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

YY/T 0833-2020

**General technical requirements for compression physiotherapy
equipment for limbs
(English Translation)**

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Table of Contents

Foreword
1 Scope
2 Normative references
3 Terms and Definitions

Foreword

All technical contents of this standard are mandatory:

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

This standard replaces YY 0833-2011 "Extremity Compression Physiotherapy Equipment": Compared with YY 0833-2011, except for editorial modifications, the main the technical changes are as follows:

- Increased the definition of treatment pressure, pulse width, output pressure (see Chapter 3);
- Added requirements for treatment procedures and test methods (see 5.1, 6:1);
- Modified the requirements and test methods for treatment pressure (see 5.2, 6:2, 5:3, 5:4, 5:5, 6:3, 6:4, 6:5 of the:2011 edition);
- Modified the requirements and test methods for overvoltage protection (see 5.3, 6:3, 5:6, 6:6 of the:2011 edition);
- Modified the requirements and test methods of the functional switch (see 5.4, 6:4, 5:8, 6:8 of the:2011 edition);
- Modified the requirements and test methods for pressure relief measures (see 5.5, 6:5, 5:9, 6:9 of the:2011 edition);
- Increased the requirements and test methods for fault prompts (see 5.6, 6:6);
- Modified the requirements and test methods for working noise (see 5.7, 6:7, 5:15, 6:15 of the:2011 edition);
- Modified the requirements and test methods for appearance and structure (see 5.8:1, 6:8:1, 5:2, 6:2 of the:2011 edition);
- Modified the requirements and test methods for pressure resistance (see 5.8:2, 6:8:2, 5:11, 6:11 of the:2011 edition);

- Modify the fatigue performance requirements and test methods (see 5.8:3, 6:8:3, 5:12, 6:12 of the:2011 edition);
- Modify the connection requirements (see 5.9, 5:14 of the:2011 edition);
- Increased electromagnetic compatibility requirements and test methods (see 5.11, 6:11);
- Deleted the requirements and test methods for timing devices (see 5.7, 6:7 of the:2011 edition);
- Deleted the airtightness requirements and test methods (see 5.10, 6:10 of the:2011 edition);

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by the State Drug Administration:

This standard is under the jurisdiction of the Physical Therapy Equipment Sub-Technical Committee (SAC/TC10/SC4) of the National Medical Electrical Appliances Standardization Technical Committee:

1 Scope

This standard specifies the terms and definitions, classification and composition, requirements and test methods of limb compression physiotherapy equipment (hereinafter referred to as equipment):

This standard is applicable to putting the pressurized cavity around the limbs, applying positive pressure to the limbs according to a certain treatment procedure, and treating the patient with the changed air pressure:

Electrical equipment for physical therapy:

This standard does not apply to the following equipment:

- Hemostasis equipment;
- Anti-decubitus air cushion;
- Shock wave therapy equipment;
- Cupping device;
- Air bag type external counterpulsation device;
- Ballistic extracorporeal pressure wave therapy equipment;
- Training equipment for ischemic preconditioning;
- First aid equipment:

2 Normative references

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

GB 9706.1 Medical Electrical Equipment Part 1: General Safety Requirements GB/T 14710
Environmental requirements and test methods for medical electrical appliances GB/T
16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing YY 0505
Medical Electrical Equipment Part 1-2: General Safety Requirements Collateral Standard:
Electromagnetic Compatibility Requirements and Tests

3 Terms and Definitions

The following terms and definitions defined in GB 9706.1 apply to this document:

Put the pressurized cavity around the limb, apply positive pressure to the limb according to a certain treatment procedure, and perform physical therapy on the patient through the changing air pressure:

medical electrical equipment:

therapeutic sequence it consists of parameters such as pressurization chamber type, pressurization sequence, treatment pressure, holding time, intermittent time (if applicable), total treatment time, etc:

A complete output program that can be run automatically:

therapeutic pressure in a specific treatment procedure, the target pressure expected to be delivered to the surface of the limb usually refers to the pressure that can be maintained for more than 1 second in a pressure maintenance phase:

YY 0833-2020