4702F O_2/$EtCO_2$ Divided Nasal Sampling Cannula – Pediatric

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

O_2/$EtCO_2$ Divided Nasal Sampling Cannula, Female Luer, Adaptor	
Reference Number	4702F-7-0-10 4702F-7-0-25
Manufacturer	SunMed LLC/Salter Labs
FDA	Class II K151421
Product Code	CCK Analyzer, Gas Carbon-Dioxide, Gaseous-Phase
CE Mark / Notified Body	2797/BSI Group
Device Classification – EU	Class I, Rule 2 EU MDR 2017/745 Annex VIII
EMDN Code	R9099, Respiratory and Anesthesia Devices, Other Z120306, Vital Signs Monitoring Instrument
GMDN Code	36306, Carbon Dioxide Nasal Cannula
UMDNS Code	11838, Gas Sampling Unit
Made In	Mexico
Oxygen Delivery	Yes
CO_2 Sampling	Yes
Patient Population	Pediatric
Usage	Disposable, Single Patient Use
Sterile	Non-Sterile
Packaging	Individually Packaged, 10/case or 25/case
Shelf Life	3 years

Description: Over-the-ear style nasal cannula with a divided face piece. Supplemental oxygen is delivered to one nostril, while sampling patients' exhaled gases from the other nostril. CO_2 sampling line has a female-style luer connector. Packing includes an adaptor, 22 mm x 6 mm.

Intended use: The O_2 Delivery / CO_2 Sampling Nasal Cannula is intended to be used with spontaneous breathing patients who require simultaneous low flow oxygen delivery and exhaled gas sampling.

Patient population: For use with spontaneously breathing, non-intubated pediatric patients.

Usage: Non-sterile, disposable, single-patient multiple use.

Area of use: Locations where procedures are performed where the patient requires monitoring of exhaled gases e.g. procedural sedation, lower GI procedures, EMS, or surgical cases. Used in hospital, sub-acute, and pre-hospital settings.

Contraindications: No known.

Benefits: 1) Improve oxygen saturation. 2) Notifies clinicians of change in patient's ventilatory status. 3) Improves accuracy of $EtCO_2$ value while delivering oxygen.

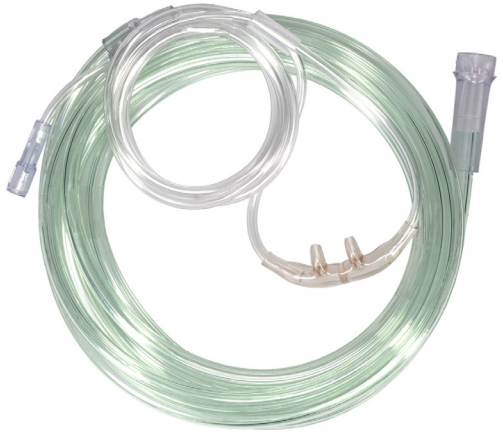
Device Specifications

Description	Specification
CO_2 Sampling Line Internal Diameter	0.075" (1.91 mm)
CO_2 Sampling Line Length	2" (0.05 m)
CO_2 Line End Connectors	Female Luer Style
CO_2 Sampling Rate	≤ 0.5 LPM
O_2 Supply Tubing	7' (2.1 m)
O_2 Tubing Diameter	3/16"
O_2 Flow Rate	≤ 6 LPM
O_2 End Connector	Trumpet, Push-On
Adaptor	22 mm ID / 6 mm OD
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

Product Material

Part Description	Material
Nasal Face Piece	Plastisol
Oxygen Tubing	Polyvinyl Chloride
Oxygen End Connector	Polyvinyl Chloride
CO_2 Tubing	Polyvinyl Chloride
CO_2 Connector	Acrylonitrile Butadiene Styrene
Bolo	Low Density Polyethylene

Part Number	UOM	GTIN
4702F-7-0	Each	00607411000263
4702F-7-0-10	Case	10607411000260
4702F-7-0-25	Case	10607411400435



Latex: SunMed® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does not contact components or finished goods during the manufacturing process.

Phthalates: The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

Mercury-Lead: The selected materials do not contain lead or mercury.

Biocompatible: per device classification in ISO 10993. SunMed manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMPs) as listed in 21 C.F.R. (U.S. Code of Federal Regulations).

TDS-10085 Rev 1

SunMed®