

# 4700 Series O<sub>2</sub>/EtCO<sub>2</sub> Divided Nasal Sampling Cannula

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

## Device Manufacturing Specifications

|                              |                                                                         |
|------------------------------|-------------------------------------------------------------------------|
| Reference Number             | 4700, 4701, 4702, 4703, 4704, 4705, 4707, 4783                          |
| Manufacturer                 | SunMed LLC/Salter Labs                                                  |
| Classification – US          | Class II                                                                |
| FDA Product Code             | CCK Analyzer, Gas Carbon-Dioxide, Gaseous-Phase                         |
| Classification – EU          | Class IIa                                                               |
| CE Mark/Notified Body        | CE 2797/BSI Group                                                       |
| EU Authorized Representative | Mt Promedt Consulting GmbH                                              |
| Classification – Australia   | Class IIa                                                               |
| Classification – Canada      | Class 2                                                                 |
| Classification – Japan       | Class II                                                                |
| EMDN Code                    | 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 <sub>2</sub> Sampling     | Yes                                                                     |
| Patient Population           | Spontaneously Breathing Non-Intubated Infant, Toddler, Pediatric, Adult |
| Usage                        | Disposable, Single Patient Use                                          |
| Sterile                      | Non-Sterile                                                             |
| Packaging                    | Individually Packaged, 10/Case or 25/Case                               |
| Shelf Life                   | 5 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. The adult cannula prongs have two small holes, Salter Eyes, to enable uninterrupted monitoring should the prongs become occluded. CO<sub>2</sub> sampling line is available with male luer, female luer or male slip tip connector. Packing includes an adaptor, 22 mm x 6 mm.

**Intended Purpose:** The O<sub>2</sub> delivery/CO<sub>2</sub> sampling nasal cannula is intended to be used with spontaneous breathing patients who require simultaneous low flow oxygen delivery and exhaled gas sampling.

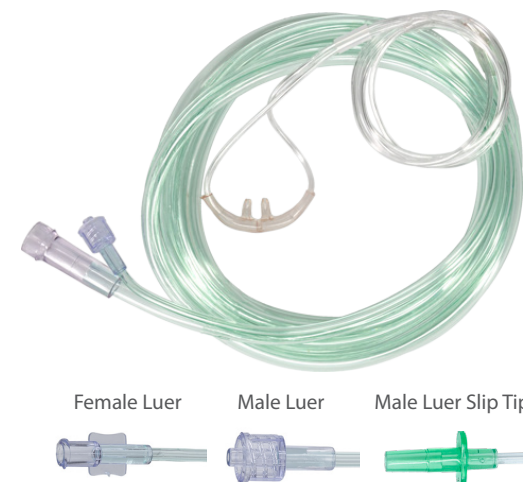
**Area of Use:** Locations where procedures are performed where the patient requires monitoring of exhaled gases e.g. procedural sedation, lower GI procedures, EMS, or surgical cases. Used in hospital, sub-acute, and pre-hospital settings.

## Device Specifications

| Description                                     | Specification                                                 |
|-------------------------------------------------|---------------------------------------------------------------|
| CO <sub>2</sub> Sampling Line Internal Diameter | 0.055" (1.4 mm)                                               |
| CO <sub>2</sub> Sampling Line Length            | 2' (0.6 m), 7' (2.1 m), 10' (3.0 m), 13' (3.9 m), 14' (4.2 m) |
| CO <sub>2</sub> Line Connectors                 | Male Luer Style, Male Luer Slip Tip                           |
| CO <sub>2</sub> Line Connector (F)              | Female Luer Style                                             |
| CO <sub>2</sub> Sampling Rate                   | ≤ 0.5 LPM                                                     |
| O <sub>2</sub> Supply Length                    | 2' (0.6 m), 7' (2.1 m), 10' (3.0 m), 13' (3.9 m), 14' (4.2 m) |
| O <sub>2</sub> Tubing Diameter                  | 3/16"                                                         |
| O <sub>2</sub> Flow Rate Infant                 | ≤ 3 LPM                                                       |
| O <sub>2</sub> Flow Rate Pediatric              | ≤ 6 LPM                                                       |
| O <sub>2</sub> Flow Rate Adult                  | ≤ 6 LPM                                                       |
| O <sub>2</sub> 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                                                 |

## Device Material

| Component                    | Material                        |
|------------------------------|---------------------------------|
| Nasal Face Piece             | Plastisol                       |
| O <sub>2</sub> Tubing        | Polyvinyl Chloride              |
| O <sub>2</sub> End Connector | Polyvinyl Chloride              |
| CO <sub>2</sub> Tubing       | Polyvinyl Chloride              |
| CO <sub>2</sub> Connector    | Acrylonitrile Butadiene Styrene |
| Bolo                         | Low Density Polyethylene        |



**Contraindications:** No known.

**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.

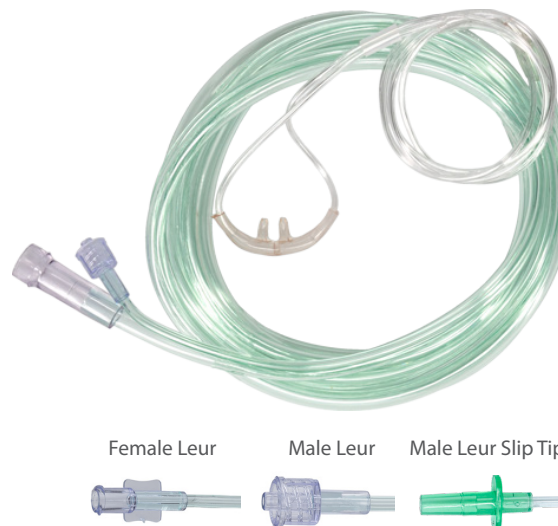
**Mercury-Lead:** The selected materials do not contain lead or mercury.

**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). Device contains TNPP.



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| Size      | Part Number  | CO <sub>2</sub> Connector | UOM  | GTIN           |
|-----------|--------------|---------------------------|------|----------------|
| Infant    | 4700-7-7     | Male Luer                 | Each | 00607411400391 |
| Infant    | 4700-7-7-25  | Male Luer                 | Case | 20607411400395 |
| Infant    | 4701-7-0     | Male Luer                 | Each | 00607411400414 |
| Infant    | 4701-7-0-25  | Male Luer                 | Case | 20607411400418 |
| Infant    | 4700F-7-7    | Female Luer               | Each | 00607411400407 |
| Infant    | 4700F-7-7-25 | Female Luer               | Case | 20607411400401 |
| Infant    | 4701F-7-0    | Female Luer               | Each | 00607411400421 |
| Infant    | 4701F-7-0-25 | Female Luer               | Case | 20607411400425 |
| Toddler   | 4704-7-7     | Male Luer                 | Each | 00607411400698 |
| Toddler   | 4704-7-7-25  | Male Luer                 | Case | 20607411400692 |
| Toddler   | 4705-7-0     | Male Luer                 | Each | 00607411400476 |
| Toddler   | 4705-7-0-25  | Male Luer                 | Case | 20607411400470 |
| Toddler   | 4704F-7-7    | Female Luer               | Each | 00607411400704 |
| Toddler   | 4704F-7-7-25 | Female Luer               | Case | 20607411000708 |
| Toddler   | 4705F-7-0    | Female Luer               | Each | 00607411400483 |
| Toddler   | 4705F-7-0-25 | Female Luer               | Case | 10607411400480 |
| Pediatric | 4702-7-0     | Male Luer                 | Each | 00607411400438 |
| Pediatric | 4702-7-0-25  | Male Luer                 | Case | 10607411400435 |
| Pediatric | 4703-7-7     | Male Luer                 | Each | 00607411400452 |
| Pediatric | 4703-7-7-25  | Male Luer                 | Case | 20607411400456 |
| Pediatric | 4702F-7-0    | Female Luer               | Each | 00607411400263 |
| Pediatric | 4702F-7-0-25 | Female Luer               | Case | 20607411000267 |
| Pediatric | 4703F-7-0    | Female Luer               | Each | 00607411000270 |
| Pediatric | 4703F-7-0-10 | Female Luer               | Case | 10607411000277 |
| Pediatric | 4703F-7-0-25 | Female Luer               | Case | 20607411000274 |
| Adult     | 4707-7-7     | Male Luer                 | Each | 00607411400544 |
| Adult     | 4707-7-7-25  | Male Luer                 | Case | 20607411400548 |



| Size  | Part Number    | CO <sub>2</sub> Connector | UOM  | GTIN           |
|-------|----------------|---------------------------|------|----------------|
| Adult | 4707-10-10     | Male Luer                 | Each | 00607411401978 |
| Adult | 4707-10-10-25  | Male Luer                 | Case | 10607411401975 |
| Adult | 4707-13-13     | Male Luer                 | Each | 00607411401060 |
| Adult | 4707-13-13-25  | Male Luer                 | Case | 10607411401067 |
| Adult | 4707SP-7-7     | Male Luer                 | Each | 00607411401251 |
| Adult | 4707SP-7-7-25  | Male Luer                 | Case | 10607411401258 |
| Adult | 4707F-7-7      | Female Luer               | Each | 00607411400551 |
| Adult | 4707F-7-7-25   | Female Luer               | Case | 20607411400555 |
| Adult | 4707F-14-14    | Female Luer               | Each | 00607411401985 |
| Adult | 4707F-14-14-25 | Female Luer               | Case | 10607411401982 |
| Adult | 4783-7-2       | Male Luer Slip Tip        | Each | 00607411400599 |
| Adult | 4783-7-2-25    | Male Luer Slip Tip        | Case | 10607411400596 |