



USER MANUAL

REHALER™

MIGRAINE TREATMENT WITHOUT DRUGS

PLEASE READ THIS USER MANUAL CAREFULLY BEFORE USING REHALER

1. INTENDED USE OF THE DEVICE

Rehaler is a CE-approved medical device intended for treatment of patients suffering from acute migraine with aura. The accompanying control unit is intended to measure the oxygen level in your blood throughout the treatment. Before using Rehaler, it is important that you read the user manual for the control unit.

2. PRODUCT DESCRIPTION

The effect of Rehaler is achieved by increasing the level of CO₂ in the breathing air while ensuring that the user gets enough oxygen – no matter how long the treatment lasts. Rehaler ensures this by recycling a portion of the CO₂ that the body produces, mixed with fresh air in a precisely and individual measured ratio. The effect of Rehaler is increased if treatment is initiated before the migraine pain instigates. Therefore, Rehaler is primarily aimed at migraine patients who feel a migraine attack on its way before the pain develops properly.

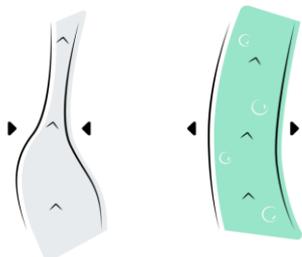


Figure 1. Increase of oxygen supply to the brain. By inhaling an increased mixture of CO₂ and oxygen, the supply of blood, oxygen, and blood sugar to the brain increases up to 70%. This counteracts the contraction of the blood vessels, which is often seen before and during migraine attacks, and is suspected of being the underlying cause of many attacks due to the oxygen deficiency in the brain that the contraction may cause.

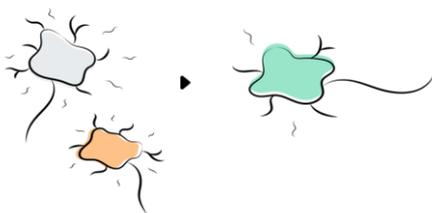


Figure 2. Reduction of the sensitivity and pain of the nervous system. Increased CO₂ level in the body decreases the pH level in the body, which reduces, and in some cases, removes the pain during migraine attacks.

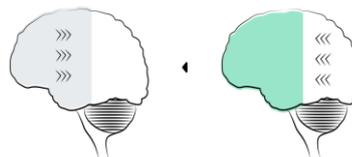


Figure 3. Terminates Cortical Spreading Depression (CSD). CSD is a slow, but very destructive wave that spreads through the brain and causes the pain, nausea, photosensitivity and loss of energy of the migraine attack. By changing the levels of oxygen and CO₂ in the body it is possible to slow down CSD and thereby reduce and, in many cases, stop the migraine attack.

3. SAFETY

3.1 Warnings and precautions

- ⚠ Rehaler is intended for use on patients suffering from migraine with aura, e.g. migraine attacks where disturbances such as visual, sensory, and speech disturbances, may occur within the last hours before the headache arises. If you are in doubt whether you are suffering from migraine with aura, please talk with your doctor.
- ⚠ Rehaler may not be used by children below the age of 18 years as there are no clinical data available on such patients.
- ⚠ Rehaler may not be used by pregnant or breastfeeding patients as there are no clinical data available on such patients.
- ⚠ Rehaler may not be used on an airplane at/or above 2000 meter over sea level.
- ⚠ Rehaler should always be used with the accompanying control unit. Black control units will give a visual information signal, and white control units will give an audible information signal if the oxygen level (%SpO₂) of the blood decrease below 90%. Before using Rehaler it is important that you read the user manual for the control unit.
- ⚠ Each Rehaler-inhaler is for single-use only. For hygiene reasons you should only use an inhaler within 12 hours from the time you opened the package. Do not use the inhaler if the seal is broken.

3.2 Do not use Rehaler if you suffer from any of these disorders or conditions

- ⚠ Pulmonary diseases (e.g. Chronic Obstructive Pulmonary Disease (COPD), pulmonary fibrosis, acute asthma, acute pneumonia or a bad cold).



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- ⚠** Cardiovascular disease (e.g. hypertension, heart attack, angina, heart failure, heart valve disorder, irregular heart arrhythmia or cardiomyopathy).
- ⚠** Anemia, i.e. low hemoglobin level in the blood.
- ⚠** Neuralgia/neuritis, epilepsy, intercranial hypertension, current or previous aneurysm in the brain, other brain- or nerve disease besides migraine, as well as patients previously operated in the brain (including stenting).

4. THE REHALER SYSTEM

Rehaler consist of four components:

- a) Rehaler-inhalers, for single-use, that you breathe through. The inhaler increases the level of CO₂ in your breathing air while ensuring that you get enough oxygen.
- b) A control unit (manufactured by Beijing Choice Electronic Technology Co., Ltd.), which measures the oxygen level of your blood.
- c) Rehaler-nose-clips, which ensures that you only breath through your mouth and the inhaler. Each inhaler package contains one nose-clip.
- d) Rehaler-app (requires iOS 9.0 or above, or Android Marshmallow 6.0 or above), which help you with the use of the device. The Rehaler-app can be downloaded from App Store and Google Play.

fresh air. **B3**: Valves. **B4**: Regulator (green). Used for adjustment of the inhaled CO₂, from level 1 (lowest CO₂ level) to level 7 (highest CO₂ level). Even if the regulator is set to level 7, you will still get enough oxygen through the valves – no matter how long you use the Rehaler.



Figure 6. Control unit with corresponding case and micro USB cable. (Wireless Fingertip Pulse Oximeter, manufactured by Beijing Choice Electronic Technology Co., Ltd. Room 4104, No. A12 Yuquan Road Haidian District, 100143 Beijing, P.R. China, EC|REP Shanghai International Holding Corp. GmbH (Europe), Eiffestrasse 80, 20537, Hamburg Germany. The control unit is automatically turned on when you place your finger inside. By using LED's, the control unit keeps track on your oxygen level (%SpO₂) in your body during treatment with the Rehaler.

The Rehaler System is displayed in Figure 4 to Figure 11.

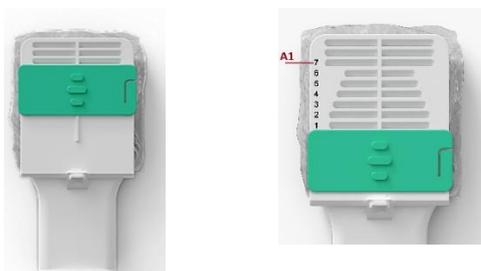


Figure 4. Folded Rehaler-inhaler. **A1**: Numbers (from 1 to 7) for adjustment of the regulator (green).



Figure 5. Unfolded inhaler. **B1**: Mouthpiece to keep between the teeth. **B2**: Cube, the squared bag where exhaled air is mixed with

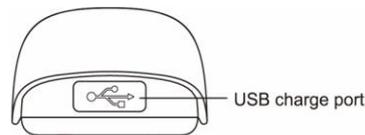


Figure 7. Close-up of USB charge port

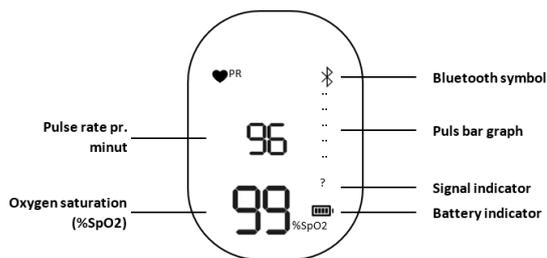


Figure 8. Display of black control unit. The control unit will give a visual information signal if the oxygen saturation (%SpO₂) of the blood falls below 90%.

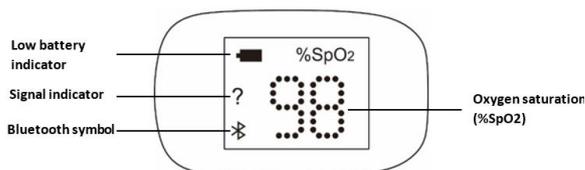


Figure 9. Display of white control unit. The control unit will give an audible information signal if the oxygen saturation (%SpO₂) of the blood falls below 90%.



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Figure 10. Smartphone or tablet with Rehaler-app. The Rehaler-app helps you to: a) use the equipment, b) find the optimal setting for the inhaler for you, c) provides you with a treatment plan, d) personalizes and gives advices for use of Rehaler. The Rehaler-app requires iOS 9.0+ or Android Marshmallow 6.0+. The Rehaler-app can be downloaded from App Store and Google Play.



Figure 11. Rehaler-nose-clip. It is not a requirement to have the nose-clip tight. It is just important to push the nostrils a bit together. Each inhaler package contains one nose-clip.

5. USER MANUAL

5.1 Preparation – Do this BEFORE you get a migraine attack

1. Follow the steps in the ‘get started’ leaflet that was included in your Rehaler Starter Kit.
2. Download the Rehaler-app and sign up.
3. Charge your control unit for minimum 1 hour.
4. Next, follow the instructions in the app for configuration of the device. **The configuration is required** and is an important part of the Rehaler system, as it helps finding the optimal setting of the inhaler. **It is important that you do not have migraine or suffers from any other illness during the configuration.** The configuration takes approximately 25 minutes, and we recommend that you do it in seated or lying position and in calm surroundings. We recommend that you configure your device as soon as possible so it is ready for your next migraine attack.
5. Following configuration, the Rehaler-app will supply you with a treatment plan, which are a range of personalized advices for when, how long, and on which regulator setting you should use Rehaler the next time you feel an attack on its way.

5.2 Treatment – Do this WHEN you feel an attack on its way

1. Find a Rehaler-inhaler and your control unit.

2. Find a place with calm surroundings and unpack and inflate the inhaler.
3. Open the Rehaler-app and press the button “Start treatment”.
4. You can then start treatment with or without a guide.
5. If you choose **not to have a guide**: you will proceed to a screen where you will be able to see your regulator setting and the number of minutes to use the device. Follow step a to i:
 - a. Ensure that bluetooth is on, on your smartphone or tablet.
 - b. Pull the plastic strip on the back of the cube so it unfolds.
 - c. Gently reposition by folding the mouthpiece together until the little white snap lock fixates in 25 degrees.
 - d. Take a deep breath and exhale through the mouthpiece of the inhaler.
 - e. Put on the nose-clip.
 - f. Put the control unit on your finger and connect by pressing the small icon in the lower corner of the screen saying “press to connect”.
 - g. When ready, start treatment by pressing play in the app.
 - h. Breath through the inhaler (using the specified regulator setting) through your whole aura phase, and minimum for 20 minutes. If your aura symptoms are longer than the 20 minutes, continue the treatment by pressing the five more minutes as many times as needed. Try to relax as much as possible during the treatment.
 - i. Next, decrease the regulator to level 1 and breath through the inhaler for additional 5 minutes.
6. If you choose **to have a guide**: you will proceed to video instructions that you need to follow. Subsequent the instructions, you will continue to a screen where you will be able to see your regulator setting and the minutes to use the device. Follow step 5a to 5i above.
7. If you did not get the desired effect after the treatment, you will have the opportunity to continue the treatment, until you obtain the wanted effect. We encourage you to contact customer support (support@rehaler.com), if you do not get an effect.
8. We recommend that you register your migraine attack several hours after treatment. Go to “Show treatment plan” and press “Register attack”. You will then go through a questionnaire. It is important



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that you register each attack and answer all questions, as your answers are used to update your treatment plan for future use. These tips are tailored to you in order to optimize your effect of Rehaler. Once you have answered all the questions, your treatment plan will be updated. Read the updated treatment plan now. Follow the treatment plan advice next time you feel a migraine attack on your way.

Remember to always have a Rehaler-inhaler package and a control unit on you when you leave home, so you can start a treatment as soon as you feel an attack on its way.

5.3 Troubleshooting and good advices for Rehaler

- **To get the best effect:** you should use Rehaler as soon as you feel an attack on its way. You can use Rehaler as often and for as long as you desire. Since migraine patients are very different, there is not one correct way to use Rehaler. You will obtain the best treatment by learning when to start your treatment and which regulator setting and time to use. The treatment plan in the app will help finding the best way for you to use Rehaler.
- **If you need to swallow or cough while using Rehaler:** take out the inhaler and possibly the nose-clip. Cough or swallow and then put on the nose-clip and the inhaler again. This does not influence the effect of the treatment, providing you don't inhale and exhale without the inhaler for a longer period, and if you remember to put on the nose-clip afterwards.
- **If you experience stronger side-effect during a treatment than during your configuration:** stop the treatment, adjust the regulator one level down (i.e. if the regulator was at level 4, adjust it to level 3), wait one minute, and then continue treatment. You may continue this until you reach level 1.
- **If your aura symptoms have not disappeared after using Rehaler:** continue the treatment until you feel your symptoms have disappeared.
- **If you feel worse as soon as you stop the Rehaler treatment:** set the regulator down to level 1 for the last five minutes of each treatment. This ensures that you gradually return to your normal CO₂ level.
- **If the oxygen percentage (% SpO₂) of the black control unit blinks continuously, or for the white control unit makes noise:** This is an information signal. Follow the instructions below 6.1 IF THE INFORMATION SIGNAL ACTIVATES in this manual.

6. CONTROL UNIT

The control unit turns on automatically when you insert your finger and is used to monitor the oxygen level (%SpO₂) in your

body during treatment with Rehaler. Black control units will give a visual information signal, and white control units an audible information signal, if your %SpO₂ value falls below 90%.

6.1 IF THE INFORMATION SIGNAL ACTIVATES

On black control units, the information signal is shown by the lower number/large number (%SpO₂) on the control unit display is flashing continuously. On white control units, the information signal is audible.

If the information signal is activated, do following:

1. Remove the nose-clip and the inhaler from the mouth and breathe normally.
2. Adjust the regulator one level down (i.e. if it is set to 4, adjust it to 3).
3. Wait 1 minute.
4. Put back the nose-clip and the inhaler.
5. Continue the treatment.

You may continue this until you reach level 1. If the information signal continuous, even though the regulator is set to level 1: Contact us by e-mail support@rehaler.com, so we can help with troubleshooting.

6.2 Inaccurate measurement may be caused by

- Significant levels of dysfunctional hemoglobin.
- Intravascular dyes such as indocyanine green or methylene blue.
- High ambient light. Shield the sensor area if necessary.
- Excessive movement.
- High-frequency electrosurgical interference and defibrillators.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Fingernail polish or false fingernails.
- Weak pulse quality (low perfusion).
- Low hemoglobin.

6.3 Possible errors and solutions

Error	Passable cause	Solution
%SpO ₂ or pulse is not displayed	<ol style="list-style-type: none"> 1. Your finger is not correctly inserted. 2. Your oxygen level is too low, and this cannot be measured. 	<ol style="list-style-type: none"> 1. Try again and insert your finger correctly. 2. Try multiple times. If you are sure that nothing is wrong, contact us at support@rehaler.com.
%SpO ₂ or pulse is unstable.	<ol style="list-style-type: none"> 1. Your finger is not inserted deep enough. 2. Your finger is shaking, or you are moving. 	<ol style="list-style-type: none"> 1. Try again and insert your finger correctly. 2. Try not to move.
The control nit cannot be turned on	<ol style="list-style-type: none"> 1. The battery is discharged. 2. The control unit is damaged. 	<ol style="list-style-type: none"> 1. Charge the control unit. 2. Contact us at support@rehaler.com.



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The display disappears	1. Turns off and restarts every 8. second. 2. Low battery.	1. This is normal for some black control units. 2. Charge the control unit.
"ea7" appears on the display	1. Low battery. 2. There is a malfunction in the control unit.	1. Charge the control unit. 2. Contact us support@rehaler.com .

If you experience other problems with the control unit, contact us via email support@rehaler.com and describe your problem. We will contact you as soon as possible to try and resolve the issue.

6.4 Battery charge

Black control units: The battery indicator symbol on the front panel display will flash continuously when the battery voltage is too low. Please charge the battery for minimum 1 hour when indicator symbol flash.

White control units: The battery indicator symbol on the front panel display will only appear when the battery voltage is too low. Please charge the battery for minimum 1 hour when the indicator symbol appears.

If you experience other problems with the control unit, contact us via email support@rehaler.com and describe your problem. We will contact you as soon as possible to try and resolve the issue.

7. IF THE TREATMENT DID NOT WORK

The Rehaler-app will continuously supply you with advices in order to give you the best treatment. The most important advices for Rehaler are:

- Rehaler should be used early in the course of an attack and before the headache starts. Therefore, learn how to interpret any signals about an upcoming attack so you can treat well in advance.
- Use Rehaler for at least twenty minutes, preferably longer, and possibly, repeatedly. Each inhaler can be used up to 12 hours.

8. SIDE EFFECTS

8.1 Common

Deep breathing, a feeling of being a little warmer or colder, increased sweating, mouthwatering, light shortness of breath, light dizziness.

11. SYMBOL DEFINITIONS

The following symbols are used on Rehaler (packaging material, labels and instructions) *:

Symbol Description

Symbol Description

These side effects are harmless and a completely natural response to the treatment. The side effects disappear within minutes after the end of treatment.

8.2 Rare

Strong shortness of breath, nausea, dizziness, turmoil, anxiety, headache (which is not due to the migraine).

These rare side effects may occur for especially new Rehaler users. The Rehaler-app's configuration procedure helps you find the optimal setting for you, that does not give you any of these rare side effects. If any of these side effects occur, do the following:

1. Remove the nose clip and the inhaler from the mouth and breathe normally.
2. Adjust the regulator one level down (i.e. if it was on level 4, adjust to level 3).
3. Wait one minute.
4. Put back on the nose-clip and the inhaler and then continue the treatment.

If the side effects are not reduced, the regulator can be adjusted to a lower position as described above. If side effects get worse, stop using Rehaler and contact us at support@rehaler.com.

9. STORAGE

- Each Rehaler-inhaler is for single-use only. For hygiene reasons you should only use an inhaler within 12 hours from the time you opened the package. Do not use the inhaler if the seal is broken.
- Rehaler should be kept out of reach of children.
- Rehaler should be stored in a dark and dry place at 0°C to 50°C.
- Do not leave Rehaler out in the sun for a long period of time.
- Do not use Rehaler after the expiry date stated on the package.

10. DISPOSAL

- DO NOT dispose used Rehaler-inhalers in the toilet. They should be disposed in the waste bin with household waste.
- DO NOT dispose the control unit in household waste. It should be disposed in the waste for electrical and electronic equipment.



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Manufacturer

Indicates the name and address of the manufacturer.



Catalogue number

Indicates the manufacturer's catalogue number so that the medical device can be identified.



Batch code

Indicates the manufacturer's batch code so that the batch or lot can be identified.



Temperature limit

Indicates the temperature limits to which the medical device can be safely exposed.



Keep away from sunlight

Indicates a medical device that needs protection from light.



Do not use on airplane

Indicates that the medical device is not to be used on an airplane.



Plastic type Polyethylene terephthalate.



Consult instructions for use

Indicates the need for the user to consult the instructions for use.



Caution

Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.



Use-by date

Indicates the date after which the medical device is not to be used.



Do not re-use

Indicates a medical device that is intended for one use.



Do not dispose in the toilet

Indicates that the product should not be flushed in the toilet.



Plastic Type Acrylonitrile Butadiene Styrene



Plastic type low density polyethylene

The symbol definitions for the control units are found in the corresponding user manual. * The illustrations used in this manual may differ slightly from the appearance of the actual product.

12. REPORTING AND CONTACT

Contact BalancAir if:

- You experience other side effects than described in this manual or you have been injured when using Rehaler.
- Rehaler does not work or one of the parts breaks, including the control unit.

Address: BalancAir ApS, Diplomvej 381, 2800 Kongens Lyngby, Denmark.

E-mail: support@rehaler.com

13. CHANGES

Following is revised in this version of the user manual:

- Editorial updates,
- Section 3.2. Do not use Rehaler if you suffer from any of these disorders or conditions,
- Addition of white control unit.



BalancAir ApS hereby declares that this device meets all requirements and relevant rules of Class I medical devices according to the EU Medical Device Directive 93/42/EEC.
Patent pending WO2011044914A1