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Replacing GB 9706.28-2006

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

医用电气设备

第 2-12 部分:重症护理 呼吸机的基本安全和基本性能专用要求

(ISO 80601-2-12:2011, MOD)

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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 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

GB 9706.1-2020, Clause 1 applies, except as follows:

201.1.1 Scope

Subclause 1.1 of GB 9706.1-2020 is replaced by:

— This Part applies to the basic safety and essential performance of a ventilator combination with its accessories, hereinafter referred to as ME equipment: intended to be attended by a professional operator for those patients who are dependent on mechanical ventilation; and

Note 1: Such ventilators are considered a life-supporting ME equipment or ME system.

— intended for use in critical care environments in a professional healthcare facility or intended for use in transport within a professional healthcare facility.

Note 2: A critical care ventilator intended for use in transport within a professional healthcare facility is not considered an emergency and transport ventilator.

This Part is also applicable to those accessories intended by their manufacturer to be connected to a breathing system, or to a ventilator, where the characteristics of those accessories can affect the basic safety or essential performance of the ventilator.

This Part is not applicable to ME equipment or an ME system operating in ventilation modes intended for patients who are not dependent on mechanical ventilation.

Note 3: A critical care ventilator, when operating in such a mode, is not considered life-supporting ME equipment or ME system.

If a clause or subclause is specifically intended to be applicable to ME equipment only, or to ME systems only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME equipment and to ME systems, as relevant.

Hazards inherent in the intended physiological function of ME equipment or ME systems within the scope of this Part are not covered by specific requirements in this Part except in GB 9706.1-2020, 7.2.13 and 8.4.1.

across the ventilator breathing system and that such changes to the ventilator breathing system can adversely affect the ventilator performance.

d) a warning statement to the effect that nebulisation or humidification can increase the resistance of breathing system filters and that the operator needs to monitor the breathing system filter frequently for increased resistance and blockage.

If applicable, the instructions for use shall include the following:

e) a warning statement to the effect that the ventilator shall not be used in a hyperbaric chamber.

f) a warning statement to the effect that the ventilator shall not be used with nitric oxide.

g) a warning statement to the effect that the ventilator shall not be used with helium or mixtures with helium.

h) a warning statement to the effect that the ventilator accuracy can be affected by the gas added by use of a nebuliser.

Check compliance by inspection.

201.7.9.2.8.101 * Additional requirements for start-up procedure

Note: A start-up procedure for this Part is a pre-use functional test that is used to determine that the ventilator is ready for use.

The instructions for use shall disclose a method by which all of the alarm signals can be functionally tested to determine if they are operating correctly. Portions of this test method may be automatically performed by the ventilator or may require operator action.

Example: Combination of the power-on self-test routines and operator action.

Check compliance by inspection.

201.7.9.2.9.101 * Additional requirements for operating instructions

The instructions for use shall disclose:

a) a listing of the following pressures:

— maximum limited pressure ($P_{LIM\ max}$);

— if provided, the rated range to which the maximum working pressure ($P_{W\ max}$) can be set, if adjustable;

— the means by which the maximum working pressure is ensured;

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