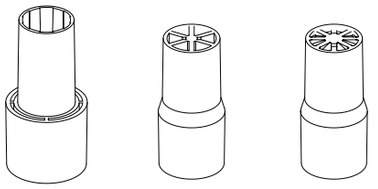
Instructions For Use: MaxCap CO_2 Indicator

SunMed

Not Made with Natural Rubber Latex | NON STERILE | Single Use | 5°C (41°F) | 37°C (98°F) | Rx ONLY USA Law Only

REF



Regular R500P30 | Pediatric R500P31 | Neonatal R500P32

1.0 SYSTEM OVERVIEW

1.1 Description

The MaxCap is a disposable, single-use CO_2 indication device designed for placement between a breathing device and a patient's endotracheal tube or mask for visualization of exhaled CO_2. 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.

1.2 Indications for use

The MaxCap is indicated to provide a semi-quantitative visualization of the CO_2 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.

- For use up to 6 hours.
- MaxCap-REG (R500P30) is intended for use with patients greater than 15 kg (33 lbs.)
- MaxCap-Ped (R500P31) is intended for use with pediatric patients 1 kg to 15 kg (2.2 to 33 lbs.)
- MaxCap-Neo (R500P32) is intended for use with neonates and infants 250 g to 6 kg (0.55 to 13 lbs.)
- Environment of use—hospital, sub-acute facilities, pre-hospital, transport

1.3 Contraindications

- **DO NOT** use the MaxCap for the detection of Hypercapnia/ Hypercarbia.
- **DO NOT** use the MaxCap for the detection of main-stem bronchial intubation.
- **DO NOT** use the MaxCap during mouth to tube ventilation.
- **DO NOT** use the MaxCap 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 MaxCap 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 outside the range listed in the indications for use (Section 1.2) due to the potential for rebreathing exhaled CO_2 or significant flow restriction.
- **DO NOT USE** the MaxCap 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 MaxCap for a duration of more than 6 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 MaxCap.

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

- Do not use if it is beyond the Use-By date marked on the pouch.
- 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 or limit litmus function. The MaxCap should be replaced immediately if this occurs.
- Reflux of any kind into the MaxCap may compromise its accuracy or performance. The MaxCap should be replaced immediately if this occurs.
- The MaxCap 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 MaxCap.

During cardiac arrest, CO_2 levels in the lungs may be too low to affect a color change in the MaxCap. Re-establishment of pulmonary blood flow is required for the MaxCap to function properly.

Storage for extended periods at temperatures above 37°C may result in reduced shelf life.

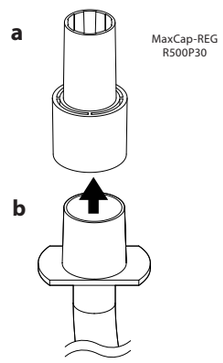
- **DO NOT** use if the package is already unsealed.
- **DO NOT** open the pouch until ready to use, prolonged exposure to ambient air may affect accuracy or performance.
- DO NOT use in an environment with insufficient lighting.
- Inspect the MaxCap for damage prior to use.
- **DO NOT** use in the presence of acidic liquid or medication.

Avoid exposure to strong sunlight and other sources of ultraviolet light.

- If the MaxCap is used for more than 2 hours, the response time for CO_2 changes may extend beyond 6 breaths.
- If the MaxCap is used for more than 2 hours, the edges of the foam may remain yellow even if the CO_2 level decreases below 5%.

2.0 INSTRUCTIONS FOR USE

1. **To open:** Open the pouch, remove and inspect the MaxCap. 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 MaxCap 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 MaxCap 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 6 hours of use.
- During the course of ventilation, if the MaxCap returns to and remains purple or beige colored, this indicates insufficient exhaled CO_2. This requires immediate attention.

3.0 COLOR & FLOW INDICATOR INTERPRETATION

Purple (0%).....No carbon dioxide detected
Beige (1-2%).....Exposed to CO_2, approx. 1% to 2%
Yellow (5%)..... Exposed to 5% or greater CO_2

Mechanical Specifications	MaxCap-Reg (R500P30)	MaxCap-Ped (R500P31)	MaxCap-Neo (R500P32)
Internal Volume (mL)	7.0	2.5	1.0
Pressure Drop According to ISO 9360-1 (cmH_2O)	0.6 @ 30 LPM 2.4 @ 60 LPM 5.4 @ 90 LPM	0.2 @ 5 LPM 0.5 @ 10 LPM 2.8 @ 30 LPM	2.1@ 5 LPM 5.2 @ 10 LPM 9.8 @ 15 LPM
Device Weight (g)	6	4	5
Patient End Connector Ports according to ISO 5356-1	15 mm I.D./ 22 mm O.D.	15 mm I.D.	15 mm I.D.
Ventilator End Connector Ports according to ISO 5356-1	15 mm O.D.	15 mm O.D.	15 mm O.D.

SunMed, LLC
2710 Northridge Dr. NW, Suite A
Grand Rapids, MI 49544 USA

SunMed
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a Subsidiary of SunMed Holdings, LLC
www.Sun-Med.com
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