

IS 13450 (Part 2/Sec 12) : 2023

Medical Electrical equipment Part 2 : Particular requirements for basic safety and essential performance: Section 12 Critical care ventilators

Critical Care Ventilators are medical devices designed to provide mechanical ventilation to patients who are unable to breathe on their own due to severe illness or injury. These ventilators help support or replace natural breathing by delivering controlled air or oxygen into the lungs. They are essential in intensive care units (ICUs) and emergency settings, where patients require precise, continuous respiratory support. Critical Care Ventilators are equipped with advanced settings for adjusting airflow, pressure, and oxygen levels, ensuring that patients receive optimal respiratory assistance tailored to their needs.

Critical Care Ventilators must adhere to stringent quality standards to ensure patient safety and optimal performance. Key parameters include reliable performance, ensuring the device delivers accurate, consistent airflow, pressure, and oxygen levels. Ease of use is essential, with intuitive controls and clear displays for healthcare providers. The ventilator should be durable and able to operate continuously without failure, particularly in critical situations. Safety features like alarms for low oxygen or airflow, and compatibility with various patient needs are crucial.

IS 13450 (Part 2/Section 12) : 2023 defines key quality parameters for Critical Care Ventilators to ensure patient safety and effective performance. The standard emphasizes reliable **functionality**, ensuring ventilators deliver accurate and consistent airflow, pressure, and oxygen levels to support patients in critical care. It mandates user-friendly controls and clear displays to enable healthcare providers to operate the device with ease. The ventilator should be **durable** and capable of continuous operation without failure. Safety features, such as alarms for oxygen or airflow irregularities, are required to protect patients. The standard also ensures **compatibility** with various patient conditions, providing adjustable settings for diverse medical needs. Additionally, the ventilator must comply with regulatory standards and undergo regular maintenance for optimal performance.

These quality measures guarantee the ventilator's safety, reliability and effectiveness in critical care environments.