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

GB 10035-2017

Replacing GB 10035-2006

Air-bag type sequential external counter-pulsation device

气囊式体外反搏装置

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Quarantine;
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 10035-2006 "balloon-type external pacing device." The main differences between this standard and GB 10035-2006 are.

--- Deleted part of the electronic system terms and working hours (see the 2006 edition of 5.3.1 ~ 5.3.4, 5.6);

--- Remove the safety requirements, test methods and inspection rules (see 2006 edition of Appendix A);

--- Increased part of the relevant requirements and test methods ECG (see 5.4);

--- Increased normative references YY0784 (see Chapter 2);

--- Increased part of the pulse oximeter, trigger waves, pressure stability, display content, heart rate protection, anti-Bo bed fixed, flame retardant Sex, load bearing capacity, airbag, pressure indication, electromagnetic compatibility, etc. (see 5.3, 5.5.1, 5.5.7, 5.6, 5.7.1, 5.8.3 ~ 5.8.6, 5.9, 5.12.2);

--- The terms of Chapter 3 of this standard in the text with bold on the 5th. Please note that some of this document may be patentable. The issuing agencies of this document do not bear the responsibility of identifying these patents. This standard is proposed and managed by the State Food and Drug Administration. This standard was drafted. Chongqing Pu Shikang Technology Development Co., Ltd., the State Food and Drug Administration Guangzhou medical equipment quality Supervision and Inspection Center, Guangzhou Yi Code Medical Devices Co., Ltd., China Professional Committee of EECF. The main drafters of this standard. Wang Zhihui, Xu Yuchun, Wei Fang, Xu Zhaohua, Zhu Pengzhi, Huang Xiulian, Liang Xiaoming, Wu Guifu. This standard replaces the standards previously issued as follows:

--- GB 10035-1988, GB 10035-1994, GB 10035-2006. Airbag EECF device

1 Scope

China's mandatory standard for air-bag type sequential external counter-pulsation devices - the EECP equipment used to treat and rehabilitate patients with ischaemic disease. Cuffs are wrapped around the calves, thighs and buttocks and inflated in sequence from the periphery inward, timed to the patient's ECG so that the wave of compression arrives during diastole: the effect is to drive blood back toward the heart and raise the diastolic pressure that perfuses the coronary arteries, then release the moment before the next systole so that the heart ejects against a lower afterload. It specifies the terms and definitions, the classification and structure, the requirements, the test methods, the marking and instructions for use, and the packaging, transport and storage of the device, and it applies to the air-bag type external counter-pulsation devices used by medical institutions for the treatment and rehabilitation of patients with ischaemic disease. The requirements clause is the longest and covers what makes the therapy work and what makes it safe: the counter-pulsation performance itself with the inflation and deflation pressures and their timing, the ECG triggering and the way the device follows an irregular rhythm, the cuffs and the pneumatic circuit, the monitoring of the patient including the pulse oximetry, the alarms and the safety interlocks, and the electrical safety and electromagnetic compatibility, referred to GB 9706.1 and YY 0505 as for any medical electrical equipment, with the environmental requirements taken from GB/T 14710 and the symbols and labelling from YY/T 0466.1. Issued on 29 December 2017 and in force since 1 July 2019, it replaces GB 10035-2006.

This standard specifies the terms and definitions of balloon-type external pacing device, classification and structure, requirements, test methods, signs, instructions for use, Packaging, transportation, storage. This standard applies to the balloon-type external pacing device (hereinafter referred to as counter-pumping device). The counterpulsation device is currently being used by patients in medical units Ischemic disease treatment and rehabilitation.

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..1998, IDT)

GB/T 9969 Industrial Products Manual General

GB/T 14710 medical appliances environmental requirements and test methods

YY/T 0466.1 Medical Devices Labeling, Labeling and Information Symbols for Use in Medical Devices - Part 1. General Requirements (YY/T 0466.1-2016, ISO 15223-1..2012,

IDT)

YY0505 Medical electrical equipment Part 1-2. General requirements for safety Collateral standards. EMC requirements and tests (YY0505-2012,

IEC 60601-1-2..2004, IDT)

YY0784 Medical electrical equipment Medical pulse oximeter equipment basic safety and performance requirements (YY0784-2010, ISO 9919..2005, IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Controlling the balloon to exert on the body during diastole by a physiological signal synchronized with the heart (including but not limited to electrocardiogram, etc.)
Appropriate pressure, the human arterial pressure increase during diastole, and to cancel the pressure before systole, reducing systolic blood pressure of the auxiliary circulation device.

3.2 Sequential From distal to proximal to the heart, air pressure applied sequentially.

3.3 Enhanced In addition to the body balloon, but also increased the buttocks balloon.

3.4 Working pressure operationpressure Peak pressure in the airbag during normal operation.