Instructions for Use

lympha-mat®
300N GRADIENT 12

12-step system for gradient intermittent compression therapy

passion for compression

www.lymphamat.de

BÖSL

Contents

Manufacturer

Bösl Medizintechnik GmbH,
Charlottenburger Allee 13, 52068 Aachen, GERMANY
Phone: +49(0)241/900 77-0, Fax: +49(0)241/900 77-10
Email: info@boesl-med.de
Contact the manufacturer in the event of any questions or any inconsistencies with the system or the sleeves.

General safety instructions

Please read the instructions for use before putting the system into service and observe the list of indications and contraindications. In the event of any uncertainties, ask your doctor or specialist dealer before starting the treatment.
The system complies with the applicable safety regulations including the EN 60601-1:2006/A1:2013, VDE0750:2013-12.

Basic safety warnings

Electrical equipment can be dangerous if used improperly.
The housing of the equipment may only be opened by authorised qualified personnel. Repairs may only be carried out by authorised specialist dealers or the manufacturer. Under no circumstances should unauthorised persons open the product. For safety equipment reasons, neither the device nor the sleeves may be modified or changed by the user. Failure to observe these warnings will result in the guarantee becoming void. Please refer to our customer service in the event of any malfunction in the device. The device must not be used in the presence of flammable gases such as anaesthetics. The sleeves are bio-compatible but should only be used on healthy skin. Talk with your doctor before using in the case of all types of open wounds. Open wounds should be covered completely during use. If problems still arise however, contact your doctor immediately.
Any product with cables, tubes etc. poses a potential strangulation hazard source. Tubes and cables within the patient's reach should always be kept and used out of the reach of small children and with appropriate caution.
Only use the sleeves on the extremities to be treated (arm, leg, hip, torso). Never pull the sleeves over the head.

Safety Precautions

For your own safety and to protect the device, the following precautionary measures must be taken:

- Check regularly when using the product that the device is functioning correctly and that the sleeves are attached correctly.
- Keep the equipment away from pets and small children.
- Keep the equipment away from liquids and protect it from moisture. Do not expose the equipment or the sleeves to excessive amounts of dirt, dust, moisture nor to any open flames, cigarette ash etc. nor to any radiation (e.g. sunlight).
- The product consists of precision and electronic components. Protect the product and accessories from shocks, dirt and sources of electromagnetic interference. Do not drop the equipment.
- Before cleaning or inspecting the appliance, switch off the mains switch and disconnect the mains plug from the mains socket to disconnect it completely from themains.
- Only use alcohol-based cleaning agents to clean the device.
- Never clean the device when it is damp, but dry.
- Make sure that the equipment is clean and dry before storing it.
- Never examine the equipment using sharp objects.
- Only use the sleeve combinations and matching extension inserts specified by BÖSL Medizintechnik (see also list of accessories on page 21). Proper functioning of the device can only be guaranteed if the correct devices and sleeve combinations are used.
- Use of this device immediately adjacent to other devices or stacked with other devices should be avoided as this could result in incorrect operation. If such use is necessary, this device and the other devices should be observed to ensure their proper functioning."
- The use of accessories other than those provided may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may lead to incorrect operation.

Intended purpose and proper use

The device is used for the therapy of venous and lymphatic congestion complaints and is to be used according to a medical diagnosis. The patient is intended to be the operator. The product's operational safety is only guaranteed if it is used properly by an informed user or patient. The product has no essential performance. Intended purposes include cases where:

- the product is used in home therapy or in the doctor's office for the treatment of venous or lymphatic stasis complaints.
  (See indications on page 14)
- the choice of treatment time and average treatment pressure have been agreed with a doctor,
- Children and people in need of help can be treated with the lympha-mat® 300N under expert guidance and supervision.

Reporting of incidents

If serious incidents (death, serious deterioration of health) occur in connection with the product described in these instructions for use, they must be reported by the user to the manufacturer and the competent authority.
In Germany, the competent authority is:
Federal Institute for Drugs and Medical Devices (BfArM)
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Phone: +49 (0)228 99 307-0
www.bfarm.de For information on the competent authority outside Germany, ask the authority in your respective country.

Maintenance

Neither the device nor the sleeves require servicing. Neither the patient nor any other operator is to carry out any maintenance work themselves.

Cleaning

Maintenance and cleaning should be carried out using a dry cloth (please do not have the equipment chemically dry-cleaned). Alcohol-based cleaning agents may be used.

Disinfection

The treatment sleeves must be disinfected after use or before being used on a new patient. For this purpose, the wipe disinfection recommended by the Robert Koch Institute is used (see "List of disinfectants and disinfection methods tested and approved by the Robert Koch Institute").
You can find further information and instructions on our "Instructions for Cleaning and Disinfection" information sheet.

Guarantee

The manufacturer grants a two-year guarantee for the device and its accessories, provided defects can be attributed to material and/or manufacturing defects. The manufacturer considers itself responsible for the impact on the safety, reliability and performance of the device only if: expansions, readjustments, changes or repairs are carried out by persons authorised by the same and the electrical installation of the room in which the device is used meets the VDE requirements and the device is used in conformity with the instructions for use. In the event of a malfunctioning of the device, please refer to the supplying company immediately. With proper use, the typical average service life of the devices and accessories is 10 years.

ElektroG: Electrical and Electronic Equipment Act

Correct disposal of old appliances (electrical waste)
(In countries of the European Union and other European countries with a separate collection system)
The marking on the product, accessories or associated documentation indicates that the product and accessories must not be disposed of with other household waste at the end of their working life. Please dispose of this device and its accessory parts separately from other miscellaneous waste, to prevent damage to the environment or to human health from unregulated waste disposal. Potentially contaminated sleeves should be disposed of in the normal household waste with an appropriate notice and after consultation with the manufacturer. Help to dispose of used appliances and accessory parts properly in order to promote the sustainable recycling of material resources.
Private users should refer to the dealer from which the product was purchased or contact the relevant authorities to find out where they can deliver the used appliance or accessory parts for environmentally friendly disposal. Industry users should refer to their suppliers and proceed in accordance with the conditions of the purchase agreement. This product and electronic accessory parts may not be disposed of together with other industrial waste.

The product is disposed of as electrical waste and must not be placed in normal household waste.
Take the product to the collection points of the public waste management authorities or send the product for disposal:
Central Disposal Point GDW-Sindelfingen
Waldenbucher Str. 30, 71065 Sindelfingen, GERMANY

Key to symbols

Note

CAUTION!
This symbol indicates dangers that may lead to health hazards, injuries, permanent physical injury or to death.
It is imperative that you strictly adhere to the specified instructions for work safety and act with particular caution in these
cases.

Manufacturer

2020 Year of manufacture

Observe the instructions for use.
The instructions for use must have been fully read and understood to ensure the safe operation of the appliance, because incorrect usage may pose an unacceptable risk.

LOT Lot number

SN Serial number

IP 32 Protected against solid foreign bodies with diameter ≥ 12.5 mm and protection against dripping water

CE 0197 CE marking with identification number of the notified body

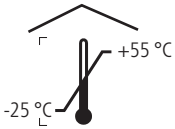
~ Alternating current

Disposal

Protect from moisture

Protection class II

Equipment classification Type BF



Ambient temperature for transport and storage. Transport and storage outside the specified temperature ranges can damage the device and thus endanger the patient, user or third parties.

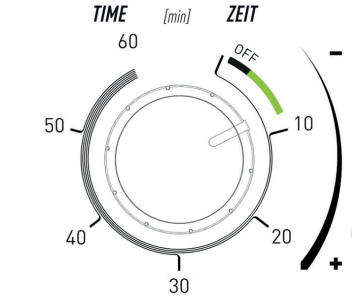
Ambient temperature for use, operation outside the specified temperature ranges may cause damage to the device and thus endanger the patient, user or third parties.

Key to symbols

PRESSURE / DRUCK

Pressure setting on the rotary knob and pressure display 20 - 100 mmHg

POWER ON / AN



On/off switch and setting of the treatment time between 10 - 60 min

Technical data

The **lympha-mat® 300N** is intended for use in a domestic environment directly connected to a public supply network.

Use of the device abroad: For proper operation of the device and its connection to the power supply network, please use a country-specific mains plug adapter (not included in the scope of delivery) that corresponds to the specifications of the device.

Pressure settings without intervals
20 – 100 mmHg
(accuracy approx. 15%)

Interval/pulse set fixed at
15 seconds

Rated voltage
lympha-mat 300N Gradient
(Article No. 1211)
rated voltage ~230V

lympha-mat 300N Gradient 110V
(Article No. 1212)
Rated voltage ~110V

Rated frequency	50/60 Hz
Rated current	0,45 A

With a daily usage time of 1 hour, this results in a total consumption of approx. 20 kWh per year at the highest possible pressure level.

Dimensions: W - 34 cm, H - 14 cm, D - 36 cm

Weight: 5 kg

Device classification:

Application part type BF - Treatment sleeves 

Protection class:

Protection class II 

Ambient conditions for transportation and storage:
The environmental conditions for transport and storage are -25 °C to +55 °C at Humidity: 15% - 93% RH.

Ambient conditions for usage:
The ambient conditions for use are +5 °C to +40 °C,
Humidity: 15 % to 93 % RH
Air pressure: 700 to 1070 hPa

Electromagnetic compatibility (EMC)

lympha-mat® 300N fulfils the EMC requirements for medical devices according to EN 60601-1-2. The requirements with regard to circuit feedback for electrical medical appliances according to EN 61000-3-2 and EN 61000-3-3 are also met.

If electromagnetic interference influences the performance of the lympha-mat® 300N, the success of the therapy may be reduced.

The lympha-mat® 300N device is intended for operation in an electromagnetic environment as specified below. The customer or the user of the lympha-mat® 300N should ensure that the device is operated in such an environment.

Guidelines and manufacturing formula - electromagnetic interference emissions

Interference emission measurements	**Compliance**
HF emissions as per CISPR 11	Group 1
HF emissions as per CISPR 11	Class B
Harmonic emissions as per IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions as per IEC 61000-3-3	complies

The lympha-mat® 300N is intended for use in a domestic environment directly connected to a public supply network.

Electromagnetic immunity tests		**Compliance level**
Electrostatic discharge (ESD) as per IEC 61000-4-2	+/- 8 kV Contact discharge +/- 15 kV Air discharge	+/- 8 kV Contact discharge +/- 15 kV Air discharge
Electrical fast transient disturbances / bursts as per IEC 61000-4-4	+/- 2 kV at 100 kHz for power cables	+/- 2 kV at 100 kHz for power cables
Surge voltages as per IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV voltage outer conductor-outer conductor +/- 0.5 kV, +/- 1 kV, +/- 2 kV voltage outer conductor-earth	+/- 0.5 kV, +/- 1 kV voltage outer conductor-outer conductor +/- 0.5 kV, +/- 1 kV, +/- 2 kV voltage outer conductor-earth
Voltage dips, short-time interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	Voltage dips: 0% U_T. 1/2 period at 0 to 315 degrees 0% U_T. 1 period and 70% U_T; 25/30 periods single phase voltage dips: 0%$_{UT}$; 250/300 periods	Voltage dips: 0% U_T. 1/2 period at 0 to 315 degrees 0% U_T. 1 period and 70% U_T; 25/30 periods single phase voltage dips: 0%$_{UT}$; 250/300 periods
Magnetic field at supply frequency (50/60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m

Electromagnetic immunity tests	**IEC 60601 test level**	**Compliance level**
Conducted HF disturbances as per IEC 61000-4-6	3 V at 0.15 MHz to 80 MHz, 6 V in ISM and amateur radio bands between 0.15 MHz to 80 MHz, 80% AM at 1 KHz	6 $V_{effective\ value}$ over the entire frequency range
Radiated HF disturbances as per IEC 61000-4-3	10 V/m; 80 MHz to 2.7 GHz; 80% (compliance level also 10V)	10 V/m; 80 MHz to 2.7 GHz; 80% (compliance level also 10V)

Above the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m

The tested RF frequencies correspond to the following radio frequencies:

Test frequency	Frequency band (MHz)	Service	Interference immunity testing level (V/m)
385	380 to 390	TETRA 400	27
450	430 to 470	GMRS 460, FRS 460	28
710	704 to 787	LTE Band 13, 17	9
745			
780			
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,LTE Band 5	28
870			
930			
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
1845			
1970			
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	28
5240	5100 to 5800	WLAN 802.11 a/n	9
5500			
5785			

The customer or user of the lympha-mat® 300N can help prevent electromagnetic interference to minimise damage. Portable high-frequency communication devices including their accessories should therefore not be used at a distance of less than 30 cm from the parts and lines of the lympha-mat® 300N. Non-observance of this may result in a decrease of performance.

Troubleshooting

Fault
No function:
Is the device connected to the mains voltage?
-> Plug in mains cable

Is the device switched on?
-> Switch on device

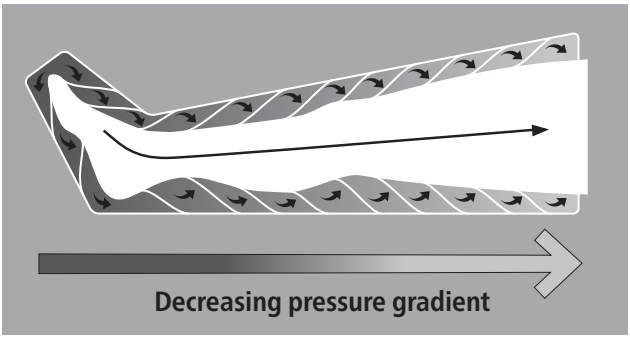
Fault
Sleeves are not filled or vented:
Are all tubes connected to the device?
-> Connect tubes

Are all connections not in use sealed with a dummy plug?
-> Insert dummy plug

Pressure display fluctuates:
No interference. Unit always shows the current pressure in the sleeve

Mode of action of the lympha-mat® 300N

The **lympha-mat ® 300N** gradient system is used for the therapy of venous and lymphatic congestion problems. The characteristic function of the lympha-mat 300N is intermittent pressure build-up. The sleeves apply intermittent gradient pressure to the extremities (arm, leg, hip, torso). The 12/24 chambers of the sleeves fill with air one after the other, starting at the foot or hand. As a result, the pressure built up in the process then drops through varying pressure ranges from the first to the last chamber. This gradient treatment pressure generates a physiologically effective pressure gradient. whereby the fluid mobilised by the pressure built up in the overlapping chambers can disperse unhindered and without return flow.



The air chambers remain filled with air until the topmost chamber has reached the relevant pressure. Then the pressure escapes from all the air chambers simultaneously and starts the pumping up cycle again after a break period. The intermittent compression acts on the individual tissue layers and the blood and lymphatic vessels in these.
The tissue is decongested, the venous and lymphatic reflux is promoted sustainably, and the metabolism and the gas exchange is improved.

Treatment recommendations

The patient should be lying comfortably and relaxed during the treatment. The legs or arms subject to treatment can be elevated slightly to support the treatment. At the start of the treatment, a low sleeve pressure should be selected and this can be increased if so required. The pressure should never be set at a level that causes the patient to feel discomfort or pain. The treatment should be relaxing and pleasant.

Indications

- Thromboembolism prophylaxis
- Post-thrombotic syndrome
- Leg ulcers
- Venous oedema
- Post-traumatic oedema
- Lymphoedema
- Lipoedema
- Mixed forms of oedema
- Peripheral arterial occlusive diseases (with strict monitoring)
- Sensory disorders in cases of hemiplegia

Contraindications

- Decompensated heart failure
- Extensive thrombophlebitis, thrombosis or suspected thrombosis
- Erysipelas
- Severe, uncontrolled hypertension
- Acute soft tissue trauma of the extremities
- Neuropathy
- Occlusive processes in the sector of lymphatic drainage
- compartment syndrome
- Acute phlegmon

Side effects

Although the sleeves have been tested as being bio-compatible in accordance with sections -1, -5 and -10 of DIN EN ISO 10993, in very rare cases

- Skin irritations
- Allergic reactions

may occur. In these cases, please contact your doctor. In case of doubt, only use the sleeves over covered skin.

The operating noises of the system may be perceived as a slight level of noise pollution.

After the application, marks may appear on the skin that will however disappear again without any further intervention.

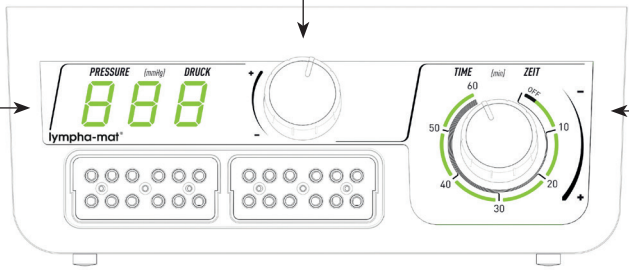
Technical information for set-up

- The product is ready for operation as soon as it is removed from the packaging
- Check the device visually for any external damage
- Do not set up the device if there is any visible damage
- Place the product on a level and solid surface, e.g. table
- Insert the mains cable into the mains connector (**B2**) and connect to the socket (voltage supply)
- Connect the product to a voltage supply in line with the specifications
- Position the device so that the mains cable can be unplugged by the patient or operator in an emergency during treatment
- Do not cover the ventilation slots (B1) on the device with cloths, blankets or similar. Do not stack devices. Do not use the appliance as a storage surface.
- Remove the dummy connector from the connection to be used (**A4**) and connect the sleeve
- Connect the sleeves to the device (**A4**)
- All functions of the device can be used safely by the patient.
- Turn the timer (A3) clockwise and set it to the desired treatment time. All displays are now illuminated. After the set treatment time has elapsed, the device automatically stops the treatment
- Set the desired average treatment pressure on the pressure regulator (**A2**) and check it on the pressure display.
- After the end of the treatment, turn the pressure regulator (**A2**) back to "minimum" (anticlockwise)
- To end the clock timer (**A3**) prematurely, turn it in the “OFF” direction (anticlockwise)
- After treatment, remove the tube plug from the device to deflate the sleeve better

Design of the lympha-mat® 300N

Front side of device

A2
Pressure regulator for setting the intended average treatment pressure

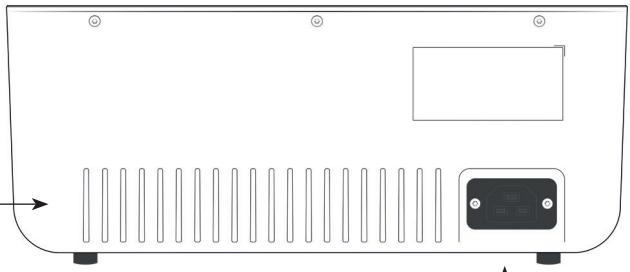


A1
LED display for monitoring the set pressure (mmHg)

A3
On/off switch, Timer

A4 2 connection sockets for sleeves

Rear side of device



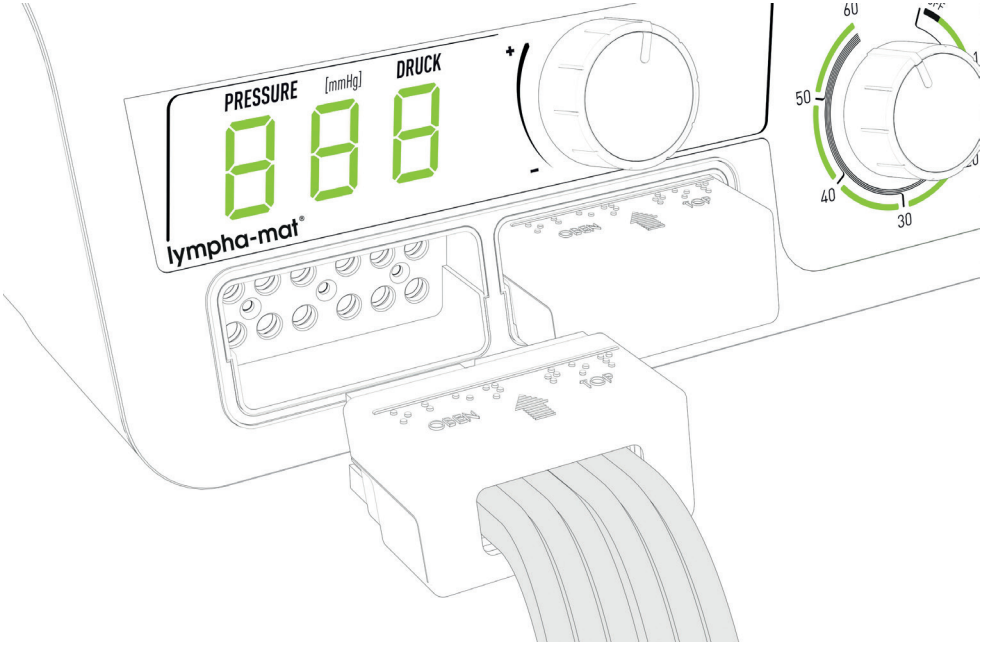
B1 Ventilation slots

B2
Mains connection

lympha-mat 300N Gradient (Article No. 1211) ~230V 50/60 Hz	lympha-mat 300N Gradient 110V (Article No. 1212) ~110V 50/60 Hz

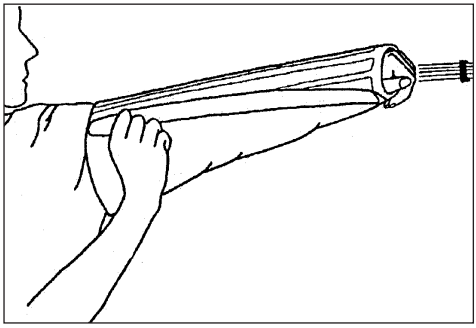
Connecting the sleeves

- Two sleeves can be connected to the device (**A4**) at the same time.
- Insert the tube plug of the sleeves into the connection socket (**A4**).
- The air tubes for the sleeves must not be bent in order to ensure the proper filling of the individual air chambers.
- During the treatment period, the connection (**A4**) that is not needed must be closed with the dummy plug supplied.



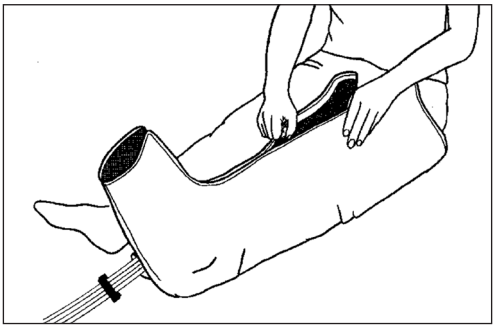
A4 2 connection sockets for sleeves

Putting on the sleeves

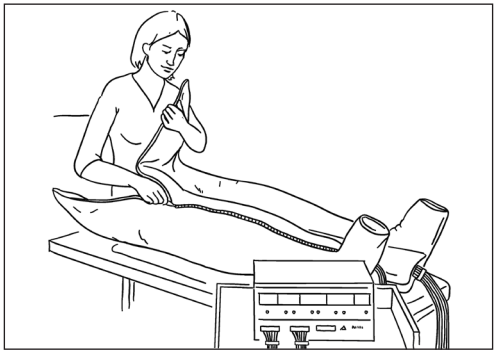


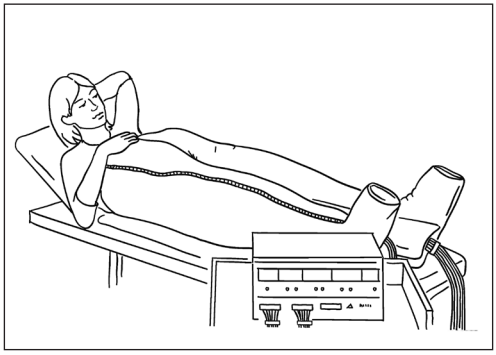
Arm sleeve
Put the sleeve on comfortably and smoothly. Use up as much of the holding surface of the Velcro as possible to avoid the sleeve opening during the treatment. The covering channel with the tubes must be on the side turned away from the body.

Leg sleeve
Put on the sleeve and close the zip fastening fully. The Velcro catch also helps to prevent the zip fastening from opening.
The zipper must not become opened under pressure.



Compression trousers
Close the zipper completely.

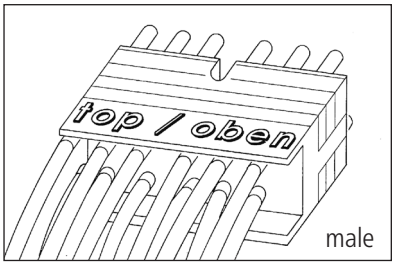




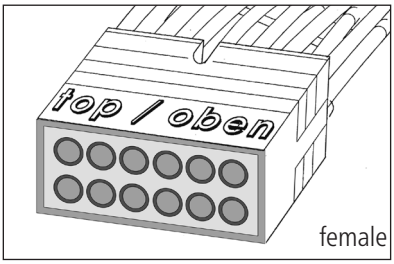
Connecting the tube extensions of the lympha-mat®

A tube extension, which can be attached between the control unit and sleeve, is available for all sleeves of the type lympha-mat. This extends the entire connection between the control unit and the sleeve by 2 m.

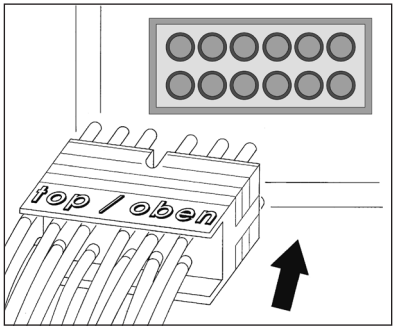
The tube extension has a "male" connector and a "female" connector.



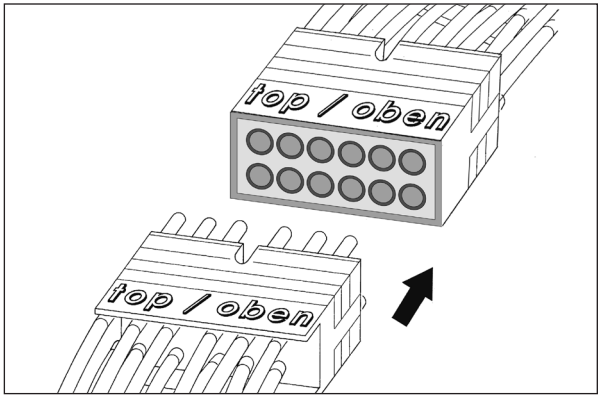
male



female



The "male connector" is plugged into the connection sockets of the control unit. Please pay attention to the top and bottom markings on the tube connector.



The "female" plug is connected to the tube end of the sleeve. Please pay attention to the top and bottom markings on both tube connectors and plug the connectors together so that "top" matches "top" and "bottom" matches "bottom".

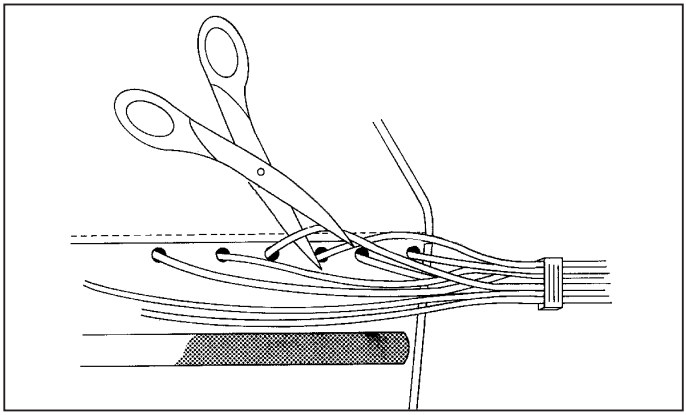
Connecting the extension

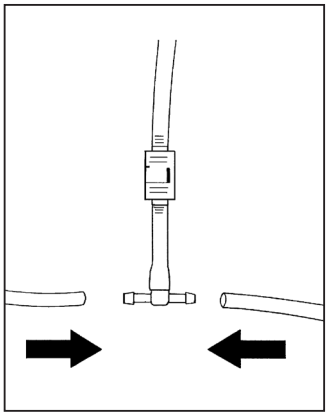
Extension

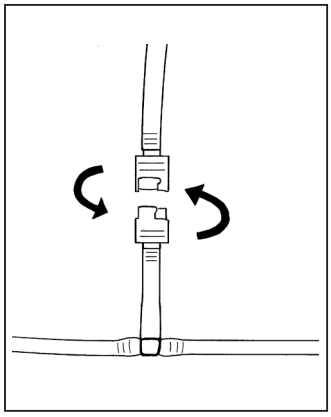
The extension increases the circumference of the leg sleeve/compression trousers by 13 cm. The zip fastenings at the sides fasten the sleeve.

Assembly note

The extension is mounted as follows:
When opening the side cover on the sleeve, the tube connections are visible. **Cut the tube of air chamber 4 at the marked point (black line)** and connect the connecting piece of the extension.







When removing the extension loosen this at the tube coupling.

Sleeves and additional accessories

Leg sleeve
with 12 air chambers

Size M
Thigh circumference up to 75 cm
Length 85 cm
Art. No. 1220

Size M - short
Thigh circumference up to 75 cm
Length 72 cm
Art. No. 1221

Size L
Thigh circumferences of up to 88 cm
Length 85 cm
Art. No. 1230

Size L - Short
Thigh circumferences of up to 88 cm
Length 72 cm
Art. No. 1231

Extension leg sleeve
with one air chamber
Circumferential extension 13 cm
Art. No. 1240

Extension leg sleeve Short
with one air chamber
Circumferential extension 13 cm
Art. No. 1241

Arm sleeve
with 12 air chambers
Upper arm circumference
adjustable up to 58 cm
Length 71 cm
Art. No. 1250

Jacket
with 24 air chambers
Abdominal girth up to 134 cm,
upper arm circumference up to 55 cm
Art. No. 1180

Jacket
left with Bolero
with 12 air chambers
stomach size up to 134 cm,
upper arm size up to 55 cm
Art. No. 1181

Jacket
right with Bolero
with 12 air chambers
stomach size up to 134 cm,
upper arm size up to 55 cm
Art. No. 1182

Extension Jacket
Back
Circumferential extension 13 cm
Art. No. 1185

Extension Jacket
Arm
Circumferential extension 10 cm
Art. No. 1190

Extension Jacket
Front
Circumferential extension 13 cm
Art. No. 1195

Compression pants
with 24 air chambers
Hip circumference up to 145 cm
Thigh circumferences of up to 83 cm
Art. No. 1260

Compression pants size S
with 24 air chambers
Hip circumference up to 131 cm
Thigh circumference up to 75 cm
Art. No. 1261

Extension
for compression pants
with additional air chamber
Circumferential extension 13 cm
Art. No. 1265

Extension compression pants
size S
with additional air chamber
Circumferential extension 13 cm
Art. No. 1266

Belt for compression pants
and jacket
To intensify pressure
in the abdominal area
Art. No. 1280

Tube extension
for **all** 12-chamber sleeves
Length 2 m
Art. No. 1290

The sleeves are made out of easy-clean nylon/polyurethane fabric.

Please only use the supply lines approved by the manufacturers.

CE 0197

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BÖSL

Made in Germany

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