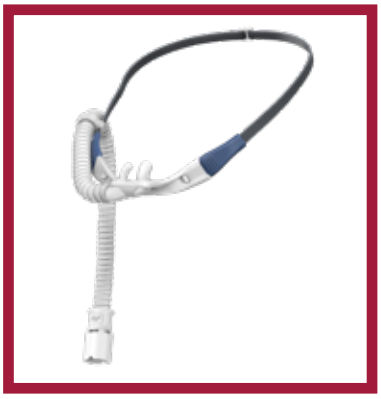
Commercially available

Asymmetric nasal high-flow therapy*

Country of origin | New Zealand
Primary use | Other
Category | Medical device (including in vitro diagnostics)



Commercial information

List price (USD): N/A
Year of commercialization: 2021
Number of units distributed: >10 000
Currently marketed in: 100+ countries including Kenya, Mali, Malawi, Rwanda, Uganda, and Zambia.
Model: OPT96X

Product description

Optiflow+ Duet is an improvement on the standard nasal high-flow (also called high-flow nasal cannula or HFNC). It has a unique, innovative asymmetric design, the right prong of the interface being larger than the left. The asymmetric nature of the prongs results in a significant improvement in the two primary mechanisms over the standard nasal high-flow therapy. They increase dynamic positive airway pressure and dead space clearance. This results in decreased breathing work for the patient and decreased minute ventilation. It has the added of making it harder to inadvertently occlude both nares and quieter therapy delivery.

Product details

Accessories: Not applicable
Consumables: Not applicable
Warranty duration: Optiflow+ Duet cannula have a shelf life of 3 years. As the product is a consumable it does not have a warranty duration.
Lifetime: 14 days duration of use (single patient use), 3 years shelf life
Energy requirements: Not applicable to Optiflow+ Duet. The flow driver will require energy.
Facility requirements: Not applicable

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*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Acute respiratory failure can complicate several acute or chronic respiratory and cardiovascular conditions. A high-flow nasal cannula (HFNC) has become an increasingly popular option to provide supplemental oxygen and respiratory support to spontaneously breathing patients. Advantages include patient comfort, delivery of a warmed and humidified air/oxygen mix, reduced respiratory work through a variable level of positive end-expiratory pressure, and increased dead space washout.

This technology optimizes the nasal cannula with an asymmetrical design, in which the right nasal prong has a larger diameter than the left nasal prong. The effect of this design change is to improve clearance of expired gas from the upper airways by reverse flow via the choanae at the end of expiration, decrease exhalation effort, and reduce noise levels during treatment. Clinical data show that this improves minute ventilation and reduces the work of breathing, with negligible effects on other parameters such as positive end-expiratory pressure. In summary, an asymmetric nasal cannula seems to increase HFNC efficacy and comfort when this modality of respiratory support is indicated.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Based on the technical specifications declared in the submission form and the documentation provided in support, compliance with WHO technical specifications available for the device "Cannula, nasal" (original name of the specifications is "Nasal oxygen cannula with prongs") is confirmed.

With regards to the other, similar WHO technical specification available named "High-flow nasal cannula (HFNC)" unit, as the innovative technology proposed does not include the whole unit (with monitor, displayed parameters, power supply requirements, etc.) but only the patient interface, compliance could be confirmed only for the sections related to consumables and to other technical requirements , such as the adult/paediatric interface of the entire HFNC system.

Regulatory

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

Pre-market: This product is a Class IIa medical device in the EU and has obtained market approval in Australia, Canada and the EU. The manufacturer claims that design verification and validation test reports have been conducted, but only some of the reports were available.

Post-market: The manufacturer did not submit the post-market surveillance and vigilance documentation. The field safety corrective action plan and recall procedure documentation were not submitted. The regulatory approvals, including market authorizations, were not supported with documents.

Quality management system (QMS): The manufacturer has submitted an ISO13485:2016 certificate valid until 13 November 2024. Based on the certification and standards for performance, the product is safe and effective.

Security: Introduction of this technology does not lead to biosecurity or cybersecurity risks. The manufacturer did not submit complete risk management documentation, risk analysis, risk management plan, risk control, post-production information, and other hazard reports. risk management activities were could not be verified.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical		
Safety		
Economy		
Organizational		
Legal		
Social		
Ethical		
Green environment		

The device is commercially available in over 100 countries, including LMICs, with more than 10 000 units distributed. The innovation proposes a novel way to provide nasal high-flow therapy with an asymmetric design, with the right prong being larger than the left. Studies indicate that it enhances enhanced clinical outcomes and patient safety as compared with the standard of care. The device is CE-marked, and a risk assessment has been performed. The available data are insufficient to prove that the device is cost-effective for LMIC, as exact pricing is not provided. Despite that, the manufacturer claims its price is similar to the standard of care. Because of this similarity, the product can be expected to be easily adopted. Additional equipment, such as a high-flow device manufactured by the innovator or any other high-flow system used with a humidifier produced by the innovator, is needed to guarantee the device's expected functioning, according to the innovator's response. This should be taken into consideration as an additional economic constraint. Other set-ups may be used, but the results are not verified. The innovator provides training and education free of charge.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance — N/A
- Environmental conditions — N/A
- Affordability
- Local access to technical support
- Ease of cleaning — N/A
- Infrastructure requirements

Health-care delivery platform

Optiflow Duet offers an innovation over standard nasal high-flow therapy; it can be used with an Airvo device or a high-flow ventilator, which makes it versatile. It is suitable for low-resource settings because it reduces the possibility of patient escalation, avoiding the need to transfer patients to a referral hospital that may be several hours away. No price information is available. It is important to note that sterile water is required (sometimes difficult to source in the volumes required). This disposable product does not require engineering resources or product maintenance.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: It is protected by trade secrets, patents, registered industrial designs, and trademarks. The use of all intellectual property will require clearance.

Local production: Current regional volumes are considerably low, weakening the business case for dedicated local production. However, this can be a promising product if volumes increase in the years to come.

WHO guidance

- Clinical management of COVID-19: living guideline. (2023). https://iris.who.int/bitstream/handle/10665/372288/WHO-2019-nCoV-clinical-2023.2-eng.pdf?sequence=1