



# Saving lives with the right ventilator for critical care patients

In early 2020, countries around the world found they needed more ventilators to help patients critically ill with COVID-19. As global medical authorities dealt with the COVID-19 pandemic, it soon became apparent that many countries had insufficient supplies of critical care ventilators to successfully cope with the threat.

It has been reported that several countries spent large sums on inappropriate ventilators. This was not only financially damaging, but it could also lead to further harm to the patient or even death.

In SGS we look at the different types of ventilators and know why it is important for the right type of ventilator to be matched with the patient.

## TYPES OF VENTILATOR

Critical care patients need a ventilator that is specifically designed and tested for use in the most life-threatening situations. Ventilators come in a variety of different types. These can be broadly split into ventilators for home use and ventilators for clinical use.

The simplest machines are those that can be used in the home:  
Continuous positive airway pressure (CPAP) – helps with sleep apnoea, etc.  
Ventilatory support equipment – offers basic or advanced ventilatory support

Ventilators for clinical settings are more technical and can be broadly split into emergency and critical care. While both types of ventilator need to be operated by trained medical staff, the former must be able to safely operate in a variety of different environments, for example, in emergency vehicles or at altitude if they are in an air ambulance.



## A CRITICAL CARE VENTILATOR MUST HAVE

- Mechanisms to regulate delivery of gas and the safe removal of carbon dioxide (CO<sub>2</sub>), incorporating protective features in order to guarantee the safety of the patient: Pressure limitations, alarms, etc.
- Ability to connect to a humidifier. This ensures the gas delivered to the patient is moist (100% relative humidity) and at body temperature (37 °C).
- Flow sensor – to see how much gas is entering and/or leaving the patient
- Interface between the ventilator and the patient – various options are available, including the face mask and endotracheal tube
- Additional functions needed for critically ill patients – for example, ventilation manoeuvres, recruitment, measurement of patient's inspiratory effort, etc.

## EU VENTILATOR STANDARDS

Implementing Decision (EU) 2020/437, of March 24, 2020, contains a list of harmonized standards for medical devices in support of Directive 93/42/EEC.

The standard for critical care ventilators is listed as:

**EN 60601-2-12:2006** Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators (IEC 60601-2-12:2001)

Ventilator evaluations must be made in all conditions to ensure the correct amount of gas is always delivered to the patient:

- Under 50ml – newborn
- 50ml to 300ml – child
- Over 300 ml – adult

It should be noted, this standard does not necessarily cover the requirements introduced by Directive 2007/47/EC. Additionally, this standard dates from 2006 and has not kept pace with the state of the art.

## ISO/IEC 80601-2-12:2020

This standard provides the basic safety and essential performance requirements for critical care ventilators. Ventilators that conform to this standard have been shown to work safely for both the patient and the operator in a wide variety of situations, including rough treatment tests and mains electricity failure tests. This is a comprehensive standard which conforms to current ventilator technologies. Manufacturers are advised to conform to this standard to successfully access the European Union market.





## SGS TESTING AND CERTIFICATION SERVICES

SGS has considerable experience in testing ventilators of all types to ensure they conform to relevant standards. In the end, a product is only trusted because it's tested.

Our state-of-the-art laboratories offer testing and certification to a wide variety of global standards, including:

- IEC 60601-1 Electrical Safety Testing including Risk Management File evaluation
- IEC 60601-1-2 Electromagnetic Compatibility Testing including Essential Performance verification under specific Immunity conditions
- IEC 60601-1-8 Testing of Alarm system architecture and sound pressure levels
- ISO 80601-2-12 Testing of particular requirements for basic safety and essential performance for critical care ventilators
- ISO 80601-2-87 Testing of High frequency critical care ventilators
- ISO 80601-2-84 Testing of Emergency and transport ventilators
- IEC 62304 Evaluation of Software Lifecycle Process
- Out of hospital Testing (IEC 60601-1-12, EN 1789, EN 13718, RTCA DO-160G)
- Test program for devices used in the home health care environment (IEC 60601-1-11)
- Pre-compliance evaluation, Evaluation of constructional requirements
- IEC 60601-1:2020 Amendment 2 Gap Analysis program
- Evaluation of requirements for "combined equipment" of Medical System incl. wireless-function acc. ETSI EG 203 367 with reference to EN 301 489-x and e.g. EN 300 220 or EN 300 328
- Battery Testing (IEC 62133-1, IEC 62133-2)
- Cyber Security (AAMI TIR57, AAMI TIR97, AAMI SW96, UL2900-2-1, IEC TR 60601-4-5)
- Functional Safety according to IEC 61508 series
- Protective Packaging Testing (ISTA series)
- Biocompatibility Testing (ISO 10993, ISO 18562)

Based on the evaluation according to the applicable standards SGS provides certain certification services to access global markets:

- IECEE CB Scheme testing and certification
- US-NRTL certification according to ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1
- EU MDR Certification
- Brazil INMETRO Certification

**SGS**

**SGS IS THE WORLD'S LEADING INSPECTION,  
VERIFICATION, TESTING AND  
CERTIFICATION COMPANY**

**CONTACT US:**

SGS Germany GmbH  
Benzstrasse 26 / 28  
82178 Puchheim near Munich  
phone: +49 89 / 78 74 75 - 133  
email: [cqe@sgs.com](mailto:cqe@sgs.com)  
[www.sgs-cqe.de](http://www.sgs-cqe.de)

**[WWW.SGS.COM](http://WWW.SGS.COM)  
[WWW.SGSGROUP.DE](http://WWW.SGSGROUP.DE)**

**WHEN YOU NEED TO BE SURE**

**SGS**