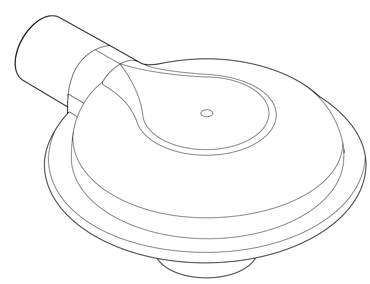
FLOCAP™



OPERATING MANUAL & INSTRUCTIONS FOR USE

R500P21

1.0 SYSTEM OVERVIEW

1.1 Description:

The FLOCAP is a simple, disposable, single-use CO_2 and flow indication device designed for placement between a breathing device and a patient's endotracheal tube or mask for visualization of exhaled CO_2 and to give a visual indication of the presence of expiratory flow. The CO_2 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 CO_2. The flow indicator allows the caregiver to visually detect if the patient is still exhaling.

1.2 Indications for use:

The FLOCAP is used to provide a semi-quantitative visualization of the CO2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.

The FLOCAP has a visual indicator to visually detect the end of exhalation.

For use up to 24 hours.

For patients greater than 15 kg (33 lbs.)

Environment of use – hospital, sub-acute, pre-hospital, transport

1.3 Contraindications:

- DO NOT use the FLOCAP for the detection of Hypercapnia/Hypercarbia.
- DO NOT use the FLOCAP for the detection of main-stem bronchial intubation.
- DO NOT use the FLOCAP during mouth to tube ventilation.
- DO NOT use the FLOCAP to detect oropharyngeal tube placement.
- Standard clinical assessment must be used.

When low pulmonary perfusion coincides with accidental esophageal intubation, colorimetric CO_2 indication cannot be properly interpreted. However, if proper tube placement is ascertained by independent means, then the FLOCAP may be used to help assess the progress of positive pressure ventilation as evidenced by an increase in end-tidal CO_2.

1.4 Warnings:

- DO NOT use if you have blue-yellow color blindness.
- DO NOT use on patients with body weight less than 15kg (33lbs) due to the potential for rebreathing exhaled CO_2.
- DO NOT use the FLOCAP with devices that elevate humidity such as nebulizers or heated humidifiers.
- DO NOT use in the presence of the following agents: atropine, infasurf, naloxone, intratracheal epinephrine, trichloroethylene, chloroform.
- DO NOT use the FLOCAP for a duration of more than 24 hours.
- For use with air and oxygen only; chemical interactions will affect device accuracy.
- Read the entire contents of this operating manual before using the FLOCAP.

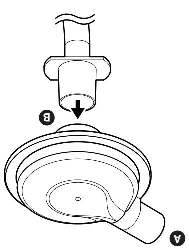
Periodic color changes reflect the breathing pattern of the patient. However, a permanent purple to purple-beige color indicates a lack of exhaled carbon dioxide, the cause of which requires immediate attention. If the purple-beige color does not appear during a breathing cycle, this may indicate a significant degree of carbon dioxide rebreathing and should also be of immediate concern.

1.5 Cautions:

- Single use only, discard after use.
- Interpreting color change before 6 complete breaths may lead to a false result.
- Excessively low cardiac output will result in low CO_2 content in the lungs.
- Excessive CO_2 in the stomach may cause erroneous color change.
- Contamination, liquid water or excessive moisture may cause poor visibility, limit litmus function or inhibit spinner motion. The FLOCAP should be replaced immediately if this occurs.
- Reflux of any kind into the FLOCAP may compromise its accuracy or performance. The FLOCAP should be replaced immediately if this occurs.
- The FLOCAP is an adjunct assessment tool and should not be relied upon as the sole means of verifying proper intubation. Follow your institutional guidelines for verifying proper intubation in addition to use of the FLOCAP.
- During cardiac arrest, CO_2 levels in the lungs may be too low to affect a color change in the FLOCAP. Re-establishment of pulmonary blood flow is required for the FLOCAP to function properly.
- Storage for extended periods at temperatures above 25°C may result in reduced shelf life.
- Do not use if the package is already unsealed.
- Do not open the pouch until ready to use, prolonged exposure to ambient air may affect accuracy or performance.
- The bright colored vane of the flow indicator is not intended to be a quantitative flow meter.
- At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.
- Do not use in an environment with insufficient lighting.
- Inspect the FLOCAP for damage prior to use.
- 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 CO_2 monitoring which remains necessary to provide quantitative measurements and patient alarms.

2.0 INSTRUCTIONS FOR USE:

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 around the edge is permissible.
2. To connect: Attach the FLOCAP securely between the ventilation source and the mask or endotracheal tube, by pushing together and rotating slightly, as illustrated here:
   - A Connect to breathing device here.
   - B Connect to endotracheal tube here.



3. For CO_2 Detection: Ventilate the patient with 6 complete breaths. At the end of the 6 breath cycles, check the color of the FLOCAP indicator.
   - 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 beige, continue to ventilate with 6 additional breaths and recheck. If the color has not moved towards yellow, this indicates insufficient exhaled CO_2. **This requires immediate attention**. Employ your institution's protocol to verify proper tube placement and adequate gas exchange.
   - If the color remains purple, or a color similar to purple, the patient may not have a patent airway or the endotracheal tube may not be positioned correctly. **This requires immediate attention.** Employ your institution's protocol to verify proper tube placement and adequate gas exchange.
   - Continue to monitor the color of the CO_2 indicator throughout the entire time the device is in use.
   - 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 CO_2. **This requires immediate attention.**
4. For Exhalation Monitoring: Monitor the rate at which the flow indicator rotates during exhalation to visually observe the patient's exhalation and detect when exhalation is complete. The FLOCAP is not intended to be a quantitative indicator. Follow your institution's guidelines for breath frequency and tidal volume during resuscitation and for avoiding auto-PEEP during resuscitation. At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.

3.0 COLOR & FLOW INDICATOR INTERPRETATION:

Note that the detector color will continue to fluctuate from inspiration to expiration for up to twenty-four hours. When the gas contains CO_2 (i.e., expired gas from the patient), the indicator color will change. Following are the color indications of the FloCap indicator device.

Purple (0%)	No carbon dioxide detected
Beige (1-2%)	Exposed to CO_2, approx. 1% to 2%
Yellow Beige (2-5%)	At intermediate CO2 concentrations of 2%-5%
Yellow (5%)	Exposed to 5% or greater CO_2
Permanent Yellow	A damaged indicator

Spinning*	Patient is exhaling
Not Spinning	Exhalation flow < 1 LPM

**At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.*

4.0 MECHANICAL SPECIFICATIONS:

Internal Volume:	< 25 ml
Pressure Drop according to ISO 9360-1:	
at 30 LPM	0.7 cmH2O
at 60 LPM	2.7 cmH2O
at 90 LPM	5.7 cmH2O
Leak rate according to ISO 9360-1:	0.0 ml/min
Compliance according to ISO 9360-1:	0.44 ml/kPa
Device Weight:	23 grams
Connector ports according to ISO 5356-1:	
Patient end	15mm I.D./22mm O.D.
Ventilator end	15mm O.D.

5.0 SYMBOL GUIDE:

Federal law (USA) restricts this device to sale on or by the order of a physician	Rx ONLY	Not Manufactured with Natural Rubber Latex	LATEX	Contains no Polyvinyl Chloride	PVC
Single Use Only	2	Storage Temperature	5°C (41°F) 25°C (75°F)	Keep Dry	
Consult instructions for use	i	Non-sterile	non sterile	Keep Out of Sunlight	
Manufacturer		DO NOT		Caution	!
Made in USA	MADE IN USA	Authorized Representative	EC REP		

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