AirLife®

AirLife™
Open Et Oxygen Mask

REF Catalogue number

℞ ONLY Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

LOT Lot Number

Manufacturer

QTY Quantity

Date of manufacture

LATEX Not made with natural rubber latex

Single Use Do not re-use

Consult Instructions for Use

NON STERILE Non-Sterile

PHT DEHP Not made with DEHP

Caution

MR MR Safe

Use-by Date

% Humidity limitation

M Medium

STORAGE TEMP Storage Temperature

L Large

S Small

Warning

AU REP

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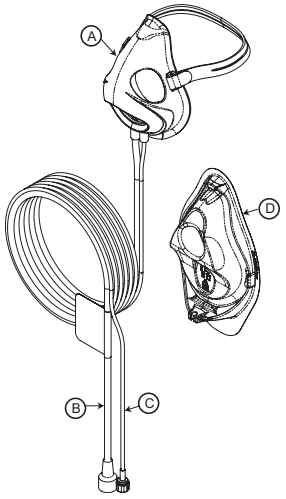
EN English

The AirLife Open Et Oxygen Mask consists of:

A Mask With Head Strap
B Oxygen Tubing
C Capnography Tubing
D Protective Packaging



Intended Use:

The AirLife Open Et Mask is a single use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients (≥20 kg).

Indications for Use

The AirLife Open Et Mask is a single use device that delivers supplemental oxygen while monitoring capnography for non-intubated spontaneously breathing patients (≥20 kg) in institutional settings under the supervision of a licensed healthcare practitioner.

Contraindication for Use

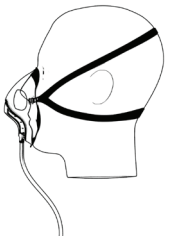
The AirLife Open Et Mask is contraindicated for use with humidification devices.

Directions for Use

1. Select the appropriate size for the patient where the mask covers upper nose bridge and lower chin area.

Mask Size	Catalogue number
Small	AM-2200
Medium	AM-2000
Large	AM-2100

2. Remove device from the Protective Packaging (D).
3. Inspect for signs of damage. Do not use if damage is apparent.
4. Securely connect the Oxygen Tubing (B) with universal oxygen connector to an oxygen source with flow meter.
5. Adjust oxygen flow rate as indicated by the clinical condition of the patient. Confirm that gas is flowing through the mask.
6. Place the Mask with Head Strap (A) on the patient's face and position the elastic strap around the back of the patient's head. Avoid placing the strap directly onto the patient's ears. Adjust strap tension for proper fit and secure the strap end with the hook and loop tab.



7. Securely connect Capnography Tubing (C) to capnography monitor. Separate tubing as needed. When using a standard capnography monitor, connect the luer connector to the monitor.

   Note: The displayed CO_2 values may vary with the sampling port position, oxygen flow rate and respiratory pattern.
8. Monitor the patient while delivering oxygen therapy, including SpO2, and titrate the oxygen flow rate as indicated by the clinical condition of the patient and to achieve prescribed saturation range.
9. This product is a Non-Sterile device and may be used for a maximum of 7 days.

   Note: Replace mask set if Capnography Tubing (C) is occluded or signs of deterioration such as discoloration and/or cracking occur.
10. When using instruments through the Oral Access opening, refer to the maximum Outer Diameter (OD) stated on Oral Access Chart in Technical Specifications.

⚠ Cautions

1. Mask is single use only.
2. Do not clean or sterilize.
3. Replace mask if mask strap appears frayed or damaged.
4. The use of capnography in patients with severe respiratory failure can lead to erroneous $PETCO_2$ values.

⚠ Warnings

1. AirLife Open Et Oxygen Mask is only for use by a trained clinician, trained professionals, or under a trained healthcare professional's supervision.
2. Read all instructions prior to using AirLife AirLife Open Et Oxygen Mask.
3. Monitor the patient's oxygen levels during use. Do not over oxygenate; such action may lead to patient injury.
4. Discontinue using the mask if there is an allergic reaction to any part of the mask.
5. Do not use the mask near spark or open flame.
6. Do not over tighten the mask strap or apply mask over other oxygen delivery devices. Excess pressure may cause skin breakdown; evaluate the patient and periodically inspect for any signs of skin deterioration.
7. Route the tubings to avoid tangling, pinch point and crush damage. Damage to tubing may interrupt oxygen delivery to patient or $EtCO_2$ monitoring.
8. Supervise and monitor children to avoid risk of mask removal or entanglement within the tubing.
9. Do not connect Capnography Tubing to anything other than a capnography monitor.
10. Replace mask if soiled prior to 7 day duration.
11. Mask is MRI safe when used with MRI compatible equipment.
12. Do not use above recommended instrument size as it may cause damage.

36-23176.INIFU, Rev. 1 2025/03

Technical Specifications

1. Oxygen flow rate 1 -15 lpm, plus flush Input pressure 240 kPa to 550 kPa (35 Psi to 80 Psi)

2. This device is not made with the plasticizer Diethyl-hexylphthalate (DEHP).

3. Maximum Outer Diameter (OD) for Oral Access opening on mask.

Maximum Outer Diameter (OD) of Instruments for oral access opening in mask			
	AM-2200 (Small)	**AM-2000 (Medium)**	**AM-2100 (Large)**
Oral Access	✓	✓	✓
Maximum Instrument Diameter	9.5mm OD	17.5mm OD	17.5mm OD

⚠ **Warning**

Inserting instruments into the mask openings that are larger than the maximum diameter specified may cause damage to the device and harm to the patient.

4. The gas sampling line terminates in a luer lock compliant with ISO 80369-7:2021. Gas sampling flow rates are controlled by the capnography equipment and may sample gas at a rate up to 250 cc/min.

Storage & Transport Environment

Temperature: -20°C to 50 °C
Humidity: 0% to 85% RH

Disposal Specifications

Dispose of all materials in accordance with local, state, and federal regulations. Decontaminate and dispose of all potentially biohazardous material.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer at productquality@myAirLife.com.