Pulmodyne[®]

GO-PAP[™] With Included Nebulizer

Pulmodyne's GO-PAP™ System delivers continuous positive airway pressure (CPAP) throughout the breathing cvcle. It provides CPAP at preset levels throughout inspiration and exhalation, independent of the patient's flow rate, GO-PAP System is intended for use on spontaneously breathing patients, SINGLE PATIENT USE ONLY.

INDICATIONS FOR USE:

To provide CPAP to spontaneously breathing adult (>30kg) patients in the hospital and pre-hospital (EMS) environment.

May be contraindicated for patients with any of these conditions:

- Facial lacerations
- Laryngeal trauma
- · Recent tracheal or esophageal anastomosis
- · Gastrointestinal bleeding or ileus
- Recent gastric surgery
- Basilar skull fracture
- Patients at high risk of vomiting
- Emphysematous Bulla when an area of the lung may be brittle and present a risk of bursting
- Hypovolaemia low blood volume

HOW IT WORKS:

GO-PAP device is a fixed flow venturi device that uses an oxygen supply in conjunction with entrained air to generate an output flow. GO-PAP is designed to connect to a metered flow oxygen supply set to 10 LPM. The PEEP valve is integrated into the housing of the device and is designed to provide positive pressure.

OPERATING THE SYSTEM:

- Connect O2 tubing directly to gas source.
- Prior to use, check to be sure the device is free of obstructions and verify proper valve function.
- Set O2 gas flow to 10 LPM. Do not exceed 10 LPM.
- Place mask over patients face. Utilize the head strap to secure the mask in place.

ATTACHING THE NEBULIZER CANISTER:

Insert prescribed solution into medication port.

- Connect supply tubing with nebulizer canister to oxygen supply.
- Push nebulizer canister into port, turning 1/4 of a turn to secure. Ensure that the valve is open.
- Set nebulizer gas flow to 8 LPM. Check for aerosol mist. If necessary, tap the device until it begins to nebulize.
- To add more medication, insert pillow into medication port.

WARNING:

- Do not connect any gas supply other than oxygen to the GO-PAP System.
- For use only by thoroughly trained personnel.
- · Do not use the device if it becomes occluded. An occluded device may obstruct patient's exhalation and result in potential injury. If this occurs, discard entire system.
- If the oxygen gas flow fails, the anti-asphyxia feature in the device will minimize the risk of asphyxia when there is no oxygen pressure. When there is not oxygen flow from the device, the mask should not be worn.

MONITORING THE PATIENT:

During operation, be sure to check the following on a regular basis:

- Ensure that there are no leaks at the patient connection.
- Ensure that there is flow from the GO-PAP device during inspiration (which means ٠ that the device is supplying adequate flow to meet patient demand).
- Monitor the patient's arterial blood oxygen saturation (SaO₂).
- Monitor the patient's end tidal CO₂
- Nebulizer (not pictured) Mask with Head Strap Monitor the patient for signs of dehydration and discomfort 5. Neb Connect (not pictured) in the upper airways.
- Monitor the patient's delivered FiO₂

CAUTIONS:

Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Do not sterilize or immerse the GO-PAP System or any of its components in any solution. Dispose of GO-PAP System according to local established protocols when finished with use.



Storage Specifications: -20°C to 60°C at relative humidity up to 95% non-condensing

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PEEP and nebulizer port

Oxygen Supply Tube

Nebulizer (not pictured)



Made in USA

Operating Specifications: 5°C

to 95%

non-condensina

to 40°C at humidity range of 15%

Storage Specifications: -20°C to

60°C at relative humidity up to 95%







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Single Patient Use

System includes:

MD

Medical Device

Oxygen Supply Tube

Fixed Flow Device with integrated PEEP and nebulizer port

ulmodvne Inc.

www.pulmodyne.com

Made in USA

55 Executive Drive

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2020

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