

**TENS Back Pain Belt**  
Instruction for Use



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## Contents

- Back belt with control unit
- Extension belt
- Batteries, 3 x 1.5 V AAA (LR03, micro)
- This instruction manual

Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

### 1. About the unit




#### Pain relief on the lower back

The back belt works on the basis of electrical nerve stimulation (TENS). The more precise term is transcutaneous (meaning „through the skin“) electrical nerve stimulation (TENS). TENS is approved as a clinically proven, effective, medicationfree method of treating certain types of pain which, when used properly, is also free of side effects. It is also approved as a means of simple self-treatment.








The pain-relieving or pain-suppressing effect is caused by suppressing the transmission of pain in the nerve fibres (particularly through high-frequency impulses) and increasing the release of the body's own endorphins, which decrease the sensation of pain by their effect in the central nervous system. This method is clinically tested and approved. Every condition that calls for the use of TENS must be clarified by your doctor. He or she will also give you information about the specific benefits of a TENS self-treatment.

## 2. Signs and symbols

The following symbols appear in these instructions.

	<b>Warning</b>	Warning instruction indicating a risk of injury or damage to health.
	<b>Important</b>	Safety note indicating possible damage to the unit/accessories.
	<b>Note</b>	Important information to be noted.

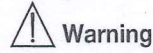
The following symbols are used on the identification plate.

	Type BF applied part
	Read the instructions for use
	Caution! Read the instructions for use. Refer to accompanying documents.
	Manufacturer
<b>SN</b>	Serial number
	The CE labelling certifies that the product complies with the essential requirements of Directive 93/42/EEC on medical products.
	Disposal in accordance with EC Directive 2002/96/EC – WEEE (Waste Electrical and Electronic Equipment).
	Direct current



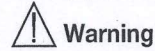
### 3. Important notes

#### Safety notes



- Use the belt only:
  - On humans
  - For external use
  - For the purpose for which it was developed and in the manner specified in these instructions for use.
- Any improper use can be dangerous!
- In acute emergencies, first aid takes priority.
- This unit is not intended for commercial or clinical use, but only for individual, private household use!
- Before use, ensure that there is no visible damage to the unit or accessories. When in doubt, do not use the unit and contact your dealer or the customer service address provided.
- If you have health concerns of any kind, contact your doctor!
- Use the unit in the lower back area only! Using it on other body parts can cause severe health problems.
- A slight reddening of the skin after use is normal and disappears after a short time. Refrain from using the unit until the reddening has gone away.
- If skin irritation results from a long therapy time, select a shorter application time.
- In case of more severe skin irritation, discontinue treatment and consult a doctor.
- This unit is not intended for use by children or persons with physical, sensory (e.g. insensitivity to pain) or mental impairments or those who do not know how to use it due to a lack of experience or knowledge, unless they are supervised by a person responsible for their safety or have received instructions from them on how to use the unit.
- Keep children away from packaging materials (risk of suffocation).
- Do not use attachments that are not recommended by the manufacturer.

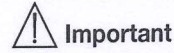
#### Safety precautions



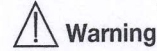
- Carry out the first few minutes of treatment while sitting or lying down, so that if you experience a rare vasovagal reaction (i.e. you feel faint), you are not at unnecessary risk of injury. If you start to feel faint, shut off the unit immediately and elevate your legs (for approx. 5–10 min.).

- The treatment should be pleasant. If the unit does not function correctly or if you begin to feel unwell or feel pain, stop using the unit immediately.
- Take off the belt only when the unit is switched off!

#### Notes about the electrodes



- Never apply the electrodes to injured skin areas.
- Max. recommended initial value for electrodes: 5 mA/cm<sup>2</sup>.
- Effective current density levels over 2 mA/cm<sup>2</sup> require increased attention on the part of the user.



#### To prevent harm to your health, we urgently recommend that you do not use the unit in the following situations:

- Do not use the unit if you use a pacemaker or other implants, such as an insulin pump or metallic implants.
- If you have a high fever (e.g. > 39 °C).
- If you have known or acute arrhythmias or other problems involving cardiac stimuli and their transmission to the heart.
- If you have seizure disorders (such as epilepsy).
- If you are pregnant.
- If you have cancer.
- After operations in which increased muscle contractions could interfere with the healing process.
- On acutely or chronically diseased (injured or inflamed) skin, e.g. painless or painful inflammation or reddening.
- If you have rashes (e.g. allergies), burns, bruises, swelling and open wounds or those in the process of healing.
- On surgical scars in the process of healing.
- When simultaneously connected to a high-frequency surgical instrument. In this case, burns under the stimulation current fields can result.
- When under the influence of pain medication, alcohol or sleep aids.
- Whenever doing anything in which an unforeseen reaction (such as increased muscle contraction despite low intensity) can be hazardous, for example while driving a car or operating machinery.
- On sleeping persons.
- Do not use this unit simultaneously with other



- units that transmit electrical pulses to your body.
- The unit is suitable for private, individual use.
- For hygienic reasons, the belt may be used by one person only.
- Ensure that during stimulation, no metallic objects can contact the electrodes, as otherwise localised burns can occur.

**The unit must not be used in the following situations:**

- In the head area: Here, it can trigger cramping.
- In the neck/carotid artery area: Here, it can trigger cardiac arrest.
- In the throat and larynx area: Here, it can trigger muscle cramps that can cause suffocation.
- In the ribcage area: Here, it can increase the risk of ventricular fibrillation and cause cardiac arrest.

**Safety precautions**

- Do not use the unit in close proximity to shortwave or microwave units (e.g. cell phones), as these can cause fluctuations of the initial values of the unit.
- Do not use while sleeping, driving a motor vehicle or simultaneously operating machinery.
- Never immerse the unit in water or other liquids.
- Do not use in close proximity to highly inflammable materials, gases or explosives.

**Consult a doctor before use in the following situations:**

- Acute diseases, particularly in case of suspected or known blood coagulation disorders, susceptibility to thromboembolic disease or malignant growths.
- If you have diabetes or other diseases.
- Chronic pain conditions that have not been clarified, regardless of the region of the body.
- Any sensitivity disorders with reduced sensation of pain (such as metabolic disorders).
- Simultaneously carried out medical treatments.
- Discomfort experienced as a result of the stimulation treatment.
- Persistent skin irritation under the electrodes.

**Warning**

Using the unit is not a substitute for consultation or treatment from a doctor. Whenever you have any pain or illness, always contact your doctor first.

**Before using the unit for the first time**

**Important**

- Before you use the unit for the first time, remove all packaging materials.
- Switch the unit off immediately if it is defective

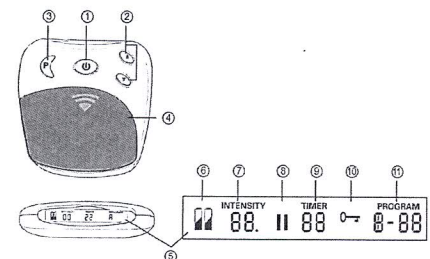
- or malfunctioning.
- If the self-adhesive covers for the electrode connection are missing or become detached, we recommend urgently that you affix the electrode covers provided.
- Never wear the belt with bare metal electrodes. Using the belt without electrode covers can cause injuries.
- The manufacturer shall not be held liable for damage or injuries caused by improper or incorrect use.
- Protect the unit from dust, dirt and moisture.
- If the unit has fallen or been dropped, exposed to extreme moisture or incurred other types of damage, it must no longer be used. Do not expose the unit to high temperatures or direct sunlight.
- Never open or attempt to repair the unit by yourself, as otherwise proper function is no longer guaranteed. Failure to observe this regulation shall void the warranty.
- If the unit is faulty and is within the guarantee period, contact your local Boots store.

**Notes on handling batteries**

- Keep batteries out of the reach of children. Children can put batteries in their mouth and swallow them. This can cause severe harm to their health. In this case, consult a doctor immediately!
- Normal batteries must not be recharged, heated or thrown into an open flame (danger of explosion!).
- Always replace all batteries at the same time and use batteries of the same type.
- Leaking batteries can damage the unit. If you do not intend to use the unit for a prolonged period, remove the batteries from the battery compartment.
- Leaking or damaged batteries can cause caustic injuries if they touch the skin. In this case, wear suitable safety gloves.

**4. Unit description**

**Overview of the control unit**





- 1 On/off/pause button
- 2 Intensity adjustment ▲increase ▼decrease
- 3 Program/locking key
- 4 Battery compartment
- 5 LCD Display
- 6 Battery status, appears when batteries are used up
- 7 Intensity, level 0 - 20
- 8 Pause symbol, flashes when activated
- 9 TIMER: Remaining time of the active programs in minutes
- 10 Keylock active
- 11 Active program

## 5. Using the unit for the first time and changing the batteries

### Putting on the belt

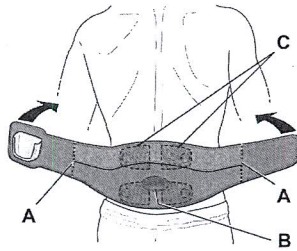
Before each use, ensure that your skin is clean and free of creams or oils. Only in this way the unit can work optimally.

- Lay out the belt before you with the electrodes facing you.
- Moisten the electrodes and your back with water. Ensure that the electrode surfaces are moistened evenly to avoid localised voltage peaks when they are applied to your skin.
- Fit the belt around your waist so that the vertical seams A are at the same place on each side of your body. The Boots logo B is then in the middle of the spinal column.

See the diagram.



When positioned correctly, the electrodes C are slightly to the left and right of your spinal column.



- Then, close the Velcro fastener.



Ensure that the belt fits tightly enough to provide a good contact between the electrodes and your skin, but does not constrict.

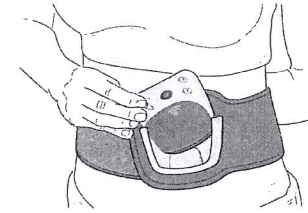
### Extending the belt



If the belt is not adequate for your waistline, you can use the extension belt provided. Depending on your waistline, the holder for the control unit may be away from the centre of your body. It is important that the belt is positioned correctly, therefore the electrodes C must be to the left and right of the spinal column.

### Inserting the control unit

- Insert the control unit into the holder on the belt.
- The operating buttons should be facing outwards and the display should be facing upwards and towards you.



- If inserted correctly, the control unit clicks into the holder.

### Automatic shutoff

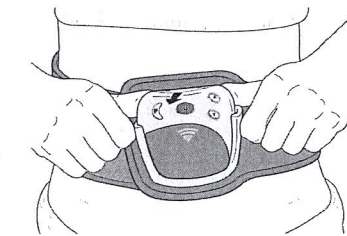
If the unit is not used after being switched on, it switches off automatically after 3 minutes.

### Changing the batteries



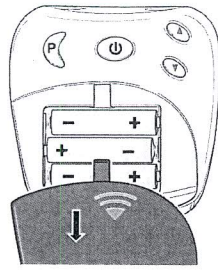
If the battery status indicator [6] flashes, it is time to change the batteries. To insert or replace batteries, you have to remove the control unit from the holder of the belt. flashes, it is time to change the batteries. To insert or replace batteries, you have to remove the control unit from the holder of the belt.

- Release the magnetic connection by gently pulling the control unit away from the belt. You can feel the magnetic connection of the two contact buttons unsnap.



- Pull the unit upwards and out of the holder.

- Open the battery compartment [4] by pushing the cover downwards at the arrow mark.




- Insert 3 x 1.5 V batteries, type AAA (LR 03 Micro). Ensure the correct polarity. See the diagram inside the battery compartment.
- Do not use any rechargeable batteries!

## 6. Operation

### General information about use

The back belt is intended for individual treatment of pain in the lower back area.

-  Do not switch on the unit until the belt is fitted correctly. See item 5.


### Switching on the unit


Press and hold down the on/off button [1] until a brief signal sounds and the LCD display [5] switches on. When the unit is started for the first time, Program A is activated automatically.

### Selecting the program

Press the program button P [3] to switch through the programs. The following programs are available:

Program	Frequency	Time
A	4 Hz – 110 Hz (3 phases)	30 min.
B	4 Hz	25 min.
C	2 Hz (burst)	25 min.
D	100 Hz	25 min.

-  **Note**  
For program A, you can feel the effect become stronger when switching from phase 1 to phase 2 (after approx. 10 minutes). This is normal and intentional. If the intensity seems too high, decrease it using the ▼ intensity button [2].

-  **Note**  
If you change the program during the stimulation (for example from A to B), the initial intensity in the new program increases incrementally up to the previously set intensity.


This can be stopped if necessary by pressing the ▼ intensity button [2] for two seconds or by switching off the unit by pressing the on/off button [1] for two seconds.

### Stopping impulses that are too strong

You can decrease the intensity at any time or switch off the unit by pressing the on/off button [1] (approx. 2 seconds).

### Adjusting the intensity

Press the ▲ intensity button [2] to increase the intensity incrementally or press the ▼ intensity button [2] to lower the intensity. You can adjust the intensity in 20 increments. Depending on the intensity level, you feel a prickling at first that can escalate to a muscle contraction.

-  Select a setting that is within your comfort level.

### Preventing unwanted pulse changes

To prevent an accidental increase in intensity during a treatment session, simply activate the keylock. To do so, press the program selection button P [3] for approx. 2 seconds. An acoustic signal sounds and the “0—” symbol appears in the display [5]. To cancel the keylock, press and hold

down the P [3] button for approx. 2 seconds.

### Reacting to unpleasant sensations

If you feel a stinging or itching sensation, switch off the unit and proceed as follows:

- Check whether the electrodes are working properly or are defective.
- Check whether the round cover is still present over the electrode connections.
- Take off the belt and moisten it completely once again.
- When refitting the belt, ensure good skin contact and good moistening.

### Inserting a pause

If you want to take a break or pause a program, press the pause button [1] briefly. An acoustic signal sounds and the „||“ pause symbol flashes in the display [5]. You can resume the program by pressing the button [1] again.

### Contact detection

If the electrodes have no contact with the body, the intensity is set automatically to zero. This prevents unwanted stimulation. The intensity cannot be increased without contact with the body.

### Memory function

The unit stores the most recently configured program. After a battery change, the unit starts with the first program again.

## 7. Cleaning and care of the unit and belt

### Cleaning the unit

- Remove the batteries from the unit before each cleaning.
- Clean the unit with a soft cloth moistened slightly with water after use. If the dirt is heavier, you can also moisten the cloth with a mild soap solution.
- Ensure that no water penetrates the unit. If this should occur, do not use the unit until it is completely dry.
- Do not use any chemical cleaners or abrasives for cleaning.



### Important

The belt and control unit are not suitable for machine washing.

### Cleaning the belt

Once you have removed the control unit from the belt, you can clean the belt using a soft cloth. To do so, use a mild soap solution or liquid detergent. Do not use bleaching agents.

## 8. Disposal

In the interest of protecting the environment, the unit must not be thrown out with the household waste at the end of its service life. Dispose of the unit at a suitable local collection or recycling point. Observe the local regulations for material disposal.

Dispose of the unit in accordance with EC Directive 2002/96/EC – WEEE (Waste Electrical and Electronic Equipment).

If you have questions, contact the municipal agency responsible for disposal.

Standard and rechargeable batteries should be disposed of separately from the household waste.

As a consumer, you are legally obliged to return used batteries for proper disposal. You can hand in your used batteries at public collection points in your district or sales outlets where batteries of this type are sold.



The codes below are printed on batteries containing harmful substances:

Pb = battery contains lead

Cd = battery contains cadmium

Hg = battery contains mercury

The batteries for this unit are free of hazardous substances.



## 9. Troubleshooting

Problem/question	Possible cause/remedy
The unit does not switch on when you press the ON/OFF button.	1. Ensure that the batteries are inserted correctly and have contact. The ON/OFF button must be pressed and held down to switch the unit on.
	2. If necessary, replace the batteries.
	3. Please contact your local Boots store.
No stimulation can be felt.	1. Increase the pulse intensity incrementally.
	2. Press the on/off button to restart the program.
	3. The batteries are almost empty. Replace them.
You feel an unpleasant sensation from the electrodes.	The electrodes are poorly moistened. This can lead to skin irritation, as the current is no longer distributed evenly over the entire surface. Switch off the unit. Take off the belt, moisten the belt (electrodes) and your lower back and restart the program according to the manual.
The skin in the treatment area becomes red.	Discontinue the treatment immediately and wait until the skin condition has normalised. Temporary skin reddening under the electrode is harmless and can be explained by the localised increase in blood flow. However, if the skin irritation persists and you feel itching or irritation, consult your doctor before continuing use. The cause may be an allergy to the surface of the electrode.



## 10. Technical specifications

Type	EM 38
Belt size for waist sizes from:	Approx. 75 to 140 cm
Weight (belt and unit)	Approx. 415 g with batteries
Electrode size	Approx. 81 x 65 mm
Parameters (500 Ohm load)	Output voltage: max. 50Vpp / 5.5Vrms Output current: max. 100mApp / 11mArms Output frequency: 2-110Hz
Pulse duration	60 - 220 $\mu$ s per phase
Wave form	Symmetric, biphasic rectangular pulses
Power supply	4.5 V (3 x 1.5 V AAA, type LR 03)
Operating conditions	0° C to 40° C, 20 to 65% relative humidity
Storage	0° C to 55° C, 10 to 90% relative humidity
Protection against ingress of water	IPX0, ordinary protection

We reserve the right to make any technical alterations that are necessary in order to improve and develop the product further. If the unit is used outside of the specifications, proper function is no longer guaranteed!

This unit complies with European standards EN60601-1, EN60601-2-10 and is subject to special precautions regarding electromagnetic compatibility. Note that portable and mobile RF communication equipment can affect this unit. For detailed information, contact customer service at the address provided.

The unit conforms to the requirements of the European Directive for Medical Devices 93/42/EC.

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