

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electrical equipment for measurement, control and laboratory use – EMC requirements –

Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

Matériel électrique de mesure, de commande et de laboratoire – Exigences relatives à la CEM –

Partie 2-6: Exigences particulières – Matériel médical de diagnostic in vitro (IVD)



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ELECTRICAL EQUIPMENT FOR MEASUREMENT,
CONTROL AND LABORATORY USE –
EMC REQUIREMENTS –****Part 2-6: Particular requirements –
In vitro diagnostic (IVD) medical equipment**

FOREWORD

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

This second edition cancels and replaces the first edition published in 2005. This edition constitutes a technical revision.

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

- update of the document with respect to IEC 61326-1:2012.

The text of this standard is based on the following documents:

FDIS	Report on voting
65A/631/FDIS	65A/640/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This part of the IEC 61326 series is to be used in conjunction with IEC 61326-1:2012 and follows the same numbering of clauses, subclauses, tables and figures.

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, control and laboratory use – EMC requirements* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS –

Part 2-6: Particular requirements – *In vitro* diagnostic (IVD) medical equipment

1 Scope

In addition to the scope of IEC 61326-1, this part of IEC 61326 series specifies minimum requirements for immunity and emissions regarding electromagnetic compatibility for *in vitro* diagnostic medical equipment, taking into account the particularities and specific aspects of this electrical equipment and their electromagnetic environment.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 61326-1:2012 applies, except as follows:

Addition:

IEC 61326-1:2012, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

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

Addition:

3.101

***in vitro* diagnostic medical equipment**

instruments and apparatus intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease

Note 1 to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body.

3.102

analyte

constituent of a sample with a measurable property

EXAMPLES In “mass of protein in 24-hour urine”, “protein” is the analyte and “mass” is the property. In “concentration of glucose in plasma”, “glucose” is the analyte and “concentration” is the property. In both cases, the full phrase designates the measurand.