



NSAI
Standards

Irish Standard
I.S. EN 60731:2012

Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy (IEC 60731:2011 (EQV))

I.S. EN 60731:2012

Incorporating amendments/corrigenda issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

<i>This document replaces:</i> EN 60731:1997/A1:2002	<i>This document is based on:</i> EN 60731:2012 EN 60731:1997/A1:2002	<i>Published:</i> 6 April, 2012 13 September, 2002
This document was published under the authority of the NSAI and comes into effect on: 19 April, 2012		ICS number: 11.040.50
NSAI 1 Swift Square, Northwood, Santry Dublin 9	T +353 1 807 3800 F +353 1 807 3838 E standards@nsai.ie W NSAI.ie	Sales: T +353 1 857 6730 F +353 1 857 6729 W standards.ie
Údarás um Chaighdeáin Náisiúnta na hÉireann		

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60731

April 2012

ICS 11.040.50

Supersedes EN 60731:1997 + A1:2002

English version

**Medical electrical equipment -
Dosimeters with ionization chambers as used in radiotherapy
(IEC 60731:2011)**

Appareils électromédicaux -
Dosimètres à chambres d'ionisation
utilisés en radiothérapie
(CEI 60731:2011)

Medizinische elektrische Geräte -
Dosimeter mit Ionisationskammern zur
Anwendung in der Strahlentherapie
(IEC 60731:2011)

This European Standard was approved by CENELEC on 2012-03-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62C/506/FDIS, future edition 3 of IEC 60731, prepared by SC 62C, "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC TC 62, "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60731:2012.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2012-12-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-03-14

This document supersedes EN 60731:1997 + A1:2002.

EN 60731:2012 includes the following significant technical changes with respect to EN 60731:1997 + A1:2002:

The technical modifications versus EN 60731:1997 + A1:2002 concerns performance requirements of RADIOTHERAPY DOSIMETERS intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA in heavy ion RADIATION FIELDS and SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60731:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60051-1:1997 NOTE Harmonized as EN 60051-1:1998 (not modified).

Annex ZA
(normative)
Normative references to international publications
with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60417	data base	Graphical symbols for use on equipment	-	-
IEC 60601-1 + corr. December + corr. December	2005 2006 2007	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 + corr. March	2008 2010
IEC 60601-2-8	2010	Medical electrical equipment - Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	EN 60601-2-8	201X ¹⁾
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60976	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	EN 60976	2007
IEC 61010-1 + corr. May	2010 2011	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	2010
IEC 61187	-	Electrical and electronic measuring equipment - Documentation	EN 61187	-
IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC 61676	2002	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN 61676	2002
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

¹⁾ To be published.

I.S. EN 60731:2012

- 4 -

EN 60731:2012

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO/IEC Guide 99	2007	International vocabulary of metrology - Basic and general concepts and associated terms (VIM)	-	-
ISO 3534-1	2006	Statistics - Vocabulary and symbols - Part 1: General statistical terms and terms used in probability	-	-

CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope and object.....	9
1.1 Scope.....	9
1.2 Object	9
2 Normative references	9
3 Terms and definitions	10
4 General requirements	22
4.1 BASIC SAFETY and ESSENTIAL PERFORMANCE.....	22
4.2 Performance requirements	22
4.3 REFERENCE VALUES and STANDARD TEST VALUES.....	22
4.4 General test conditions and methods.....	23
4.4.1 STANDARD TEST CONDITIONS.....	23
4.4.2 Test of components	23
4.4.3 RATED or EFFECTIVE RANGE of dose (or KERMA) rates	23
4.4.4 UNCERTAINTY OF MEASUREMENT.....	24
4.4.5 Adjustments during test	24
4.4.6 Test conditions particular to CHAMBER ASSEMBLIES.....	24
4.4.7 Test conditions particular to MEASURING ASSEMBLIES.....	24
4.4.8 Test conditions particular to STABILITY CHECK DEVICES	25
4.4.9 Use of STABILITY CHECK DEVICES	25
4.5 Summary tables	25
4.6 Classification of equipment according to LIMITS OF VARIATION	32
4.6.1 FIELD-CLASS DOSIMETER.....	32
4.6.2 REFERENCE-CLASS DOSIMETER.....	32
4.6.3 SCANNING-CLASS DOSIMETER	32
5 CHAMBER ASSEMBLY performance requirements	33
5.1 General.....	33
5.2 General performance requirements for (RADIOTHERAPY) IONIZATION CHAMBERS.....	33
5.2.1 CHAMBER ASSEMBLY LEAKAGE CURRENT without IRRADIATION.....	33
5.2.2 Stability	33
5.2.3 STABILIZATION TIME	34
5.2.4 Post-irradiation leakage.....	34
5.2.5 RATED or EFFECTIVE RANGE of dose rate (continuous radiation).....	35
5.2.6 Maximum RATED dose per pulse (pulsed radiation)	36
5.2.7 RATED RANGE of field sizes.....	37
5.2.8 STRAY RADIATION	38
5.2.9 Guard/collector insulation	38
5.2.10 Cable microphony.....	39
5.2.11 Polarity of polarizing voltage effect	39
5.2.12 ELECTROMAGNETIC COMPATIBILITY	40
5.3 Performance requirements particular to SHELL CHAMBERS.....	40
5.3.1 Dependence on RADIATION QUALITY	40
5.3.2 RATED RANGE of field sizes.....	43
5.3.3 Chamber orientation	44
5.4 Performance requirements particular to PARALLEL-PLATE CHAMBERS	45

5.4.1	Dependence on RADIATION QUALITY	46
5.4.2	Chamber orientation	47
5.5	Performance requirements particular to VENTED CHAMBERS	47
5.5.1	Atmospheric pressure change	48
5.5.2	Temperature	48
5.5.3	Humidity	48
5.6	Performance requirements particular to SEALED CHAMBERS	49
5.6.1	Atmospheric pressure change	49
5.6.2	Temperature	49
6	MEASURING ASSEMBLY performance requirements	50
6.1	General	50
6.2	General performance requirements for RADIOTHERAPY DOSIMETERS	50
6.2.1	EFFECTIVE RANGES	50
6.2.2	RESOLUTION of the display or data output terminal	51
6.2.3	Repeatability	51
6.2.4	Long-term stability	51
6.2.5	STABILIZATION TIME	52
6.2.6	ELECTROMAGNETIC COMPATIBILITY	52
6.3	Performance requirements particular to dosimeters	53
6.3.1	ZERO DRIFT	53
6.3.2	ZERO SHIFT	54
6.3.3	NON-LINEARITY	55
6.3.4	Range changing	56
6.3.5	Dead time	57
6.3.6	Temperature	57
6.3.7	Humidity	57
6.3.8	STRAY RADIATION effect	58
6.3.9	Charge leakage	58
6.3.10	Dose rate dependence of dosimeters	59
6.4	Performance requirements particular to dose rate meters	60
6.4.1	ZERO DRIFT	60
6.4.2	ZERO SHIFT	61
6.4.3	NON-LINEARITY	61
6.4.4	Range changing	62
6.4.5	RESPONSE TIME	64
6.4.6	Temperature	65
6.4.7	Humidity	65
6.4.8	STRAY RADIATION effect	66
6.5	Performance requirements particular to battery-operated MEASURING ASSEMBLIES	66
6.6	Performance requirements particular to supply mains-operated MEASURING ASSEMBLIES	67
6.6.1	MAINS VOLTAGE – static	67
6.6.2	MAINS VOLTAGE – VARIATION during a measurement	67
7	STABILITY CHECK DEVICE performance requirements	68
7.1	General	68
7.2	General performance requirements for STABILITY CHECK DEVICES	68
7.2.1	Long-term stability	68
7.2.2	Repeatability	68

8	Constructional requirements as related to PERFORMANCE CHARACTERISTICS	69
8.1	Constructional requirements on CHAMBER ASSEMBLIES	69
8.2	Constructional requirements on MEASURING ASSEMBLIES	69
8.2.1	Adjustment of RESPONSE	69
8.2.2	Display device	69
8.2.3	Battery indication and compensation	70
8.2.4	Input current threshold	70
8.2.5	Automatic termination of measurement in the dose mode	70
8.3	Constructional requirements on STABILITY CHECK DEVICES	70
8.3.1	Output of the STABILITY CHECK DEVICES	70
8.3.2	Constructional requirements particular to a radioactive type STABILITY CHECK DEVICE	71
8.3.3	Constructional requirements particular to an overall STABILITY CHECK DEVICE	71
8.4	Constructional requirements on PHANTOMS and build-up caps	71
9	Marking	72
9.1	Marking required on CHAMBER ASSEMBLY	72
9.1.1	Information required in IEC 60601-1	72
9.1.2	Other information	73
9.1.3	Compliance check	73
9.2	Marking required on MEASURING ASSEMBLY	73
9.2.1	CHAMBER ASSEMBLY in contact with the PATIENT	73
9.2.2	CHAMBER ASSEMBLY not in contact with the PATIENT	73
9.2.3	Each MEASURING ASSEMBLY	73
9.2.4	MEASURING ASSEMBLY with a display scaled in dose	74
9.2.5	Multi-range MEASURING ASSEMBLY	74
9.2.6	MEASURING ASSEMBLY with more than one chamber	74
9.2.7	Graphical symbols	74
9.2.8	Compliance check	74
9.3	Marking required on STABILITY CHECK DEVICE	74
9.3.1	General	74
9.3.2	STABILITY CHECK DEVICE containing a RADIOACTIVE SOURCE	74
9.3.3	Device which contributes to protection against IONIZING RADIATION	74
9.3.4	Compliance check	74
9.4	Marking required on PHANTOM or build-up cap	75
10	ACCOMPANYING DOCUMENTS	75
10.1	ACCOMPANYING DOCUMENTS for CHAMBER ASSEMBLY	75
10.1.1	INSTRUCTIONS FOR USE of CHAMBER ASSEMBLY	75
10.1.2	Test sheet for CHAMBER ASSEMBLY	77
10.1.3	Calibration certificate for CHAMBER ASSEMBLY	77
10.2	ACCOMPANYING DOCUMENTS for MEASURING ASSEMBLY	78
10.2.1	INSTRUCTIONS FOR USE of MEASURING ASSEMBLY	78
10.2.2	Test sheet for MEASURING ASSEMBLY	80
10.2.3	Calibration certificate for MEASURING ASSEMBLY	80
10.3	ACCOMPANYING DOCUMENTS for STABILITY CHECK DEVICE	81
10.3.1	INSTRUCTIONS FOR USE of STABILITY CHECK DEVICE	81
10.3.2	Test sheet for STABILITY CHECK DEVICE	81
10.3.3	Measurement certificate for STABILITY CHECK DEVICE	81
10.4	ACCOMPANYING DOCUMENTS for PHANTOMS and build-up caps	82

I.S. EN 60731:2012

60731 © IEC:2011

– 5 –

Annex A (informative) Values, error and UNCERTAINTY	84
Annex B (normative) Test equipment for cable microphony	85
Annex C (normative) UNCERTAINTY OF MEASUREMENT	86
Bibliography.....	95
Index of defined terms used in this standard	96
Figure 1 – Tolerance of depth in PHANTOM.....	72
Figure 2 – Tolerance of lateral position in PHANTOM	72
Figure A.1 – Graphical illustration of values, error and UNCERTAINTY	84
Figure B.1 – Test equipment for cable microphony.....	85
Figure C.1 – PROBABILITY DISTRIBUTIONS for the PERFORMANCE CHARACTERISTICS to be within the LIMITS OF VARIATION $\pm L$ and the expression of their VARIANCES in terms of L	88
Table 1 – REFERENCE CONDITIONS and STANDARD TEST CONDITIONS – CHAMBER ASSEMBLY	26
Table 2 – REFERENCE CONDITIONS and STANDARD TEST CONDITIONS – MEASURING ASSEMBLY	27
Table 3 – Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS – CHAMBER ASSEMBLY	27
Table 4 – Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS – MEASURING ASSEMBLY	28
Table 5 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – CHAMBER ASSEMBLY.....	29
Table 6 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – MEASURING ASSEMBLY.....	31
Table 7 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – chamber and MEASURING ASSEMBLIES combined	32
Table C.1 – Estimate of COMBINED STANDARD UNCERTAINTY for performance of a hypothetical dosimeter	90
Table C.2 – A hypothetical example of the assessment of the UNCERTAINTIES on the output measurement of an X-ray set using a FIELD-CLASS DOSIMETER.....	94

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

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) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60731 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1997 and its Amendment 1 (2002) and constitutes a technical revision. The technical modifications versus the second edition of this standard concerns performance requirements of RADIOTHERAPY DOSIMETERS intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA in heavy ion RADIATION FIELDS and SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

I.S. EN 60731:2012

60731 © IEC:2011

– 7 –

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

FDIS	Report on voting
62C/506/FDIS	62C/511/RVD

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

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, general statements, exceptions and notes: in small roman type;
- *test specifications: in italic type;*
- terms used throughout this particular standard that have been listed in the Index of defined terms and defined in Clause 3, or in other standards: SMALL CAPITALS.

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.

INTRODUCTION

This International Standard is applicable to the performance of RADIOTHERAPY DOSIMETERS with IONIZATION CHAMBERS as used in RADIOTHERAPY.

The effectiveness of treatment of PATIENTS receiving RADIOTHERAPY depends on the accuracy of the dose of radiation received, as well as on the accuracy of their spatial distribution. An excessive dose can lead to excessive tissue damage, while an insufficient dose will not provide the therapeutic benefit sought. The equipment covered by this standard plays an essential part in achieving the required accuracy.

This standard is not concerned with the safety aspects of dosimeters. The relevant IEC standards covering safety depend upon the way in which the dosimeter is used:

- if it is used in the PATIENT environment, the requirements for safety applying to dosimeters with IONIZATION CHAMBERS as used in RADIOTHERAPY are contained in IEC 60601-1;
- if it is not used in the PATIENT environment, then the safety requirements for dosimeters with IONIZATION CHAMBERS as used in RADIOTHERAPY are contained in IEC 61010-1.

Dosimeters which comply with this standard should nevertheless be used in accordance with the relevant national or international dosimetry protocol (code of practice). In particular, measurements should be made to determine the ion collection efficiency and polarity effect of the chamber under the exact conditions of use.

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

1 Scope and object

1.1 Scope

This International Standard specifies the performance requirements of RADIOTHERAPY DOSIMETERS, intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA (and their rates and spatial distributions) in PHOTON, ELECTRON, proton or heavy ion RADIATION FIELDS as used in RADIOTHERAPY.

The DOSE MONITORING SYSTEMS incorporated in RADIOTHERAPY treatment machines are not covered by this standard, neither are the re-entrant IONIZATION CHAMBERS used for BRACHYTHERAPY source calibration and constancy check devices.

This standard is applicable to the following types of dosimeter:

- a) FIELD-CLASS DOSIMETERS normally used for
 - 1) the measurement of KERMA or dose in a RADIATION BEAM, either in air or in a PHANTOM;
 - 2) in vivo skin surface or intracavitary measurements of dose on PATIENTS.
- b) REFERENCE-CLASS DOSIMETERS normally used for the calibration of FIELD-CLASS DOSIMETERS;

NOTE REFERENCE-CLASS DOSIMETERS may be used as FIELD-CLASS DOSIMETERS.
- c) SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

1.2 Object

The object of this standard is:

- to establish requirements for a satisfactory level of performance for RADIOTHERAPY DOSIMETERS;
- to standardize methods for the determination of compliance with this level of performance.

Three levels of performance are specified:

- a lower level of performance applying to FIELD-CLASS DOSIMETERS;
- a higher level of performance applying to REFERENCE-CLASS DOSIMETERS;
- a specific level of performance applying to SCANNING-CLASS DOSIMETERS.

2 Normative references

The following referenced documents are indispensable for the application 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.

IEC 60417, *Graphical symbols for use on equipment*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-