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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0777-2023

Radio frequency hyperthermia equipment

射频热疗设备

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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 for Standardization Documents" drafting. This document replaces YY 0777-2010 "Radio Frequency Hyperthermia Equipment". Compared with YY 0777-2010, except for structural adjustment and editorial changes In addition, the main technical changes are as follows:

- Deleted the content of the composition (see Chapter 4 of the.2010 edition);
- Changed the output power requirements and test methods (see 4.2, 5.3, 5.3, 6.3 of the.2010 edition);
- Changed the temperature measurement requirements and test methods (see 4.3, 5.4, 5.4, 6.4 of the.2010 edition);
- Changed the temperature control requirements and test methods (see 4.4, 5.5, 5.5, 6.5 of the.2010 edition);
- Changed the functional requirements and test methods (see 4.5, 5.6, 5.6, 6.6 of the.2010 edition);
- Removed the appearance requirements and test methods (see 5.7, 6.7 of the.2010 edition);
- Changed the safety requirements and test methods (see 4.7, 5.8, 5.8,

1 Scope

YY 0777 is the mandatory Chinese standard for radio frequency hyperthermia equipment, the devices that raise the temperature of tumour tissue with radio frequency energy as an adjunct to radiotherapy or chemotherapy. It specifies the requirements such equipment has to meet and the test methods that verify them, covering how the device produces, delivers and controls RF energy and the checks that demonstrate the treatment stays within safe limits. Because it carries the YY prefix without /T, compliance is compulsory in China: a hyperthermia system cannot be registered without evidence against this text. It came into force in January 2026. For a foreign manufacturer this is the product-specific document that sits on top of the general medical electrical safety requirements.

3.Particular Requirements for Basic Safety and Essential Performance of Shortwave Therapy Equipment

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 9706.1 Medical Electrical Equipment Part

GB 9706.203-2020 Medical Electrical Equipment Part 2-

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

3 Terms and Definitions

The following terms and definitions defined in GB 9706.1 and GB 9706.203-2020 apply to this document.

3.1 The electromagnetic field with a frequency of 3MHz~120MHz is used to act on the human body in the form of external radiation to heat the treatment area to achieve Devices for tumor treatment or adjuvant therapy.

3.2 Automatic temperature control mode temp-autocontrolmode The equipment can automatically adjust the radio frequency output to stabilize the temperature of the corresponding parts of the patient within a certain range above and below the temperature control target temperature model.

4 Requirements

4.1 Operating frequency The operating frequency of the equipment shall not exceed $\pm 2\%$ of the nominal value.

4.2 Output power

4.2.1 The device should be able to display the RF output power in watts (W), and the output power can be adjusted.

4.2.2 The rated output power should not be less than 500W, and the output power error should not be greater than $\pm 20\%$.

4.3 Temperature measurement

4.3.1 The equipment should be able to measure and display the temperature of at least 5 different parts at the same time.