NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB 9706.224-2021

Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020, Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents.

This document is part 2-24 of GB 9706, Medical electrical equipment. The following parts have been published under GB 9706.

-- 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 2-5.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 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 2-24.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 mammographic X-ray equipment and mammographic stereotactic devices;

Medical electrical equipment - Part 2-24.Particular requirements for the basic safety and essential performance of infusion pumps and controllers

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows.

201.1.1 Scope

Replacement.

This particular standard specifies the requirements for ENTERAL NUTRITION PUMPS, INFUSION PUMPS, INFUSION PUMPS FOR AMBULATORY USE,

SYRINGE OR CONTAINER PUMPS, VOLUMETRIC INFUSION CONTROLLERS and VOLUMETRIC INFUSION PUMPS, as defined in 201.3.204, 201.3.206, 201.3.207, 201.3.220, 201.3.222 and 201.3.223.

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS, hereafter referred to as ME EQUIPMENT.

This standard applies to ADMINISTRATION SETS as far as their characteristics influence the BASIC SAFETY or ESSENTIAL PERFORMANCE of INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS. However this Standard does not specify requirements or tests for other aspects of ADMINISTRATION SETS.

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 Standard are not covered by specific requirements in this Standard except in 7.2.13 and 8.4.1 of the general standard.

Note. See also 4.2 of the general standard.

This Standard does not apply to the following.

a) devices specifically intended for diagnostic or similar use (e.g., angiography or other pumps permanently controlled or supervised by the OPERATOR);

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