TDS-10100 Rev

4000 EtCO₂ Nasal Sampling Cannula – Adult

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

EtCO ₂ Nasal Sampling Cannula, Male Luer				
Reference Number	4000-7-10 4000-7-25 4000-7-250			
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	No			
CO ₂ Sampling	Yes			
Patient Population	Adult			
Usage	Disposable, Single Patient Use			
Sterile	Non-Sterile			
Packaging	Individually packaged, 10/case, 25/case, or 250/case			
Shelf Life	3 years			

Description: Over-the-ear style EtCO₂ nasal sampling cannula with a male luer style connector.

Intended use: The Nasal CO₂ Sample Line is intended to be used to sample exhaled gas in spontaneously breathing patients requiring expired gas monitoring.

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

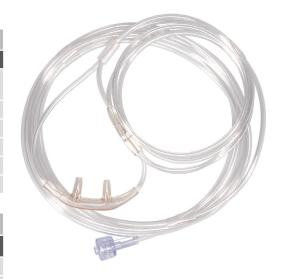
Contraindications: No known.

Benefits: Notifies clinicians of change in patient's ventilatory status.

Device Specifications			
Description	Specification		
CO₂ Sampling Line Internal Diameter	0.050"(1.27 mm)		
CO ₂ Sampling Line Length	7' (2.1 m)		
CO ₂ Line End Connectors	Male Luer Style		
CO₂ Sampling Rate	≤ 0.5 LPM		
Operating Temperature	5°C to 40°C		
Storage Temperature	-20°C to 50°C		
Operating Temperature	5°C to 40°C		

Product Material		
Part Description	Material	
Nasal Face Piece	Plastisol	
Headset Tubing	Polyvinyl Chloride	
CO ₂ Tubing	Polyvinyl Chloride	
CO ₂ Connector	Acrylonitrile Butadiene Styrene	
Bolo	Low Density Polyethylene	

Part Number	UOM	GTIN
4000-7	Each	00607411400001
4000-7-10	Case	10607411400008
4000-7-25	Case	20607411400005
4000-7-250	Case	30607411400002



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).

