

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.17 Specification for remote-controlled automatically driven gamma-ray afterloading equipment

The European Standard EN 60601-2-17:1996 has the status of a
British Standard

ICS 11.040.60

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/81, upon which the following bodies were represented:

- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Institute of Radiology
- College of Radiographers
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Institute of Physical Sciences in Medicine
- Institution of Electrical Engineers
- National Radiological Protection Board
- Royal College of Radiologists

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 July 1990

© BSI 09-1999

The following BSI references relate to the work on this standard:
Committee reference HCC/81
Draft for comment 87/54131 DC

ISBN 0 580 18628 8

Amendments issued since publication

Amd. No.	Date	Comments
9281	December 1996	Indicated by a sideline in the margin

Contents

	Page
Committees responsible	Inside front cover
National foreword	iii
Foreword	2
Introduction	3
Section 1. General	
1 Scope and object	3
1.1 Scope	3
1.2 Object	3
1.3 Particular Standards	4
1.4 Environmental conditions	4
2 Terminology and definitions	4
3 General requirements	4
4 General requirements for tests	4
5 Classification	4
6 Identification, marking and documents	5
6.1 Marking on the outside of equipment	5
6.7 Indicator lights and push-buttons	5
6.8 Accompanying documents	5
7 Power input	7
Section 2. Safety requirements	
8 Basic safety categories	7
9 Removable protective means	7
10 Special environmental conditions	7
11 Special measures with respect to safety	7
12 Single fault condition	7
Section 3. Protection against electric shock hazards	
Section 4. Protection against mechanical hazards	
Section 5. Protection against hazards from unwanted or excessive radiation	
29 X-radiation	7
30 Alpha, beta, gamma, neutron radiation and other particle radiation	7
30.1 Protection in normal use and normal condition	7
30.1.1 Limitation of leakage radiation from the storage container(s)	8
30.1.2 Indication of the position of radioactive sources	8
30.1.3 Key control of the possibility of pre-setting controlling timer, and of selection, confirmation and movement of radioactive sources	9
30.1.4 Treatment time	9
30.1.5 Indications by the controlling timer and of treatment time	9
30.1.6 Selection and confirmation of channels, radioactive sources and positions and movements of radioactive sources	9
30.1.7 Initiation, continuation, interruption, and termination (of irradiation)	10
30.1.8 Distant interruption	10
30.2 Protection against other than normal use	11
30.2.1 Rendering the treatment control panel inoperative	11
30.2.2 Protection of radioactive sources	11
30.3 Protection in normal use while in single fault condition	11
30.3.1 Protection against failure of the supply mains	11

	Page
30.3.2 Protection against failure of controlling timer	11
30.3.3 Protection against failure of the positional accuracy and movement of the radioactive sources and of the source drive mechanism	12
30.3.4 Protection against failure of the couplings of the channels and the source applicators	12
30.3.5 Protection against failure of the connections (if any) to the radioactive sources	12
30.3.6 Protection against failure of interlocks	12
30.3.7 Indication of single fault conditions	13
36 Electromagnetic compatibility	13
Section 6. Protection against hazards of explosions in medically used rooms	
Section 7. Protection against excessive temperatures, fire and other hazards, such as human errors	
Section 8. Accuracy of operating data and protection against incorrect output	
50 Accuracy of operating data	13
50.1 Indications	13
50.1.1 Information of gamma irradiation	13
50.1.2 Scales and units	13
50.1.3 Indication of selection of channels, radioactive sources, and the positions and movements of radioactive sources	13
50.1.4 Information required for limiting the irradiation during transit of the radioactive sources	13
50.2 Agreement between indicated values and effective values	14
50.2.1 Position of radioactive sources within source applicators	14
50.2.2 Controlling timers	14
51 Protection against incorrect output	14
Section 9. Fault conditions causing overheating and/or mechanical damage; environmental tests	
Section 10. Constructional requirements	
Appendix AA Terminology	15
AA.1 Index of terms	15
AA.2 Definitions	16
List of references	Inside back cover

National foreword

This British Standard has been prepared by Technical Committee CH/81 (formerly HCC/81) and is the English language version of EN 60601-2-17:1996 *Medical electrical equipment — Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-17:1989, published by the International Electrotechnical Commission (IEC). EN 60601-2-17:1996 supersedes CENELEC HD 395.2.17 S1:1992.

This Particular Standard should be read in conjunction with its Supplement, which implements amendment A1 to the European Standard EN 60601-2-17. The Supplement, published separately, is designated as follows:

BS EN 60601-2-17/A1:1996

(BS 5724-2.17:Supplement 1:1996 *Revised and additional text*)

(IEC 601-2-17 Amendment 1:1996)

Together with its Supplement, this Particular Standard amends and supplements the General Standard, which is designated as follows:

BS EN 60601-1:1990

(BS 5724-1:1989)

(IEC 601-1:1988)

Medical electrical equipment — Part 1. General requirements for safety

This Particular Standard takes priority over the General Standard.

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc. and additional items are lettered aa), bb) etc. The changes from the text of the General Standard are specified by the use of the following words.

“Replacement” means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

“Amendment” means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.

“Addition” means that the text of this standard is additional to the requirements of the General Standard.

An index of the terms used in this Particular Standard and their definitions is given in Appendix AA.

Cross-references

See national foreword of the Supplement, BS EN 60601-2-17/A1:1996 (BS 5724-2.17:Supplement 1:1996).

Additional information. The following print types are used in this standard.

Requirements, compliance with which can be tested, and definitions: in roman type.

Explanations, advice and general statements: in small roman type.

Test procedures: in italic style.

Terms defined in clause 2 of the General Standard and this Particular Standard: in SMALL CAPITALS.

For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

Attention is drawn to the difference between the recommendations of paragraph 157 of ICRP Publication 33 (1982) *Protection against ionizing radiation from external sources used in medicine*¹⁾ and **30.1.1 b)** of this Particular Standard.

Textual errors. When adopting the text of the International Standard, the textual errors listed below were discovered. They have been marked in the text and have been reported to IEC in a proposal to amend the text of the International Standard.

In **1.3**, after the title, the word in italics should be read as “Replacement”.

In **50.1.4**, the following sentence should be inserted at the end of the first paragraph. “The other is to limit the IRRADIATION of other parts of the PATIENT’s body.”

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ ICRP Publication 33 (1982) has been prepared by the International Commission for Radiological Protection and is obtainable from Pergamon Press, Headington Hill Hall, Oxford OX3 0BW.

Descriptors: Medical electrical equipment, gamma-ray therapy, sealed radioactive sources, remote-controlled automatically-driven afterloading equipment, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment

(IEC 601-2-17:1989)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des
appareils projecteurs de sources radioactives
automatiques télécommandés utilisés en
radiothérapie par rayonnement gamma
(CEI 601-2-17:1989)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit ferngesteuerter, automatisch
betriebener Afterloading-Geräte für
Gamma-Strahlung
(IEC 601-2-17:1989)

This European Standard was approved by CENELEC on 1996-03-05. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of the International Standard IEC 601-2-17:1989, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.17 S1 on 1991-12-10.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60601-2-17 on 1996-03-15.

The following date was fixed:

- latest date by which the
EN has to be implemented
at national level by
publication of an identical
national standard or by
endorsement (dop) 1997-03-01

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given for information only. In this standard, Appendix AA is informative.

For the normative references to international publications with their corresponding European publications, see Annex ZA to EN 60601-2-17:1996/A1:1996.