COMMERCIALLY AVAILABLE

2022

High flow nasal cannula with CPAP

Country of origin | New Zealand
Primary function | Treatment
Category | Medical device

Commercial information

Year of commercialization: 2021
Number of units distributed: 101-1,000
Currently marketed in: New Zealand
Brand: Company: Fisher & Paykel Healthcare Ltd. Brand: Optiflow
Model: Airvo 3

Product description

Airvo 3 delivers Nasal High Flow therapy (HFNC). High humidified room air flows provide respiratory support (reducing anatomical dead space & giving positive airway pressure). If needed, O_2 can also be delivered via Airvo 3, but O_2 is not required to provide respiratory support or a high flow of air. The gas is heated/humidified to provide patient comfort and therapy compliance. Airvo 3 can also provide bubble CPAP (Junior model) and CPAP/NIV therapy (Adult Acute model).

Product details

Consumables: Heated breathing tube & chamber, Optiflow Nasal Cannula – comes in three sizes for Adults and six sizes for Paediatrics or Bubble CPAP or Non-invasive ventilation Masks

Warranty duration: 2 years

Lifetime: 5 years

Energy requirements: Rechargeable battery, Continuous power supply, AC, 110V, 220V, 6-hour battery recharge cycle,0.67-hour battery life

Facility requirements: Specific temperature and/or humidity range, Operating conditions: Temperature: 18-28 C°, Humidity: 10-95% (RH), Altitude: 0-3000 m (9840 ft), Storage temperature: -10 to 50C° and Humidity: 10% to 95% Relative Humidity

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In low-resource settings, the COVID-19 pandemic has worsened and further exacerbated the long-standing need for accessible and reliable oxygen supplies. Lower respiratory tract infections are a leading cause of morbidity and mortality in low and lower-middle income countries and often necessitate supplemental oxygen therapy and/or non-invasive ventilation.

Airvo™3 allows for the delivery of high-flow nasal cannula oxygen (it retains all Airvo™2 features) and for C-PAP non-invasive ventilation among infants and adults. These characteristics contribute to making it a device of interest to treat severely hypoxemic patients in low-resource environments. Its use and application should be limited to secondary or tertiary healthcare facilities, where monitoring of the patient's clinical status can be ensured.

WHO specification comparison

AIRVO™3 compliance evaluation has been done using both the WHO "HFNC – High Flow Nasal Cannula" and "CPAP – Continuous Positive Airway Pressure" technical specifications.

This device fully complies with the "HFNC adult and paediatric" and "CPAP" WHO technical specifications

COMPLIANCE WITH "HFNC" and "CPAP": adult/paediatric. User/service draft manual provided. In-built turbine. Capability to generate a high flow of mixed room air and oxygen. Flow up to 60 L/min. Temperature of the warmed air. FiO_2 % available 21-100%. Pressure range compliant (up to 45 cmH2O). Graphical display and user interface with all required parameters available to be displayed. All required alarms provided. Trolley with wheels, brakes and dedicated spaces for accessories. Compliant power supply characteristics and possibility to use it in combination with an UPS to provide battery back

up in the case of AC power failure. IP22 protection level. RH% range. Automatic switch from AC power electric-line mode to battery operating mode. Compliant length of the main power cable (≥ 2 m). Necessary accessories and consumables are available. More than 10 languages available including English. Two years of warranty provided. Environmental requirements for storage/operations available.

NON-COMPLIANCE WITH "HFNC" and "CPAP": None.

Regulatory assessment

Pre-market assessment	Proceed with caution
Post-market assessment	Proceed with caution
Quality system assessment	Proceed

This product is commercially available in New Zealand and not distributed globally. Reports on pre-market design verification and validation have not been submitted. The clinical evaluation report and post-market documentation were not available. Adequate documentation should be provided to conduct regulatory and quality system reviews to demonstrate safety and efficacy of the device.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	→	→
Safety	→	→
Economy	!	!
Organizational	→	→
Legal	→	→
Social	→	→
Ethical	→	→
Green environment	!	!

Airvo3 is innovative due to its technical features. Similar to the predecessor model Airvo2, a recommendation can only be made with caution. This is mainly due to the questionable affordability. This cannot be conclusively assessed on the basis of the documents submitted.

Summary

Innovation		Technology evidence assessment	Recommend with caution
Technology readiness level	9		

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	✓	Ease of cleaning	!
Ease of Use	✓	Ease of maintenance	!
Positive impact on clinical outcomes	✗	Infrastructure requirements	✓
Affordability	!	Local access to sales support	!
Engineering resources minimization	✓	Local access to technical support	✗
Cultural and social acceptability	N/A	Local access to training	!
Environmental conditions	✓	Local access to spare parts	!
Aesthetics	✓	Locations of use within target setting	!

Target settings: Secondary & Tertiary level

Both the User and Technical manuals claim that the product life cycle is 5 years, with a shelf life of 0-2 years. These are ranges that are much shorter than users and industry are accustomed to for comparable products. This product contains software, motor, electronic display, alarm speaker, heating plate, and sensor but yet the manuals claim that preventive maintenance is not required. For a product that is expected to be subjected to fluid spills, electrical power instability, software glitches controlling a heating plate all operating around oxygen lines - there is a need for guidance on the frequency and process for testing and maintaining such a product on regular basis. The statement that PM is not required places patients and users in otherwise preventable hazard.

Intellectual property and local production

Technology transferability	✓
Openly access intellectual property	✗
Local production	!

Intellectual property – It is patent-protected with registered industrial designs and trademarks. The use of all intellectual property will require clearance. The use of patented compatible third-party products may also require clearance.

Local production – Current regional volumes are significantly low, creating a poor business case for dedicated local production.

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death
- WHO Coronavirus (COVID-19) Dashboard - https://covid19.who.int/
- Coronavirus disease (COVID-19) technical guidance: Patient management - https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management
- Living guidance for clinical management of COVID-19 - https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2
- Therapeutics and COVID-19: living guideline - https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.3
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - https://www.who.int/publications/i/item/WHO-MCA-17.07
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured
- Emergency care - https://www.who.int/emergencycare/systems/en/
- WHO Medical Emergency Checklist - https://www.who.int/publications/i/item/who-medical-emergency-checklist
- Guidelines for essential trauma care - https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care
- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - https://apps.who.int/iris/handle/10665/204584
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - https://apps.who.int/iris/handle/10665/331746