

Ambu CO₂ Detector- Pedi, Disposable

Directions for Use



US: Rx
Only



Single Use
Do not
re-use



Maximum
Temperature



Not Made
with Natural
Rubber Latex



Product is
Phthalates and
DEHP Free



NON
STERILE



Caution

Description

The Ambu CO₂ Detector-Pedi is a carbon dioxide detector designed to detect CO₂ in the exhaled breath of a patient. The Ambu CO₂ Detector-Pedi provides a colorimetric indication of end-tidal CO₂ by changing from violet at ambient levels of CO₂ to yellow at normal respiratory levels. The Ambu CO₂ Detector-Pedi is used during mechanical ventilation to assist in the placement of an endotracheal or nasotracheal tube, or to verify the condition of a patient airway. The detector may be used for up to 2 hours of continuous use and is designed for patients between 1-15kg (2.2-33lbs).

Indications for Use

Use during mask ventilation to assist in the determination of a patent airway.

Use to assist in the placement or verification of the location of an endotracheal or nasotracheal tube.

Contraindications:

- Do not use to detect hypercarbia.
- Do not use during mouth to mask or mouth to tube ventilation.
- Do not use for oropharyngeal tube placement.
- Do not use to detect the location of the tube within the airway (main stem bronchial intubation). Standard assessment methods must be used.
- Do not use this device on patients with body weight greater than 15kg (33lbs) due to potential increased airway resistance.
- Do not use with humidification.

Warnings

1. Interpreting results before 6 clearing breaths can result in a false positive indication of tube placement.
2. The Ambu CO₂ Detector-Pedi only detects the presence of CO₂ and can not detect main stem bronchial intubation. Standard assessment methods must be used.
3. Do not use this device on patients with body weight greater than 15kg (33lbs) due to potential increased airway resistance.
4. The detector may not be suitable for use by clinicians with color blindness.
5. If application of the resuscitator syringe port is required, do not use the CO₂ Detector-Pedi unless you use the optional adapter with syringe port (Ambu PN 000-172-716) which is mount below the CO₂ Detector-Pedi (mount adapter to the patient end connector of the CO₂ Detector-Pedi).

Cautions

1. The Ambu CO₂ Detector-Pedi must be inspected for damage prior to use. If any damage is noted or if the indicator is not violet, do not use.
2. Avoid exposing the Ambu CO₂ Detector-Pedi to direct sunlight or excessive temperatures (above 24C (75F)) as these conditions accelerate aging and reduces the product's shelf life.
3. The Ambu CO₂ Detector-Pedi is a single patient use device. Do not sterilize as this may affect the indicator.

4. Large airway leaks may decrease tidal volume delivered to the detector which can limit the accuracy of the Ambu CO₂ Detector-Pedi.
5. Do not use the Ambu CO₂ Detector-Pedi with a heated humidifier or other high humidity devices as extreme humidity can degrade the function of the indicator.
6. Immediately replace the Ambu CO₂ Detector-Pedi if it is exposed to gastric or other contamination. This contamination can prevent the function of the indicator and can increase airway resistance. Continued use after contamination can also allow aspiration of the gastric contents on the next inhalation cycle.
7. When using the Ambu CO₂ Detector-Pedi during cardiac arrest, the CO₂ exhaled may be below the detection limit of the Ambu CO₂ Detector-Pedi (0.5%). Establishing forward blood flow is essential if the indication of the Ambu CO₂ Detector-Pedi is to be relied upon.
8. The Ambu CO₂ Detector-Pedi must not be the only indicator of proper tube placement or the effectiveness of resuscitation or CPR. Other clinical procedures and techniques should still be used.
9. The use of chemicals in the airway of the patient may affect the indicator of the Ambu CO₂ Detector-Pedi. Do not use with trichloroethylene or chloroform as these chemicals are known to affect the indicator.

Instructions for Use

1. Open the foil bag. Remove and inspect the Ambu CO₂ Detector-Pedi color. Verify that the detector color is as dark as or darker than the "Check" color (the violet shown on the detector's label). If the detector is not as dark as or darker than the Check color, the detector should not be used.
2. If the patient is to be intubated, insert the endotracheal tube and inflate the cuff, if applicable.
3. In the case of mask ventilation, connect the Ambu CO₂ Detector-Pedi between the ventilation source and the mask. With tube ventilation connect the Ambu CO₂ Detector-Pedi between the ventilation source and the tube. Note if an HME is being used, connect the HME to the endotracheal tube and connect the Ambu CO₂ Detector-Pedi between the HME and the ventilation source.
4. Ventilate the patient with 6 clearing breaths; then at the end of the exhalation cycle, check the color of the Ambu CO₂ Detector-Pedi indicator. If the color of the indicator is in the "Yes" range of colors on the color reference label, secure the tube and/or continue to ventilate the patient. If the color of the indicator is in the "Transitional" color range (colors lighter than the "Check" color range but not yet in the "Yes" color range) ventilate with 6 additional breaths and recheck. If the color has not moved to the "Yes" range, consult the "Color Interpretation Section" that follows for more detail in interpreting the results. If the color is as dark or darker as the violet of the "Check" color, this is indicative of no or extremely low CO₂. Consult the "Color Interpretation Section" that follows.
5. Under normal conditions the Ambu CO₂ Detector-Pedi will fluctuate on a breath-to-breath basis back and forth from the violets of the "Check" colors to a color in the "Yes" range of colors during inspiration and exhalation respectively. If the detector returns to and remains violet colored, tube placement has been dislodged from the trachea or the patient is in cardiac arrest/respiratory distress. Near the end of the useful life of the Ambu CO₂ Detector-Pedi, the indicator will not change colors on a breath-to-breath basis between inspiratory and expiratory cycles but instead will remain a fixed color. When the indicator's useful life has expired it will change to yellow permanently.

Color Interpretation

With Mask Ventilation

Color range "Yes" indicates the presents of CO₂ in the exhaled breath. This is indicative of forward blood flow and an uncompromised airway. Continue to ventilate as required. Use standard procedures to determine requirement for additional airway management.

Transitional color range (colors lighter than the "Check" color range but not yet in the "Yes" color range) This may indicate a blocked airway, low blood flow or hypocarbia. Evaluate pulmonary and cardiac condition and follow standard procedures regarding airway management and / or CPR.

Color range "Check" color not yet in the "Yes" color range indicates no CO₂ or extremely low levels of CO₂ in the exhaled breath. This is indicative of low or no forward blood flow and/or a compromised airway. Evaluate pulmonary and cardiac condition and follow standard procedures regarding airway management and/or CPR.

Ventilation with Endotracheal Tube

Color range "Yes" indicates the presents of CO₂ in the exhaled breath. This indicates that the tube is in the trachea. Secure the tube and continue to observe color change.

Transitional color range (colors lighter than the "Check" color range but not yet in the "Yes" color range) This may indicate misintubation with retained CO₂ in the esophagus, low blood flow or hypocarbia. Give 6 additional breaths and check color on full end expiration. If the color remains in the transition range and shows a distinguishable change in color from inspiration to exhalation, the tube is located in the trachea with low blood flow. Secure the tube and continue to observe color change.

Color range "Check" colors not yet in the "Yes" color range indicates no CO₂ or extremely low levels of CO₂ in the exhaled breath. This can be caused by an esophageal intubation or low pulmonary blood flow. Visually check to verify the ET tube is through the vocal cords. If the ET tube passes through the vocal cords this condition is indicative of inadequate pulmonary blood flow. Take clinical action appropriate for this condition. If the ET tube has not passed through the vocal cords, the tube is not in the trachea. Reintubate and check position with the detector.

Mechanical Specifications

Internal Volume:	3cc
Resistance to Flow:	3.5cm H ₂ O ± 0.5 cm at 10L/min
Weight:	Less than 5g
Connector Ports:	Patient end: 18 mm O.D. / 15 mm I.D. Proximal end: 15 mm O.D. / 5mm I.D.

Patent Pending

Ambu

Distributed by Ambu Inc:
6721 Columbia Gateway Drive, Suite 200
Columbia, Maryland 21046
www.ambuusa.com
1-800-262-8462

Ambu A/S
Baltorbakken 13
2750 Ballerup DENMARK

Assembled in Mexico
74622, Rev. 5 2023/06