



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 9706.212-2020

**Medical electrical equipment - Part 2-12: Particular
requirements for basic safety and essential performance of
critical care ventilators**

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Foreword

All technical contents of this Part are mandatory.

GB 9706 consists of the following parts, under the general title Medical electrical equipment.

- Part 1.General requirements for basic safety and essential performance;
- Part 1-3.General requirements for basic safety and essential performance - Collateral standard. Radiation protection in diagnostic X-ray equipment;
- Part 2-1.Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV;
- Part 2-2.Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories;
- Part 2-3.Particular requirements for the basic safety and essential performance of short-wave therapy equipment;
- Part 2-4.Particular requirements for the basic safety and essential performance of cardiac defibrillators;

- Part 2-5.Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment;
- Part 2-6.Particular requirements for the basic safety and essential performance of microwave therapy equipment;
- Part 2-8.Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV;
- Part 2-11.Particular requirements for the basic safety and essential performance of gamma beam therapy equipment;
- Part 2-12.Particular requirements for basic safety and essential performance of critical care ventilators;
- Part 2-13.Particular requirements for the basics safety and essential performance of an anaesthetic workstation;
- Part 2-16.Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment;
- Part 2-17.Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment;
- Part 2-18.Particular requirements for the basic safety and essential performance of endoscopic equipment;
- Part 2-19.Particular requirements for the basic safety and essential performance of infant incubators;
- Part 2-22.Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;
- Part 2-24.Particular requirements for the basic safety and essential performance of infusion pumps and controllers;
- Part 2-25.Particular requirements for the basic safety and essential performance of electrocardiographs;
- Part 2-26.Particular requirements for the basic safety and essential performance of electroencephalographs;

- Part 2-27.Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment;
- Part 2-28.Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis;
- Part 2-29.Particular requirements for the basic safety and essential performance of radiotherapy simulators;
- Part 2-36.Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy;
- Part 2-37.Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment;
- Part 2-39.Particular requirements for basic safety and essential performance of peritoneal dialysis equipment;
- Part 2-43.Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures;
- Part 2-44.Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography;
- Part 2-45.Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices;
- Part 2-54.Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy;
- Part 2-60.Particular requirements for the basic safety and essential performance of dental equipment;
- Part 2-63.Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment;
- Part 2-65.Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment;
- Part 2-66.Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

This Part is Part 2-12 of GB 9706.

This Part is drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces GB 9706.28-2006, Medical electrical equipment - Part 2.Particular requirements for the safety of lung ventilators - Critical care ventilators. Compared with GB 9706.28-2006, the main technical changes are as follows.

- MODIFY the scope to include the critical care ventilator and its accessories, where the characteristics of those accessories can affect the basic safety and essential performance of the ventilator, and thus not only the critical care ventilator itself (see 201.1.1.1; 1.1 of the 2006 edition);
- MODIFY the obstruction of the expiratory limb (continuing airway pressure) alarm condition requirement (see 201.12.4.107 and 201.12.4.108; 51.108 of the 2006 edition);
- ADD the identification of essential performance for a critical care ventilator and its accessories (see 201.4.3.101);
- ADD tests for ventilation performance (see 201.12.1.101 and 201.12.1.102);
- ADD tests for mechanical strength (see 201.15.3.5.101);
- ADD new symbols (see 201.7);
- ADD requirements for a critical care ventilator as a component of an ME system (see 201.16);
- ADD tests for enclosure integrity (water ingress) (see 201.11.6.5.101);
- ADD tests for closed suction survivability of the ventilator (see 201.9.101);
- ADD tests for cleaning and disinfection procedures (see 201.11.6.6);
- ADD consideration of contamination of the breathing gas delivered to the patient from the gas pathways (see 201.11.6.4).

Medical electrical equipment - Part 2-12.Particular requirements for basic safety and essential performance of critical care ventilators

201.1 Scope, object and related standards