BTL SPINAL DECOMPRESSION

USER’S MANUAL

CONTENTS

1 GENERAL INFORMATION

1.1 INTENDED PURPOSE

The device BTL Spinal Decompression is intended for medical use, to support and position a patient during therapeutic and diagnostic operations.

1.2 USER PROFILE

The device shall be used by medically educated personnel. The user shall be familiar with all safety precautions, operating procedures and maintenance instructions.

1.3 OPERATING ENVIRONMENT

The device is intended to be used primarily in hospitals, but it can also be used in clinics, medical centres or wherever the therapeutic and diagnostic operations are performed. The device is not intended for home-use. Do not use the device in a location where explosion or water intrusion hazards are present or in oxygen-rich, dusty or humid environment. The device can be used only with BTL-6000 Traction and can be operated only, when the BTL-6000 Traction is switched on.

1.4 PATIENT PROFILE

The use of the device is not limited by gender nor by age of the patient in general. Nevertheless, manufacturer does not recommend the use of the device on patients until the epiphyseal closure, especially on neonates and small infants.

1.5 DESCRIPTION OF THE DEVICE

The device supports the patient during decompression therapy. The height of the device can be adjusted with the help of the telescopic column. Angles of sections can be adjusted with the help of linear actuators or gas springs.

Movements are controlled by pushing buttons on the remote control.

It is recommended that the installation (and interconnection) is done by BTL service personnel.

2 USED SYMBOLS AND MARKING

	Follow instructions for use
	Warning
	Caution
	Type BF applied part
	Type B applied part
	Separate collection for electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Class II equipment
	Keep away from sunlight
	Batch code
	Catalogue number
	Trapping zone – mix of possible risk (hand injury and/or body crush)
	Warning sign – hand injury (risk of crushing or cutting fingers or hands)
	Warning sign – body crush (risk of crushing of body)
	Medical device
	Authorised representative in the European Community
	CE mark
	No sitting
	No heavy load
	No stepping on surface

3 SAFETY PRECAUTIONS AND WARNINGS

	Read the User's Manual carefully and become familiar with all its safety requirements, operating procedures and maintenance instructions before using the device. It is not allowed to use the device and its accessories in any manner other that is in accordance with the User's Manual. It is prohibited to use the device in the way that is not in accordance with the Intended use.
	Inspect the box for damage and report any damage to the transport carrier and the distributor. Do not proceed with assembly and set-up if the box is damaged.
	The mains to which the device will be connected must be installed and revised according to the current standards for electrical installations in medical locations. Make sure that voltage parameters of the power supply grid correspond with the device requirements as stated in the chapter **Technical Parameters.**
	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	In emergency situations, when stop of the device is desired, do one of these actions: Push Patient Switch. Push Operator Stop Button on BTL-6000 Traction. Trigger ON/OFF Switch (Mains switch). Disconnect Patient Switch. Disconnect power cord from mains socket.
	Make sure that the mains socket is always accessible.
	Do not immediately switch-on the device after its long-lasting storage in conditions with low/high temperature and/or low/high humidity. After bringing the device from cold to warm environment, wait until the temperature equalizes before its connection to the mains (at least 2 hours). Allowed ranges of Storage / Operating Conditions are defined in chapter **Technical Parameters.**
	For the Intended use, Contraindications and side effects of the decompression therapy, refer to the BTL-6000 Traction User's manual.
	The device must be transported, stored and operated in the environment defined in the chapter **Maintenance.** It is strictly forbidden to operate the device if any danger of explosion or particulate matter (e.g. water) penetration into the device can occur. The device cannot be in contact with flammable anaesthetics or oxidizing gasses (O_2, N_2O, etc.). The device is not suitable for use in an oxygen rich environment. The device is not intended for exterior use!
	Do not connect other accessories than those stated in this User´s Manual.
	It is prohibited to place any objects that produce heat or objects containing water or other liquid on or near the device.
	Keep the space under the device clear. Do not allow people or things to be present under the bed area.
	Accessible parts or surfaces can get hot during the operation of the device. Make sure to follow the duty-cycle instruction and environment temperature range.
	Do not place strong magnets or other electrical devices near the device because of the possible interference.

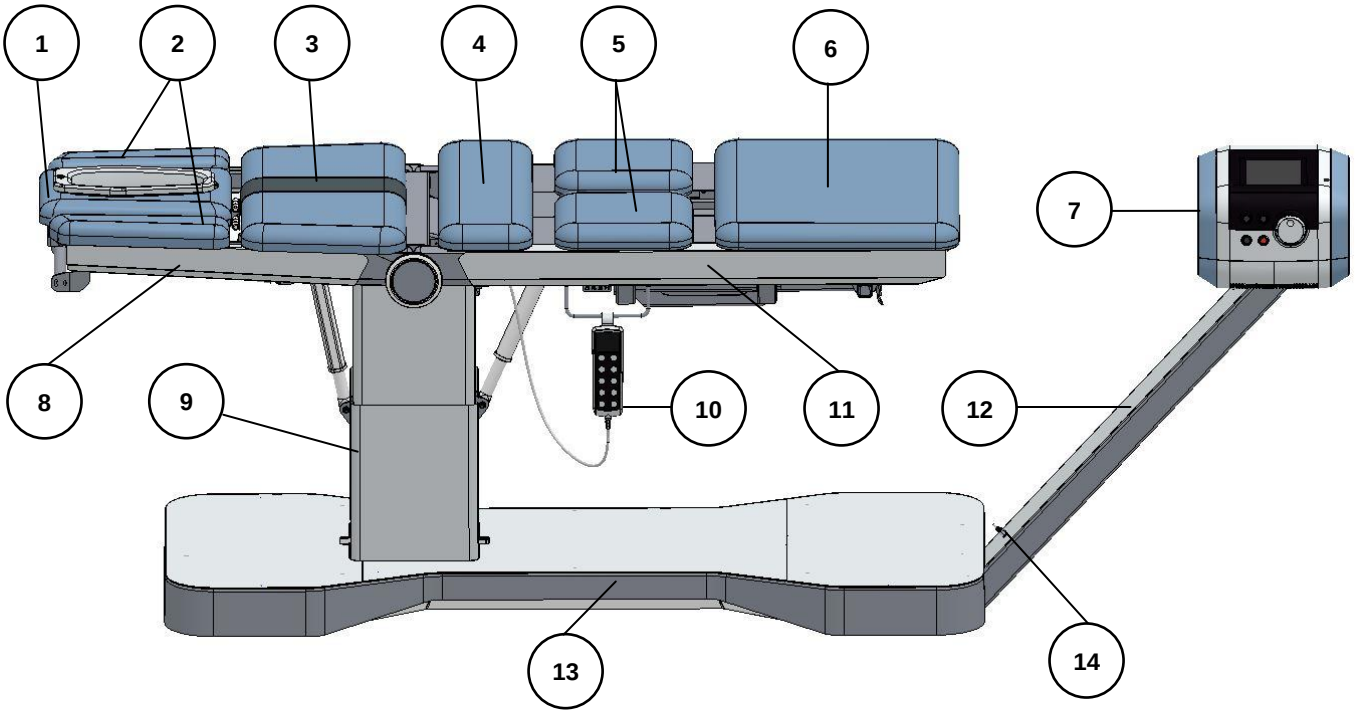
	No modifications of the device are allowed. Do not open or remove the protective covers or disassemble the device for any reason. There is risk of electric shock. There are hot and movable parts inside. All service actions must be done by an authorized BTL service only; otherwise BTL bears no responsibility for further operation of the device.
	Before changing the fuses, make sure the device is disconnected from power supply grid. Ensure that the type and rating of the new and the replaced fuses match (see the chapter **Technical Parameters**).
	When handling the device on castors, beware of trapping the foot under the bottom part of the device.
	The castors are designed for the relocation of the device only. Do not relocate the device when any additional load is present.
	When locking/unlocking castors, beware of trapping the hand under the bottom cover.
	Once the device is installed in the room, all castors must be locked.
	For correct fixation of the patient to the device, see instruction in BTL-6000 Traction User's manual. Check the belts regularly and change them once they become worn.
	In case of need to release the patient from the belts (e.g. state of emergency), unlock the buckles and unzip the velcro belts. You can check the User Manual of the BTL-6000 Traction to get more details.
	Do not put any weight on the power cord (e.g. do not stand on it).
	Do not put your hands or other things between the moving parts of the bed area.
	Before starting a therapy always check the device and its accessories (the cables, the connectors, the therapy belts, the controls, upholstery) for a possible mechanical, functional or other damage. In case that a defect or deviation from normal function is found, stop using the device immediately and contact the BTL authorized service. In case that the device is in use despite the presence of defects, the person solely responsible for any damage caused by the device is the user.
	Make sure a patient is lying on the device calmly and holding the Patient Switch before the start of positioning the device and during the therapy. The Patient Switch must be always held by the patient. Patient must be instructed to press the button immediately when any kind of discomfort appears during the movement of the device or during the ongoing therapy. By pressing the patient switch, movement of the device and/or therapy are stopped.
	Never apply the therapy on the anesthetized patient or the patient with elevated pain threshold. Inability of the patient to feel pain can cause serious harm because the operator cannot evaluate reactions of the patient during therapy.
	During cervical decompression in Build-in Cervical Adapter, the patients with long hair shall always have their hair tied or wear a hat.
	When lifting or retracting the pelvic section or thigh section (electrically or manually), pay attention to the trapping zones.
	Unlock the device´s sliding part before starting the therapy! During unlocking make sure there is no object in the trapping zone.

	Lock the device´s sliding part after the therapy is finished!
	Do not cover any part of the device with blanket, bed sheet, etc. during therapy.
	Do not use force greater than 70 kg for asymmetric decompression when using Asymmetric Therapy Adapter.
	When applying asymmetric decompression using Asymmetric Therapy Adapter to tall Patients, beware of trapping their legs during moving of the couch.
	In case of applying cervical decompression therapy in sitting position, use the chair without wheels, with a standard height of the sitting area (42–48 cm).
	The Operator shall be present during the whole therapy. Operator shall require and respect Patient´s feedback during positioning of device and during the therapy.
	The output voltage values can exceed safe values in connectors marked with the depicted symbol.
	Protect the device against unauthorized use.
	Keep the device away from direct sunlight.
	Keep the device out of reach of children.
	Strictly follow the maximum allowed weight of the patient. Do not overload the device and do not jump on it.
	Sit on the device only in its middle part. Never sit on or overload the headrest and lower part of the device.
	Make sure there is 80 cm of free space around the device in all directions. Do not place other devices in this area.
	The device must be disposed in a way common for electric and electronic equipment. Do not place the device in municipal waste containers! The device does not contain any toxic materials, which could harm the environment in case of proper way of disposal.
	This device does not contain any drugs or substances as an integral part or to be given to the user or patient. This couch does not use or emit any toxic or radioactive substances during its operation, storage or transport under the stated conditions.
	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

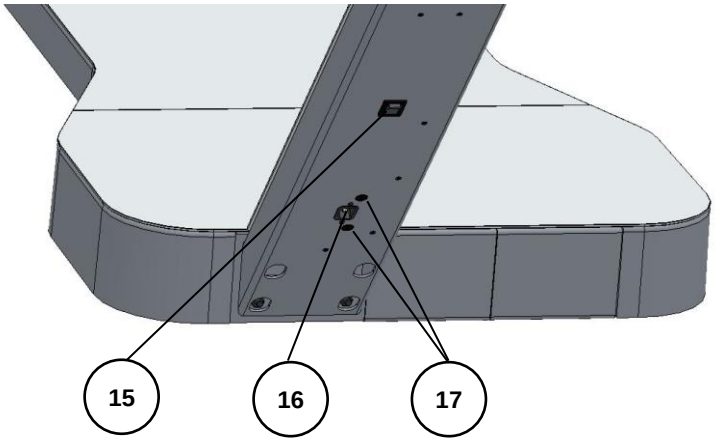
4 DEVICE AND ACCESSORIES

4.1 DESCRIPTION OF THE DEVICE

General view



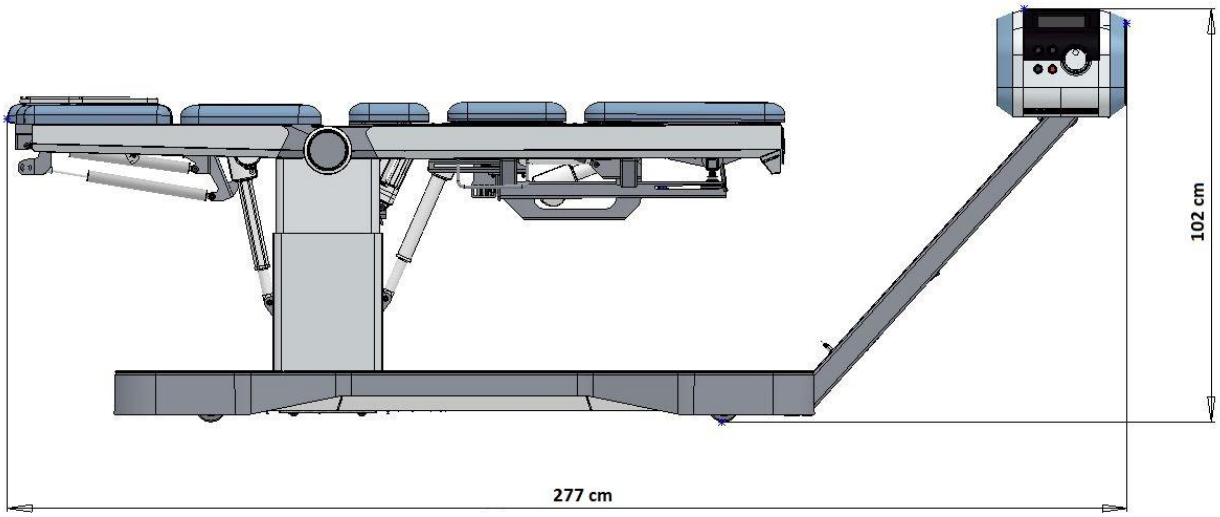
Bottom of the console

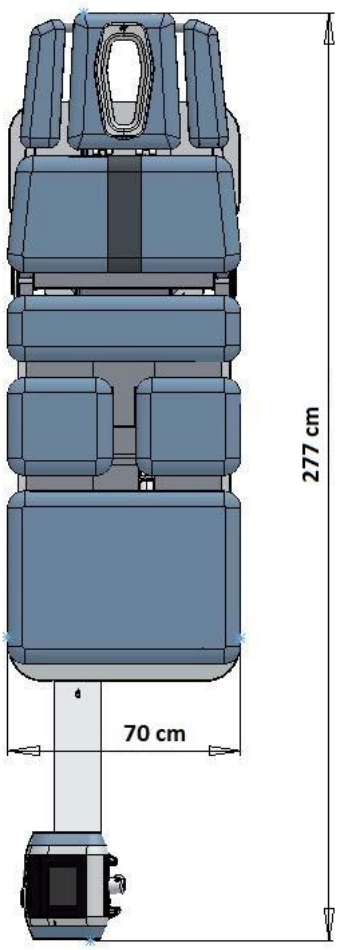


1. head part with Face Pad
2. arm rests
3. thoracic part with Velcro belt
4. pelvic tilt
5. thigh part
6. calf part
7. Traction Unit
8. upper part
9. telescopic column
10. remote control
11. lower part
12. console
13. bottom of the device
14. patient switch connector
15. on/off switch
16. power supply connector
17. fuses

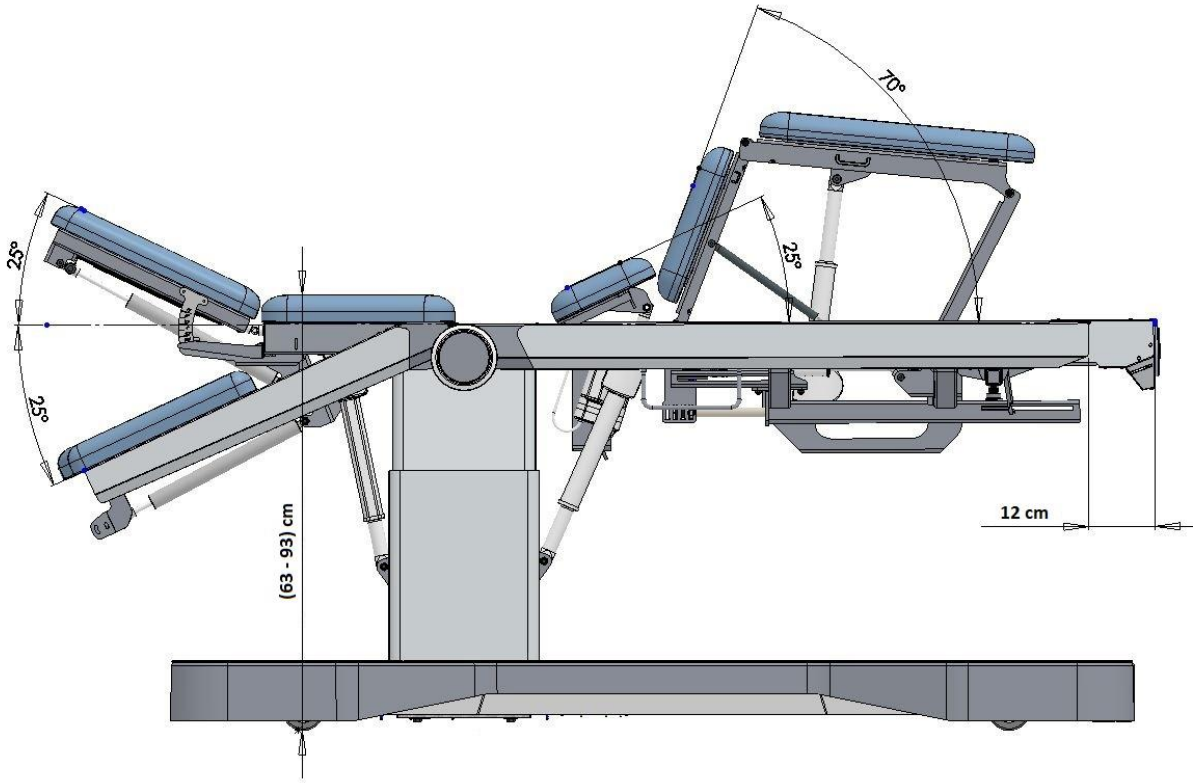
4.2 DEVICE DIMENSIONS

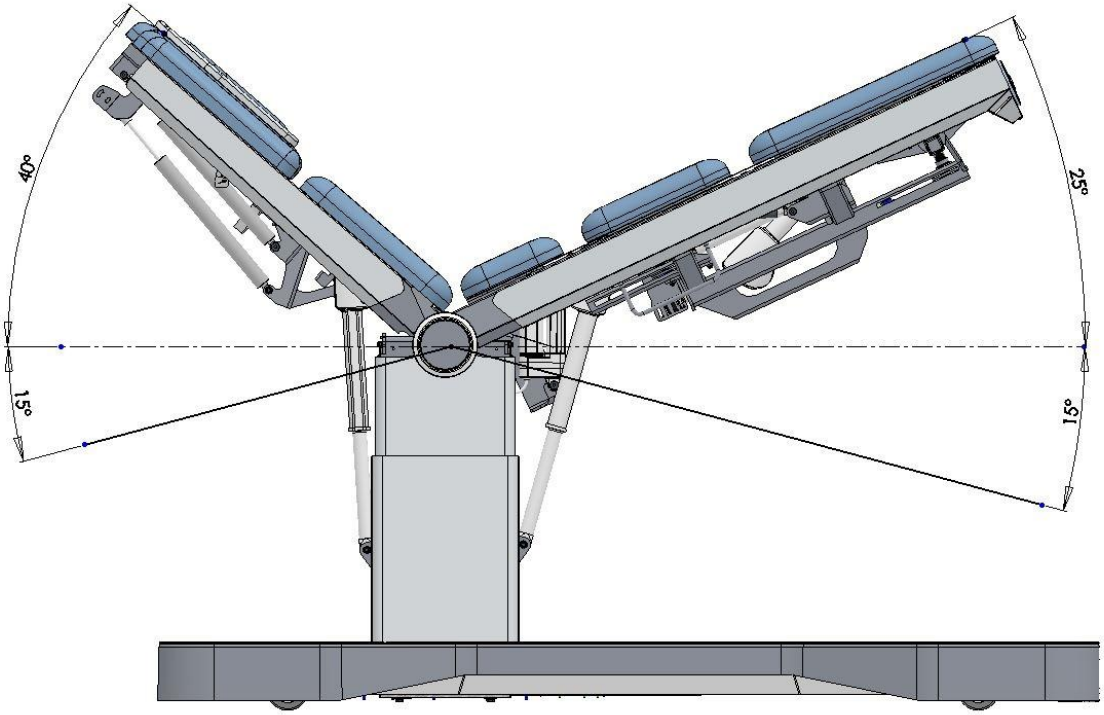
Fixed dimensions



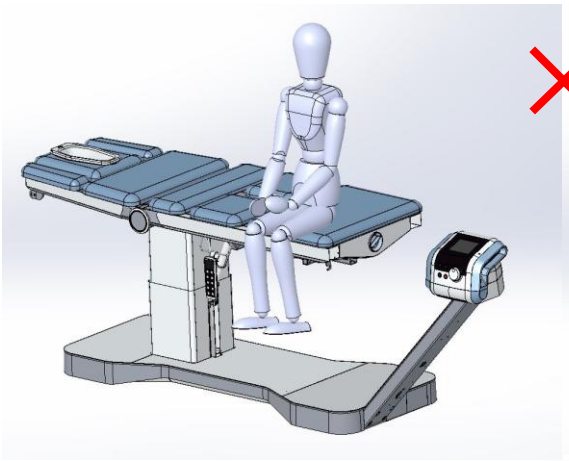


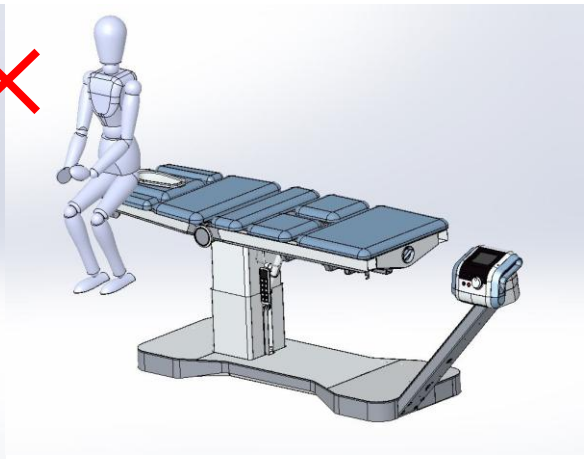
Moving parts range of motion

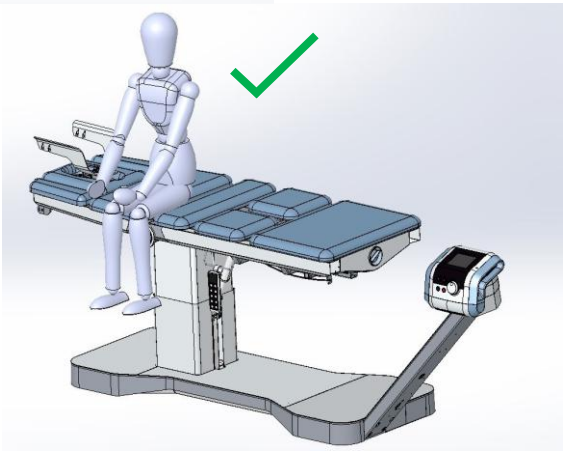


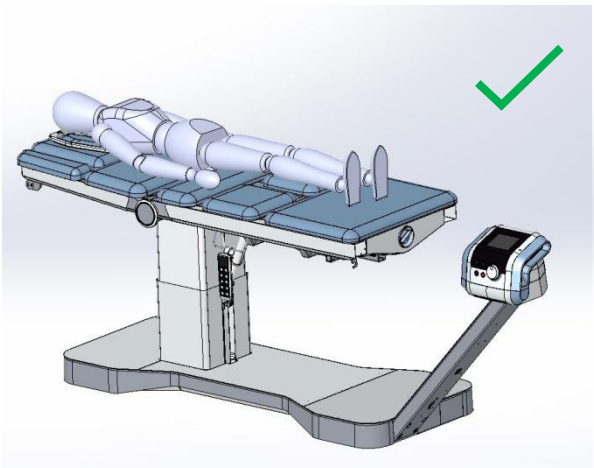


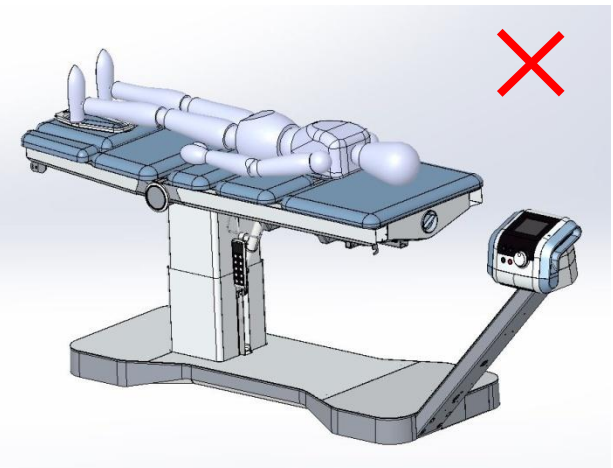
Correct and wrong positions





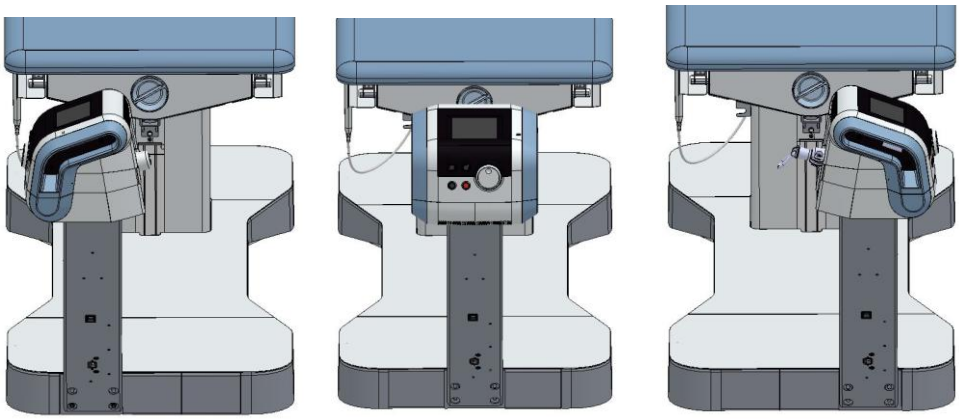






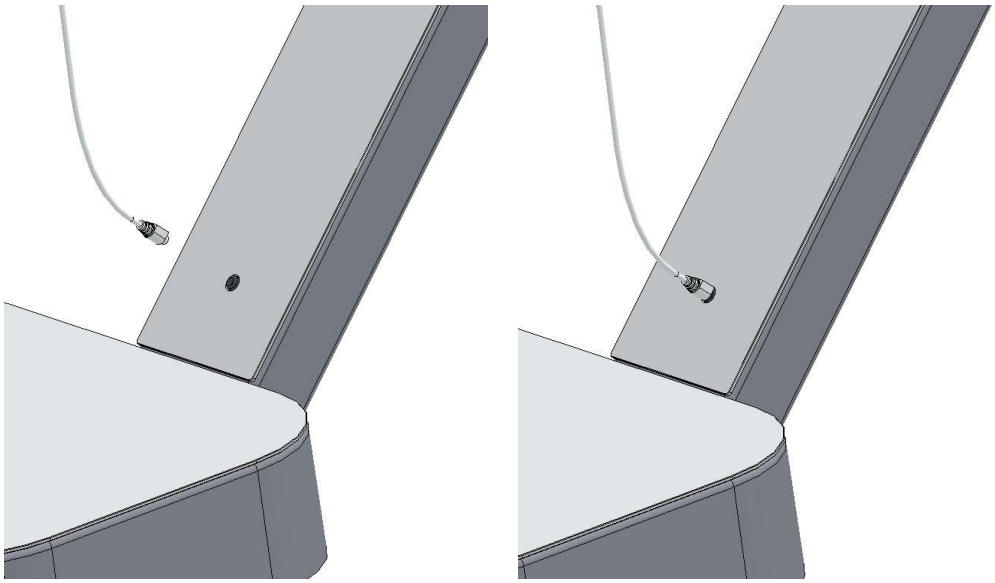
4.3 TRACTION UNIT POSITION

It is possible to mount the Traction Unit in three different positions according to user's needs. It is recommended that the assembly is done by BTL service personnel.



4.4 PATIENT SWITCH CONNECTION

Always connect the patient switch in to the connector in the console.



4.5 START-UP PROCEDURE

1. Make sure the power cord is connected to mains socket and to the device.
2. Make sure the Patient switch is connected to the device.
3. Make sure both the cables from the console of the device are correctly connected to Traction Unit.
4. Turn on the on/off switch (position "1").
5. Turn on the Traction Unit and wait until till it starts up.
6. Turn on the device.

4.6 SHUTDOWN PROCEDURE

1. Turn off the device.
2. Turn off the Traction Unit.
3. Turn off the on/off switch (Position “0”).

4.7 THE DEVICE CONTROL

display

LED indication (LED on = steady state position, LED flashing = movement of the device)
to decrease or increase the selected value, to move one or more sections, to lock the screen, to set calibration

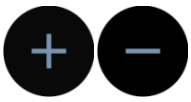
to set upper / lower section angle

to set pelvic tilt / thigh section angle

to set couch height / preset position choice / heating / lighting

to set parking position / ON/OFF button

Buttons description

	increase and decrease the selected value
	couch’s height
	lower section‘s angle
	thigh section‘s angle
	upper section‘s angle
	pelvic tilt‘s angle
	parking position selection
	preset position choice / heating / lifting
	switch on / off the device

Switch on/off the device

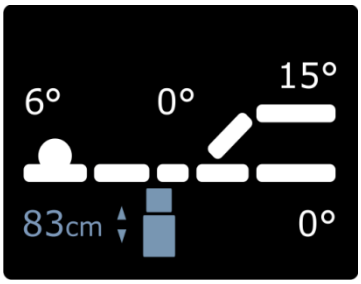
The couch can be switched on or off by long-pressing the button 

Initial screen

This screen is displayed when switching on the device.

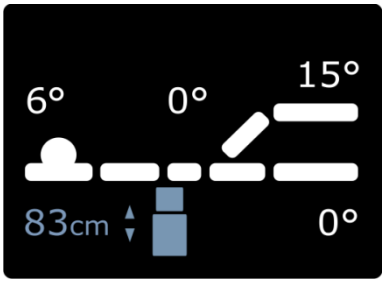
After that it switches to home screen. Initial screen is also used as sleep mode – in case the user doesn´t touch the remote control for 5 minutes, the screen switches to Initial screen. If the user presses any button, the Initial screen switches to Home screen.

Home screen



This screen is displayed after Initial or Lock screen.

The parameter to be changed or the function you want to turn on is activated by pressing the appropriate button, e.g. height of the device setting:

Picture of the button	Picture of the screen
	

Change the parameter value with help of  and  .

To set the position press and hold  or  button until the section reaches the desired position.

4.7.1 DEVICE PARAMETERS DESCRIPTION

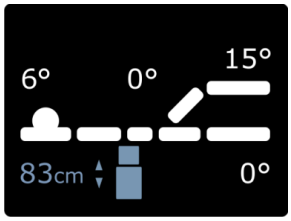
Description of all parameters that the user can change are listed below:

device height

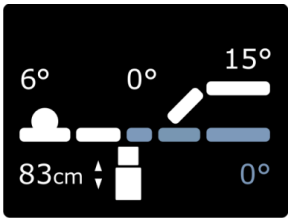
lower section angle

upper section angle

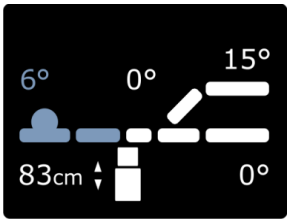
pelvic tilt angle



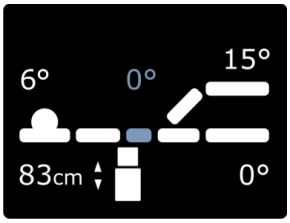
63 cm to 93 cm



-15° to 25°



-15° to 40°



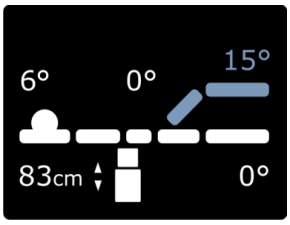
0° to 20°

thigh section angle

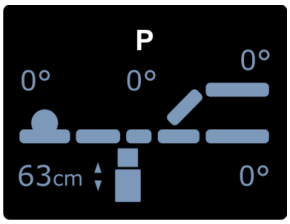
parking position

preset position

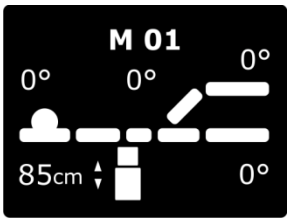
set heating



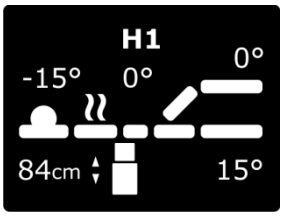
0° to 70°



all sections in 0°, couch height 63 cm

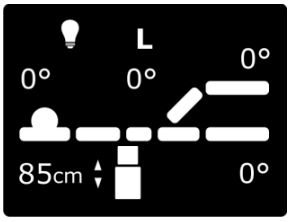


device height and section's positions according to selected position from memory



set heating level of the thoracic part

set lighting



set lighting of the device

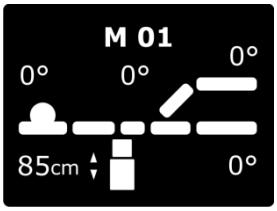
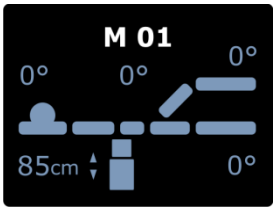
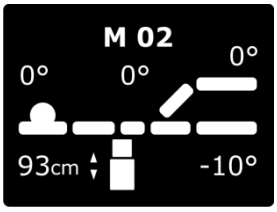
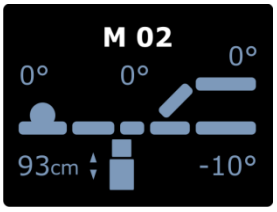
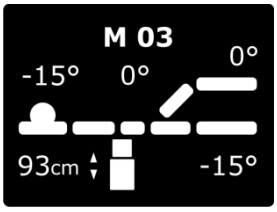
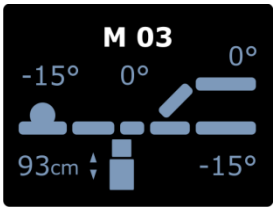
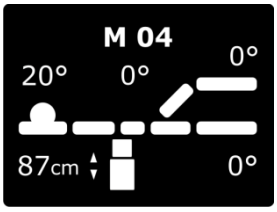
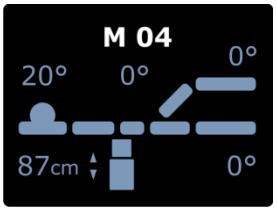
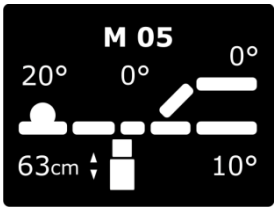
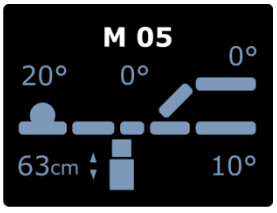
4.7.2 PRESET POSITIONS

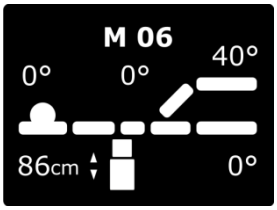
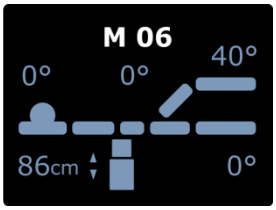
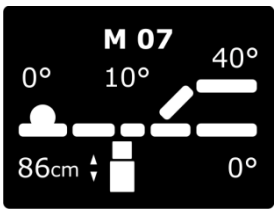
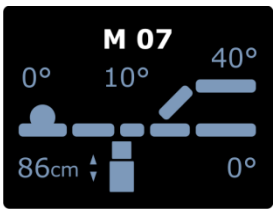
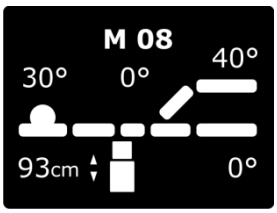
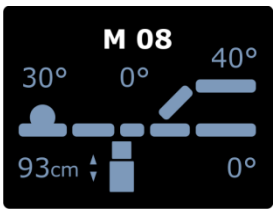
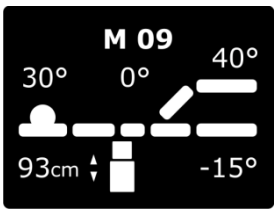
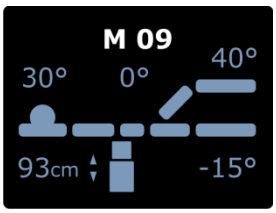
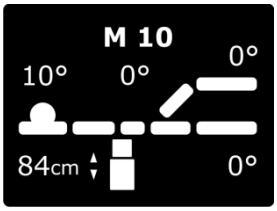
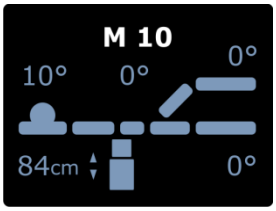
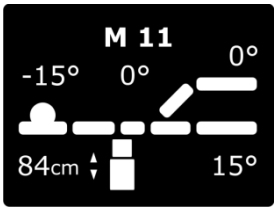
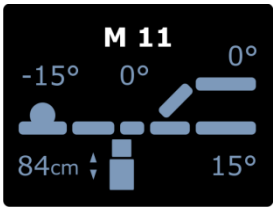
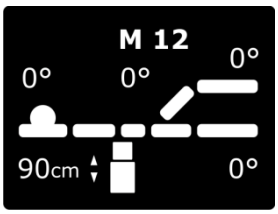
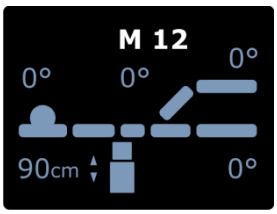
By pressing the button 

, first preset position is displayed. By pressing the button 
, next position is displayed etc. By pressing the button 
, previous position is displayed. To set the selected preset position, you need to hold the button 

until couch reaches the final position. Actuators start their movement after 1 s of holding the button.

When switching between preset positions, all sections are white (not moving). When the movement of the device to preset position is running, the device picture is blue. Once the device reaches the final position, the picture of the device change its colour to white again - so the user recognizes the device is in final position.

Name/code on the display	Screen (initial and final)	Running screen	Description
Basic position M 01			All sections go to 0°. Couch goes to 85 cm of height.
Flexion prone M 02			Lower section goes down to -10°.
Roof M 03			Lower section goes down to -15° and upper section goes down to -15°.
Extension prone M 04			Upper section goes up to 20°.
Cradle M 05			Lower section goes up to 10° and upper section goes up to 20°.

Flexion supine M 06			Thigh section goes up to 40°.
Pelvic flexion M 07			Pelvic tilt goes up to 10° and thigh section goes up to 40°.
Semi-upright M 08			Thigh section goes up to 40° and upper section goes up to 30°.
Inclined semi-upright M 09			Lower section goes down to -15°, thigh section goes up to 40° and upper section goes up to 30°.
Side-line flexion M 10			Upper section goes up to 10°.
Inversion[1] M 11			Lower section goes up to 15° and upper section goes down to -15°.
Cervical supine M 12			All sections go to 0°. Couch goes to 90 cm of height.

[1] Available only with accessory.

Parking position

Pressing and holding the button P will straighten all sections to 0° and couch descends to the lowest position.

User-defined positions

The couch offers function for saving the user-defined positions. It is possible to rewrite preset position (only related to positioning of the device, not heating or lighting). To rewrite current position, press and hold M and + for 3 sec. After that, new position parameters will be saved. The change is accompanied by the confirmation beep sound.

Reset to factory settings

To reset all rewritten positions to the original ones, press and hold M and − for 10 sec. After that, the original positions will be restored. The change is accompanied by the confirmation beep sound. During the last 7 sec of countdown, there is a text on the screen:

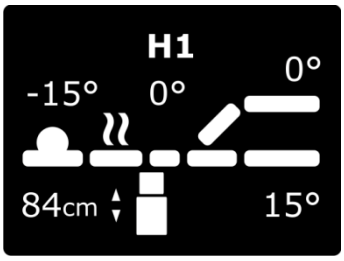
After successful reset, there will be displayed the following screen:

Set heating[2]

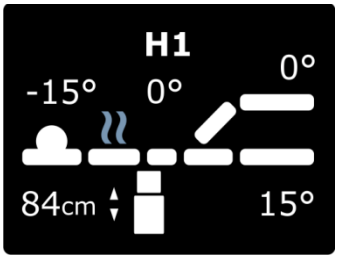
The device enables heat up its upper part in two levels (H1 and H2). Heating is automatically turned off after 30 minutes.

After H1 memory position selected via button M and buttons − or + , you will see the screen:

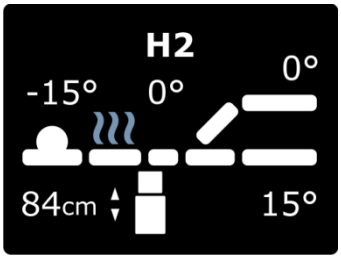
[2] Depends on couch's configuration.



To turn on the heating to level 1, press M button for 1 s. The screen changes to:

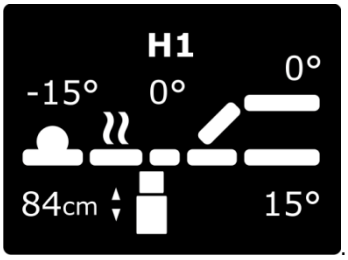


If you want to heat the device to level 2, use H2 screen:



If the heating is turned on, the symbols of heating  (H1) or  (H2) are always shown on the screen.

To turn-off the heating level 1, press M button for 1 s. The screen changes back to:



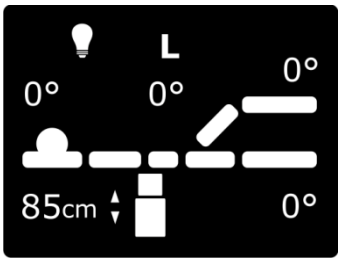
Use the same procedure to turn-off the heating level 2 on H2 screen.

Set lighting[3]

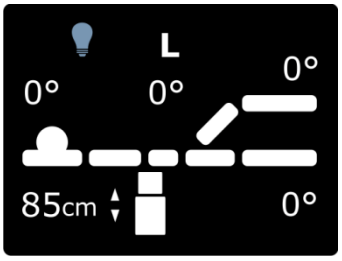
The device is equipped with lights in the middle part and under the base.

[3] Depends on couch's configuration.

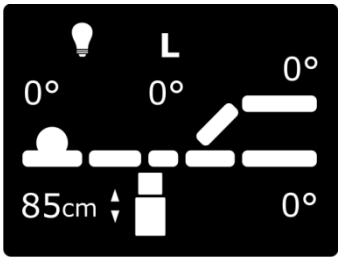
After L memory position selected via button  and buttons  or  , you will see the screen:



To turn on the lighting, press  button for 1 s. The screen changes to:



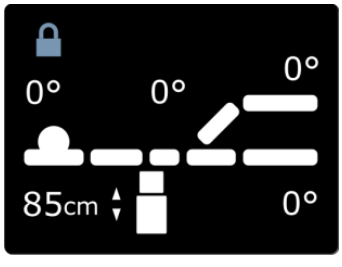
To turn-off the lighting, press  button for 1 s. The screen changes back to:



Bulb pictograms  are visible only on “L” screen.

Remote control lock/unlock

To lock the remote control, press simultaneously buttons  and  . Unlocking can be done in the same way. Once the remote control is locked, you will see  symbol on the screen:



If the remote control is locked, only on/off button is working. Once the remote control is unlocked, the locking pictogram disappears and all buttons are working. Display shows the Home screen.

4.7.3 CALIBRATION OF THE DEVICE

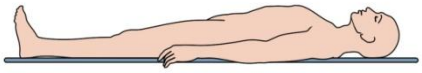
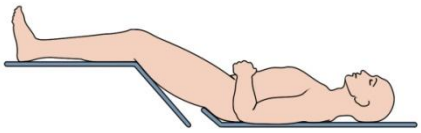
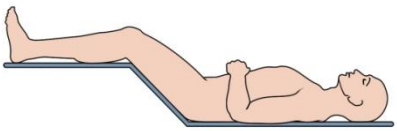
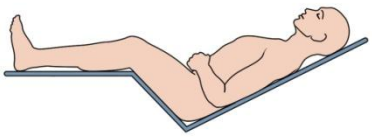
To calibrate the device, press and hold simultaneously buttons  and.  The device will move to the highest position and all sections to its lowest positions to finish the calibration. Do not calibrate with patient on the device.

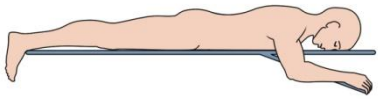
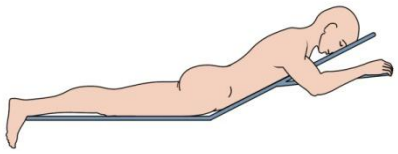
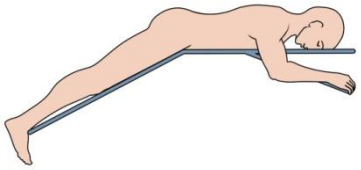
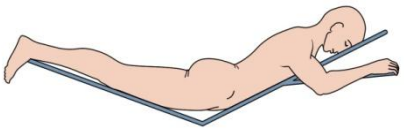
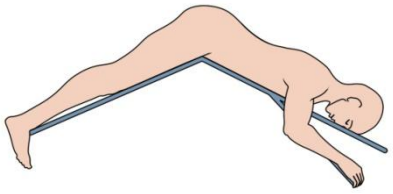
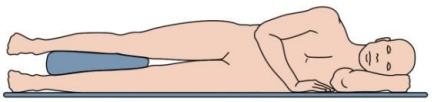
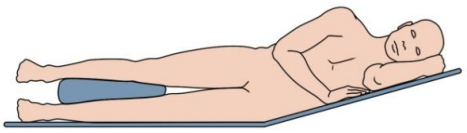
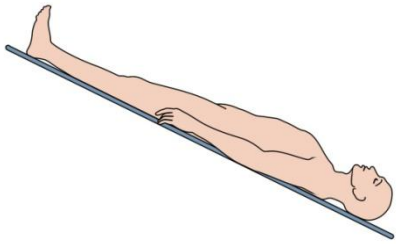
4.7.4 PATIENT SWITCH

In case of need to stop all the movements of the device, press patient switch or stop button on the Traction Unit. The patient switch must be always held by the patient. Patient must be instructed to press the button immediately when any kind of discomfort appears during the movement of the device or during the ongoing therapy. By pressing the patient switch, movement of the device and/or therapy are immediately stopped. Make sure that a patient holds the patient switch before start of positioning the device.

4.8 RECOMMENDED POSITIONS

The patient´s position is conditioned by the treated area. Choose the most suitable and relaxed position according to the evaluation.

Supine	
Pelvic flexion	
Supine flexion	
Semi-upright	
Inclined semi-upright	

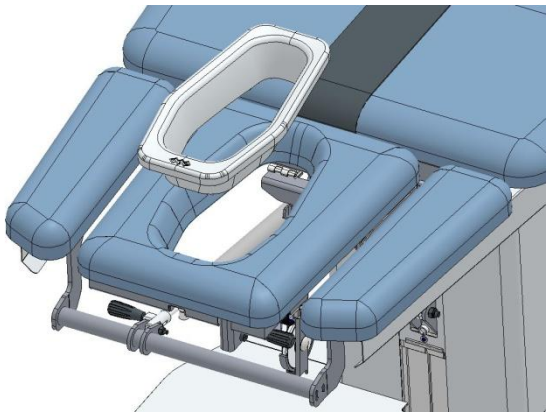
Prone	
Prone extension	
Prone flexion	
Cradle	
Roof	
Side-line	
Side-line flexion	
Inversion[4]	

[4] Depends on couch's configuration.

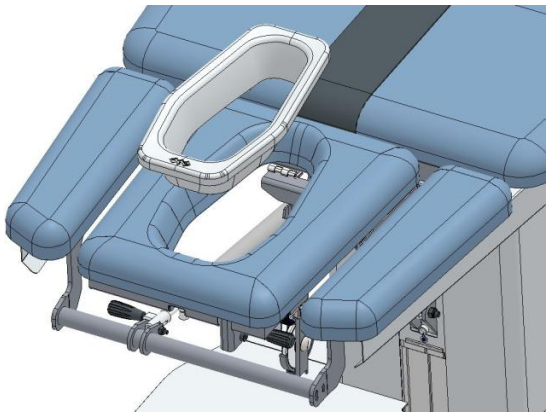
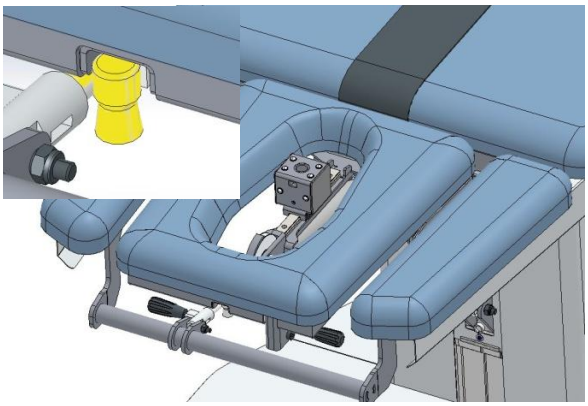
4.9 SPECIAL FUNCTIONS / ACCESSORIES

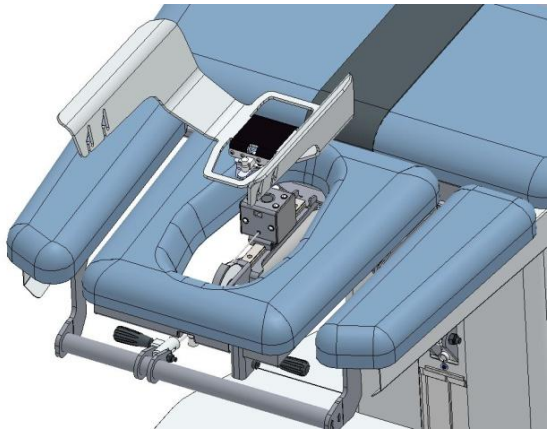
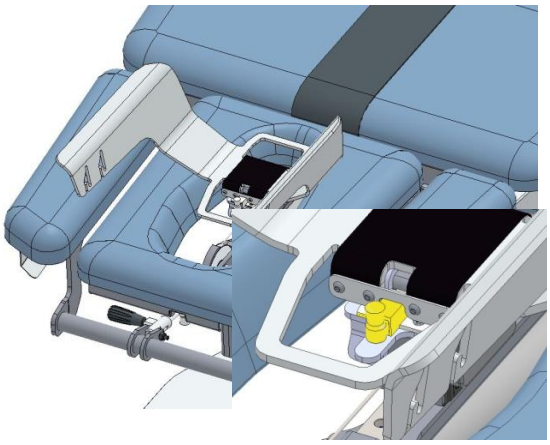
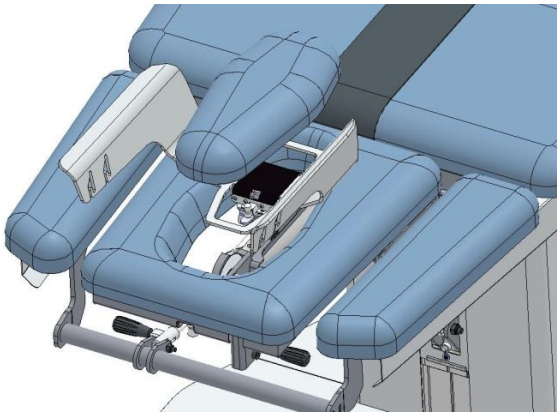
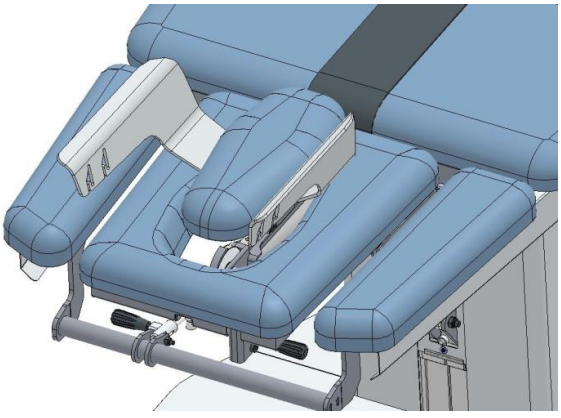
4.9.1 FACE PAD

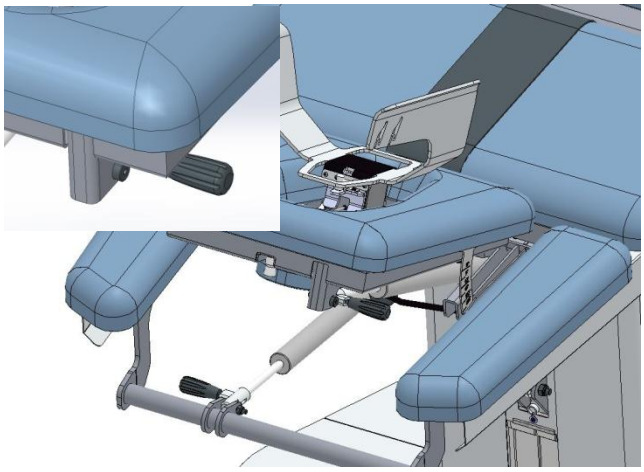
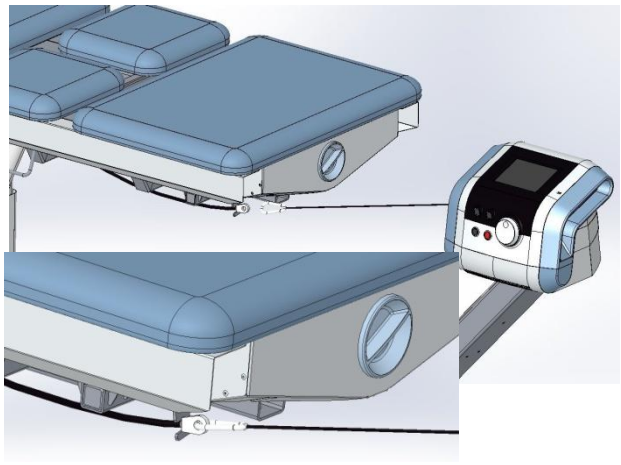
This pad was designed with respect to the maximal patient's comfort during the therapy. Use it especially for therapy in prone position. Face pad can be easily maintained, read more in the chapter **Maintenance**.

	Insert the Face pad into the face hole so BTL sign is up.

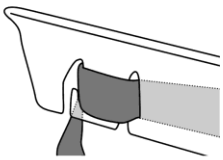
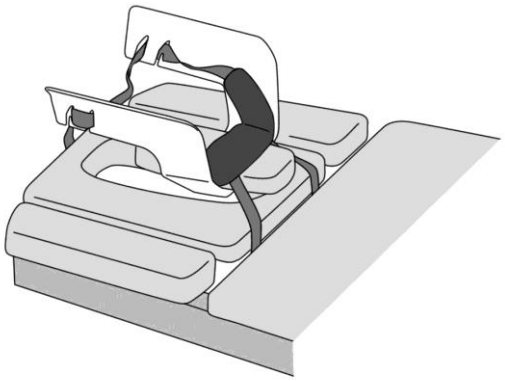
4.9.2 INSTALLATION OF CERVICAL ADAPTER

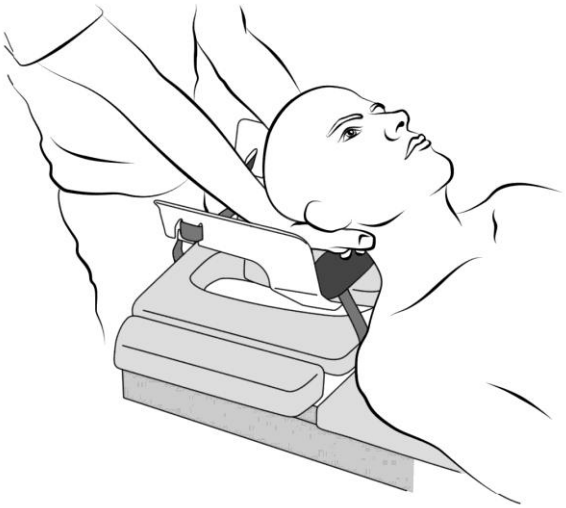
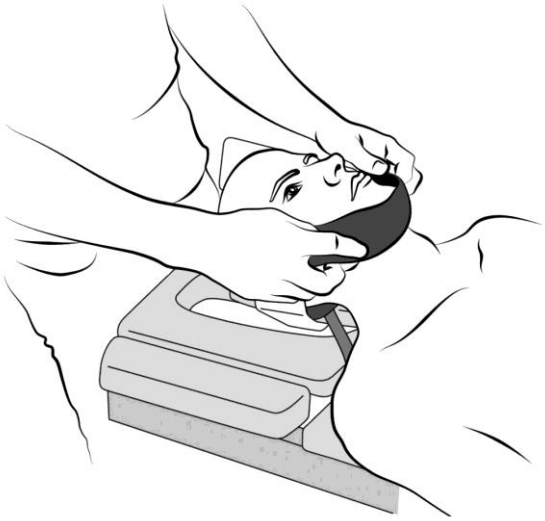
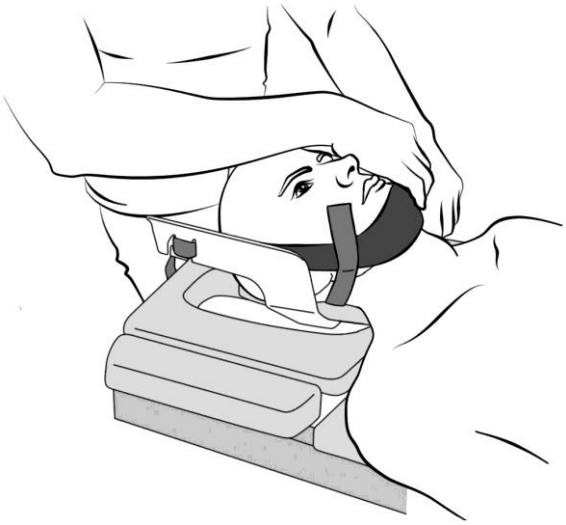
	Remove Face pad and/or Upholstery insert.
	Put the rail into the horizontal position. Note: Always use the lock to secure the rail.

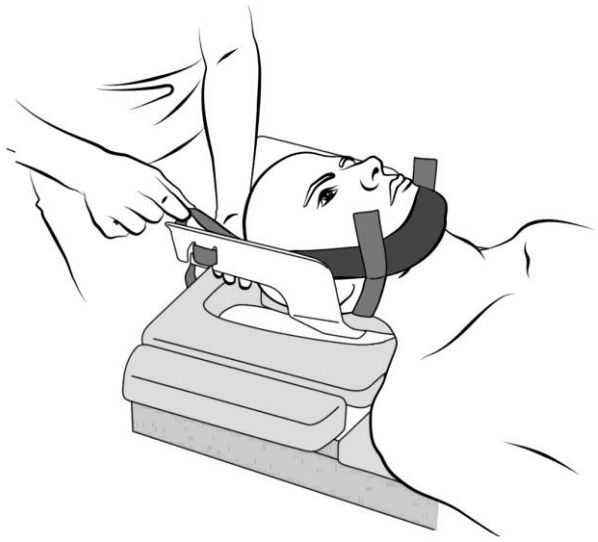
	Install the adapter on the rail.
	Use the pin to lock the adapter in the rail.
	Put the Upholstery insert on to the adapter.
	Final configuration.

	If needed, adjust the angle of the cervical adapter.
	Do not forget to connect traction rope to the device.

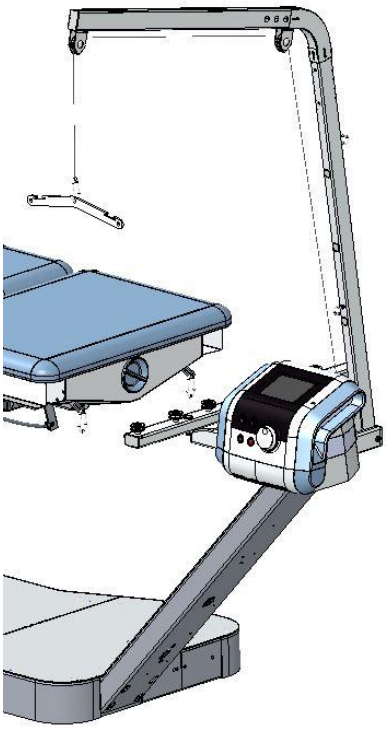
4.9.3 CERVICAL DECOMPRESSION THERAPY SET UP – LYING POSITION

 	Place the cervical belt into the cervical adapter. Note: always remove the Face pad before doing the therapy.

	Position the patient into the cervical adapter, so the rear part of the belt lies under the scruff of the neck. Note: always keep contact with the patient with both hands.
	Place the front part of the belt on the chin.
	Use the horizontal Velcro strap on both sides to fix it.

	You can adjust the tension between rear and front part by moving the straps forward or backward.
	Finally ask the patient to move little bit downwards and lay still. Note: always make sure that cervical adapter is in the lowest position and belt is not loose.

4.9.4 CERVICAL DECOMPRESSION THERAPY SET UP – SITTING POSITION

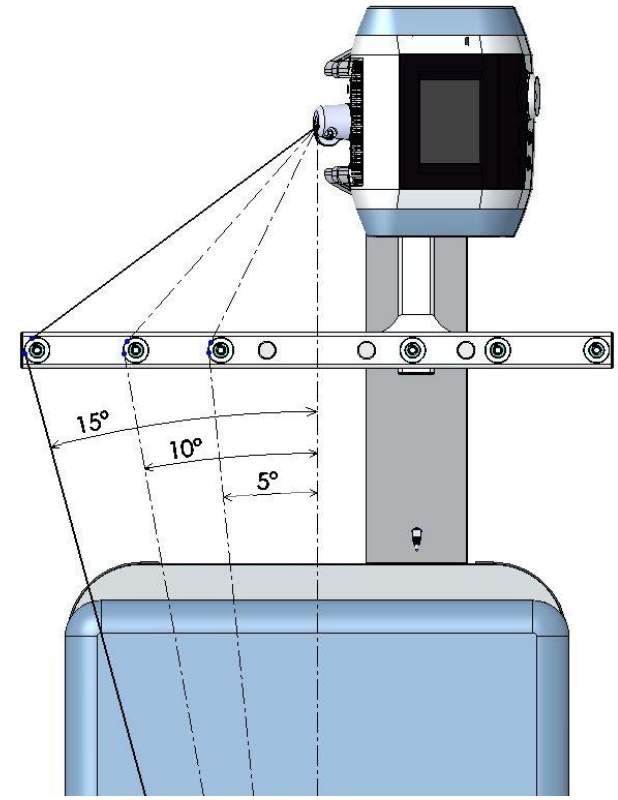
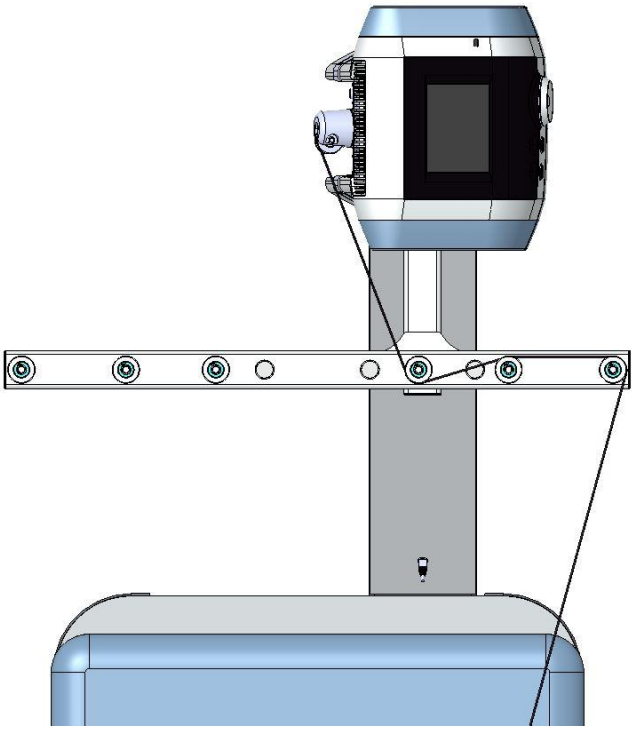


To apply cervical therapy in sitting position, use the Sitting Therapy Adapter.

Note:
For details see the User's manual of the BTL-6000 Traction.

4.9.5 ASYMMETRIC ADAPTER

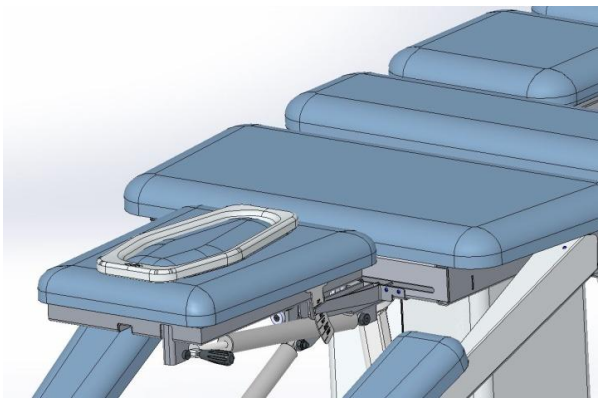
Asymmetric adapter allows performing decompression therapy in three different angles (5°, 10° and 15°). It is used in lumbar and hip therapy.[5]

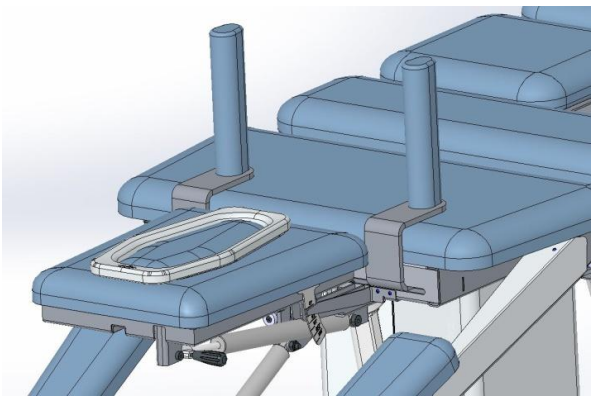
	Set up for asymmetric decompression from left side. Note: set up varies depending on the position of the Traction Unit.
	Set up for asymmetric decompression from right side. Note: set up varies depending on the position of the Traction Unit.

[5] Keep in mind smaller space between the unit and the device, when the asymmetric adapter is installed.

4.9.6 AXILLA POSTS INSTALLATION

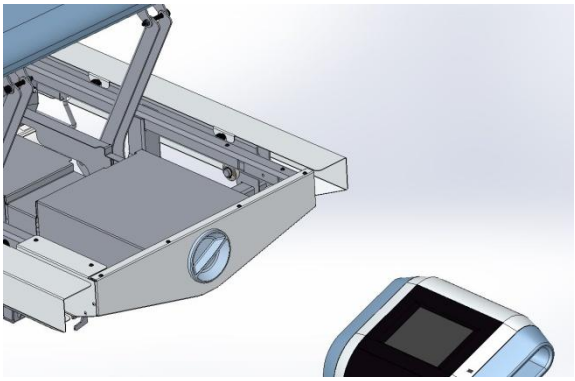
For those patients who can't tolerate the thoracic belt, use axilla posts. It is possible to adjust its width regarding to patient's size.



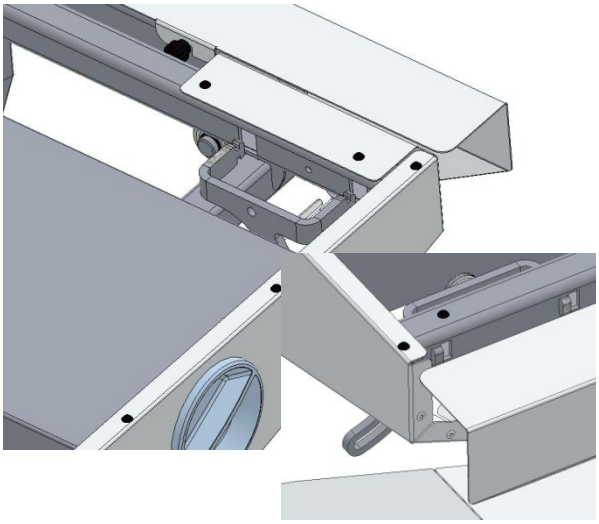


4.9.7 INSTALLATION OF THE INVERSION SET

Inversion position serves to reducing the load of thoracic and lumbar spine. It does not require connection to the Traction Unit.

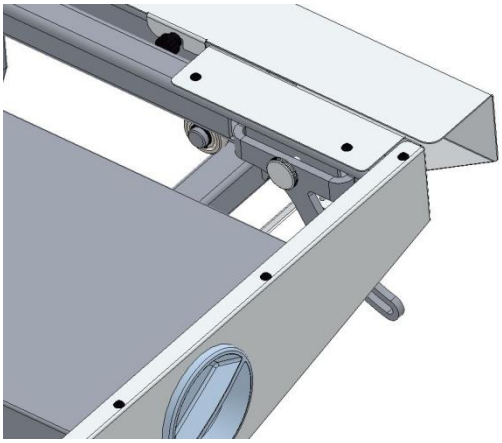
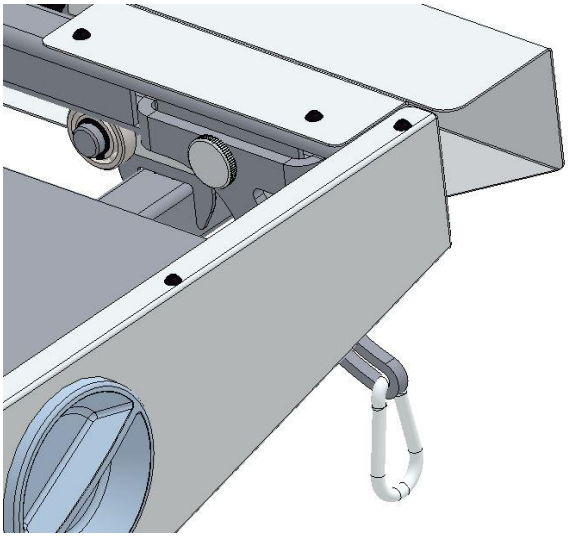
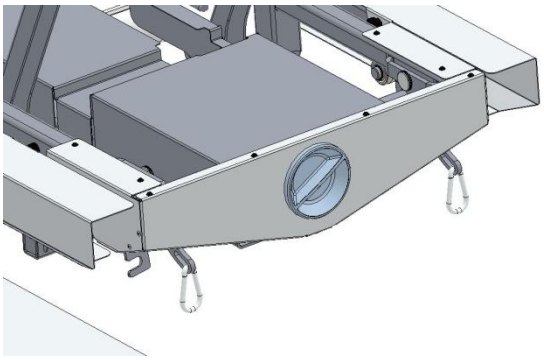


To install therapy inversion set, firstly move the thigh part of the device up.

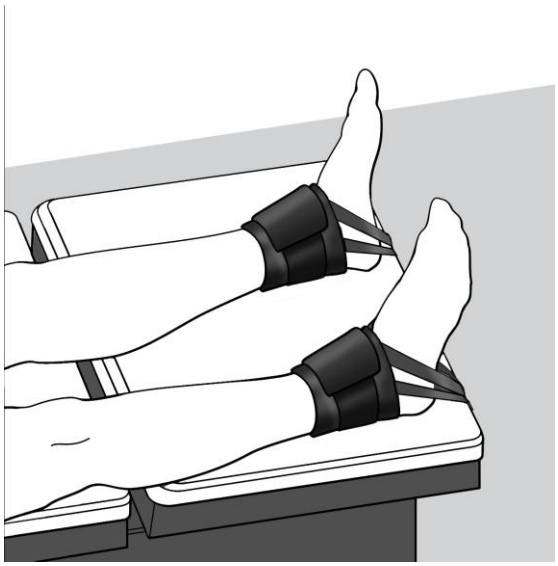


Insert the inversion holder into the holes and lock it.

Note: do it on the both sides of the device.

	Secure the inversion holder with the screw.
	Finally install the carabiner into the inversion holder. Note: do it on the both sides of the device.
	Final configuration.

4.9.8 INVERSION THERAPY SET UP

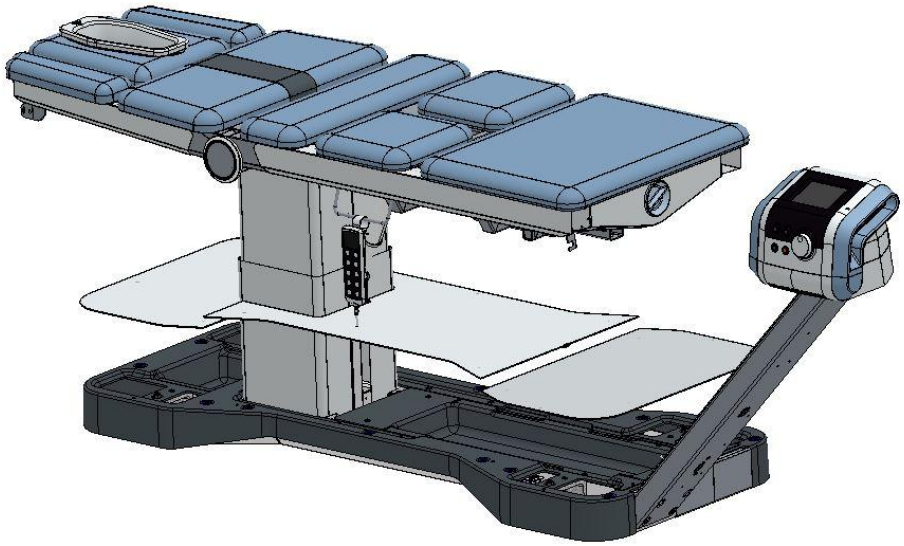


Place two belts into the carabiners at the lower part of the device. Position the patient on the device, fix both legs by the belts and set the M11 position on the remote control.

Note: Therapy time should not exceed 5 minutes. After the therapy, move the patient to the horizontal position for at least half of the therapy time.

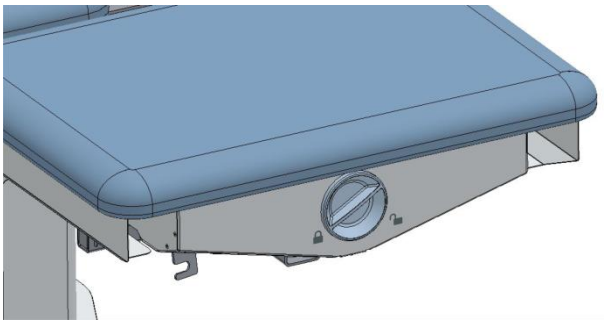
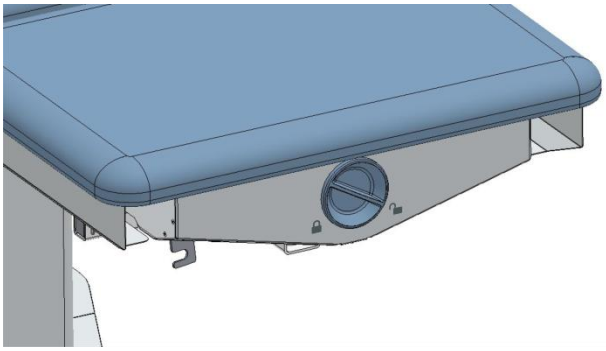
4.9.9 ACCESSORIES STORAGE

Storage case is placed in the bottom of the device. It allows storing all accessories in one place.



4.10 LOCKING SYSTEM

To avoid friction during the therapy, the lower part of the device is able to move. To lock/unlock the sliding part, use the wheel at the lower part of the device. To lock it, turn the wheel to the right until you reach symbol. To unlock it, turn the wheel to the left until you reach symbol.

	Locked position.
	Unlocked position.

5 TROUBLESHOOTING

The device is designed with operator and patient safety as well as device long lifetime in mind. If any unacceptable deviation occurs during the start-up and persists after the device restart (turn off and on again with the on/off switch), call service, please.

The following table serves as guidelines for solving common problems that can occur during the device operation:

Problem	**Possible reason and solution**
The Traction Unit can´t be turned-on.	Check the connection of power cord. Check the connection of Patient Switch. Check that the on/off switch is in ON position. Check the fuses. Check the connection of both connectors on the back of Traction Unit. If the problem remains: Unplug the device and call service.
The device can´t be turned on.	Make sure that Traction Unit is turned-on. If the problem remains: Unplug the device and call service.
An actuator or other part of couch is too hot when touched.	The duty-cycle instruction was not followed. Turn-off the device and wait 60 min to let it cool down. If the problem remains: Unplug the device and call service.
Scratching or squeezing noise while the device is moving.	Use the lubrication oil for the affected area. If the problem remains: Unplug the device and call service.
E01 appears on display.	Forbidden position reached.
E01 appears on display when positioning the device in common positions.	Start Calibration Function.
E02-E07 appears on display.	Actuator error. Turn the device on and off using on/off switch. Start Calibration Function. Actuator overheated, Duty cycle instruction not followed. Turn-off the device and wait 60 min to let it cool down. If the problem remains, the device is able to continue to work with limited functions. Call the service.
Angle on display doesn´t corresponds to the real position of the device.	Start Calibration Function. If the problem remains: Unplug the device and call service.
Expelled Parts from the device.	Unplug the device and call Service.
Overloaded grid - circuit breaker keeps tripping (shutting off the electrical flow).	Make sure that the device is the only device in the circuit connected to the appropriate circuit breaker.

6 MAINTENANCE

Before any maintenance switch the device off and unplug it from the mains! Observe all safety principles listed in the **Chapter 2**. Never dismantle the device and its accessories during cleaning!

The recommended intervals for inspection of the device are 24 months after installation, subsequently each 12 months. The intervals may differ according to the local regulations. The inspection shall be performed according to procedure authorized by BTL.

6.1 DISPOSAL

In order to dispose the device, please contact a local disposal company to enquire information about the local regulations.

6.2 CLEANING OF THE DEVICE

Control regularly the cleanness of the device and its accessories. To clean the device use a soft cloth slightly moistened with water or a 2% detergent solution. Never use agents containing alcohol, chlorine, ammonia, acetone, benzine or thinners.

The upholstery and Face pad shall be cleaned after each use with disinfectants approved for the use in health care. Do not use agents containing chlorine or those with a high alcohol content (more than 20 %). For cleaning always use soft cloth slightly moistened with disinfectant.

After disinfection, it is necessary to rinse the accessories with soft cloth slightly moistened with clean water so as to prevent undesirable allergic reaction.

The device and its accessories are designed for non-invasive use; therefore they do not need to be sterile and cannot be sterilized.

6.3 TRANSPORT AND STORAGE

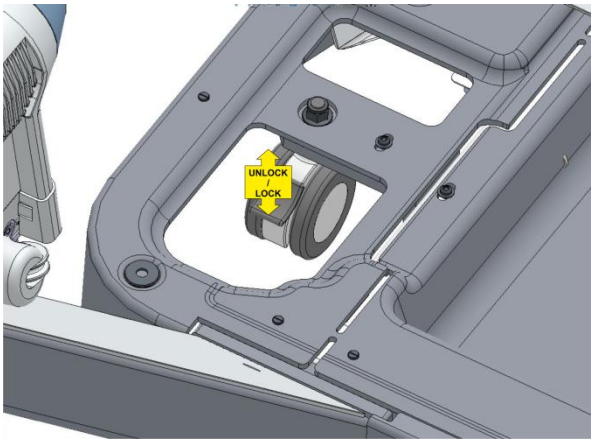
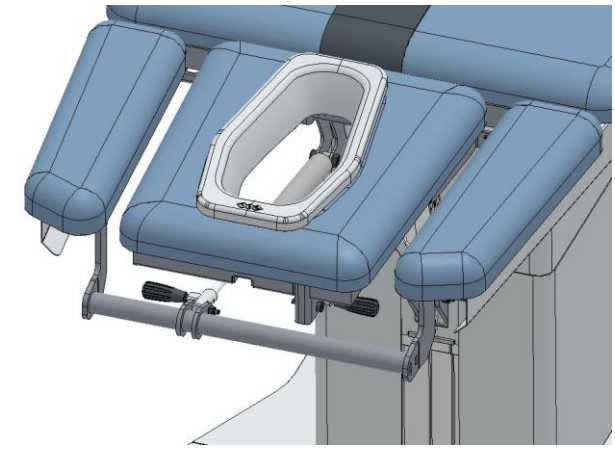
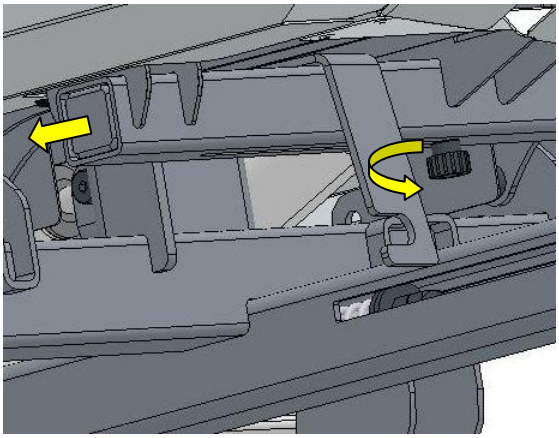
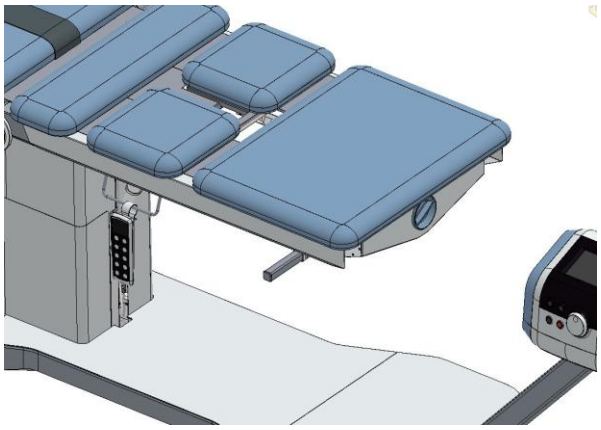
Store the packaging of the device. Transport the device in the original packaging to ensure its maximum protection. Unplug the power supply cable and all accessory cables. Avoid strong shocks. The device shall only be stored and transported under the conditions defined in the chapter **Technical Parameters.**

Inspect the box for damage and report any damage to the transport carrier and the distributor. Do not proceed with assembly and set-up if the box is damaged.

In case you need to transport the device unlock all castors or use designated handles in front and back part of the device.

Transport only in parking position.

When handling the device on castors, move it solely on a flat surface, otherwise it is necessary to lift the device.

	To lock/unlock the castor use the break.
	Handle in the front part of the device.
	To use handles in the back part of the device unscrew the black button from the groove and pull out the handle. Note: do it on both sides of the device and secure it by screwing the black button back to the groove.
	Final configuration.

6.4 FUSE REPLACEMENT

The fuse for the device is located in the black fuse housing (see the chapter **Couch and Accessories**) on the bottom side of console. Ensure that the type and rating of the new and the replaced fuses match (see the chapter **Technical Parameters**).

1. Turn off the device and disconnect the power cord from the unit and mains outlet.
2. Remove the fuse housing by using a screwdriver.
3. Remove the burnt fuse.
4. Insert a new fuse. Make sure the fuse is properly seated within the fuse housing.
5. Connect the power cable to the unit and to the mains outlet.
6. Turn on the device.

7 TECHNICAL PARAMETERS

Name	**BTL SPINAL DECOMPRESSION**		
Operating conditions			
Environment temperature range	+10 °C to +40 °C		
Relative humidity	30% to 75% (non-condensing)		
Ambient pressure range	700 hPa to 1060 hPa		
Position	Horizontal		
Type of operation	Non-continuous Duty-cycle of actuators: 10 %, max. 2 minutes ON / 18 minutes OFF		
Transport and storage conditions			
Environment temperature range	-10 °C to +55 °C		
Relative humidity	10% to 85% (non-condensing)		
Ambient pressure range	650 hPa to 1 100 hPa		
Position	Horizontal		
Power supply			
Maximum input	Max 650 VA		
Voltage	~100-240 V		
Frequency	50 to 60 Hz		
External exchangeable fuses	2 x T6,3AH~250V, size 5x20 mm		
Mains switch	On the console, positions 0 (off) and 1 (on)		
Classification			
Class according EN 60601-1	I		
Applied part type	B Patient Switch: BF		
Design			
Overall dimensions without accessories (w x h x d)	70 x 102 x 277 cm		
Weight	205 kg		
Load Capacity	180 kg		
Electrically adjustable height of couch	63 to 93 cm		
Electrically adjustable pelvic tilt	0° to 25°		
Electrically adjustable upper section	-15° to 40°		
Electrically adjustable thigh section	0° to 70°		
Electrically adjustable lower section	-15° to 25°		
Manually adjustable head section	0° to 25°		
Manually adjustable armrests	-25° to 0°		
Device Model:	**BTL Spinal Decompression PREMIUM**	**BTL Spinal Decompression PROFESSIONAL**	**BTL Spinal Decompression ESSENTIAL**
Functions:			
Build-in Cervical Adapter	●	●	-
Heated cushion (level 1: 35 °C, level 2: 38 °C)	●	●	-
Upper LED backlight	●	●	-
Bottom LED backlight	●	-	-

Distance values accuracy: ±2 cm
Angle values accuracy: ±3°
Temperature values accuracy: ±2 °C
● ... standard – ... not available

8 LIST OF ACCESSORIES

The following table contains all standard and optional accessories that can be supplied with the device.

Device Model:	**BTL Spinal Decompression PREMIUM**	**BTL Spinal Decompression PROFESSIONAL**	**BTL Spinal Decompression ESSENTIAL**
Accessories:			
Face Pad	●	●	○
Upholstery Insert	●	●	●
Inversion Therapy Set	●	○	○
Axilla Posts	●	○	○
Sitting Therapy Adapter	●	○	○
Asymmetric Therapy Adapter	●	○	○

● ... standard ○ ... optional

9 EMC DECLARATION

Medical electrical equipment should be used with precautions according to the EMC directive and must be installed in compliance with the EMC notices disclosed in this manual; otherwise the equipment could be adversely affected by mobile RF transceivers.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the The device should assure that it is used in such an environment.		
Emissions test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, the emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity				
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	***Separation distance according to frequency of transmitter (m)***			
	150 kHz to 80 MHz $d = [3.5/V_1]\sqrt{P}$ $V_1=3V$	***150 kHz to 80 MHz*** $d = [3.5/V_1]\sqrt{P}$ $V_1=6V$	**80 MHz to 800 MHz** $d = [3.5/E_1]\sqrt{P}$ $E_1= 3$ V/m	***800 MHz to 2.7 GHz*** $d = [7/E_1]\sqrt{P}$ $E_1= 3$ V/m
0.01	0.12	0.06	0.12	0.23
0.1	0.37	0.18	0.37	0.74
1	1.2	0.58	1.2	2.3
10	3.7	1.8	3.7	7.4
100	12	5.8	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Guidance and manufacturer's declaration – Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="5">Guidance and manufacturer's declaration – Electromagnetic immunity</th></tr>
<tr><td colspan="5">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th colspan="2">IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td colspan="2">3 V
0.15 MHz – 80 MHz

6 V
ISM bands between 0.15 MHz and 80 MHz</td><td>3 V
0.15 MHz – 80 MHz

6 V
ISM bands between 0.15MHz and 80 MHz</td><td rowspan="11">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = [3.5/V_1]\sqrt{P}$ 0.15 MHz to 80 MHz
$d = [3.5/E_1]\sqrt{P}$ 80 MHz to 800 MHz
$d = [7/E_1]\sqrt{P}$ 800 MHz to 2.7 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b].

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td rowspan="10">Radiated RF
IEC 61000-4-3</td><td colspan="2">3 V/m
80 MHz to 2.7 GHz</td><td colspan="2">Compliance in same levels as test levels</td></tr>
<tr><td>27 V/m</td><td>385 MHz</td><td>PM 18 Hz</td></tr>
<tr><td>28 V/m</td><td>450 MHz</td><td>FM 5 kHz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>710 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>745 MHz</td></tr>
<tr><td>780 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>810 MHz</td><td rowspan="3">PM 18 Hz</td></tr>
<tr><td>870 MHz</td></tr>
<tr><td>930 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>1720 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>1845 MHz</td></tr>
<tr><td>1970 MHz</td></tr>
<tr><td>28 V/m</td><td>2450 MHz</td><td>PM 217 Hz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>5240 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>5500 MHz</td></tr>
<tr><td>5785 MHz</td></tr>
<tr><td colspan="5">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="5">a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</td></tr>
<tr><td colspan="5">b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

10 MANUFACTURER

BTL Industries Ltd.
161 Cleveland Way
Stevenage
Hertfordshire
SG1 6BU
United Kingdom

E-mail: sales@btlnet.com

For service, please contact service department at service@btlnet.com.

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