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Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

医用电气设备 第 2-3 部分：

短波治疗设备的基本安全和基本性能专用要求

(IEC 60601-2-3:2016, MOD)

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Foreword

All technical content of this Part is mandatory.

GB 9706 *Medical Electrical Equipment* is divided into the following parts:

- Part 1: General requirements for basic safety and essential performance;
- Part 1-3: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
- Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV;
- Part 2-2: Particular requirements for the safety of high frequency surgical equipment;
- Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment;
- Part 2-4: Particular requirements for the safety of cardiac defibrillators;
- Part 2-5: Particular requirements for the safety 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 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 basic safety and essential performance of an anaesthetic workstation;
- Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment;
- Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after-loading 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 safety 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 electroencephalograph;

- 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 the safety of peritoneal dialysis equipment;

- Part 2-43: Particular requirements for the safety 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 safety of mammographic X-ray equipment and mammographic 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;

Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This Part of GB 9706 specifies the requirements for the safety of SHORT-WAVE THERAPY EQUIPMENT, hereafter referred to as ME EQUIPMENT.

The defined LOW POWER EQUIPMENT is exempted from certain requirements of this Part.

NOTE: Some of the more important requirements are annotated in the "Special Guidance and Explanation" section, see Annex AA. Clauses or subclauses corresponding to annotations in Annex AA are marked with an asterisk (*).

201.1.2 Object

Replacement:

The object of this Part is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SHORT-WAVE THERAPY EQUIPMENT as defined in 201.3.206.

201.1.3 Collateral standards

Addition:

This Part refers to those applicable collateral standards that are listed in Clause 2 of GB 9706.1-2020.

201.1.4 Particular standards

Replacement:

In the particular standards may modify, replace or delete requirements contained in the general

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