GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

SUPPLY CHAIN MANAGEMENT

Specification and Packaging Requirement

Product: GENERATOR INFANT NASAL FLOW

1. Product Specification

1.1 General Description

Product Name: infants Flow Specification Generator

The Infant Flow® LP is a variable-flow, microprocessor-controlled CPAP and bilevel CPAP (duoPAP) generator designed for premature infants, newborns, and children up to 30 kg, with automatic leak compensation and stable pressures.

Core Specifications and Features

- **Indication:** Non-invasive ventilation (NIV) for premature infants, newborns, and children ≤ 30 kg
- **Modes:**
  - **nCPAP** (nasal CPAP)
  - **duoPAP** (bilevel CPAP)
  - HFNC (high-flow nasal cannula) support
- **Flow control:** Variable flow with automatic dynamic control; flow is directly related to airway pressure (e.g., 8–9 L/min ≈ 5 cmH_2O)
- **Leak compensation:** Automatic dynamic leak compensation.
- **Work of breathing:** Minimal (iWOB) due to variable flow and stable pressure.
- **O_2 delivery:** Predicted intelligent closed-loop O_2 weaning (PRICO)
- **Humidification:** Integrated humidifier; optional abdominal sensor for apnea/low breath rate detection .

Equipment Components

- **Generators:** Infant Flow LP nCPAP Generator/Circuit Kit (various humidifier options).
- **Interfaces:** Nasal prongs (XS–XL), nasal masks (XS–XL), headgear, bonnets (size 000–7).
- **Accessories:** Extension tubes, fixation devices, optional transducer interface.

Operational Notes

- **Flow–pressure relationship:** Direct; adjust flow to achieve target pressure
- **Modes:** Select nCPAP or duoPAP via front panel; monitor parameters on display
- **Safety:** Do not attach to patient until setup and verification complete

In summary: The Infant Flow LP is a fully specified, variable-flow NIV generator for infants, with documented setup, calibration, and operational procedures in the CareFusion manua For full technical details, refer to the official *Infant Flow LP nCPAP System* workbook and quick guide from CareFusion

- Adhesion Type:
- Drainage Type:
- Filter:
- Coupling Mechanism:

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2. Performance Requirements
- Leak-Proof: N/A
- Skin Protection: yes
- Odor Control: N/A
- Wear Time: Continuously
- Flexibility: N/A
- Convexity Depth: N/A

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3. Packaging Requirements
3.1 Each in a closed package

- Labeling:
  - Product name & size
  - Lot number & expiration date
  - Sterility confirmation
  - Manufacturer details
  - Usage instructions & precautions

3.2 Box Packaging
- Quantity: each
- Material: Sturdy cardboard with tamper-evident seal
- Labeling:
  - Product specifications
  - Storage conditions
  - Batch number & expiration date
  - Regulatory compliance (e.g., CE Mark, FDA)

3.3 Shipping Carton

- Material: Corrugated cardboard
- Quantity: 15 BOXES =150 UNITS
- Handling Instructions:
  - Store in a cool, dry place
  - Protect from direct sunlight and moisture
  - Fragile – handle with care

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4. Regulatory & Compliance

- Sterilization: Ethylene oxide (EtO)
- Certifications: CE, FDA, ISO 13485
- Biocompatibility: Tested per ISO 10993

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5. Storage & Shelf Life

- Storage Conditions: 10°C – 30°C, dry environment
- Shelf Life: more than 5years manufacturing date



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