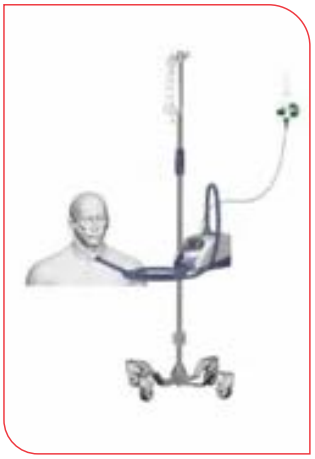
COMMERCIALLY AVAILABLE

2022

High flow nasal cannula

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



Commercial information

List price (USD): 3500
Year of commercialization: 2012
Number of units distributed: 50,000+
Currently marketed in: Globally
Brand: Company: Fisher & Paykel Healthcare. Brand: Optiflow
Model: Airvo 2

Product description

The Airvo 2 delivers Nasal High Flow therapy (HFNC). The delivery of high flows of humidified air provides respiratory support. Washout of anatomical dead space and positive airway pressure are two advantages. Supplemental oxygen can also be delivered via Airvo 2 if needed.

Heating/humidified gases, minimized condensation, and comfortable interfaces are used to ensure patient comfort and therapy compliance.

Product details

Consumables: 1. Heated breathing tube & chamber 2. Optiflow Nasal Cannula – comes in three sizes for Adults and two sizes for Paediatrics
Warranty duration: 2 years
Lifetime: 5-10 years
Energy requirements: Continuous power supply, AC, 110V, 220V, 165W
Facility requirements: Storage temperature: -10C to 60C°, 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.

High-flow nasal cannula oxygen can be employed in a variety of conditions, including respiratory distress syndrome in premature newborns, and hypoxemic respiratory failure in children and adults. High-flow oxygen devices have several advantages over traditional oxygen delivery systems, including increased comfort, more accurate delivery of fraction of inspired oxygen, warming and humidification of secretions to facilitate expectoration, washout of upper airway dead space, and a positive airway pressure effect. Compared to oxygen face masks, high-flow nasal cannulas have been linked to a decreased need for mechanical ventilation (but not mortality) in observational studies and randomized clinical trials.

Patients who require high-flow nasal cannula oxygen are at high risk of severe respiratory failure or mechanical ventilation. Hence, Airvo™ 2 may be best used in a monitored setting, such as an intensive or critical care unit, and may be applied in selected resource-limited contexts with comparable features.

WHO specification comparison

AIRVO 2 Optiflow System has been evaluated by comparing the technical documents provided with the High Flow Nasal cannula WHO technical specifications currently used and updated on November 2020.

This device COMPLIES with the "HFNC adult and paediatric" WHO technical specifications.

compliance: adult/paediatric. User manual/instructions for use provided. Built-in turbine. Capability to generate a high flow of mixed room air and oxygen. Flow up to 60 L/min. The temperature of the warmed air. FiO_2 % available 21-100%. Graphical display and user interface. Trolley with wheels, brakes, and dedicated spaces for accessories. Compliant power supply characteristics and the possibility to use it in combination with a UPS to provide battery backup in the case of AC power failure. Necessary accessories and consumables are available. More than ten languages are available, including English. Two years of warranty provided. Environmental requirements for storage/operations available. IP22 certified. Compliant RH% range. Displayed parameters and alarms required are available. The length of the main power cable is longer than 2m.

Non-compliance: None.

Regulatory assessment

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

There was insufficient documentation to perform a pre-market and post-market medical device regulatory review.

AIRVO-2 had received approvals from Australia, the USA, Canada, Japan, India, China, Yemen, South Africa, Russia, and Nigeria at the time of this report.

Technology evidence assessment

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

The device is commercially available in up to 120 countries, including LMICs. The device has a good safety profile based on the given clinical data provided. It is easy to operate and maintain. Transferability is provided. The device is used in accordance with prescribed guidelines. In high-income settings, cost-effectiveness has been demonstrated. Transfer to LMI settings based on provided documents however, is not possible. To provide robust statements on affordability in LMICs, additional documents are required.

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: Urban, Indoors, Secondary & Tertiary level

The Nasal High Flow System is integrated with UPS-supported gas heating and humidification. The system's portability and usability are clearly demonstrated. The unit and accessory (i.e. parts) costs for this application appear to be high, with a product life expectancy of 5 years. Maintenance is required with insufficient guidance for changing filters, heating element functionality, fluid spills damage, and attending to the UPS on a frequent basis. Field-based evaluation is pending.

Intellectual property and local production

Technology transferability	✓
Openly access intellectual property	✗
Local production	!

Intellectual property – It is patent-protected with registered industrial designs. AIRVO, MY AIRVO, and OPTIFLOW have trademark registrations.
The use of all intellectual property will require clearance. The use of patented compatible third-party products may also require clearance.

Local production – Due to the low volume of current regional demand, there is a weak 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