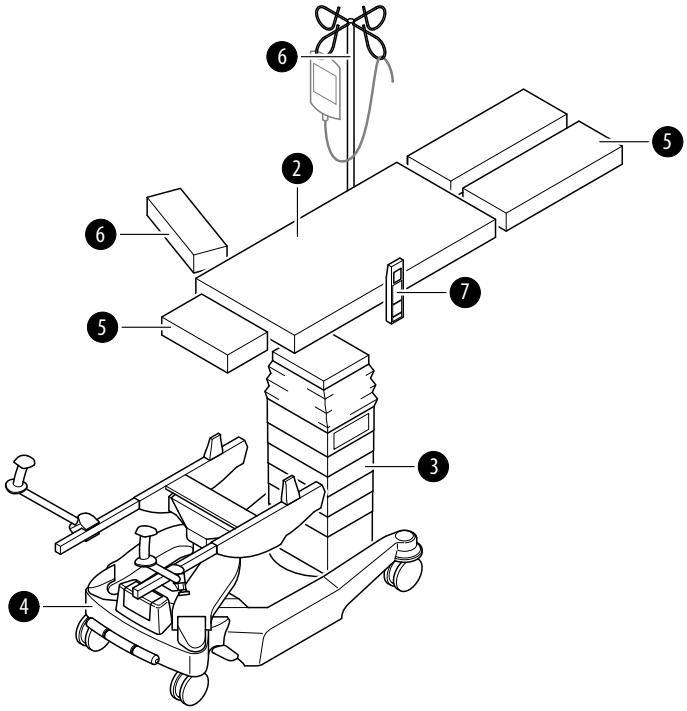
The device label must be present and undamaged in the prescribed locations on the product. A damaged, illegible or missing device label must be replaced immediately. The device label may not be altered or removed.

No.	Information notice	Meaning
[1]	System device label for the TruSystem 7500 operating table (on the operating table column)	
		Manufacturer
	UDI	Unique device identification (UDI), comprising: – Data Matrix Code – (01) Global Trade Item Number (GTIN) – (11) Date of manufacture (Year Month Day) – (21) Serial number – (240) Part number
	REF	Baxter part number
	SN	Serial number
	MD	Medical product
	CE	The device conforms to Regulation 2017/745/EU concerning medical devices.
		Caution! Follow the warnings in the instructions for use!
	IPX4	All-round splash protection
		The product must be disposed of at a suitable disposal facility for the recycling of electrical and electronic devices in accordance with the requirements of Directive WEEE II 2012/19/EU and country-specific regulations.
	I.P.S	Device has an internal power supply
		Degree of protection against electric shock: Type B applied part
		Date of manufacture

3 Summary

The operating tables are individually configurable and consist of an operating table column, an operating tabletop and a transporter, with which the operating tabletop or operating table column can be transported.

The operating table can be combined with other Baxter products. The combination options are indicated in the instructions for use of the individual components.



TruSystem 7500 operating table:

[2] Operating tabletop
The operating tabletops are single- or two-part operating tabletops which can be adapted to the required patient position with the use of various functions.

[3] Operating table column
Fixed-installation operating table column:
The operating table column is permanently installed in the operating room and cannot be moved to another location.
Mobile operating table column:
The operating table column can be moved with the transporter. The setup location of the operating table column is flexible.

[4] Transporter (Shuttle)

Combinations:

[5] Tabletop section
The tabletop section is fastened to hook coupling points at the head or foot end of the operating tabletop and extends the positioning surface for the patient.

[6] Side rail accessories

[7] Remote control

4 Description

4.1 Summary of control modules

The operating table is operated as standard with the remote control. The remote control is absolutely necessary for using the operating table to its full potential. If the remote control is temporarily unavailable, due to reasons such as a flat battery, the basic functions of the operating table can still be executed using the column keypad. Other optional control modules are available from Baxter.

The operating table can be adjusted using the following control modules:

- Column keypad
- Remote control
- Footswitch
- Sensor Control FloatLine cable operating unit (only for OR table top Carbon FloatLine)

The range of functions of the different control units varies.

The commands of the individual control units are listed in the following sequence:

1. Column keypad
2. Cable remote control
3. Sensor Control FloatLine cable operating unit (only OR table top Carbon FloatLine)
4. Radio remote control
5. Footswitch
6. IR remote control

The simultaneous activation of keys on various control units results in audible error messages or in the execution of table functions in order of priority.

Press the respective function key on the control unit until the desired position has been reached.

The function stops in the following situations:

- The key is released.

  For further adjustment, press the function key again.
- The level position has been reached.

  This option must be configured in the operating table (default setting). The automatic stop at the level position is indicated by an audible signal. For any further adjustment, briefly release the function key and then press it again.
- The intermediate stop is reached.

  You will hear an audible signal when the intermediate stop has been reached. For any further adjustment, briefly release the function key and then press it again.
- The end position has been reached.

  The automatic stop in the end position is indicated by an audible signal.

4.2 Setting options for the operating table

The available functions on the operating table are dependent on the configuration and combination of the operating table. Take note of the operating instructions of the operating tabletop and the operating table column used.

4.2.1 Patient orientation

For the motor functions on the operating table, the operating table must be aware of the patient's current head position on it. Only if the indicator on the column keypad matches the orientation of the patient on the operating table will the operating table's functions be carried out on the correct side.

The direction of the operating tabletop is automatically recognized by the operating table column after transfer from a shuttle to the operating table column. The head position of the patient corresponds to the relevant indicator when the patient lies with the head on the head side of the operating tabletop.

The adjustment ranges for the functions may be different with normal and inverted patient orientations, since the function is carried out based on the patient's position. For example, the leg section joints assume the function of the back section in the inverted patient position. Commands are given using the keys for the back section.

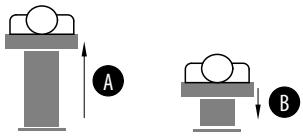
Normal patient orientation (default setting):

The patient lies with their head at the head end of the operating tabletop. After the operating table has been switched on, normal patient orientation is always automatically activated.

Inverted patient orientation:

The patient lies with their head at the foot end of the operating tabletop. The patient orientation must be inverted. The inverted patient orientation remains activated only for as long as the operating table is switched on, or until the patient orientation is switched back to normal.

4.2.2 Lift

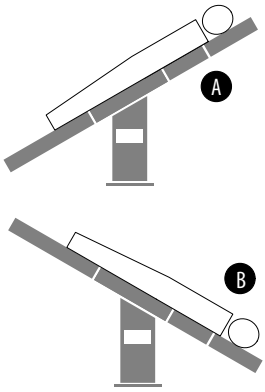


The operating tabletop is moved electrically upward [A] or downward [B].

4.2.3 Tilt

The operating tabletop is tilted around its longitudinal axis to the left [A] or right [B]. The side specification is based on the user's perspective when standing at the head end of the patient.

4.2.4 Trendelenburg

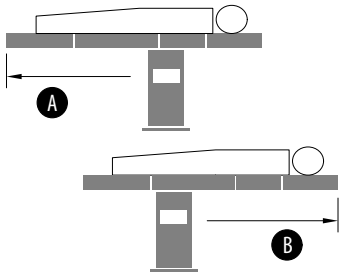


The operating tabletop is moved electrically around its transverse axis.

With the reverse Trendelenburg function [A], the operating tabletop is moved with the foot end downward.

With the Trendelenburg function [B], the operating tabletop is moved with the head end downward.

4.2.5 Longitudinal slide



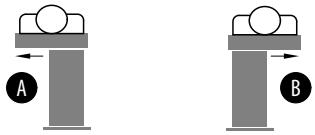
Manually adjustable:

The operating tabletop is manually moved towards the foot end [A] or head end [B] of the patient.

Electrically adjustable:

The operating tabletop is moved electrically towards the foot end [A] or head end [B] of the patient.

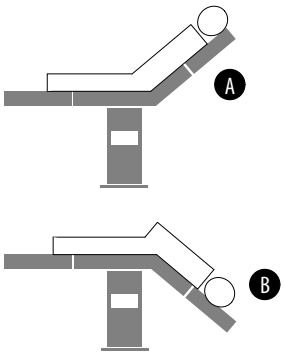
4.2.6 Transverse slide



The operating tabletop is moved electrically towards the left side [A] or right side [B] of the patient.

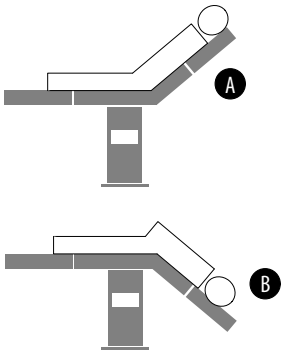
The transverse slide function can only be selected with the remote control.

4.2.7 Back section



The back section is electrically moved upwards [A] or downwards [B].

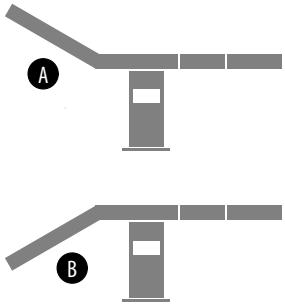
4.2.8 Back section joints



The joints are inclined electrically upward [A] or downward [B]. The joints can only be moved together with the column keypad.

With the remote control, when the inverted patient orientation is selected, the right and left joints can be moved independently of each other. The default setting on the remote control is for the joints to be adjusted together. The joints cannot be adjusted individually if a single-part tabletop section is attached to both joints. The single-part tabletop section is automatically recognized by the operating table and the functions of the individual joints are locked.

4.2.9 Leg section joints



Manually adjustable:

The joints on the seat section can be individually manually adjusted upwards [A] or downwards [B].

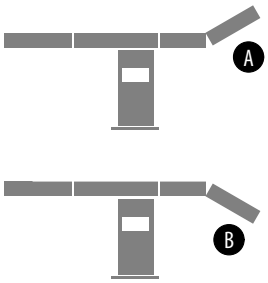
The position of the joint for the seat section can be seen from the line markings on the gears. The joint is on the same plane as the seat section when the gearing line markings from both parts match up.

Electrically adjustable:

The joints are inclined electrically upward [A] or downward [B]. The joints can only be moved together with the column keypad.

With the remote control, when the normal patient orientation is selected, the right and left joints can be moved independently of each other. The default setting on the remote control is for the joints to be adjusted together. The joints cannot be adjusted individually if a single-part tabletop section is attached to both joints. The single-part tabletop section is automatically recognized by the operating table and the functions of the individual joints are locked.

4.2.10 Joints of the upper back section



Manually adjustable:

The rails on the back plate can be individually manually adjusted upwards [A] or downwards [B].

The position of the joint for the back plate can be seen from the line markings on the gears. The joint is on the same plane as the back section when the gearing line markings from both parts match up.

Electrically adjustable:

The joints on the back section are electrically tilted upwards [A] or downwards [B]. The joints can only be moved together with the column keypad.

In the inverted patient position, the back plate takes over the function of the seat section extension, and the joints take over the function of the lower leg plate. With the remote control, when the inverted patient orientation is selected, the right and left joints can be moved independently of each other. The default setting on the remote control is for the joints to be adjusted together. The joints cannot be adjusted individually if a single-part tabletop section is

attached to both joints. The single-part tabletop section is automatically recognized by the operating table and the functions of the individual joints are locked.

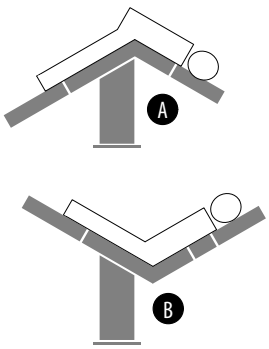
4.2.11 Level position

The level position is a defined starting position in which the operating tabletop is moved to a horizontal position. The level position function combines the following functions:

- Tilt function:
  The operating tabletop is adjusted horizontally around its longitudinal axis.
- Trendelenburg function:
  The operating tabletop is adjusted horizontally around its transverse axis.
- Longitudinal slide and transverse slide functions [2)]:
  The operating tabletop moves to its original position. The original position is dependent on the operating tabletop used.
  The mechanical longitudinal travel of the pediatric operating tabletop must be manually moved to the level position.
  If the extension adapter is attached to the operating tabletop, longitudinal travel is locked.
- The motorized joints of the operating tabletop are set horizontally. [2)]
  If the extension adapter is attached to the operating tabletop, the leg section joints are locked.
- Lifting function:
  The operating table column without the operating tabletop is moved into the lower lift position (transfer position).
  The operating table column with the operating tabletop is moved into the upper lift position (transfer position).

For a completely level position on the operating table, the mechanical hinges on the operating tabletop must be brought manually into the horizontal position.

4.2.12 Flex down / flex up



The operating tabletop folds electrically between the seat and back section.

In the flex down position [A], both ends of the operating tabletop are moved downward (reverse Trendelenburg function and back section down).

In the flex up position [B], both ends of the operating tabletop are moved upward (Trendelenburg function and back section up).

2) Dependent on the equipment of the operating tabletop

4.2.13 CPR position

The incline of the operating tabletop must be reduced to an angle of less than 15° (Trendelenburg and tilt) in the event of reanimation (CPR - cardiopulmonary resuscitation).

To bring the patient into the necessary position for resuscitation more quickly, the operating table has a CPR function. For the CPR function, the operating tabletop is first placed into the horizontal position and then the longitudinal travel is brought into the level position.

Attention: collision protection is deactivated during CPR function and the adjustment is made at higher speed. The CPR function may only be used in emergencies.

The transverse slide and joints of the operating tabletop (if present) remain unchanged in the CPR position.

4.2.14 Brake

The fixed operating table column is rotatable and fixed in position by a brake. As soon as the brake is released, the operating table column can be turned on its own axis.

The brake on the operating table column can be released and activated via the foot pedal, the remote control or the column keypad. The TS7500 MOBIUS (#1704695) operating table column has no foot pedal. The brake on the TS7500 MOBIUS operating table column can be released and activated via the remote control or the column keypad.

4.2.15 Localize wireless remote control

The function helps to locate the wireless remote control when e.g. it is concealed under cloths. The remote control will be visually and acoustically noticeable.

4.2.16 Floor lighting (EndoLight)

There are LED lamps on both sides of the column head, which slightly light up the foot area on the operating table when the operating room is darkened. The floor lighting can only be switched on and off with the remote control.

4.3 Software settings

The change is carried out via the service interface of the operating table (ethernet connection from the operating table to the PC required). The desired option must be installed on site by a qualified service technician.

The following settings can be made via the service interface of the operating table:

- Stop on passing through the level position (activated for all functions by default):

  All electrical adjustment functions of the operating table stop automatically when the level position is reached. For any further adjustment, briefly release the function key and then press it again.
- Restricted leveling (not active by default):

  With the level position function, the operating tabletop motorized hinges set upward remain in position and are no longer leveled.
- Interim stop for table tilt, Trendelenburg and longitudinal travel (not activated by default):

  An intermediate stop can be established for the tilting, Trendelenburg, and longitudinal slide functions. The function stops automatically upon reaching the position set individually, and not at the level position. A message appears on the TruSystem 7500 remote control display. For additional adjustment beyond the threshold value, briefly release the function key and press it again. For safety reasons, the tilting intermediate stop cannot be deactivated (intermediate stop at a tilt angle of <15° is possible).
- Sensor-supported transfer (activated by default):

  Extreme centers of gravity outside the center can prevent full insertion of the mount wedges (operating table column) into the wedge receptacles of the operating tabletop. With the help of the sensor-supported transfer, the center of gravity of the operating tabletop is automatically optimized during the transfer, so that the mount wedges are easier to engage.
- Signal tone volume:

  Signal tone volume can be set individually at the operating table.

5 Use

5.1 Safety instructions

Commissioning:

- Before using the products for the first time, they must first be cleaned and disinfected according to the hygiene specifications of the medical facility. Cleaning and disinfecting may be performed only by trained staff and using cleaning and disinfecting agents approved by Baxter.

Combination:

- The operating table may be used only with tabletop sections and accessories approved by Baxter.
- Check the operating table to ensure that it is functional and intact before use. The use of faulty or damaged products is prohibited.
- Check before each use that the tabletop sections and the accessories are securely fastened to the operating table.

Pads:

- The operating table must not be used with damaged pads.
- Do not stick any sharp-edged objects into the pads or place them onto the pad. Do not attach any adhesive film.

Patient positioning:

- Securely attach the patient to the operating table with the appropriate accessories (for example, using straps).
- The maximum permissible patient weight must not be exceeded.
- Lift the patient into the desired position on the operating table and do not pull the patient over the pads. After each change of position, lift the patient's affected body parts. Any wrinkles or shearing forces that have developed will be eliminated.
- The patient may not climb onto or down from the operating table over the back sections or attached tabletop sections. Improper weight distribution can break the tabletop sections off the operating table or cause the table to tip over. Patients may only get on or off in the column area via the seat section. Do not sit on the back section or attached tabletop sections.
- The patient's extremities must not extend beyond the end of the operating tabletop in the longitudinal direction. This does not apply in the case of accessories designed for this purpose.

Operating table functions:

- Carry out all patient repositioning in a controlled and responsible manner. Monitor all of the operating table’s motorized movements to prevent the patient being endangered or material damage occurring as a result of a collision. Stop the function immediately before a dangerous situation arises. Ensure that the adjustment ranges on the operating table are not obstructed.
- The cables and tubes to the patient must not be placed under tension or crushed during the operating table's motorized movements. Stop the function in good time.

- There is a risk of crushing for the user between mobile parts of the operating table. Stop the function immediately before a dangerous situation arises.
- The operating table maintains the position set by the user. A change in position will only occur by means of a proactive action by the user.

5.2 Installation of the fixed-installation operating table column

The fixed operating table column must be installed by qualified service technicians at the place of use. The mounting of the operating table column is described in the installation manual.

Before using it for the first time, the operating table must be cleaned and disinfected. Cleaning and disinfection are described in Chapter 6.

5.3 Unpacking the operating table

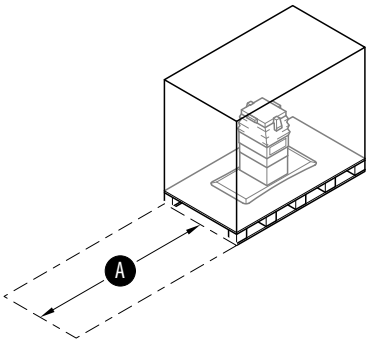
Delivery is made on a pallet with outer packaging.

The accessories are packed individually on the pallet or delivered in a separate package.

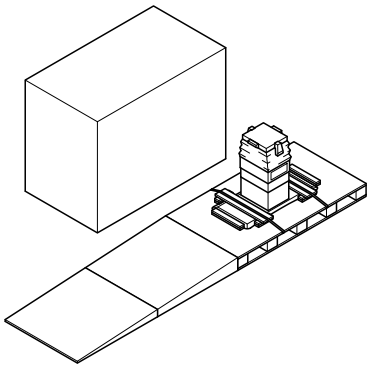
5.3.1 Individual shipment of mobile operating table column

Do not switch the operating table column on immediately after delivery. When transitioning from a cold to a warm environment or vice versa, moisture can form inside the operating table column and cause a short circuit. After delivery, leave the operating table column for at least 12 hours in the environment in which it will be used before switching it on for the first time.

Unpack the operating table column in a room with a level floor and sufficient open space.



1. Position the pallet so that clearance of around 5 m length [A] is available on the narrow side of the packaging.
2. Remove the straps on the box and take out the ramp.
   If the ramp is not attached to the box, it is located on the two narrow sides on the inside of the packaging. The box is screwed to the ramp.
3. Remove the box fasteners below the pallet and pull off the box upwards.
4. Remove the ramp from the box (3 screws each).
5. Position the two parts of the ramp on the front of the pallet. Push the ramp up to a closed area on the pallet.



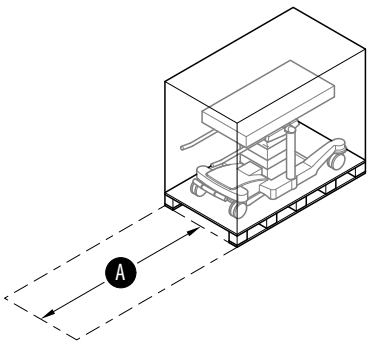
6. Remove the protective sheath from the operating table column.
7. Remove and unpack the accessories from the pallet.
8. Remove the straps from the pallet.
9. Remove all wooden securing blocks from the floor plate of the pallet (2 screws on each wooden securing block) and remove the protective film.
10. With the help of an appropriate transporter, transfer an existing operating tabletop to the operating table column (observe the Compatibility Matrix [3]).
11. Transfer the entire operating table onto the transporter.
12. **CAUTION!** The transporter may tip over if it is moved over the side edge of the pallet. Ensure that the ramp is pushed up to a closed area on the pallet.
    Carefully remove the transporter from the pallet using the ramp and activate the brake. This requires at least 2 people.
13. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
14. Charge the batteries in the operating table column.
15. Before using it for the first time, the products supplied must be cleaned and disinfected.

5.3.2 Mobile operating table column with operating tabletop and transporter

Do not switch the operating table column on immediately after delivery. When transitioning from a cold to a warm environment or vice versa, moisture can form inside the operating table and cause a short circuit. After delivery, leave the operating table for at least 12 hours in the environment in which it will be used before switching it on for the first time.

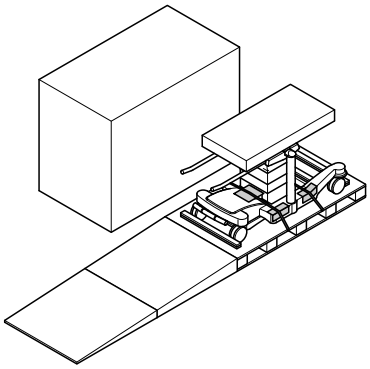
Unpack the operating table in a room with a level floor and sufficient open space.

The floor at the location of use must be level, so that the operating table column is secure and does not wobble. The required flatness tolerance is 3 mm to 1 m measuring point distance (the floor must have a flatness according to DIN 18202, Table 3, Line 4).



1. Position the pallet so that clearance of around 5 m length [A] is available on the narrow side of the packaging.
2. Remove the straps on the box and take out the ramp.
   If the ramp is not attached to the box, it is located on the two narrow sides on the inside of the packaging. The box is screwed to the ramp.
3. Remove the box fasteners below the pallet and pull off the box upwards.
4. Remove the ramp from the box (3 screws each).
5. Position the two parts of the ramp on the front of the pallet. Push the ramp up to a closed area on the pallet.

3) Document number 7990090



6. Remove the protective cover from the operating table.
7. Remove and unpack the accessories from the pallet.
8. Remove all wooden securing blocks on the sides of the transport from the pallet (2 screws on each) and remove the protective cardboard.
9. Remove the straps from the pallet and take off the protective cardboard.
10. Remove the protective adapter from the OR table top Carbon FloatLine, Carbon Spine and MR Neuro. To do this, unscrew the sheet metal angle from the pallet and take off the protective adapter.
11. Clear the pallet so that the transporter can be driven off the pallet.
12. Remove the protective film from the bolts on both sets of receiving wedges on the transporter. For this, lightly lift the operating tabletop.
13. Transfer the operating table onto the transporter.
14. **CAUTION!** The transporter may tip over if it is moved over the side edge of the pallet. Ensure that the ramp is pushed up to a closed area on the pallet.
    Carefully remove the transporter from the pallet using the ramp and activate the brake. This requires at least 2 people.
15. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
16. Charge the batteries in the operating table column.
17. Before using it for the first time, the products supplied must be cleaned and disinfected.

5.3.3 Transporter with operating tabletop

Unpack the transporter with the operating tabletop in a room with a level floor and sufficient open space.

1. Position the pallet so that clearance of around 5 m length [A] is available on the narrow side of the packaging.
2. Remove the straps on the box and take out the ramp.
   If the ramp is not attached to the box, it is located on the two narrow sides on the inside of the packaging. The box is screwed to the ramp.
3. Remove the box fasteners below the pallet and pull off the box upwards.
4. Remove the ramp from the box (3 screws each).
5. Position the two parts of the ramp on the front of the pallet. Push the ramp up to a closed area on the pallet.
6. Remove the protective cover from the transporter.
7. Remove and unpack the accessories from the pallet.
8. Remove all wooden securing blocks on the sides of the transport from the pallet (2 screws on each) and remove the protective cardboard.
9. Remove the straps from the pallet and take off the protective cardboard.
10. Remove the protective adapter from the OR table top Carbon FloatLine, Carbon Spine and MR Neuro. To do this,

unscrew the sheet metal angle from the pallet and take off the protective adapter.

11. Clear the pallet so that the transporter can be driven off the pallet.
12. **CAUTION!** The transporter may tip over if it is moved over the side edge of the pallet. Ensure that the ramp is pushed up to a closed area on the pallet.
    Carefully remove the transporter from the pallet using the ramp and activate the brake. This requires at least 2 people.
13. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
14. Remove the protective film from the bolts on both sets of receiving wedges on the transporter. For this, lightly lift the operating tabletop.
15. Before using it for the first time, the products supplied must be cleaned and disinfected.

5.3.4 Mobile operating table column with operating tabletop

Do not switch the operating table column on immediately after delivery. When transitioning from a cold to a warm environment or vice versa, moisture can form inside the operating table and cause a short circuit. After delivery, leave the operating table for at least 12 hours in the environment in which it will be used before switching it on for the first time.

Unpack the operating table in a room with a level floor and sufficient open space.

The floor at the location of use must be level, so that the operating table column is secure and does not wobble. The required flatness tolerance is 3 mm to 1 m measuring point distance (the floor must have a flatness according to DIN 18202, Table 3, Line 4).

1. Position the pallet so that clearance of around 5 m length [A] is available on the narrow side of the packaging.
2. Remove the straps on the box and take out the ramp.
   If the ramp is not attached to the box, it is located on the two narrow sides on the inside of the packaging. The box is screwed to the ramp.
3. Remove the box fasteners below the pallet and pull off the box upwards.
4. Remove the ramp from the box (3 screws each).
5. Position the two parts of the ramp on the front of the pallet. Push the ramp up to a closed area on the pallet.
6. Remove the protective cover from the operating table.
7. Remove and unpack the accessories from the pallet.
8. Remove the straps from the pallet and take off the protective cardboard.
9. Remove all wooden securing blocks from the floor plate of the pallet (2 screws on each wooden securing block) and remove the protective film.
10. Remove the protective adapter from the OR table top Carbon FloatLine, Carbon Spine and MR Neuro. To do this, unscrew the sheet metal angle from the pallet and take off the protective adapter.

11. Clear the pallet so that the transporter can be driven to the operating table.
12. Put the hub of the operating table column in the upper end position.
13. Transfer the operating table onto the transporter (observe the Compatibility Matrix [4)]).
14. **CAUTION!** The transporter may tip over if it is moved over the side edge of the pallet. Ensure that the ramp is pushed up to a closed area on the pallet.
    Carefully remove the transporter from the pallet using the ramp and activate the brake. This requires at least 2 people.
15. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
16. Charge the batteries in the operating table column.
17. Before using it for the first time, the products supplied must be cleaned and disinfected.

5.3.5 Single shipment transporter

Unpack the transporter in a room with a level floor and sufficient open space.

1. Position the pallet so that clearance of around 5 m length [A] is available on the narrow side of the packaging.
2. Remove the straps on the box and take out the ramp.
   If the ramp is not attached to the box, it is located on the two narrow sides on the inside of the packaging. The box is screwed to the ramp.
3. Remove the box fasteners below the pallet and pull off the box upwards.
4. Remove the ramp from the box (3 screws each).
5. Position the two parts of the ramp on the front of the pallet. Push the ramp up to a closed area on the pallet.
6. Remove the protective cover from the transporter.
7. Remove and unpack the accessories from the pallet.
8. Remove the straps from the pallet and take off the protective cardboard.
9. Remove all wooden securing blocks on the sides of the transport from the pallet (2 screws on each) and remove the protective cardboard.
10. **CAUTION!** The transporter may tip over if it is moved over the side edge of the pallet. Ensure that the ramp is pushed up to a closed area on the pallet.
    Carefully remove the transporter from the pallet using the ramp and activate the brake.
11. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
12. Before using it for the first time, the products supplied must be cleaned and disinfected.

4) Document number 7990090

5.3.6 Operating tabletop individual shipment

Unpack the operating tabletop in a room with a level floor and sufficient open space.

1. Remove the box fasteners below the pallet and pull off the box upwards.
2. Remove the protective sheath from the operating tabletop.
3. Remove and unpack the accessories from the pallet.
4. Remove the straps from the pallet and take off the protective cardboard.
5. Lift the operating tabletop from the pallet with a suitable tool (loading crane).
6. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
7. Before using it for the first time, the products supplied must be cleaned and disinfected.

5.3.7 Individual shipment of the fixed-installation operating table column

The fixed-installation operating table column must be unpacked and installed by qualified service technicians at the place of use.

5.3.8 Individual shipment of cleaning shuttle

Unpack the cleaning shuttle in a room with a level floor and sufficient open space.

1. Remove the straps on the box and take out the ramp.
   If the ramp is not attached to the box, it is located on the two narrow sides on the inside of the packaging. The box is screwed to the ramp.
2. Remove the box fasteners below the pallet and pull off the box upwards.
3. Remove the ramp from the box (3 screws each).
4. Position the two parts of the ramp on the front of the pallet. Push the ramp up to a closed area on the pallet.
5. Remove the protective cover from the cleaning shuttle.
6. Remove and unpack the accessories from the pallet.
7. Remove the straps from the pallet and take off the protective cardboard.
8. Remove all wooden securing blocks on the sides of the cleaning shuttle from the pallet (2 screws on each) and remove the protective cardboard.
9. **CAUTION!** The cleaning shuttle may tip over if it is moved over the side edge of the pallet. Ensure that the ramp is pushed up to a closed area on the pallet.
   Carefully remove the cleaning shuttle from the pallet using the ramp and activate the brake.
10. Dispose of the pallet, the ramp, and packing material in an environmentally responsible manner.
11. Before using it for the first time, the products supplied must be cleaned and disinfected.

5.4 Summary of how to use the operating table

The operating table is fitted with tabletop sections and accessories according to the procedure planned. Before the patient is transferred, the operating table must be checked as follows:

- Are the tabletop sections and the accessories properly attached?

  Check that the tabletop sections and accessories are securely fastened to the operating tabletop.
- Is the battery status of the mobile operating table column sufficient?

  Charge the battery if necessary.
- Is the operating table hygienically clean?

  Clean and disinfect the operating table if necessary.
- Are the pads damaged?

  Check the pads for cracks or other visible damage. Damaged pads may not be reused.

When transferring the operating tabletop onto the operating table column, adhere to the following:

- Before transferring the operating tabletop onto the operating table column, ensure that no objects or cloths are lying on the operating table column. Nothing should be placed on the operating table column.
- Does the operating tabletop lie correctly on the operating table column after the transfer?

  The receiving wedges of the operating table column must be fully locked in the wedge fixtures of the operating tabletop.

After patient contact, the operating table must be cleaned and disinfected.

5.5 Decommissioning

For temporary or permanent decommissioning of the operating table, disconnect it from the power supply and secure it against being started back up. Refer to the instructions for use of the operating table column. The disassembly of the fixed-installation operating table column must be carried out by qualified service technicians only.

6 Cleaning and disinfection

This chapter describes in detail how the operating table must be cleaned and subsequently disinfected after each contact.

A distinction is made between cleaning and disinfection. Cleaning is carried out with water and a suitable cleaning agent. During cleaning, visible and invisible contamination is removed. Disinfection is carried out using a suitable disinfectant agent and disinfection method. The disinfection kills or inactivates pathogens, thus infection is no longer probable.

Baxter has verified the procedures described in this section to confirm their effectiveness in principle. Other methods may be used for cleaning and disinfection, although their effectiveness must be checked by the operator.

The operator must ensure that the procedures for cleaning and disinfecting the operating table are hygienically effective and comply with the specifications of the medical facility, as well as the applicable regulations of the state or country.

Additionally adhere to the instructions for use of individual components and accessories when cleaning and disinfecting.

6.1 Cleaning and disinfecting agents

⚠ CAUTION

Cleaning and disinfecting agents can cause rashes or irritation if they come into contact with the skin.

- Follow the instructions on the product label or in the safety data sheet included with the product used.
- Wear personal safety equipment (note the manufacturer's specifications).

Cleaning

Do not use any abrasive cleaning products.

Disinfecting

Disinfectants based on the following active substance groups or a combination of these active substance groups with quaternary compounds:

- aldehyde
- alcohols
- alkylamines

Disinfectants based on halogens and peroxide compounds are not suitable.

Do not use any abrasive products for disinfection.

Baxter recommends the following disinfectants:

Manufacturer	Product designation
Ecolab Deutschland GmbH	Incidin™ Plus
B. Braun Melsungen AG	Melsitt®
BODE Chemie GmbH	Bacillol® plus

6.2 Summary of cleaning and disinfection

Cleaning and subsequent disinfection must be performed promptly after any contact with the operating table. The operating tabletop with attached tabletop sections is positioned on the operating table column since this allows cleaning and disinfection to be carried out without strain on the back. The operating tabletop is first cleaned and disinfected. The operating tabletop is then placed onto a transporter. The operating table column is then individually cleaned and disinfected without the operating tabletop on top of it. The cleaning of an individual transporter (shuttle) is described in the transporter's instructions for use.

Alternatively, the operating tabletop can be cleaned and disinfected on a transporter. The steps for cleaning and disinfection should be carried out as described in Chapter 6.4. The plate operating unit is required for this so that the longitudinal slide and joints of the operating tabletop can be adjusted.

The scope, timing and procedure used for cleaning and disinfection is determined by the operator.

In these instructions for use, Baxter describes how the operating table can be manually cleaned and disinfected.

Before each use, the user must ensure that the operating table has been cleaned and disinfected.

Before the operating table is used for the first time, it must undergo cleaning and disinfection.

Ensure adequate wetting of the surfaces with each pass. Comply with the manufacturer's specifications at all times regarding the concentration of the cleaning agents and disinfectants. The concentration of the disinfectant affects the dwell time. The disinfectant used must be allowed to work undisturbed. Do not wipe off.

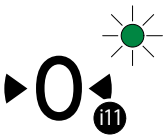
Cleaning the operating table with a high-pressure cleaner, steam cleaner or water jet is prohibited.

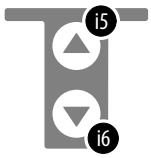
The operating table must not be cleaned mechanically. Cleaning is carried out by hand using suitable utensils.

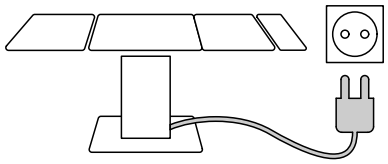
The operating table must not be dried by the direct effect of heat.

Lift, carry or move the tabletop sections with care. Work with an additional person if necessary. Never remove multiple tabletop sections or heavy, unwieldy accessories from the operating table at the same time.

6.3 Preparing the operating table



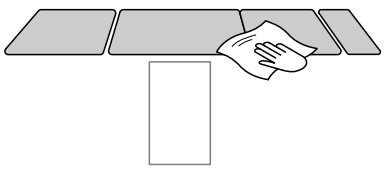


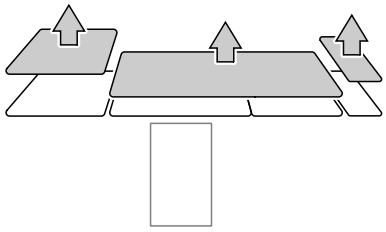


For cleaning and disinfection, the operating tabletop is placed on the operating table column.

1. Remove all accessories from the operating table, such as equipment on the floor plate or accessories on the side rails. Note the manufacturer's instructions for the various products.
   The tabletop sections remain attached to the operating table for now.
2. Remove all towels or drapes from the operating table.
3. Move the operating table to the level position using button [i11].
   Press the key until the operating table stops automatically. An audible signal then sounds.
4. Move adjustable tabletop sections to a horizontal position by hand.
5. Adjust the height of the operating table with the [i5] or [i6] button so that the work does not strain your back.
6. With the mobile operating table column, remove the power cable plug from the socket.
7. For the mobile operating table column, disconnect the equipotential bonding plug.

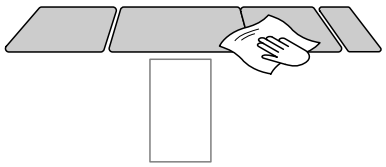
6.4 Cleaning and subsequently disinfecting the operating tabletop



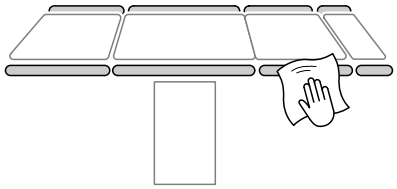


1. Prepare the operating table as described in Section 6.3. Wear the required personal safety equipment.
2. Remove coarse dirt from the operating table using suitable means.
3. Prepare the cleaning solution. Note the concentration of the cleaning agent.
4. Prepare a resting surface for the pads and tabletop sections. Disinfect the resting surface. Note the disinfectant’s dwell time.
5. Wipe all residues from the pads on the operating tabletop in sequence. First wipe the top and then the sides of the pads. The pads must be visibly clean.
6. Once the pads are dry, remove them from the operating table and place them with the clean side facing downward on the prepared resting surface.

7. Clean all residues from the uppermost side of the pad. Wipe the sides of the pads again.
8. Leave the pads on the resting surface until dry. Also ensure that the Velcro tape is completely dry.

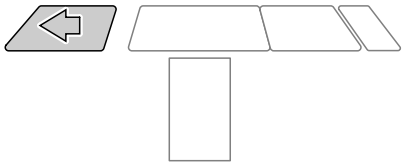


9. Wipe the surface of the operating tabletop and the individual tabletop sections so there are no residues.



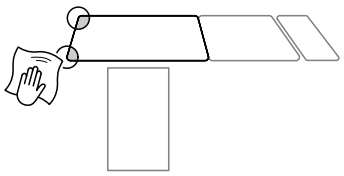
10. Wipe the side rails on the operating tabletop and the tabletop sections so there are no residues.

Once the upper surface of the tabletop sections is visibly dry, the tabletop sections can be removed one by one.

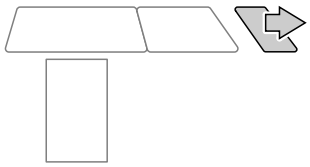


11. Remove the individual tabletop section at the foot end of the operating table and place it with the clean, dry side facing downward on the prepared resting surface.

12. Clean the uppermost side and the hook couplings of the tabletop section so there are no residues.

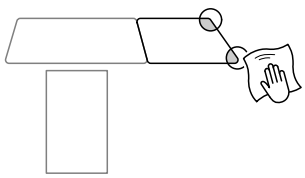


13. Move the hook couplings on the operating table all the way up and clean them to remove any residue. Then move the hook couplings all the way down and clean again so there are no residues.



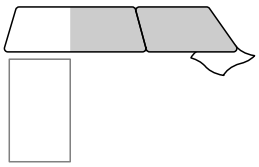
14. Remove the individual tabletop section at the head end of the operating table and place it with the clean, dry side facing downwards on the prepared resting surface.

15. Thoroughly clean the upper surface and the hook couplings of the tabletop section using disinfectant.



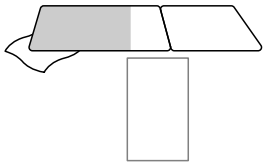
16. Move the hook couplings on the operating table all the way up and clean them to remove any residue. Then move the hook couplings all the way down and clean again so there are no residues.

17. Extend the operating tabletop all the way to the head end using the [i16] button.



18. Clean the extended operating tabletop from underneath so there are no residues.

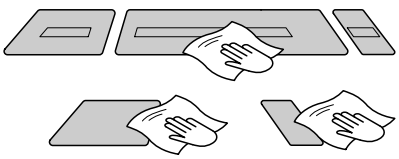
19. Extend the operating tabletop all the way to the foot end using the [i17] button.



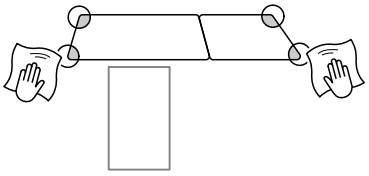
20. Clean the extended operating tabletop from underneath so there are no residues.
21. Visually inspect the surfaces of the operating tabletop. The surfaces must be free of residue and any visible contamination. Clean any surfaces with contamination still visible again.

Only when the operating tabletop, all pads and tabletop sections are completely dry can the disinfection process begin.

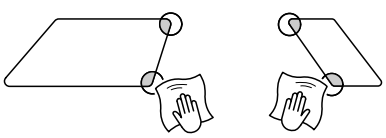
22. Prepare a suitable disinfectant and disinfection method. During disinfection, ensure that all surfaces are adequately moistened at all times.
23. Prepare an additional resting surface for the pads. Disinfect the resting surface. Note the disinfectant's dwell time.



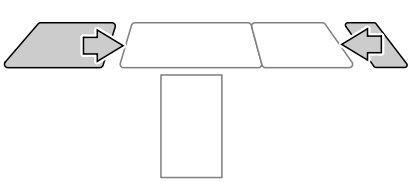
24. The pads and tabletop sections are still on the disinfected resting surface. Disinfect the uppermost side of the pad and tabletop sections.



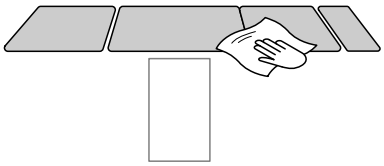
25. Move the hook couplings on the operating table all the way up and disinfect them. Then move the coupling points all the way down and disinfect them again.



26. Disinfect the coupling points on the tabletop sections.



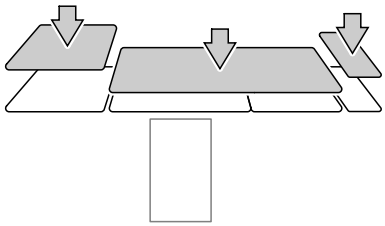
27. Once the coupling points are dry, attach the tabletop sections to the operating table.



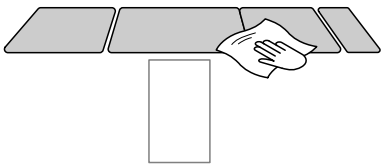
28. Disinfect the surface of the operating table, including the tabletop sections. Allow the surface to dry.

29. Once the underside of the pads is dry, place the pads with the disinfected side facing downward on the additionally disinfected resting surface.

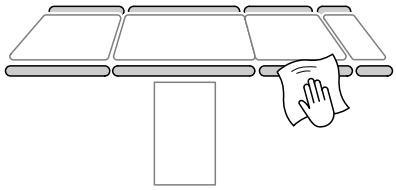
30. Disinfect the uppermost side of the pad.



31. Attach the pad to the dried tabletop sections on the operating table.

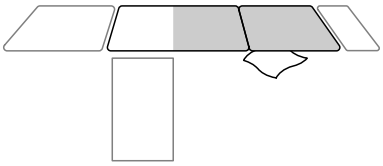


32. Disinfect all pad edges again.



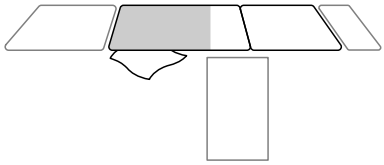
33. Disinfect the side rails.

34. Extend the operating tabletop all the way to the head end using the [i16] button.

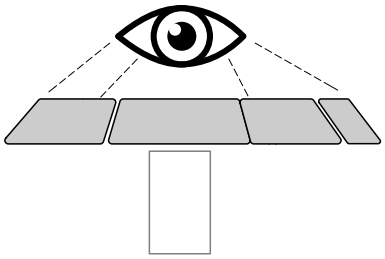


35. Disinfect the extended operating tabletop from underneath.

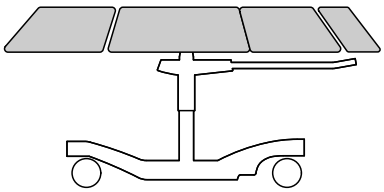
36. Extend the operating tabletop all the way to the foot end using the [i17] button.



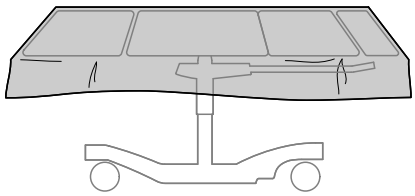
37. Disinfect the extended operating tabletop from underneath.



38. Check the pad for cracks or other visible damage. Damaged pads must not be reused.

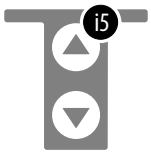


39. Transfer the operating tabletop to a clean transporter (shuttle).

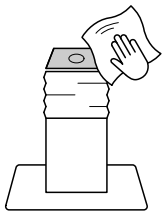


40. Protect the operating tabletop from contamination using suitable means.

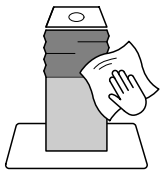
6.5 Clean and then disinfect the operating table column



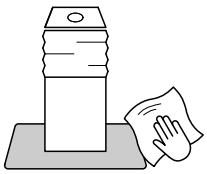
1. Prepare the cleaning solution. Note the concentration of the cleaning agent.
2. Transfer the clean operating tabletop to a clean transporter (shuttle).
3. Move the lifting function of the operating table column to the upper end position using the [i5] key.
   The sheet cladding and bellows of the operating table column are pulled apart from each other in this position and can be cleaned thoroughly.



4. Clean the column head (docking point) from above and on all sides, removing all residue.



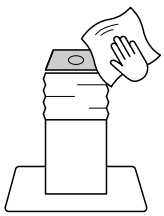
5. Clean the bellows and sheet cladding on the operating table column from top to bottom on all sides, removing all residue.



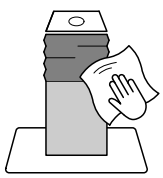
6. Clean the floor plate from above without leaving any residue. With the help of the cleaning shuttle, the mobile operating table column without the operating tabletop is raised so that the underside of the floor plate can be cleaned. The description can be found in the instructions for use of the cleaning shuttle.
7. Visually inspect the surfaces of the operating table column. The surfaces must be free of residue and any visible contamination. Clean any surfaces with contamination still visible again.

The disinfection process can only start once the operating table column is completely dry.

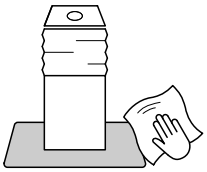
8. Prepare a suitable disinfectant and disinfection method. During disinfection, ensure that all surfaces are adequately moistened at all times.



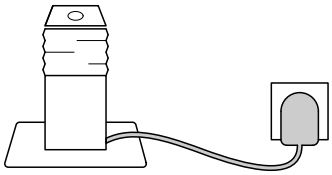
9. Disinfect the column head (docking point) from above and on all sides.



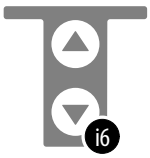
10. Disinfect the bellows and sheet cladding from top to bottom on all sides.



11. Disinfect the floor plate from above.



12. For the mobile operating table column, reinsert the power cable plug into the socket.
13. For the mobile operating table column, reconnect the equipotential bonding cable.



14. Move the lifting function of the operating table column to the lower end position using the [i6] key so that the transporter can be moved into position for the next transfer.

7 Maintenance

⚠ WARNING

Do not carry out any maintenance work during surgery or while the device is in use.

The first maintenance of the TruSystem 7500 operating table after handover to the user takes place in the 2nd year. The second maintenance takes place in year 4. From the 5th year onwards, the operating table is maintained annually.

Product maintenance must be carried out by qualified service technicians only. The contact details of service technicians can be obtained from the Technical Customer Service at Baxter.

Baxter recommends concluding a maintenance agreement, so that maintenance can be carried out promptly and reliably.

8 Repair

⚠ WARNING

Do not carry out any maintenance work during surgery or while the device is in use.

The operating table must be repaired by qualified service technicians only. The contact details of service technicians can be obtained from the Technical Customer Service at Baxter. The replacement of parts and other service work on the operating table is described in separate repair instructions. The repair instructions are intended exclusively for use by the service engineers of Baxter and service engineers authorized, trained, and certified by Baxter.

9 Disposal

Within the European Union, the product is subject to Directive 2012/19/EU on Waste Electrical and Electronic Equipment and complies with the requirements in Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, amended by the Commission delegated directive 2015/863 of 31 March 2015 as regards the list of restricted substances (RoHS). The operating table system must not be disposed of via municipal collection points for waste electrical devices.

In countries outside the European Union (EU), the legal regulations applicable in the respective country must be observed.

If you have any questions about proper disposal, please contact the Technical Customer Service at Baxter, your local dealer, or the appropriate national authority.

In addition to regional disposal, faulty or obsolete products can be returned to Baxter. Baxter will ensure environmentally sound disposal. Detailed information about returns is provided by the Technical Customer Service at Baxter.

When the TruSystem 7500 operating table is taken out of operation, the batteries need to be removed by a qualified service technician. Once removed, send the batteries to the Technical Customer Service at Baxter in suitable packaging. Attention: returns must be declared as hazardous materials of class 9/UN3480.

10 Technical data

The technical data are indicated in the instructions for use of the individual components.

Outer packaging Cardboard, wood, plastic bag and metal parts: 80 kg

10.1 SVHC (Substance of very high concern)

According to Article 33 of the REACH regulation (EC) no. 1907/2006, the products may contain components with reportable substances in concentrations exceeding 0.1 mass percent. A list of affected components will be provided by Baxter on request. The list can also be viewed online at ois.hillrom.com/ois.

10.2 Electromagnetic compatibility

Notice: The operating table may not be used in direct proximity to any other devices. If this is required, the operating table must be continually monitored to ensure its proper operation under these conditions.

The operating table may only be operated with the cables supplied with the product. The use of cables other than those specified may result in an increased transmission or reduced interference immunity of the TruSystem 7500 operating table.

The properties of this device, determined according to its EMISSIONS, allow for its use in the industrial sector and in hospitals (CISPR 11, Class A). When used in domestic situations (for which Class B is normally required according to CISPR 11), this device may not provide adequate protection from radio services. If necessary, users must take remedial measures, such as the relocation or realignment of the device.

Table 1 according to IEC 60601-1-2:2014		
Guidelines and manufacturer's declaration – electromagnetic interference		
The TruSystem 7500 operating table is intended for use in the electromagnetic environments as specified below. The operator or user of the aforementioned device should ensure that it is operated in one of the environments as described.		
Measurement of interference emissions	Compliance	Electromagnetic environment – guidelines
HF emissions in accordance with CISPR 11	Group 1	The TruSystem 7500 operating table only uses HF energy for its internal FUNCTIONS. Its HF emission is therefore very low and interference with adjacent devices is unlikely to happen.
HF emissions in accordance with CISPR 11	Class A	The TruSystem 7500 operating table is suitable for use in non-domestic establishments and those connected directly to the PUBLIC MAINS NETWORK that also supplies buildings used for domestic purposes.
Harmonic Emissions as per IEC 61000-3-2	Class A	
Voltage fluctuation/flicker emissions in accordance with IEC 61000-3-3	fulfilled	

Table 2 according to IEC 60601-1-2:2014			
Guidelines and manufacturer's declaration – electromagnetic immunity			
The TruSystem 7500 operating table is intended for use in the electromagnetic environments as specified below. The operator or user of the aforementioned device should ensure that it is operated in one of the environments as described.			
Immunity testing	EN/IEC 60601-1-2 testing level	Compliance level	Electromagnetic environment – guidelines
Static electricity discharge (ESD) according to EN/IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	The floor should be made of wood or concrete, or should be covered with ceramic tiles. If a floor is covered with synthetic material, the relative humidity must be at least 30 %.
Electrical fast transient disturbances/bursts in accordance with EN/IEC 61000-4-4	±2 kV for mains power cables 100 kHz repeat frequency	±2 kV for mains power cables 100 kHz repeat frequency	Mains power quality should correspond to a typical commercial or hospital environment.
Impulse voltages (surges) in accordance with EN/IEC 61000-4-5	±0,5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to earth	±0,5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to earth	Mains power quality should correspond to a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines pursuant to EN/IEC 61000-4-11	0% U_T; 0.5 cycle [a]	0% U_T; 0.5 cycle [a]	Mains power quality should be that of a typical commercial or hospital environment.
	0 % U_T; 1 cycle	0 % U_T; 1 cycle	
	70% U_T; 25/30 cycles [b]	70% U_T; 25/30 cycles [b]	
	0 % U_T; 250/300 cycles [b]	0 % U_T; 250/300 cycles [b]	
Magnetic field at supply frequency (50/60 Hz) in accordance with EN/IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields for the supply mains frequency should comply with values commonly found in commercial and hospital environments.
a)	at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°		
b)	at 0°		
Comment	U_T is the AC mains voltage prior to applying the test level.		

Attention: Distance for portable RF communications equipment and its peripherals

Do not use portable RF communications equipment (including peripherals such as an antenna cable and external antennas) at a distance of less than 30 cm (12 inch) from the TruSystem 7500 operating table, including its cables that have been specified by the manufacturer. Otherwise, the functionality of the system may be impaired.

The TruSystem 7500 operating table satisfies the following EN/IEC 60601-1-2 test levels with the specified compliance levels; the operator or user of the TruSystem 7500 operating table should ensure that it is being used in such an environment.		
Immunity testing	**EN/IEC 60601-1-2 testing level**	**Compliance level**
Conducted HF disturbance variables in accordance with EN/IEC 61000-4-6	3 V effective value 150 kHz to 80 MHz 6 V effective value in the ISM band between 0.15 MHz and 80 MHz [a)] 80 % AM at 1 kHz	3 V effective value 150 kHz to 80 MHz 6 V effective value in the ISM band between 0.15 MHz and 80 MHz [a)] 80 % AM at 1 kHz
Radiated HF disturbance in accordance with EN/IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
a)	The ISM bands (ISM = industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, and 50.0 MHz to 54.0 MHz.	

Immunity levels for RF fields of wireless communications equipment

Table: Special frequencies

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	Immunity level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM pulse modulation ±5 kHz variation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	Immunity level (V/m)
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Controlled HF disturbance variables

Recommended separation distances between portable and mobile HF communication devices and the TruSystem 7500 operating table			
The TruSystem 7500 operating table is intended for use in an electromagnetic environment where HF disturbances are controlled. The operator or user of the TruSystem 7500 operating table can help to minimize electromagnetic interference by complying with the minimum distances between portable and mobile HF telecommunications equipment (transmitters) and the TruSystem 7500 operating table, as recommended below in accordance with the maximum output of the communications equipment.			
Nominal transmitter power W	**Safety distance (m) according to transmission frequency**		
	150 kHz to 80 MHz D=1.2√P	**80 MHz to 800 MHz D=1.2√P**	**800 MHz to 2.5 GHz D=2.3√P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a nominal power not found in the table above, the distance can be calculated using the equation for the respective column, where P is the nominal power of the transmitter in watts (W) according to the transmitter manufacturer's data.			
Note 1	To calculate the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, an additional factor of 10/3 is used in order to reduce the likelihood that a mobile / portable communications device unintentionally brought into the PATIENT area will cause any interference.		
Note 2	These guidelines might not be applicable in all situations. The propagation of electric waves is influenced by the absorptions and reflections of buildings, objects and human beings.		

EMC-relevant wireless properties of the TruSystem 7500 Operating Table

Notice: Interference caused by other devices

The TruSystem 7500 operating table may be subject to interference from other devices, even if these devices comply with the applicable CISPR-defined emission requirements.

11 Product certification

11.1 European Union

The TruSystem 7500 operating table is a Class I medical device according to Regulation 2017/745/EU concerning medical devices, and is compliant with the version of the regulation currently in force at the time of product sale. Baxter declares the conformity of the operating table with the essential safety and performance requirements according to Regulation 2017/745/EU concerning medical devices, Annex I. A conformity assessment procedure required for Class I devices shall be carried out in accordance with Article 52 (7), taking into account a quality management system in accordance with Annex IX, Chapter 1. The manufacturer certifies conformity with the CE marking.

11.2 Ukraine

УкрСЕПРО: Це маркування підтверджує, що вироби, промарковані перевірочним знаком, пройшли всі необхідні процедури підтвердження відповідності та підкоряються визначеним технічним керівництвам України.

Відповідність: Технічний регламент щодо медичних виробів, затверджений Постановою Кабінету міністрів України від 02 жовтня 2013 р. № 753 (поточна редакція від 18.08.2016) = ТР № 753

11.3 Serbia

Certificate / registration number 515-02-03704-16-001

11.4 EAEU

This product has passed all conformity assessment procedures (proof) specified in technical regulations as part of regular customs procedures for assessment of conformity (proof), and furthermore complies with all industrial regulations. It is approved in the following countries: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia.

12 Radio license

Radio license information is listed in Document 7990101 (Radio information).

This page is intentionally blank.

This page is intentionally blank.

Baxter

7990010_030_08 – 2078288 – 2023-01-19