IEC 61326-2-6

Edition 4.0 2025-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electrical equipment for measurement, control and laboratory use - EMC requirements -
Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM -
Partie 2-6: Exigences particulières - Matériel électromédical de diagnostic in vitro (DIV)

ICS 17.220.20, 25.040.40, 33.100.20

ISBN 978-2-8327-0509-4

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications, symboles graphiques et le glossaire. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment

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 61326-2-6 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2020. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

– Update of the document with respect to test levels and documentation.

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

Draft	Report on voting
65A/1174/FDIS	65A/1180/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

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 document the following print types are used:

Terms used throughout this document which have been defined in Clause 3 of this document and of IEC 61326-1:2020 are printed in SMALL CAPITALS.

This part of IEC 61326 is to be used in conjunction with IEC 61326-1:2020 and follows the same numbering of clauses, subclauses, tables and figures.

If an IEC 61326-2-6 report is available, the report of IEC 61326-1 is integrated.

When a particular subclause of IEC 61326-1 is not mentioned in this part, that subclause applies as far as is reasonable. When this standard states "addition", "modification" or "replacement", the relevant text in IEC 61326-1 is to be adapted accordingly.

NOTE The following numbering system is used:

– subclauses, tables and figures that are numbered starting from 101 are additional to those in IEC 61326-1;

– unless notes are in a new subclause or involve notes in IEC 61326-1, they are numbered starting from 101 including those in a replaced clause or subclause;

– additional annexes are lettered AA, BB, etc.

A list of all parts of the IEC 61326 series, under the general title *Electrical equipment for measurement, control and laboratory use – EMC requirements,* 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.

1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IN VITRO DIAGNOSTIC MEDICAL ELECTRICAL EQUIPMENT (IVD MEE). This part of IEC 61326 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IVD MEE in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by IVD MEE.

BASIC SAFETY with regard to electromagnetic disturbances is applicable to all IVD MEE.

NOTE 1 Performance with respect to electromagnetic disturbances other than ESSENTIAL PERFORMANCE is the subject of IEC 61326-1:2020

NOTE 2 IT equipment can be a part of an IVD MEE, if it is required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Clause 2 of IEC 61326-1:2020 applies, except as follows:

Addition:

IEC 61010 (all parts), *Safety requirements for electrical equipment for measurement, control, and laboratory use*

IEC 61326-1:2020, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms, definitions and abbreviations

For the purposes of this document, the terms and definitions given in IEC 61326-1 apply, except as follows.

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp