Instructions for Use

vasoflow® GRADIENT 100 3

3-level system for
gradient intermittent compression therapy

passion for compression

www.vasoflow.de

BÖSL

Contents

Manufacturer

Bösl Medizintechnik GmbH
Charlottenburger Allee 13, 52068 Aachen, GERMANY
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E-mail: info@boesl-med.de

If you have any questions or if there are any discrepancies with the device or the sleeves, contact the manufacturer.

General safety instructions

Please read the Operating Manual prior to starting up the device and note indications and counter-indications. If there are uncertainties, consult your doctor or your specialist before beginning the therapy.
The system meets the applicable safety rules, including
EN 60601-1:2006/A1:2013, VDE0750:2013-12.

Basic safety warnings

Electrical devices can be dangerous if not used according to their intended use. The device's housing may only be opened by trained specialists. Repairs may only be performed by authorised specialists or the manufacturer. Untrained persons may not open the product in any event. The device and the sleeves may not be modified or changed by the user for technical safety reasons. If these warnings are not followed, the warranty no longer applies. In the event of functional interruptions of the device, please contact customer service.
The device may not be used in the presence of flammable gasses such as some anaesthetics. The cuffs 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.
Every product with cables, hoses, etc. presents a potential source of hazard for strangulation. Hoses and cables that can be accessed by patients should always be kept out of reach of small children and be protected and used with the corresponding level of caution.
The sleeves may only be used on the extremities to be treated (arm, leg, hips, upper body). Sleeves must never be pulled over the head.

Safety precautions

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

- Check the product regularly during use to ensure that the device is functioning properly and the sleeves are attached properly.
- Keep the device away from house pets and small children.
- Keep the device away from liquids and protect it from dampness. Do not subject the device and the sleeves to any excessive soiling, dust, dampness, no open flame, cigarette embers etc. or radiation (e.g. sunlight).
- The product consists of precision and electronic components. Protect the product and its accessories from impact and dirt as well as from sources of electro-magnetic interference. Do not allow the device to fall.
- Do not carry out any service or maintenance work while the device is being used.
- Switch the equipment off at the mains and pull the plug out of the mains socket to separate it completely from the power supply, before cleaning or inspecting it.
- To clean the device, only use commercially available cleaning products.
- Never clean the device with liquid products, rather always use dry ones.
- Ensure that the device is clean and dry before you store it.
- Never clean the device with pointed objects.
- Only use the sleeve combinations and the corresponding expansions, that are prescribed by BÖSL Medizintechnik (also see the list of accessories on page 20). The machine's proper function can only be guaranteed if the correct devices and sleeve combinations are used.
- The use of this device immediately adjacent to other devices or when stacked together with other devices should be avoided as this could lead to the equipment malfunctioning. If such usage is essential, the equipment and the other devices should be monitored in order to ensure that they are functioning correctly.

- The use of accessories other than those which have been provided can lead to increased emission of electro-magnetic interference or reduced levels of electro-magnetic immunity for the equipment, which could result in the equipment malfunctioning.

Intended purpose and proper use

The device should be used based on a doctor's diagnosis. It is intended for the patient to be the operator. The operational safety of the product can only be ensured with proper use by informed users or patients. The important performance characteristics consist of the handling period and the handling pressure Intended use is present only if:

- the product is used in home therapy or in a doctor's practice for the treatment of venous or lymphatic congestion ailments. (See the indications on page 14)
- The selection of the treatment period and the average treatment pressure has been agreed upon with a doctor,
- Children and impaired people have been given technical instruction and are under observation while being given therapy with the vasoflow® 100.

Maintenance

Device and sleeves are maintenance-free. No maintenance work of any kind should be carried out either by the patient themselves or by any other operator.

Cleaning

Care and cleaning must be performed with a dry cloth (please do not perform any chemical dry-cleaning). Commercially available cleaning products may be used.

Disinfection

Disinfection of the treatment sleeves must be carried out before use or before changing patients. To do so, use the corresponding commercially available disinfectant. To perform this, use wipe-down disinfectants that are recognised by the Robert Koch Institute (see the "List of disinfectants and disinfection procedures tested and approved by the Robert Koch Institute"/ „Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren"). You can find further information and instructions on our "Instructions for Cleaning and Disinfection" information sheet.

Warranty

The manufacturer guarantees a two-year warranty for the device and accessories, as long as the cause is defects in material and/or manufacturing defects. The manufacturer is only responsible for the effects on safety, reliability and performance of the device if: Expansions, new settings, changes or repairs by persons authorised by the manufacturer were carried out and the area affected by the electrical installation in which the application takes place corresponds to the VDE requirements and the device is used in compliance with the Operating Manual. If the device malfunctions, please contact the supplier company immediately.
The supplier can obtain circuit diagrams, replacement parts lists, descriptions, settings instructions and other documents that can be of use to the correspondingly qualified technical personnel of the user as required. When used appropriately, the typical, median lifespan of the device and accessories is 10 years.

Electro G: Electrical and Electrical Equipment Act

Correct disposal of old devices (electronic scrap)
(in the countries belonging to the European Union and other European countries with a separate collection system)

The designation on the product, accessories and the corresponding documentation indicates that the product and accessories (e.g., charging machine, headphones, cables) may not be disposed with normal household waste upon conclusion of their lifetime. Please dispose of this device and accessories separately from other waste in order to avoid damaging the environment or human health through uncontrolled waste disposal. Potentially contaminated sleeves may be disposed of in the normal household waste with a corresponding warning and after consultation with the manufacturer. Please help to ensure that old devices and accessories are disposed of properly in order to promote sustainable recycling of material resources.

Private users should contact the vendor from whom they purchased the product or contact the responsible authorities in order to find out where they can dispose of the old device or accessories in an environmentally friendly manner.

Commercial users should contact their supplier and proceed according to the conditions of the purchase agreement. This product and electronic accessories may not be disposed of with other commercial waste.

The product is to be disposed of as electronic waste, and may not be disposed of in the normal household waste.

Bring the product to the collection point for the waste disposal agent under public law or send the product to the following address for disposal:

Zentrale Entsorgungsstelle GDW-Sindelfingen
Waldenbucher Str. 30, 71065 Sindelfingen, GERMANY

Explanation of symbols

Note

ATTENTION!
This symbol indicates dangers that can lead to damage to health, injuries, permanent damage to the body or death. Always follow the warnings on occupational safety precisely and take special caution in these situations.

Manufacturer

2015 Year of manufacture

Follow the Operating Manual.
It is necessary to have read and understood the Operating Manual completely for safe operation, because improper use could present an unwarranted risk.

LOT Lot number

SN Serial number

IP 21 Protected against solid foreign objects with a diameter = 12.5 mm and protection against dripping water

CE 0197 CE-Marking with identificationnumber of the Notified Body

Fuse

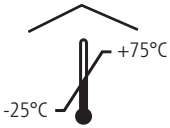
~ Alternating current

Disposal

Protect from dampness

Protection Class II

Device classification Type BF



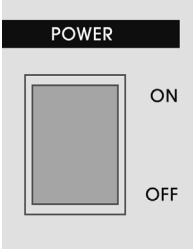
Ambient temperature for transport and storage; exceeding the specified ranges can lead to damage to the device and, through it, to an endangerment of the patient, user or third parties.

Ambient temperature for use; exceeding the specified ranges can lead to damage to the device and, through it, to an endangerment of the patient, user or third parties.

Explanation of symbols

Pressure setting/pressure indicator

20 – 100 mmHg



On/off switch

Technical Data

The model **vasoflow® 100** is intended for use in all facilities including living quarters and those that are directly connected to a public mains network that supplies buildings used for domestic purposes.

For the proper operation of the device and its connection to the electricity grid, please use a country-specific mains plug adapter (not included in the delivery) that meets the specifications of the device.

Infinite pressure adjustment
20 - 100 mmHg
(accuracy approx. 15%)

Interval/Break
set fixed at 20 seconds

Rated voltage	~ 230 V
Rated frequency	50/60 Hz
Rated current	0.2 A
	2 x T 1.6 H 250 V

Dimensions:
W - 23 cm, H - 13 cm, D - 21 cm
Weight: 3.6 kg

Classification:

Type BF

Protection Class

Protection Class II

Ambient temperature for transport and storage:
The ambient temperature for transport and storage is –25 °C to +75 °C at humidity: 15% – 93% rH.

Ambient temperature for use:
The ambient temperature for use is +5 °C to +40 °C at humidity: 15% – 93% rH.

Electromagnetic compatibility (EMC)

vasoflow® 100 fulfils the requirements of the EMC on medicinal products according to EN 60601-1-2. Furthermore, the requirements of circuit feedback for medicinal devices according to EN 61000-3-2 and EN 61000-3-3 are met.

Should disruptive electro-magnetic disturbances influence the performance of the vasoflow®100, the success of the treatment may be reduced.

The vasoflow® 100 device is intended for use in electro-magnetic environments such as those given below. The customer or the user of the vasoflow® 100 should ensure that that the device is operated in environments such as this.

Guidelines and the manufacturer's declaration – Electro-magnetic interference emissions

Interference emissions measurements	**Compliance**
HF emissions according to CISPR 11	Group 1
HF emissions according to CISPR 11	Class B
Emissions of harmonic oscillations according to IEC 61000-3-2	Class A
Emission of voltage fluctuations/ flickersaccording to IEC 61000-3-3	In compliance

vasoflow® 100 product is suitable for use in all facilities, including those in residential areas and those that are directly connected to the PUBLIC ELECTRICITY NETWORK that also supplies power to buildings used for residential purposes.

Interference resistance tests		**Compliance level**
Discharge of static electricity (ESD) according to IEC 61000-4-2	+/- 6 kV Contact discharge +/- 15 kV Air discharge	+/- 6 kV Contact discharge +/- 15 kV Air discharge
Rapid transient electrical disturbance levels/bursts according to IEC 61000-4-4	+/- 2 kV at 100 kHz for power cables	+/- 2 kV at 100 kHz for power cables
Surge voltages/surges according to 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
Magnetic field at the power supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m

Interference resistance tests	**IEC 60601 test level**	**Compliance level**
Conducted HF disturbance levels according to IEC 61000-4-6 Radiated HF disturbance levels according to IEC 61000-4-3	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 10 V/m; 80 MHz to 2.7 GHz; 80% (compliance level also 10V)	6 V effective value over the entire frequency range 10 V/m; 80 MHz to 2.7 GHz; 80% (compliance level also 10V)

Over the frequency range between 150 kHz and 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 bis 390	TETRA 400	27
450	430 bis 470	GMRS 460, FRS 460	28
710	704 bis 787	LTE Band 13, 17	9
745			
780			
810	800 bis 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,LTE Band 5	28
870			
930			
1720	1700 bis 1990	GSM 1800; CDMA 1900;GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
1845			
1970			
2450	2400 bis 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	28
5240	5100 bis 5800	WLAN 802.11 a/n	9
5500			
5785			

The customer or user of the vasoflow® 100 can help by preventing electro-magnetic disturbances to minimise any damage. Portable high-frequency communication devices including their accessories should therefore not be used at a distance of less than 30 cm to the parts and cables of the vasoflow® 100. Non-observance of this may result in a decrease of performance.

Troubleshooting

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

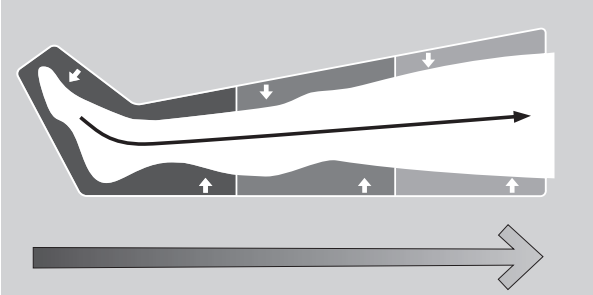
Is the device switched on?
-> Switch on the device

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

Are unused connections connected with a dummy connector?
-> Plug in the dummy connector

Effectiveness of the vasoflow® 100 device

The **vasoflow® 100** gradient system is used to treat venous stasis. The key performance feature of the vasoflow® 100 is an intermittent pressure build up.
The sleeves apply an intermediate gradient pressure on the extremities (arm and leg). The 3 chambers of the cuffs fill up with air one after another, beginning at the foot/the 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 chambers can disperse unhindered and without return flow.



Falling pressure gradient

The air chambers remain filled with air until the uppermost chamber has reached the corresponding pressure. After that, the pressure escapes from all air chambers simultaneously and begins the pump-up cycle anew after a pause period. The intermittent compression has an impact on the individual tissue layers and the blood and lymphatic vessels they contain.
The tissue is decongested, the venous and lymphatic reflux is promoted sustainably, and the metabolism and the gas exchange is improved.

Treatment recommendations

During treatment, the patient should lie comfortably and relaxed.
The legs or arms subject to treatment can be elevated slightly to support the treatment. The sleeve pressure should be selected as low at the beginning of therapy and increased as needed. The pressure must never be set so high that the patient experiences discomfort or pain. The treatment should be relaxing and comfortable.

Indications

- thromboembolic prophylaxis
- post-thrombothic syndrome
- ulcus cruris
- venous oedema
- post-traumatic oedema
- mixed forms of oedema
- peripheral arterial occlusive disease under strict observation
- sensory disturbance caused by hemiplegia

Contraindications

- decompensated cardiac insufficiency
- extensive thrombophlebitis, thrombosis or suspected thrombosis
- erysipelas
- severe unstabilised hypertension
- acute soft-part-trauma of extremities
- neuropathy
- occlusive processes in the sector of lymphatic drainage
- compartment syndrome
- Acute phlegmon

Side effects

Although the cuffs 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 cuffs over covered skin.

The operating noises of the system may be considered 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 warnings on commissioning

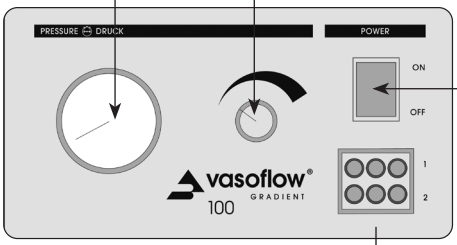
- The product is ready for operation as soon as it is removed from the packaging.
- Check the device visually for any external damage.
- Do not set up the device if there is any visible damage.
- Place the product on a level and solid surface, e.g. table.
- Insert the mains cable into the mains connector (**B2**) and connect to the socket (voltage supply).
- For the proper operation of the device and its connection to the electricity grid, please use a country-specific mains plug adapter (not included in the delivery) that meets the specifications of the device.
- Connect the product to a voltage supply in line with the specifications
- Set the device up so that, in an emergency, the mains cable can be pulled out by the patient or the operator during treatment.
- Do no place the device on cloths, blankets, duvets etc. due to the risk of overheating
- Do not cover the ventilation openings (**B1**) on the device to prevent overheating. Do not stack devices, and do not use the device as a storage surface.
- Remove the dummy plug from the connections that are to be used (**A4**)
- Connect the sleeves to the connections (**A4**) and put on.
- All functions of the device can be used safely by the patient.
- Move the on/of switch (**A3**) to the "ON" position and the pilot light comes on
- Set the desired treatment pressure on the pressure adjuster (**A2**) and monitor using the manometer (**A1**) (infinite adjustment).
- After the treatment is complete, set the pressure adjuster (**A2**) to "0"
- Move the on/off switch (**A3**) to the "OFF" position
- After treatment, remove the hose plug from the device to deflate the sleeve better

Structure of the vasoflow® 100 device

Front side of device

A1
Pressure gauge to check the set pressure (mmHg)

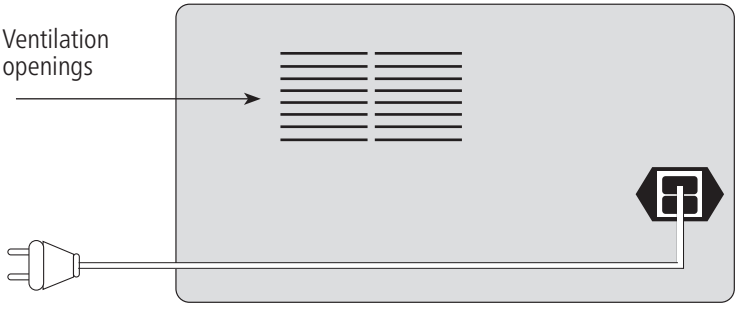
A2
Pressure regulator to set the intended average treatment pressure



A3
On/off switch

A4
2 connection sockets for leg/arm sleeves

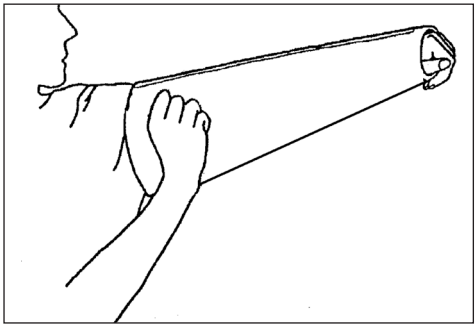
Rear side of device



B1 Ventilation openings

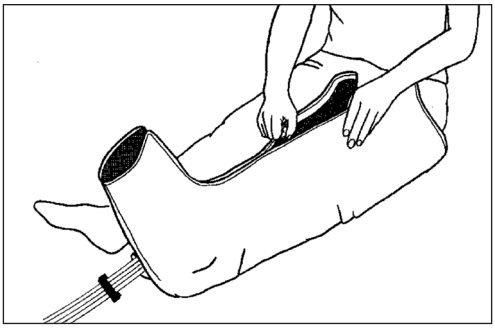
B2
Mains connection ~ 230 V 50/60 Hz
with fuse protection 2 x T 1.6A H 250V

Arranging the sleeves



The arm sleeve
Place treatment sleeve and close zip completely.
Do not open the zip under pressure.

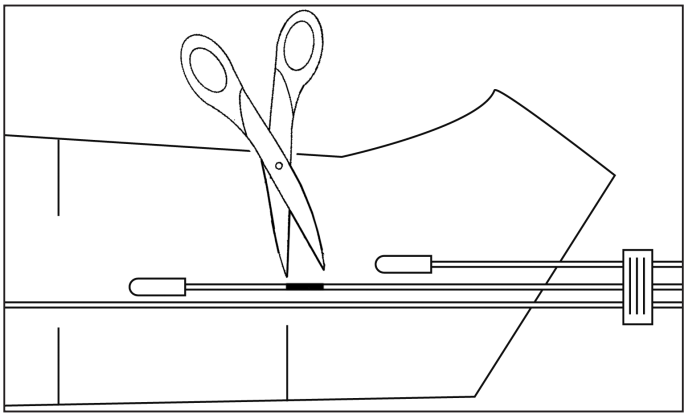
The leg sleeve
Put on the sleeve and close the zip fastening fully. The velcro catch also helps to prevent the zip fastening from opening.
The zip fastening should not be opened when the sleeve is pressurised.

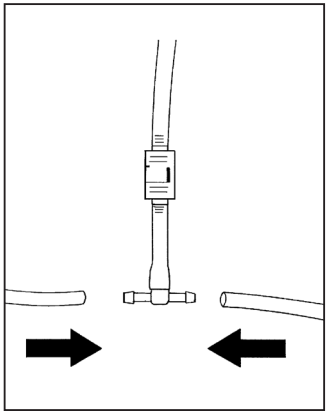


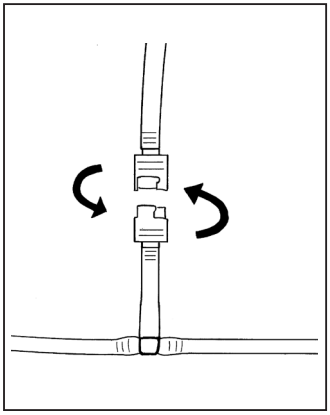
Attaching the expansion

Expansion
The expansion increases the scope of the leg sleeve by 13 cm.
It is fastened with side zippers.

Assembly note
The expansion is assembled as follows:
Sever the tube for the middle air chamber at the marked point (black line) and connect the connecting piece of the expansion.



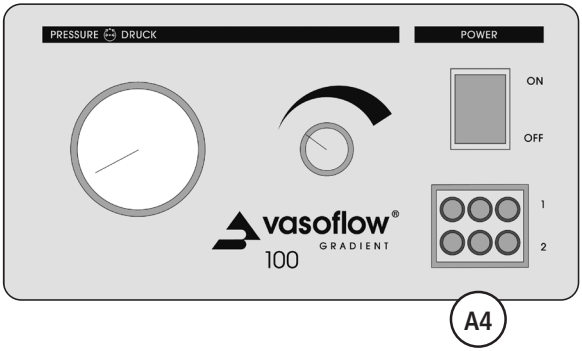




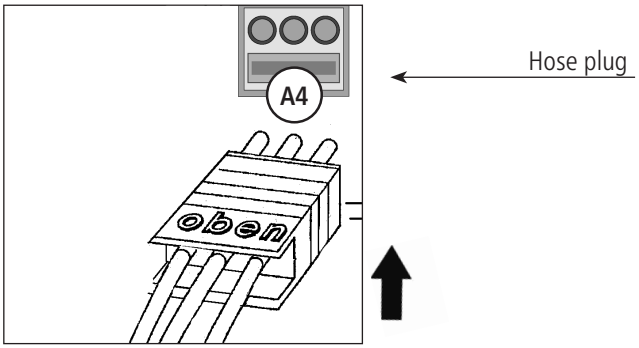
When removing the expansion, loosen it on the hose coupling.

Connecting the sleeves

- Up to two sleeves can be connected to the device at the same time.
- Either two leg sleeves or two arm sleeves
  or one leg and one arm sleeve
- Insert the tube connectors of the treatment sleeves into the connection sockets (**A4**).
- Please pay attention to the top/up and bottom/down symbols on the hose plugs!
- The air hoses of the sleeves must not become kinked
  to ensure filling of the individual air chambers.
- During the treatment duration, the non-required connections (**A4**) must be closed with the dummy connectors.



A4 2 connection sockets for sleeves



The sleeves and other accessories

3-chamber leg sleeve
Size M
Thigh circumferences up to 70 cm
Length 85 cm
Item no. 330

Size L
Thigh circumferences up to 83 cm
Length 85 cm
Item no. 340

Expansion for leg sleeve,
Size M and **L**
with 1 air chamber,
13 cm expansion
Item no. 1240

3-chamber arm sleeve
Upper arm circumferences
up to 60 cm
Length 67 cm
Item no. 350

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

CE 0197

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BÖSL

Made in Germany

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