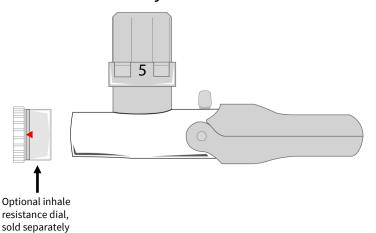


OxyBREATH™



Indications for Use

The OxyBREATH is a respiratory muscle trainer (RMT) used by patients with COPD, CHF, Dysphagia, and Neuromuscular Disease. It trains both inspiratory and expiratory muscles independently. Clinical benefits of RMT include improved dyspnea, peak cough flow, laryngeal function, quality of life, vent weaning, and speech and swallow performance.

General Specifications

OPERATING ENVIRONMENT

Temperature: $10 - 40^{\circ}\text{C} (50 - 104^{\circ}\text{F})$ Relative humidity: 0 - 95%Atmospheric pressure: 540 - 1060 hPa

STORAGE CONDITIONS

Temperature: $-20 - 45^{\circ}\text{C} \ (-4 - 113^{\circ}\text{F})$ Relative humidity: 0 - 95%Atmospheric pressure: $440 - 1060 \ \text{hPa}$

Single patient use only.

Do not share or use on multiple patients. Not manufactured from natural rubber latex.

D • R Burton Healthcare LLC

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Reorder #564

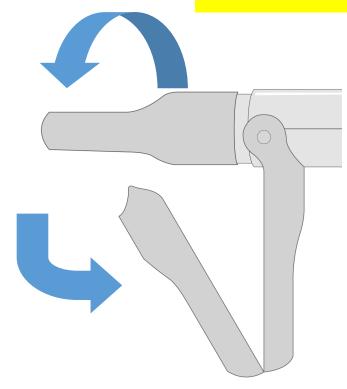
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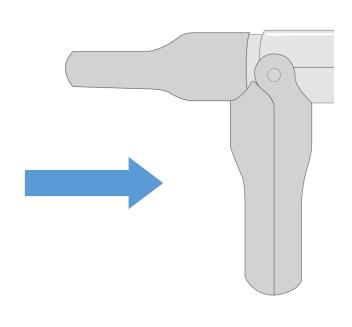
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IFU part number 358rev03

The OxyBREATH mouthpiece cover opens and rotates to form a handle for use during respiratory muscle training.

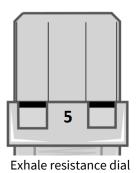




Directions for Use

Setup:

- 1. Open the OxyBREATH™ mouthpiece cover
- 2. Rotate the OxyBREATH mouthpiece cover and position the handle perpendicular to the device body*
- 3. Press the mouthpiece cover together to form a handle
- 4. Set the expiratory resistance dial to the lowest setting (5)
- 5. Set the optional inspiratory resistance dial, if attached, to the lowest setting (1)



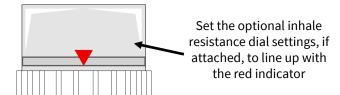


Optional inhale resistance dial

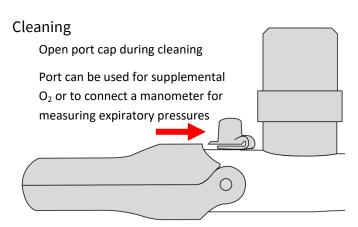
*Refer to the diagram on the reverse side for correct handle position.

Procedure:

- 1. Sit upright
- 2. Hold the handle and position the mouthpiece between your lips
- Breathe in and out through the OxyBREATH using diaphragmatic (abdominal) breathing
- 4. Rotate the exhale resistance dial (settings 5—20) to a setting at which you can manage 10 breaths** without puffing your cheeks or getting out of breath
- 5. Rotate the optional inhale resistance dial (settings 1 6), if attached, to a setting at which you can manage 10 breaths** without puffing your cheeks or getting out of breath
 - Increase the exhale and inhale resistance dial settings independently of each other if the set of 10 breaths becomes too easy
 - b. Reduce the dial settings if you have not been using your OxyBREATH for a period of time



**You want to feel as if you've been giving 70% of your effort to get the 10th breath.



During the course of treatment, the OxyBREATH may accumulate secretions or become soiled and require cleaning. Please follow the instructions below to clean the OxyBREATH, as required.

Disassembly

- 1. Open the mouthpiece cover / handle
- 2. Remove the mouthpiece from the device body
- 3. Remove the inhale resistance dial from the device body
- 4. Open the supplemental connector port cap

Cleaning

- Wash the mouthpiece and inhale resistance dial in warm, soapy water
- 2. Rinse the mouthpiece, inhale resistance dial, and OxyBREATH body under running tap water, taking care not to submerge the exhale resistance dial when rinsing

Notes:

- A bottle brush or pipe cleaner may be used to remove accumulations from the OxyBREATH body during cleaning
- The exhale resistance dial can be cleaned by wiping the outside surface with a tissue moistened with 70% isopropyl alcohol

Drying:

- Air dry the parts thoroughly or dry with a lint free cloth before reassembly
- 2. Visually inspect the device:
 - a. if any soil is seen, repeat cleaning steps
 - b. if any damage is seen, discard and replace the device

Reassembly:

- 1. Open the mouthpiece cover / handle
- 2. Insert the mouthpiece into the device body
- 3. Attach the optional inhale resistance dial to the device body (if necessary)
- 4. Close the supplemental connector port cap
- 5. Set the optional inspiratory resistance dial (if attached) to the lowest setting (1)
- 6. Set the expiratory resistance dial to the lowest setting (5)
- 7. Inhale and exhale forcefully to release possible moisture seal prior to next use