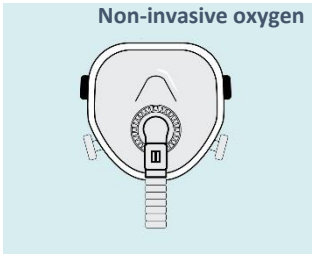
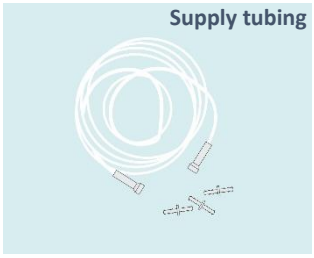
Oxygen Generation and Storage: Oxygen Therapy Interfaces

Technical overview

Oxygen therapy interfaces are specialized, single-use products involved in respiratory disease management. These products enable health care professionals to administer supplementary oxygen to patients so that appropriate oxygen levels in the blood are maintained. Consumable products include nasal cannulae (prongs), nasal catheters or nasopharyngeal catheters, masks for non-invasive oxygen therapy (i.e., non-ventilator use), supply tubing, bubble humidifiers, and an assortment of connectors and adapters.





Key specifications

Key requirements for oxygen therapy interfaces noted above are:

- ***Nasal cannulae***: Must be fitted with prongs and available in multiple sizes, including preterm, neonatal, pediatric, and adult.
- ***Supply tubing***:
  - Different lengths of supply tubes should be available.
  - Single-use tubing is typically made from flexible clear or colored transparent polyvinyl chloride and should be kink- or crush-resistant to prevent permanent deformation if bent. Reinforced elastomeric or rigid tubing may be used in reusable applications, and is typically capable of withstanding higher pressures.
  - For tubing, products also need to comply with US Food and Drug Administration (FDA) Title 21/USP VI, be certified for medical use, and 60 Shore A (ASTMD-2240).
  - Tubing wall thickness must be between 1.58 and 2.38 millimeters (mm) (1/16 and 3/32 inches). Internal diameter must range from 3 to 5 mm (1/8 to 3/16 inches) and must be compatible with standard 6-mm barbed (ribbed and tapered) fitting.
  - For a nasal catheter, sizing is presented in units of French gauge, which is equivalent to three times the tubing diameter in millimeters.
  - Masks should be available in both pediatric and adult sizes. The World Health Organization recommends a supply of 30 non-invasive masks per ventilator to be available.[1]

[1] This information comes from: World Health Organization (WHO). Chapter 4: Technical specifications for invasive and non-invasive ventilators. In: *Priority Medical Devices List for the COVID-19 Response and Associated Technical Specifications.* Geneva: WHO; 2020. https://www.who.int/medical_devices/priority/Chapter_4_20167_WHO_Priority_medical_devices_list_for_COVID_19_response_4.pdf?ua=1.

- ***Bubble humidifier***: Must have a flow rate capacity of up to 15 liters per minute, with a pressure relief safety valve of less than or equal to 14 kilopascals (kPa) or two pounds per square inch gauge (psig). It must also be paired with a Diameter Index Safety System (DISS) inlet connector for easy connection to flowmeter, and a barbed outlet connector for easy connection to tubing. A bubble humidifier works best at a water temperature of at least 30°C.
- ***Barbed conical outlet adapter***: To ensure safety, a barbed conical oxygen-specific outlet adapter must be used for connection to the DISS oxygen outlet port. DISS outlets differ in size depending on the type of medical gas used.

Review the specifications and technical requirements as listed in the *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices* for oxygen therapy interfaces.

Regulatory considerations

Oxygen therapy interfaces are required to provide proof of regulatory compliance and risk classifications per product, including the registration, clearance, and approval of each. This compliance should be appropriate per the risk classification of the given product. Oxygen therapy interfaces must comply with the following standards:

- ISO standards for biomedical equipment.
- ISO 13485 for medical devices and quality management regulatory requirements.
- ISO 14971 for application of risk management to medical devices.
- ISO 10993-1 for part 1 of the evaluation and testing within a risk management process.

Infrastructure requirements

Oxygen therapy interfaces have no infrastructure requirements.

Supply/shipping

Production and shipping lead times for oxygen therapy interfaces vary and depend on multiple factors, including the port of origin and destination. Placing bulk orders can help avoid stockouts.

Maintenance

Oxygen therapy interface products are single-use and, therefore, require no maintenance. If any interface product breaks, it is not repairable. Consumables such as (but not limited to) nasal cannulae, nasal catheters, and masks must be disposed of after a single use to prevent contamination. Some bubble humidifiers can be reused if properly decontaminated before use with another patient. Water inside a bubble humidifier must be replaced daily while in use, and the bottle must be decontaminated between uses.[2]

Cost

Oxygen therapy interfaces are generally low-cost, with pricing varying based on the selection of products, the number of orders, manufacturers, and location. Indicative price ranges for the accessories are as follows[3]:

[2] This information comes from: World Health Organization (WHO), United Nations Children's Fund (UNICEF). *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices*. Geneva: WHO; 2019. https://apps.who.int/iris/bitstream/handle/10665/329874/9789241516914-eng.pdf?ua=1.

[3] Sources for the ranges cited include Grainger, UNICEF, 911 Emergency Supply, United Health Supply, Medex Supply.

- Nasal cannulae, US$0.34 to US$3.25.
- Nasal catheters or nasopharyngeal catheters, US$3.49 to US$4.80.
- Masks for non-invasive oxygen therapy, US$0.89 to US$2.95.
- Oxygen supply tubing, US$0.55 to US$3.95.
- Bubble humidifiers, US$3.95 to US$127.00.
- Barbed conical adapters, US$24.00 to US$50.00.

COVID-19 considerations

In the context of a global pandemic like COVID-19, additional considerations should be flagged, including:

- Surface decontamination should be practiced when handling or disposing of used consumables.
- Production and shipping lead time should account for potential delays.

Acknowledgements

This brief is part of a larger series on technologies and equipment related to ***Oxygen Generation and Storage***. It is intended to serve as a concise primer for decision makers that govern, lead, support, or manage health systems and provide a starting point for understanding the solutions available to meet a health system's need for medical oxygen and its delivery.

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For more information

path.org/programs/market-dynamics/covid-19-and-oxygen-resource-library

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