GOOD MEDICA

OrtoFlexL2

CPM rehabilitation device

USER MANUAL

PLEASE READ THE USER MANUAL OF THE DEVICE PRIOR TO USE!

OrtoFlexL2

CPM rehabilitation device

Continuous Passive Motion

PLEASE READ THE USER MANUAL OF THE DEVICE PRIOR TO USE!

Product	Model	Manufacturer
CPM rehabilitation device for continuous, passive mobilization of the lower limb.	OrtoFlex L2	Good Medica Sp. z o.o. ul. Opolska 149 52-013 Wrocław, Poland

Contents

DEVICE DESCRIPTION

1. Thigh rest
2. Lever for setting the thigh rest height and a fixing bolt for adjusting appropriate thigh length. Thigh length scale on the lever
3. Shin support
4. Lever for setting the shin rest height and a fixing bolt for adjusting appropriate shin length. Shin bone length scale on the lever
5. Remote control
6. Main switch
7. Remote control plug-in socket
8. Control panel, independent from the remote control
9. Fixing bolt for adjusting the foot rest position
   a. Foot rotation setting
   b. Dorsiflexion and plantar flexion setting
10. Foot rest with a foot-securing strap
11. Knee flexion angle and extension sensor
12. Emergency stop button
13. Power socket

The range of motion of the device

	From	To
Knee joint motion angle range	–5°	120°
Hip joint motion angle range	25°	100°
Femur alignment range	32 cm	49 cm
Tibia alignment range	25 cm	57 cm

Device size

Length	95 cm
Width	32 cm
Height	36-45 cm
Weight	12 kg

Additional information

Minimum height of the patient	150 cm
Mains voltage	100-230 V, 50-60 Hz, 70 VA

The device uses a 24V motor, which enables generating slowed-down movement allowing continuous passive motion of the lower limb - flexion and extension of the hip and knee joints.

The 200 N power of the device enables its quiet and uninterrupted operation. The noise of the running device does not exceed 65 dB.

The device is equipped with a processor, which enables controlling the operation of the device through setting the motion ranges, speed and time.

The range of motion does not exceed permissible clinical standards (from -5° to 120°). The device has a 9-step speed scale and is fitted with a display, which enables setting the range of motion, speed, operating time and other options.

Furthermore, it is equipped with a remote control, which enables setting and adjusting all exercise parameters.

INDICATIONS FOR USE

An indication for using a motorized motion device shall always be specified by a doctor or physiotherapist.

Main indications for using the CPM device are:

- knee joint endoprostheses,
- hip endoprostheses,
- corrective osteotomies,
- intra-articular procedures (e.g. synovectomy),
- joint arthroscopies,
- cruciate ligament reconstructions,
- joint mobilization after prolonged immobilization,
- stable post-fracture bone fixation,
- procedures on soft issues near the joint,
- joint sprains and injuries,
- any disorders leading to restricted mobility,
- and many more.

CONTRAINDICATIONS

An absolute contraindication to exercise is the acute inflammation of the joints and periarticular tissues, veins, as well as significantly elevated body temperature.

Using the device after bone fracture repositions and stabilizations shall be consulted with an operator, attending physician or a specialist in the field of orthopaedics or locomotor system traumatology, since the exercise shall be postponed in the case of unstable osteosynthesis.

Exercise with the use of the device shall be stopped in the event of the patient's feeling growing pain. The decision to suspend, discontinue or decrease the frequency and parameters of the therapy lies with the specialist supervising the improvement process.

Inability to properly fit the device to a limb is a contraindication to use the rehabilitation device, in particular due to:

- too long (very tall persons) or too short limbs (e.g. shorter children, very short persons)
- various lower limb deformations (e.g. significant valgus and varus knee joint deformations).

APPLICATION OF THE ORTOFLEX L2 CPM REHABILITATION DEVICE

The presented device is a mechanized CPM device for continuous and passive motion of the knee and hip joints.

A CPM device is utilized within the process of movement improvement among patients with disorders or after surgeries in the lower limb area. It supplements the rehabilitation scheme with passive motion therapy, which enables regaining joint mobility. Continuous passive movement prevents mobility loss - it maintains the correct length and flexibility of the tissues, ensures their better nutrition, and is also a source of proprioceptive pulsation.

A CPM device must be used following the approval and recommendations of an attending physician. The device shall be individually adapted to each patient.

The product is intended for use in professional healthcare facilities such as hospitals, clinics, rehabilitation centers as well as by physiotherapists and patients at home.

FITTING THE DEVICE TO THE PATIENT'S LIMB

1. Position the device on a firm surface.
2. Connect the power cable of the device to the connection socket of the device (13) and then the mains plug to an AC socket (100-240 V, 50 Hz).
3. Press the main switch (6).
4. SETTING THE THIGH REST LENGTH (2):

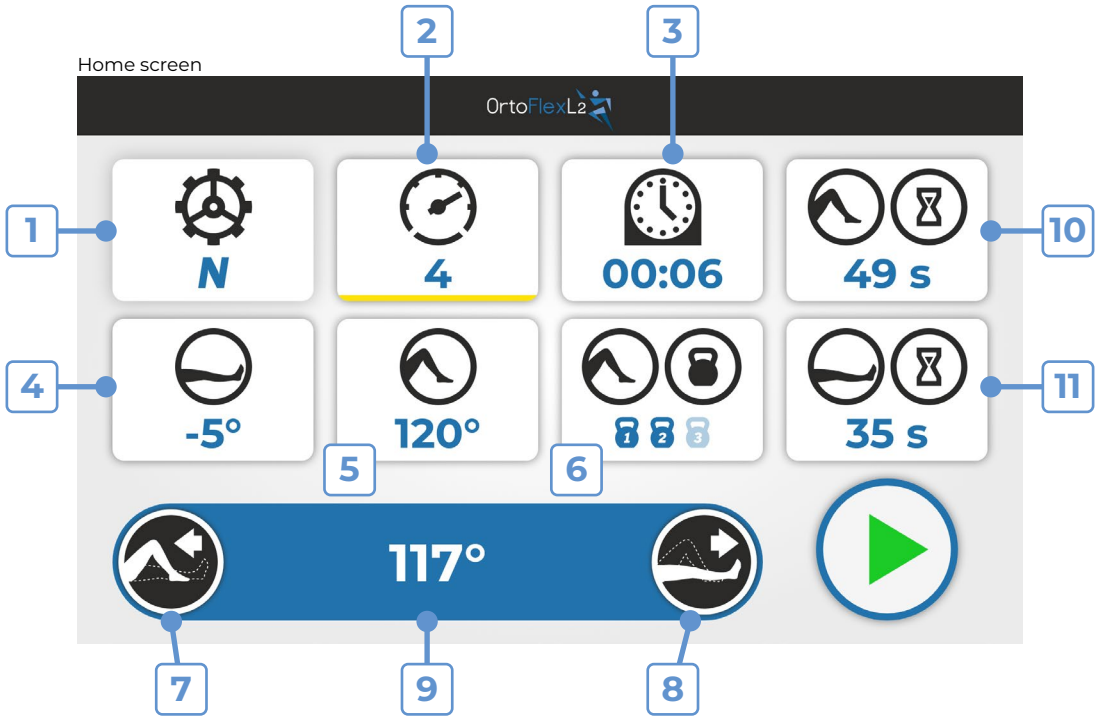
   Measure the patient's femur length from the greater trochanter to the knee joint gap. Unscrew the fixing bolts, set the measured length on the hip lever and then tighten the fixing bolts.
5. SETTING THE LOWER LEG AND FOOT REST:

   Unscrew the fixing bolts and slide out the lower leg length lever (4). Position the lower leg within the rail, make sure whether the hinge connecting the femoral and tibial sections (11) is located at the height of the knee joint gap. Slide, so that the foot comfortably positions within the rest (10). Set the optimum position of the foot, flexion and rotation (9). After initial start-up, fasten the foot in the rest using the Velcro.
6. If necessary, adjust the thigh and lower leg rest (1,3) so that the exercises with the device do not cause pain or abrasions. The device with a limb can be positioned in a slight abduction.
7. SETTING PROCEDURE-RELATED VALUES:

   The device can operate without a connected remote control. The flexion and extension angles, as well as the device speed, operating time, mode and torque can be set on the control panel and the remote control.

THE DEVICE IS CORRECTLY ADJUSTED TO A PATIENT'S LIMB WHEN THE KNEE AXIS OF THE PATIENT IS ALIGNED WITH THE PIVOT AXIS OF THE CPM.

DESCRIPTION OF FUNCTIONAL ICONS



1. Operating mode settings
2. Operating speed settings
3. Operating time settings
4. Setting the extension angle
5. Setting the flexion angle
6. Setting the torque control level
7. Immediate change of the device operating direction
8. Immediate change of the device operating direction
9. Current rail bending angle
10. Setting the pause for flexion
11. Setting the pause for extension

TIP

The menus on the panel and the remote control have the same functions and appearance

Start is used to start the device.

Stop is used to stop the device.

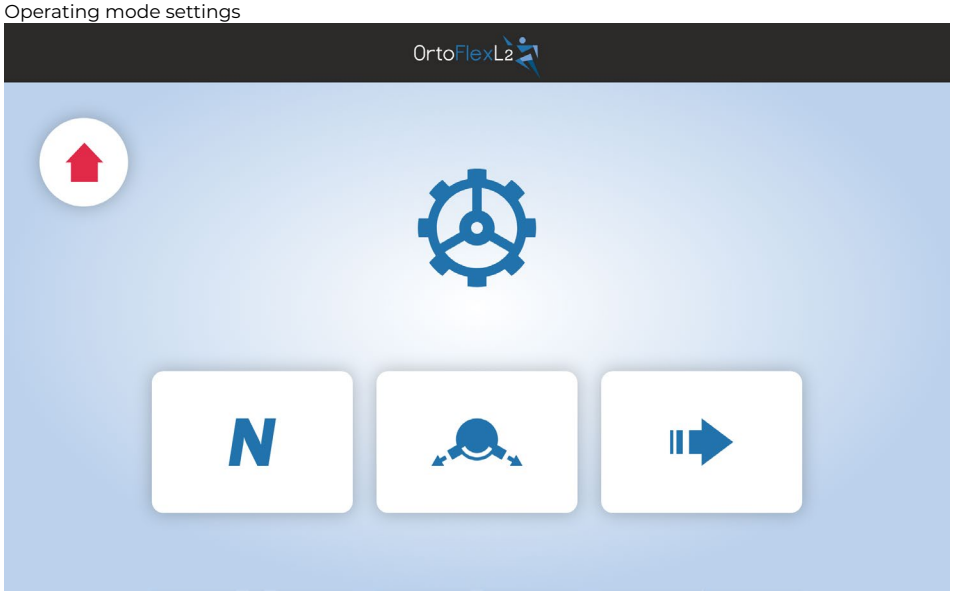
Return is used to confirm the settings and return to the ***Home screen***.

OPERATING MODE SETTINGS

After pressing the ***Operating mode settings*** icon, the option to select the operating mode appears.

The device has 3 operating modes of the rail.

Operating mode settings



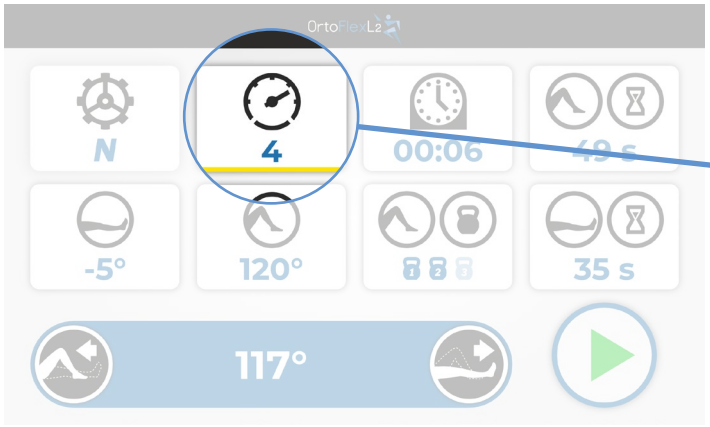
Normal mode, the device operates as per the pre-set flexion and extension angle, and speed values.

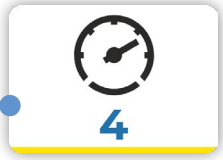
Angle mode, the device increases the flexion angle by 3° every 15 minutes.

Speed mode, the device increases the motion speed by 1 level every 15 minutes.

In order to confirm the desired mode of rail operation, select the program icon. The ***Home screen*** will appear automatically

OPERATING SPEED SETTINGS

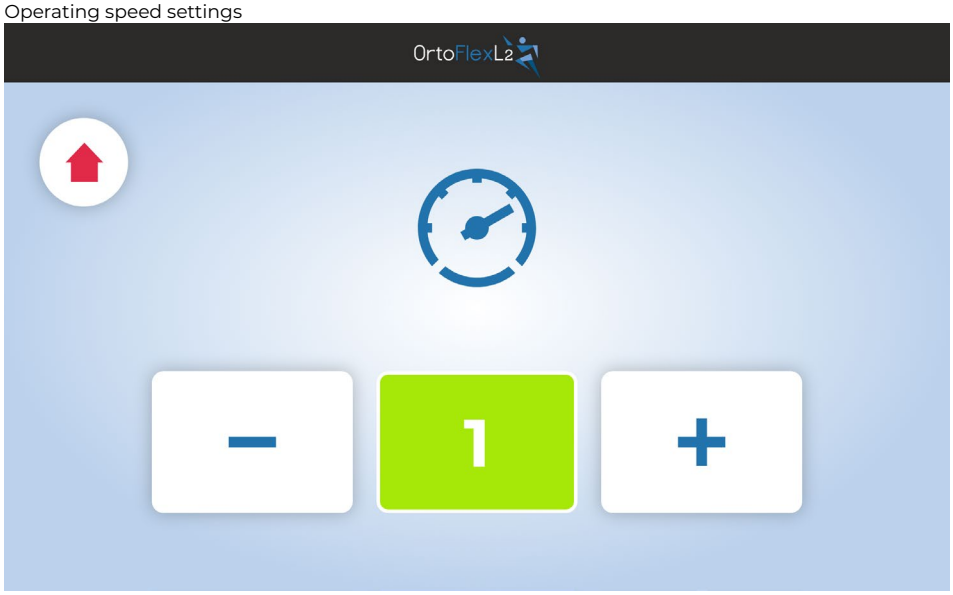




After pressing the ***Operating speed settings*** icon it is possible to change the speed of the rail on a scale from 1 to 9.

1 is the minimum speed and 9 is the maximum.

Operating speed settings

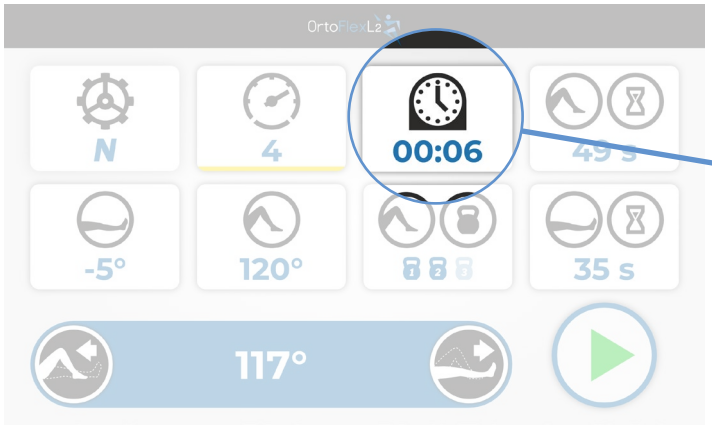


With the button **+** we increase the speed.

With the button **–** we decrease the speed.

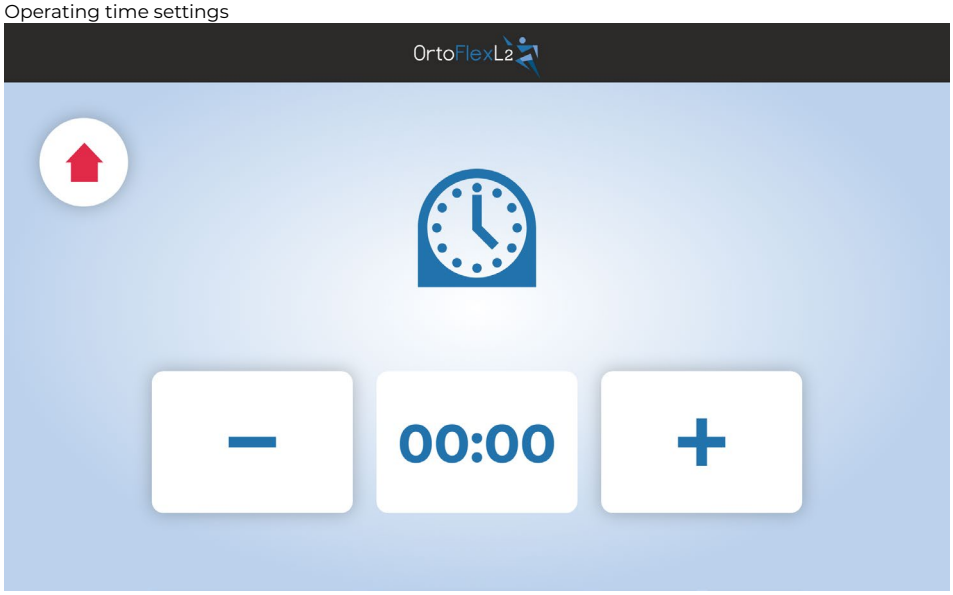
After selecting the appropriate speed, we go back to ***Home screen*** with the ***Return*** button.

OPERATING TIME SETTINGS



After pressing the ***Operating time settings*** icon we set the treatment time in the range from 1 to 240 minutes.

Operating time settings



With the button **+** we increase the time.

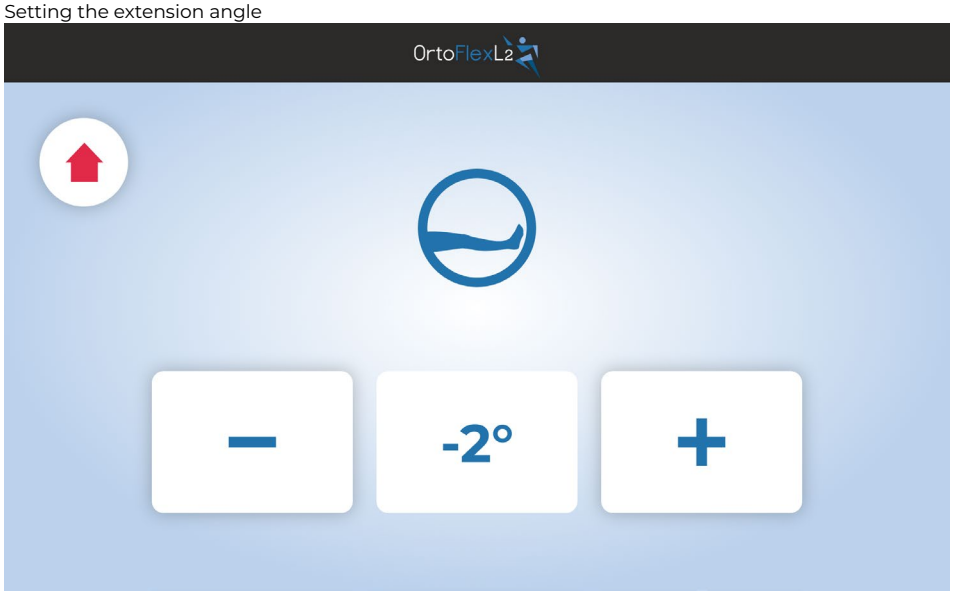
With the button **–** we decrease the time.

After selecting the appropriate time, we go back to ***Home screen*** with the ***Return*** button.

SETTING THE EXTENSION ANGLE

After pressing the ***Setting the extension angle*** icon we set the extension angle in the range from –5 ° to 120°.

Setting the extension angle

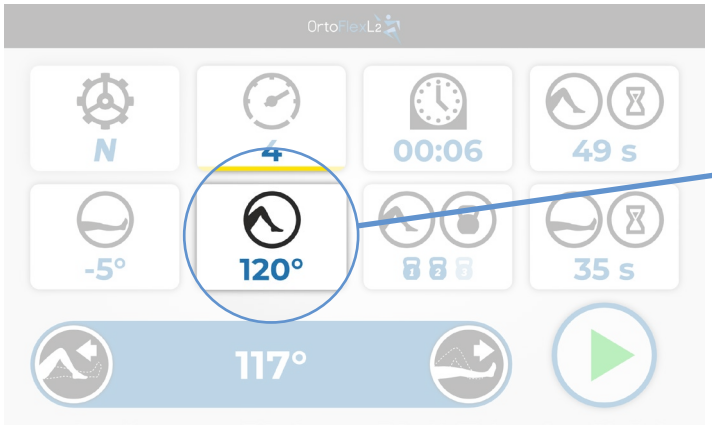


With the button **+** we increase the extension angle.

With the button **–** we decrease the extension angle.

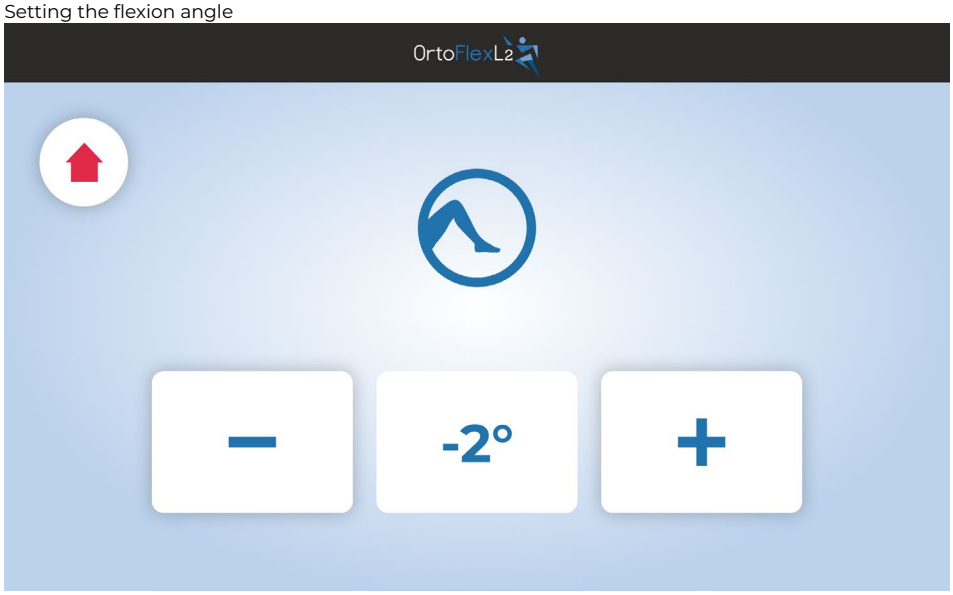
After selecting the appropriate extension angle, we go back to ***Home screen*** with the ***Return*** button.

SETTING THE FLEXION ANGLE



After pressing the ***Setting the flexion angle*** icon we set the flexion angle in the range from –5 ° to 120°.

Setting the flexion angle

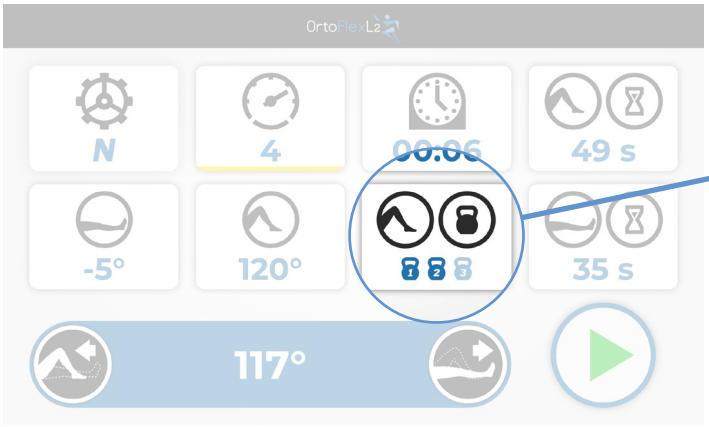


With the button **+** we increase the flexion angle.

With the button **–** we decrease the flexion angle.

After selecting the appropriate flexion angle, we go back to ***Home screen*** with the ***Return*** button.

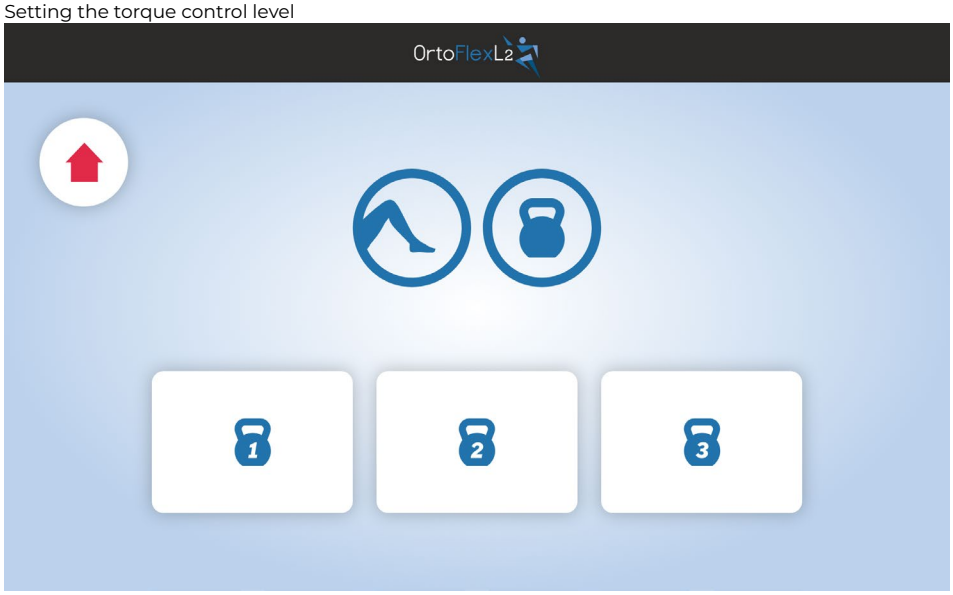
SETTING THE TORQUE CONTROL LEVEL



After pressing the ***Setting the torque control level*** icon we set the torque in the range of 1, 2 or 3.

Should the resistance applied on the rails exceed a selected maximum torque level, the device starts operating in the reverse direction.

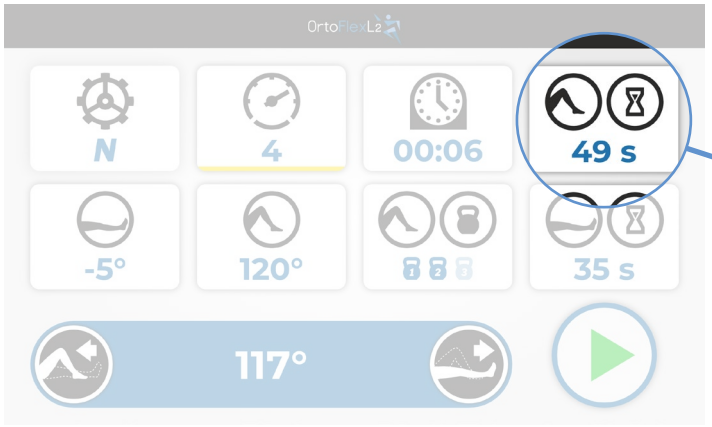
Setting the torque control level



Buttons for selecting the torque.

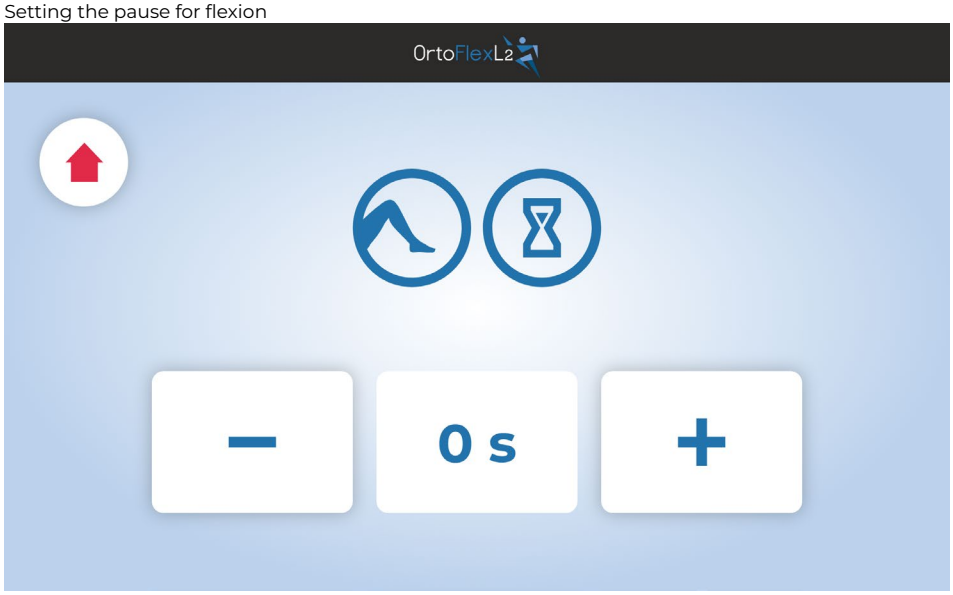
After selecting the appropriate torque, we go back to ***Home screen*** with the ***Return*** button.

SETTING THE PAUSE FOR FLEXION



After pressing the ***Setting the pause for flexion*** icon we set the pause in the range from 0 to 59 seconds.

Setting the pause for flexion



With the button **+** we increase the pause time.

With the button **–** we decrease the pause time.

After selecting the appropriate pause time, we go back to ***Home screen*** with the ***Return*** button.

SETTING THE PAUSE FOR EXTENSION

After pressing the ***Setting the pause for extension*** icon we set the pause in the range from 0 to 59 seconds.

Setting the pause for extension

With the button **+** we increase the pause time.

With the button **–** we decrease the pause time.

After selecting the appropriate pause time, we go back to ***Home screen*** with the ***Return*** button.

IMMEDIATE CHANGE OF THE DEVICE OPERATING DIRECTION

After pressing the ***Immediate change of the device operating direction*** the device changes the direction of movement from extension to flexion.

After pressing the ***Immediate change of the device operating direction*** the device changes the direction of movement from flexion to extension.

TIP

With the device stopped, after pressing and holding the icon, the device increases the flexion range until the icon is released.

With the device stopped, after pressing and holding the icon, the device decreases the flexion range until the icon is released.

EMERGENCY STOP BUTTON

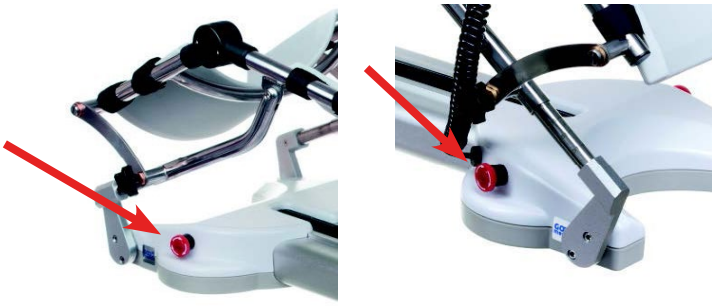
The emergency stop is used to immediately stop the device in the case of sudden pain or another event, which requires immediate suspensions of exercises using the CPM.

EMERGENCY STOP SWITCH IMMEDIATELY STOPS THE UNIT. IT IS LOCATED ON BOTH SIDES OF THE COVER WITHIN PATIENT'S REACH DURING THE THERAPY ON BOTH LEFT AND RIGHT LEG.

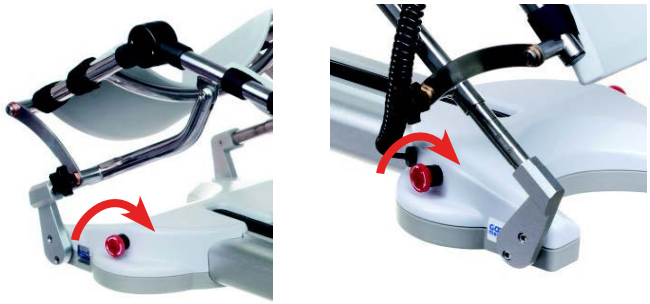
TIP

To unlock the emergency stop buttons, do the following:

1. Press the emergency stop buttons on both sides.



2. Twist both emergency stop buttons clockwise.



The device will now switch on.

TIP

Danger means immediate threat. Failing to follow these instructions may result in death.

DANGER!

Threat means A threat to patient's safety. Failing to follow these instructions may result in serious injury and even death.

THREAT!

Warning means a dangerous situation, which may result in minor injuries to a patient and/or damage to the unit.

WARNING!

DANGER!

Commencing a therapy using the CPM shall be in accordance with medical indications and after prior medical consultation. The device shall be operated by trained personnel or individually by the patient, under the supervision and in accordance with the recommendation of a physician or physiotherapist. Exercises utilizing the CPM shall be painless and irritation-free. The guard rail shall be perfectly adapted in accordance with the anatomical values of the patient's limb. In the course of a procedure with the use of the CPM, the patient is to be awake and conscious, and should know how to immediately discontinue the treatment in the event of pain.

THREAT!

Risk of explosion!

The OrtoFlex L2 unit cannot be used in medical rooms with a risk of explosion present. A risk of explosion can arise after contact with flammable anaesthetics or, e.g., skin disinfectants.

WARNING!

Risk for the patient!

Do not use OrtoFlex L2 CPM for any other purpose than continuous passive motion of the hip and knee joints. The OrtoFlex L2 CPM can be operated solely by a person trained in the field of its operation and being familiar with the contents of the user manual. Prior to each use, the user shall check the condition of the device in terms of safe use; in particular the cables and plug-in connectors for possible damage. In the event of identifying any malfunctions, contact the service department. Prior to each procedure, conduct a trial run of the device, without the patient's limb. Check the tightening of all bolts. In the event of doubts regarding the correct alignment of the guard rail or its configuration, discontinue any exercise.

Make sure that the device is properly adapted to the patient's limb. For this purpose, check whether the knee joint flexion axis is aligned with the rail flexion axis and whether the femur and shin bone lengths are correctly set on the device. Exercises on the unit cannot cause pain or irritation. The patient shall wear clothing not constricting movement but protecting the limb skin against direct contact with elements of the device (track suit, leggings, socks). Do not allow the formation of epidermal abrasions due to poorly chosen clothing when using the device.

When using the device, the patient must be fully conscious.

The decision to use the device is made by a physician or physiotherapist.

Treatment parameters are to be selected by a physician or physiotherapist.

Do not use the device while wearing orthosis, unless your doctor says otherwise.

Each patient using the OrtoFlex L2 machine must be able to immediately stop it. The remote control of the device must always be within the patient's reach.

The patient must be informed about the emergency stop and instructed on how to immediately stop the device.

Be careful so that the moving parts of the machine do not entangle any body parts or objects, e.g. fingers, blankets or cables.

Do not use OrtoFlex L2 CPM in a room without ventilation or an adequate light source.

Do not use OrtoFlex L2 CPM on a water bed.

WARNING!

Risk to the environment!

Do not allow animals or children to play near a CPM running.

WARNING!

Electrical shock hazard!

In order to avoid an electrical shock hazard, strictly observe the warnings below. Failure to observe them can pose a threat to the life and health of the patient and/or the operator of the machine.

If the machine has to be transported in negative temperatures, prior to starting the device, warm it up to room temperature. Leave the device for approx. 2h until potential condensate dries out.

The OrtoFlex L2 device can be used only in dry rooms, at a room temperature.

When isolating the device from the mains, first pull out the plug and then the cable from the device.

Do not use extension cables or multiple sockets for supplying electricity.

The OrtoFlex L2 device can be connected only to a correctly installed and earthed socket. Prior to connecting the machine, fully extend the cable of the device, so that it does not get trapped between the moving parts of the machine.

Prior to commencing cleaning, disinfecting or maintenance, remove the plug from the socket. Be careful to avoid getting the device, remote control and power cable wet. In the event of the above getting wet, contact the service department. Restarting will be possible after the device is inspected at the service facility.

Do not leave an unattended live device. When the device is not in use, disconnect it from the power source. Make sure not to pull the cable when disconnecting the machine.

WARNING!

Interference to device operation.

Magnetic and electric fields can affect the operation of the device.

When using OrtoFlex L2 machine, make sure that all other devices working in the vicinity meet the electromagnetic compatibility requirements.

Devices constituting an electromagnetic radiation source, i.e., X-ray instruments, MRI devices, radio transmitters or cell-phones can interfere with the operation of the machine. Maintain a specified distance from such devices, and prior to using the CPM, check its functioning.

Do not use OrtoFlex L2 CPM near a fire source.

Inspect the device at least once a year for possible damage or loose connections.

DANGER!

Prevention of abrasions and injuries.

A patient shall exercise in clothing covering the skin, e.g. leggings, track suit, socks.

In the case of obese or very short persons, pay special attention so that no elements of the machine rub against the patient's limb.

If necessary, position the lower limb in a slight abduction.

DANGER!

Damage to the machine.

Make sure that the parameters of the mains network are compatible with the voltage and frequency on the rating label of the device.

The maximum load on the device cannot exceed 20 kg.

Be careful so that the moving parts of the machine do not entrap any objects, e.g., bed linen or cable.

Do not expose the device to sunlight and extremely low or high temperatures.

Exercise particular care when handling the machine.

In the event of a damage, stop operating the machine and contact the manufacturer for repair.

TRANSPORT AND STORAGE

DANGER!

When transporting the device over long distances, it must be carefully secured, wrapped in protective film, at least 4 mm thick.

Transport and storage conditions

Storage temperature	5°C – 40°C
Optimal humidity	≤ 80%
Atmospheric pressure	500-1060 hPa

Prior to fastening the device to a patient after prolonged storage or transport, conduct a trial run to check its correct functioning.

The device shall be stored in conditions of optimal humidity, in order to prevent the formation of corrosion.

CLEANING AND DISINFECTION

WARNING!

Electrical shock hazard, device damage.

Prior to commencing cleaning and disinfection, remove the plug from the socket. Do not allow any liquid to penetrate the device or the remote control.

The device shall be cleaned, e.g., with Sani-Cloth Active alcohol-free soft tissues with washing & disinfecting properties by Ecolab sp. z o.o. Ready-to-use alcohol-free soft tissues have a bactericidal, yeasticidal and tuberculocidal effect.

First of all, wipe the silicon rests supporting the limb and the strap fastening the foot to the rest.

Use another tissue to thoroughly wipe the body with the control panel, and the metal tubes and the foot rest. The remote control shall also be wiped with this tissue.

Use more tissues if necessary.

If necessary, use a soft cotton cloth to wipe the device dry.

DANGER!

Damage to the machine:

In order to prevent damage, do not use any other disinfectants, gasoline and solvent in particular, for cleaning than the aforementioned ones.

Do not clean the drive elements of the guide rail.

Do not clean the electrical switches and contacts.

In order to avoid discolouration, use only colour-free disinfectants.

REMARKS

Electromagnetic compatibility

The device has been designed in a manner ensuring resistance to external electromagnetic factors. However, when in operation, the device generates electromagnetic waves, which can affect the functioning of other devices.

Environmental care:

After the service life of the device elapses, the machine can be disposed (electronic, metal and plastic elements).

COMMON FAILURES

If the machine does not start:

1. CHECK THE POWER CABLE

Uncouple the device from the power supply.

Check the power cable for mechanical damage.

If the cable is not damaged, connect the device to another mains socket.

Check whether the machine starts after connecting to another mains socket.

If the cable is damaged, contact the service.

2. CHECK THE EMERGENCY SWITCHES

If the device is not operating, check whether the emergency stops are not active.

If they are - deactivate them.

If the power cable is not damaged, or the emergency stops are deactivated, and the device is still stopped – contact the service.

If the remote control is defective:

1. REMOTE CONTROL SOCKET

Check whether the remote-control plug is correctly secured in the socket.

If the remote control is still off, contact the service.

Contact the service in the event of:

1. Device getting wet.
2. Mechanical damage, i.e., fall from a height, impact or other.
3. Louder or non-smooth (skipping) operation of the device's drive.
4. Incorrect values shown on LCD displays.
5. Doubts regarding the operation of the device.

ELECTROMAGNETIC COMPATIBILITY

The declaration of electromagnetic compatibility in accordance with EN ISO 60601-1-2 is available on request at the manufacturer's premises.

The CPM device model OrtoFlex L2 has been checked for compliance with the standard EN ISO 60601-1-2. Report of the accredited laboratory: No. CHTEM19040017. The CPM OrtoFlex L2 has been classified as a Group 1, Class B device in accordance with EN ISO 60601-1-2.

The CPM device model OrtoFlex L2 is intended for use in professional health facilities such as hospitals, clinics, rehabilitation centers as well as for patients for use at home.

The CPM OrtoFlex L2 is intended for use in the electromagnetic environment specified below. It is the responsibility of the user to ensure that the environment in which the device is used meets the following requirements.

Emission of interference voltage according to PN-EN 55011:2012	Range 30-1000 Mhz
Emission of interference voltage according to PN-EN 55011:2012	Range 0,15-30 Mhz
Immunity to electrostatic discharge according to PN-EN 61000-4-2:2011	
Immunity to radiated, radio-frequency, electromagnetic field according to eN 61000-4-3:2007+A1; 2008+A2:2011	Range 80-2700 Mhz
Immunity to electrical fast transient/burst according to PN-EN 61000-4-4:2013-05	
Immunity to surge according to PN-EN 61000-4-5:2014-10	
Immunity to conducted disturbances, induced by radio-frequency fields according to PN-EN 61000-4-6:2014-04	0,15-80 Mhz 3 V r. m. s.
Immunity to voltage dips, short interruptions and voltage variations according to PN-EN 61000-4-11:2007	

DANGER!

Avoid using this device in close proximity to other devices or placing it on top of or under other devices, as this may cause malfunction. If such setting of devices is necessary, it should be monitored whether both devices are working properly.

DANGER!

The use of accessories or cables other than those specified in this manual or supplied with the product may lead to an increase in electromagnetic radiation generated by the device or to a reduction in the electromagnetic immunity of the device, and consequently to its incorrect operation.

DANGER!

Portable devices using wireless communication (including external antennas or antenna cables) should be used at a distance of not less than 30 cm from any part of the CPM device OrtoFlex L2, including cables specified by the manufacturer. Otherwise, the performance of the device may be reduced.

List of accessories and cables

Description	Pieces
Two core cable, C17	1
Thigh rest	1
Shin support	1
Remote control	1

Legal status of the spare parts included in the scope of delivery

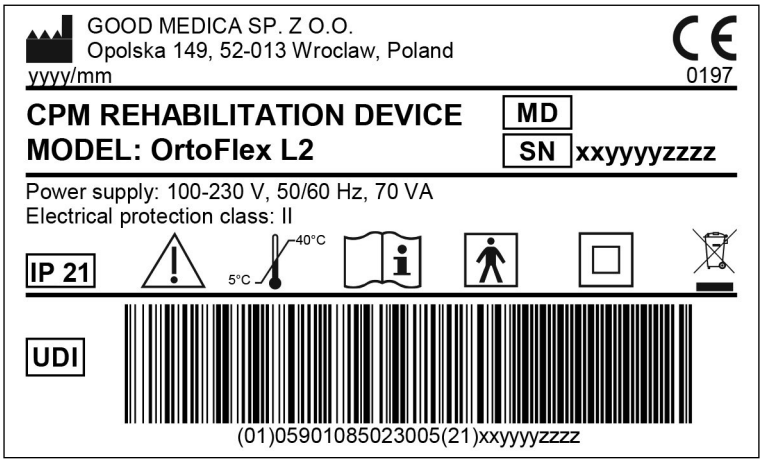
Element	Description	Pieces
Power cord	Part without which the device does not fulfill its functions	1
Thigh rest	Part without which the device does not fulfill its functions. Detachable for cleaning	1
Shin suport	Part without which the device does not fulfill its functions. Detachable for cleaning	1
Remote control	Detachable for transport	1

Zawartość opakowania

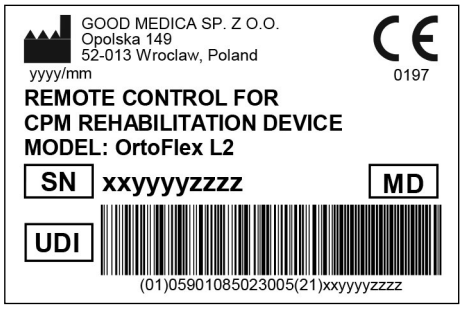
Description	Pieces
CPM device with a foot rest	1
Silicone thigh and shin rests	2
Remote control	1
Power cable	1
Manual in English	1
Technical Passport	1
Warranty	1

LABELS

Product label



Remote control label



SYMBOLS USED

Manufacturer

Follow local provisions regarding utilization of equipment, packages and additions

93/42/EEC

SN Serial number

Applied parts type BF

UDI Unique device identifier

IP21 Degree of protection provided by enclosures

Minimum and maximum temperature of storage areas

Follow/refer to the user manual

Equipment of class II

Warning, danger, threat

MD Medical device

DANGER!

Changes to this device are not permitted. The CPM device does not contain any components that can be serviced by the user. Do not disassemble, modify or repair any internal parts. Poorly maintained devices can endanger the user and the patient.

Each OrtoFlex L2 device shall be subjected to maintenance inspection at the Good Medica Sp. z o.o. service site once a year. The first inspection should be conducted one year after the date of activation, recorded in the warranty card.

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Good Medica Sp. z o.o.
Opolska 149
52-013 Wrocław, Poland

serwis@goodmedica.pl

NIP: 7010372451
REGON: 146578763
KRS: 0000453965