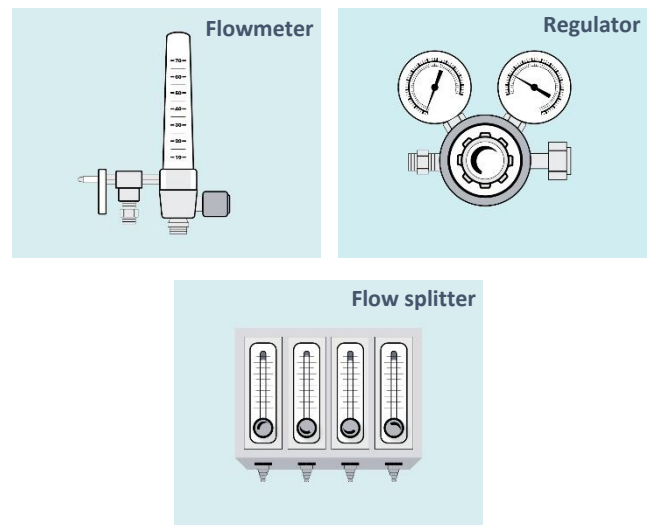


Oxygen Generation and Storage: Oxygen Therapy Accessories

Technical overview

Oxygen therapy accessories are devices that help regulate the delivery of oxygen from sources, such as central lines, cylinders, or concentrators, to patients. These products include various types of flowmeters (i.e., Thorpe tube flowmeters, click-style dial flowmeters, Bourdon tube gauges); pressure-reducing valves (or regulators); and flow splitters. These devices ensure safe delivery of oxygen to the patient and reduce costs through the proper management of oxygen volumes delivered.



Key specifications

Key specifications for oxygen therapy accessories are as follows:

- **Pressure-reducing valve or regulator:** When fully closed, it must have a minimum flow rate of zero liters per minute.
- **Input connection:** There should be either a Diameter Index Safety System (DISS) threaded fitting or a 6mm barbed fitting for the inlet port.
- **Cylinder valves:** There are three common types of fitting: pin-index, bullnose, and integral.
- **Thorpe tube flowmeters:** These should have a clear, readable, and graduated column made of a shatter-resistant medically certified polymer. The needle valve and body of the Thorpe tube flowmeter should be made from aluminum or brass and must be calibrated to between 345 and 380 kilopascals (kPa) inlet gauge pressure. Flowmeters must be compatible with in-situ terminal units, and product selection decisions should take the required specifications into account. Terminal units have different connection styles, including DISS, Ohmeda, Chemetron, AFNOR, Oxequip/Medstar, Schrader, and Puritan-Bennett.

Regulatory considerations

Oxygen therapy accessories are required to provide proof of regulatory compliance and risk classifications per product under the following United States (US), European Union (EU), and Japan regulations:

- 21CFR part 820 (US).
- 21CFR part 868.2320 (US) – Uncompensated Thorpe tube flowmeter.
- 21CFR part 868.2340 (US) – Compensated Thorpe tube flowmeter.
- Regulation (EU) 2017/745.

- MHLW Ordinance No. 169 (Japan).
- 37132000 Flowmeter (Japan), oxygen therapy.

Oxygen therapy accessories must comply with the following international standards:

- ISO 13485 regulatory requirements of medical devices – Quality management systems – requirement for regulatory purposes.
- ISO 14971 for the application of risk management to medical devices.

Compliance with the latest available version is recommended, and devices must be rated and cleaned for service as part of regular maintenance at or equivalent to the standards set by the Compressed Gas Association's guidance CGA-4.1 for the cleaning of equipment for oxygen service.

Review the specifications and technical requirements as listed in the [*WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices*](#) for these oxygen accessories.

Infrastructure requirements

Oxygen therapy accessories require no electricity. All devices are passive, operating via the flow of medical gases. Accessories can be connected to piped or cylinder oxygen supplies. Flowmeter stands can also be used with oxygen concentrators. Note that a pressure regulator must always be connected with cylinders before using a Thorpe tube flowmeter.

Supply/shipping

Production and shipping lead times for oxygen therapy accessories vary and depend on multiple factors, including the port of origin and destination. During peak demand or stockouts, delays of up to 12 weeks could be expected. Placing bulk orders in advance can reduce the probability of stockouts. See the [*Respiratory Care Equipment Market Report*](#) for additional information.

Maintenance

Maintenance for oxygen therapy accessories can be preventive (scheduled) or corrective:

Preventive maintenance involves the following elements:

- Accessories must be used according to the rated pressure of the flowmeter.
- Flowmeters must be regularly checked and cleaned, and prior to cleaning, the device must be disconnected.
- A flowmeter's exterior surface must be clean and sanitized according to the manufacturer's prevention and control protocol.
- The use of lubricants is prohibited, as they are flammable.

Corrective maintenance involves the following elements:

- Use of any defective device must stop immediately.
- Faulty devices are not recommended for repair, but instead should be promptly replaced.

Cost

The cost of oxygen therapy accessories varies according to the selection of products, the number of units procured (discounts may be available for volume purchases), manufacturers, and locations. Furthermore, desired technical performance

specifications, from percent accuracy (flowmeters) and pressure rating (valves and regulators), broaden the spread of anticipated costs for the accessory in question. Anticipated ranges for the accessories may include¹:

- Thorpe tube flowmeter, US\$20 to US\$140.
- Click-style dial flowmeter, US\$57 to US\$150.
- Bourdon tube gauge, US\$65 to US\$200.
- Pressure-reducing valve (or regulator), US\$30 to US\$280.
- Flow splitter, US\$113 to US\$220

Additional information

Flowmeters should be connected to humidifiers when delivering oxygen to patients via nasal cannulae and catheters at a higher flow rate (greater than two liters per minute).

COVID-19 considerations

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

- Accessories in patient environments should undergo regular surface decontamination.
- Production and shipping lead times should account for potential delays.

¹ For the click-style flowmeter and the pressure-reducing valve/regulator, the range can be predicated on accuracy specifications and pressure rating, respectively. Sources for the anticipated ranges cited include Grainger, Medical Gas Installers, Broward A&C Medical Supply, 4MD Medical, and Medex Supply.

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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