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GB 9706.222-2022

Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

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foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules of Standardization Documents"

drafted.

This document is part 2-22 of GB 9706 "Medical Electrical Equipment". GB 9706 has released the following parts.

--- Part 1.General requirements for basic safety and basic performance;

--- Part 1-3.General Requirements for Basic Safety and Essential Performance Collateral Standard. Radiation Protection of Diagnostic X-ray Equipment;

--- Part 2-1.Specific requirements for basic safety and basic performance of electron accelerators with energies from 1MeV to 50MeV;

--- Part 2-2.Special requirements for basic safety and basic performance of high-frequency surgical equipment and high-frequency accessories;

--- Part 2-3.Specific requirements for basic safety and basic performance of shortwave therapy equipment;

--- Part 2-5.Specific requirements for the basic safety and basic performance of ultrasonic physiotherapy equipment;

--- Part 2-6.Specific requirements for basic safety and basic performance of microwave therapy equipment;

--- Part 2-8.Particular requirements for basic safety and basic performance of therapeutic X-ray equipment with energy from 10kV to 1MV;

--- Part 2-11.Particular requirements for basic safety and basic performance of gamma beam therapy equipment;

--- Part 2-12.Specific requirements for basic safety and basic performance of critical care ventilators;

--- Part 2-13.Particular requirements for basic safety and basic performance of anesthesia

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workstations;

--- Part 2-16.Particular requirements for basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;

--- Part 2-17.Special requirements for the basic safety and basic performance of automatically controlled brachytherapy afterloading equipment;

--- Part 2-18.Particular requirements for basic safety and basic performance of endoscopic equipment;

--- Part 2-19.Specific requirements for the basic safety and basic performance of infant incubators;

--- Part 2-22.Particular requirements for the basic safety and basic performance of laser equipment for surgical, orthopedic, therapeutic and diagnostic use;

--- Part 2-24.Particular requirements for basic safety and basic performance of infusion pumps and infusion controllers;

--- Part 2-25.Particular requirements for basic safety and basic performance of electrocardiographs;

--- Part 2-26.Specific requirements for basic safety and basic performance of EEG machines;

--- Part 2-27.Particular requirements for basic safety and basic performance of ECG monitoring equipment;

--- Part 2-28.Particular requirements for basic safety and basic performance of medical diagnostic X-ray tube assemblies;

--- Part 2-29.Specific requirements for basic safety and basic performance of radiotherapy simulators;

--- Part 2-36.Particular requirements for the basic safety and basic performance of in vitro induced lithotripsy equipment;

--- Part 2-37.Particular requirements for basic safety and basic performance of ultrasonic diagnostic and monitoring equipment;

--- Part 2-39.Particular requirements for basic safety and basic performance of peritoneal dialysis equipment;

--- Part 2-43.Particular requirements for basic safety and basic performance of interventional X-ray equipment;

--- Part 2-44.Particular requirements for the basic safety and basic performance of X-ray computed tomography equipment;

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--- Part 2-45.Special use for basic safety and basic performance of mammography equipment and mammography stereotaxic devices

Require;

--- Part 2-54.Particular requirements for basic safety and basic performance of X-ray photography and fluoroscopy equipment;

--- Part 2-60.Particular requirements for basic safety and basic performance of dental equipment;

--- Part 2-63.Special requirements for basic safety and basic performance of dental X-ray machines for extraoral imaging;

--- Part 2-65.Special requirements for basic safety and basic performance of intraoral imaging dental X-ray machines.

This document replaces GB 9706.20-2000 "Medical electrical equipment - Part 2.Special requirements for the safety of diagnostic and therapeutic laser equipment

Compared with GB 9706.20-2000, in addition to structural adjustment and editorial changes, the main technical changes are as follows.

--- The general part refers to GB 9706.1-2020;

--- Modified the scope and purpose (see Chapter 1 of.201.1,.2000 edition);

--- Added normative references (see.201.2);

--- Delete the terms "aiming spot", "(medical) laser equipment", "shutter" and "working laser" (see 2.1.103 of the.2000 edition,

2.1.111, 2.1.116 and 2.1.121);

---Added "Class 1C", "Enclosed Laser", "Good Contact", "Laser Emission Control Switch", "Laser Operator", "Maximum Allowable Irradiation"

terms and definitions of "quantity" and "stray light radiation" (see.201.3.206,.201.3.212,.201.3.213,.201.3.214,.201.3.217,

201.3.220 and.201.3.224);

--- Merge the term "laser output" into the terms "laser energy" and "laser power". (See.201.3.216 and.201.3.218,.2000

versions 2.1.110, 2.1.112 and 2.1.113);

--- Modified the terms "operator protection filter", "target indicating device", "working beam" (see.201.3.221,.201.3.225 and

201.3.227, 2.1.115, 2.1.118 and 2.1.120 of the.2000 edition);

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--- Modified the term "preparation" and the part of the standard involving "preparation" [see.201.3.219,.201.3.222,.201.10.4.101d),

Chapter 32 d), Chapter 32 e), 56.101, 104 of Table D1, 105 of Table D1];

--- Revised the requirements for ME equipment identification, marking and documentation (see Chapter 6 of.201.7,.2000 edition);

--- Added "It is necessary to give information that the measuring equipment has been periodically calibrated to meet the requirements of the corresponding technical regulations." [See.201.7.9.2.101f)];

--- Added requirements for "parts isolation" (see.201.8.5);

--- Deleted "If the laser equipment has an emergency terminator that meets the requirements of IEC 60947-3, it is not required to have an emergency laser termination.

stopper" (see 51.101 of the.2000 edition);

---Added the requirement of "Laser", and integrated the original standard "Light Radiation", "Enclosure and Cover" and "Standby/Ready" modification and integration

into this clause. At the same time, "restrictions on laser output", "interlocking system for Class 1C laser equipment", "optical

"Laser radiation filters in observers" requirements. (see.201.10.4, Chapters 32, 55 and 56.101 of the.2000 edition);

--- Added requirements for "spectral impurity" (see.201.12.4.4.102);

--- Deleted the requirement of "creepage distances and clearances" (57.10 of the.2000 edition);

--- Revised "ME EQUIPMENT HAZARDOUS CONDITIONS AND FAILURE STATES", replacing the original standard "abnormal operation and fault status" and "timer" parts.

Sub-modifications were incorporated into this clause, adding the requirements for "excessive laser output" and "irradiation termination failure after loss of good contact"

(see Chapter 52 and 56.102 of.201.13,.2000 edition).

This document uses the redrafting method to modify and adopt IEC 60601-2-22.2019 "Medical Electrical Equipment Part 2-22.Surgery, Plastic Surgery,

Particular requirements for the basic safety and essential performance of laser equipment for therapeutic and diagnostic use.

The technical differences between this document and IEC 60601-2-22.2019 and their reasons are as follows.

--- Regarding normative reference documents, this document has made adjustments with

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