

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Medical electrical equipment –  
Part 2-39: Particular requirements for the basic safety and essential performance  
of peritoneal dialysis equipment**

**Appareils électromédicaux –  
Partie 2-39: Exigences particulières pour la sécurité de base et les performances  
essentielles des appareils de dialyse péritonéale**



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**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-39: Particular requirements for the basic safety and essential performance of peritoneal dialysis equipment****FOREWORD**

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IEC 60601-2-39 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2018. This edition constitutes a technical revision.

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

- a) update of references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;
- b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;
- c) including the information given in the document 62D/1771A/INF regarding 201.11.8;
- d) including the information given in the document 62D/1734/INF regarding technical issues of the previous edition;
- e) including SECURITY (CYBERSECURITY) requirements;
- f) additions related to online PD SOLUTION generation (ONLINE PD);
- g) improvements regarding the definition of the APPLIED PART;
- h) improvement of the essential performance requirements clause/subclauses;
- i) improvements for labelling;
- j) other minor technical improvements;
- k) editorial improvements.

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

Draft	Report on voting
62D/2162/FDIS	62D/2182/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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://www.iec.ch/publications).

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- *test specifications: italic type;*
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- 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:

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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.

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## INTRODUCTION

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of PERITONEAL DIALYSIS ME EQUIPMENT.