YY

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

YY 0899-2020

General requirements for accessories of microwave equipment in medical use

医用微波设备附件的通用要求

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Foreword

This document was issued on 30 June 2020 by the National Medical Products Administration and takes effect on 1 June 2022.

It is a YY standard without the /T suffix: compliance is mandatory in China.

1 Scope

YY 0899 sets the general requirements for the accessories of medical microwave equipment: the applicators, antennas, cables and probes through which microwave energy reaches the patient in ablation and in physiotherapy. The accessory is where the energy is actually delivered, so it determines the shape of the treated volume and it is the part that heats, ages and fails: a cable with a degraded connector reflects power back into the generator and delivers less than the operator believes. This standard covers what such accessories have to satisfy and the test methods that verify them, including the compatibility with the generator they are used on. Being a YY standard without the /T suffix, compliance is compulsory in China. It took effect in June 2022.

This Standard specifies the terms and definitions, requirements, and test methods for accessories of microwave equipment in medical practices. This Standard applies to accessories of microwave equipment in medical practices used in conjunction with microwave equipment in medical practices for therapeutic purposes.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB 9706.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

GB 9706.6, Medical electrical equipment - Part 2: Particular requirements for the safety of microwave therapy equipment

GB/T 14233.1-2008, Infusion, transfusion, injection equipment for medical use - Part 1: Chemical analysis methods

GB/T 14233.2, Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods

GB/T 16886.1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

GB/T 16886.7-2015, Biological evaluation of medical devices - Part 7: Ethylene oxide

sterilization residuals

YY/T 0149, Medical instruments of stainless steel - Test methods of corrosion resistance

YY 0838, Microwave ablation/coagulation equipment

3 Terms and definitions

For the purposes of this document, the following terms and definitions, as well as those given in GB 9706.1, GB 9706.6 and YY 0838, apply. 3.1 microwave equipment in medical practices Microwave equipment that treats patients using electromagnetic waves with frequencies greater than 300 MHz but not exceeding 30 GHz, commonly including microwave physiotherapy equipment, microwave ablation/coagulation equipment, and microwave diathermy equipment. 3.2 accessories of microwave equipment in medical practices Accessories used in conjunction with microwave equipment in medical practices to achieve therapeutic purposes, typically including output cables and connectors, applicators, temperature measuring accessories, cooling assemblies, etc. 3.3 non-contact physiotherapy applicator Non-contact applicator used in conjunction with microwave physiotherapy equipment for physiotherapy. 3.4 contact physiotherapy applicator Contact applicator used in conjunction with microwave physiotherapy equipment for physiotherapy in areas such as the ear canal, vagina, and anus. 3.5 diathermy applicator Non-contact applicator, used in conjunction with microwave diathermy equipment, for tumor treatment. 3.6 intracorporal organization ablation/coagulation applicator Ablation/coagulation applicator, also known as ablation needle, used to coagulate/ablate intracorporal proliferative and diseased tissues under the guidance of imaging and other auxiliary equipment. 3.7 prostate ablation/coagulation assembly Ablation/coagulation applicator and its accessories, which are introduced via the urethra, can be positioned at the prostate, and are intended for coagulation/ablation treatment of benign prostatic hyperplasia tissue. 3.8 temperature measuring accessories Accessories used in conjunction with microwave equipment in medical practices, intended to come into contact with a patient for the purpose of providing therapeutic protection or temperature control, for measuring the temperature of patient tissues. 3.9 cooling assembly Assembly used in conjunction with microwave equipment in medical practices to control/reduce the temperature of the contact area between the ablation/coagulation applicator and normal tissue by circulating gas or liquid.

4 Requirements

4.1 Appearance All metal surfaces of accessories shall be smooth, free from sharp edges, burrs, pits, and other defects; non-metallic surfaces shall be free from cracks and other defects.

4.2 External markings Accessories shall have the following markings on the outside.

a) All accessories shall at least be marked with the manufacturer's name or trademark, model number, serial number/batch number, etc.;

b) Disposable accessories shall be marked as not to be reused multiple times;

c) Sterile products shall be marked with the sterilization methods, production date, sterilization date, and expiration date;

d) The applicator shall also be marked with information such as operating frequency and maximum power; if this information cannot be marked due to the shape and size of the applicator, it shall be marked with reference to the instruction manual;

e) Disposable accessories may be marked on the individual packaging;

f) The marking of non-disposable accessories shall conform to the requirements in GB 9706.1 regarding external marking durability.

4.3 Instruction manual The instruction manual for accessories shall include the following.

a) Information on operating frequency and maximum power of output cables, and applicators;

b) Output cable length and applicator shape, size, and other parameters;

c) Information regarding the intended use and usage of the applicator;

d) Information on confirmation and verification methods for output cables, applicators, temperature measuring accessories, and cooling assemblies before use;

e) The intracorporal organization ablation/coagulation applicator shall include a description of the coagulation/ablation effect, which shall explain the correspondence between the ablation/coagulation area and the set power and time, the conditions that may have an effect, and the conditions under which the data shall be obtained.

4.4 Physical properties

4.4.1 Physical dimensions The manufacturer shall specify the shape, size, and tolerance requirements of the accessories.

4.4.2 Puncture force Accessories that require skin or tissue puncture, such as ablation/coagulation applicators and temperature measuring accessories, shall have good puncture capability, and the puncture force shall not exceed 3 N.

4.4.3 Rigidity For accessories of intracorporal organization ablation/coagulation equipment that require skin or tissue puncture, such as ablation/coagulation applicators and .....
Source: Translated/reviewed by www. ChineseStandard.net / Wayne Zheng et al. ## Similar standards [YY 0950](https://www.chinesestandard.net/PDF.aspx/YY0950-2015 "Click to view detail/PDF for YY 0950-2015")|[YY 0903](https://www.chinesestandard.net/PDF.aspx/YY0903-2013 "Click to view detail/PDF