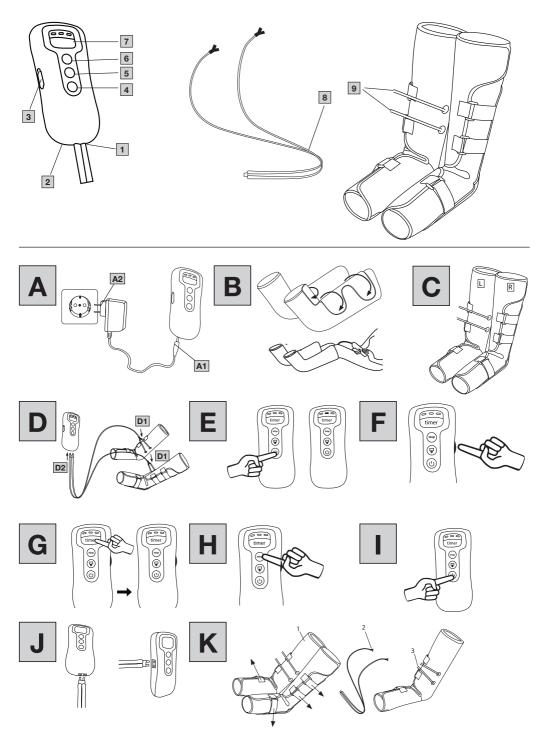
# beurer

## **FM 150**



ΕN	Leg compression massager	
	Instructions for use	3







Read these instructions for use carefully and keep them for later use. Make them accessible to other users and note the information they contain.

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#### 1. INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that there is no visible damage to the leg compression massager or its individual components and that all packaging material has been removed. If you are in any doubt, do not use the massager and contact your retailer or contact us on the service hotline number provided.

- 1 x right leg cuff
- 1 x left lea cuff
- 2 x air hoses
- 1 x hand switch
- 1 x storage bag
- 4 x AA batteries (1.5 V)
- 1 x mains adapter
- 1 x set of these instructions for use

#### 2. SIGNS AND SYMBOLS

The following symbols are used on the device, in these instructions for use, on the packaging, and on the type plate for the device:

#### **A** WARNING

Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.

#### **A** CAUTION

Indicates a potentially impending danger. If it is not avoided. slight or minor injuries may result.

#### NOTICE

Indicates a potentially harmful situation. If it is not avoided, the device or something in its vicinity may be damaged.



#### Product information

Note on important information



Observe the instructions Read the instructions before starting work and/or operating devices or machines



Manufacturer



Separate the packaging elements and dispose of them in accordance with local regulations.

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Permissible operating temperature and humidity

A S	Permissible storage temperature and humidity
Tomporates X SS	Permissible transport temperature and humidity
	Protection class II device
(Is)-	Switching mains adapter
LOT	Batch designation
UDI	Unique device identifier (UDI) Identifier for unique product identification
MD	Medical device
REF	Article number
SN	Serial number
#	Type number
IP20	Protected against solid foreign objects 12.5 mm in diameter and larger
IP22	Device protected against foreign objects ≥ 12.5 mm and against water dripping at an angle

#### 3. INTENDED PURPOSE

Rated ambient temperature

#### Intended use:

to-45°C

The leg compression massager is suitable for air pressure massage of the legs with inflatable and deflatable air cushions and continuously adjustable intensity.

#### Intended users:

The leg compression massager is suitable for people aged 14 and above that have a lower leg circumference of 29 – 53 cm. The device is only intended for domestic/private use in the home, not for commercial use.

#### Clinical benefits:

The leg compression massager is intended to prevent swollen legs, lymphoedema and sports injuries (such as bruises, haematomas and sprains). The device also prevents the formation of varicose veins and spider veins.

#### Indication:

- Lymphoedema
- · Swelling in the legs
- · Varicose veins and spider veins
- Sports injuries (bruises, haematomas, sprains)
- Muscle tension

#### Undesirable side effects:

- Prolonged use may cause leg numbness
- · Compression of an existing epifascial arterial bypass

#### Contraindication:

#### **A** WARNING

Do not use the leg compression massager

if you suffer from a medical abnormality or injury in the area
of the feet and legs; this applies to external skin-related
disorders and injuries and to internal injuries to the leg/foot
area (e.g. the muscles or tendons as well as bones and joint
systems).

- during the first two trimesters of pregnancy unless you have permission from your doctor; do not use during the last trimester of pregnancy.
- if you have illness symptoms that have not been diagnosed by a doctor.
- if you have acute illnesses that require treatment.
- if you are undergoing ongoing medical interventions or treatments, such as ongoing haemofiltration.
- after the consumption of substances that lead to impaired cognitive function (e.g. pain medication, alcohol, psychotropic drugs, antihistamines).
- on children under 14 years old.
- if you have acute heart disease and/or vascular disease.
- if you have arterial vasodilations (e.g. infrarenal or suprarenal aneurysms).
- if you have venous vasodilations; use is only possible following consultation with your doctor.
- if you have arterial or venous inflammatory disease, whether due to an infectious or immunological cause.
- if you have venous insufficiency of the leg vessels in your lower legs and/or thighs.
- if you have a previous history of leg vein thrombosis with or without embolic complications to the pulmonary vessels.
- on patients undergoing ongoing heparin, direct oral anticoagulant, or coumarin treatment.
- if you suspect or have a confirmed compartment syndrome on your lower leg or foot.
- if you suffer from sensitivity impairments of the skin or have reduced pressure sensitivity.
- if you are diabetic; use of the device is only possible following consultation with your doctor.
- in the event of chronic skin ulcerations, whether as a result of diabetes or not.
- if you have an arterial occlusive disease, depending on the location of the diagnosed vasoconstrictions.

#### **AWARNING**

Consult your doctor regarding the safe application of the FM 150 if you have any existing acute or underlying diseases, and in particular in the following cases:

- if you have had a surgical procedure on your legs or feet and your doctor does not think the wound has completely healed.
- if you have an acute or chronic skin condition on your legs or feet.
- · if you have a pacemaker, implants or other aids.
- · if you have diabetes mellitus.
- if you are suffering from pain, the cause of which is unknown.
- if you are suffering from severe inflammations and/or illnesses.
- if you are suffering from impairment to cardiac function, in particular that associated with water retention in the legs.
- if you are suffering from pulmonary oedema.
- if you are suffering from high blood pressure.
- if there is any suspicion of or the presence of malignant tumours.
- if you suffer from lymphatic circulation problems in your legs and/or feet.
- if you have sensitive skin.
- if you have any known heart disease.
- if you have any known disorders or diseases concerning cerebral blood flow.
- if you have any known kidney disease.
- if you have or suspect accumulation of fluid in the abdominal area (ascites).

#### 4. WARNINGS AND SAFETY NOTES

Failure to observe the following information may result in personal injury or material damage.

#### NOTICE

- Biocompatibility: None of the materials with which the patient or user comes into contact pose an unreasonable risk.
   Our products only contain materials that have been tested according to strict regulations to ensure safe use.
- · Place the hand switch beside your body during use.

#### **AWARNING**

- Keep packaging material away from children. There is a risk of suffocation.
- The device is only intended for domestic/private use, not for commercial use.
- This device may be used by children over the age of 14 and by people with reduced physical, sensory, or mental skills, or a lack of experience or knowledge, provided that they are supervised or have been instructed on how to use the device safely, and are fully aware of the consequent risks of use.
- Children must not play with the device.
- Cleaning and user maintenance must not be performed by children unless supervised.
- Do not use the device if it shows signs of damage or does not function properly. In these cases, contact Customer Services.
- Repairs must only be carried out by Customer Services or authorised suppliers.
- If the mains connection cable of this device is damaged, it must be disposed of. If it cannot be removed, the device must be disposed of.
- Do not use this device while bathing or while sleeping.
- Use the device as per the specific permissible operating and storage conditions.
- The device cannot replace medical treatment.

#### **A** WARNING

- Only use this device on legs and feet.
- Do not use the leg compression massager on animals.
- Do not use the leg compression massager whilst undertaking any activities where an unexpected reaction could be dangerous.
- Do not use the leg compression massager for more than 30 minutes (risk of overheating) and allow the leg compression massager to cool down for at least 20 minutes before using it again.
- In order to prevent burns or material damage, this device must not be used together with high-frequency devices.
- Do not touch the direct voltage adapter with wet hands so as to avoid any risk of electric shock.
- Do not walk or move while using this device, as this may be uncomfortable for the patient. You could also damage the device.
- Handle the device with care so that it does not fall and cause you injury.
- Do not use this device while bathing or sleeping.
- If the device causes discomfort to the user, immediately stop use and consult a doctor.
- Do not use this device together with other medical electrical devices, e.g. pacemakers, artificial pacemakers, artificial heartlung machines, electrocardiographs or other life-supporting devices.

- Do not disassemble, repair or modify device, to avoid malfunctions or risk of electric shock.
- For emergencies, the device should be placed so that the plug can be easily moved aside.
- Disconnect the device from the power supply after use or when not in use.
- Do not use this device in places where it is exposed to high temperatures, flammability, electromagnetic radiation, or high humidity.
- If the customer uses this device together with high-frequency surgical devices, the device may be damaged. If the device is used in the vicinity (1 m) of shortwave or microwave therapy devices, the device may not function reliably.
- Do not make any changes to this device without the manufacturer's approval.

#### Handling:

#### **AWARNING**

- After each use and before each time it is cleaned, switch off the device and disconnect the mains plug.
- . Make sure that the air hoses are not bent.
- Do not sit or stand on the leg cuffs with your whole weight.
- Do not place anything on the leg cuffs or the hand switch.
- Do not expose the device to high temperatures.

#### **Precautions**

- Use for long periods could result in a feeling of numbness in the legs and could cause the device to overheat. In this case, stop the current treatment.
- Avoid undoing the leg cuff hook-and-loop fasteners during use as this could impair the functionality of the device. Only open the leg cuff hook-and-loop fasteners if the pressure on your legs becomes uncomfortable or press the stop button.
- Do not cover the leg cuffs with a blanket or other objects during use.
- Ensure that any clothing you are wearing is not folded under the cuff and that no objects such as belt buckles, buttons, or pockets containing objects are located under the cuffs.

#### **AWARNING**

As with all electrical devices, use the leg compression massager carefully and cautiously, in order to avoid hazards due to electric shock.

Therefore, observe the following instructions for use of the leg compression massager:

- use the device with the supplied mains adapter and only at the mains voltage specified on the type plate,
- never use the leg compression massager if it or its individual components show visible signs of damage,
- do not use the device during a storm.

In the event of defects or operational faults, switch the leg compression massager off immediately and disconnect it from the mains socket. Do not pull on the mains cable or on the device to disconnect the mains adapter from the socket. Never hold or carry the device by the mains cable. Keep the cables away from hot surfaces. Do not crush, bend, or twist the cables. Do not insert needles or any sharp objects. Never open the hand switch.

Ensure that the device, the hand switch, and the mains cable do not come into contact with water, steam, or other liquids. Only use the device in dry rooms (i.e. NEVER in the bath or a sauna).

Never reach for the leg compression massager if it has become submerged in water. Unplug the mains adapter from the socket immediately.

Never use the device if it or its individual components show visible signs of damage. Do not drop the device or subject it to any impacts.

#### **AWARNING**

#### Repairs

Only specialist personnel may perform repairs on electrical devices. Improper repairs may put users in significant danger. For repairs, please contact Customer Services or an authorised retailer

#### **AWARNING**

#### Risk of fire

There may be a risk of fire if the device is used improperly or these instructions for use are ignored!

Therefore, observe the following instructions for use:

- Never operate the massager underneath a cover, such as a blanket, pillow, etc.
- Never use the device near petrol or other highly flammable substances.

#### **AWARNING**

#### **Batteries**

- If your skin or eyes come into contact with battery fluid, rinse the affected areas with water and seek medical assistance.
- Choking hazard! Small children may swallow and choke on batteries. Therefore, store batteries out of the reach of small children!
- Observe the plus (+) and minus (-) polarity signs.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- · Risk of explosion! Do not throw batteries into a fire.
- If the device is not to be used for a long period, take the batteries out of the battery compartment.
- Always replace all the batteries at the same time.
- Never use rechargeable batteries!
- Do not disassemble, open, or crush the batteries.

#### 5. DEVICE DESCRIPTION

The associated drawings are shown on page 2.

- Air inlet ("in")
- Mains socket
- 3 Air outlet 1
- 4 ON/OFF button
- 5 Air outlet button
- Stop button\*
- 7 Timer button 10/20/30 min.
- 8 Air hoses
- Connection for air hoses

(\*The stop button interrupts inflation in the event of unpleasant and high pressure)

#### 6. INITIAL USE

- · Remove the packaging.
- Remove the blue protection on the hook-and-loop fasteners of the leg cuffs.
- Check the device, mains adapter, and cable for damage.
- You can either operate the leg compression massager with batteries (4 x 1.5-V AA alkaline type LR06) or using the supplied mains adapter.

#### 6.1 Initial use with batteries

- 1. Open the battery compartment on the rear of the hand switch.
- 2. Insert four 1.5-V AA (alkaline type LR06) batteries. Make sure that the batteries are inserted the correct way round in accordance with the markings. Observe the graphic in the battery compartment. Never use rechargeable batteries!
- Close the battery compartment on the rear of the hand switch until you see and hear it click into place.

#### 6.2 Initial use with mains adapter

#### NOTICE

Before initial use with the mains adapter, check there are no batteries fitted in the hand switch.

- 1. Connect the mains adapter to the hand switch as shown A1.
- Plug the other end of the mains adapter into a suitable socket
   A2.
- 3. The leg compression massager is now ready for use.

#### 7. USAGE

#### 7.1 Starting use

### **A**IMPORTANT

- 1. Follow the instructions in the "Initial use" section.
- 2. Place the leg cuffs one at a time securely over your lower legs and feet as shown; have your legs bare or wear closely fitting clothing (e.g. tights). The leg cuffs should be fastened so that two fingers can fit under the cuff. If the leg cuffs feel too tight, fit the cuffs so that you can get your flat hand under them.
- 3. C For best results, your legs should be slightly bent/elevated during the treatment to aid circulation.
  - The cuff for the left leg is marked with an "L" on the inside.
  - The cuff for the right leg is marked with an "R" on the inside.
- 4. D Connect the air hose to the leg cuffs. Ensure the air hoses are securely in place and cannot slip.

Connect the other end of the air hose to the air inlet ("in") on the hand switch. D2

- E Press the ON/OFF button to switch on the leg compression massager. Once the device is switched on, the 20-minute timer LED lights up.
- Please note that the timer begins to count again when you change the timer setting.

#### Usage:

Selectable treatment time	10–30 min.
Recommended treatment time	2 x daily, 10-20 min. each

#### **IMPORTANT**

Using the massager for long periods might result in a feeling of numbness in the legs and could cause the device to overheat. In this case stop the current treatment.

- 7. F The intensity is adjusted using the air pressure controller. Start at the lowest level so that you get used to the massage gradually. For best effects, the intensity should be set high, but at a level where it still feels comfortable.
- 8. G Press the "Timer" button to switch between three time settings 10 minutes, 20 minutes and 30 minutes. The default value is 20 minutes. If the remaining time is 5 minutes, the current time display flashes slowly; if the remaining time is 1 minute, the current time display flashes quickly.
- 9. H If, during use, you experience an excessive or unpleasant feeling of pressure, press the "Stop" button to stop the treatment.

#### NOTICE

The leg compression massager will now start to massage the legs alternately. The legs will never be massaged at the same time. This is not an indication that the device is faulty.

The device features an automatic switch-off function, which is set to the maximum operating duration of 30 minutes. If the batteries are almost flat, the timer LEDs begin to flash from right to left. The device will switch off after a few seconds and then be in a 30-second stand-by mode. During this time, all 3 timer LEDs light up.

#### 7.2 Stopping treatment

To stop the treatment, you should first switch the device off and then let the air out of the leg cuffs.

To do so, proceed as follows:

- Switch the leg compression massager off by pressing the ON/OFF button on the hand switch. The set timer LED then goes out. The device is now in standby mode for 30 seconds. During this time. all 3 timer LEDs light up.
- 2. J During the 30-second stand-by mode, remove the air hose from the hand switch and insert the air hose into the side air outlet (\frac{1}{3r^2}) of the hand switch and press the air outlet button 5. All 3 timer LEDs flash at the same time. They go out again when the process has ended.
- 3. K Then undo the hook-and-loop fasteners and take the leg cuffs off. Remove the air hoses on the "Y-adapter" from the leg cuffs, but leave the short end pieces on the leg cuffs as shown. If you used the device with the mains adapter, remove it from the socket and the hand switch.

#### 8. CLEANING AND MAINTENANCE

#### 8.1 Cleaning the leg cuffs

- Always switch the device off before cleaning and remove the air hoses (apart from the short end pieces) from the leg cuffs and the hand switch.
- Clean the leg cuffs with a soft, slightly damp cloth. Do not use any chemical or alcohol cleaning agents or abrasives for cleaning.
- Ensure that no water enters when cleaning the components.
- Do not use the leg cuffs until they are completely dry.

#### 8.2 Storage

- If you do not intend to use the device for longer periods, remove the batteries from the hand-held device. Leaking batteries may damage the device.
- . Do not make sharp kinks in the air hoses and the leg cuffs.
- Store the device in a cool, well-ventilated space in its original packaging.

#### 9. DISPOSAL

For environmental reasons, do not dispose of the device in household waste at the end of

its service life. Dispose of the device in accordance with EC Directive Waste Electrical and Electronic Equipment (WEEE). If you have any questions, please contact the local authorities responsible for waste disposal.



The empty, completely flat batteries must be disposed of at specially designated collection boxes, recycling points, or electronics retailers. This is a legal requirement.

The codes below are printed on batteries containing harmful substances:

Pb = Battery contains lead,

Cd = Battery contains cadmium

Hg = Battery contains mercury.



#### 10. WHAT IF THERE ARE PROBLEMS?

Problem	Possible cause	Solution
The leg cuffs are not inflating	Batteries are flat	Replace the batteries in the hand switch.
	Mains adapter not plugged in	Plug the mains adapter into a suitable socket.
	Air hoses are not correctly con- nected	Reconnect the air hoses.
The timer LEDs on the hand- held device start to flash during the treat- ment and the device switches itself off	Batteries are flat	Replace the batteries in the hand switch.

If you cannot find a solution to your problem here, contact our Customer Services.

#### 11. TECHNICAL SPECIFICATIONS

Cuff pressure	Max. 120 mmHg (when correctly used, as described in section 7.1.)
Cuff size	29 – 53 cm
Timing duration	10 – 30 minutes with a deviation of ±10%
Voltage supply for battery operation	6.0 V DC (4 x 1.5-V ——— AA batteries (alkaline type LR06))
Permissible operating conditions	+5°C to +40°C, 15 – 93% relative humidity (non-condensing), 700 – 1060 hPa ambient pressure.
Permissible storage conditions	-25°C to +70°C, 0 – 93% relative humidity (non-condensing)

Permissible transport conditions	-25°C to +70°C, 0 – 93% relative humidity (non-condensing)
Dimensions	Leg cuff: 61 x 67 x 0.5 cm Hand switch: 17 x 7.7 x 3 cm
Total weight	Approx. 1400 g (without mains adapter)
Protection class	
Classification	Type BF 🐧
Expected service life of the device	Information on the service life of the device can be found on the homepage

#### 12. MAINS ADAPTER

Voltage supply for mains operation	Input: 100 – 240 V~, 50/60 Hz, 0.2 A Output: 6.0 V DC, 0.5 A, 3.0 W
Polarity	♦ <del>•</del> ♦
Protection class	

#### Notes on electromagnetic compatibility

• This device conforms with the European standard EN 60601-1-2 (Group 1, Class A and B, in accordance with CISPR 11, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 6100-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-11, IEC 61000-4-8) and is subject to particular precautions with regard to electromagnetic compatibility.

Please note that portable and mobile HF communication systems may interfere with this device. For more details, please contact our Customer Services at the address indicated.

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner outlined above, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's resistance to electromagnetic interference; this can result in faulty operation.
- Failure to comply with the above could impair the performance of the device.

#### 13. GUARANTEE / SERVICE

Further information on the guarantee and guarantee conditions can be found in the guarantee leaflet supplied.

#### Notification of incidents

For users/patients in the European Union and identical regulation systems, the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

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