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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 12263-2017

Replacing GB 12263-2005

**Cardiopulmonary bypass systems - Water heating/cooling
system**

心肺转流系统 热交换水箱

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Standardization Administration of the PRC**

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Foreword

The technical content of this standard is mandatory. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces GB 12263-2005 "artificial heart-lung machine heat exchange water tank." The main differences between this standard and GB 12263-2005 are as follows:

- Modify the standard name for "cardiopulmonary bypass system heat exchange water tank";
- Modify the normal working conditions (see 4.1,.2005 version 4.1);
- Modify the appearance and structure requirements (see 4.2,.2005 version 4.2);
- Modify the connection test method of robustness (see 5.2.2,.2005 version 5.2.2);
- Modify the tank capacity requirements and test methods (see 4.4, 5.2.3,.2005 edition of 4.4, 5.2.3);
- Modify the water tank flow requirements and test methods (see 4.5, 5.2.4,.2005 edition of 4.5, 5.2.4);
- Increased water tank temperature control requirements and test methods (see 4.6, 5.2.5);
- Modify the temperature display requirements and test methods (see 4.7, 5.2.6,.2005 version 4.6,5.2.5);
- Modify the requirements and test methods over-temperature tips (see 4.8, 5.2.7,.2005 version 4.7,5.2.6);
- Modify the water heating/cooling rate requirements and test methods (see 4.9, 5.2.8,.2005 version 4.8,5.2.7);
- Increase the prompt sound requirements and test methods (see

4.11 and 5.2.10);

--- Increased pipeline pressure requirements and test methods (see

1 Scope

China's mandatory standard for the heater-cooler unit of a cardiopulmonary bypass system - the water tank that supplies heated water, chilled water and the drive for the heat exchanger through which the patient's blood passes while the heart is stopped. It is how the perfusion team cools a patient to the temperature at which the brain will tolerate low flow, and how they warm them again afterwards, and both directions have to be done at a controlled rate: cool too fast and gas comes out of solution in the blood, warm too fast and the blood is damaged at the exchanger surface. It specifies the terms and definitions, the requirements, the test methods, the marking and instructions, and the packaging, transport and storage of the heat exchange water tank, and it applies to the units used by medical institutions to regulate temperature during extracorporeal perfusion. The requirements cover the temperature range and the accuracy and stability with which it is held, the rate at which the water temperature can be changed and the limits placed on it, the flow the unit must deliver to the heat exchanger, the over-temperature protection which is the single most important safety feature since the water is separated from the blood by nothing more than the exchanger wall, the alarms, and the electrical safety referred to GB 9706.1 with the environmental requirements of GB/T 14710, the symbols of YY/T 0466.1 and the vocabulary of YY/T 1145. Issued on 29 December 2017 and in force since 1 July 2019, it replaces GB 12263-2005.

This standard specifies the terms and definitions, requirements, test methods, signs, instructions, packaging, transportation, Storage. This standard applies to cardiopulmonary bypass system heat exchange water tank (hereinafter referred to as water tank), the water tank is for extracorporeal circulation blood heat exchange system Of the heat exchanger to provide heating water, cooling water and raw water drive for medical institutions to carry out extracorporeal perfusion temperature regulation.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 191 Packaging - Pictorial signs (GB/T 191-2008, ISO 780.1997, MOD)

GB 9706.1 medical electrical equipment Part 1. General requirements for safety (GB 9706.1-2007, IEC 60601-1.1988, IDT)

GB/T 9969 Industrial Products Manual General Environmental requirements and test methods for medical electrical appliances GB/T 14710-2009

YY/T 0466.1 Medical Devices Labeling, Marking and Notification of Use for Medical Devices Part 1. General Requirements (YY/T 0466.1-2016, ISO 15223-1.2012, IDT)

YY/T 1145 cardiopulmonary bypass system terminology

3 Terms and definitions

YY/T 1145 defined terms and definitions apply to this document.

4.1 Normal working conditions

4.1.1 Unless otherwise specified by the manufacturer in the accompanying documents, the ambient conditions shall meet the following requirements.

- Ambient temperature range. 5 °C ~ 40 °C.
- Relative humidity range. $\leq 80\%$.
- Atmospheric pressure range. 50kPa ~ 106kPa.

4.1.2 Power .ac220V ± 22 V, 50Hz ± 1 Hz.

4.2 Appearance and structure

4.2.1 tank shape should be correct; the outer surface should be clean, the coating should be smooth, uniform, without obvious sharp edges, scratches; parts of the coating No rusting or spalling is allowed.

4.2.2 water tank at the inlet, outlet should be marked, the surface of the text, symbols and signs should be clear and accurate.

4.2.3 tank control and adjustment mechanism should be flexible and reliable, fasteners should be no loose.