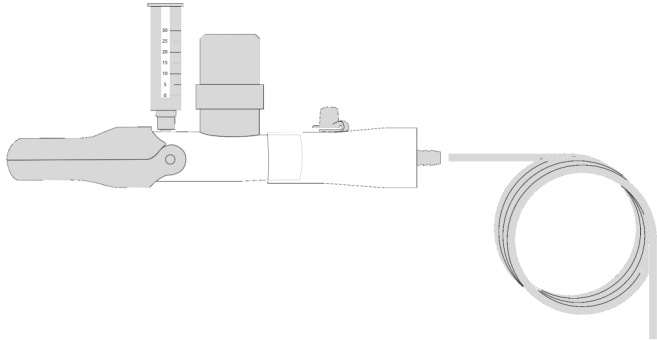


OxyPAP[®]

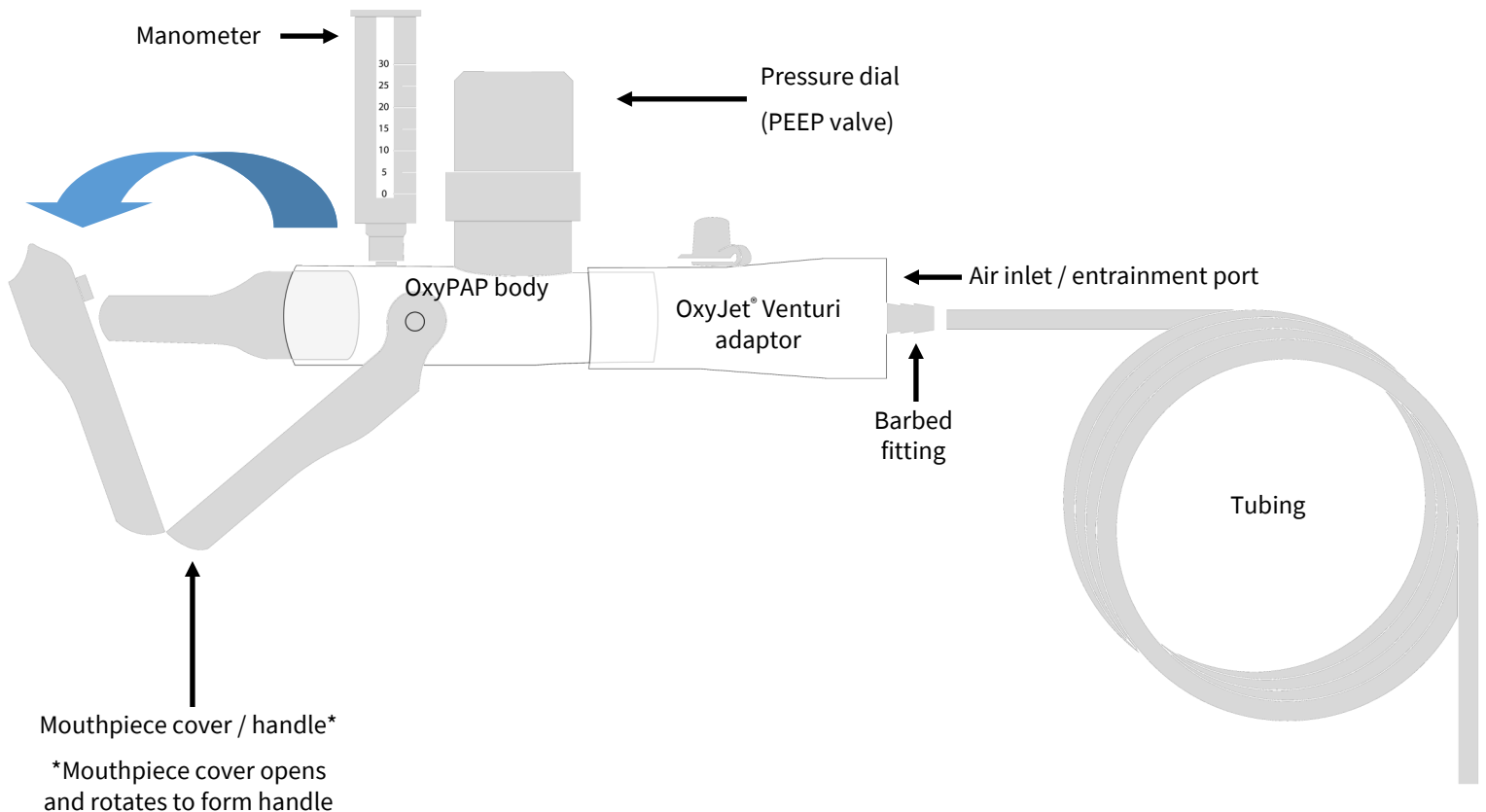
Directions for use



Indications for use

The D R Burton[®] OxyPAP[®] device is indicated for the treatment and prevention of atelectasis. It also has the ability to provide supplemental oxygen when used with compressed oxygen. The device is for patients (ages 5 years and above) who are capable of following directions for positive airway pressure (PAP) therapy. Normal use of the OxyPAP should not be more than 24 hours total combined time.

OxyPAP Parts



Contraindications

Although no absolute contraindications for the use of PAP therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Intracranial pressure (ICP) > 20mm Hg
- Recent facial, oral, esophageal, or skull surgery or trauma
- Untreated pneumothorax
- Known or suspected tympanic membrane rupture or other middle ear pathology
- Hemodynamic instability
- Acute sinusitis
- Epistaxis
- Active hemoptysis
- Nausea

Warnings

Adverse reactions may include:

- Increased work of breathing that may lead to hypoventilation and hypercarbia
- Increased cranial pressure
- Cardiovascular compromise
- Myocardial ischemia
- Decreased venous return
- Air swallowing with increased risk of vomiting and aspiration
- Claustrophobia
- Pulmonary barotrauma

Directions for use

Setup:

1. Attach OxyJet® Venturi adaptor to the OxyPAP® body as shown on the previous page
2. Open OxyPAP mouthpiece cover and position perpendicular to device body for use
3. Connect manometer (if included) to OxyPAP pressure port, between mouthpiece and pressure dial
4. Connect one end of tubing (included) to OxyPAP barbed fitting
5. Connect other end of tubing to gas source flowmeter
6. Set gas source flowmeter to 10 LPM
7. Rotate pressure dial to desired expiratory airway resistance setting

Procedure:

1. Place mouthpiece in patient's mouth and instruct patient to breathe against the resistance generated by the OxyPAP
 - Instruct patient to relax during diaphragmatic breathing
 - Verify that patient maintains a tight seal on mouthpiece during therapy
 - Advise patient to use a nose clip, if necessary
2. Monitor airway pressure and adjust gas source flowmeter to achieve desired expiratory pressure
3. Have patient continue to breathe using the OxyPAP until instructed to stop

Note: A therapy session is intended to last no more than 20 minutes. Perform therapy 3 times per day, or as instructed by your physician.

Warnings:

- IT IS NOT RECOMMENDED TO ALLOW PRESSURES ABOVE 20cm H₂O DURING BREATHING
 - DO NOT INCREASE GAS SOURCE FLOWMETER ABOVE 15 LPM
 - DO NOT OBSTRUCT AIR INLET / ENTRAINMENT PORT DURING USE
 - DO NOT ATTEMPT TO STERILIZE THE DEVICE
 - DO NOT IMMERSE THE DEVICE IN LIQUID
 - THE OxyPAP IS NOT INTENDED FOR USE WITH INVASIVE VENTILATION
- Note:** Replace the OxyPAP device after 24 hours of cumulative use or immediately if damaged.

General Specifications

OPERATING ENVIRONMENT

Temperature:	10 - 40°C (50 - 104°F)
Relative humidity:	0 - 95%
Atmospheric pressure:	540 - 1060 hPa

STORAGE CONDITIONS

Temperature:	-20 - 45°C (-4 - 113°F)
Relative humidity:	0 - 95%
Atmospheric pressure:	440 - 1060 hPa

Manometer accuracy has been verified from 0 - 30 cmH₂O.

Single patient use only.

Do not share or use on multiple patients.

Not manufactured from natural rubber latex.



R only



Cleaning the OxyPAP

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

Disassembly

1. Ensure that the gas source flowmeter is shut off
2. Disconnect the gas supply tubing from the OxyJet® barbed fitting
3. Disconnect the manometer (if present) from the OxyPAP
4. Remove the mouthpiece from the OxyPAP body
5. Disconnect the OxyJet Venturi adaptor from the OxyPAP body

Cleaning

1. Wash the mouthpiece and OxyJet Venturi adaptor using liquid dish detergent and clean, warm water
2. Rinse the mouthpiece, OxyJet, and OxyPAP body using clean water, *taking care not to submerge the OxyPAP pressure dial when rinsing*

Notes:

- A bottle brush or pipe cleaner may be used to remove accumulations from the OxyPAP body during cleaning
- The OxyPAP pressure dial, manometer, and air supply tubing can be cleaned by wiping the outside surfaces with a tissue moistened with 70% isopropyl alcohol

Drying and Reassembly

1. Air dry the parts thoroughly or dry with a lint free cloth before reassembly
2. Visually inspect the device; if any soil is seen, repeat cleaning steps. If any damage is seen, discard and replace the device.
3. Reassemble the device by following the instructions on the previous page prior to next use

D R Burton Healthcare LLC

3936 South Fields Street
Farmville, NC 27828

Telephone: (252) 228 - 7038

Web: www.drburtonhpi.com

Reorder # 562 (w/ manometer)

Reorder # 563 (w/o manometer)

Reorder # 562-TS (w/ 22mm adaptor & manometer)

Reorder # 563-TS (w/ 22mm adaptor)

D R Burton, OxyPAP and OxyJet are registered trademarks of D R Burton Healthcare LLC.

©2021 D R Burton Healthcare LLC.

All rights reserved.