

**ELEKTRILISED MEDITSIINISEADMED. KIIRITUSRAVIL
KASUTATAVAD IOONKAMBRIGA DOSIMEETRID**

**Medical electrical equipment - Dosimeters with
ionization chambers as used in radiotherapy
(IEC 60731:2011 + IEC 60731:2011/A1:2016)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60731:2012+A1:2022 sisaldab Euroopa standardi EN 60731:2012 ja selle muudatuse A1:2022 ingliskeelset teksti.	This Estonian standard EVS-EN 60731:2012+A1:2022 consists of the English text of the European standard EN 60731:2012 and its amendment A1:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.04.2012, muudatused A1 12.08.2022.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 06.04.2012, for A1 12.08.2022.
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English Version

**Medical electrical equipment - Dosimeters with ionization
chambers as used in radiotherapy
(IEC 60731:2011 + IEC 60731:2011/A1:2016)**

Appareils électromédicaux - Dosimètres à chambres
d'ionisation utilisés en radiothérapie
(CEI 60731:2011 + IEC 60731:2011/A1:2016)

Medizinische elektrische Geräte - Dosimeter mit
Ionisationskammern zur Anwendung in der Strahlentherapie
(IEC 60731:2011 + IEC 60731:2011/A1:2016)

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Europäisches Komitee für Elektrotechnische Normung

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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.

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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.

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

A1 Amendment A1 European foreword

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CONSOLIDATED VERSION

VERSION CONSOLIDÉE



Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy

Appareils électromédicaux – Dosimètres à chambres d'ionisation utilisés en radiothérapie



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Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy

Appareils électromédicaux – Dosimètres à chambres d'ionisation utilisés en radiothérapie

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CONTENTS

FOREWORD.....	6
■ ^{A1} Amendment A1 FOREWORD ■ ^{A1}	8
INTRODUCTION.....	9
1 Scope and object.....	10
1.1 Scope.....	10
1.2 Object.....	10
2 Normative references	10
3 Terms and definitions	11
4 General requirements	23
4.1 BASIC SAFETY and ESSENTIAL PERFORMANCE.....	23
4.2 Performance requirements.....	23
4.3 REFERENCE VALUES and STANDARD TEST VALUES.....	23
4.4 General test conditions and methods	24
4.4.1 STANDARD TEST CONDITIONS.....	24
4.4.2 Test of components.....	24
4.4.3 RATED or EFFECTIVE RANGE of dose (or KERMA) rates.....	24
4.4.4 UNCERTAINTY OF MEASUREMENT	25
4.4.5 Adjustments during test.....	25
4.4.6 Test conditions particular to CHAMBER ASSEMBLIES	25
4.4.7 Test conditions particular to MEASURING ASSEMBLIES	25
4.4.8 Test conditions particular to STABILITY CHECK DEVICES.....	26
4.4.9 Use of STABILITY CHECK DEVICES	26
4.5 Summary tables.....	26
4.6 Classification of equipment according to LIMITS OF VARIATION.....	33
4.6.1 FIELD-CLASS DOSIMETER	33
4.6.2 REFERENCE-CLASS DOSIMETER	33
4.6.3 SCANNING-CLASS DOSIMETER.....	33
5 CHAMBER ASSEMBLY performance requirements.....	34
5.1 General.....	34
5.2 General performance requirements for (RADIOTHERAPY) IONIZATION CHAMBERS.....	34
5.2.1 CHAMBER ASSEMBLY LEAKAGE CURRENT without IRRADIATION	34
5.2.2 Stability	34
5.2.3 STABILIZATION TIME	35
5.2.4 Post-irradiation leakage	35
5.2.5 RATED or EFFECTIVE RANGE of dose rate (continuous radiation)	36
5.2.6 Maximum RATED dose per pulse (pulsed radiation)	37
5.2.7 RATED RANGE of field sizes	38
5.2.8 STRAY RADIATION	39
5.2.9 Guard/collector insulation.....	39
5.2.10 Cable microphony	40
5.2.11 Polarity of polarizing voltage effect.....	40
5.2.12 ELECTROMAGNETIC COMPATIBILITY	41
5.3 Performance requirements particular to SHELL CHAMBERS	41
5.3.1 Dependence on RADIATION QUALITY	41
5.3.2 RATED RANGE of field sizes	44
5.3.3 Chamber orientation.....	46

5.4	Performance requirements particular to PARALLEL-PLATE CHAMBERS	46
5.4.1	Dependence on RADIATION QUALITY	47
5.4.2	Chamber orientation.....	48
5.5	Performance requirements particular to VENTED CHAMBERS.....	49
5.5.1	Atmospheric pressure change	49
5.5.2	Temperature	49
5.5.3	Humidity	49
5.6	Performance requirements particular to SEALED CHAMBERS	50
5.6.1	Atmospheric pressure change	50
5.6.2	Temperature	50
6	MEASURING ASSEMBLY performance requirements.....	51
6.1	General.....	51
6.2	General performance requirements for RADIOTHERAPY DOSIMETERS	51
6.2.1	EFFECTIVE RANGES.....	51
6.2.2	RESOLUTION of the display or data output terminal.....	52
6.2.3	Repeatability.....	52
6.2.4	Long-term stability	53
6.2.5	STABILIZATION TIME	53
6.2.6	ELECTROMAGNETIC COMPATIBILITY	53
6.3	Performance requirements particular to dosimeters	54
6.3.1	ZERO DRIFT.....	54
6.3.2	ZERO SHIFT.....	55
6.3.3	NON-LINEARITY.....	56
6.3.4	Range changing.....	57
6.3.5	Dead time	58
6.3.6	Temperature	58
6.3.7	Humidity	59
6.3.8	STRAY RADIATION effect.....	59
6.3.9	Charge leakage	60
6.3.10	Dose rate dependence of dosimeters.....	60
6.4	Performance requirements particular to dose rate meters	61
6.4.1	ZERO DRIFT.....	61
6.4.2	ZERO SHIFT.....	62
6.4.3	NON-LINEARITY.....	63
6.4.4	Range changing.....	64
6.4.5	RESPONSE TIME.....	66
6.4.6	Temperature	66
6.4.7	Humidity	67
6.4.8	STRAY RADIATION effect.....	67
6.5	Performance requirements particular to battery-operated MEASURING ASSEMBLIES	68
6.6	Performance requirements particular to supply mains-operated MEASURING ASSEMBLIES	68
6.6.1	MAINS VOLTAGE – static.....	68
6.6.2	MAINS VOLTAGE – VARIATION during a measurement	68
7	STABILITY CHECK DEVICE performance requirements.....	69
7.1	General.....	69
7.2	General performance requirements for STABILITY CHECK DEVICES	69
7.2.1	Long-term stability	69

7.2.2	Repeatability	70
8	Constructional requirements as related to PERFORMANCE CHARACTERISTICS	70
8.1	Constructional requirements on CHAMBER ASSEMBLIES	70
8.2	Constructional requirements on MEASURING ASSEMBLIES	70
8.2.1	Adjustment of RESPONSE	70
8.2.2	Display device	71
8.2.3	Battery indication and compensation	71
8.2.4	Input current threshold	72
8.2.5	Automatic termination of measurement in the dose mode	72
8.3	Constructional requirements on STABILITY CHECK DEVICES	72
8.3.1	Output of the STABILITY CHECK DEVICES	72
8.3.2	Constructional requirements particular to a radioactive type STABILITY CHECK DEVICE	72
8.3.3	Constructional requirements particular to an overall STABILITY CHECK DEVICE	72
8.4	Constructional requirements on PHANTOMS and build-up caps	73
9	Marking	74
9.1	Marking required on CHAMBER ASSEMBLY	74
9.1.1	Information required in IEC 60601-1	74
9.1.2	Other information	74
9.1.3	Compliance check	74
9.2	Marking required on MEASURING ASSEMBLY	74
9.2.1	CHAMBER ASSEMBLY in contact with the PATIENT	74
9.2.2	CHAMBER ASSEMBLY not in contact with the PATIENT	74
9.2.3	Each MEASURING ASSEMBLY	75
9.2.4	MEASURING ASSEMBLY with a display scaled in dose	75
9.2.5	Multi-range MEASURING ASSEMBLY	75
9.2.6	MEASURING ASSEMBLY with more than one chamber	75
9.2.7	Graphical symbols	75
9.2.8	Compliance check	75
9.3	Marking required on STABILITY CHECK DEVICE	75
9.3.1	General	75
9.3.2	STABILITY CHECK DEVICE containing a RADIOACTIVE SOURCE	75
9.3.3	Device which contributes to protection against IONIZING RADIATION	76
9.3.4	Compliance check	76
9.4	Marking required on PHANTOM or build-up cap	76
10	ACCOMPANYING DOCUMENTS	76
10.1	ACCOMPANYING DOCUMENTS for CHAMBER ASSEMBLY	76
10.1.1	INSTRUCTIONS FOR USE of CHAMBER ASSEMBLY	76
10.1.2	Test sheet for CHAMBER ASSEMBLY	78
10.1.3	Calibration certificate for CHAMBER ASSEMBLY	78
10.2	ACCOMPANYING DOCUMENTS for MEASURING ASSEMBLY	79
10.2.1	INSTRUCTIONS FOR USE of MEASURING ASSEMBLY	79
10.2.2	Test sheet for MEASURING ASSEMBLY	81
10.2.3	Calibration certificate for MEASURING ASSEMBLY	81
10.3	ACCOMPANYING DOCUMENTS for STABILITY CHECK DEVICE	82
10.3.1	INSTRUCTIONS FOR USE of STABILITY CHECK DEVICE	82
10.3.2	Test sheet for STABILITY CHECK DEVICE	82
10.3.3	Measurement certificate for STABILITY CHECK DEVICE	83

10.4 ACCOMPANYING DOCUMENTS for PHANTOMS and build-up caps	83
Annex A (informative) Values, error and UNCERTAINTY	85
Annex B (normative) Test equipment for cable microphony	86
Annex C (normative) UNCERTAINTY OF MEASUREMENT	87
Annex ZA (normative) Normative references to international publications with their corresponding European publications	96
Bibliography	98
Index of defined terms used in this standard	99
Figure 1 – Tolerance of depth in PHANTOM	73
Figure 2 – Tolerance of lateral position in PHANTOM	73
Figure A.1 – Graphical illustration of values, error and UNCERTAINTY	85
Figure B.1 – Test equipment for cable microphony	86
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	89
Table 1 – REFERENCE CONDITIONS and STANDARD TEST CONDITIONS – CHAMBER ASSEMBLY	27
Table 2 – REFERENCE CONDITIONS and STANDARD TEST CONDITIONS – MEASURING ASSEMBLY	28
Table 3 – Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS – CHAMBER ASSEMBLY	28
Table 4 – Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS – MEASURING ASSEMBLY	29
Table 5 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – CHAMBER ASSEMBLY	30
Table 6 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – MEASURING ASSEMBLY	32
Table 7 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – Chamber and MEASURING ASSEMBLIES combined	33
Table C.1 – Estimate of COMBINED STANDARD UNCERTAINTY for performance of a hypothetical dosimeter	91
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	95

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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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.

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.

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A1 Amendment A1 FOREWORD

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

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

CDV	Report on voting
62C/596A/CDV	62C/630/RVC

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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*

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

IEC 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

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*

3 Terms and definitions

For the purpose of this International Standard the terms and definitions listed in index of defined terms and the following apply.

NOTE The definitions given in this standard are generally in agreement with those in IEC TR 60788:2004 and ISO International vocabulary of basic and general terms in metrology, except that some definitions have been made more restricted. Any such special definitions should be regarded as applying only to this standard.

Any terms not defined in this standard have the meanings defined in the above publications or are assumed to be in general scientific usage.

Throughout this standard:

- if no material is specified, the term "ABSORBED DOSE" or "dose" means "ABSORBED DOSE TO WATER (in water)" and the term "KERMA" means "AIR KERMA (in air)";
- when the quantity "AIR KERMA (in air)" in units "Gy" is used, the quantity "EXPOSURE" in units "C/kg" is also allowable;