

## SLOVENSKI STANDARD SIST EN ISO 80601-2-13:2022/oprA1:2025

01-november-2025

Medicinska električna oprema - 2-13. del: Posebne zahteve za osnovno varnost in bistvene lastnosti delovnega mesta za anestezijo - Dopolnilo A1 (ISO 80601-2-13:2022/DAM 1:2025)

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation - Amendment 1 (ISO 80601-2-13:2022/DAM 1:2025)

## iTeh Standards

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2022/DAM 1:2025)

#### Document Preview

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie - Amendement 1 https://stand(ISO 80601-2-13:2022/DAM 1:2025) 18-3113-4779-b385-0b5e29e563e3/sist-en-iso-80601-2-13-2022-opra1-

Ta slovenski standard je istoveten z: EN ISO 80601-2-13:2022/prA1

ICS:

11.040.10 Anestezijska, respiratorna in Anaesthetic, respiratory and reanimacijska oprema reanimation equipment

SIST EN ISO 80601-2- en,fr,de 13:2022/oprA1:2025

SIST EN ISO 80601-2-13:2022/oprA1:2025

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

<u>SIST EN ISO 80601-2-13:2022/oprA1:2025</u> https://standards.iteh.ai/catalog/standards/sist/c37f2c18-3f13-4779-b385-0b5e29e563e3/sist-en-iso-80601-2-13-2022**Document Preview** 



# **DRAFT**Amendment

ISO 80601-2-13:2022/ DAM 1.2

Medical electrical equipment —

Part 2-13:

Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie

AMENDEMENT 1

ICS: 11.040.10

ISO/TC 121/SC 1

Secretariat: **DIN** 

Voting begins on: **2025-09-17** 

Voting terminates on: **2025-11-12** 

9-b385-0b5e29e563e3/sist-en-iso-80601-2-13-2022-

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

### ISO/CEN PARALLEL PROCESSING

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

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.

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.

© ISO 2025

Reference number ISO 80601-2-13.2:2022/DAM 1:2025(en) ISO 80601-2-13.2:2022/DAM 1:2025(en)

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

SIST EN ISO 80601-2-13:2022/oprA1:2025

https://standards.iteh.ai/catalog/standards/sist/c37f2c18-3f13-4779-b385-0b5e29e563e3/sist-en-iso-80601-2-13-2022-opra1-2025



#### **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

#### ISO 80601-2-13:2022/DAM 1:2025(en)

#### Foreword

- 22 ISO (the International Organization for Standardization) and IEC (the International Electrotechnical
- 23 Commission) form the specialized system for worldwide standardization. National bodies that are
- 24 members of ISO or IEC participate in the development of International Standards through technical
- committees established by the respective organization to deal with particular fields of technical activity.
- 26 ISO and IEC technical committees collaborate in fields of mutual interest. Other international
- organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the
- 28 work.

21

- 29 The procedures used to develop this document and those intended for its further maintenance are
- described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the
- different types of document should be noted. This document was drafted in accordance with the editorial
- 32 rules of the ISO/IEC Directives, Part 2 (see <u>www.iso.org/directives</u> or
- 33 <u>www.iec.ch/members\_experts/refdocs</u>).
- 34 Attention is drawn to the possibility that some of the elements of this document may be the subject of
- patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details
- of any patent rights identified during the development of the document will be in the Introduction and/or
- on the ISO list of patent declarations received (see <a href="https://www.iso.org/patents">www.iso.org/patents</a>) or the IEC list of patent
- declarations received (see <u>patents.iec.ch</u>).
- 39 Any trade name used in this document is information given for the convenience of users and does not
- 40 constitute an endorsement.
- 41 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
- 42 expressions related to conformity assessment, as well as information about ISO's adherence to the World
- 43 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see
- 44 <u>www.iso.org/iso/foreword.html</u>. In the IEC, see <u>www.iec.ch/understanding-standards</u>.
- 45 Amendment 1 to ISO/IEC 80601-2-13:2022 was prepared jointly by Technical Committee ISO/TC 121,
- 46 Anaesthetic and respiratory equipment, Subcommittee SC 1, Breathing attachments and anaesthetic
- 47 machines, and Technical Committee IEC/TC 62 Electrical equipment in medical practice, Subcommittee SC
- 48 62D Electromedical equipment, in collaboration with the European Committee for Standardization (CEN)
- 49 Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, in accordance with the
- 50 Agreement on technical cooperation between ISO and CEN (Vienna Agreement).
- A list of all parts in the ISO 80601 and the IEC 80601 series can be found on the ISO and IEC websites.
- Any feedback or questions on this document should be directed to the user's national standards body. A
- 53 complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-
- 54 <u>committees</u>.