prorelax® direct

Electronic patch for pain treatment

TENS TECHNOLOGY







OPERATION MANUAL

Read Before Using

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Dear Customer,

Thank you for purchasing our **pro**relax direct. This product has been designed for people who suffer from muscular tension. The **pro**relax direct fights back pain the natural way with no side effects. We want you to be totally satisfied with this product, which should help you reduce your pain.

In order to achieve all the benefits from the prorelax° direct, we ask you to carefully read the following safety information and warnings.

Intended Use

The **pro**relax direct series are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Precautions & Adverse Reactions

SAFETY INSTRUCTIONS



Read instruction manual before operation. Be sure to comply with all "CAUTIONS" and "WARNINGS" in the manual. Failure to follow instructions can cause harm to user or device. Please read the following information carefully before using the **prorelax direct.**

Contraindications: Do not use this Device if any of the following conditions are present.

- Do not use this device if you have a cardiac pacemaker, implanted defibrillators or any other implanted metallic or electronic device.
- Do not use this device if you have undiagnosed chronic pain.

Warnings for proper use and safety

- If you are under the care of a Physician, consult with your Physician before using this device.
- The long-term effects of this device are not known.
- Do not place the prorelax direct on or close to your heart.

- Do not place the prorelax direct around or close to your neck. Do not apply stimulation over the neck. Severe spasm of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
 Stimulation over the neck could also effect hearing or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart.
- Do not place the prorelax direct on or around your head. The effects of stimulation of the brain are unknown.
- Do not use the prorelax direct over or close to sores.
- Do not use this device while sleeping.
- Do not use if you feel numbness.
- Do not use these devices in or close to water.
- Use the prorelax direct only on normal, healthy, clean and dry skin. Do not use it on open wounds or rashes, or over swollen, red, infected or inflamed skin.

- If you have ever had back surgery, consult your Physician before using this device.
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not use the device on children, if it has not been evaluated for pediatric use.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

Precautions for the safe use of prorelax direct.

- Read this User Manual before using this device for the first time.
- Keep this manual available whenever you use this device.
- This device is intended for individual person use only.
- This device is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This device is for pain caused by muscle soreness, and should be placed only around muscles where pain originates.
- The pain may indicate that you have some other health problem. You should know the reason and source of your pain before using these devices.
 Do not solely rely on the treatment of this device for pain.

- The safety of using the **prorelax direct** during pregnancy or birth has not been established.
- The effectiveness of this device depends greatly on a person's individual physical condition. It may not always be effective for every user.
- If you have had medical or physical treatment for your muscle pain, consult with your treatment provider before using this device. You should contact your physician prior to using this device following recent surgical procedures. Stimulation may disrupt the healing process.



Use Caution and consult your Physician before using the Mini Patchif any of the following conditions apply to you:

- If you have suspected or diagnosed heart problem.
- If you have suspected or diagnosed epilepsy.
- If you have a tendency to bleed internally following an injury.
- If you recently had surgery, or have ever had surgery on your back.
- If areas of skin lack normal sensations, such as skin that tingles or is numb.
- During menstruation or during pregnancy.

- Some people may feel skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using these devices and consult your Physician.
- If skin under the pad feels irritated after using the stimulator for a long period of time, use the stimulator for a shorter period of time.
- Minor redness at stimulation placement is a normal skin reaction. It is not considered a skin irritation, and it will normally disappear within 30 minutes after the electrodes are removed. If the redness does not disappear after 30 minutes from the removal of electrodes, do not use the stimulator again until after the excessive redness has disappeared.
- Turn off your device if the stimulation feels unpleasant or does not provide pain relief.
- Keep this device out of the reach of children.
- Use this device only with the pads and accessories recommended by the manufacturer.
- Do not use this device when driving, operating machinery or when swimming.
- Before removing the Mini Patch, be sure to turn it OFF, avoiding unpleasant stimulation.
- If your pain does not improve, (!) or if it continues for four to six days, stop using this device and consult your Physician.

- TENS is not a substitute for pain medications and other pain management therapies
- TENS devices have no curative value
- TENS is a symptomatic treatment and, as such, suppresses the sensation pain that would otherwise serve as a protective mechanism.



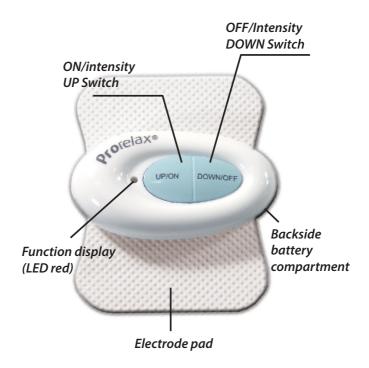
Adverse Reactions

- Skin irritation and burns under the pads have been reported by some people who have applied electronic stimulators to their skin.
- You should stop using the device and should consult with your physician if you experience adverse reactors from the device.

Introduction of prorelax direct

The **prorelax direct** is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

1. Components and Functional Parts of the Unit



2. Prior to Use

Before using, always check the package included in the delivery:

- 1x Device
- 1x Self –Adhesive Pad
- 1x 3V CR2032 Battery
- 2.1 Insert battery in the correct direction (+ Up).
 To check that the battery has been fitted correctly please press the ON/UP button once and the led willgo blank. Having made this check press the OFF/DOWN button to switch the unit off.
- 2.2 Place the electrode with the contact plugs up onto a flat surface. Place the device with the contact jacks down onto the Electrode pad so that plugs and jacks are aligned. Then press down until completely snapped in.
 Do not remove the clear plastic shield from electrode until the unit is ready to be placed on the body.
- 2.3 Ensure that whenever you intend to place the electrode, the skin is clean and thoroughly dry.
- 2.4 For treatment you can now remove the plastic shield from electrode by holding the edge of electrode in turn, then peeling off the clear plastic shield. Do not discard it!

3. Installing/Changing the Battery



4. Use and Functions

- 4.1 Familiarise yourself with the safety notes, and then proceed as described in section 1~3.
- 4.2 Place electrode on the area of skin selected and smooth it down with firm pressure.
- 4.3 Switch the device on by pressing ON/+
 button, function display lights up brightly.
 By pressing On/+ button again, the device starts
 to work at the lowest level of intensity.
 The device has 10 levels of intensity for strength
 of treatment. Select these intensity levels by
 simply pressing On/+ button the appropriate
 number of times.
- 4.4 The device has an automatic cut-out function which switches it off automatically after 20 minutes of treatment.
- 4.5 Treatment may be discontinued at any time by pressing -/OFF button repeatedly (depending on the level of intensity) until the function display lights off.

5. After Use

- 5.1 The adhesiveness of Electrode is very high when first used and care should be taken when removing the complete unit especially the first time.
- 5.2 Remove the pad form the skin by taking the electrode pad at the edge and pulling carefully.
 Don not grasp at the unit. Replace the electrode pad onto the clear plastic shield.
- 5.3 Never remove the unit when it is switched on.
- 5.4 Notes for safety and care:
 - Do not switch on he unit before the electrode pad is positioned on the body.
 - Keep the electrode pad from direct sunlight.
 - Take care, that no water penetrates the unit.

Cleaning and Maintenance

Device

- The device does not require any special maintenance.
- Remove the battery before cleaning the device.
- Never use aggressive cleaning products of stiff brushes.
- Clean he device with a soft, possibly slightly moistened cloth. Do not allow water to penetrate the device. Do no use the device again until it is completed dry.
- Remove the battery from the device if it is not going to be used for some time.
- Do not expose the device to direct sunlight and protect it against dirt and moisture.
- With the electrode pad on the protective plastic film, store the device in a cool, dry place.

Electrode

- For single person use only!
- Clean the adhesive surface after use to achieve better adhesion. Moisten the gel with a drop of water and allow it to dry briefly. Then stick the electrode back on the protective film.

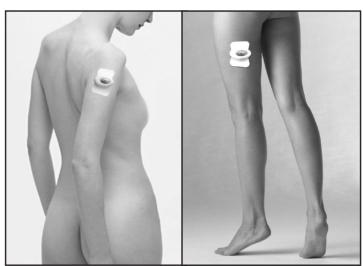
- The length of time the electrodes remain usable depends on their storage, skin type and use.
 Store the electrode in a cool, dry place.
 - Replace electrode when it is no longer tick or show cracks/blemishes.
 - The electrode is good for 20~30 times of use, 20 min each time.
- Be sure to use only prorelax originally supplied of Self Adhesive Electrodes (510k Nr. K082065).

Self-adhesive Pads	CM7257
prorelax Part no. measured by length and width of electrode	size 72 x 57 mm
size	snap type

 Contact prorelax for ordering information for replacement part(s), at <u>www.euromedics.de</u>, or authorized distributor(s).

Placement of Electrode





Troubleshooting Guide

Problem	Cause	Remedy
Led fails to light up	No battery in the device or battery dead Battery not insertedcorrectly Device not switched on Insulating film has not be removed	Replace battery Insert Battery again (+up) Switch device on Remove insulating film from between battery and device
Led lights up weakly	Battery low	Replace battery
Low output from device	Electrode pad dirty Device not applied properly	Clean/replace electrode pad Re-apply Device
LED function normal but no power output	Battery dead Electrode pad dirty or short-circuited	Replace battery Check electrode pads and replace if necessary
Device switches off prematurely	Battery dead Electrode pad worn out or dirty Device not applied properly	Replace battery Check electrode pads and replace if necessary Re-apply device

Technical Specifications

Name and model	: prorelax direct, WL-2301B
Channel	: Single Channel
Output Voltage	: 0~30V +/-20% (at 500 Ohm load)
Pulse intensity	: Adjustable from 0~60mA +/-20%
Pulse Width	:150~250uS
Pulse Rate	:30~60Hz
Power Source	: 1 Lithium Coin Cell battery (CR2032)
Auto. Cut-out	: 20 minutes
Operating Conditi	:+50 $^\circ$ F (10 $^\circ$ C) to +104 $^\circ$ (40 $^\circ$ C), 40-90% max.Relative humidity
Storage Condition	:+14° F (10°C) to +140° (60°C), 30-95% max. Relative humidity
Weight	: 0.5 oz (12.3 g) (battery included)
Dim.	2.3 in x 1.2 in x 0.5 in (59 x 30 x 12.15 mm)

Warranty

This **prorelax direct** carries a two-year warranty from the date of purchase.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.

The warranty applies to the main device and necessary parts and labor relating thereto.

Battery, electrodes, and other accessories are warranted to be free from defects in workmanship and materials at the time of delivery.

The distributors reserve the right to replace or repair the unit at their discretion.



Exclusively imported and distributed in Europe by: EUROMEDICS GmbH

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