Manual

1. What is somnipax belt and what is it used for?

somnipax belt is an active positional therapy device used for the relief of simple snoring caused by sleeping on the back (also known as tongue snoring), as well as for mild or moderate positional sleep apnoea. somnipax belt is a class 1 medical device, Regulation (EU) 2017/745.

2. Intended use and scope of application

The intended use is positional therapy for snoring related to sleeping on the back, as well as for mild and moderate sleep apnoea. If you are in a back-sleeping position that promotes snoring / sleep apnoea, the device vibrates until you change position onto your side or front.

It should not be used:

- by wearers of cardiac pacemakers,
- during convalescence following intervertebral disc surgery,
- if you suffer from severe spinal complaints,
- positional vertigo,
- position-independent central sleep apnoea syndrome and its associated waking reactions (so-called arousals),
- latex allergy (belt contains latex) or
- by persons under 18 years of age.
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Should you have any doubts (e.g. because of possible interactions between medication and the positional therapy), please talk to your doctor.

3. For whom is the therapy with somnipax belt intended?

Therapy with somnipax belt is aimed in the first instance at patients who suffer from positional, mild or moderate sleep apnoea. In this group of patients, sleep apnoea is caused by the slackened tongue base muscle slipping into the throat during sleep and thereby temporarily closing the airways. This leads to interruptions in breathing. If you are in a back-sleeping position that promotes snoring / sleep apnoea, the device vibrates until you change position onto your side or front. This prevents the tongue base muscle from slipping into the throat.

In non-pathological tongue snoring, the slackened tongue base muscle again slips into the throat during sleep, but only narrows the throat rather than obstructing it entirely. The narrowing of the throat causes the snoring sounds. somnipax belt prevents this narrowing of the throat by vibrating to signal a back-sleeping position (which promotes snoring / sleep apnoea) until you change position onto your side or front.

Contraindications:
Wearers of cardiac pacemakers must not use this device.

4. Product features and expected clinical benefits of therapy

Product features

somnipax belt vibrates to signal that you are in a back-sleeping position (which promotes snoring / sleep apnoea) and does so until you change position onto your side or front. The slackened tongue base muscle can then no longer obstruct or significantly narrow the throat.

Expected clinical benefits of the therapy

Reduction or complete prevention of interruptions in breathing caused by obstruction of the throat during sleep (positional, mild and moderate sleep apnoea). Reduction or complete prevention of tongue snoring.

5. Risks and unwanted effects

The somnipax belt requires an acclimatisation period of approx. 1–2

weeks. If, during use, you experience discomfort of the spine or other supporting structures (particularly in the shoulder, neck or throat area), you should consult your doctor before continuing use.

⚠ Warning and safety instructions

Please read through the instruction manual. Failure to follow the terms of use and instructions contained in this instruction manual may affect the safety and effectiveness of the device. The manufacturer and distributor do not bear liability if the device has been modified or repaired by unauthorised persons or if the device has been subject to any other form of technical intervention by unauthorised persons.

- Please also read the instruction manual before using the product. The instruction manual is an integral part of the device. Please store it in the same place as the device. Only use the device for its intended purpose.
- If you experience daytime sleepiness, you may be suffering from sleep apnoea; in this case, please be sure to visit your doctor for an in-depth assessment.
- When opening the packaging, check that the device is undamaged, paying particular attention to the plastic parts.
- Only use alkaline batteries of the type specified in this instruction manual. Please remove the batteries from the device if it will be left unused for an extended period.
- Wear the device over undergarments or nightwear.
- Do not use the device in the presence of flammable anaesthetic mixtures containing air, oxygen, or nitrous oxide.
- This medical device requires special safety precautions with regard to electromagnetic compatibility (EMC) and must not be used near portable or mobile RF communication devices (mobile phones, radios, etc.) as they may interfere with its operation.
- Do not touch the device with wet hands, and protect it from contact with liquids.
- In the event of breakage or malfunction, stop using the device immediately and contact your retailer.
- Children and/or people with learning disabilities may only use the device under the strict supervision of a responsible adult.
- Repairs may only be carried out by the manufacturer‘s repair service or a service centre authorised by the manufacturer with the use of original spare parts. Making any modifications to the device without prior authorisation from the manufacturer is prohibited. With the exception of replacing the battery, no electrical and/or mechanical components of the device are designed to be repaired or modified by the user.
- Please take note of the temperature ranges indicated in the technical data.
- If you show any signs of hypersensitivity or allergic reactions to the device materials, stop using the device and consult a medical specialist. Please also notify the manufacturer or retailer.

6. Preliminary steps

Please refer here to the information in 7.

7. How do I use somnipax belt correctly?

Fitting the belt:

- Pull the protective film out of the batteries at the red tabs.
- Attach the device to the belt and insert the clips into the blue slots

on the belt.
- Position the belt lightly around your chest and close it with the fuzzy fastener.

How it works and how to use it

To switch on the device:

- Press the on/off button briefly (less than one second). Two short vibrations tell you that the system is active. You can relax and lie down on your side or front.
- If you roll over into a back-sleeping position, after 10 to 15 seconds the system will begin to produce vibrations at regular intervals until you move back into a side- or front-sleeping position.

To switch off the device:

- Press the on/off button for 2 to 3 seconds. A long vibration indicates that the device has switched off.

Adjust the intensity of vibration:

- With the device switched off, hold down the on/off button for at least 5 seconds. The device will produce vibrations of varying intensity. Release the button once the vibrations have reached a comfortable level. The device has now saved your vibration setting and remains switched off and ready to start.

8. How do I determine whether somnipax belt is working and/or being used correctly?

Habitual snoring

The easiest way to do this is to ask your sleeping partner whether you are now sleeping on your side or stomach and whether you are continuing to snore while you sleep (please note that even with effective anti-snoring therapy, a certain residual noise level can persist due to natural breathing noises).

If you sleep alone, smartphone apps can be used to record snoring. These can help you check whether the therapy is working effectively. A dry mouth in the morning is also an indicator – albeit a weaker one – that breathing took place through an open mouth and snoring probably continued.

Obstructive sleep apnoea

Here too, your sleeping partner can be asked whether you are now sleeping on your side or on your stomach and whether interruptions in breathing are still occurring. Since treatment for obstructive sleep apnoea is always under the supervision of a doctor, however, this assessment will not be enough. Your doctor will also need to determine whether the therapy is effective (sleep endoscopy examination / polygraphy).

9. What do I do if the function of the positional therapy belt is impaired?

The battery is mostly or completely discharged (red indicator light is on):

1. Remove the device from the belt. Unscrew the two screws in the middle of the clips. Remove the clips and the bottom of the casing.
2. Remove the empty batteries and then press the on/off button several times. Insert two new batteries type AAA 1.5 V.
3. When the batteries are inserted, the system will vibrate and the green INDICATOR LIGHT (new batteries) will light up for about 1 second**. The vibration is set to maximum intensity by default.
4. Then close the bottom of the casing again. Do this without applying extra force and turn it by a half turn if necessary. Attach the clips and tighten the two screws. Attach the device to the belt with the clips. The device is ready to be used again.

*Note: Use a T8 Torx screwdriver only

**Note: If the device does not respond when new batteries are inserted, check the batteries are the right way round. If the problem persists, check that the inserted batteries are new and charged.

The fabric belt has significant nicks or tears or the device itself is cracked:

If the fabric belt displays significant nicks or even tears or the device itself is cracked, please stop using somnipax belt immediately and replace the damaged part. Slight imperfections on the fabric belt (e.g. loosened seam or loose threads) will not generally affect its function.

10. When should I seek medical advice?

If you show any signs of hypersensitivity or allergic reactions to the device materials, stop using the device and consult a medical specialist. Please also notify the manufacturer or retailer.

11. Correct cleaning, care and storage

Cleaning and care

Clean the device with a damp cloth. Do not rinse under running water. The fabric belt can be washed by hand as per the instructions on the wash label.

Protection against water: Not protected!

Storage

Please store your somnipax belt in a dry place away from direct sunlight. Permissible storage temperatures for somnipax belt during storage and transport are between -20 and +50 degrees Celsius (at a humidity of 35% to 80%). During use, permissible temperatures are between 10 and 30 degrees Celsius (at a humidity of 35% to 80%).

12. How do I determine if my somnipax belt is still ok to use?

Please always check that the device is still working correctly before use: The green indicator light will flash at regular intervals (approx. every 5 seconds). When the system is switched on, briefly pressing the on/off button causes a short vibration. Note: When the system is switched off, the green indicator light flashes every 30 seconds.

Battery display:

If the red indicator light is on instead of the green indicator light, this means the batteries will soon need to be changed. If the batteries are not replaced in time, the device will not switch on and three consecutive pulses of vibration and flashes of the red indicator light will be shown.

Automatic switch-off:

To prevent the batteries running down prematurely, the device switches itself off after approximately 14 hours.

If the device is cracked or otherwise damaged, it must be replaced. The same applies if the fabric belt is damaged or defective. The fabric belt can be disposed of with your household waste. The device itself must be disposed of in accordance with the regulations in effect for electrical appliances.

13. Technical data

Power supply	2 alkaline batteries AAA 1.5 V
Battery life	2 to 6 months*
Classification	Class 1 medical device in accordance with (EU) 2017/745.
Vibration function	Adjustable intensity of vibration
Display elements	One red indicator light and one green indicator light
Belt size	S/M/L – circumference 70 cm to 100 cm, XL/XXL circumference 100 cm to 125 cm

Weight	30 g (without batteries)
Dimensions with clips, without belt	75.5 mm x 38.5 mm x 18 mm**
Operating conditions	**room temperature:** 10÷37 °C **humidity:** 35÷80% rF (free of condensation)
Storage and transport conditions	**room temperature:** -20÷50 °C **humidity:** 35÷80% rF (free of condensation)
Applied part type	BF

*Calculated using brand new, fully charged, high quality batteries available as standard on the market. The minimum battery life of two months is guaranteed with a total maximum vibration time of one hour per night.

**Device with clips, without belt.

14. Information on environmentally friendly disposal of electrical appliances

1. Disposal of waste electrical and electronic equipment (WEEE)

The symbol of the 'crossed-out wheelie bin' means that you are legally required to dispose of these appliances separately from your residential waste. Disposing of them via household waste, such as in the recycling bin or general waste bin, is prohibited. Avoid waste being misdirected by disposing of it correctly at special collection and return points.

2. Removal of batteries and bulbs

This product contains 2 AAA 1.5 V alkaline batteries which can be removed from the end-of-life device without causing any damage. These must be removed and disposed of as batteries separately before disposing of the device.

3. Options for returning end-of-life devices

Owners of end-of-life devices can return them free of charge within the range of options provided by public waste management authorities for the return or collection of WEEE, in order to ensure proper disposal of the end-of-life device.

4. Data protection

We would like to point out to all end users of WEEE that you are responsible for deleting personal data on the end-of-life device to be disposed of.

5. WEEE registration number

We are registered as a manufacturer of electrical and/or electronic equipment under the registration number DE10291720 with the Stiftung Elektro-Altgeräte (stiftung ear) register, Nordostpark 72, 90411 Nuremberg, Germany.

6. Collection and recycling quotas

In accordance with the WEEE Directive, EU member states are obliged to collect data on WEEE and to transmit this data to the European Commission. Further information is available on the website of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection.

15. Information on environmentally friendly disposal of batteries

As the battery end user, you are legally obliged to return used batteries. Batteries and rechargeable batteries must not be disposed of with household waste. After use, you can return batteries free of charge at a retail outlet.

Meaning of the symbols on the batteries:

- The crossed-out wheelie bin means that the product must not be dis-

posed of with household waste.

- Hg = battery contains more than 0.0005% mercury by weight; Cd = battery contains more than 0.002% cadmium by weight; Pb = battery contains more than 0.004% lead by weight.

Avoid waste by using batteries with the longest possible battery life or rechargeable batteries („accumulators“). Please avoid polluting our environment with waste and do not throw batteries away carelessly or leave them lying around. Before disposing of a battery according to regulations, please check the options available for preparing used batteries for reuse.

Please be aware of the possible harmful effects of the substances contained in batteries on the environment and human health, particularly the risks associated with handling batteries containing lithium. Separate collection and recycling of used batteries is intended to help minimise the impact of batteries on the environment and human health.

17. Required information on electrical safety

Device class	I
Applicable standard	IEC 60601-1: 2005 + A1:2012
Applied part type	BF
Sterilisation	None

18. Required information on electromagnetic compatibility

Classification: The device has been designed to comply with the requirements of the IEC 60601-1-2:2015 standard on electromagnetic compatibility.

However, certain materials may inadvertently emit strong RF signals which may interfere with the device

It is recommended that the device be kept away from other electrical equipment (in accordance with **section 7.9.2.2 IEC 60601-1-2).**