GOOD medica

CompressMed C1

Lymph drainage device

USER MANUAL

PLEASE READ THE USER MANUAL BEFORE USING THE DEVICE.

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Product name	Model	Manufacturer
Lymph drainage device	CompressMed C1	Good Medica Sp. z o.o. ul. Opolska 149 52-013 Wrocław, Poland

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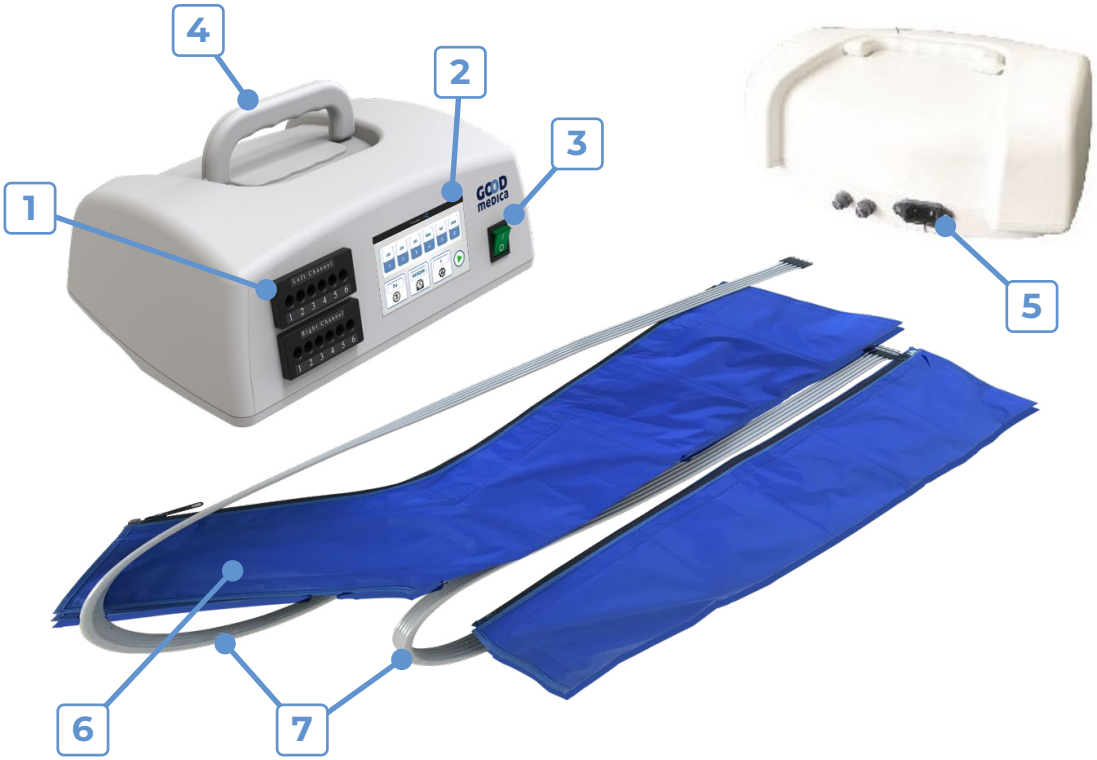
INTRODUCTION

Thank you for trusting us and choosing Good Medica Sp. z o.o. We guarantee that the CompressMed C1 lymph drainage device is a medical product of the highest quality, which meets European standards, confirmed by the CE mark.

In order to use the full capabilities of the equipment and minimise the risk to the patient, please read this User Manual. Failure to comply with the instructions contained in the Manual may result in damage to the device or threat to the health and life of patients and operating personnel.

DEVICE DESCRIPTION



1. pressure line supply ports
2. touch screen
3. on / off switch
4. handle
5. power socket
6. cuff
7. pressure line supplying air to the cuff

ABOUT THE DEVICE

The CompressMed C1 lymph drainage device consists of the main device, which includes: compressor, pressure sensors and solenoid valves, casing and control panel.

It is also equipped with pressure cuffs for upper and lower limbs. CompressMed C1 operation is based on the compressor generating pressure, which is supplied via solenoid valves to the pressure cuff. The pressure in the cuffs is successively supplied, distributed and managed throughout the cuff.

The CompressMed C1 lymph drainage device has 4 device operation programs. In each of them, the pressure can be set for each of the six pairs of channels (20 to 200 mmHg). An additional feature is the option to set a pause of 3 s to 15 s between pumping the next chamber. The treatment time can be set in the range of 1 min. to 120 min., adjustable every 1 min.

The product can be used by professionals in the environment such as a hospital, clinic, doctor's or physiotherapy office as well as by patients at home.

DEVICE PARAMETERS

Information

Operating conditions	Ambient temperature: 5°C - 40°C
	Air humidity: ≤ 80%
	Atmospheric pressure: 700hPa – 1060hPa
Power supply	110-240 VAC
	60 VA
	50/60 Hz
Fuse	2x T1AL 250V 5x20mm
Work sound volume	≤ 55 dB
Range of generated pressure	0 - 200 mmHg
Work time range	0 - 120 min
Performance	Maximum gas outlet pressure 200 mmHg ± 15 mmHg
Number of attached cuffs at the same time	2 cuffs
Weight	6 kg
Dimensions	Height 14,5 cm
	Width 36 cm
	Depth 26 cm
Storage conditions	Temperature: -25°C - 70°C
	Air humidity: ≤ 83%
	Atmospheric pressures: 700hPa - 1060hPa
Kit accessories	Main device
	Power cable 1 pc.
	Pressure port plug 1 pc.
	User Manual

PROPERTIES

Treatments using the CompressMed C1 lymph drainage device have a positive effect on the patient's body by:

- Stimulation of the circulatory and lymphatic system, causing oxygenation of organs and nourishment with nutrients.
- Acceleration of swelling absorption and removal of congestive symptoms.
- Help with venous blood outflow.
- Improvement of heart function by reducing arterial blood resistance.
- Increasing the blood circulation speed by dilating blood vessels.

INDICATIONS FOR USE

- Rehabilitation after contusions and injuries.
- Prevention of thromboembolic disease.
- Swelling of upper and lower limbs after mastectomy and swelling of other origin.
- Slimming and anti-cellulite massages.
- Prevention of venous insufficiency.
- Treatment of lymphatic insufficiency.

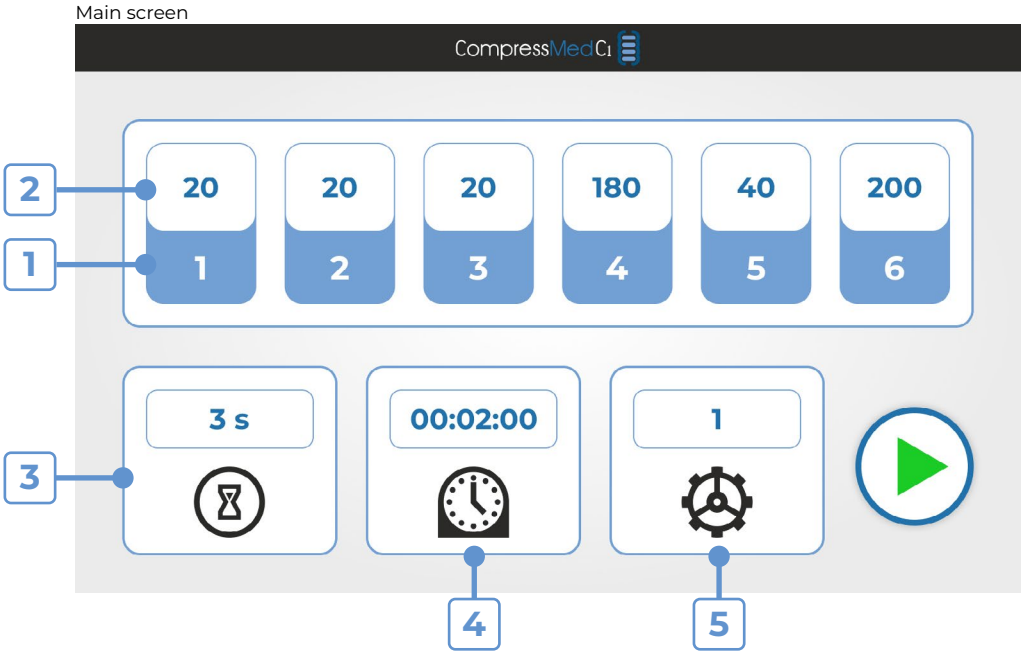
CONTRAINDICATIONS

- Pain and discomfort in the patient - treatment intolerance.
- In the case of cancer, it is necessary to consult a doctor.
- Inflammation of lymph nodes.
- Skin infection.
- Arterial circulation disorders.
- Newly formed venous thrombosis.
- Acute inflammation.
- Skin ulcers.
- Advanced varicose veins.

1) Place the device on a stable surface.
2) Connect the power cord to the power socket, connect the mains plug to a 230V mains socket.
3) Put on the cuff:
   - Choose the cuff dedicated to a given part of the body.
   - Connect the cuff pressure line to the device; pay attention to the correct numerical designation (numbers 1, 2, 3, 4, 5, 6 must match).
   - Wear a wristband or tight elastic clothing on a given part of the body.
   - Put on the cuff and close it with the zipper.
4) Turn on the device with the main switch on the front of the casing.

DESCRIPTION OF FUNCTION ICONS

Main screen



1. Numbers of individual chambers
2. Pressure set in any chamber
3. Set the pause between pumping consecutive chambers
4. Work time setting
5. Work program setting

TIP

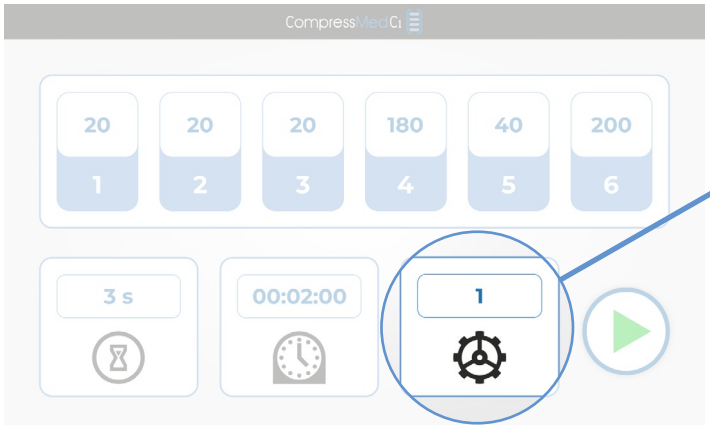
The device stores the previous parameter settings after switching off.

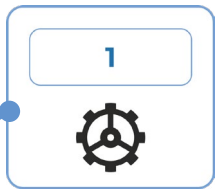
Start is used for starting the device.

Stop is used for stopping the device.

Return is used for confirming the settings and returning to the ***Main screen***.

SET THE WORK PROGRAM

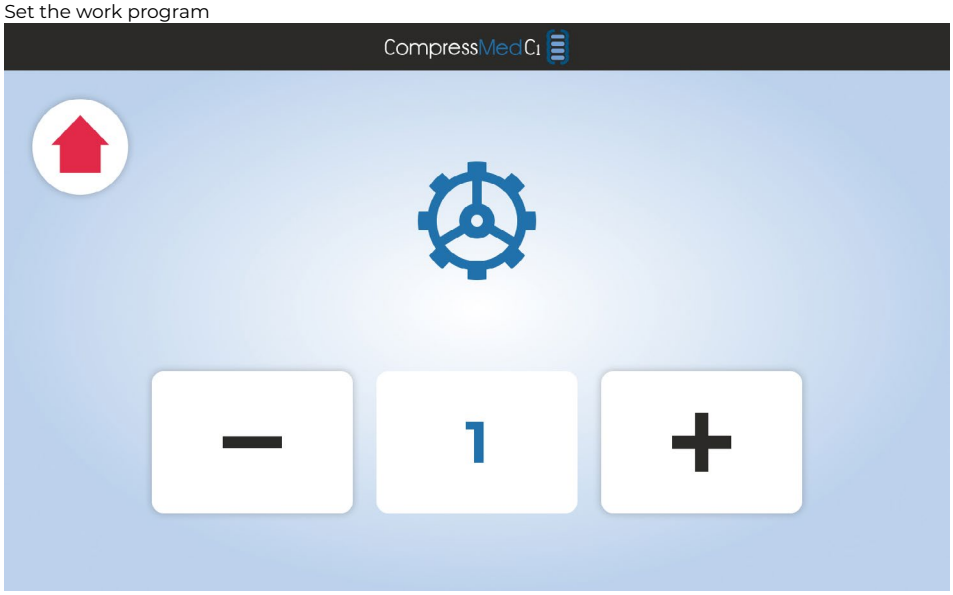




After pressing the ***Set the work program*** icon, you can select the program.

The device has 3 operation programs.

Set the work program



Press the **+** button to change the program to the next one

Use the **–** button to change the program to the previous one

After selecting the desired program, return to the ***Main screen*** with the ***Return*** button

Opis programów

Program	Description	Sequence	Recommendation
1	(sequence) Bottom-up pushing algorithm variant 1	1+, 2+, 3+, 4+, 5+, 6+, [1–, 2–, 3–, 4–, 5–, 6–]	· Lymphatic insufficiency of lower limbs · Acceleration of swelling absorption and removal of congestive symptoms.
2	Lymphatic Drainage	1+, 2+, [3+, 1–], [4+, 2–], [5+, 3–], [6+, 4–], [1+, 5–], [2+, 6–]	· Acceleration of swelling absorption and removal of congestive symptoms. · Help with venous blood outflow. · Prevention of venous insufficiency.
3	Bottom-up pushing algorithm variant 2	Sequence as in 1st program, with each subsequent channel being pumped to a pressure of 5 mmHg lower than set in the first channel.	· Lymphatic insufficiency of lower limbs.
4	Lymphatic drainage according to E. Vodder	Sequence as in 2nd program, with each subsequent channel being pumped to a pressure of 5 mmHg lower than set in the first channel.	· Help with venous blood outflow.

ATTENTION!

- **The data given above should be treated as examples.**
- **The pressures are not specified intentionally as they should be selected individually for each patient.**
- **The CompresMed C1 lymph drainage device can be used for other conditions not listed above.**
- Do not use pressure that causes pain and discomfort to the patient.
- The pressure set in the cuffs must not be higher than the patient's diastolic pressure.
- Switching off the device with the main switch located on the front part of the casing does not release the pressure from the cuffs!

TIP

Numbers 1, 2, 3, 4, 5, 6 indicate the consecutive chambers in the cuffs.

If two cuffs are used simultaneously, numbers from 1 to 6 indicate a pair of chambers in two cuffs.

When using one cuff, close the empty supply port with the plug included in the set.

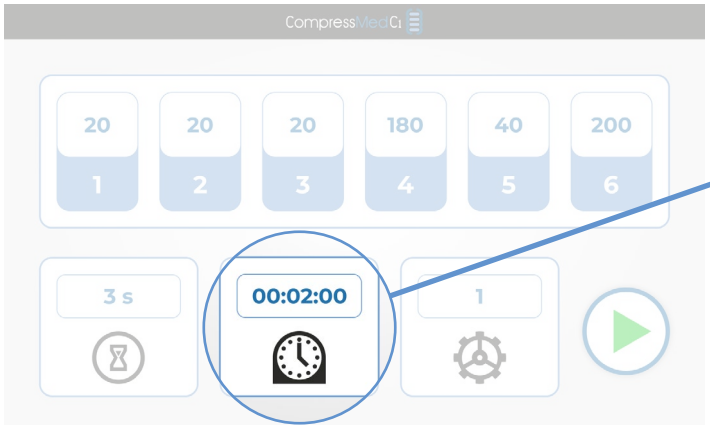
The "+" sign indicates an increase in the cuff pressure.

The "-" sign indicates a drop in the cuff pressure.

The "[ ]" means a simultaneous pressure change in the channels with numbers in parentheses

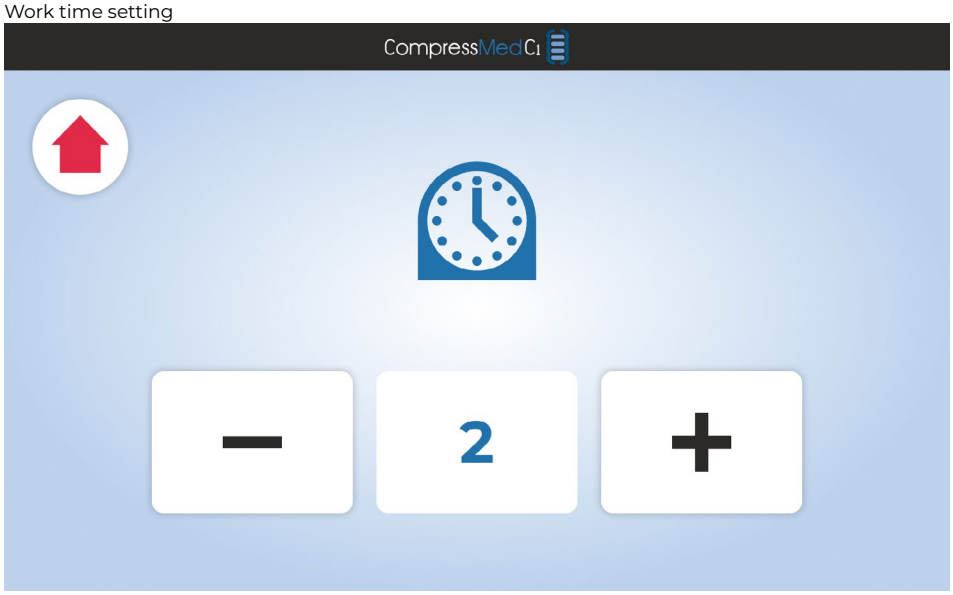
The sequence will be repeated until the preset treatment time has elapsed. After the end of the working time, the device will release the pressure in the cuff(s).

WORK TIME SETTING



Press the ***Work time setting*** to set the treatment time in the range of 1 to 120 minutes.

Work time setting

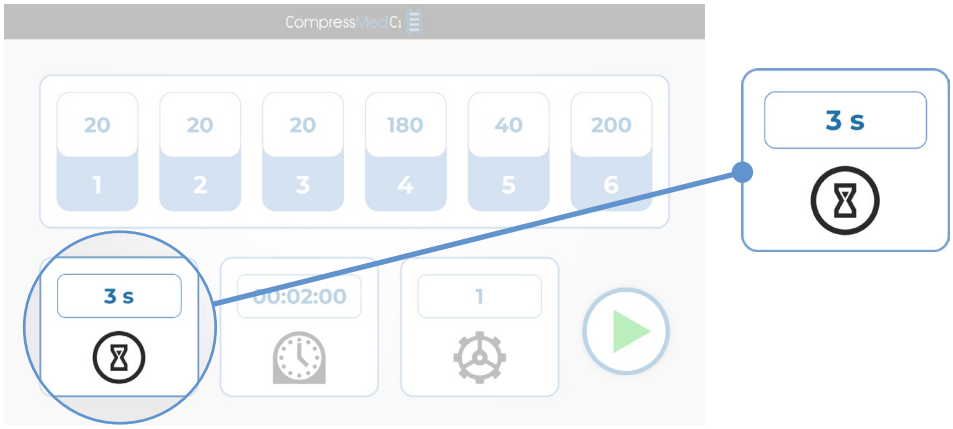


Press the **+** button to increase the work time.

Press the **–** button to reduce the work time.

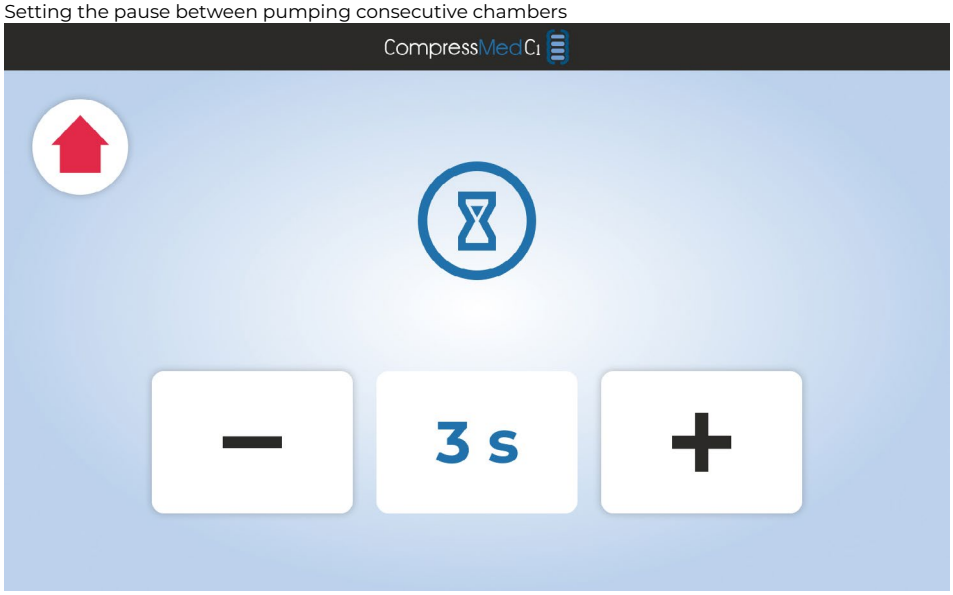
After selecting the desired work time, return to the ***Main screen*** with the ***Return*** button.

SETTING THE PAUSE BETWEEN PUMPING CONSECUTIVE CHAMBERS



After pressing the ***Set the pause between pumping consecutive chambers*** icon, set the pause time in the range of 3 to 15 seconds.

Setting the pause between pumping consecutive chambers

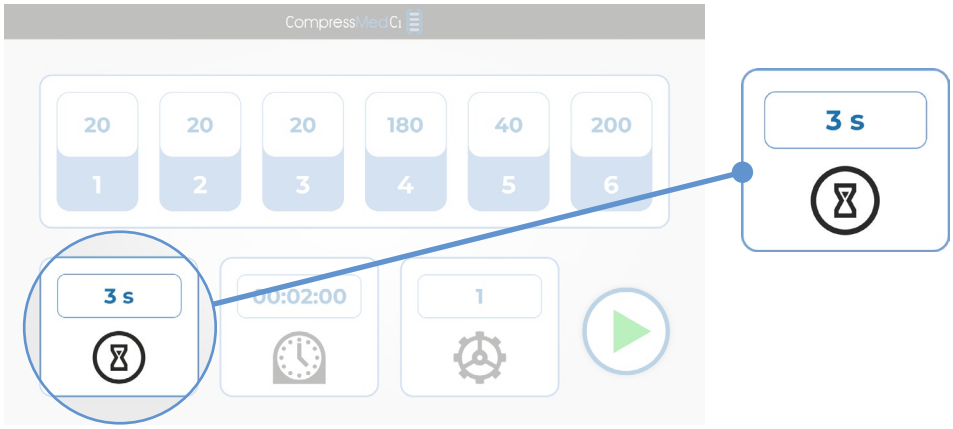


Press the **+** button to increase the pause time.

Press the **–** button to reduce the pause time.

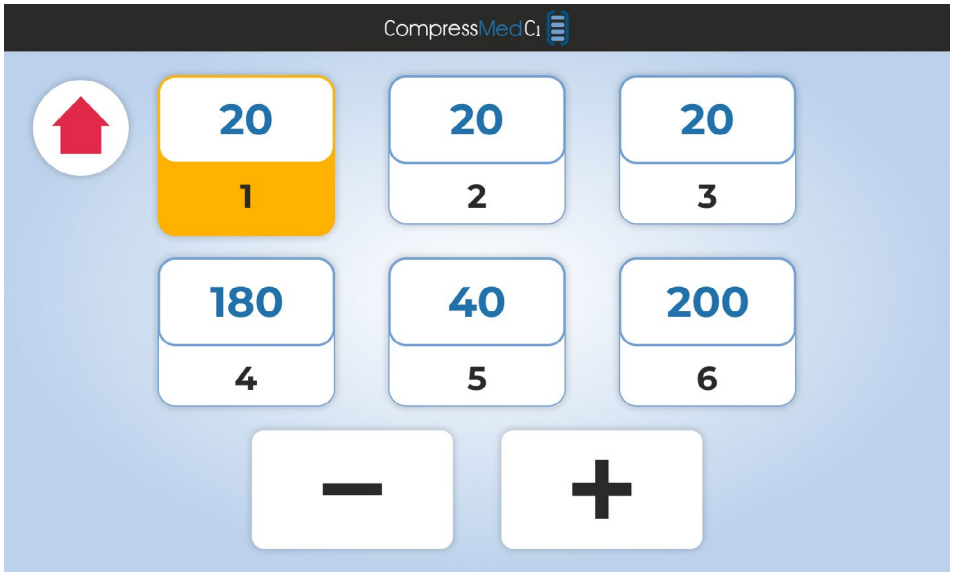
After selecting the desired pause time, return to the ***Main screen*** with the ***Return*** button.

PRESSURE SET IN CHAMBER



After pressing the ***Pressure set in chamber*** icon, set the pressure in the range of 0-200 mmHg

Pressure set in chamber



Press the **+** button to increase the pressure in the chamber.

Press the **–** button to reduce the pressure in the chamber.

After selecting the desired pressure, return to the ***Main screen*** with the ***Return*** button.

TIP

Mark one, multiple or all chambers in yellow.

The initiation of treatment with the CompressMed C1 lymphatic drainage device should be in accordance with medical indications and after prior medical consultation.

The device should be operated by trained personnel. Treatments using the CompressMed C1 lymph drainage device must not cause pain or irritation: The CompressMed C1 parameters should be set according to the recommendations of the doctor or physiotherapist.

During the treatment, the patient must be conscious and aware, and should know how to immediately discontinue the treatment in case of pain.

TIP

Indicates a direct hazard. Failure to comply may lead to death.	**HAZARD!**
Indicates a threat. Failure to comply may lead to severe injuries, including fatal ones.	**WARNING!**
Indicates a possible hazardous situation that may lead to minor injuries and/or damage to the device.	**ATTENTION!**

HAZARD!

Explosion hazard - CompressMed C1 must not be used in medical rooms where there is a risk of explosion. Explosion hazard may occur after contact with flammable anaesthetics or e.g. skin disinfectants.

WARNING!

Do not use CompressMed C1 for any purpose other than compression therapy. The device may only be operated by a person who has read the User Manual.

ATTENTION!

Checking the technical condition

Before each use, always check the condition of the device in terms of safe use, in particular the lines and power connector for possible damage. If any damage is found, contact the service centre. Before starting the treatment, perform a test run with the cuff attached to the device, but without putting it on the body.

ATTENTION!

Avoiding risks to the patient

- When using the device, the patient must be fully aware.
- The decision to use the device is made by a doctor or physiotherapist.
- The selection of therapy parameters must be determined by a doctor or therapist.
- Any patient undergoing the treatment using CompressMed C1 must be able to stop the device operation. The control screen must be within easy reach.
- Do not use CompressMed C1 in a room without ventilation or sufficient light source.

ATTENTION!

Environmental hazard

Children and animals should not be allowed to play near the CompressMed C1 lymph drainage device.

ATTENTION!

Electric shock hazard

To avoid the risk of electric shock, be sure to always follow the warnings below. Failure to comply may lead to a threat to the life and health of the patient and/or the person operating the CompressMed C1 device

If it is necessary to transport the device at negative temperatures, heat it to a room temperature before switching on the device. Leave the device off for approx. 2 hours until any condensation has dried.

CompressMed C1 can only be used in dry rooms at room temperature.

When disconnecting the device from the mains, first turn off the power supply with the on/off button, pull out the mains plug and finally remove the plug from the device.

CompressMed C1 can only be connected to a correctly installed socket.

Before cleaning, disinfection or maintenance, remove the plug from the power socket.

Be careful that CompressMed C1 and the power cord do not get wet. If the said elements become wet, contact the service centre. Restarting will be possible once the device is checked at the service centre.

Do not leave the device connected to the mains unattended. When the device is not in use, disconnect it from the power source.

Be careful not to pull on the cord when disconnecting the device.

If you notice mechanical damage or unpredictable operation of the device (e.g. loud operation), immediately disconnect it from the power source and contact the service centre.

SAFETY DURING USE

ATTENTION!

Disturbances in device operation

The device operation may be affected by magnetic and electrical fields.

When using CompressMed C1, make sure that all other devices operating nearby meet the requirements of electromagnetic tolerance.

A device that is a source of electromagnetic radiation, such as X-ray machines, MRI devices, radio transmitters and mobile phones, may cause disturbances in device operation.

Keep a distance from this type of device and check its operation before using the CompressMed C1 device.

Do not use CompressMed C1 near a source of fire.

Check the device at least once a year for possible damage.

Repairs and inspections should be carried out at the manufacturer's service centre.

PREVENTION OF ALLERGIES AND INJURIES

ATTENTION!

The patient should wear an outfit that does not restrict movement but protects the skin at the place of contact with the cuff, e.g. leggings, socks and tight elastic long-sleeve T-shirt.

Injuries

See the "Contraindications" section

Damage to the device

Make sure that the power grid parameters are compatible with the voltage and frequency on the device nameplate.

Do not expose the device to sunlight, excessively low and high temperatures.

Special precautions must be taken when moving the CompresMed C1 device.

If the device is damaged, stop using it and contact the manufacturer for repair.

ATTENTION!

When transporting the device over long distances, it must be carefully secured, packed in a cardboard box lined with protective foam.

Transport and storage conditions:

- Storage temperature: -25°C - 70°C
- Air humidity: ≤ 83%
- Atmospheric pressure: 700hPa - 1060hPa

The device should be stored in optimal humidity to prevent corrosion.

Before using CompresMed C1 after long-term storage or transport, test whether the device functions work properly.

WARNING!

Before using CompresMed C1 after long-term storage or transport, test whether the device functions work properly.t

The device should be cleaned with non-alcoholic wipes with disinfectant and washing properties, e.g. ready-to-use non-alcoholic wipes Sani-Cloth Active from Ecolab Sp. z o.o. have bactericidal, yeasticidal and mycobactericidal effect.

First, turn off the power supply with the switch off/on button, disconnect the power cord from the socket (7). Then, carefully wipe the section with the control panel - LCD screen. Wipe the cuff thoroughly with a new wipe from the inside and then from the outside. If necessary, use more wipes.

The fabric cuffs should be cleaned and disinfected after each patient.

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

CompressMed C1 is a ready-to-use product. No part of the device (except cuffs) is replaceable. Do not repair and interfere with the device structure on your own.

ATTENTION!

Damage to the device

In order to prevent damage, do not use disinfectants other than the above-mentioned ones, in particular: gasoline and solvents.

Do not clean electrical contacts.

To avoid discolouration on the device, use only colourless disinfectants.

WARNING!

If CompresMed C1 does not start, check the following:

Power cable

- Disconnect the device from the power supply.
- Check the power cable for mechanical damage.
- If the cable is not damaged, connect the rail to another mains socket. Check if the device starts after connecting it to a different mains socket.
- If the cable is damaged – contact the service centre.

If the touch screen does not work properly

- Turn the device off and then on again.
- If the screen still does not work properly, contact the service centre.

Contact the service centre in case of:

- Device getting wet
- Mechanical damage, i.e. fall from a height, impact etc.
- Incorrect values displayed on the LCD.
- Leaks in the pressure line or the cuff.
- Doubts as to the device operation.

ELECTROMAGNETIC COMPATIBILITY

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

The CompressMed C1 lymphatic drainage device has been tested for compliance with EN ISO 60601-1-2. Accredited laboratory report No.: CHTEM19060009, CompressMed C1 lymphatic drainage device has been classified according to EN ISO 60601-1-2 as Group 1, Class B.

The CompressMed C1 lymphatic drainage device is intended for use in professional health care facilities such as hospitals, clinics, physiotherapy offices as well as by patients in their home environment.

The CompressMed C1 lymphatic drainage device is intended for use in the electromagnetic environment specified below. The user is responsible for ensuring 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
Odporność na szybkie stany przejściowe (BURST) zgodnie z 0,5 kV, 1 kV, 2 kV 100 Hz	
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	0,15-80 Mhz 3 V r. m. s.
Immunity to conducted disturbances, induced by radio-frequency fields according to PN-EN 61000-4-6:2014-04	

ATTENTION!

Avoid using this device in the immediate vicinity of other device or placing the device on or under another device, as this may result in its improper operation. If such arrangement is necessary, observe both devices whether they are working properly

ATTENTION!

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 decrease in the electromagnetic resistance of the device, and as a result to its improper operation.

ATTENTION!

Portable devices using wireless communication (including external antennas or antenna cables) should be used at a distance of not less than 30 cm from each part of the CompressMed C1 lymph drainage device, including cables specified by the manufacturer. Otherwise, the performance of the device may be reduced.

NOTES

Electromagnetic compatibility

The device is designed in such a way as to ensure resistance to the impact of external electromagnetic factors. However, during operation, the device generates electromagnetic waves that may affect the operation of other devices.

Environmental care

The product can be fully recycled (electronic, metal and plastic components).

ACCESSORIES

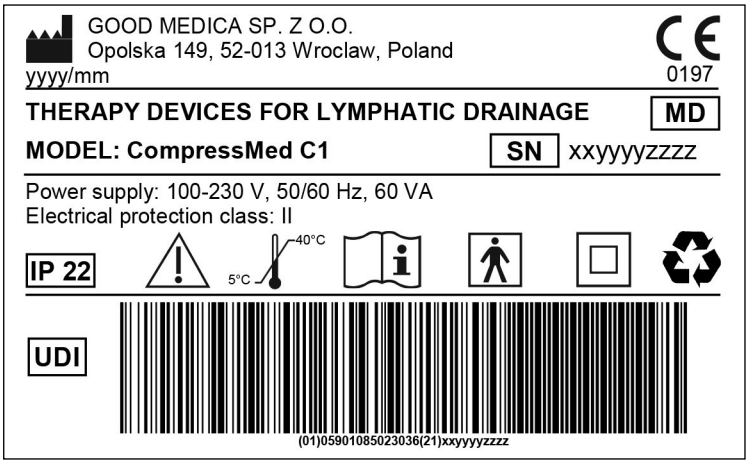
List of accessories and cables

Description	Pieces
Power cord - 2.5 m – 2-wire C17 plug	1
Pressure port plug	1

Legal status of spare parts included in the set:

Element	Description	Pieces
Upper limb cuffs	Parts without which the device does not perform its functions. Detachable to adapt the device to a given treatment.	1
Lower limb cuff	Parts without which the device does not perform its functions. Detachable to adapt the device to a given treatment. The cuffs are a class I medical device.	1
2.5 m power cord	Parts without which the device does not perform its functions.	1

LABEL



SYMBOL DESCRIPTION

Manufacturer	Degree of protection provided by enclosures
Follow local provisions regarding utilization of equipment, packages and additions	Minimum and maximum temperature of storage areas
93/42/EEC	Follow/refer to the user manual
Serial number	Equipment of class II
Applied parts type BF	Warning, danger, threat
Unique device identifier	Medical device

SERVICE

ATTENTION!

It is prohibited to modify this device.

The CompressMed C1 lymph drainage device does not contain internal service parts for the user. Do not remove, modify or repair internal components. Incorrectly or poorly maintained equipment can pose a threat to the user and the patient.

Each CompressMed C1 device should undergo an inspection at Good Medica Sp. z o.o. once a year. In the event of faults, please contact the service centre.

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