

EzPAP™ Positive Airway Pressure Therapy System



Product Description

The EzPAP Positive Airway Pressure Therapy System is a non-sterile, single patient use, handheld respiratory therapy device. Positive airway pressure therapy systems have the ability to provide supplemental oxygen when used with compressed oxygen.

Indications

The EzPAP Positive Airway Pressure Therapy System is indicated for the treatment and prevention of atelectasis. The EzPAP Positive Airway Pressure Therapy System is for patients who are capable of following directions for positive airway pressure (PAP) therapy.

Contraindications

Although no absolute contraindications to 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) >20 mm Hg
- › Recent facial, oral or skull surgery or trauma
- › Oesophageal surgery
- › Untreated pneumothorax
- › Known or suspected tympanic membrane rupture or other middle ear pathology
- › Hemodynamic instability
- › Acute sinusitis
- › Epistaxis
- › Active haemoptysis
- › Nausea

Precautions

- › Do not autoclave.
- › Do not immerse completely in any liquid.
- › Do not disassemble except for mouthpiece, mask or tubing.

Device Classification

GMDN: 57816

Classification: Class IIa

Components Composition

This device is not made with natural rubber latex.

Manufacturing Site Name and Address

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Country of Origin

USA

Sterilisation Method

Non-sterile

Shelf Life

5 years

Labelling and Packaging

Packaging Dimensions			
Container Type	Length (mm)	Width (mm)	Height (mm)
Single Unit	342.9	228.6	N/A
Transit Carton (10 units)	228.6	228.6	228.6

One (1) EzPAP unit is packaged per each polybag. Product is non- sterile, non-toxic and non-pyrogenic unless package is open, wet or damaged. Discard if open, wet or damaged. Ten (10) units are packed per transit carton. The lot number, manufacturing date and expiration date are located on the polybag and transit carton labels.

Product Specifications

EzPAP Specifications		
Item Number	Description	Units per Case
23-0747	EzPAP system with mouthpiece	10
23-0757	EzPAP system with disposable manometer	10

For more information, visit www.icumed.com or call +44 (0)845 850 0445

The product complies with current legislation and has the corresponding CE marking (2797).
For additional information, warnings and/or safety precautions, refer to the manufacturer's Instructions for Use.

