

GRINDCARE ●)))



User Manual

GRINDCARE 3

UK

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INTRODUCTION

Before use

Before using your GRINDCARE for the first time, please read this User Manual carefully and keep it handy for future reference.

Application

GRINDCARE is a device intended for use by people who suffer from tooth grinding/clenching, also called bruxism. GRINDCARE can measure and treat bruxism.

For treatment, GRINDCARE emits a small electrical impulse – what is known as biofeedback. This impulse makes the jaw muscles relax and inhibits tooth grinding.

Before treatment, we recommend that you use GRINDCARE for three nights without biofeedback in order to measure how often you grind your teeth.

When starting treatment, you should use GRINDCARE every night. In the morning, you can check to see how often you have been grinding your teeth and how often GRINDCARE has emitted biofeedback. You can also register how much pain or tension you experience after waking.

After four to six weeks of treatment, you will be able to measure the preventive effect – and experience less grinding at night, and/or less pain or tension in the morning.

Now try skipping treatment with GRINDCARE for a week. If your grinding increases again, you should resume treatment with GRINDCARE. Your aim is to find out how frequently you need to use GRINDCARE to keep your bruxism down to a minimum.

If you are unsure as to whether you are using GRINDCARE correctly, contact your clinician or supplier.



GETTING STARTED

Get to know your GRINDCARE system

Before using GRINDCARE for the first time, insert the Stimulator into Grinddock – you'll feel how it snaps into place. This is called 'docking'. Now charge them both by connecting the charger to the socket on the back of the Grinddock and to an AC power outlet (see page 9).

Using Grinddock is easy – there are only three pushbuttons on the front and a display. Power it on by pressing the middle button briefly. The display lights up showing the "Treatment" icon, which is the first of three menus for operating and configuring GRINDCARE. The other two are "Data" and "Config".

Now look at the white bar across the top of the display. On the left, the time is displayed (if it's incorrect, see pages 9 and 16). The middle of the bar is empty, but this is where the quality of the electrode contact will be displayed, when connected (1-5 bars, just like the signal quality displayed on a mobile phone).

The right part of the bar displays symbols indicating battery status of Grinddock



and the Stimulator, and whether the Stimulator is powered on or docked.

Powering the Stimulator on and off

Power on the Stimulator by pressing its on/off button for 1 sec. A blue LED (on the back, bottom left corner) flashes once and stays on for a few sec. ('On' status is then indicated by a short blue

LED flash every 30 sec., and by the battery symbol on the Grinddock screen).



To power off, press the Stimulator on/off button for 3 sec. until the blue LED switches on, then release button immediately.

'Off' status can be checked on the Grinddock display (the Stimulator battery symbol disappears), please note that there can be a delay. The Stimulator will also turn off automatically if left unused or without electrode contact for 10 minutes.

! *Note that the symbol for the Stimulator in the Grinddock display varies according to whether the Stimulator is docked or not.*

Powering Grinddock on and off

Power Grinddock on by pressing the middle button briefly – the display lights up, and you can operate the device, check battery status, etc.



To power off, hold down the middle button until the display switches off.

Navigating GRINDCARE

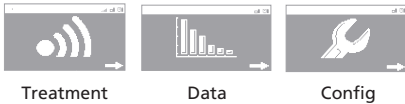
Navigation around the three GRINDCARE menus is easy.

The middle button allows you to make selections (OK, or enter).



The left and right arrow buttons allow you to scroll through the options.

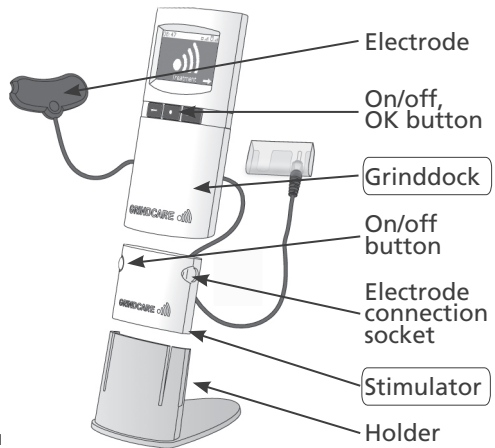
Pressing the right arrow button takes you to the next menu entry, while pressing the left arrow button takes you up one level.



Treatment

Data


Config



For example, press the middle button to start, then the right arrow button twice to display "Config". Now press the middle button once and then press the right arrow button until you display "Time/Date". Press the middle button and experiment with setting the time and date (see page 16).

Practice navigating around the different menus until you feel familiar and comfortable with GRINDCARE, then hold down the left arrow button to return to the start.

PREPARATION FOR USE

1. Switch on the Stimulator by pressing its on/off button for 1 sec. A blue LED (back, bottom left) flashes once and stays on for a few sec. 'On' status is then indicated by a short blue LED flash every 30 sec. and by the battery symbol on the Grinddock screen. 

2. Switch on the Grinddock by pressing the middle button. Check that both Grinddock and Stimulator are charged.

Make sure that there is contact between Grinddock and Stimulator.

3. Insert the electrode firmly into the Stimulator.
4. 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, so all the gel is on the electrode.

5. Place the electrode with the gel pad directly on the skin. The skin must be clean and dry. The electrode must be placed over the temporalis muscle on the temple. You can locate this by placing a couple of fingers on the flat part of your temple and biting down – you will feel the muscle bulging out.



6. 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.
7. Check that there is good contact with the skin. There should be a minimum of three bars visible in the electrode contact icon. The electrode must stick to the skin along its entire length so that all three terminals maintain good contact with the skin.
8. When the electrode is placed correctly, you can proceed with either measurement or treatment of your grinding, depending on your clinician's instructions. See detailed instructions in the next two sections.

StimCover

We recommend that you use the StimCover - especially if you are a restless sleeper. When mounted on the Stimulator, it prevents accidental switching off and ensures that the electrode clip cannot become detached during sleep.




1. Line up the StimCover as illustrated.



2. Mount the electrode clip on the Stimulator and, from above, thread the electrode and cable through the space on the right of the casing.



3. Insert the Stimulator into the StimCover and fit all sides of the rubber casing snugly into place. Ensure that the power symbol  is over the on/off button.

Time/Date



Before using GRINDCARE for the first time, make sure that the time and date (under "Config") are set correctly otherwise all measurements will be recorded with incorrect dates and times (see page 16).

Charging



Grinddock and the Stimulator must be charged at least once every five days, and it is recommended to charge them both together when not in use. Dock the

Stimulator in Grinddock and connect the charger to Grinddock. Place GRINDCARE in the holder for charging.

! *The Stimulator can only be charged when the electrode is disconnected.*

MEASURING HOW OFTEN YOU GRIND

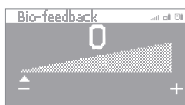
Before sleeping

Treatment



Before starting treatment, it's important to measure how often you actually grind your teeth during sleep. These 'zero biofeedback' sessions provide you with a basis for comparison of your tooth-grinding data before, during and after treatment with GRINDCARE. Select "Treatment" from the main menu.

Setting biofeedback



Use the left arrow button to set the biofeedback level to zero. Press the middle button (OK) to skip the test.

Press OK again to confirm your zero setting, and the next steps are to calibrate GRINDCARE to suit your grinding pattern.

Relax



Start by relaxing your facial muscles.

You will see an arrow on the right of the Grinddock display – when it disappears completely, you will proceed automatically.

Grind



Clench (do not grind) your teeth – especially the back teeth – in a good, firm bite (around 60% of your maximum bite strength). Repeat a couple of times until the arrow disappears.

Ready



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

Next morning

Carefully remove the electrode from your temple without pulling on the cable. Measurement will stop automatically. Press the Stimulator on/off button to establish wireless communication. The Stimulator battery symbol will reappear on the display after a brief delay.



Now select "Data" and the display will show "Log Tension" – assuming that Log Tension has been selected "on" under "Config." Rate the pain/tension you experienced on waking on the scale of 0 - 10.



Press the middle button to enter the value and next "Synchronizing" is displayed to indicate upload of data. This can take up to 30 sec. depending on the amount of data recorded.



Select "Last treatment" to view the results of your last treatment. Remember to remove the gel pad from the electrode – now while it is still soft and easy to detach.

! GRINDCARE must have recorded at least **one hour's data** for upload of data to be possible.

Possible error sources

These screens are displayed only if:



The Stimulator battery needs charging.



There is no contact with the Stimulator.



There is poor contact between the skin and the electrode.

REDUCING GRINDING/CLENCHING

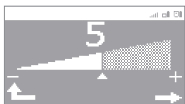
Before sleeping

Treatment



Start your treatment by selecting "Treatment" from the main menu.

Setting biofeedback



Select a biofeedback 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.

The next steps are to calibrate GRINDCARE to suit your grinding pattern.

Relax



Start by relaxing your facial muscles.
You will see an arrow on the right of the Grinddock display – when it disappears completely, you will proceed automatically.

Grind



Clench (do not grind) your teeth – especially the back teeth – in a good, firm bite (around 60% of your maximum bite strength). Repeat a couple of times until the arrow disappears.

Ready



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Next morning

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The Stimulator battery needs charging.



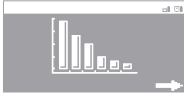
There is no contact with the Stimulator.



There is poor contact between the skin and the electrode.

DATA

Data



Select "Data" from the main menu to view the results of your measurement/treatment. Start by making sure there is contact between Grinddock and the Stimulator.

Tension/Pain



After every measurement/treatment, you should rate your sensation of facial tension/pain on a scale from 0 to 10. When "Log Tension" is displayed, 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 (see page 17).

Synchronizing



GRINDCARE transfers data from the Stimulator to Grinddock for viewing. Please note that data is not stored in Grinddock but in the Stimulator only.

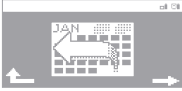
Last treatment



Select "Last treatment" to view the results of your last measurement/treatment, according to:

- How much you have been grinding your teeth in total (Grinds)
- How many hours your treatment lasted (Hours)
Remember that a minimum of one hour's data is required!
- How many times an hour you have been grinding your teeth (Grinds/Hour)
- Experienced tension/pain (Tension/Pain)

30 treatments



Select “30 treatments” to view the results of your last 30 treatments (measurements). Each column displays data for one treatment, according to:



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

! *Measurement data recorded using zero biofeedback level is saved in GRINDCARE just like all other sessions, although it is not possible to see which session used biofeedback and which did not. This information is, however, available to your clinician after the data has been transferred to a PC. For this reason, it is advisable to keep a record of zero biofeedback sessions by means of manual note-keeping, e.g. in a diary.*

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 biofeedback impulse.

Time/Date



Set the date and time using the arrow buttons. Approve each individual setting 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 treatment data. You will be asked to confirm this action so make sure you really want to delete the data collected.

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 0 to 10.

Signal Quality



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



TROUBLESHOOTING

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 biofeedback 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 treatment settings again and try to bite down harder. This allows you to set a higher threshold for when GRINDCARE is sending biofeedback.

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.

For further information, please see www.grindcare.com



UNPACKING GRINDCARE

All the components required for using GRINDCARE are supplied in a custom box containing:

- Grinddock
- Stimulator
- Charger
- Holder
- StimCover
- Electrode
- Safety cord
- Rubber clip
- Gel pads
- GRINDCARE 3 User Manual
- Quick Guide

When you unpack GRINDCARE for the first time, make sure that all these components are included. If anything is missing, please contact your clinician or supplier at once.

GRINDCARE COMPONENTS

The **Stimulator** is the central unit. It registers your grinding and sends bio-feedback through the electrode to your skin. All treatment data is saved here.

Grinddock is used to operate the Stimulator and display the results of your treatment with GRINDCARE. Communication between the two units is wireless. This wireless communication is terminated automatically while treatment is being given.

Grinddock is also used to charge the Stimulator and to transfer data from the Stimulator to your clinician's PC.

The **electrode**, with three contacts, is connected to the Stimulator and placed on the temporalis muscle (located on either temple). The electrode measures electrical EMG (electro-myographic) signals from the muscle, when it moves, and emits an electrical impulse which makes the muscle relax.

The electrode is connected to a combined cover and clip which can conveniently be attached to your nightclothes and ensures that the electrode cannot be inserted into any other socket.

A **safety cord**, which can be attached to the clip and hung around your neck.

Rubber clip, which is used to attach the cable from the electrode to the safety cord (see illustration on page 23).

Gel pads (x 30) are placed on the electrode to ensure contact between the electrode and skin. These can be found at the bottom of the GRINDCARE box.

A **charger**, which is connected to Grinddock for charging both Grinddock and the Stimulator.

A **holder**, for keeping Grinddock when not in use, when it is to be charged and when data is transferred to a PC.

StimCover, a rubber casing designed for use with the Stimulator – it prevents the Stimulator being detached or switched off during restless sleep.

A **Quick Guide** to using GRINDCARE, which you can keep handy near your bed.

This **User Manual**, which contains all the information you need for using GRINDCARE.

MAINTENANCE AND DISPOSAL

GRINDCARE unit

Wipe clean with a slightly damp cloth.

Electrode

The electrode must not be cleaned with cleaning fluids such as ethanol, propylalcohol or similar. Wipe the electrode down with water on a damp cloth.

Gel pads

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

Storage of gel pads

We recommend that you store the gel pads in a cool, dry place. 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.

Disposal



The authorities require electrical and electronic devices to be collected and parts of such devices to be recycled. Electrical and electronic devices bearing the following symbol must be handed in to a local authority recycling facility.

WEEE directive

The WEEE directive (Directive on Waste Electrical and Electronic Equipment), 2000/96/EC, has been adopted in order to ensure that products are recycled using the best processing, recovery and recycling techniques in order to safeguard human health and ensure a high degree of environmental protection. This product has been designed and produced using high quality materials and components that can be recycled.

Disposal options

- The product can be handed in to any local authority recycling facility or other collection point.
- The product can be returned to the supplier.

SAFETY



Patients with a pacemaker are not allowed to use GRINDCARE.

The following must be observed when using GRINDCARE

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

Some patients may 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.

The device must only be used for its original purpose, i.e. for the measurement and treatment of bruxism.

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

Mobile phones must not be placed closer than 50 cm (19") from GRINDCARE as they may affect its operation.

Do not position the charger so that it is difficult to remove from the AC power outlet.

When using GRINDCARE, avoid accidental contact between the gold contacts on the stimulator and other conductive articles, including those connected to protective earth, such as other electrical equipment.

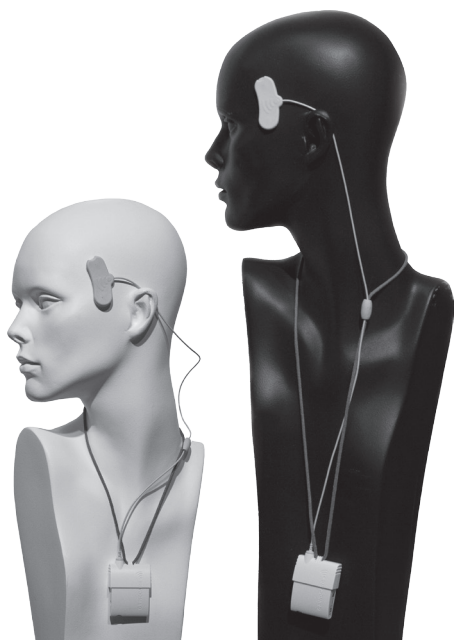


Battery warnings

Both Grinddock and the Stimulator contain a lithium polymer battery, which may get hot, explode or ignite and cause injury, if exposed to abuse. Be sure to follow the safety warnings listed below:

- Do not replace the battery yourself. If the battery needs replacement, return the device to your supplier.
- Do not place Grinddock or the Stimulator in or near fire, on stoves or in other high temperature locations. Do not place them in direct sunlight, or use or store them inside cars in hot weather. Doing so may cause the battery to generate heat, ignite or explode. It may also result in a loss of performance and reduced battery life.
- If the device is to be used by a young child, the caregiver should explain the contents of this document and provide adequate supervision to ensure the device is used appropriately.
- Immediately discontinue use of GRINDCARE if, while using, charging or storing Grinddock or the Stimulator, they emit an unusual smell, feel hot, change color or shape, or appear abnormal in any other way. Contact Medotech if any of these problems are observed.

- Do not place Grinddock or Stimulator in microwave ovens, high-pressure containers or on induction cookers.
- In the event of battery leak, exercise extreme precaution with the leakage. If the fluid should get in your eye, do not rub the eye. Rinse well with water and immediately seek medical care. If left untreated, the battery fluid could cause damage to the eye.



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

1. The device must not be subject to jolts, knocks or other mechanical impacts.
2. The electric unit must not be immersed in water or other fluids. The device must be protected against moisture.
3. The device must be cleaned in accordance with the instructions. See the section on maintenance (page 21).
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 used for charging. If the battery needs to be replaced, the device must be returned 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 under: Safety on page 22.



Type BF equipment.

IP30

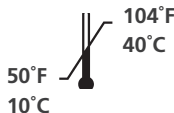
IP classification.



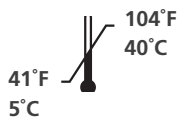
CE marking, applicable in accordance with directive MDD 93/42/EEC.



The equipment must not be exposed to moisture.



Specification of general temperature range.



Specification of temperature range for gel pads.



Not for reuse.



200x-xx

Expiry date (year and month).



Serial number.



Batch number.



WEEE symbol. See the section on maintenance and disposal (page 21).

TECHNICAL SPECIFICATIONS

Output from the Stimulator

Max. ± 40 V peak, symmetrical energy,
pulse duration 250 μ s, frequency 230
hz, current regulated, max. ± 7 mA
peak

Classification

Type BF

Protection class

IP 30

EMG

Yes

Sample rate

2000 Hz

Input impedance

4.4 MOhm

CMRR

90 dB

Wireless range

3 - 6 m (10' - 20')

RF transmitter

(Grinddock and Stimulator)

Transmission frequency: 2433 MHz
Modulation: MSK, 18 Kbit/s
Effective radiated power: 1mW

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

Maximum altitude for operating and storage

3,000m above sea level

Operating and storage humidity

5 - 85% relative humidity,
non-condensing

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.

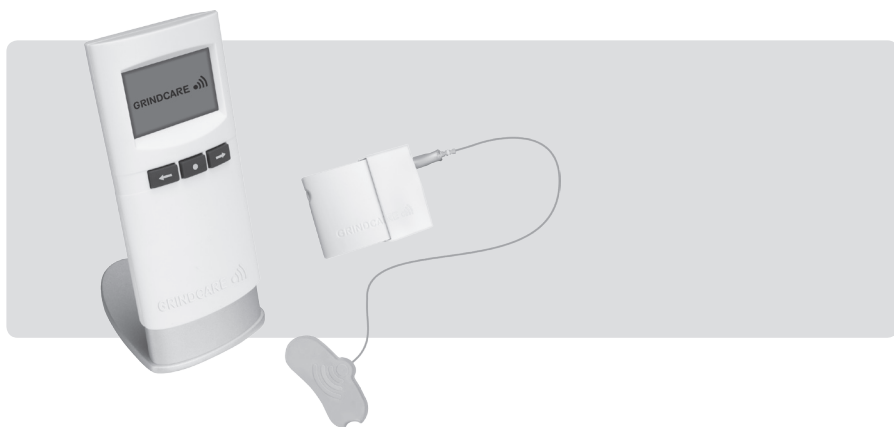
Weight of Grinddock

200 g
7 oz.

Gel pad shelf life

See label on the back of 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.

If you have any complaints or questions, please contact Medotech Customer Service at +45 8672 1500 or your supplier.

EC Declaration of conformity

GRINDCARE 3 Declaration of Conformity is available upon request at help@medotech.dk or your local distributor.

About Medotech

Medotech A/S is a Danish biotech company offering unique expertise in the development and design of electronic medical equipment. We aim to deliver relief to patients suffering from bruxism and to improve their quality of life.

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medotech