
Medicinska električna oprema - 2-56. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kliničnih termometrov za merjenje telesne temperature (ISO/DIS 80601-2-56:2025)

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO/DIS 80601-2-56:2025)

Medizinische elektrische Geräte - Teil 2 56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO/DIS 80601-2-56:2025)

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des thermomètres médicaux pour mesurer la température de corps (ISO/DIS 80601-2-56:2025)

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DRAFT International Standard

ISO/DIS 80601-2-56

Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

Appareils électromédicaux —

*Partie 2-56: Exigences particulières relatives à la sécurité
fondamentale et aux performances essentielles des thermomètres
médicaux pour mesurer la température de corps*

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54 Foreword

55 ISO (the International Organization for Standardization) is a worldwide federation of national standards
56 bodies (ISO member bodies). The work of preparing International Standards is normally carried out
57 through ISO technical committees. Each member body interested in a subject for which a technical
58 committee has been established has the right to be represented on that committee. International
59 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO
60 collaborates closely with the International Electrotechnical Commission (IEC) on all matters of
61 electrotechnical standardization.

62 The procedures used to develop this document and those intended for its further maintenance are
63 described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the
64 different types of ISO documents should be noted. This document was drafted in accordance with the
65 editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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68 patent rights identified during the development of the document will be in the Introduction and/or on
69 the ISO list of patent declarations received (see www.iso.org/patents).

70 Any trade name used in this document is information given for the convenience of users and does not
71 constitute an endorsement.

72 For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and
73 expressions related to conformity assessment, as well as information about ISO's adherence to the World
74 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL:
75 www.iso.org/iso/foreword.html.

76 This document was prepared by ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3,
77 *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in*
78 *medical practice*, Subcommittee SC D, *Electrical equipment*. 56:2026

79 This third edition cancels and replaces the second edition (ISO 80601-2-56:2017), which has been
80 technically revised.

81 The most significant changes are the following modifications:

- 82 — harmonization with the Edition 3.2 of the general standard;
- 83 — harmonization with ISO 20417;
- 84 — deletion of the clinical performance *verification* requirements and replacement by the requirement to
- 85 conform with ISO 12487