

**NORME
INTERNATIONALE
INTERNATIONAL
STANDARD**

**CEI
IEC**

60601-1

Troisième édition
Third edition
2005-12

Appareils électromédicaux –

**Partie 1:
Exigences générales pour la sécurité de base
et les performances essentielles**

Medical electrical equipment –

**Part 1:
General requirements for basic safety
and essential performance**

© IEC 2005 Droits de reproduction réservés — Copyright - all rights reserved

Aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'éditeur.

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission, 3, rue de Varembe, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE **XN**

For price, see current catalogue
For price, see current catalogue

CONTENTS

FOREWORD.....	21
INTRODUCTION.....	25
1 Scope, object and related standards.....	29
1.1 * Scope	29
1.2 Object	29
1.3 * Collateral standards	29
1.4 * Particular standards	31
2 * Normative references.....	31
3 * Terminology and definitions	39
4 General requirements	79
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS.....	79
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	79
4.3 * ESSENTIAL PERFORMANCE	81
4.4 * EXPECTED SERVICE LIFE	81
4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS	83
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	83
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT.....	83
4.8 Components of ME EQUIPMENT	85
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	85
4.10 * Power supply	87
4.11 Power input	89
5 * General requirements for testing ME EQUIPMENT	91
5.1 * TYPE TESTS.....	91
5.2 * Number of samples	91
5.3 Ambient temperature, humidity, atmospheric pressure.....	91
5.4 Other conditions	91
5.5 Supply voltages, type of current, nature of supply, frequency	93
5.6 Repairs and modifications	93
5.7 * Humidity preconditioning treatment	93
5.8 Sequence of tests	95
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS	95
6 * Classification of ME EQUIPMENT and ME SYSTEMS.....	99
6.1 General	99
6.2 * Protection against electric shock.....	99
6.3 * Protection against harmful ingress of water or particulate matter	101
6.4 Method(s) of sterilization	101
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	101
6.6 * Mode of operation.....	101



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE