BTL-CPMOTION

OPERATOR’S MANUAL

BEFORE YOU START

Dear Customer,

Thank you for purchasing BTL technology. All of us at BTL wish you every success with your system. We pride ourselves on being as responsive as possible to our customers' needs. Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line.

While we would like you to start using your new equipment right away, we encourage a thorough reading of this manual in order to fully understand the operational features of the system.

Please visit our corporate website at http://www.btlnet.com for the latest information on BTL products and services.

Again, thank you for being a BTL customer.

BTL Medical Technologies Canada Inc.

CONTENTS

1 GENERAL INFORMATION

1.1 BASIC CHARACTERISTICS OF THE DEVICE

The BTL-CPMotion is a motor driven continuous passive motion (CPM) system that works on a principle of increasing range of motion to an extremity through an externally applied force.

The device consists of main parts: unit control panel, support drive mechanism and accessories.

Support drives mechanism that allows the proper adjusting of the extremity on the device through the system of belts, tight and calf supports and footplate.

Accessories involve two types of handheld remote controls and ankle module (depending on the model of the device).

1.2 INTENDED USE

The BTL-CPMotion is a continuous passive motion (CPM) system used for treatment of injuries, diseases and in postoperative treatment of joints.

The BTL-CPMotion system is used to prevent negative effects of joints immobilization.

1.3 INDICATIONS

- improvement of joint metabolism
- prevention of joint stiffness
- promotion of the regeneration and healing of cartilage and damaged ligaments
- faster hematoma/fluid resorption
- improved lymph and blood circulation
- thrombosis and embolism prophylaxis

1.4 CONTRAINDICATIONS

- bone cancer
- unstable fractures
- inflammatory processes in the joints
- spastic paralysis

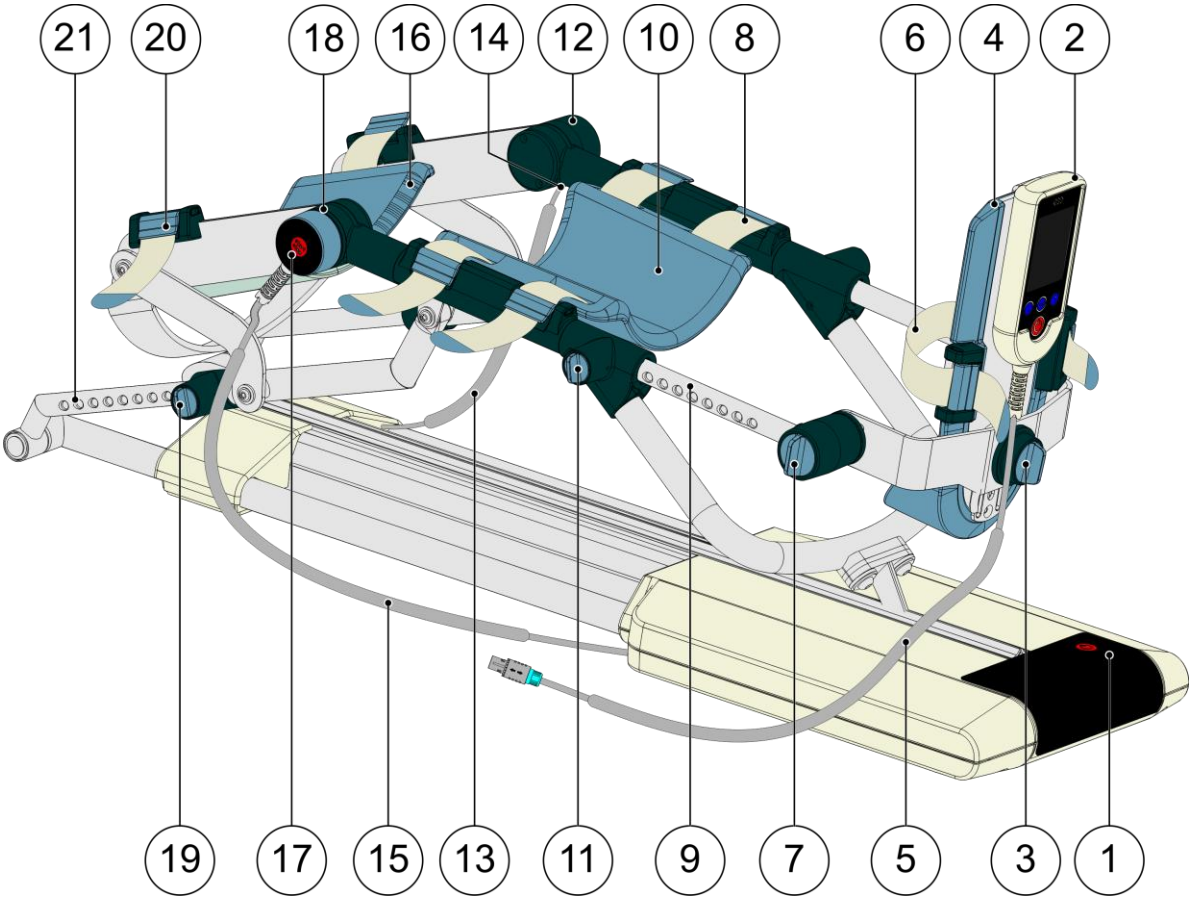
1.5 POSSIBLE SIDE-EFFECTS

Some patients may experience temporary increase of pain and swelling after the treatment.

2 OPERATING INSTRUCTIONS

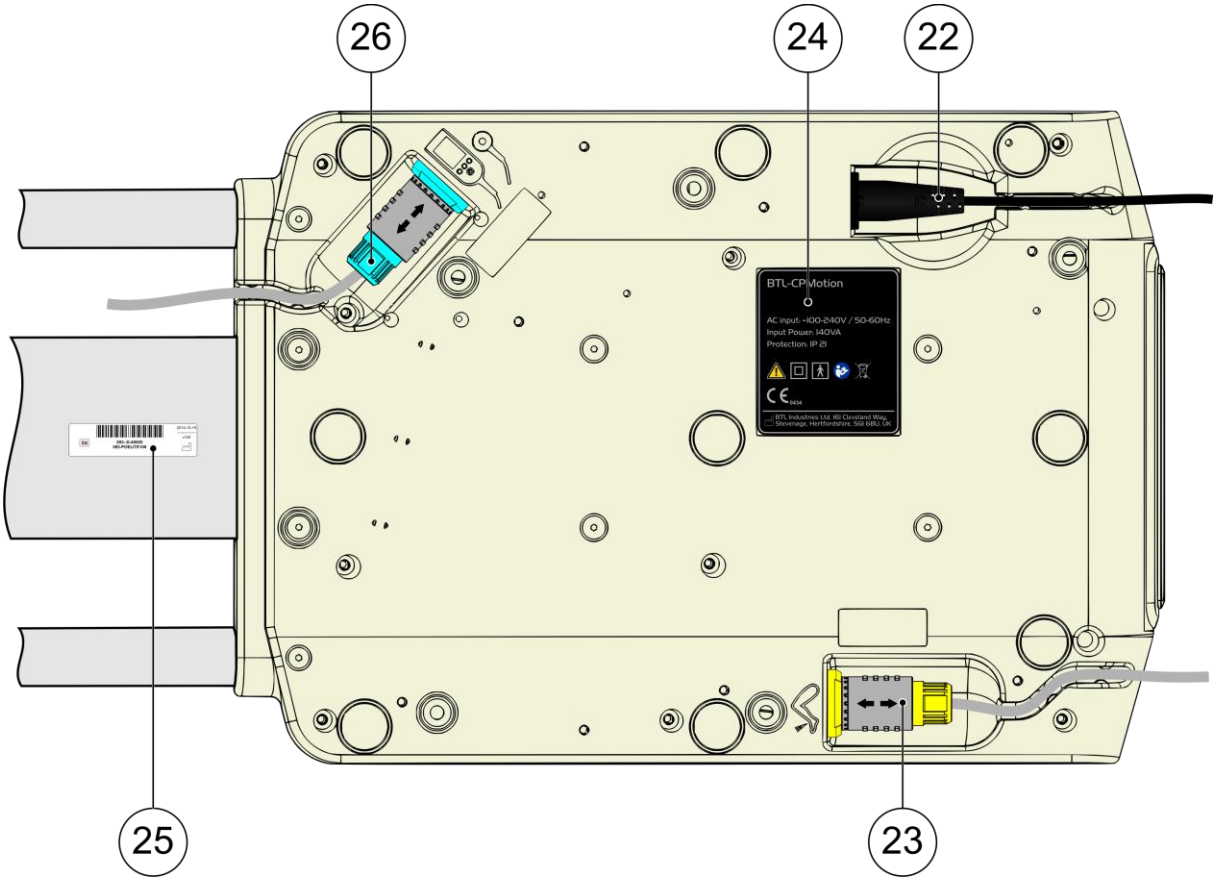
2.1 DESCRIPTION OF THE DEVICE

2.1.1 SIDE VIEW



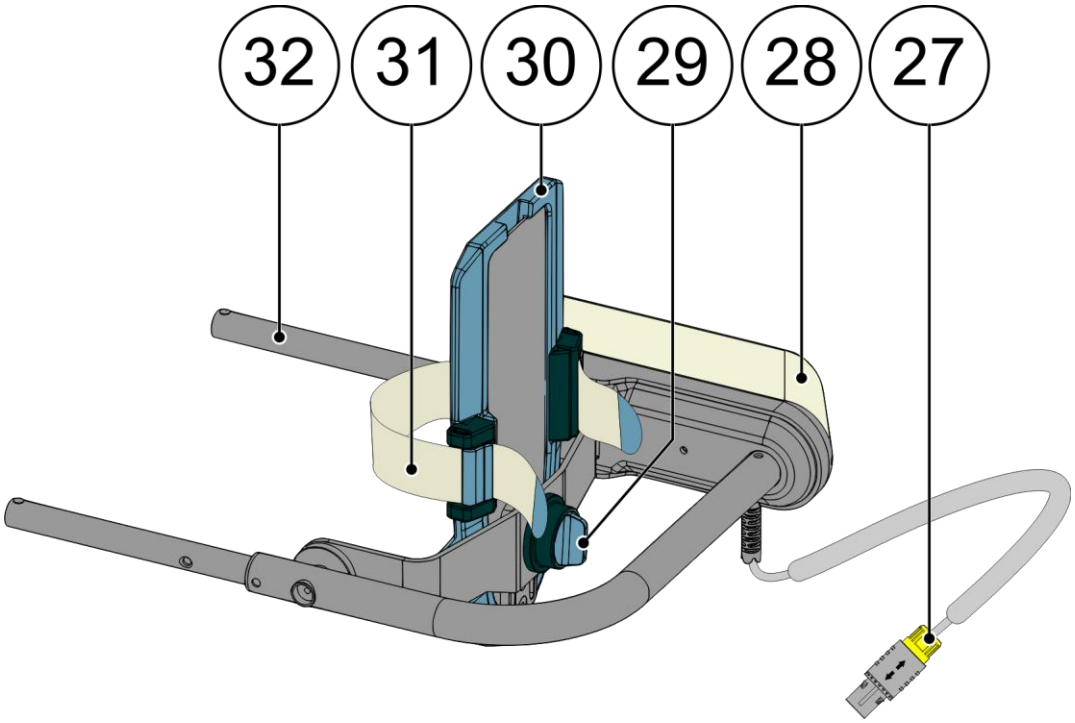
1. Unit control panel
   (see Chapter 2.1.4 for more information)
2. Remote control with touch screen
   (see Chapter 2.1.6 for more information;
   not available for BTL-CPMotion K EASY)
3. Screw for adjusting the footplate position (rotation and up/down)
4. Footplate (applied part type BF)
5. Remote control with touch screen cable (on the picture disconnected)
6. Belts to secure the foot on the footplate
7. Screw for adjusting the footplate angle
8. Height adjustment of calf support
9. Tibia length scale (cm)
10. Calf support (applied part type BF)
11. Locking system for tibia length adjusting
12. Angle sensor
13. Angle sensor cable
14. Angle sensor connector
15. START/STOP remote control cable
    (only for BTL-CPMotion K EASY)
16. Thigh support (applied part type BF)
17. START/STOP remote control
    (only for BTL-CPMotion K EASY)
18. Holder for START/STOP remote control
    (only for BTL-CPMotion K EASY)
19. Locking system for femur length adjusting
20. Adjustment of thigh support
21. Femur length scale (cm)

2.1.2 BOTTOM VIEW



22. Power cord connector
23. Ankle module connector
24. Device type label
25. Device manufacturer’s label
26. Remote control connector

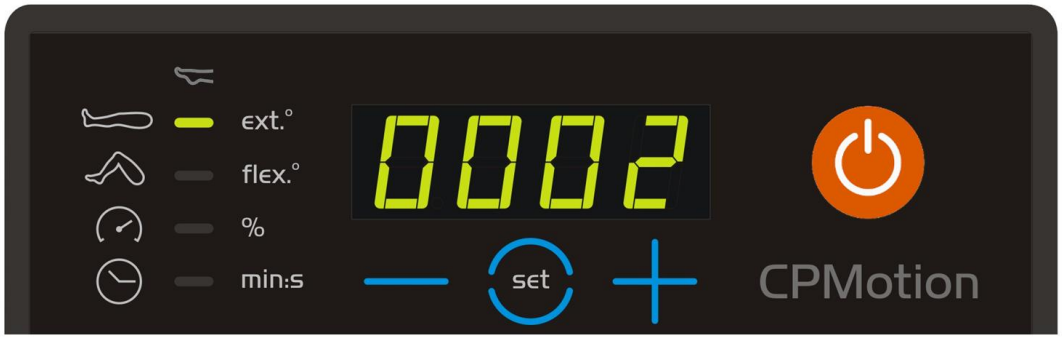
2.1.3 ANKLE MODULE



27. Ankle module cable
28. Angle sensor and module
29. Screw for adjusting the footplate position (rotation and up/down)
30. Footplate (applied part type BF)
31. Belts to secure the foot on the footplate
32. Mounting rod

Ankle module is standard accessory for BTL-CPMotion K ELITE, optional accessory for BTL-CPMotion K PRO.

2.1.4 UNIT CONTROL PANEL



	**on/off** and **start/stop** button
	for increasing or decreasing of chosen value
	SET button enables to **SET** a parameter to modify:
	extension angle (-10° to 123° in steps of 1°) flexion angle (-5° to 123° in steps of 1°) speed of the movement (10 to 100 % in steps of 10 %) therapy time (01:00 to 59:59 in steps of 1 min.)
	this icon indicates that ankle module is connected

2.1.5 REMOTE CONTROL FOR BTL-CPMOTION K EASY

The user can **start/stop** the therapy with the help of the remote control.

Always check the pre-set parameters before starting the therapy.

The patient must hold the control in their hand during the therapy to be able to interrupt the therapy if needed (see Chapter 4.1).

2.1.6 REMOTE CONTROL FOR BTL-CPMOTION K PRO AND BTL-CPMOTION K ELITE

actual angle, indicator of move, lock symbol

menu page indicator

1st menu parameters

multifunctional buttons - touchscreen

multifunctional buttons

on/off and **start/stop** button

This remote control enables to set all available parameters.

User can set the parameters via touchscreen or with buttons below the display.

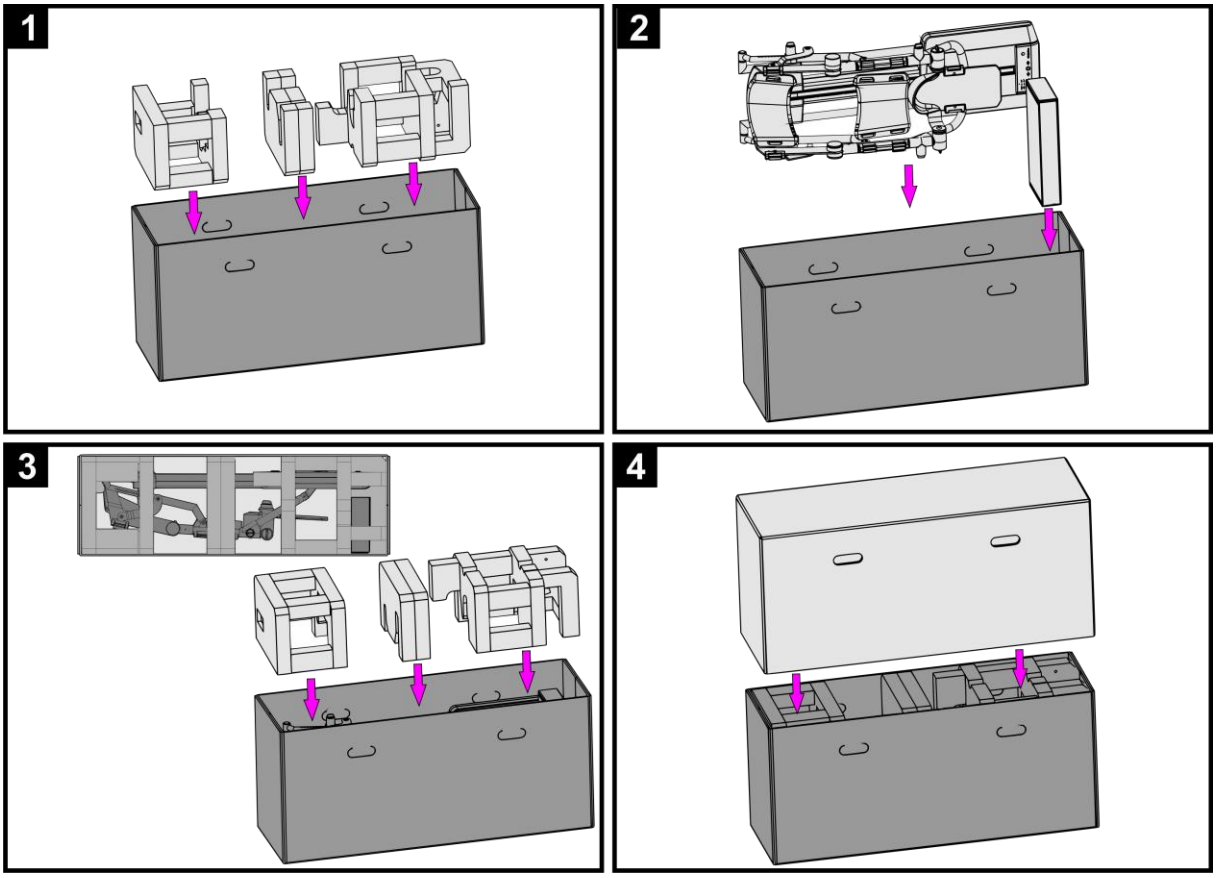
For more details see Chapter 2.4.3 Setting the therapy parameters and 2.4.4 Description of therapy parameters.

Always check the pre-set parameters before starting the therapy.

The patient must hold the control in their hand during the therapy to be able to interrupt the therapy if needed (see Chapter 4.1).

2.2 ASSEMBLY AND SET-UP

Inspect the box for damage and report any damage to the transport carrier and to the distributor. Do not proceed with assembly and set-up if the box is damaged. Keep the original box and packaging to ensure safe future transport and storage of the device. Pictures below shows, how to pack the device back to original box. Unpacking is reverse operation.



Unpack the device and place it on a stable horizontal surface that is suitable for its weight.

Keep to the operating conditions defined in the Chapter 5 and follow the instructions in the Chapter 4.1.

For any questions please contact an authorized BTL service.

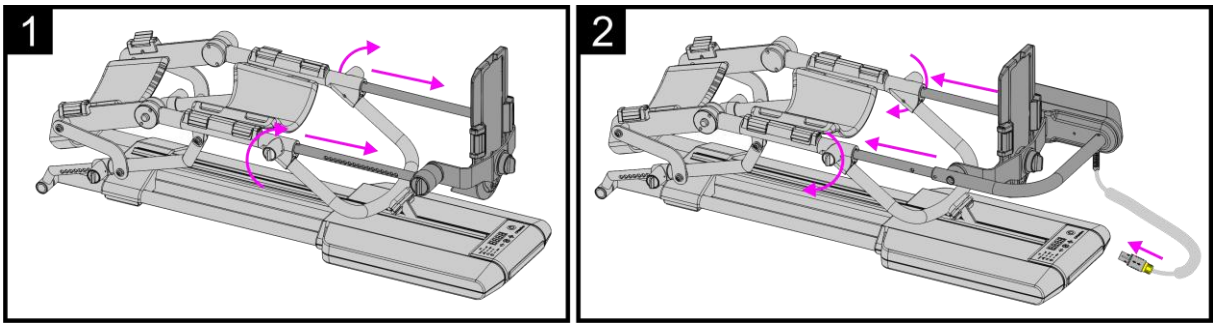
2.2.1 ASSEMBLY AND SET-UP PROCEDURE

1. Connect the remote control to the corresponding connector at the bottom panel.
2. Connect the device to the mains using the supplied power cable. Connect the device to the mains outlet directly; do not use any multi-connection extension power cable.
3. Press the **on/off** switch  located on the front panel of the device or on the remote control.

After switching on, the device will run a self-diagnostic of its internal circuits and functions. If any fault is detected, the screen will display a warning message. If necessary; the control unit will lock itself into a “secure” mode. If this situation occurs, please contact an authorized BTL service.

2.2.2 ANKLE MODULE MOUNTING

Make sure that the device is in the parking position before mounting and connecting the ankle module (see Chapter 2.4.4 – 4th menu – parking position).



1. Dismount the footplate.
2. Mount the ankle module and connect the ankle module cable.
3. Press the on/off button on front panel of the device or on the remote control.
4. Select the Service Mode Screen (see Chapter 2.3.1) for operation via remote control (see Chapter 2.3.2).
5. Entry code 1116 in the Service Mode Screen and press OK button for confirmation.
6. Wait until *"Operation done"* shows up on the remote control screen. Then you can start to use the ankle module (steps 3-6 need to be done only before first use of ankle module).
7. After approximatelly 1000 operating hours the device will automatically prompt you to calibrate ankle module by message *"Ankle angle sensor was calibrated before X operating hours. It is strongly recommended to calibrate the angle sensor. See the manual."*

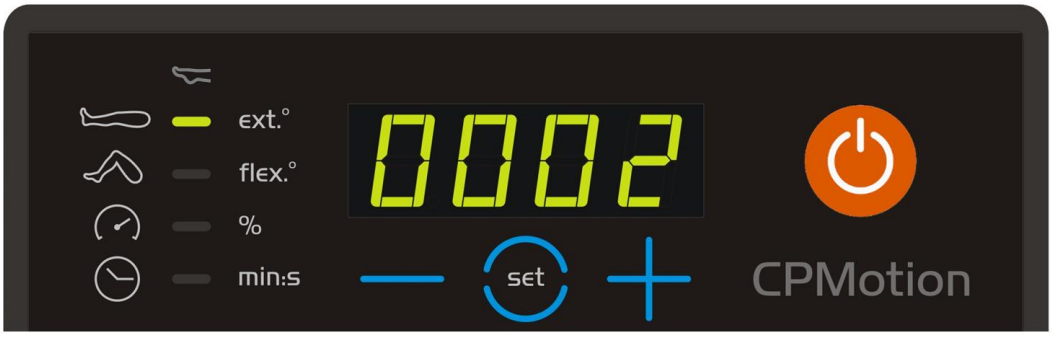
2.3 DEVICE CONTROL

The BTL-CPMotion K EASY is designed to be operated via control panel on the unit and the remote control START/STOP.

The BTL-CPMotion K PRO and BTL-CPMotion K ELITE are designed to be operated via the control panel or the remote control with touch screen.

Functions available in the BTL-CPMotion K EASY are limited to the parameters of the **1st menu** of BTL-CPMotion K PRO and BTL-CPMotion K ELITE and the service code screen with unit configuration.

2.3.1 OPERATION VIA CONTROL PANEL



For setting the parameters, press set button until the requested parameter is shown on the display. The LED diode by the therapy icons helps you to identify which parameter is chosen. Change the parameter with help of + or − button. The pre-set value is automatically saved after 3 seconds or by pressing of set button.

Once all parameters are pre-set, you can start the therapy with ⏻ button on the unit or on the remote control with touchscreen or the start stop button on remote control of the BTL-CPMotion K EASY model.

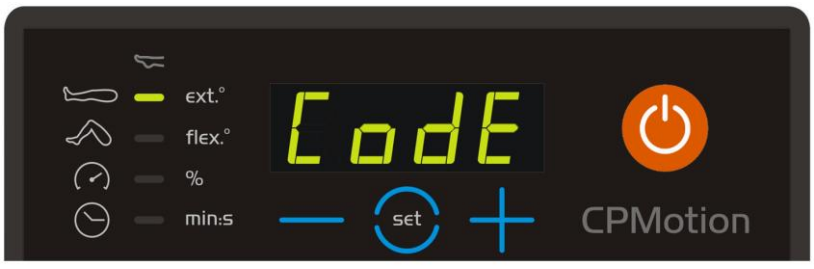
For more details about range of the therapy parameters see Chapter 2.1.4.

⚠ Always check the pre-set parameters before starting the therapy.

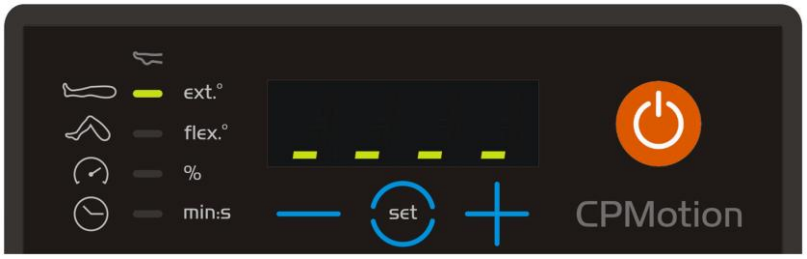
BTL-CPMotion K EASY model – Service Code Screen

The *Service Code Screen* is used to change additional device settings by entering configuration codes.

Press + and − on the control panel simultaneously to enter the *Service Code Screen*.



Use set to select the digit to be changed (active digit is indicated by higher brightness).



Use + and − to increase and decrease the value of the digit.

Use ⏻ to confirm the code.

For more details of available configuration codes in the service code screen see Chapter 2.4.4.

2.3.2 OPERATION VIA REMOTE CONTROL WITH TOUCHSCREEN

This remote control is available only for BTL-CPMotion K PRO and BTL-CPMotion K ELITE.

⚠ The items on the touch-screen can be pressed by finger or by touch pen – a special pointer with a soft tip. Do not allow any sharp objects such as knives, ballpoint pens, etc. to come in contact with the touch-screen.

Multifunctional buttons below the display have the same function as the buttons on the bottom part of the display.

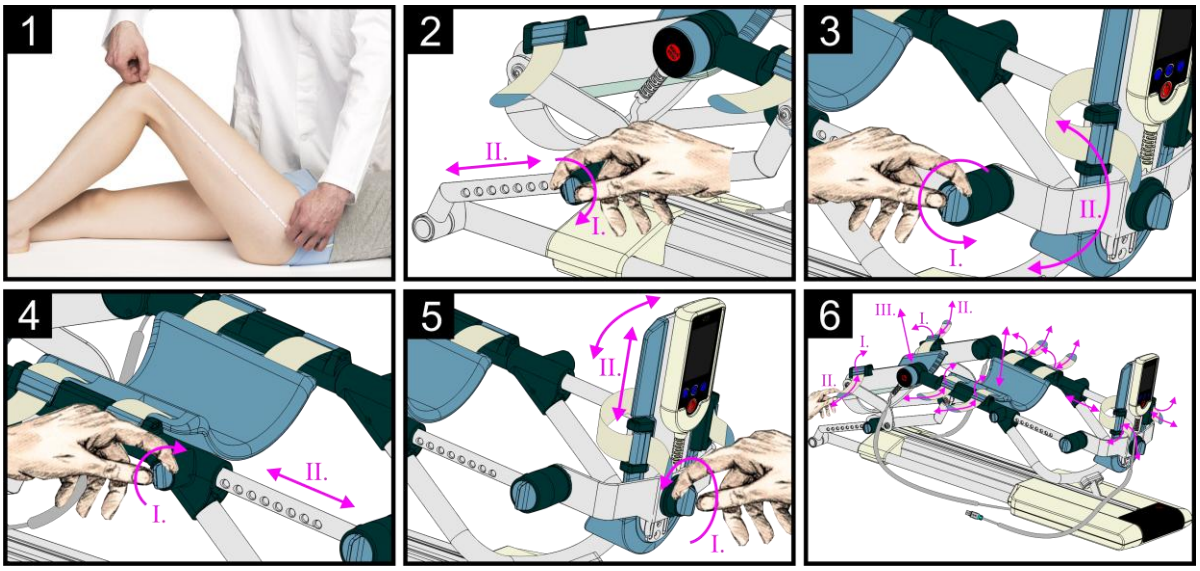
+ −	for increasing or decreasing of choosen value or enable/disable function
set	SET button enable to set which parameter will be modified
< >	for next/previous menu

The current function of the button is shown on the bottom part of the display.

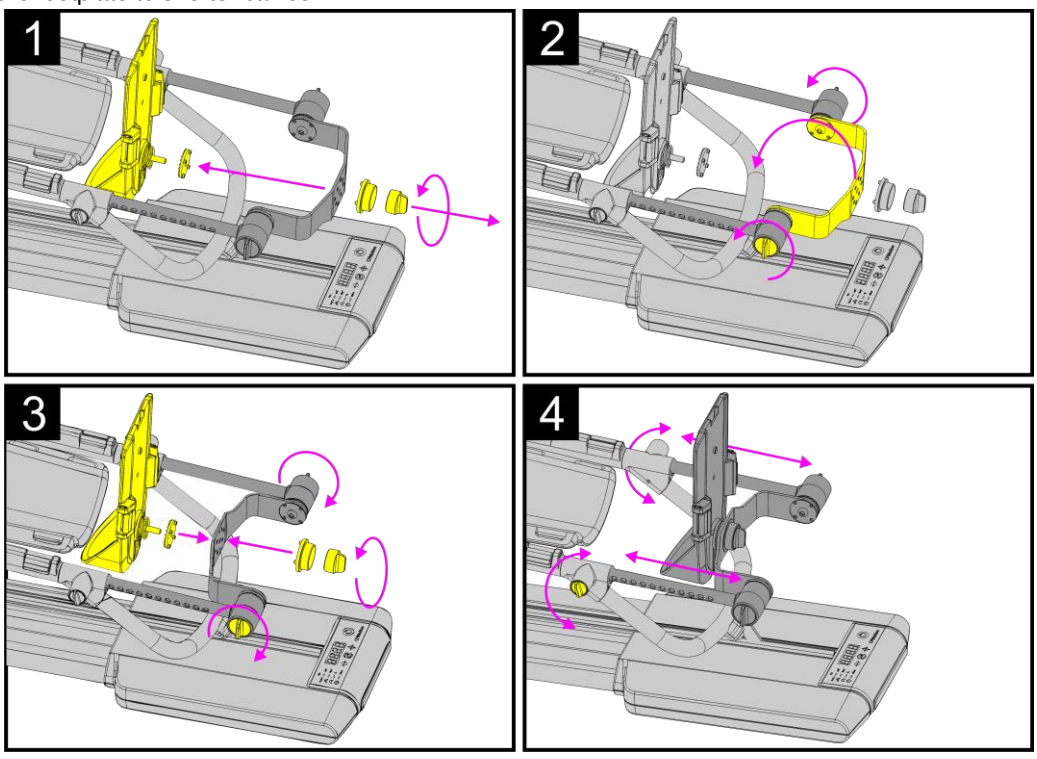
2.4 THERAPY SETTINGS

2.4.1 ADJUSTING THE DEVICE TO PATIENTS DIMENSION

Before setting the parameters, place the BTL-CPMotion system in a position, which is comfortable for the patient:

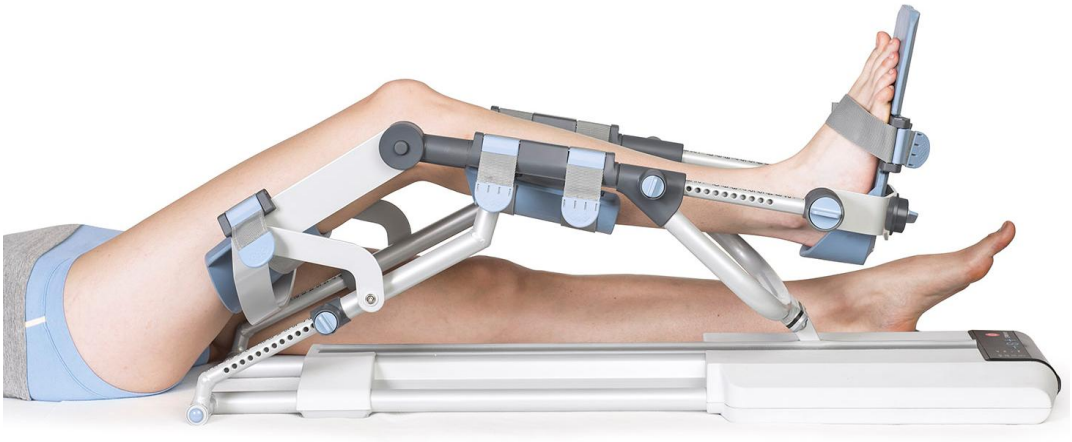


1. Measure the length of the patient's thigh (femur) from the greater *trochanter* to the outer knee joint gap.
2. With the help of the locking system adjust the measured value at the femur scale. Make sure the system is locked properly!
3. Set the axis of the patient's ankle with the axis rotation of the BTL-CPMotion system.
4. Adjust the footplate to the length of the patient´s lower leg. For short patients you can reverse the footplate 180° to adapt the footplate to shorter calves.



5. Adjust the footplate – use the screw.
6. Set the height of calf and thigh support (8, 20) using fixing system. Fix the patient´s ankle with the fixing belt.

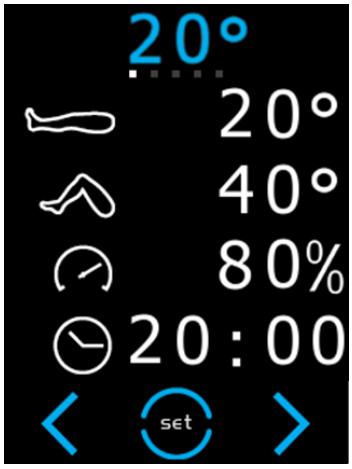
Before starting the therapy, make sure all locking systems are locked properly and the patient´s position is anatomically correct. Movements must not cause pain or irritation.



2.4.2 ADJUSTING THE ANKLE MODULE

Ankle module footplate is equipped with the same belt and locking mechanism for fixing the patient's foot and screw for adjusting the position as the basic footplate (see Chapter 2.4.1 picture 5).

2.4.3 SETTING THE THERAPY PARAMETERS

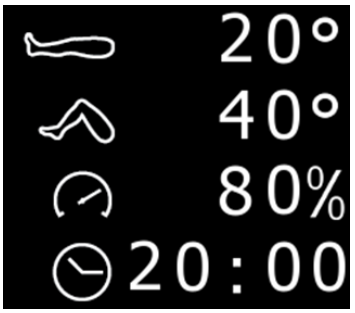
There are 5 pages of parameters in the menu. To switch between pages in menu press < or > button.	To select of the parameter to be changed touch the requested value or press **SET** button until the requested parameter is marked on the display (see the blue rectangle on the picture).
	

Change the parameter with help of + or − buttons on the display or below the display. The pre-set value is automatically saved after 3 seconds or by pressing **SET** button.

2.4.4 DESCRIPTION OF THERAPY PARAMETERS

The therapy parameters are divided into 5 screens (menus). Please check description of all parameters which can be set by the user:

1st menu:



Extension angle (-10° to 123° in steps of 1°)

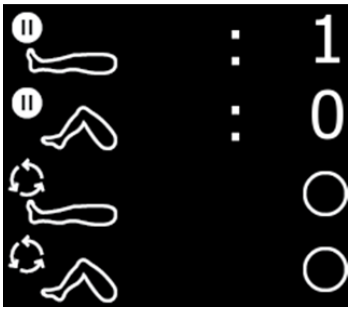
Flexion angle (-5° to 123° in steps of 1°)

Speed (10 to 100 % in steps of 10 %)

Therapy time (01:00 to 59:59 min:sec, in steps of 1:00 min.)

If the quick angle setting function is on, the unit moves during changing the flexion or extension angle!

2nd menu:



Extension pause (00:00 to 5:00 min:sec in steps of 1 s)

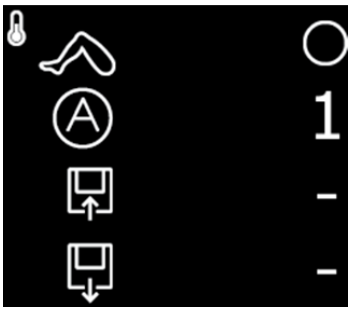
Flexion pause (00:00 to 5:00 min:sec in steps of 1 s)

Intensive extension program (on/off)

Intensive flexion program (on/off)

If the **intensive program** for extension, flexion or both is on, the unit automatically repeats last 10° of the pre-set value 5 times.

3rd menu:



Warm-up program (on/off)

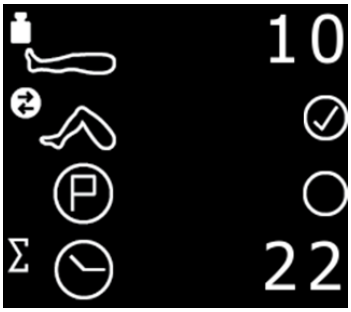
Automatic program (choose the number of program 1 to 13)

Save program

Load program

If the **warm-up program** is on, the unit begins the cycle few degrees under the pre-set values. The range of motion increases with each cycle, until the set maximum values are reached.

4th menu:



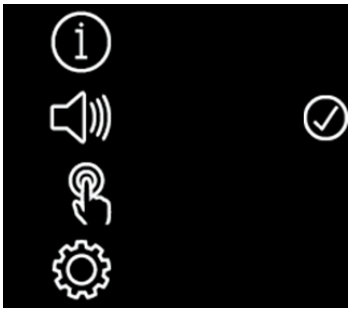
Load reversal (1 to 25)

Quick angle settings (**on**/off)

Parking position (on/**off**)

Total therapy time (working hours)

5th menu:



Information about the unit

Sound setting of the remote control (on/off)

Touch screen calibration

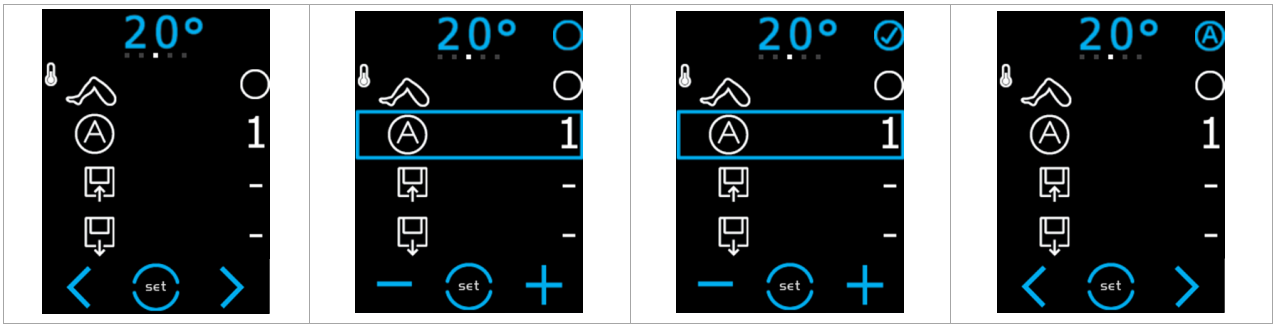
Service code screen

2.4.4.1 Automatic programs

Enable to choose one of 13 pre-set sequences of programs.

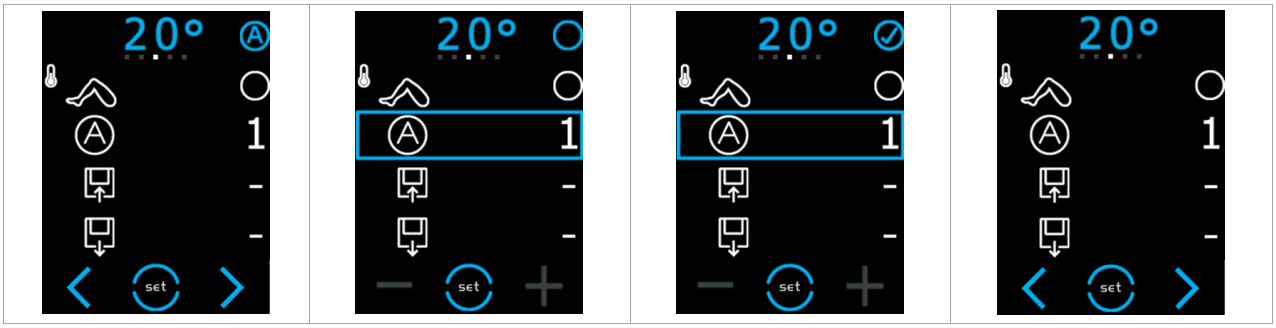
How to select and activate the automatic program:

- Select the automatic program icon (press SET button or touch the row with the icon)
- Change the program number by pressing **+** or **–** icon
- Confirm the program number selection by touching the row with the automatic program icon again
- The automatic program active icon Ⓐ shows in the top right corner of the screen



How to deactivate the automatic program:

- Select the *automatic program* icon (press **SET** button or touch the row with the icon) and confirm deactivation of the automatic program by touching the row with the automatic program icon again.
- Observe that the number of the program cannot be changed when the automatic program is active.
- The *automatic program* active pictograph Ⓐ disappears from the top right corner of the screen.



2.4.4.2 Save program

There are 50 memory positions for storage of user set therapy parameters. User set parameters that can be saved/loaded:

Extension angle

Flexion angle

Speed

Therapy time

Extension pause

Flexion pause

Intensive extension program

Intensive flexion program

Warm-up program

- Select the row with **save** icon.
- Select the memory bank number for storage of parameters. (Note: It is not possible to start e.g. from no. 10; the system saves the programs chronologically, i.e. from 1 to 50.)
- Confirm the storage by touching the row with the **save** icon again (be careful not to overwrite a program already saved in the memory).

  Correct saving of parameters is signalled by change of the pictograph in the top right corner of the screen from  to  .

2.4.4.3 Load program

There are 50 memory positions for storage of therapy parameters. How to load a program from the memory:

- Select the row with **load** icon.
- Select the memory number of the program (parameters) you wish to load.
- Confirm the choice by touching the **load** icon again.

  Correct loading of parameters is signalled by change of the pictograph in the top right corner of the screen from  to  .

2.4.4.4 Load reversal

The feature serves for patient comfort.

The device automatically starts moving in the opposite direction of the last movement (regardless on reaching the pre-set therapy angles), when the patient's load exceeds the pre-set force (max. value 25 means that the highest force is needed to activate the “load reversal”, min. value 1 means that the lowest force is needed to activate the “load reversal”).

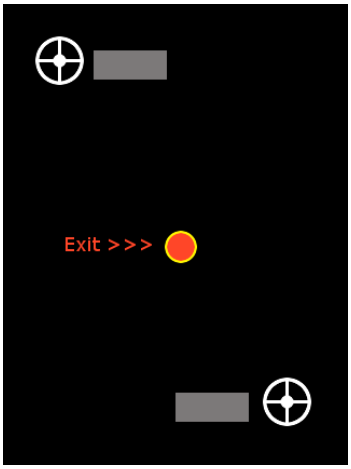
2.4.4.5 Quick angle settings

If the function *Quick angle settings* is on, the unit is moving following the setting of the angle. So if you e.g. set flexion 60°, the unit goes to 60° during the setting. So you can easily find the maximum angle which is acceptable for the patient.

2.4.4.6 Parking position

When this function is on, the unit automatically moves to 10°, which is most suitable angle for transport of the unit and for mounting the ankle module. The function is automatically on during the therapy, so the therapy always finishes in the parking position. It is possible to deactivate the function during the therapy.

2.4.4.7 Touch screen calibration



Finish the calibration procedure to leave the screen. For better results of calibration and higher precision use the touch pen.

Touch and hold for approx. 2 - 3 seconds the centre of the top left fiducial mark till its state ( ) goes from *"Touch centre*" (touch) through "*Sampling*" (hold – reading the data) to "*OK*" (release). Repeat the same for the bottom right fiducial mark.

Touch the screen anywhere to show the mark *Exit* >>> (yellow bordered red circle) in the centre of the screen. Touch the exit mark to leave the calibration screen. Touch and release possibly several times till you hit the centre of the exit mark properly and the message „*Calibration complete. Touch to exit…*“ shows up.

Touch the screen anywhere to return to the menu.

2.4.4.8 Service code screen

The *Service code screen* enables to set-up advanced user settings and service settings.

List of codes:	
11	sound setting of the unit – ON
12	sound setting of the unit – OFF
1112	user password settings
1113	delete all user settings – restart of the unit is needed
1114	restore default (factory) unit settings – restart of the unit is needed
1115 1116	calibration of knee angle sensor calibration of ankle angle sensor

Write the code and press OK to confirm or press to leave the screen.

2.4.4.9 Setting of user password

The BTL-CPMotion device is equipped with password system protecting unauthorized use (e.g. against children). The BTL-CPMotion device which can be used for home-use should have the password protection ON!

It is necessary to activate the password for home use of the device.

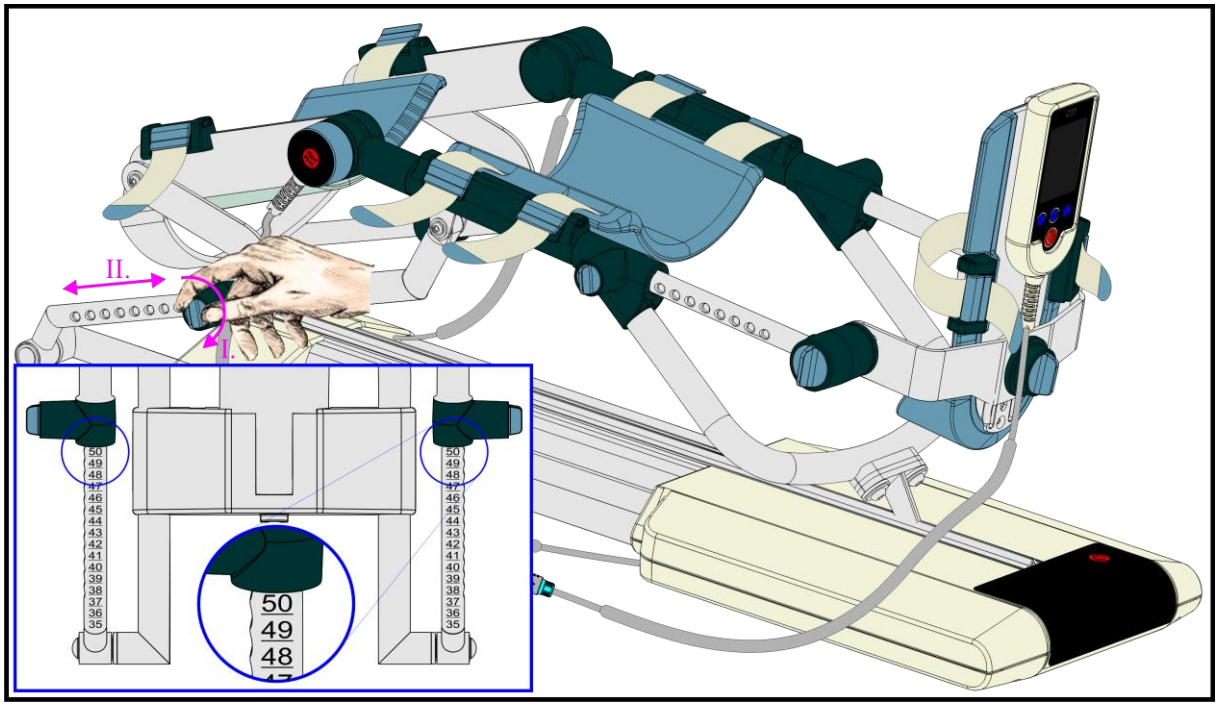
How to set/change the password:

- Insert the currently active password and press OK.
  In case there is no currently active password, insert 1111.
- Insert the new password and press OK.
  To remove the password protection, do not insert any digits (blank password).
- Insert the new password again and press OK.
  Notification about successful operation will appear. After restart the unit will prompt to input the password. Make sure that you remember the password! In case of forgotten password please contact an authorized BTL service.

2.4.4.10 Calibration of angle sensor

Requirements for correct calibration:

- Make sure that the BTL-CPMotion is without any mechanical load (no objects placed on the mechanical frame or supports)
- The BTL-CPMotion footplate must be in the basic configuration (not 180° reversed for the short calves) and the femur length scale must be in the position marked 50 (otherwise the moving parts might not reach the calibration position).



Not following the above stated requirements may result in damage of the device.

The BTL-CPMotion device moves during the calibration procedure as it needs to reach the calibration position.

2.4.5 DESCRIPTION OF THE AUTOMATIC PROGRAMS

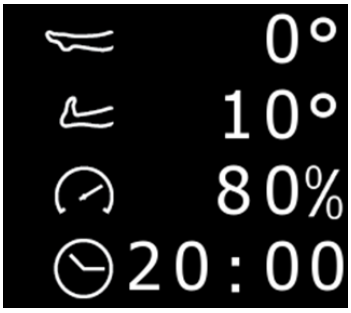
Nr.	Name	Description of the program
1.	**Progressive flexion program**	This program automatically increases the pre-set flexion angle by 1°. The sequence of programs is following: warm-up program, intensive flexion program, standard program and relaxing program.
2.	**Progressive extension program**	This program automatically decreases the pre-set extension angle by 1°. The sequence of programs is following: warm-up program, intensive extension program, standard program and relaxing program.
3.	**Progressive flexion and extension program** (with both flexion and extension progress)	This program automatically increases the range of motion by 1° (for both flexion and extension). The sequence of programs is following: warm-up program, intensive flexion and extension program, standard program and relaxing program.
4.	**Progressive flexion and extension program** (with only flexion progress)	This program automatically increases the pre-set flexion angle by 1°. The sequence of programs is following: warm-up program, intensive flexion and extension program, standard program and relaxing program.
5.	**Intensive flexion program**	This program is focused on intensive exercise in flexion position. The sequence of programs is following: warm-up program, intensive flexion program, standard program and relaxing program.
6.	**Intensive extension program**	This program is focused on intensive exercise in extension position. The sequence of programs is following: warm-up program, intensive extension program, standard program and relaxing program.
7.	**Intensive flexion and extension program**	This program is focused on intensive exercise in both flexion and extension position. The sequence of programs is following: warm-up program, intensive flexion and extension program, standard program and relaxing program.
8.	**Stretching program - extension**	This program is focused on stretching in extension position. The sequence of programs is following: warm-up program, program for stretching in extension, standard program and relaxing program.
9.	**Stretching program - flexion**	This program is focused on stretching in flexion position. The sequence of programs is following: warm-up program, program for stretching in flexion, standard program and relaxing program.
10.	**Stretching program - flexion and extension**	This program is focused on stretching in both flexion and extension position. The sequence of programs is following: warm-up program, program for stretching in flexion and extension, standard program and relaxing program.
11.	**Gentle flexion program**	This program automatically decreases the pre-set flexion angle by 5° and during the therapy the angle increases up to pre-set value. The sequence of programs is following: warm-up program, intensive flexion program with decreased flexion angle, intensive flexion program with pre-set flexion angle, standard program and relaxing program.
12.	**Gentle extension program**	This program automatically increases the pre-set extension angle by 5° and during the therapy the angle decrease up to pre-set value. The sequence of programs is following: warm-up program, intensive extension program with increased flexion angle, intensive extension program with pre-set extension angle, standard program and relaxing program.
13.	**Gentle flexion and extension program**	This program automatically decreases the range of motion by 5° (for both flexion and extension) and during the therapy the range of motion increase up to pre-set values. The sequence of programs is following: warm-up program, intensive extension and flexion program with decreased range of motion, intensive extension and flexion program with pre-set angles, standard program and relaxing program.

2.4.6 DESCRIPTION OF THE THERAPY PARAMETERS – ANKLE MODULE

Once you connect ankle module to the unit, you will see this icon  on the unit.

The therapy parameters for ankle module are divided into 5 screens. Please check below description of all parameters which can be set by the user:

1st menu:



Plantar flexion angle (-40° to 15° in steps of 1°)

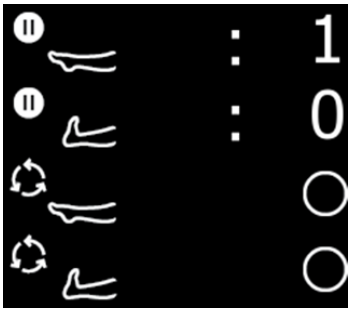
Dorsiflexion angle (-35° to 25° in steps of 1°)

Speed (10 to 100 % in steps of 10 %)

Therapy time (01:00 to 59:59 min:sec)

If the quick angle setting function is on, the unit is moving during setting of the flexion or extension angle!

2nd menu:



Plantar flexion pause (00:00 to 5:00 min:sec)

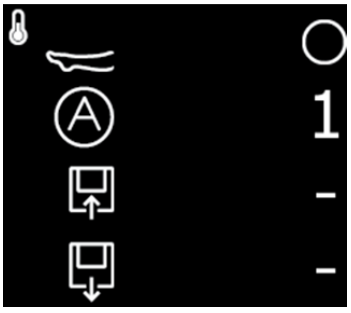
Dorsiflexion pause (00:00 to 5:00 min:sec)

Intensive plantar flexion program (on/off)

Intensive dorsiflexion program (on/off)

If the **intensive program** for plantar flexion, dorsiflexion or both is on, the unit automatically repeats last 5° of the pre-set value 5 times.

3rd menu:



Warm-up program (on/off)

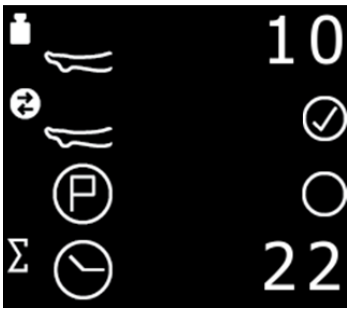
Automatic program (choose the number of program 1 to 13)

Save program

Load program

If the **warm-up** program is on, the unit begins the cycle a few degrees under the pre-set values. The range of motion increases with each cycle, until the set maximum values are reached.

4th menu:



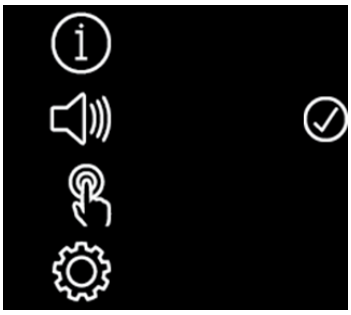
Load reversal (1 to 25)

Quick angle settings (on/off)

Parking position

Total therapy time (working hours)

5th menu:



Information about the unit (e.g. firmware version)

Sound setting (on/off)

Touch screen calibration

Service code screen

This menu is same like for BTL-CPMotion without ankle module – for more information see Chapter 2.4.4.

2.4.6.1 Automatic programs

The device enables to choose one of 13 pre-set sequences of programs.

Nr.	Name	Description of the program
1.	**Progressive dorsiflexion program**	This program automatically increases the pre-set dorsiflexion angle by 1°. The sequence of programs is following: warm-up program, intensive dorsiflexion program, standard program and relaxing program.
2.	**Progressive plantar flexion program**	This program automatically decreases the pre-set plantar flexion angle by 1°. The sequence of programs is following: warm-up program, intensive plantar flexion program, standard program and relaxing program.
3.	**Progressive plantar flexion and dorsiflexion program** (with both plantar flexion and dorsiflexion progress)	This program automatically increases the range of motion by 1° (for both plantar flexion and dorsiflexion). The sequence of programs is following: warm-up program, intensive plantar flexion and dorsiflexion program, standard program and relaxing program.
4.	**Progressive plantar flexion and dorsiflexion program** (with only dorsiflexion progress)	This program automatically increases the pre-set dorsiflexion angle by 1°. The sequence of programs is following: warm-up program, intensive plantar flexion and dorsiflexion program, standard program and relaxing program.
5.	**Intensive dorsiflexion program**	This program is focused on intensive exercise in dorsiflexion position. The sequence of programs is following: warm-up program, intensive dorsiflexion program, standard program and relaxing program.
6.	**Intensive plantar flexion program**	This program is focused on intensive exercise in plantar flexion position. The sequence of programs is following: warm-up program, intensive plantar flexion program, standard program and relaxing program.
7.	**Intensive plantar flexion and dorsiflexion program**	This program is focused on intensive exercise in both plantar flexion and dorsiflexion position. The sequence of programs is following: warm-up program, intensive plantar flexion and dorsiflexion program, standard program and relaxing program.

8.	**Stretching program - plantar flexion**	This program is focused on stretching in plantar flexion position. The sequence of programs is following: warm-up program, program for stretching in plantar flexion, standard program and relaxing program.
9.	**Stretching program - dorsiflexion**	This program is focused on stretching in dorsiflexion position. The sequence of programs is following: warm-up program, program for stretching in dorsiflexion, standard program and relaxing program.
10.	**Stretching program - plantar flexion and dorsiflexion**	This program is focused on stretching in both plantar flexion and dorsiflexion position. The sequence of programs is following: warm-up program, program for stretching in plantar flexion and dorsiflexion, standard program and relaxing program.
11.	**Gentle dorsiflexion program**	This program automatically increases the pre-set dorsiflexion angle by 5° and during the therapy the angle decrease up to pre-set value. The sequence of programs is following: warm-up program, intensive dorsiflexion program with increased plantar flexion angle, intensive dorsiflexion program with pre-set dorsiflexion angle, standard program and relaxing program.
12.	**Gentle plantar flexion program**	This program automatically decreases the pre-set plantar flexion angle by 5° and during the therapy the angle increases up to pre-set value. The sequence of programs is following: warm-up program, intensive plantar flexion program with decreased plantar flexion angle, intensive plantar flexion program with pre-set plantar flexion angle, standard program and relaxing program.
13.	**Gentle plantar flexion and dorsiflexion program**	This program automatically decreases the range of motion by 5° (for both plantar flexion and dorsiflexion) and during the therapy the range of motion increase up to pre-set values. The sequence of programs is following: warm-up program, intensive dorsiflexion and plantar flexion program with decreased range of motion, intensive dorsiflexion and plantar flexion program with pre-set angles, standard program and relaxing program.

2.4.6.2 Save program

There are 50 memory positions for storage of user therapy settings.
User set parameters that can be saved/loaded:

Plantar flexion angle

Dorsiflexion angle

Speed

Therapy time

Plantar flexion pause

Dorsiflexion pause

Intensive plantar flexion program

Intensive dorsiflexion program

Warm-up program

- Select the row with **save** icon.
- Select the memory bank number for storage of parameters.
- Confirm storage by touching the row with the **save** icon again.

  Correct saving of parameters is signalled by change of the pictograph in the top right corner of the screen from  to  .

2.4.6.3 Load program

There are 50 memory positions for storage of therapy parameters. How to load a program from the memory:

- Select the row with **load** icon.
- Select the memory number of the program (parameters) you wish to load.
- Confirm the choice by touching the **load** icon again.

  Correct loading of parameters is signalled by change of the pictograph in the top right corner of the screen from  to  .

2.4.6.4 Load reversal

The feature serves for patient comfort.

The device automatically starts moving in the opposite direction of the last movement (regardless on reaching the pre-set therapy angles), when the patient's load exceeds the pre-set force (max. value 25 means that the highest force is needed to activate the “load reversal”, min. value 1 means that the lowest force is needed to activate the “load reversal”).

2.4.6.5 Quick angle settings

If this function is on, the unit is moving following the setting of the angle. So if you e.g. set flexion 5°, the unit goes to 5° during the setting. So you can easily find the maximal angle which is acceptable for the patient.

2.4.6.6 Parking position

When this function is on, the unit automatically rotates the ankle footplate to 0°. The function is automatically on during the therapy, so the therapy always finishes in the parking position. It is possible to deactivate the function during the therapy.

2.4.7 START, INTERRUPTION AND END OF THERAPY

After adjusting the device to patients’ dimensions and setting the parameters the therapy can be started. Press the  key on the device or on the remote control to start the therapy. Therapy can only be started if the remote control is connected and all of the parameters are set correctly. The device will warn the user about any discrepancies.  and  on the top of the display is showing direction of the CPM’s movement during the running therapy (even if the BTL-CPMotion doesn’t move because of extension/flexion pause in progress).

To interrupt the therapy, press the **start/stop** key  on the device or remote control. During the running therapy all parameters can be set.

If you will not allow the patient to change the parameters, you can lock the remote control by pressing  and  buttons on the remote control at the same time. Once the remote control is locked, you will see  symbol on the display. If the remote control is locked, only **start/stop** key is working. For unlocking the remote control, press  and  at the same time again.

2.4.8 DEVICE SHUTDOWN

Turn off the device by pressing  and hold it till it will be off.

3 LIST OF ACCESSORIES

 The device is not designed for use with accessories other than those stated in this manual.

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

Model / Name and model of accessory	**BTL-CPMotion K EASY**	**BTL-CPMotion K PRO**	**BTL-CPMotion K ELITE**
Mains power cable (5 m)	●	●	●
Operator's manual	●	●	●
START/STOP remote control BTL-093-1	●	–	–
Remote control with colour touch screen BTL-093-2	–	●	●
Ankle module BTL-093-3	–	○	●
Trolley BTL-093-4	○	○	○
Trolley with adjustable height BTL-093-5	○	○	○
Touch pen	–	●	●

● ... standard ○ ... optional – ... not available

4 MAINTENANCE AND SAFETY INSTRUCTIONS

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.

To keep the device clean, do not store or use it in extremely dusty environment for a long time. Do not immerse it in any liquid. Before each use, make sure that the device and its accessories (especially cables) are not mechanically or otherwise damaged. Do not use the device if it is damaged in any way!

Exterior Surface Cleaning

Use a soft cloth slightly moistened with water or with a mild 2% detergent solution to clean the exterior of the device and its parts. Never use cleaning agents containing alcohol, ammonia, benzine, thinners, etc. Never use abrasive cleaning materials which will scratch the device's surfaces. There are no parts of the device that require sterilization.

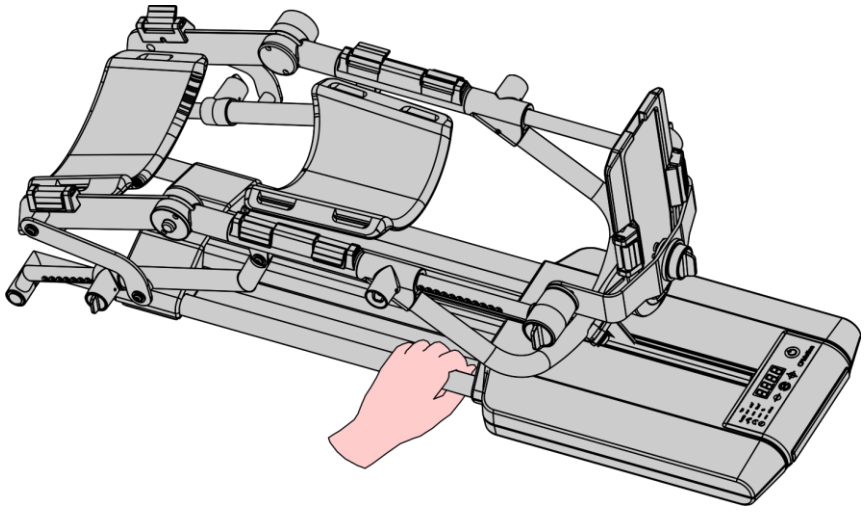
Accessories, Cleaning and Maintenance

The parts of the device that come into direct contact with a patient must be specially cleaned after each use. Clean using the hygienic cleaning agents approved by the local health department. For example Sekusept, Bacilol etc. are acceptable. For the cables of device, the user can use Incidur Spray and the alike. The silicone cover of the remote control with touchscreen can be removed for cleaning. Disconnect the remote control before cleaning, so you can remove the silicon cover easily.

Transport and Storage

Keep the original shipping container and all packaging materials. Transport the unit in the original box to ensure maximum protection. Before you pack the unit, move the CPM to parking position (10°) and set the Femur length 45 cm and Tibia length 40 cm (fully retracted). Set the footplate into horizontal position. Unplug the main power cable and all accessory cables. Pack the remote control in the original box. Take care to avoid shocks or jarring movements to the device during transport. This device should only be transported and stored under the conditions defined in the Chapter 5.

When manipulating the device hold the metal rods in the position close to the centre of mass as depicted below.



Angle sensor calibration procedure

For correct angle measurement of BTL-CPMotion it is necessary to run the automatic calibration procedure. The device shows the message* about necessity of user calibration after reaching 1000 work hours since the previous successful calibration and then every 25 work hours till the user runs the calibration procedure.

Incorrect or expired angle sensor calibration might decrease efficacy of the therapy, damage the device or cause harm to the patient.

See Chapter 2.4.4 – 5th menu – *Service Code Screen* to learn how to activate the calibration procedure.

* For BTL-CPMotion K EASY only - Unit Control Panel shows SE01.

Remote control touch screen calibration

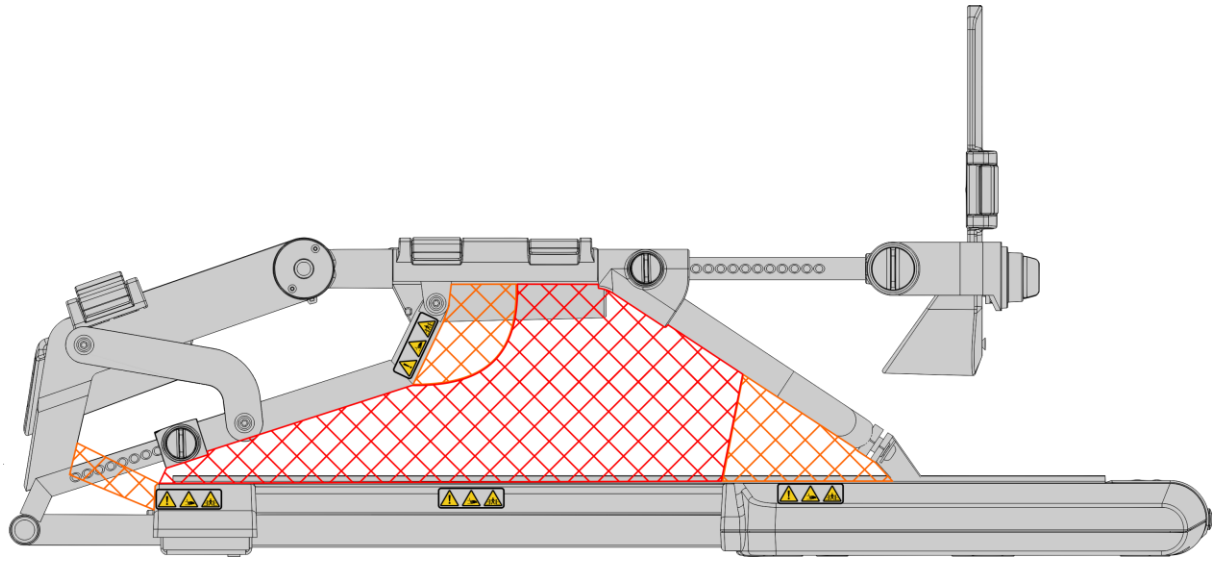
Various factors may affect precision of the touch sensing during time. That is why the remote control is equipped with touch screen calibration procedure (see Chapter 2.4.4).

4.1 GENERAL SAFETY PRECAUTIONS

- Before turning the device on for the first time, read this manual carefully.
- This device and accessories must be used, installed and maintained in compliance with this manual.
- Only authorized individuals are allowed to operate the BTL-CPMotion device. Individuals are authorized after receiving training in the operation of the device and reading this operator manual.
- The use of BTL-CPMotion without proper knowledge of the device functions and additional information from the operator manual can cause harm to the patient or the operator or damage to the device.
- It is the physician's or therapist's decision whether or not to use the BTL-CPMotion on a particular patient. Only the responsible physician or therapist is able and allowed to select the therapy parameters for the patient to use.
- When you have doubts about the device settings and/or the therapy protocol stop the therapy immediately and contact your physician or therapist.
- Patient must be fully conscious while being instructed in the use of the BTL-CPMotion and during therapy. Patient should be able to provide feedback during the therapy.
- Patient's position during the therapy must be anatomically correct (see Chapter 2.4.1).
- Patient must be informed about **start/stop** function of the remote control for BTL-CPMotion. During the therapy the remote control must be placed in patient's hand so that the patient can stop the therapy in case of

discomfort, pain, irritation or another danger. Patient that is not able to use the remote control should not be left without supervision of the operator.

- This device must be placed out of the reach of children and animals. Children should be supervised to ensure that they do not play with the device. Packaging (e.g. plastic bags) poses risk of suffocation. Cables (e.g. to the remote control) pose risk of strangulation.
- Despite the efforts of the manufacturer of the BTL-CPMotion to eliminate the risks the device might cause serious injuries or death. The mechanical moving parts pose risk of injury (e.g. crushing, cutting) of extremities and body parts. Especially make sure that no object is placed or can reach the space depicted on the picture below during the therapy.



- Paediatric patients (children) may undergo the therapy on BTL-CPMotion under supervision of authorized adult operator only. Adjustment of belts, setting of therapy parameters and switching **on/off** may be performed only by authorized adult operator that has to be present during the whole therapy.
- Inspect the device thoroughly before each use. Look for damage such as loose/cracked parts (cables, plastic or metal components, covers). Check the display function and the operating elements function. If any anomalies or inconsistencies are found, stop using the device and contact an authorized BTL service.
- Before starting therapy with a patient run several cycles without patient to test the full range of the device. Make sure all the fixation screws and locking mechanisms are tightened.
- If the device shows any defect or if the user has any doubts concerning its correct and safe functioning, terminate the therapy immediately. If the user does not determine the source of concern after a thorough study of the operator's manual, then they should contact an authorized BTL service. If the device is not used in accordance with this manual or if it is used when the device exhibits functional differences from those stated in this manual, the user is responsible for any damage to the device.
- The BTL-CPMotion must not be covered with blanket, sheet, etc. during the therapy. Such action might cover the moving parts, warning signs and symbols placed on the device (these symbols must be visible to the

operator) and cause associated risks. Also the cover might get caught in the moving parts and cause safety hazard to the patient or damage the device.

-  This device requires the environmental conditions that are stated in the Chapter 5. It must not be used in an environment where there is a danger of explosion. The danger of explosion might occur e.g. with flammable anaesthetics, oxidizing gasses (O_2, N_2O, etc.) detergents and disinfectants.
-  Make sure that voltage parameters of the power supply grid correspond to the device requirements as stated in the Chapter 5.
-  The cables must be placed in such way that it cannot be caught by the moving parts of the device.
-  After bringing the device from a cold environment into a warm one, do not plug it into the power source immediately. Allow the device to warm up to room temperature before using it (minimum 2 hours). Otherwise there is a risk of water condensation inside the device and consequent damage of the device or injury of the operator/patient (e.g. by electric shock).
-  In case of ingress of water or other liquid into the device stop using the device, unplug the mains power supply and contact an authorized BTL service (electric shock risk).
-  Before maintenance or service unplug the mains power supply from the wall socket (not from the device) (electric shock risk).
-  Do not disconnect the device from the mains power supply during therapy – the therapy would stop and device would shut down.
-  Do not place the device close to other devices and appliances which produce or emit strong electric, electromagnetic or magnetic fields or X-rays in order to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized BTL service.
-  Do not place the sources of magnetic field (e.g. magnets) into the vicinity of the angle sensor (patient injury risk). Device angular sensing might be affected. The real angle might differ significantly from the measured angle.
-  Do not disconnect the angle sensor connector during the therapy. The device might exceed the safe range of angles of the moving parts (risk of patient injury and device damage).
-  The device must not be connected to unauthorized devices or accessories. For the list of authorized accessories see Chapter 3. In case of doubts please contact an authorized BTL service. There is a danger of electrical shock and/or serious damage to the device.
-  Do not place the device in direct sunlight or near direct heat sources (such as stoves, heaters etc.). It might lead to excessive temperature raise and possible risk to the patient and/or to the device.

- Should the device enter such state that it does not react to the user control (on the device or on the remote control) and it cannot be switched off by the button  on the device or on the remote control unplug the device from the wall socket and plug it back again. If the problem persists even after next start of the device please contact an authorized BTL service.
-  When using the remote control with touch screen the operator/patient must lock the remote control to prevent incidental change of therapy parameters (therapy efficacy reduction risk and/or patient injury risk).
-  The leg support and mechanical frame withstands long term total loading of max. 20 kg.
- The device does not contain any drugs or substances as an integral part or to be applied to the user or patient.
- This device does not use or emit any toxic substances during its operation, storage or transport under the stated conditions.
- Portable and mobile high-frequency devices (such as mobile phones) can affect the device's performance.
- Place the device in a location and position which enables the quick and easy disconnection of the mains power cable from the device or of the mains power cable plug from the electrical outlet/socket. To disconnect the device from the mains, unplug the mains power cable plug from the outlet/socket. Before starting therapy, make sure that all input parameters correspond to the user's intentions.
-  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 itself does not contain any toxic materials that could harm the environment.
-  No modification of the device is allowed.
-  Do not try to open, remove protective covers or dismantle the device for any reason. There is a danger of electric shock and/or serious injury.

4.2 SYMBOLS AND MARKINGS

	General warning sign
	Type BF applied part
	Follow instructions for use
	Waste electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Catalogue number
	Batch code
	Class II equipment
	Caution (Precaution)
IP 21	Enclosure protected against dripping water (water equivalent to 1 mm rainfall per minute) and insertion of fingers or similar objects
	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)
	Hazard - Breakage due to heavy load (the leg support and mechanical frame withstands long term total loading of max. 20 kg/44 lbs)

4.3 TROUBLESHOOTING

Power Supply:

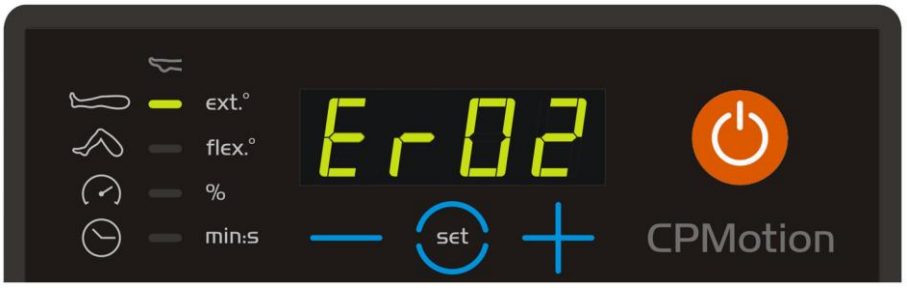
No power: the **on/off** power switch on the front is not illuminated.

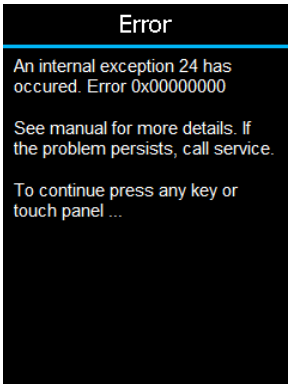
- Make sure that the power supply cable is plugged into the device.
- Make sure that the power supply cable is plugged into the wall socket and the wall socket is live.

Error Messages:

- In the event that an internal exception message ("*Error*" or "*Warning*" message) appears, immediately stop all use of the unit and follow the displayed instructions.
- Use of a unit when it indicates an internal exception message ("*Error*" or "*Warning*" messages) poses a risk of injury to the patient, the user and/or extensive internal damage to the device.

  Illustration of error messages:





Error codes (reported in the text of error message):

Code	Message
2, 5, 7, 25, 27	Check whether the remote control is properly connected. Switch off the device. Unplug the remote control, plug back in and start the device again. If the problem persists contact the BTL service.
13	Check whether the cable to the remote control or ankle module is properly connected. Switch off the device. Unplug the connectors, plug them back and start the device again.
16	Check whether cable to the angle sensor is properly connected. Switch off the device. Unplug the connector, plug it back and start the device again.
18	Check whether rear telescopes (femur scale) are properly locked. Check that the actual angle is in the range of -10° to 123°. If it is out of range, set rear telescopes so the current angle is in the range of -10° to 123°.
20, 22	Check whether the load reverse function setting is not too low for intended therapy. Check whether the moving parts of the BTL-CPMotion are not blocked.
24	Check whether the cables to the remote control, angle sensor or ankle module are properly connected. Switch off the device. Unplug the connectors, plug it back and start the device again.
28	Check whether the moving parts are in a position suitable for ankle module. Switch off the device. Disconnect and dismount the ankle module. Follow the ankle module mounting procedure from Chapter 2.2.2. Start the device again.

If a different error code message appears, try to restart the device.

If the problem persists, contact an authorized BTL service.

General:

- In case of display failure or other obvious defects, switch the unit off immediately. Then disconnect the power cord from the power outlet and notify an authorized BTL service.
- In case of damage from transport that could endanger personal safety, the unit must not be connected to the main power supply before a complete inspection of the device is made.
- In case of malfunction of the remote control display run the Touch screen calibration (see Chapter 2.4.4.7)
- In case of malfunction of the angle measurement, please run the Calibration of angle sensor process (see Chapter 2.4.4.10). If this doesn't solve the problem, please contact an authorized BTL service.

5 TECHNICAL PARAMETERS

5.1 BASIC DEVICE PARAMETERS

Name	**BTL-CPMotion**
Models	**BTL-CPMotion K EASY, BTL-CPMotion K PRO, BTL-CPMotion K ELITE**
Operating conditions	
Ambient temperature	+10 °C to +30 °C
Relative humidity	30 % to 75 % (non-condensing)
Atmospheric pressure	800 hPa to 1060 hPa
Position	Horizontal
Type of operation	Continuous
Transport and storage conditions	
Ambient temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 % (non-condensing)
Atmospheric pressure	650 hPa to 1100 hPa
Position	Horizontal
Additional conditions	Transport only in the original packaging
Power supply	
Maximum input	140 VA
Mains voltage	~100 V to 240 V
Frequency	50 Hz to 60 Hz
Electrical protection class	Class II
External replaceable fuses	-
Power switch	The device is NOT equipped with power switch. To disconnect from the main power unplug the male plug of the main cable from the electrical socket outlet.
Classification	
Applied parts type	BF
Class (In accordance with MDD 93/42 EEC)	IIa

Models	BTL-CPMotion K EASY	BTL-CPMotion K PRO	BTL-CPMotion K ELITE
Dimensions			
Weight	11 - 14 kg (18 - 21 kg including packaging and accessories)		
Dimensions (d x h x w)	390 x (min. 430, max. 580) x 970 mm (390 x 502 x 1135 mm packaging)		
Covering grade in accordance with EN 60 529	IP 21		
Display Elements			
Graphic colour touch screen	–	3.2” (240 x 320 pixels)	
LED display	4 x 7 segment		
Indicator lights	2x white, 1x orange, 3x blue and 5x green	2x white, 2x orange, 3x blue and 5x green	
Therapy parameters			
Rated load	20 kg (max. weight of patient 135 kg)		
Knee extension limit	-10°		
Knee flexion limit	123°		
Ankle plantar flexion limit	–		40°
Ankle dorsiflexion limit	–		25°
Therapy time	Max. 59 minutes 59 seconds		
Patient tibia length	23 to 55 cm		
Patient femur length	35 to 50 cm		

5.2 EMC DECLARATION

The BTL-CPMotion is designed to be used in typical environments that have been approved in accordance with the EMC safety standard EN 60601-1-2. This device complies with the CISPR standard, indicating that radio frequency (RF) emissions are not likely to cause interference with electronic equipment installed nearby (radios, computers, telephones, wireless networks, etc.).

The BTL-CPMotion is designed to withstand foreseeable disturbances from electrostatic discharge, magnetic fields from the mains power supply or RF transmitters. Nevertheless, it is not possible to ensure that the Device will not be affected by powerful RF (radio frequency) fields from other sources.

For typical wireless communication devices such as e.g. cell phone with maximum output power of transmitter 2 W and compliance level 3 V/m the recommended separation distance between the transmitter and BTL-CPMotion is ***d*** = 3.3 m. For more detailed information concerning electromagnetic emissions and immunity, refer to the EMC tables below.

Guidance and manufacturer's declaration – electromagnetic emissions		
The BTL-CPMotion is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-CPMotion should assure that it is used in such an environment.		
Emissions test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	The BTL-CPMotion 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 B	The BTL-CPMotion is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The BTL-CPMotion intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-CPMotion can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-CPMotion 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 $d = 1.17\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1.17\sqrt{P}$	***800 MHz to 2.5 GHz*** $d = 2.34\sqrt{P}$
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 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 BTL-CPMotion is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-CPMotion should assure that it is used in such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the BTL-CPMotion, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.34\sqrt{P}$ 800 MHz to 2.5 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 metres (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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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.			
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 BTL-CPMotion is used exceeds the applicable RF compliance level above, the BTL-CPMotion should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BTL-CPMotion.			
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The BTL-CPMotion is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-CPMotion 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 2 kV for power supply lines N/A – no input/output lines	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	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BTL-CPMotion requires continued operation during power mains interruptions, it is recommended that the BTL-CPMotion be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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.			

6 MANUFACTURER

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