

Medical electrical equipment —

Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

The European Standard EN 60601-2-17:2004 has the status of a
British Standard

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National foreword

This British Standard is the official English language version of EN 60601-2-17:2004. It is identical with IEC 60601-2-17:2004. It supersedes BS EN 60601-2-17:1996 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Medical electrical equipment
Part 2-17: Particular requirements for the safety
of automatically-controlled brachytherapy afterloading equipment
(IEC 60601-2-17:2004)

Appareils électromédicaux
Partie 2-17: Règles particulières
de sécurité des appareils projecteurs
de brachythérapie
avec contrôles automatiques
(CEI 60601-2-17:2004)

Medizinische elektrische Geräte
Teil 2-17: Besondere Festlegungen
für die Sicherheit ferngesteuerter,
automatisch betriebener
Afterloading-Geräte für die Brachytherapie
(IEC 60601-2-17:2004)

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CENELEC

European Committee for Electrotechnical Standardization
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Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62C/363/FDIS, future edition 2 of IEC 60601-2-17, 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 was approved by CENELEC as EN 60601-2-17 on 2004-03-01.

This European Standard supersedes EN 60601-2-17:1996 + A1:1996.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
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- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2007-03-01

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements, exceptions and references: small roman type;
- *test specifications: italic type;*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH ARE DEFINED IN CLAUSE 2 OR IN THE GENERAL STANDARD EN 60601-1, ITS COLLATERAL OR PART 2 STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-17:2004 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 60601-1-3 NOTE Harmonized as EN 60601-1-3:1994 (not modified).

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INTRODUCTION

The use of AFTERLOADING EQUIPMENT for BRACHYTHERAPY purposes may expose PATIENTS to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIOACTIVE SOURCE(S) adequately within the STORAGE CONTAINER(S) and/or if there are inadequacies in the design of the TREATMENT ROOM.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of AFTERLOADING EQUIPMENT for use in temporary BRACHYTHERAPY procedures; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT. It places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists and where an INTERLOCK then operates to return the RADIOACTIVE SOURCE(S) to the STORAGE CONTAINER(S) and afterwards to prevent continued operation of the EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

1.1.101 This Particular Standard specifies requirements for the safety of automatically-controlled EQUIPMENT for BRACHYTHERAPY of patients using AFTERLOADING techniques.

1.1.102 This Standard specifies requirements for automatically-controlled AFTERLOADING EQUIPMENT

- which contains and uses only beta, gamma, and NEUTRON-emitting SEALED RADIOACTIVE SOURCES,
- which automatically drives the sealed radioactive source(s) from a storage container to a treatment position inside the source applicator(s) and returns the source(s) to the storage container,
- which is designed for connection to a PATIENT, and
- with which movements of the RADIOACTIVE SOURCE(S) are carried out automatically by the EQUIPMENT according to a prescribed programme using a powered mechanism whose changes are controlled by the CONTROLLING TIMER(S) and TIMING DEVICES that are either PROGRAMMABLE ELECTRONIC SUB-SYSTEMS (PESS) (computer or microprocessors) or non-programmable systems.

1.1.103 This Standard specifies requirements for EQUIPMENT intended to be

- used under the supervision of QUALIFIED PERSONS;
- maintained at predetermined intervals;
- subject to regular checks by the user.

This Standard does not specify requirements for SEALED RADIOACTIVE SOURCES used with the EQUIPMENT. Such requirements are specified in other standards (see 6.8.3).

1.1.104 The requirements of this Standard are based on the assumptions that:

- a TREATMENT PLAN is available that prescribes appropriate values of the TREATMENT PARAMETERS, and
- the SOURCE STRENGTH(S) of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT is (are) known.

This Standard includes requirements intended to ensure that the prescribed values of the TREATMENT PARAMETERS can be achieved by the EQUIPMENT, in particular that:

- the selected RADIOACTIVE SOURCE(S) is (are) positioned or moved within the SOURCE APPLICATOR in the selected configuration relative to the SOURCE APPLICATOR;
- IRRADIATION is performed by the selected RADIOACTIVE SOURCE configuration for the selected duration;
- IRRADIATION is performed by the EQUIPMENT without causing unnecessary risk to the OPERATOR or other persons in the immediate surroundings.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for safety of automatically-controlled BRACHYTHERAPY AFTERLOADING EQUIPMENT and the compliance test specifications. It presents the general functional requirements of the demand for safety rather than particular technological means of implementation.

1.3 Particular Standards

ADDITION:

1.3.101 Relationship to the General Standard

This Particular Standard is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, with its Amendments 1 (1991) and 2 (1995) – hereinafter referred to as the General Standard – which it amends and supplements. As in the General Standard, the requirements are followed by compliance tests.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General and Collateral Standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard;

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard;

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables which are additional to those of the General Standard are numbered starting from 101: additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term "this Standard " is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard.

1.3.102 Relationship to other standards and documents

NOTE See Appendix L for normative references.

1.5 Collateral Standards

Addition:

1.5.101 IEC 60601-1-1

All clauses and subclauses of Collateral Standard IEC 60601-1-1 apply.

1.5.102 IEC 60601-1-2

All clauses and subclauses of Collateral Standard IEC 60601-1-2 apply.

1.5.103 IEC 60601-1-3

Collateral Standard IEC 60601-1-3 does not apply.

1.5.104 IEC 60601-1-4

All clauses and subclauses of Collateral Standard IEC 60601-1-4 apply.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

For the purposes of this document, the terms and definitions given in the General Standard or in its Collateral Standards and the following apply.

NOTE 1 The Index of defined terms at the end of this document lists defined terms alphabetically with their source reference.

NOTE 2 In this Particular Standard, IRRADIATION refers to the entire process of exposing the patient to RADIOACTIVE SOURCES in positions and for periods of time appropriate for TREATMENT. TRANSIT times are explicitly excluded from the TREATMENT TIME.

NOTE 3 Although the actual titles of the persons fulfilling the following roles may vary from country to country, in this Particular Standard the term 'OPERATOR' is used to denote the person controlling the BRACHYTHERAPY EQUIPMENT during treatment, and the term 'USER' to denote the organization or individual responsible for the use and maintenance of the BRACHYTHERAPY AFTERLOADING EQUIPMENT. The terms 'radiotherapist' and 'radiation oncologist', although not used in this Particular Standard, are used in many countries to denote the person exercising medical supervision and responsibility for determining and prescribing PATIENT treatment.

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Additional definitions:

2.1.101

ABBREVIATIONS

The following abbreviations are used in this standard:

- PESS programmable electronic sub-system
- SFC single fault condition
- TCP treatment control panel

2.1.102**BETA SOURCE STRENGTH**

ABSORBED DOSE RATE [Gy s^{-1}] in water at 2 mm along the perpendicular bisector from a RADIOACTIVE SOURCE emitting beta RADIATION

2.1.103**BRACHYTHERAPY**

INTRACAVITARY, INTERSTITIAL, SUPERFICIAL or INTRALUMINAL RADIOTHERAPY using one or more SEALED RADIOACTIVE SOURCES

2.1.104**CONTINUATION**

in <RADIOTHERAPY>, re-starting IRRADIATION after INTERRUPTION of IRRADIATION without re-selection of OPERATING conditions

2.1.105**DWELL TIME**

time a RADIOACTIVE SOURCE or a RADIOACTIVE SOURCE TRAIN remains at a selected TREATMENT position

2.1.106**GAMMA SOURCE STRENGTH**

REFERENCE AIR KERMA RATE of a BRACHYTHERAPY SOURCE emitting gamma rays. The unit of GAMMA SOURCE STRENGTH is Gy s^{-1} at 1 m

NOTE Multiples (milli, mega, etc.) are permitted.

2.1.107**INITIATION**

in <RADIOTHERAPY>, commencing IRRADIATION from the READY STATE when the READY STATE was attained by carrying out selection and confirming the operating conditions and not by INTERRUPTION OF IRRADIATION

2.1.108**INTERRUPTION OF IRRADIATION, TO INTERRUPT RADIATION**

stopping IRRADIATION prior to TERMINATION OF IRRADIATION with the possibility of CONTINUATION without reselection of operating conditions

2.1.109**INTRALUMINAL RADIOTHERAPY**

RADIOTHERAPY in which one or more RADIOACTIVE SOURCES, with or without SOURCE APPLICATORS, are introduced into a body lumen such as a blood vessel, airway, or the gastrointestinal tract

2.1.110**NEUTRON SOURCE STRENGTH**

dose rate of a brachytherapy source emitting neutrons. The unit of NEUTRON SOURCE STRENGTH is Gy s^{-1} at 1 m

2.1.111**QUALIFIED PERSON**

person recognized by a competent authority as having the requisite knowledge and training to perform particular duties

2.1.112**RADIOACTIVE SOURCE TRAIN**

sequence of SEALED RADIOACTIVE SOURCES, possibly separated by non-RADIOACTIVE spacers, either permanently combined or selected prior to each IRRADIATION, and used in AFTERLOADING EQUIPMENT. The RADIOACTIVE SOURCE TRAIN is usually selected to give a specified dose distribution

2.1.113

REFERENCE AIR KERMA RATE

air kerma rate, at a reference distance of 1 m, after correction for air attenuation and scattering

NOTE The reference air kerma rate, $\dot{K}_R$, is similar to the air kerma strength, S_K , used in the USA, which is the product of air-kerma rate in free space and the square of the distance of the calibration point from the source centre along the perpendicular bisector.

2.1.114

SOURCE STRENGTH

GAMMA SOURCE STRENGTH, BETA SOURCE STRENGTH, or NEUTRON SOURCE STRENGTH of a RADIOACTIVE SOURCE, whichever is applicable for the intended use of the EQUIPMENT

2.1.115

TERMINATION OF IRRADIATION

stopping or preventing further IRRADIATION with no possibility of re-starting without the reselection of operating conditions (i.e., returning to the PREPARATORY STATE)

2.1.116

TRANSIT

the period during which the RADIOACTIVE SOURCES move from the STORAGE CONTAINER(S) to a treatment position or move from a treatment position to the STORAGE CONTAINER(S)

2.1.117

TREATMENT PARAMETER

factor that describes one aspect of the irradiation of a patient during radiotherapy, such as radiation energy, absorbed dose, treatment time

2.1.118

TREATMENT TIME

the sum of the DWELL TIMES which constitute a TREATMENT

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Tests

Addition:

Appropriate care should be taken to carry out compliance tests safely, for example by using a non-RADIOACTIVE SOURCE wherever possible. TYPE TESTS described in this Particular Standard may also be used by the MANUFACTURER or by the installer as routine tests.

5 Classification

Replacement:

EQUIPMENT and its APPLIED PARTS shall be classified and marked/identified as described in Clause 6. This includes:

5.1 According to the type of protection against electric shock:

- EQUIPMENT within the scope of this standard shall be CLASS 1 EQUIPMENT.