POWER® breathe K SERIES

The world's 1st digital, hand-held respiratory muscle training, assessment and monitoring device

User Manual English

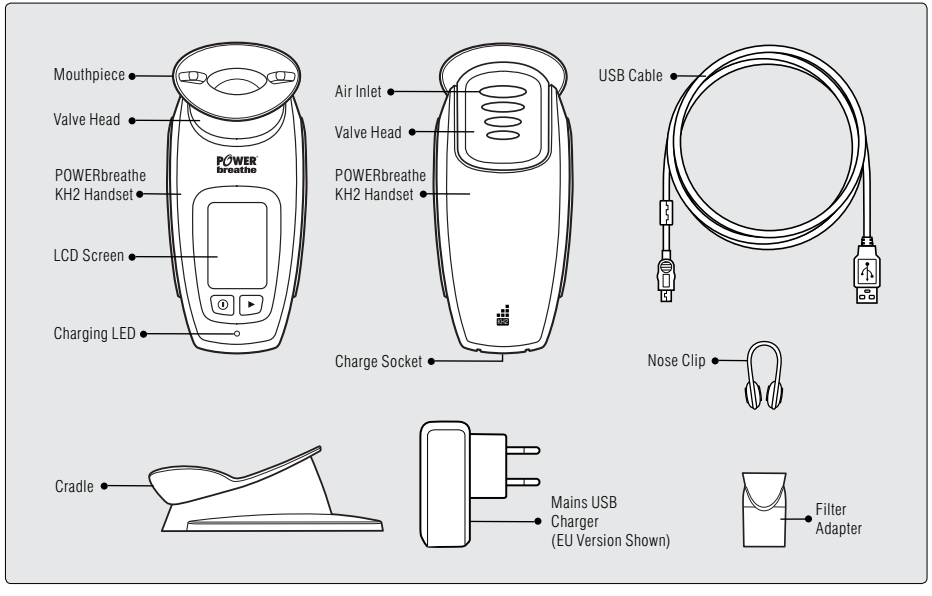
BREATHELINK™ MEDIC · LIVE FEEDBACK SOFTWARE

KH2

Large text version available at www.powerbreathe.com

Contents

1. Product Description



2. Introduction

The POWERbreathe KH2 is an electronic inspiratory-muscle training device. It is intended for use by healthcare professionals for inspiratory muscle training and assessment in patients with dyspnoea (breathlessness), including patients with asthma, COPD, bronchitis, cystic fibrosis, emphysema, heart disease, neuromuscular disease, Parkinson's disease and spinal injury*. The POWERbreathe KH2 is suitable for use with disposable filters or for single patient use at home under medical supervision.

The POWERbreathe KH2 uses an electronically controlled, rapid-response valve to create a resistance to inhalation. Training against this resistance causes the inspiratory muscles to adapt, becoming stronger and more resistant to fatigue. This leads to reduced breathlessness and improved exercise tolerance and quality of life. As the patient breathes through the POWERbreathe KH2 you will notice that they gradually have to work harder to breathe in. This is the effect of resistance training acting on the inspiratory muscles (primarily the diaphragm and intercostal muscles). When breathing out, there is no resistance and the patient should breathe out normally, allowing the chest and breathing muscles to relax, naturally pushing the air from their lungs.

The POWERbreathe KH2 training resistance is specifically designed to match the dynamic changes in breathing muscle strength throughout the breath and can automatically adapt to increases in inspiratory muscle strength at the beginning of each training session. Results are displayed on screen following a training or assessment session, or can be viewed in real-time using the Breathe-Link Medic PC software supplied. Parameters displayed include Maximal Inspiratory Pressure (cmH_2O, highest 1 second average), Peak Inspiratory Flow (L/s), Training load (cmH_2O), Average Power (Watts), Average inhaled volume (L) and Energy (Joules).

The POWERbreathe KH2 training regime of 30 breaths, twice a day typically takes only a few minutes a day and, used properly, you should start to observe the benefits within just a few weeks.

Please read all the information in this manual before using the POWERbreathe KH2.

Please see 'Section 3. Precautions' for contraindications

3. Precautions

POWERbreathe K-Series is suitable for almost anyone and will cause no harmful side effects when used properly. Please read the following precautions to ensure that you use the POWERbreathe K-Series safely and appropriately.

Contraindications:
Inspiratory muscle training, such as training with POWERbreathe K-Series, creates a negative pressure inside the chest, throat, ears and sinuses. POWERbreathe is not suitable for patients with the following conditions:

- A history of spontaneous pneumothorax (a collapsed lung that was not due to traumatic injury e.g. broken rib) as it may lead to a recurrence of the condition
- A collapsed lung due to a traumatic injury that has not healed fully.
- A burst eardrum that has not healed fully, or any other condition of the eardrum
- Asthma patients who have low symptom perception and suffer from frequent severe exacerbations
- Patients with marked elevated left ventricular end-diastolic volume and pressure
- Patients with worsening heart failure signs and symptoms after RMT / IMT

Additionally, the following conditions have been highlighted to require guidance from a medical professional, before use of the POWERbreathe K-Series devices:

- Pulmonary hypertension
- Large bullae on chest x-ray
- Marked osteoporosis with history of rib fractures
- Desaturation during or following IMT (<94%)

Intended Use:

- POWERbreathe K-Series is designed for exercising the inspiratory muscles only. No other use is intended or implied
- This product is not intended to diagnose, monitor, treat, cure or prevent any disease
- POWERbreathe K-Series is not intended for use by persons with reduced physical, sensory or mental capabilities, unless they have been given supervision or instruction concerning use of the appliance by a person responsible for their safety
- Anyone who is under the age of 16 should only use POWERbreathe K-Series with supervision from an adult
- POWERbreathe K-Series contains small parts and is not suitable for children under 7 years

Caution (information for patients):

- If the patient feels light headed or dizzy whilst training with POWERbreathe, they should slow down their rate of breathing or pause until they have fully recovered
- We recommend that the POWERbreathe K-Series should not be used whilst suffering from a cold, sinusitis or respiratory tract infection, until symptoms have disappeared
- Some users may experience slight ear discomfort when training with POWERbreathe K-Series, especially if they are recovering from a cold. This is caused by inadequate equalisation of pressure between the mouth and ears. If these symptoms persist then the patient should consult their doctor
- To prevent the potential transmission of infections, we recommend that patients do not share the POWERbreathe K-Series mouthpiece or valve head with other users, including family members
- Patients with a pacemaker or other medical implant containing magnets or electronics should consult their doctor before using this product
- Do not use POWERbreathe K-Series whilst taking part in other activities such as whilst walking, running and driving
- POWERbreathe is manufactured in a hygienic environment. However, POWERbreathe is not provided sterile – we recommend that the mouthpiece be cleaned prior to use
- Whilst training with the POWERbreathe K-Series the patient should feel resistance when inhaling but it should not be painful. If the patient should feel pain whilst using the POWERbreathe K-Series, they should stop immediately and consult their doctor
- Patients should not make changes to any prescribed medication or prescribed treatment programme without consulting their doctor

Patients should consult their doctor if they have any doubts about the suitability of POWERbreathe, or have a medical condition.

Danger:

- Only use the mains adapter supplied (DCH3-050UK/EU/US/AU-0004)
- The adapter contains a transformer. Do not cut off the adapter to replace it with another plug as this causes a hazardous situation
- The adapter transforms the mains voltage (100-240Volts) to a safe voltage (5V)
- Make sure the adapter does not get wet
- Do not use a damaged adapter
- Always unplug your POWERbreathe before cleaning

Electromagnetic Fields (EMF):
POWERbreathe K-Series complies with medical standards regarding electromagnetic fields (EN 60601-1-2). If handled properly and according to the instructions in this user manual, the appliance is safe to use.

Handling:

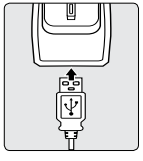
- Do not drop, disassemble, open, crush, bend, deform, puncture, shred, microwave, incinerate, paint or insert foreign objects into the POWERbreathe K-Series
- The POWERbreathe K-Series Valve Head is designed for regular cleaning (see section 11.1) in order to maintain hygiene and correct operation. However, the POWERbreathe K-Series handset is not waterproof and should not be submerged or exposed to liquids

If you suspect a defect has occurred, please contact your local customer service centre using the details listed in Section 17.

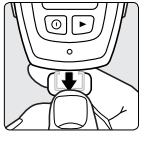
4. Basics

4.1 Charging

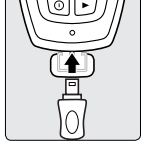
Remove the POWERbreathe K-Series and power adapter from the packaging. For portable use, recharge the POWERbreathe KH2 fully by following the instructions below. Alternatively, the POWERbreathe KH2 may be used whilst connected to the mains using the power/charge adapter provided.



1. Plug the USB cable into the adapter and then plug the adapter into a suitable wall socket.



2. Pull out the charging socket cover from the base of the unit.

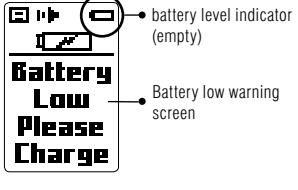


3. Plug the other end of the USB cable into the base of the unit. The charging LED light will switch on to indicate that the device is charging.

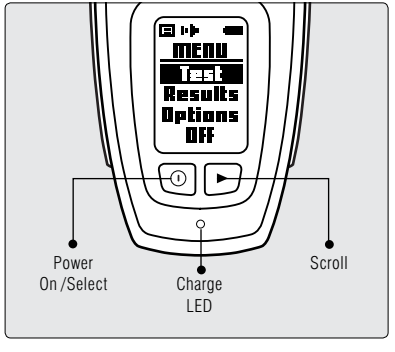
4. Once the charging LED light has switched off (up to 16 hours), remove the power adapter from the wall socket and from the base of the unit. Now replace the charging socket cover in the base of the unit. Your POWERbreathe KH2 is now ready for portable use.

POWERbreathe KH2 may also be charged from a PC or laptop using the USB to mini-USB adapter cable provided.

Battery low warning:
Recharge the battery again when the battery level indicator shows empty or when the battery low warning screen is displayed.



4.2 Buttons and Display Symbols



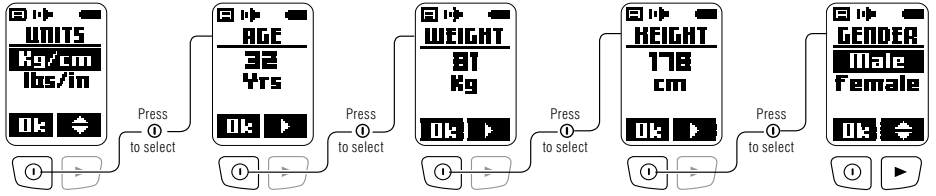
To switch on your POWERbreathe KH2, press and hold the ⏻ button for 1 second or more. To turn off your POWERbreathe KH2 scroll to the OFF option under the MENU screen using the ▶ button and select by pressing the ⏻ button. Alternatively, the POWERbreathe KH2 will switch off automatically after 5 minutes of not being used.

Display symbols:

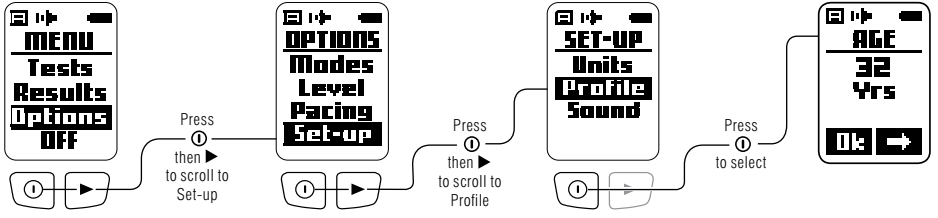
- Automatic load Set-up
- Manual load Set-up
- Button Sound On
- Button Sound Off
- Battery Fully Charged
- Battery Empty
- Mains Power Connected
- Number of breaths remaining in current breathing session

4.3 Entering Patient Information

Each time you turn-on the POWERbreathe KH2 you will be prompted to enter the units of measurement (**UNITS**), and patient age (**AGE**), weight (**WEIGHT**), height (**HEIGHT**) and gender (**GENDER**). Use the ▶ button to scroll values, then select using the ⓘ button.
This information will be used in order to provide feedback on inspiratory muscle assessment results (See Section 8.2).



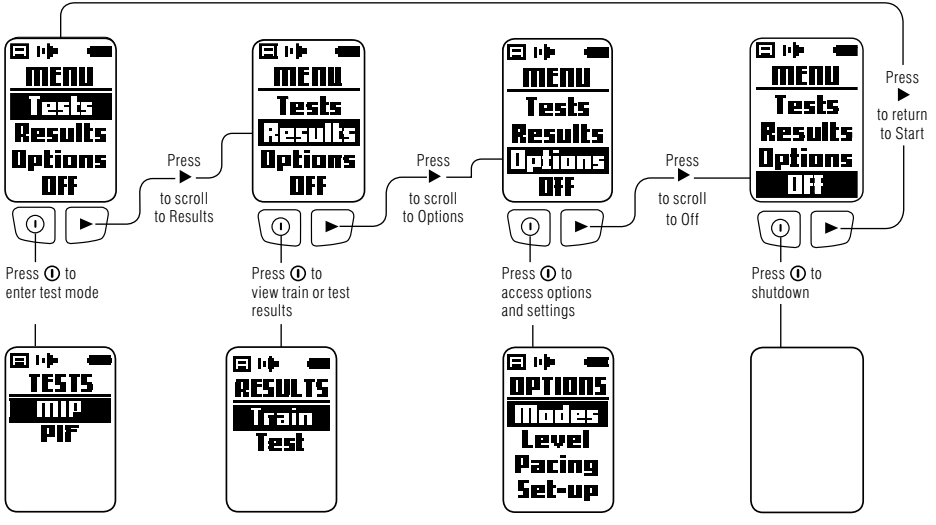
This information can be edited at any time by selecting **Profile** under the **Set-up** menu.



Note: if you wish to change the units of measurement for profile information, then select the **Units** *option under the* **Set-up** *menu then choose from* **Kg/cm** *or* **lbs/in**. *This will not affect the units of measurement used for the results display.*

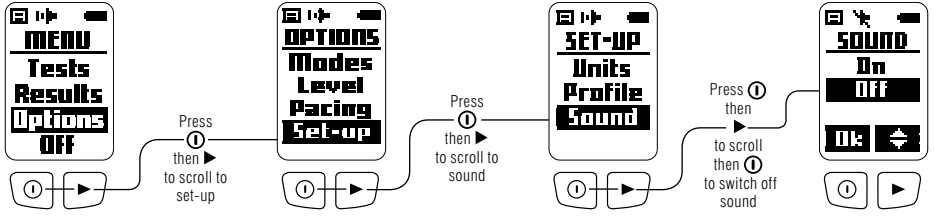
4.4 Menu System

POWERbreathe KH2 uses an LCD menu system to navigate between different settings and to view training results. Use the ▶ button to move between different options and use the ⓘ button to select the highlighted option. Scroll past the last option within a screen using the ▶ button in order to return to the previous screen.



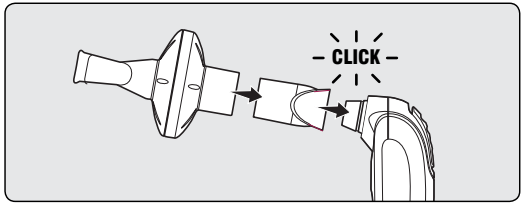
4.5 Disabling Button Sounds

Button sounds may be disabled by navigating to the **SOUND** screen and selecting **OFF** by following the button sequence below:



4.6 Antibacterial Filter Attachment

The POWERbreathe KH2 is provided with a filter adapter, which allows the device to be used with disposable bacterial/viral filters for multi-patient use. The filter adapter converts the POWERbreathe KH2 mouthpiece connector to a standard 22mm male connector interface. This may then be connected to POWERbreathe 'TrySafe' filters or other standard respiratory filters with a 22mm female connector.



5. Before Training

Contraindications: Please read Section 3: Precautions in order to assess a patient's suitability for inspiratory muscle training

5.1 Training Load

The POWERbreathe KH2 provides a resistance to inhalation that varies in relation to the volume of air inhaled during a breath. Training resistance is greatest at the start of inhalation (at RV - residual volume) and gradually reduces to near zero at the end of inhalation (at TLC - total lung capacity). This resistance is designed to match the length-tension relationship of the inspiratory muscles, providing a constant relative training intensity at all lung volumes. This method of training ensures optimum training stimulus across the full range of inspiratory muscle movement.

Training load is gradually introduced over the first five breaths of a training session. The first two breaths are unloaded. During these breaths, inhaled volume and flow are measured and used to set an appropriate training load. Loading is then gradually introduced during breaths three and four until full loading is achieved for breath five and onwards.

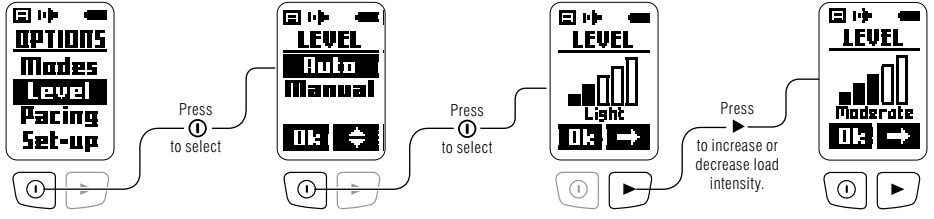
Training load is adjustable and must be set to a level appropriate for the patient in order to train the inspiratory muscles effectively. Research has shown that inspiratory muscle training loads must exceed 30% of the patient's maximal inspiratory muscle pressure (strength) in order to be effective. There is also evidence that heavier loads yield greater improvements in inspiratory muscle strength. For the best training results, the patient should train at a level at which they feel they can only just complete the full session of 30 breaths. Training should feel hard – the more effort that is put into training, the better the results that will be achieved. The POWERbreathe KH2 is equipped with two different methods for setting load: automatic (**Auto**) and user specified (**Manual**) set-up methods (see Section 5.2 and 5.3).

5.2 Automatic Set-up

By default, the POWERbreathe KH2 is set in the automatic set-up mode (indicated by the symbol). When automatic set-up is selected, the device will automatically estimate the patient's training requirements at the beginning of every training session. Training load is calculated using the peak inspiratory flow and the maximum inhaled volume from the first two breaths of the training session and is based on the typical force-velocity relationship of the inspiratory muscles. During these first two 'set-up' breaths there is no load and the patient should inhale as **quickly** and as **fully** as possible to ensure that the POWERbreathe KH2 can measure their maximum capability and set the load appropriately – see 'Section 6.3 Coaching Breathing Technique'.

Adjusting training intensity

The automatic load set-up feature provides an estimated optimum training resistance. However, patients will have differing inspiratory muscle characteristics and exercise intensity tolerance. When using the automatic set-up mode, you may find that the training load intensity is too high or too low, making it too hard or too easy for the patient to inhale through the device. To adjust the load intensity, navigate to the **LEVEL** screen by following the sequence below. Use the ▶ button to increase or decrease the load intensity to an appropriate level.

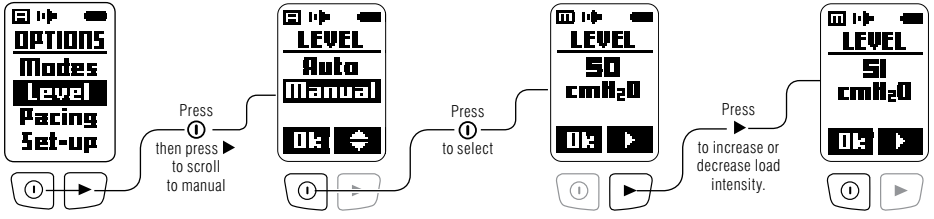


5.3 Manual Set-up

Manual set-up mode allows you to set the training load yourself and to adjust this load manually as the patient's breathing muscles become stronger or as you feel necessary in order to maintain training intensity. This method gives greater control of training load.

Adjusting training intensity

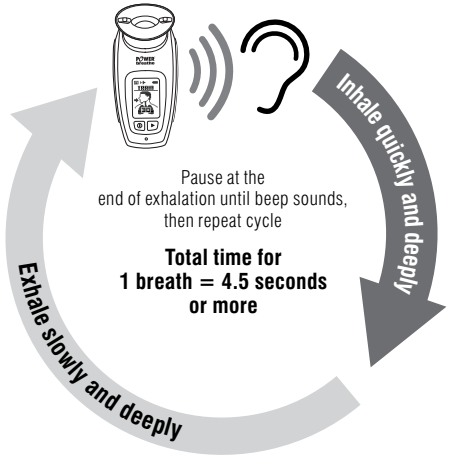
Once you have selected manual set-up mode you will need to enter the load at which the patient will train. In order to do this, navigate to the **LEVEL** screen by following the sequence below. Increase the training load by pressing the ▶ button (press and hold to scroll rapidly, scroll past the maximum of 200cmH_2O to start again).



As a guideline, for optimum training results manual training load should be set at approximately 50 to 70% of a patient's maximum inspiratory pressure result (MIP, see Section 8.1). It may take some time for the patient to become accustomed to training at this intensity. If the patient is unable to successfully complete 30 breaths at this intensity, try reducing the load setting to as low as 30-40% of MIP until the patient becomes used to the training.

5.4 Breathing Pacing

This feature is for guidance only. If the patient feels dizzy or light-headed, they should slow down their breathing or stop and take a break.



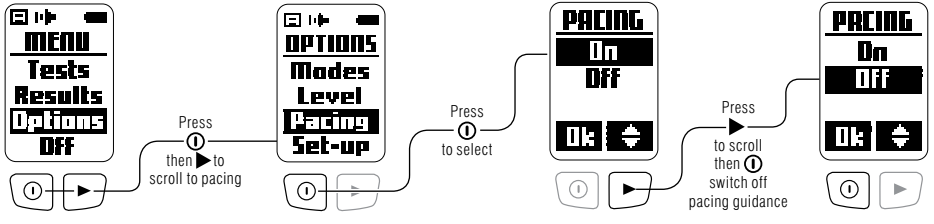
POWERbreathe is equipped with an adaptive pacing guidance feature, which is intended to guide the user to breathe at an appropriate rate (see also Section 6.3). This is important in order to prevent dizziness due to hyperventilation during the breathing exercises.

Whilst breathing through the POWERbreathe during a training session, you will hear an audible beep, which sounds a minimum of 4.5 seconds after the patient starts to inhale. The patient should try to only start their next inhalation once they have heard this beep. The beep will not sound during inhalation or exhalation, only once they have completed their breath.

If they have taken longer than 4.5 seconds to complete a full breath, then the beep will sound as soon as they have finished breathing out. In this instance they can begin to breathe in again immediately. If they have taken less than 4.5 seconds to complete their breath, they should pause, holding their breath until they hear the beep, or until they feel the urge to breathe again, then begin to inhale. If the patient chooses to breathe faster than 4.5 seconds per breath, then they will not hear the pacing beep. Encourage the patient to breathe in as **quickly** and as **deeply** as possible, but to breathe out **slowly** and **deeply** so that the time between inhalations is long.

5.5 Disabling Pacing Guidance:

If you prefer to guide the patient's breathing yourself, or are happy that they can regulate their own breathing patterns during a training session, you may wish to disable the pacing guidance feature. In order to do this, navigate to the **PACING** screen and select **OFF** by following the button sequence below:



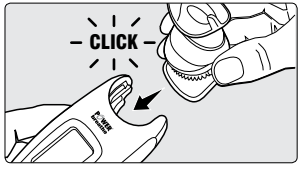
6. Training

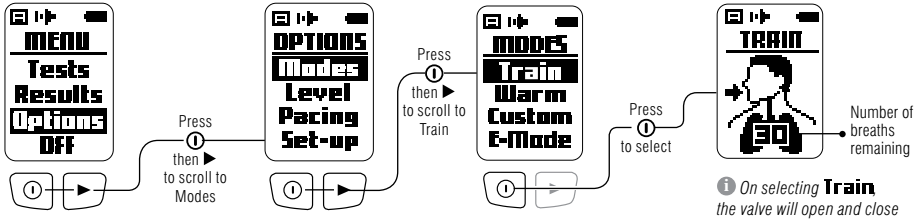
The POWERbreathe KH2 creates a resistance to inhalation in order to train the inspiratory muscles. This resistance strengthens the inspiratory muscles by making them work harder, in much the same way as weights might be used to increase strength of other skeletal muscles. By training these muscles, breathlessness will be reduced, improving exercise tolerance and enhancing quality of life. The recommended POWERbreathe training routine consists of 30 breaths, twice a day (once in the morning and once in the evening). This adds up to about 5 minutes of training per day. Please follow steps 6.1 to 6.3 below to guide you through a training session.

We advise all healthcare professionals who are instructing patients in the correct use the POWERbreathe KH2 to familiarise themselves with the sensation of using the device before instructing patients.

6.1 Starting a Training Session

Before commencing training, please ensure that all equipment that will come into contact with the patient is sterile and/or protected by a disposable bacterial/viral filter (see Section 4.6). To start a training session, check that the Valve Head is securely in position, then select **Train** from the **Options** menu.





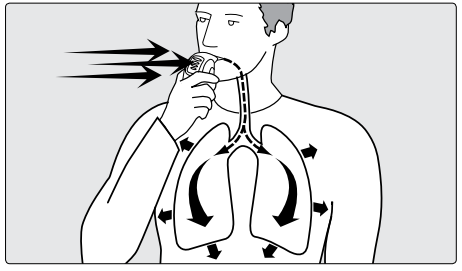
On selecting **Train**, *the valve will open and close to reset the valve position.*

6.2 Holding the Device Correctly

The patient should be relaxed and standing or sitting upright. Instruct the patient to hold the device with their hand cupped around the lower rear section of the device, with their fingers and thumb on the coloured rubber grips. Make sure that the air inlet is not obstructed. Now instruct them to place the device in their mouth so that their lips cover the outer shield to make a seal and the mouthpiece bite blocks are gripped between their upper and lower teeth (if using a bacterial filter, ensure that the patient uses their lips to form an airtight seal with the filter opening).

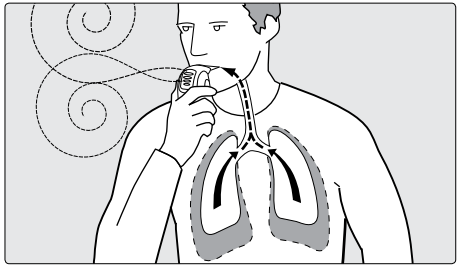
6.3 Coaching Good Breathing Technique

Correct breathing technique is essential to ensuring effective training. Please follow the guidelines below to guide the patient in the correct breathing technique.



1. Instruct the patient to breathe out as far as they can, then to take a fast, forceful breath in through the mouthpiece. They should take in as much air as they can, as quickly as they can, straightening their back and expanding their chest as they inhale.

Inhalation is the portion of breathing during which training occurs. It is important to follow this breathing technique in order to elicit training improvements.

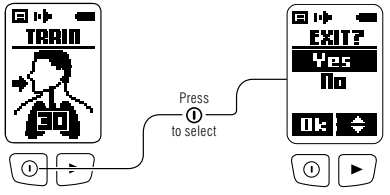


2. Now instruct the patient to breathe out slowly and passively through their mouth until their lungs feel completely empty, letting the muscles in their chest and shoulders relax. The patient should then pause until they hear the pacing beep [see Section 5.4: Pacing Breathing] or until they feel the urge to breathe in again. If it makes them feel more comfortable they can remove the unit from their mouth in order to breathe out, then return it to their mouth before they breathe in again.

It is important to breathe out slowly in order to prevent dizziness due to hyperventilation. If the patient starts to feel light headed, they should slow down or take a break.

The patient should try to complete 30 breaths using the breathing method described. The first two breaths will feel easy, but as they continue to breathe in and out through the device they will find it gradually becomes harder to breathe in. This is the effect of the training resistance being gradually introduced until full resistance is reached at the fifth breath.

The breathing exercises may take some getting used to and the patient may need to pause for a short rest. To resume the training session, they should simply return the device to their mouth and start breathing again. To exit a training session, press ⓘ then select Yes by pressing the ⓘ button again. Once the patient has completed 30 breaths, the POWERbreathe KH2 will beep to indicate the end of the session and the valve will open.



Breathing against the training load should be challenging, but not painful. In order to achieve the maximum training benefits, it is important that this load is set at a level appropriate for the patient (see Section 5.1). It is also important to use the correct breathing technique in order to maximise the training effect and to prevent dizziness due to hyperventilation.

6.4 Using the Nose-clip

POWERbreathe is provided with a nose-clip to help prevent inhalation through the nose. However, it is not essential and some people find it more comfortable to train without the nose-clip, or to pinch their nose.

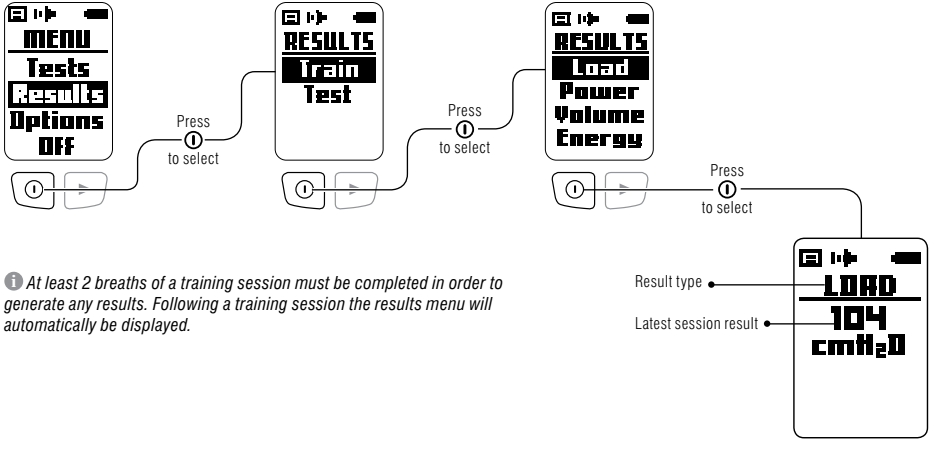
6.5 Maintenance Training

After four to six weeks of training for 30 breaths, twice a day, inspiratory muscle strength should have improved substantially and the patient should feel less breathless during activity (see Section 14). At this stage they will not need to use the POWERbreathe KH2 every day to maintain improved breathing. Using the POWERbreathe KH2 twice every other day will be sufficient to maintain the training benefits.

7. After Training

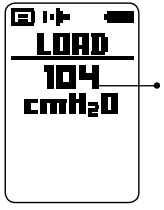
7.1 Viewing Training Results

The POWERbreathe KH2 Results system provides feedback on respiratory training sessions. Using these results you can monitor a patient's training progress. To view training results, select **Train** from the **RESULTS** menu then select from **Load**, **Power**, **Volume** or **Energy**.



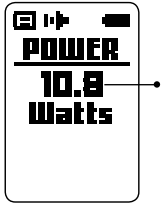
At least 2 breaths of a training session must be completed in order to generate any results. Following a training session the results menu will automatically be displayed.

7.2 About the Training Results



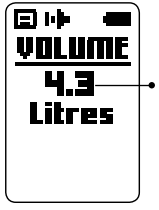
LOAD (LOAD) is a measure of resistance to inhalation, and represents the pressure generated in the airways due to the force of the inspiratory muscles during a training session. As the training load decays with increasing lung volume (in order to match the length tension characteristics of the inspiratory muscles), the load displayed corresponds to the resistance at the start of inhalation (i.e. at RV). A higher load result means that the patient is training their inspiratory muscles harder, leading to stronger muscles. Stronger inspiratory muscles will need to work less hard to cope with the demands of breathing, leading to reduced breathlessness.

When training using the automatic set-up method, the load displayed is based upon estimated inspiratory muscle strength. This is measured each time a new training session is completed and should reflect improvements in inspiratory muscle strength. When using the manual set-up method, load displayed is the same as the level entered. In this case, load displayed will track the increases in load that you manually enter via the level setting screen.



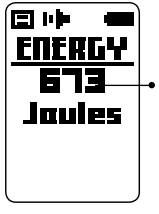
POWER (POWER) is a measure of muscle performance which combines strength and speed of movement (Pressure x Flow). More powerful muscles will be more resistant to fatigue at a given level of work and therefore, breathlessness will be reduced. The value displayed is the average power for all breaths in a training session.

In order to maximise the inspiratory muscle power result, the patient should try to breathe in as quickly as possible. However, the patient should always breathe out slowly, so as not to hyperventilate



Average volume inhaled per breath during latest session

VOLUME (VOLUME) is a measure of the average amount of air inhaled per breath during a training session. A higher value of volume indicates that the patient is breathing deeply and training the inspiratory muscles across their full range of movement. A relatively small value of volume may indicate that the patient is training at a level that is too high and is unable to properly complete each breath.



Breathing energy achieved during latest session

ENERGY (Breathing Energy) is a measure of the mechanical work (or effort) of breathing during your breathing training session. It is a result which combines the force exerted by your inspiratory muscles and the volume of air inhaled. The higher the value of breathing energy you attain, the longer and harder you have worked your inspiratory muscles.

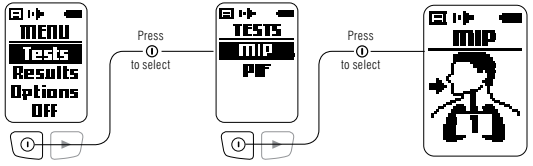
8. Test Modes

In addition to training mode, the POWERbreathe KH2 is equipped with test modes, which may be used to assess a patient's inspiratory muscle performance.

8.1 MIP Test Mode

Measurement of MIP (maximal inspiratory pressure) is a simple way to gauge inspiratory muscle strength. In order to measure MIP, the patient is required to inhale maximally against a closed airway from residual volume (RV). As the result is highly effort dependant, careful instruction and encouraged motivation are essential. Please follow the guidelines below to optimise the MIP test procedure:

1. Ensure that all equipment that will come into contact with the patient (e.g. mouthpiece) is sterile and/or protected by a disposable bacterial/viral filter
2. Explain to the patient exactly what you wish them to do before starting the test. During the MIP measurement, the patient will be unable to generate any airflow, and they must be prepared for this.
3. Enter the MIP test mode by following the sequence below:



4. Instruct the patient to breathe out slowly until their lungs are completely empty. Encourage the patient to 'squeeze' all the air from their lungs.
5. Now instruct the patient to breathe in hard, holding the effort for at least 2 seconds. Keep encouraging the patient throughout the test.
6. Then instruct the patient to relax and take the mouthpiece from their mouth. The unit will beep and the valve will open to indicate that the test has been completed. Test results will automatically be displayed on screen following the test.

This test should be repeated and the maximum of three values that vary by less than 20% recorded [for further guidance please see - ATS/ERS Statement on respiratory muscle testing. Am J Respir Crit Care Med 166, 518-624].

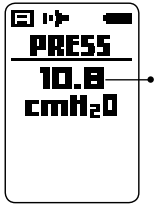
8.2 About MIP Test Results:

The MIP result displayed corresponds to highest 1 second average pressure achieved during the manoeuvre (measured at 50Hz). This measurement reflects the pressure developed by the respiratory muscles plus the elastic recoil pressure of the respiratory system at residual volume and is an indices of global respiratory output rather than a direct measure of the contractile properties of the inspiratory muscles. This result should be used to monitor the influence of respiratory muscle training.

A MIP rating is also provided. This rating is based upon predicted population normal values from research, calculated using the patient profile information (see Section 4.3). Ratings are derived as follows:

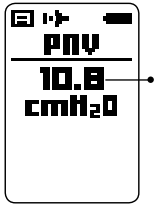
V.POOR : Measured value of MIP is more than 2 standard deviations below the predicted normal value (5th percentile)
POOR: Measured value of MIP is between 1.2 and 2 standard deviations below the predicted normal value
FAIR: Measured value of MIP is between 0.4 and 1.2 standard deviations below the predicted normal value
AVERAGE: Measured value of MIP is within ±0.4 standard deviations of the predicted normal value
GOOD: Measured value of MIP is between 0.4 and 1.2 standard deviations above the predicted normal value
V.GOOD: Measured value of MIP is between 1.2 and 2 standard deviations above the predicted normal value
EXCELLENT: Measured value of MIP is more than 2 standard deviations above the predicted normal value (95th percentile)

It should be noted that a large variation in MIP between subjects is normal. A low result (and corresponding low rating) may also be due to lack of motivation during the test and does not necessarily indicate inspiratory muscle weakness. It would be appropriate to undertake more detailed studies in order to interpret a very low result. As a guideline, a MIP of 80cmH2O or above usually excludes clinically important inspiratory muscle weakness. However, patients without inspiratory muscle weakness have been demonstrated to benefit from reduced dyspnoea and improved exercise tolerance as a result of inspiratory muscle training. Even highly trained athletes have been shown to experience reduced breathing effort and improved exercise performance following inspiratory muscle training.



Training Index achieved during latest session

PRESS (Average Pressure) is a measure of total average pressure generated by the respiratory muscle for the entire session. Pressure is measured in units of cmH2O, a unit of pressure commonly used in respiratory medicine to represent the pressure generated in the lungs due to the force of the inspiratory muscles. A higher Pressure result means that you are training your inspiratory muscles harder, leading to stronger muscles. A higher load result means that you are training your inspiratory muscles harder, leading to stronger muscles. Stronger inspiratory muscles will need to work less hard to cope with the demands of breathing, leading to reduced breathlessness. Muscles will need to work less hard to cope with the demands of breathing, leading to reduced breathlessness.



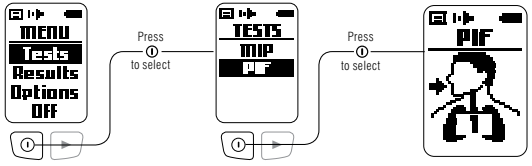
Training Index achieved during latest session

PNV (Predicted Normal Values) PNV is based upon predicted population normal values from research, calculated using the patient profile information (see Section 4.3).

8.3 PIF Test Mode

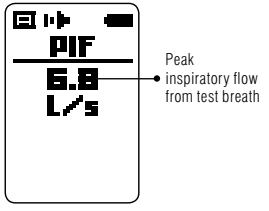
When a patient is unable to satisfactorily complete a MIP test, the peak inspiratory PIF test may be used as a useful alternative method for monitoring inspiratory muscle performance. Please follow the guidelines below to optimise the PIF test procedure:

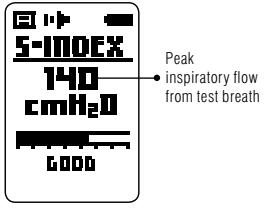
1. Ensure that all equipment that will come into contact with the patient (e.g. mouthpiece) is sterile and/or protected by a disposable bacterial/viral filter
2. Explain to the patient exactly what you wish them to do before starting the test. During the PIF measurement, the patient will be asked to inhale as hard and as fast as possible, and they must be prepared for this. There is no load during the PIF test.
3. Enter the PIF test mode by following the sequence below:



7. Instruct the patient to breathe out slowly until their lungs are completely empty. Encourage the patient to 'squeeze' all the air from their lungs.
8. Now instruct the patient to breathe in as hard and as fast as possible until their lungs are full.
9. The unit will beep to indicate that the test has been completed. The patient should then remove the device from their mouth and relax.
10. Test results will automatically be displayed on screen following the test. By pressing the ⓘ button from the PIF test result screen you will return to the test results menu where you may also review the Strength Index result (see Section 8.4 for details)

8.4 About PIF Test Results:





PIF (Peak Inspiratory Flow) is a measure which reflects the ability of the inspiratory muscles to contract rapidly and to overcome the inherent resistance and elastance of the respiratory system. Inspiratory musculature demonstrates a force-velocity relationship and hence inspiratory flow typically shows a reduction at all lung volumes in response to inspiratory muscle weakness. Improvements in inspiratory muscle strength may be observed by monitoring changes in peak inspiratory flow.

ⓘ *Inspiratory muscles also adhere to the principles of training specificity, and therefore training at high resistive loads but low flows may result in increases in inspiratory muscle strength without observable changes in peak inspiratory flow.*

S-INDEX (Strength Index) is a measure of inspiratory muscle strength derived from the peak inspiratory flow result i.e. a predicted value of MIP. It may be accessed via the **RESULTS** menu following a **PIF** manoeuvre. Calculation of strength index is based upon a typical inspiratory muscle force-velocity relationship. Strength index result is rated (V. Poor to Excellent) based upon predicted population normal values from research, calculated using the patient profile information (Section 4.3). Please refer to Section 8.2 for guidance on interpretation of Strength Index ratings

9. Modes

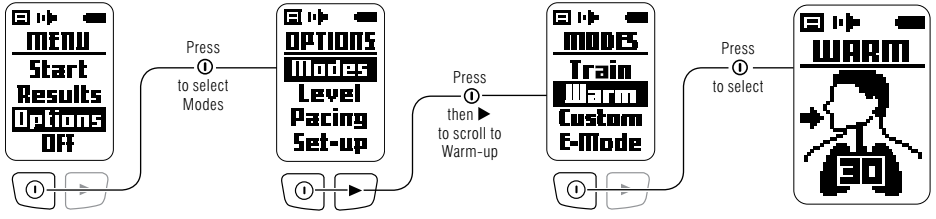
In addition to training mode, the POWERbreathe KH2 is equipped with three different breathing modes, which can be accessed via the **OPTIONS** menu.

9.1 Warm-up Mode

Research has shown that a normal pre-exercise warm-up routine neglects to warm-up the breathing muscles, leading to excessive breathlessness during the start of exercise. The POWERbreathe KH2 can be used to specifically warm-up these muscles prior to exercise using a reduced load setting leading to improved exercise performance.

The POWERbreathe KH2 warm-up session consists of 30 breaths at approximately 80% of your normal training intensity and should be completed twice with a two minute rest between sessions. These exercises should be completed around five to ten minutes prior to starting your workout, training or competition.

Select **Warm** from the **MODES** menu to begin an inspiratory muscle warm-up session. The load for your warm-up session will be automatically set at a proportion of your normal training level. Follow the same breathing technique as described in section 6.3.

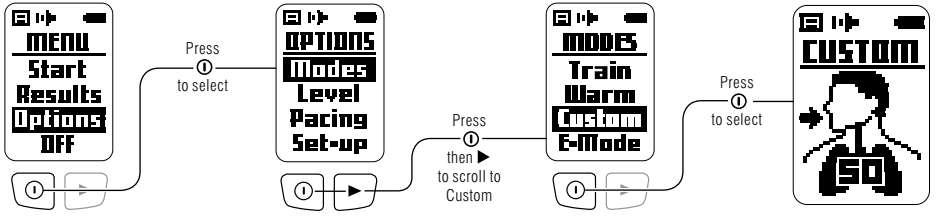


No results are displayed following a warm-up session

9.2 Custom Training Mode

The Custom training mode can be used to access custom training sessions created and uploaded from a computer using the POWERbreathe Breathe-Link Medic software. Custom training sessions may consist of between 3 and 60 breaths, with a custom load set for every individual breath. As loads are set for each breath from the computer, normal level settings (Manual and Automatic) are disabled when in custom training mode. Please refer to the software instructions for guidance on how to create and upload a custom training session.

Select **CUSTOM** from the **MODES** menu to begin a custom training session. The POWERbreathe KH2 will automatically recall the latest custom training session to be uploaded from the computer. Follow the same breathing patterns as used for a normal training session (see Section 6.3)

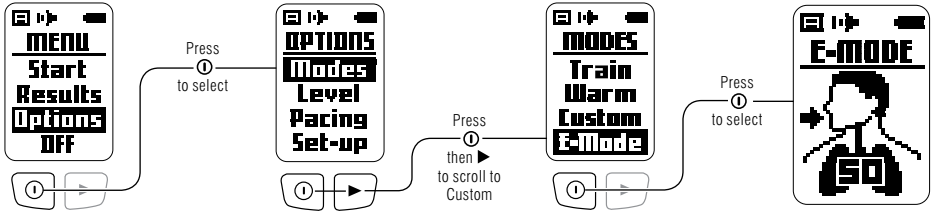


Results will be displayed in the normal way following a custom training session (see Section 7.1)

9.3 E-mode (Endurance Mode)

The Endurance Mode is an alternative to the traditional strength training protocol of the respiratory muscles of 30 breaths twice a day. The POWERbreathe KH2 Endurance mode allows up to a maximum of 150 breaths at training load based on training mode (Automatic or Manual). The goal is to breathe for as long as possible until no breaths can be fully completed, and thus respiratory fatigue has occurred.

Select **E-Mode** from the **MODE** menu to begin an Endurance mode training session. The Endurance training results will be saved with all results stored in training. (See Section 7.1)

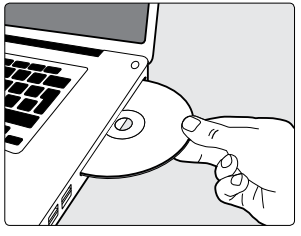


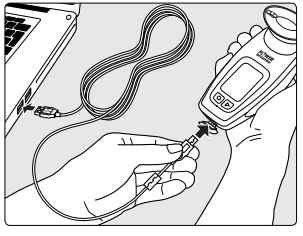
Results will be displayed in the normal way following an endurance mode training session (see Section 7.1)

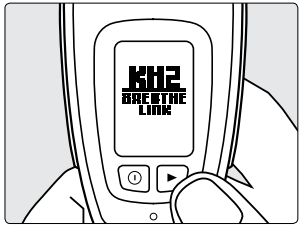
10. PC Connection and Software Installation

The POWERbreathe KH2 Breathe-Link Medic software allows you to view live training and test data, customise your training sessions and record your training progress. Please follow the instructions below to install the software and connect your POWERbreathe KH2.

- Insert the POWERbreathe Breathe-Link Medic software installation disk into your computer's CD-ROM drive
- Set-up should launch automatically. If it does not, manually launch the setup file by navigating to the CD drive folder and clicking on the icon
- Follow the instructions on your computer screen to install the software
- Once software installation is complete, plug the large connector of the USB cable into an available USB port on your computer
- Plug the mini-USB connector (small connector) into your POWERbreathe KH2 unit
- After a short pause, the Breathe-Link Medic application should start-up and your POWERbreathe KH2 unit should display the Breathe-Link screen If the Breathe-Link Medic application does not start automatically, manually launch the application by clicking on the desktop icon







11. Care and Maintenance

The POWERbreathe KH2 should be used in conjunction with disposable bacterial/viral filters for multi-patient use. For single patient use, please following the guidelines below to ensure that the POWERbreathe KH2 remains hygienic and in good working order.

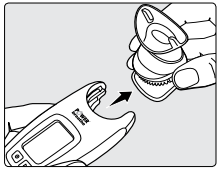
11.1 Cleaning

The POWERbreathe KH2 will be exposed to saliva during use. It is important to clean the POWERbreathe KH2 frequently to keep it hygienic and in good working order.

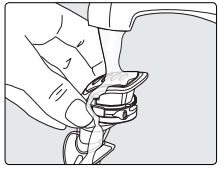
Regular cleaning
After each training session, remove the Valve Head from the POWERbreathe KH2, as demonstrated below, and soak it in warm water for about ten minutes. Now hold the valve head under warm running water whilst opening and closing the valve to aid cleaning of the valve surfaces. Shake off excess water and leave on a clean towel to dry.

Wipe-clean the POWERbreathe handset with a damp cloth. Do not immerse the handset or expose it to running water as this may damage the internal electronics.

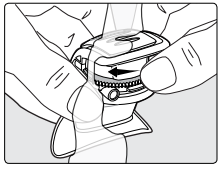
Removing the valve head

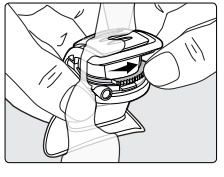


Rinsing the valve head



Rotating the valve to aid cleaning





Once a week
Once a week, perform the same procedure but soak the valve head in a mild disinfectant solution instead of water. The disinfectant solution used must be intended for use on equipment that comes into contact with the mouth, such as that used for babies' bottles. If in doubt, ask your pharmacist or check the POWERbreathe website for further information.

After cleaning, hold the valve head under a running tap allowing water to run through it. Shake off excess water and leave on a clean towel to dry.

Never use scouring pads, abrasive cleaning agents or aggressive liquids such as petrol or acetone to clean the appliance. POWERbreathe KH2 is not suitable for dishwasher or autoclave use.

11.2 Blocked Valve Head

If the valve head becomes clogged with dirt or saliva then the POWERbreathe unit cannot function correctly and an error message may be displayed. When this happens, you should follow the cleaning instructions detailed in section 11.1

Replacement valve head
For maximum training performance, we recommend that you replace the valve head once a year.

11.3 Storage

Please store your POWERbreathe KH2 at a temperature between -10°C and 60°C. Please store your POWERbreathe KH2 in the storage pouch provided or a suitable clean container. Always make sure that your POWERbreathe KH2 is dry before storage.

11.4 Calibration

The POWERbreathe KH2 should be recalibrated once a year in order to ensure its continued accuracy. Please contact the manufacturer using the details at the end of this manual for further information on this procedure.

12. Technical Specifications

Load display:	5 to 200cmH_2O
Power display:	0 to 99.9 Watts
Volume display (training):	0 to 8 Litres*
Energy display:	0 to 9999 Joules
Pressure display:	5 to 200cmH_2O
MIP display:	0 to 240cmH_2O
MIP rating:	V.Poor, Poor, Fair, Average, Good, V.Good Excellent
PIF display:	0 to 13L/s*
Strength index display:	0 to 240cmH_2O
Strength index rating:	V.Poor, Poor, Fair, Average, Good, V.Good Excellent
Accuracy:	Pressure: ±3% Flow: ±10% Volume: ±10%
Resolution:	Pressure: 1cmH_2O Flow: 0.1L/s Volume: 0.1L
Sounds:	Scroll/Select; Pacing; Low battery; End of training session
Buttons:	1 x select/on, 1 x scroll

Charging:	5V dc mains adapter
Charge time:	Up to 16 hours
Charge indicator:	Red LED during charging
Battery life:	Approx 60mins in training mode (2 weeks normal use)
Battery:	3x AAA NiMH rechargeable battery pack
Dimensions (handset):	130 x 58 x 70mm
Weight (handset):	136g
Storage temperature:	-10°C to 60°C
Operating temperature:	5°C to 40°C
Expected service life:	1 year
Safety:	EN 60601-1, EN 60601-1-2
Regulatory:	Class 1 Medical Device (93/42/EEC)

*Measured at atmospheric temperature and pressure conditions

Materials:

Mouthpiece:	Phthalate and latex free PVC
Soft-touch grips and seals:	TPE
Screen cover:	PMMA
Buttons:	PC
Stand:	PC-ABS
Gears:	Acetal
Valve Rotor:	PBT (PTFE filled)
Valve Stator:	Acetal (PTFE filled)
O-ring:	Nitrile rubber
Nose-clip rubber:	Silicone 40
Nose-clip bridge:	Nylon
Filter Adapter:	Polypropylene
All other components:	PC-ABS

Note: Materials are compliant with regards to composition, additives and properties, where applicable, in accordance with the Medical Device Directive 93/42/EEC Essential Requirements (Annex 1)

Available POWERbreathe Accessories:

- Additional Valve Heads
- Cleansing Tablets
- POWERbreathe TrySafe Bacterial/Viral Filter
- Filter Adapter
- Face Mask

Symbols:

This symbol indicates that this Class I medical equipment complies with the European Medical Device Directive (93/42/EEC)

This symbol indicates that this device should not be disposed of with normal household waste

Consult accompanying documents

Precedes the batch number of the device.

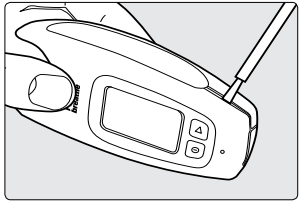
The first four integers of the LOT number denote year of manufacture

13. Disposal

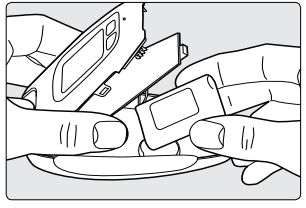
Environment:
The use of the crossed out wheeled bin symbol on this product indicates that it should not be treated as household waste. Please help to preserve the environment by disposing of this product at a designated WEEE collection facility. For more detailed information on recycling of waste electrical and electronic equipment, please contact your local city office, your household waste disposal service or the shop where you purchased the product.

Disposal of the battery:
The built-in, rechargeable POWERbreathe battery pack contains substances that may pollute the environment. Please remove the battery pack as described below before you discard the product at an official collection point. Dispose of the batteries separately at a battery recycling point.

Only remove the battery when you discard the POWERbreathe KH2. Make sure the battery is completely discharged when you remove it.



Insert a screwdriver between the two halves of the main casing and twist until the two halves break apart.



Push apart the two clips retaining the circuit board and lift the battery out from underneath the circuit board

14. About Inspiratory Muscle Training

The main debilitating symptom of cardio respiratory disease is dyspnoea (breathlessness). Dyspnoea is also a common symptom in other conditions, and in all cases, it has a profoundly impairing influence upon quality of life and independence.

Dyspnoea is a complex phenomenon with a multifactoral origin that incorporates inputs from chemoreceptors and the cortical areas of the brain. Although the aetiology of dyspnoea may differ widely between pathologies, there is one common input to all forms of dyspnoea, including that associated with the healthy perception of breathing during exercise. This input arises from the sense of effort associated with the action of the inspiratory muscles.

The magnitude of the breathing effort and dyspnoea is proportional to the magnitude of the motor drive to the inspiratory muscles. The weaker a muscle is, or the greater the impedance it must overcome, the higher is the motor drive required to bring about a given action, and vice versa.

Accordingly, strengthening the inspiratory muscles has a universally beneficial effect upon motor drive and dyspnoea. Thus, irrespective of its pathophysiological origin, dyspnoea can be ameliorated by specific strength training of the inspiratory muscles.

The presence of weakness is not a pre-requisite for this effect, as inspiratory muscle training has been shown to reduce breathing effort in healthy young athletes, as well as patients.

The POWERbreathe KH2 applies the tried and trusted principles of resistance (weight) training to the inspiratory muscles, and can be thought of as ‘dumbbells for the diaphragm’. When the inspiratory muscles are overloaded regularly for a period of a few weeks, they adapt, becoming stronger and more resistant to fatigue. Activating stronger inspiratory muscles requires less effort during a given task, hence dyspnoea is reduced.

For further information about the science of respiratory muscle training, please refer to the website www.powerbreathe.com.

15. Troubleshooting and FAQs

1. When in Auto set-up mode, the device doesn't seem to give a high enough load.
2. There is too much resistance to inhalation and the patient is unable to breathe through the device.
3. The POWERbreathe KH2 will not switch on.
4. The POWERbreathe KH2 is switched on but will not respond to any button presses.
5. The mouthpiece has become discoloured or cloudy.
6. The exercises create a lot of saliva – is there anything I can do to stop this?
7. I have cleaned the valve head but I still see the Error Please Clean message.
8. How often should I clean the valve head?
9. There doesn't seem to be any resistance to breathing until several breaths have already been completed.
10. I can't hear the pacing buzzer
11. How hard should the training feel?
12. The results displayed vary a lot, is this normal?
13. The load seems to disappear towards the end of the breath, is this right?
14. Does the volume displayed correspond to lung capacity?
15. How is strength Index calculated?
16. Can more than one person use the same POWERbreathe KH2 unit?
17. What if the patient doesn't see any improvements?
18. What happens if the patient coughs during a breath?
19. Where can I find out more information about inspiratory muscle training with the POWERbreathe KH2?

1. When in Auto set-up mode, the device doesn't seem to give a high enough load.

When using Auto set-up mode, the POWERbreathe KH2 sets the training load based upon the speed and depth of inhalation during the first two breaths of the session. The harder the patient inhales during these breaths, the higher the load will be set. If the patient is putting maximum effort into their inhalation but are still not experiencing a significant load, try adjusting the intensity level as described in section 5.2.

2. There is too much resistance to inhalation and the patient is unable to breathe through the device.

If the patient is unable to inhale through the POWERbreathe KH2, remove the valve head and check that the valve can open and close freely. If necessary, clean the valve head as described in section 11.1. Now re-attach the valve head to the handset, ensuring that it is properly seated. If the valve is moving freely, reduce the training level, as described in section 5.2, or manually set a lower load.

3. The POWERbreathe KH2 will not switch on

If the POWERbreathe KH2 will not switch on, the battery may be completely flat. You may use the device immediately by plugging into the mains using the adapter and USB cable supplied. Alternatively, recharge the device as detailed in section 4.1.

4. The POWERbreathe KH2 is switched on but will not respond to any button presses.

Press and hold the ⏻ and ▶ buttons simultaneously for at least 3 seconds then release. This will reset and switch off the device. Now press the ⏻ button for approximately one second to switch the device on again.

5. The mouthpiece has become discoloured or cloudy.

When the mouthpiece is soaked in water or disinfectant solution for a prolonged period of time, a small amount of moisture may be absorbed by the material, leading to cloudiness or discolouration. If this occurs, leave the mouthpiece to dry on a clean towel and the cloudiness will gradually disappear.

6. The exercises create a lot of saliva – is there anything I can do to stop this?

If you find that the patient is producing excess saliva during training, encourage them to pause during the training in order to allow saliva to clear. Alternatively, encourage the patient to remove the unit from their mouth during exhalation in order to reduce the build up of saliva. This will not reduce the training effect that occurs during inhalation.

7. I have cleaned the valve head but I still see the 'Error Please Clean Valve' message.

In some circumstances the valve head may become very clogged with dirt or saliva. Make sure that you soak the valve head thoroughly and rotate the valve back and forth to dislodge any dirt or debris trapped in the valve. When you reattach the valve head, ensure that it is properly seated on the handset so that no gaps are visible.

8. How often should I clean the valve head?

If used without the protection of a bacterial/viral filter, the valve head should be cleaned after every training session, in order to maintain hygiene and effective operation.

9. There doesn't seem to be any resistance to breathing until several breaths have already been completed.

During the first two breaths of every training session, the POWERbreathe KH2 is taking measurements of the patients breathing. During these two breaths there is no resistance. During the third and fourth breaths, training resistance (load) is gradually introduced until full training load is achieved for breath 5 and onwards.

10. I can't hear the pacing buzzer

If the patient takes less than 4.5 seconds per breath then you will not hear the pacing buzzer – the patient must pause at the end of exhalation in order to hear the pacing buzzer (see Section 5.4).

11. How hard should the training feel?

Training with the POWERbreathe KH2 is a form of resistance training and may be compared to training with weights in the gym. Inhaling against the training resistance should feel hard and for the best training results the patient should aim to breathe against a load at which they can only just complete 30 breaths. Like any other training, the more effort that is put into POWERbreathe training, the greater the results that will be achieved.

12 The results displayed vary a lot, is this normal?

The action of breathing is by its very nature extremely variable and difficult to control accurately. Initially, training results may vary widely between different training sessions. However, as the patient gets used to the action of inhaling against a resistance with maximum effort, you should find that their results become more consistent and controllable. There may still be some variation from day to day, depending on the patients physical condition and state of mind, just as with any other form of exercise.

13. The load seems to disappear towards the end of the breath, is this right?

The POWERbreathe KH2 creates a resistance to inhalation that varies in relation to the volume of air inhaled. This load is designed to match the strength characteristics of the inspiratory muscles for optimum training effectiveness. The load will be highest at the start of the breath and will gradually reduce to near zero at the end of the breath.

14. Does the volume displayed correspond to lung capacity?

The volume displayed following a training session corresponds to the average inhaled volume of air per breath. This will be lower than typical expiratory vital capacity measured by spirometry. This is due to differences in the temperature and humidity of the air under the different measuring conditions and the effects of the inspiratory muscle length-tension relationship.

15. How is strength Index calculated?

Strength index is a measure of inspiratory muscle strength that is based upon the maximum flow of inhaled air that the user can generate. The calculation of Strength Index is based upon scientific research which investigates the force-velocity characteristics of the inspiratory muscles.

16. Can more than one person use the same POWERbreathe KH2 unit?

For hygiene reasons, we recommend that users do not share the same POWERbreathe KH2 Valve Head. However, users may share the POWERbreathe KH2 if used in conjunction with bacterial/viral filters. Alternatively, additional Valve Heads may be purchased separately and used with the same POWERbreathe KH2 handset.

17. What if the patient doesn't see any improvements?

If you are not seeing any improvements in training or test results, try increasing the training load or level (see section 5.1). It is important that you are training against a load which is challenging in order to increase the strength of your inspiratory muscles. However, remember that after 6 to 8 weeks your training improvements will tend to plateau. After this time, aim to maintain your improved breathing by continuing to train regularly (see section 6.5)

18 What happens if the patient coughs during a breath?

If the patient coughs during a breath, they should remove the POWERbreathe KH2 from their mouth and take a rest until they feel they have recovered. They can then return the device to their mouth and continue the training session.

19 Where can I find out more information about inspiratory muscle training with the POWERbreathe KH2?

Please see www.powerbreathe.com for further information

16. Limited One Year Manufacturer's Warranty*

Please retain this information for your records

This warranty gives the purchaser specific legal rights. The purchaser may also have other statutory rights. POWERbreathe International Ltd hereby warrants to the original purchaser whose name shall be duly registered with the company, that the product sold by it is free from manufacturing defects in material and/or workmanship.
The obligations of POWERbreathe International Ltd under this warranty are limited to the repair and replacement of such part or parts of the unit as shall be found upon inspection to be defective in material or workmanship.

This warranty does not apply to the battery, mouthpiece, nose-clip or software (when applicable), cracked or broken cases as well as, misuse, abuse or accidents, negligence of the precautions, poor maintenance (e.g. parts blocked by scale) or commercial use. During the one year warranty period, the product will be either repaired or replaced (at our option without charge).

*Warranty for commercial, professional or institutional use, is limited to 3 months (90 days) from date of purchase. All other terms remain the same.

No responsibility is assumed for any incidental or consequential damages including, without limitation, damages resulting from inaccuracy or mathematical inaccuracy of the product or the loss of stored data

The warranties contained herein are expressly in lieu of any other warranties including implied warranty of merchantability and / or fit for purpose.

Warranty specifications may change without notice due to manufacturers continuous programme of development. Please check www.powerbreathe.com/(warranty) for latest results

To Activate Your Warranty

Please ensure that you register the purchase of your POWERbreathe KH2 model by visiting www.powerbreathe.com/warranty.

Thank You.

17. Customer Service Contact

If you need to send your POWERbreathe KH2 to an official service centre, please refer to the contact information below. To help us to provide a better service, please include a description of the reason for returning the unit. Please also include proof of purchase. We recommend that returns are sent by recorded delivery.

Head Office:
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For customer service enquiries in all other countries and for POWERbreathe K-Series calibration enquiries, please consult the website or contact POWERbreathe International Head Office in the UK.

POWERbreathe International Ltd.
Northfield Road, Southam, Warwickshire, CV47 0FG, UK

For UK enquiries, please contact us on:
Tel: +44 (0)1926 816100
Email: enquiries@powerbreathe.com

For International enquiries, please visit our website for your local distributor:

powerbreathe.com

POWERbreathe devices are not toys. This product is designed to be used for breathing exercise only. Any other use is not recommended.

Always seek the advice of your doctor or other health provider with any questions you may have regarding a medical condition. This product is not intended to diagnose, cure or prevent any disease. Individual results may vary. No claims are made or implied in the use or results by the use of the equipment herein.

Always read the user manual before use. The material in this manual is for information purposes only.

Designed and developed with pride in the United Kingdom

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