



User Manual GRINDCARE 3.0

medotech

US

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INTRODUCTION

Before use

Before using your GRINDCARE for the first time, you should read the user manual carefully and keep it for future reference.

CAUTION: Federal (U.S.) Law restricts this device to sale by or on the order of physician.

Application

GRINDCARE is a device intended for use by people who suffer from tooth grinding/clenching, also called bruxism. GRINDCARE can measure and help to manage bruxism. During use, GRINDCARE emits a small electrical impulse – what is known as bio-feedback.

This impulse makes the jaw muscles relax and may help you to stop grinding your teeth. Your doctor or dentist will advise you as to the most appropriate way to use GRINDCARE for your particular condition.

GRINDCARE consists of

Stimulator, which is the central unit. The Stimulator registers your grinding and sends bio-feedback. All usage data is saved.

Grinddock, which is used to operate the Stimulator and display the data from your use of GRINDCARE. Wireless communication (i.e. communication between the docking station and stimulator) is used when the Stimulator is to be operated, and when data is to be transferred from the Stimulator to Grinddock.

This wireless communication is terminated automatically when the device is in use. Grinddock is also used to charge the Stimulator and to transfer data from the Stimulator to your doctor's PC.

Electrode, which is connected to the Stimulator and placed on the temporalis muscle on the temple. This electrode measures electrical signals from the muscle when it moves and emits an electrical impulse which makes the muscle relax.

The electrode is combined with a cover which operates as a clip and at the same time ensures that the electrode cannot be placed into any other socket.

Safety cord, which can be attached to the clip and hung around the neck.

Rubber clip, which is used to attach the wire from the electrode to the safety cord.

Disposable gel pads, (x30) placed on the electrode to ensure good contact between the electrode and the skin.

Charger, which is connected to Grinddock for charging both Grinddock and the Stimulator.

Stand, which Grinddock is placed in when not in use, when it is to be charged and when data is to be transferred to a PC.

Your doctor has reviewed with you the general instructions for using GRINDCARE when you received your device. Keep these instructions for reference to help you remember how to use your device.

GENERAL INSTRUCTIONS

Ready for use

1. Switch on the Stimulator and Grinddock. Check that both are charged, see Fig. 1, Photo A, icons 2 and 3. Make sure that there is contact between Grinddock and the Stimulator, see Fig. 1, Photo A, icon 2.
2. Connect the electrode to the Stimulator.
3. Place the electrode on a flat surface. Remove the short plastic liner from the gel pad. Place the gel pad with the recesses over the three terminals. Remove the long plastic liner from the gel pad. Check that there is no gel left on the liner.
4. Place the electrode with the gel pad directly on the skin. It is important to ensure that the skin is clean and dry. The electrode must be placed over the temporalis muscle on the temple as shown in Fig. 1, Photo B. You can locate this by placing a couple of fingers on your temple and biting down – you will feel the muscle bulging out.
5. Attach the Stimulator to your nightclothes using the clip, or hang it around your neck using the safety cord supplied. The safety lock must be at the back of your neck. Switch on the Stimulator by pressing Stimulator button for 1 sec. Blue LED will flash once and stay on for a few sec. (On status is then indicated by a short blue LED flash every 30 sec. and by Grinddock Fig. 1, Photo A, icon 2 active).
6. Check that there is good contact with the skin. You must see a minimum of three bars in the contact icon, see Fig. 1, Photo A, icon 1. The electrode must stick to the skin along its entire length so that all three terminals maintain good contact with the skin.
7. The electrode is now correctly placed and you can start calibrating GRINDCARE (see page 6).
8. Before use, GRINDCARE must measure how much you grind your teeth. Find out more about this baseline function in the section on configuration (see page 8).

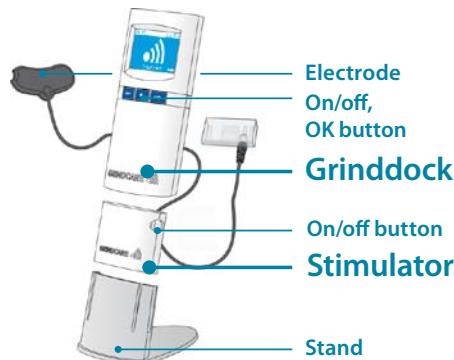


Figure 1: Usage Photos A, B and C

① indicates the contact between the electrodes and skin - a minimum of 3 bars is required for adequate performance. ② indicates the Stimulator battery charge and whether the Stimulator is docked or not. The battery symbol is only visible if the Stimulator is switched on. ③ indicates the Grinddock battery charge.

Charging

Grinddock and the Stimulator must be charged at least once every five days. Place the Stimulator in Grinddock (the Stimulator can only be charged when the electrode is disconnected). Connect the

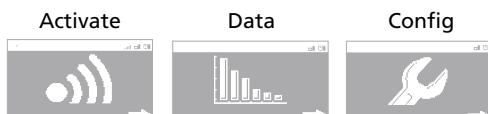


charger to Grinddock, as shown in Fig. 1, photo C. Set GRINDCARE for charging in the stand.

Grinddock

When Grinddock is switched on, the display shows the "Activate" icon.

Levels on menu 1:



The middle button allows you to make selections (OK, or enter). The two arrow buttons allow you to scroll through the options. Pressing the right arrow button takes you to the next menu entry. Pressing the left arrow button takes you back to the previous level. Holding down the left arrow button will return you to the start.



Switching off GRINDCARE

Hold down the middle button to switch off Grinddock. Switch off the Stimulator by pressing the on/off button for 3 sec. (until blue LED switches on, then release button). The Stimulator will also turn off automatically if left unused or without electrode contact for 10 min.

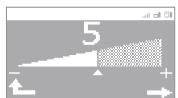
USAGE

Activate



To begin using the device, select "Activate" from the main menu.

Setting bio-feedback



Select a bio-feedback level using the arrow buttons. Press the middle button to test it. The level is correct when you can feel a tingling sensation. Press OK to confirm, or select a different level.

Before every activation, you have to calibrate GRINDCARE to suit your grinding pattern.

Relax



Start by relaxing your facial muscles. When the arrow disappears completely, you will proceed automatically.

Grimace



Now make a grimace, without clenching. When the arrow disappears completely, you will proceed automatically.

Grind



Clench your teeth in a good, firm bite (around 60% of your maximum bite strength). Repeat a couple of times until the arrow disappears.

Ready



Your activation has now started and there is no wireless communication between the Stimulator and Grinddock. You can place Grinddock in its stand (it will switch to standby after 5 sec.).

Next morning: Carefully remove the electrode from your temple without pulling on the wire. The device will automatically stop. Before reviewing data, switch the Stimulator off and then on again and the Stimulator battery symbol will reappear on the display.

Possible error sources



These icons are displayed only if:



The battery needs charging



There is no contact with the Stimulator.



There is poor contact between the skin and the electrode.

Find out more under: General Instructions on the previous page.



DATA

Data



Select "Data" from the main menu to view the results of your activation. Start by making sure there is contact between Grinddock and the Stimulator (find out more under: General Instructions).

Tension/Pain



After every activation, you should rate your sensation of facial tension/pain on a scale from 1 to 10. Use the arrow buttons and press OK to approve your settings. GRINDCARE has now saved data on your tension/pain.

The "Tension/Pain" function gives you an opportunity to record your own experiences of any tension or pain. You can enable or disable the tension/pain query in the "Config" menu.

Synchronizing



GRINDCARE transfers data from the Stimulator to Grinddock.

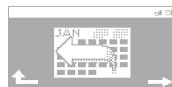
Last activation



Select "Last activation" to view the results of your last activation, according to:

- How much you have been grinding your teeth in total (Grinds)
- How many hours your activation lasted (Hours)
- How many times an hour you have been grinding your teeth (Grinds/Hour)
- Experienced tension/pain (Tension/Pain)

30 activations



Select "30 activations" to view the results of your last 30 activations. Each column displays data for one activation, according to:

- How much you have been grinding your teeth, in total (Grinds)
- How many hours your activations lasted (Hours)
- How many times an hour you have been grinding your teeth (Grinds/Hour)
- Experienced tension/pain (Tension/Pain)

Last Baseline



Select "Last Baseline" to view your latest baseline data:

- How much you have been grinding your teeth, in total (Grinds)
- How many hours measurement continued (Hours)
- How many times an hour you have been grinding your teeth (Grinds/Hour)
- Experienced tension/pain (Tension/Pain)
- How hard you have been grinding your teeth (Intensity)

CONFIGURATION

Settings



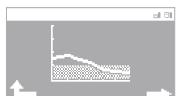
In "Config", you can change your settings and view more information on your GRINDCARE and how to use it.

Demo



Select "Demo" if you want to feel a bio-feedback impulse.

Baseline



Select "Baseline" when you want to measure how much you actually grind your teeth before you commence activation with GRINDCARE. All data will be saved so that you can review it later and assess the effect of your activations.

Start by working through steps 1-7 under General Instructions. Then select "Baseline" from "Config" and work through the three steps for adjusting GRINDCARE (in the same way as described under "Activation" on page 6.) In "Baseline", bio-feedback is automatically set to zero.

Time/Date



Set the date and time using the arrow buttons. Approve your settings by pressing OK.

Language



Choose your required language using the arrow buttons. Approve your settings by pressing OK.

Clear Data



Select "Clear Data" if you want to delete all activation data.

Set Sensitivity



In "Set Sensitivity", you can adjust the sensitivity of the electrode. Use the arrow buttons to select a number between 1 and 99, then press OK. The lower the number, the less hard a bite is required before you receive bio-feedback.

SW Info



Select "SW Info" if you would like to view more information on the software installed on your GRINDCARE.

Tension/Pain



Here, you can enable or disable the query on tension/pain which is asked by default when you select "Data" from the main menu. Use the right arrow button to select, then press OK.

Remember that "Tension/Pain" is your option for rating your own experiences of any tension/pain on a scale from 1 to 10.

Signal Quality



In "Signal Quality", you can view the number of times the electrode lost contact during your last activation. If this figure is greater than 10, you should check the contact between the electrode and your skin.

TROUBLE SHOOTING

1. The gel on the gel pad sticks to the electrode

You have positioned the gel pad the wrong way round! The gel should be against your skin, not against the electrode.

2. I wake up at night and get bio-feedback even though I am not grinding my teeth

Make sure that the electrode is sticking to your skin along its entire length so that all terminals maintain good contact with the skin. Review your activation settings again and try to bite down harder. This allows you to set a higher threshold for when GRINDCARE is sending bio-feedback.

3. I find it difficult to achieve good contact between the electrode and my skin

Make sure your skin is clean and dry. There must be no hair between the electrode and your skin. The electrode must be attached along its entire length. If necessary, try dampening the gel on the gel pad with a drop of water before you calibrate GRINDCARE.



MAINTENANCE

GRINDCARE unit

May only be wiped clean with a damp cloth.

Electrode

There may be a little gel left on the electrode after use. Wipe the electrode down with water on a damp cloth. The electrode must not be cleaned with cleaning fluids such as ethanol, propylalcohol or similar.

Gel pads

These are for single use only and must not be cleaned. These must be replaced every night before use of GRINDCARE.

Storage of gel pads

The properties of the gel pads may be reduced if they are stored in temperatures below 5°C (41°F) and above 40°C (104°F). To keep the gels moist, it is important to keep the gel pads in the plastic bag provided. The gel pads must not be exposed to direct sunlight.

SAFETY MEASURES

Contraindications

Patients with a pacemaker are not allowed to use GRINDCARE.

Warnings

1. The long-term effects of chronic use of GRINDCARE are unknown.
2. The GRINDCARE electrode is only intended to be placed over the temporalis muscle on the temple. The electrode should not be applied in the following areas:
 - a. over the carotid sinus nerves (on the side of the throat),
 - b. on the chest since the introduction of electrical current into the heart may cause cardiac arrhythmias,
 - c. over the cerebrum (brain),
 - d. over swollen, infected or inflamed areas or skin eruptions, e.g. phlebitis, varicose veins, etc.
 - e. over or near cancer lesions.
3. Simultaneous connection of a patient to high-frequency surgical equipment may result in burns at the site of the Stimulator electrodes and possible damage to the Stimulator.
4. Operation in close proximity (e.g. 1 m, 3 ft.) to short wave or microwave therapy equipment may produce instability in the Stimulator output.

The following precautions must be observed when using GRINDCARE:

When using GRINDCARE together with a hearing aid, the function of the hearing aid may be impaired.

Approximately 5% of the population will have an allergic reaction to electrode gel, i.e. redness, rash or irritation at the point of contact. In such case, remove electrode, wash off any gel residue and contact your clinician.

Electric blankets and magnetic bed linen must not be used when the device is in use.

The GRINDCARE warranty will be void in the event of failure to comply with the following:

1. The device must not be subjected to jolts, knocks or other mechanical impacts.
2. The electric unit must not be immersed in any fluid and must be protected against moisture.
3. The device must be cleaned in accordance with the instructions. See the section on maintenance.
4. The performance of the device may be impaired if it is exposed to temperatures below 10°C (50°F) and above 40°C (104°F).
5. The device must not be dismantled.
6. Only the charger supplied may be used to charge the device.
7. Only the supplied battery may be recharged. If it needs replacing, return the device to the supplier.
8. During transportation, the device must be kept in the original packaging supplied, otherwise the warranty will be void.
9. If the device stops working as intended for any reason, the supplier must be contacted.

KEY TO SYMBOLS



Warning! Read the user manual before starting to use GRINDCARE.



Read the user manual before starting to use GRINDCARE.



There is wireless communication between the Stimulator and Grinddock which may affect patients with pacemakers or hearing aids. See the section on contraindications.



Type BF equipment

IP30

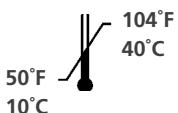
IP classification

CE 0482

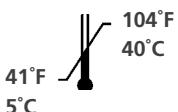
CE labelling, applicable in accordance with directive MDD 93/42/EEC.



The equipment must not be exposed to moisture.



Specification of general temperature range.



Specification of temperature range for gel pads.



Not for reuse



Expiry date (year and month).

SN

Serial number

LOT

Batch number

TECHNICAL SPECIFICATIONS

Output from the Stimulator

Current controlled, biphasic, charge-balanced pulses, up to 7 mA with voltage max ± 40 V. Pulse duration 250 μ s, frequency 230 Hz.

Classification

Type BF

Protection class

IP 30

EMG

Yes

Sample rate

2000 Hz

Input impedance

4.4 M Ω

CMRR

90 dB

Max. wireless range

2 m (6' 6") in a straight line

Length of electrode

Max. 50 cm (19")

Data memory capacity

30 days activation data

Charger

100 - 240 V AC, 50-60 Hz

Battery

3.7 V Lithium-Polymer battery

Average battery charge time

3.5 hours

Anticipated operating time between charges

5 days

Temperature during operation

10°C - 40°C

50°F - 104°F

Storage and transport temperature

10°C - 40°C

50°F - 104°F

Storage temperature, gel pads

5°C - 40°C

41°F - 104°F

Dimensions of the Stimulator

53.8 x 39.9 x 13.4 mm

2.12" x 1.57" x 0.53"

(W x H x D)

Dimensions of Grinddock

62 x 120.8 x 21 mm

2.44" x 4.76" x 0.83"

(W x H x D)

Weight of the Stimulator

27 g

0.9 oz.

Weight of Grinddock

200 g

7 oz.

Gel pad shelf life

See gel pad pack





Complaints

Complaints may be submitted in accordance with applicable legislation. An invoice/receipt showing the date of purchase must be submitted with any complaints. In the event of a complaint, the device must be returned to the place where it was purchased.

GC3 User Manual US

About Medotech

Medotech A/S is a Danish biotech company offering unique expertise in the field of development and design of medical equipment. Medotech's core expertise relates to the development of custom devices capable of recording and analysing signals from the human body.