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

YY 0781-2025

Replacing YY 0781-2010

Blood pressure transducers

血压传感器

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. This document replaces YY 0781-2010 "Blood Pressure Sensors". Compared with YY 0781-2010, the only changes are structural adjustments and editorial modifications. In addition, the main technological changes are as follows:

---The normative references have been changed (see Chapter 2, Chapter 2 of the.2010 edition);

---Some terms and definitions have been changed (see Chapter 3, Chapter 3 of the.2010 edition);

---Change some tagging requirements (see 4.1, 4.1.2 in the.2010 version);

---The pressure range has been changed to allow manufacturers to define a wider pressure range (see 4.2.2.1,.2010 version 4.2.2.1);

---The requirements for AC excitation and phase offset have been removed (see 4.2.3.2 in the.2010 version);

---Electromagnetic compatibility requirements have been added (see 4.4);

---The testing methodology has been changed, and a simplified method has been added to the frequency response test (see Chapter 5, Chapter 5 of the.2010 edition). Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the Medical Electronic Instruments Subcommittee of the National Technical Committee for Standardization of Medical Electrical Appliances (SAC/TC10/SC5). The release history of

this document and the document it replaces is as follows:

---First released in.2010 as YY 0781-2010;

---This is the first revision.

The requirements and tests in this document are designed and developed around devices intended for blood pressure measurement, but not for purposes other than blood pressure. This type of sensor can also be used to measure physiological parameters. This document primarily focuses on the safety and efficacy of sensors used for blood pressure measurement, and recommends... It is recommended to focus on ensuring compatibility between dedicated sensors and blood pressure monitoring devices. Blood pressure sensor

1 Scope

YY 0781 governs the disposable pressure transducer that sits between an arterial line and a patient monitor. It sets the requirements for blood pressure transducers and the tests that verify them, covering measurement accuracy across the applied pressure range, drift, zero pressure and sensitivity behaviour under combined temperature error band conditions, frequency response, leakage current and defibrillator tolerance, with an informative annex setting out the underlying principles. It sits on top of the GB 9706.1 general safety standard and the YY 9706.234 particular standard for invasive blood pressure monitoring, and it adopts the ISO 80369-7 small-bore connector requirements. Note the prefix: this is a YY standard without the /T suffix, so compliance is mandatory rather than recommended. The transition is unusually long, running to 1 October 2028, which gives manufacturers three years to requalify existing transducer families.

This document specifies the safety and performance requirements for sensors and cables designed for measuring blood pressure via indwelling catheters or direct puncture. Note

1.This document also provides a reference for users to determine the compatibility between sensors and blood pressure monitoring devices. Note

2.This document does not specify operating procedures for sensors or monitoring equipment. Therefore, please refer to the appropriate instruction manual for proper installation, balancing, and calibration. A blood pressure measurement system is absolutely necessary. This document applies to pressure sensors used to measure blood pressure via catheter or direct vascular puncture, including cables. This document does not apply to sensors designed to measure other physiological parameters. Note

3.Appendix A provides explanations of some of the clauses in this document.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For

references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 9706.1-2020 Medical electrical equipment - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 accuracy The ratio of error (measured value minus true value) to true value (or theoretical value).

Note. Expressed as a percentage.

3.2 balance With appropriate excitation (3.8), the Wheatstone bridge is symmetrical or comes from the zero-point condition of the bridge output.

3.3 critical damping The damping value required to produce the minimum settling time for a step input without overshoot.