

FINAL DRAFT International Standard

IEC/FDIS 80601-2-89

Medical electrical equipment —

Part 2-89:

Particular requirements for the basic safety and essential Standar performance of medical beds for children ISO/TC 173

Secretariat: SIS

Voting begins on: **2025-07-07**

Voting terminates on: 2025-09-01

FC/FDIS 80601-2-89

Document Preview

https://standards.iteh.ai/catalog/standards/iso/6f1a17d9-9364-475b-9f53-9c366ad46c8d/iec-fdis-80601-2-89

This draft is submitted to a parallel vote in ISO and in IEC.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

IEC/FDIS 80601-2-89:2025(en)

iTeh Standards (https://standards.iteh.ai) Document Preview

IEC/FDIS 80601-2-89

https://standards.iteh.ai/catalog/standards/iso/6f1a17d9-9364-475h-9f53-9c366ad46c8d/iec-fdis-80601-2-89



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

CONTENTS

FOREWO	PRD	4
INTRODU	JCTION	6
201.1	Scope, object and related standards	7
201.2	Normative references	9
201.3	Terms and definitions	10
201.4	General requirements	16
201.5	*General requirements for testing of ME EQUIPMENT	17
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	22
201.7	ME EQUIPMENT identification, marking and documents	22
201.8	Protection against electrical HAZARDS from ME EQUIPMENT	30
201.9	Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	31
201.10	Protection against unwanted and excessive radiation HAZARDS	63
201.11	Protection against excessive temperatures and other HAZARDS	63
201.12	Accuracy of controls and instruments and protection against hazardous outputs	66
201.13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	67
201.14	Programmable electrical medical systems (PEMS)	68
201.15	Construction of ME EQUIPMENT	68
201.16	ME SYSTEMS	72
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	72
Annexes	Document Preview	73
Annex AA	(informative) Particular guidance and rationale	74
Annex BB MEDICAL B	3 (normative) Additional design requirements and recommendations for SEDS	891-2
	C (informative) Particular guidance for assessing RISK of entrapment in V-penings	93
Annex DD	(informative) Guidance and recommendations for periodic inspection	99
Bibliograp	phy	101
Index of c	defined terms	103
•	1.101 - COT, general arrangement (example, schematic presentation only)	
_	1.102 - CRIB, general arrangement (example, schematic presentation only)	12
	1.103 – MEDICAL BED, general arrangement (example, schematic presentation	14
Figure 20	1.104 – HEAD DOWN TILT, Example	15
Figure 20	1.105 – FOOT DOWN TILT, Example	16
Figure 20	1.106 – Small finger probe Ø 5,6	17
Figure 20	1.107 - Entrapment test TOOLS	19
Figure 20	1.108 – Loading pad	20
Figure 20	1.109 – Impactor	21
Figure 20	1.110 – Side impactor TOOL	22
Figure 20	1.111 - Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD	23

Figure 201.112 – Graphic symbol for mass; weight	23
Figure 201.113 – Graphic symbol for machine washable MEDICAL BED	23
Figure 201.114 – Graphic Symbol for jet stream washable MEDICAL BEDS	24
Figure 201.115 – Graphic symbol for manual cleaning only	24
Figure 201.116 – Description of allowed length of PATIENT	25
Figure 201.117 – Example of marking for positioning PATIENT in MEDICAL BED	26
Figure 201.118 – MEDICAL BED function controls and actuators: guidelines for creating graphic symbols	27
Figure 201.119 – Examples of marking on the MEDICAL BED of storage location for wired and wireless PENDANT CONTROLS	28
Figure 201.120 – Example of MEDICAL BED with segmented or split SIDE RAIL	32
Figure 201.121 – Example of MEDICAL BED with single piece SIDE RAIL and PROTECTION PANEL	33
Figure 201.122 – Dimension of handle for LIFTING POLE	38
Figure 201.123 – Allowable spacing for fingers in areas of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM	40
Figure 201.124 – Example using barriers for clearance measurement around the perimeter of the MATTRESS SUPPORT PLATFORM to mitigate PATIENT-finger entrapment	41
Figure 201.125 – Clearance areas	42
Figure 201.126 – Required minimum radii of edges and corners	43
Figure 201.127 - Retention of loop and mass	44
Figure 201.128 – Lateral stability test along the side of the MEDICAL BED	47
Figure 201.129 – Longitudinal stability test with removable FOOT BOARD	47
Figure 201.130 – Longitudinal stability test with fixed HEAD BOARDS and FOOT BOARDS	48
Figure 201.131 – Distribution of SAFE WORKING LOAD per maximum PATIENT weight for tests	52
Figure 201.132 – Position of loading pad and impactor (see Figure 201.108 for loading pad and Figure 201.109 for impactor)	55
Figure 201.133 – Impact to slats and solid elements of MEDICAL BEDS	57
Figure 201.134 – Application of forces for test of SIDE RAIL	59
Figure 201.135 – Height of PROTECTION PANELS, SIDE RAIL and PROTECTION PERIMETER	62
Figure 201.136 – Direction of movement for rough handling test	69
Figure 201.137 – Configurations of the MATTRESS SUPPORT PLATFORM	70
Figure 201.138 – Small parts cylinder	72
Figure AA.1 – Example of marking for compatible mattresses specified by the MANUFACTURER	76
Figure AA.2 – Example of marking for detachable SIDE RAILS specified by the MANUFACTURER	76
Figure AA.3 – Resultant forces without mattress	79
Figure AA.4 – Resultant forces with mattress	79
Figure AA.5 – 40 mm gap measurement of B	79
Figure AA.6 – Angle measurement example of B	79
Figure AA.7 – Placement of a measurement TOOL for the measurement of D _X	80
Figure AA.8 – Example of area D _X measurement that passes	81
Figure AA 9 – Example of area Dy measurement that fails (on limit)	

Figure AA.10 – Example of area D _X measurement that fails	81
Figure AA.11 – Example of potential PATIENT entrapment in area A within the SIDE RAIL	82
Figure AA.12 – Example of potential PATIENT entrapment in area A below the SIDE RAIL	82
Figure AA.13 – Example of potential PATIENT entrapment in area B	82
Figure AA.14 – Example of potential PATIENT entrapment in area C between split SIDE RAIL	82
Figure AA.15 – Example of potential PATIENT entrapment in area C between SIDE RAIL and HEAD BOARD	82
Figure AA.16 – Example of potential PATIENT entrapment in area D	82
Figure AA.17 – Example of potential PATIENT entrapment in area A below a single piece SIDE RAIL	83
Figure BB.1 – Schematic presentation of under MEDICAL BED clearance	91
Figure BB.2 – Recommendations and requirements regarding angles for different sections of the mattress support platform	92
Figure CC.1 – Wedge TOOL	94
Figure CC.2 – V-shaped opening in relation to B	95
Figure CC.3 – Acceptance criteria in relation to area B	95
Figure CC.4 – Positioning of wedge TOOL	96
Figure CC.5 – Acceptance criteria in relation to area C between HEAD BOARD and FOOT BOARD	97
Figure CC.6 – Acceptance criteria in relation to area C between split SIDE RAILS	98
Table 201.101 – Protection against PATIENT entrapment	34
Table 201.102 - Minimum SAFE WORKING LOADS	51
Table 201.103 – Protection against inadvertent PATIENT falls and climbing out of MEDICAL BED	62
Table 201.104 – Allowable maximum temperatures for skin contact with MEDICAL BED APPLIED PARTS	63
Table 201.105 – Machine washable compliance PROCEDURE	65
Table AA.1 – Protection against PATIENT entrapment in non-moving parts	78
Table AA.2 – Height of protective barriers according to age	87

INTERNATIONAL ELECTROTECHNICAL COMMISSION

Medical electrical equipment Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 80601-2-89 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO technical committee 173: Assistive products. It is an International Standard.

This publication is published as a double logo standard.

The text of this International Standard is based on the following documents of IEC:

Draft	Report on voting
62D/XX/FDIS	62D/XX/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table. In ISO, the document was approved by XXX P members out of YYY having cast a vote.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this standard, the following print types are used:

- requirements and definitions: roman type;
- test specifications: italic type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 Normative text of tables is also in a smaller type;
- terms defined in clause 3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with
 https://sta.this.document; talog/standards/iso/6f1a17d9-9364-475b-9f53-9c366ad46c8d/iec-fdis-80601-2-89
 - "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
 - "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- · withdrawn, or
- revised.