

ICS 11.040.50

CCS C 43



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

GB/T 20012-2026

Replacing GB/T 20012-2005

Medical electrical equipment - Dose area product meters

医用电气设备 剂量面积乘积仪

(English Translation)

Issued on: February 27, 2026

Implemented on: September 1, 2027

Issued by: State Administration for Market Regulation

Table of Contents

Preface	
1 Scope	
2 Normative References	
3 Terms and Definitions	
4 General Requirements	
4.1 Performance Requirements	
4.2 Minimum effective range	
4.3 Measurement plane	
4.4 Reference values and standard test conditions	
4.5 General Test Conditions	
4.6 Statistical fluctuations	
4.7 Measurement uncertainty	
4.8 Performance-related structural requirements	
4.9 Stability testing device	
4.10 Adjustment	
4.11 Electrical Safety	
5 Limits of performance indicators under standard test conditions	
5.1 Classification of Dose-Area Product Instruments by Limit of Variation	
5.2 Linear	
5.3 Alarm Function	
5.4 Repeatability	
5.5 Reading resolution	
5.6 Settling time	
5.7 Resetting the dose-area product range	
5.8 Indicator value drift	
5.9 Long-term stability	
5.10 Response time	
5.11 Spatial uniformity of response	
6 Limit of variation caused by the influencing quantity	
6.1 General Requirements	
6.2 Energy Response	
6.3 Correlation between dose-area product measurement and dose-area product rate	

6.4	Irradiation time
6.5	Field size
6.6	Operating voltage
6.7	Atmospheres of pressure
6.8	Temperature and humidity
6.9	Fluctuations in air density in the ionization chamber
6.10	Electromagnetic compatibility
6.11	Combined standard uncertainty
7	Mark
7.1	Measurement Component
7.2	Radiation Detector
8	Accompanying Documents
	References
	Index

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 GB/T 20012-2005 "Medical Electrical Equipment - Dosage-Area Product Analyzer". Compared with GB/T 20012-2005, Aside from structural adjustments and editorial changes, the main technical changes are as follows.

---Added dose-area product meters, which are classified into two categories based on their variation limits. field-grade and reference-grade (see Chapter 1, 4.9, 5.1);

---Change "ionization chamber" to "radiation detector" (see 3.28, 3.18 in the 2005 edition);

---The transmittance of the radiation detector has been changed (see 4.8.5, 4.8.5.3 in the 2005 version);

---The minimum rated range and reference conditions for radiation quality have been changed (see 4.8.5, Tables 5 and 6.2; 4.8.5.4, Tables 2 and 6.1 in the 2005 edition);

---Added "Indication Drift", "Long-Term Stability", "Air Density Fluctuation, Pressure", and "Air Density Fluctuation, Temperature", as well as a reference level.

The variation limits of the dose-area product meter (see Table 5);

---The relative inherent error has been removed (see section 5.1 and Table 4 in the 2005

edition);

---Linearity has been added (see 5.2);

---The alarm function has been changed (see 5.3, version 5.2 of the 2005 edition);

---Added a requirement for the one-year variation limit of the reference-grade dose-area product meter (see 5.9);

---Added correlation requirements for the reference-grade dose-area product meter measurement components (see 6.3.1);

---The combined standard uncertainty has been changed (see 6.11, 6.10 in the 2005 edition);

--- Examples of revised assessment uncertainty (see Tables 8 and 9, Table 7 in the 2005 edition).

This document is modified to adopt IEC 60580:2019 "Medical electrical equipment - Dosage area product meter".

The technical differences between this document and IEC 60580:2019, and the reasons therefor, are as follows.

---The scope has been changed (see Chapter 1) to suit my country's technological conditions;

---Electrical safety has been changed, replacing IEC 60601-1:2005 (see Chapter 3) with the normatively referenced GB 9706.1-2020.

4.11, Chapter 3 of IEC 60580:2019, replaces IEC 62368-1 with normatively referenced GB 4943.1 (see section 4.11).

Chapter 3, 4.11 (IEC 60580:2019), to adapt to my country's technical conditions;

---The radiation conditions have been changed, replacing IEC 61267 (see Tables 3, 5, and 6.2, IEC 60580) with the normatively referenced YY/T 0481.

Tables 3, 5, and 6.2 of 2019 are used to adapt to my country's technological conditions;

---Electromagnetic compatibility has been modified, replacing IEC 60601-1-2 (see 6.10.1, IEC 60580) with the normatively referenced YY9706.102.

IEC 61000-4-3 (see 6.10.3, IEC 60580:2019) has been replaced by the normatively referenced GB/T 17626.3 in section 6.10.1 of 2019.

(6.10.3), to adapt to my country's technological conditions;

---The graphic symbols have been changed, replacing IEC 60417 (see 7.1, IEC 60580:2019) with the normatively referenced GB/T 5465.2.

7.1), to adapt to my country's technological conditions;

---The random file has been modified, replacing IEC 61187 (see Chapter 8, IEC 60580:2019) with the normatively referenced GB/T 16511.

Chapter 8), to adapt to my country's technological conditions.

The following editorial changes have been made to this document.

---IEC 61000-4-2 (see 6.10.2, IEC 60580:2019) has been replaced by GB/T 17626.2 (for informative reference).

---IEC 61000-4-4 (see 6.10.4, IEC 60580:2019) has been replaced by GB/T 17626.4 (informative reference).

---IEC 61000-4-5 (see 6.10.5, IEC 60580:2019) has been replaced by GB/T 17626.5 (for informative reference).

---IEC 61000-4-6 (see 6.10.4, IEC 60580:2019) has been replaced by GB/T 17626.6 (referenced for informational purposes).

--- IEC 61000-4-11 (see 6.10.6, IEC 60580:2019) has been replaced by GB/T 17626.11, which is used for informational reference.

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 National Technical Committee on Standardization of Medical Electrical Appliances (SAC/TC10).

1 Scope

This document specifies the performance requirements and test methods for dose-area product meters.

This document applies to the following two types of dose-area product meters.

- a) Low-performance field-grade dose-area product meter;
- b) A high-performance reference-grade dose-area product meter.

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.