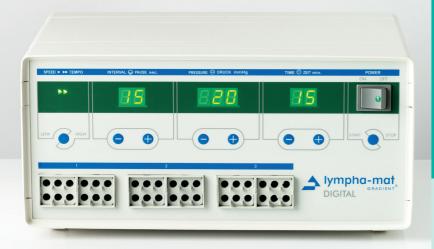
Instructions for Use English





12-level gradient system for intermittent pneumatic compression therapy

passion for compression

www.lymphamat.de





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Manufacturer

BÖSL Medizintechnik GmbH, Gut-Knapp-Straße 14, 52080 Aachen, GERMANY Phone +49(0)2405 / 6 93 90 - 00, fax +49(0)2405 / 6 93 90 - 10

Email: info@boesl-med.de

If you have any questions or problems with the device or the sleeves, please contact the manufacturer. Visit our website: www.boesl-med.de. You will find the latest version of these instructions for use in the download area.

General safety regulations

Please read the instructions for use before putting the device into operation and observe the list of indications and contraindications. If anything is unclear, ask your doctor or specialist retailer before commencing therapy.

The system meets the relevant safety regulations including EN 60601-1:2006/A1:2013, VDE0750:2013-12.



General safety warnings

Electrical devices can be dangerous if used incorrectly.

The device housing may be opened by authorized experts only. Repairs may only be carried out by authorized specialist retailers or the manufacturer. Under no circumstances may unauthorized persons open the device. For safety reasons, the device and the sleeves must not be modified or altered by the user. Failure to heed these warnings will void the warranty. In case of device malfunction, please contact Customer Service. This also applies to the fuses of the power socket on the rear device panel. These may be replaced only by authorized experts and never by the patient or the operator. The device must not be used in the presence of flammable gases such as anesthetic agents. The sleeves are biocompatible but should be used only on healthy skin. If you have open wounds of any kind, speak to your doctor before using the device. Open wounds must be covered completely during use. Should you nevertheless experience problems, contact your doctor immediately. Any product equipped with cables, hoses, etc. poses a potential strangulation hazard. Hoses and cables that are accessible to the patient should always be stored and used with caution and out of the reach of small children. Use the sleeves only on the extremities to be treated (arm, leg, hips, upper body). Never pull the sleeves over the head.





Safety precautions

For your own safety and to protect the device, the following precautions must be observed:

- During use, check the device regularly to ensure that it is operating properly and that the sleeves have been applied correctly.
- Keep the device out of the reach of pets and small children.
- Keep the device away from liquids and protect it from moisture. Do not expose
 the device and the sleeves to excessive soiling, dust, moisture, open flames,
 cigarette ash, etc. and irradiation (e.g., sunlight).
- The device consists of precision and electronic components. Protect the device and the accessories from impact, dirt, and electromagnetic interferences. Do not drop the device.
- Do not carry out service and maintenance activities while the device is in operation.
- Turn off the power switch before cleaning or inspecting the device and remove the power plug from the socket in order to disconnect it completely from the mains.
- Use only commercial cleaning agents to clean the device. Clean the device only with a dry cloth, never with a damp cloth.
- Make sure the device is clean and dry before placing it into storage.
- · Never inspect the device using sharp objects.
- Use only the sleeve combinations and the appropriate extensions specified by BÖSL Medizintechnik (see also section "The sleeves and further accessories").
- Proper device function can only be guaranteed if the correct devices and sleeve combinations are used.
- Use of this device in the immediate vicinity of other devices or stacked with other
 devices should be avoided, as this could result in faulty operation. If this form of use
 is necessary, both this device as well as the other devices should be monitored to
 ensure proper function.
- The use of accessories other than those provided can result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and can lead to faulty operation.



Intended purpose

The control units from BÖSL Medizintechnik GmbH are active medical devices that are used in conjunction with sleeves for intermittent pneumatic compression. Taking into consideration the treatment parameters specified by the doctor, the control units are suitable for the treatment of disorders related to venous and lymphatic obstruction according to the following indications, taking into account the contraindications. The operational safety of the control units is guaranteed only when used as intended by an informed user. The user groups include doctors, nurses and physical therapists, and the control units must be used only in professional health care facilities. There are no restrictions regarding the patient population. Children and people in need of assistance can be treated under professional guidance and supervision.

Indications

- · Prophylaxis of thromboembolism
- Post-thrombotic syndrome
- Crural ulcer
- Venous edema
- · Post-traumatic edema
- Lymphedema
- Lipedema
- · Mixed forms of edema
- Peripheral arterial occlusive disease (with close monitoring)
- Sensory deficits in hemiplegia

Contraindications

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



Undesirable effects

While the sleeves have been shown to be biocompatible under Parts 1, 5 and 10 of DIN EN ISO 10993, in very rare cases

- · skin irritation
- allergic reactions

can occur. In these cases, please talk to your doctor.

If in doubt, use the sleeves only on top of clothing.

The noises emitted by the system during operation may be perceived as minor noise pollution.

After use, marks may appear on the skin, which will however disappear by themselves.

Reporting of incidents

If serious incidents (death, severe deterioration in health) occur in connection with the device described in these instructions for use, they must be reported by the user to the manufacturer and the competent authority.

The competent authority in Germany 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 body outside of Germany, please contact the authorities in your respective country.

Maintenance

The device and sleeves are maintenance-free. Neither the patient nor any other operator is required to perform any maintenance work.

Cleaning

Device care and cleaning should be done only with a dry cloth (please do not subject the device to chemical dry-cleaning). Alcohol-based cleaning agents may be used.



Disinfection

Disinfection of the treatment sleeves must be carried out after use and/or before each patient change. In this regard, please perform wipe disinfection as recommended by the Robert Koch Institute (see "Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren").

For more information and instructions, please refer to our leaflet "Cleaning and disinfection instructions".

Warranty

The manufacturer offers a two-year warranty for the device and accessories, provided defects are due to material and/or manufacturing errors. The manufacturer considers itself responsible for effects on the safety, reliability, and performance of the device only if: extensions, new settings, modifications or repairs are carried out by persons authorized by the manufacturer, the electrical installation of the respective room in which the device is used meets the requirements of the VDE (Association of German Electricians), and the device is used in accordance with the instructions for use. In case of device malfunction, please contact the supplier directly. When used properly, the typical, average useful life of the device and the accessories is 10 years.





ElektroG (German Electrical and Electronic Equipment Act)

Correct disposal of waste equipment (electronic waste)

(With separate collection systems in the countries of the European Union and in other European countries)

The marking on the device, on accessories and/or on the respective documentation states that the device and its accessories must not be disposed of with regular household waste after the end of their service life. Please dispose of this device and its accessories separately from other waste in order not to jeopardize the environment or human health through uncontrolled waste disposal. Potentially contaminated sleeves are to be disposed of in regular household waste with a corresponding note and after consultation with the manufacturer. Please help us dispose of waste equipment and accessories correctly in order to promote the sustainable recycling of material resources.

Private users should contact the retailer from whom they purchased the device, or the competent authority for information as to where they can return the waste equipment and/or the accessories to ensure environmentally friendly disposal. Commercial users should contact their supplier and proceed according to the conditions of the purchase agreement. This device and electronic accessories must not be disposed of with other industrial waste.

The device is disposed of as electronic waste and must not be thrown away in regular household waste.

Return the device to the collection points of the public waste disposal authorities.



Symbols



Information



CAUTION!

This symbol indicates hazards that can lead to health impairments, injuries, permanent bodily injury or death. Follow the occupational safety instructions closely and take particular caution in these cases.



Manufacturer

2015

Year of manufacture



Refer to instruction manual. To ensure safe device operation it is necessary that the instructions for use are read and understood completely, as improper use can pose an unacceptable risk.



Disconnect power before opening



Batch code



Serial number



CE marking with identification number of the Notified Body



Fuse



Alternating current



Disposal/WEEE



Keep away from rain



Class I equipment



Device classification Type BF applied part



Ambient temperature for transport and storage. Transport and storage outside the specified temperature ranges can lead to damage of the device and thus to a hazard for the patient, user, or third persons.



Ambient temperature for use. Device operation outside the specified temperature ranges can lead to damage of the device and thus to a hazard for the patient, user, or third persons.



Symbols



Controller to adjust slow (>) or fast (>>) filling of the treatment sleeves



Interval controller/indicator 5–90 seconds to set interval between compression cycles



Pressure setting/pressure indicator 20–120 mmHg



Timer 5-60 min



On/Off switch



Start/Stop switch



Technical data

The model **lympha-mat**[®]**DIGITAL** is designed for use in professional facilities with a direct connection to a public supply network.

To ensure correct operation of the device and its connection to the power supply grid, please use a country-specific mains adapter, where necessary, corresponding to the device specifications (not included in the scope of delivery)

Continuous pressure setting

20-120 mmHg

(accuracy approx. 15 %)

Device classification:

Type BF applied part –

treatment sleeves

∱

Interval/pause adjustable from

5-90 seconds.

Protection class:

Class I equipment



Nominal voltage

Nominal frequency 50/60 Hz

Nominal current 0.5 A

Environmental conditions for transport and storage:

and Storage.

The environmental conditions for transport and storage are -25 °C to +55 °C with

humidity: 15 % to 93 % rH. without condensation



~ 230V

Dimensions:

W - 37 cm, H - 18 cm, D - 25 cm

Weight: 6.1 kg

Environmental conditions for use:

The environmental conditions for use are +5 °C to +40 °C, humidity: 30 % to 75 % rH atmospheric pressure: 700 to 1060 hPa

Electromagnetic compatibility (EMC)

lympha-mat[®]**DIGITAL** meets the EMC requirements for medical devices set forth in EN 60601-1-2. In addition, it meets the limits for mains voltage distortion for medical electrical devices pursuant to EN 61000-3-2 and EN 61000-3-3.



a corresponding environment.

If electromagnetic interferences compromise the performance of the **lympha-mat**[®]**DIGITAL**, the therapeutic effect may be reduced.

The lympha-mat[®]DIGITAL device is designed for use in an electromagnetic environment as indicated below. Customers or users of the lympha-mat[®]DIGITAL should ensure that the device is operated in

a corresponding environment.						
Guidelines and manufacture	r's declaration	n — Electromagnetic e	missions			
Emission measurements					Conformity	
RF emissions according to CISPR 11					Group 1	
RF emissions according to CISPR 11					Class B	
Harmonic current emissions according to IEC 61000-3-2				Class A		
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3					Conforms	
The lympha-mat [®] DIGITAL dev	vice is suitable	for use in professional fa	cilities with	h a direct connection to a public supply network.		
Interference testing					Compliance level	
Electrostatic discharge (ESD) according to IEC 61000-4-2				+/- 6 kV contact discharge +/- 15 kV air discharge	+/- 6 kV contact discharge +/- 15 kV air discharge	
Electrical fast transients/bursts according to IEC 61000-4-4				+/- 2 kV at 100 kHz for power supply lines	+/- 2 kV at 100 kHz for power supply lines	
Impulse voltages/surges according to IEC 61000-4-5				+/- 0.5 kV, +/- 1 kV voltage line to line +/- 0.5 kV, +/- 1 kV, +/- 2 kV voltage line to earth	+/- 0.5 kV, +/- 1 kV voltage line to line +/- 0.5 kV, +/- 1 kV, +/- 2 kV voltage line to earth	
Voltage dips, short interruptions and voltage fluctuations according to IEC 61000-4-11				Voltage dips: 0 % U _T ; 1/2 cycle at 0 to 315 degrees 0 % U _T ; 1 cycle and 70 % U _T ; 25/30 cycles single phase Voltage interruptions: 0 %U _T ; 250/300 cycles	Voltage dips: 0 % U _T , 1/2 cycle at 0 to 315 degrees 0 % U _T ; 1 cycle and 70 % U _T , 25/30 cycles single phase Voltage interruptions: 0 %U _T , 250/300 cycles	
Magnetic field at power freque	ncy (50/60 Hz)	according to IEC 61000	-4-8	30 A/m	30 A/m	
Interference testing				IEC 60601 test level	Compliance level	
Conducted RF disturbances according to 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} across entire frequency range	
Radiated RF disturbances according to 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)	
The field strength should be le	ss than 3 V/m	across the frequency rar	nge of 150	kHz to 80 MHz		
The tested RF frequencies cor	respond to the	following radio services:	:			
	Test frequency	Frequency band (MHz)		Service	Immunity test level (V/m)]
	385	380 to 390		TETRA 400	27	1
	450	430 to 470		GMRS 460, FRS 460	28]
	710 745 780	704 to 787		LTE band 13, 17	9	
810		800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	28			
- - -	1720 1845 1970	1700 to 1990	GSM	1800; CDMA 1900;GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	28	
F	19/0	04001 0570			00	1

Customers or users of the **lympha-mat**[®]**DIGITAL** can help prevent electromagnetic interferences in order to minimize damages. To this end, portable high-frequency radio devices, including their accessories, should not be used within a distance of 30 cm to the parts and cables of the **lympha-mat**[®]**DIGITAL**. Failure to follow these instructions can lead to a reduction in performance.

Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7

WLAN 802.11 a/n

2400 to 2570

5100 to 5800

2450 5240

5500



Troubleshooting

Fault

No function:

Is the device connected to the power supply?

-> Connect power cord

Is the device switched on?

-> Switch on device

Fault

Sleeves are not filled or vented:

Are all hoses connected to the device?

-> Connect hoses

Are unused connections closed with a dummy connector?

-> Connect dummy connector

Pressure indicator fluctuates:

No fault. Device always indicates current pressure in the sleeve

Fault

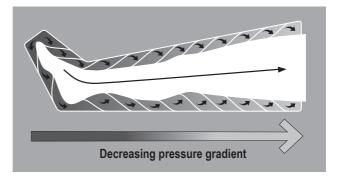
Display flashes during pressure build-up:

- -> Switch the device off and then on again
- -> If the fault persists, please contact the manufacturer



Mode of action of the lympha-mat®DIGITAL device

The **lympha-mat**[®]**DIGITAL** gradient system is designed for the treatment of disorders related to venous and lymphatic obstruction. The characteristic function of the **lympha-mat**[®]**DIGITAL** is the intermittent build-up of pressure. The sleeves exert intermittent gradient pressure on the extremities (arms and legs). The 12/24 chambers of the sleeves are filled with air one by one, starting from the foot or the hand. The pressure that is built up in the process decreases over various pressure ranges from the first to the last chamber. This gradient treatment pressure exerts a physiologically efficient drop in pressure. The liquid that is mobilized by means of the pressure inside the overlapping chambers can flow out unhindered and without returning.



The air chambers remain filled with air until the top chamber has reached a specified pressure level. The pressure then escapes simultaneously from all air chambers before the process of inflation is restarted after a set interval. The intermittent compression acts on the individual layers of tissue and on the blood and lymph vessels inside them. Congestion in the tissue is reduced, venous and lymphatic return is supported, and metabolism and gas exchange are improved.

Treatment recommendations

During the treatment the patient should lie down in a comfortable and relaxed position. To further support the treatment effect, the legs or arms being treated can be slightly elevated. At the start of the therapy, a low pressure setting should be selected and subsequently increased as needed. The pressure setting must never be so high that the patient experiences discomfort or pain. The treatment should feel relaxing and pleasant.



Technical instructions for installation

- After removal from the packaging, the device is ready for operation.
- Visually inspect the device for external damage.
- Do not use the device if there is visible damage.
- Place the device onto a flat and solid surface, e.g., a table.
- Connect the power cord to the power line (B2) and then to the socket (power supply).
- Connect the device to a power supply that corresponds to the specifications.
- To ensure correct operation of the device and its connection to the power supply grid, please use a country-specific mains adapter, where necessary, corresponding to the device specifications (not included in the scope of delivery).
- WARNING: To prevent the risk of electric shock, this device may only be connected to a supply network WITH a protective conductor.
- Position the device in such a way that the patient or the operator can pull out the power cord during treatment, if necessary.
- To prevent overheating, do not cover the air vents (B1) on the device.
 Do not stack devices, and do not use device as a storage surface.
- Remove the dummy connector from the connection jack to be used (A7) and connect the sleeve.
- Connect the sleeves to the device (A7) and apply the sleeves.

. The following standard setting appears:

Speed (filling of the sleeves): >> high (A1)

Interval (break between compression cycles): 15 sec. (A2)

Pressure (compression pressure): 20 mmHg (A3)

Time (treatment period): 15 min. (A4)

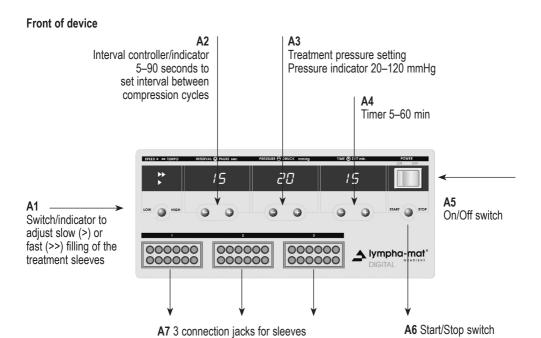
- After setting the desired compression pressure (A3) the treatment is commenced by pressing the button (A6) ("Start").
- The speed at which the treatment sleeves are filled can be adjusted by pressing the button (A1) "high >>" (fast) or "low >" (slow).
- The break / interval (adjustable between 5–90 sec.) between the individual compression cycles can be set/adjusted in the area (A2) by pressing the "+" or "-" button.
- The compression pressure can be adjusted by pressing the "+" or "-" button (A3) (pressure mmHg). Each push of the button changes the display by 5 mmHg.
 The display indicates the currently set treatment pressure.

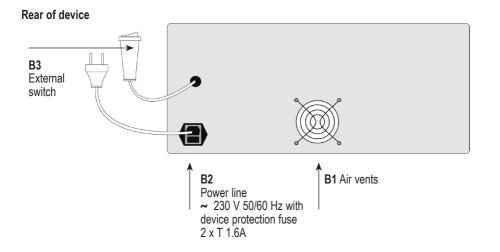


- The treatment time (adjustable between 5–60 min) can be set/adjusted by increments of 5 in the area (**A4**) by pressing the "+" or "-" button.
- The treatment ends automatically once the preset treatment time (A4) has passed, but can also be ended earlier by pressing the button "Start/Stop" (A6) or the external switch (B3).
- To better vent the sleeves after the treatment, disconnect the hoses from the device.



Design of the lympha-mat®DIGITAL device

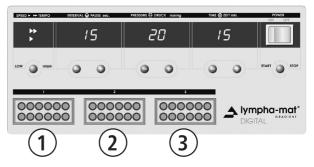




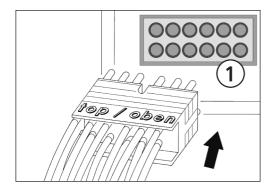


Connecting the sleeves

- Three sleeves can be connected to the device (A7) at the same time.
- Connectors 1 and 2 are intended for the leg sleeves/arm sleeves and compression pants, connector 3 is intended for the hip sleeve.
- Insert the hose connectors of the sleeves into the connection jacks (A7).
- Please note the markings 'top' and 'bottom' on the hose connectors!
- To ensure that the individual chambers can be filled with air, the air hoses of the sleeves must not be bent.
- The connection jacks (A7) that are not required for the duration of the treatment must be closed with the dummy connectors provided.

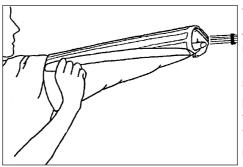


A7 3 connection jacks for sleeves





Applying the sleeves

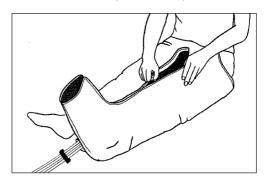


The arm sleeve

Apply the sleeve comfortably, making sure there are no creases. Use as much of the adhesive surface of the Velcro fastener as possible to prevent opening of the sleeve during the treatment. The canal covering the hoses must be placed on the side facing away from the body.

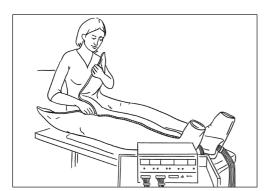
The leg sleeve

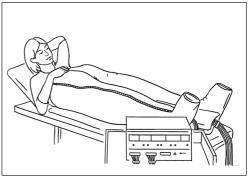
Apply the sleeve and close the zipper completely. The Velcro fastener additionally prevents possible opening of the zipper. The zipper should not be opened under pressure.



The compression pants

Close the zippers completely.

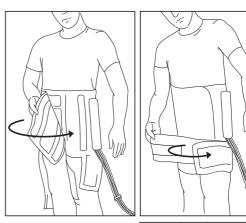






The hip sleeve

The hip sleeve consists of two halves, with 3 air chambers each, that are connected to one another using Velcro fasteners. The back Velcro fastener (blue) is used to adjust the circumference (up to 155 cm), the front Velcro fastener (gray) to close the sleeve.



The canals covering the hoses must be placed to the outside of the body.

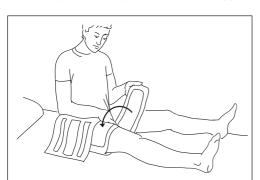
Apply the sleeves comfortably, making sure there are no creases.

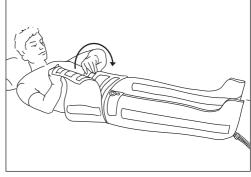
Use as much of the adhesive surface of the Velcro fastener as possible to prevent opening of the sleeve during the treatment.



Trouser combination

Apply and close the hip sleeve. Apply the leg sleeves and pull them over the bottom parts of the hip sleeve. Close the zipper completely.







24-chamber jacket sleeve

In addition to manual lymph drainage and use of compression stockings, intermittent pneumatic compression (IPC) is a globally recognized treatment for edema that undergoes continuous further development based on innovations from the circle of users.

The desire for seamless intermittent compression treatment for arm edema that includes parts of the upper body led to the development of the jacket sleeve.

This sleeve enables active compression of the entire upper body. The compression is built up gradually from the fingertips and travels over the arms all the way to the back, chest, and abdomen.

The intermittent build-up and release of pressure stimulates vasomotion of the lymphatic vessels, mobilizes the edematous fluid, and effectively promotes its removal from the body.

The simultaneous compression of both limbs prevents a potential displacement of the edematous fluid into the other half of the torso.

Apply the sleeve and close the zipper completely.

The zipper should not be opened under pressure.

PLEASE NOTE THE FOLLOWING SAFETY INSTRUCTIONS:

The air chambers in the arm area restrict the mobility of the hands during the treatment. Please make sure that a second person is present during the treatment who can switch off the device in case of emergency, or keep the zipper of the arm that is not being treated open in order to be able to switch off the device yourself.



Please use the external switch. (Wired remote control)

Always start a therapy series with the lowest possible treatment pressure.

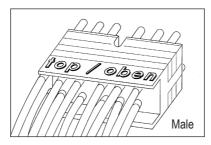
Maximum treatment pressure 50 mmHg

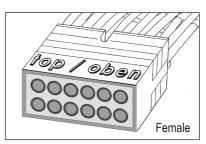


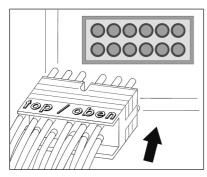
Connecting the lympha-mat® hose extensions

A hose extension that can be inserted between the control unit and the sleeve is available for all sleeves of the lympha-mat device type. It extends the entire connection between the control unit and the sleeve by 2 m.

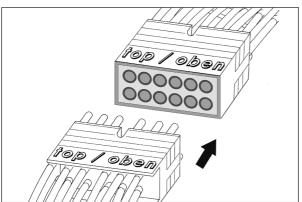
The hose extension has a "male" connector and a "female" connector.







The "male" connector is inserted into the connection jacks of the control unit. Please note the marking 'top' and 'bottom' on the hose connector.



The "female" connector is connected to the hose end of the sleeve. Please note the marking 'top' and 'bottom' on the two hose connectors and connect them in such a way that 'top' aligns with 'top' and 'bottom' with 'bottom'.



Connecting the extension

Extension

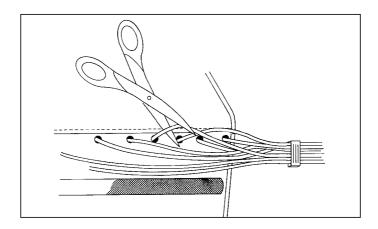
The extension extends the circumference of the leg sleeve/compression pants by 13 cm. It is attached to the sleeve using side zippers.

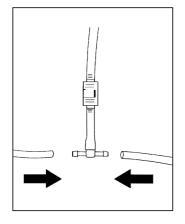
Assembly instructions

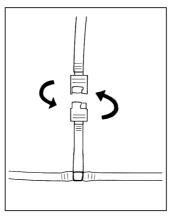
How to assemble the extension:

Expose the hose connections by opening the cover on the side of the sleeve.

Cut the hose of the 4th air chamber at the marked spot (black line) and connect the connecting piece of the extension.







When removing the extension, disconnect it at the hose coupling.



The sleeves and further 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 circumference up to 88 cm

Length 85 cm Art. No. 1230

Size L - Short

Thigh circumference up to 88 cm

Length 72 cm

Art. No. 1231

Extension

for lea sleeve

with one air chamber extension 13 cm

Art. No. 1240

Extension

for lea sleeve Short with one air chamber.

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 sleeve

with 24 air chambers

Circumference of abdomen up to 134 cm Circumference of upper arm up to 55 cm

Art. No. 1180

Extension Back extension 13 cm

Art. No. 1185

Extension Arm extension 10 cm

Art No. 1190

Extension Front

extension 13 cm Art. No. 1195

Hip sleeve

with 6 air chambers

Hip circumference

adjustable up to 150 cm

Art. No. 1270/12

Extension set for hip sleeve

extension 40 cm

Art. No. 1275

Compression pants

with 24 air chambers

Hip circumference up to 145 cm Thigh circumference 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

extension 13 cm

Art. No. 1265

Extension for compression

pants size S

with additional air chamber

extension 13 cm

Art. No. 1266

Belt for pants and jacket

To intensify pressure in the

abdominal area

Art. No. 1280

Hose extension

for all 12-chamber sleeves

Length 2 m

Art. No. 1290

The sleeves are made of easy-care

nylon/polyurethane fabric.

Please use only the supply lines approved by the manufacturer.



Notes	



DIGITAL	





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