1.0 SYSTEM OVERVIEW

1.1 Description:

The FLOCAP is a simple, disposable, single-use CO₂ flow indicator designed for placement between a breathing device and a patient's endotracheal tube or mask for visualization of exhaled CO₂. The FLOCAP is a visual indicator to detect the end of exhalation. It is indicated for patients over 15 kg (33 lbs.) and made of latex-free materials to reduce the risk of transcutaneous CO₂ rebreathing. The flow indicator allows the caregiver to visually observe the patient's exhalation and detect when exhalation is complete. The FLOCAP is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms. The FLOCAP is an accessory device and is not a substitute for a main CO₂ monitor.

1.2 Indications for use:

The FLOCAP is intended for the visualization of exhaled CO₂ in the patient's lungs. It is used to verify proper ET tube placement. A lack of color change may indicate improper intubation. Exhaled gas passes through the device and indicates a range of end-tidal CO₂. The flow indicator allows the caregiver to visually detect if the patient is still exhaling.

1.3 Contraindications:

Do not use the FLOCAP for a duration of more than 24 hours. DO NOT use on patients with body weight less than 15 kg (33 lbs.) due to the potential for rebreathing of exhaled CO₂. DO NOT use the FLOCAP for a duration of more than 24 hours. DO NOT use the FLOCAP for a duration of more than 24 hours.

1.4 Precautions:

- Follow your institutional guidelines for verifying proper intubation in addition to use of the FLOCAP.
- Do not use if the package is already unsealed.
- Do not use if the presence of acidic liquid or medication.
- Avoid exposure to strong sunlight and other sources of ultraviolet light.
- The FLOCAP does not take the place of traditional end tidal CO₂ monitoring.
- When low pulmonary perfusion coincides with accidental esophageal intubation, colorimetric CO₂ monitoring may be helpful for the visualization of exhaled CO₂.

1.5 Cautions:

- Standard clinical assessment must be used.
- Interpretation of color change requires the assessment of other factors.
- The FLOCAP is an adjunct assessment tool and should not be relied upon as the sole means of interpreting patient respiratory status.
- The FLOCAP should be replaced immediately if the indicator does not move to the purple or beige color.
- Do not use if the indicator does not move to the purple or beige color.
- The FLOCAP should be replaced immediately if the indicator does not move to the purple or beige color.

2.0 MECANICAL SPECIFICATIONS:

- Internal Volume: 25 mL
- Pressure Drop according to ISO 9360-1
  - at 30 LPM: 0.7 mm/H²O
  - at 60 LPM: 2.3 mm/H²O
  - at 90 LPM: 5.7 mm/H²O
- Compliance according to ISO 9360-1: 0.44 mm/H²O
- Weight: 23 grams
- Connector ports according to ISO 5356-1
- Patient end: 15 mm O.D.
- Ventilator end: 15 mm O.D.

3.0 SYMBOL GUIDE:

- Rx ONLY
- Single Use Only
- Non-stabilized
- Contains no Potentially Noxious Substances
- Keep Dry
- Authorized Representative
- Manufactured with Natural Rubber Latex
- Made in USA
- DO NOT
- Storage Temperature
- Keep Out of Sunlight
- Warning: The FLOCAP has a visual indicator to detect the end of exhalation. A lack of color change may indicate improper intubation. Exhaled gas passes through the device and indicates a range of end-tidal CO₂. The flow indicator allows the caregiver to visually detect if the patient is still exhaling.

4.0 INSTALLATION INSTRUCTIONS:

1. To open: Open the pouch, remove and inspect the FLOCAP. Ensure the element inside the housing is still purple. If its color looks to be closer to beige the device should be discarded. Some yellowing indicates insufficient exhaled CO₂.
2. To connect: Attach the FLOCAP securely between the ventilation connector ports according to ISO 5356-1:
3. To use: The FLOCAP has a visual indicator to visually detect the end of exhalation. For patients greater than 15 kg (33 lbs.) the FLOCAP should be replaced immediately if the indicator does not move to the purple or beige color.

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6.0 SYSTEM OVERVIEW

1.1 Description:

The FLOCAP is a simple, disposable, single-use CO₂ flow indicator designed for placement between a breathing device and a patient's endotracheal tube or mask for visualization of exhaled CO₂ and to give a visual indication of the presence of exhaled CO₂. The CO₂ indicator will assist the caregiver in verifying proper ET tube placement. A lack of color change may indicate improper intubation. Exhaled gas passes through the device and indicates a range of end-tidal CO₂. The flow indicator allows the caregiver to visually detect if the patient is still exhaling.

1.2 Indications for use:

The FLOCAP is intended for use as a semi-quantitative visualization of the CO₂ in the patient's airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms in the upper airway and on the order of a physician.

1.3 Contraindications:

- Do not use if the color of the indicator is yellow, continue to ventilate the patient and monitor clinical cues for adequate ventilation.
- If the color of the indicator is purple or beige, do not exceed 24 hours of use.
- During the course of ventilation, if the FLOCAP returns to and remains purple or beige colored, this indicates insufficient exhaled CO₂.
- Interpreting color change before 6 complete breaths may lead to a false result.
- Do not use if the presence of acidic liquid or medication.
- Avoid exposure to strong sunlight and other sources of ultraviolet light.
- The FLOCAP does not take the place of traditional end tidal CO₂ monitoring.

1.4 Precautions:

- Standard clinical assessment must be used.
- Interpretation of color change requires the assessment of other factors.
- The FLOCAP is an adjunct assessment tool and should not be relied upon as the sole means of interpreting patient respiratory status.
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