

Medical electrical equipment —

Part 2: Particular requirements for safety —

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

Supplement 1: Revised and additional text

The European Standard EN 60601-2-17:1996/A1:1996 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 to Technical Committee CH/81, Radiotherapy equipment, 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
- Institution of Electrical Engineers
- Institution of Physics and Engineering in Medicine and Biology
- Royal College of Radiologists

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 December 1996

© BSI 09-1999

The following BSI references relate to the work on this standard:
Committee reference CH/81
Draft for comment 95/560385 DC

ISBN 0 580 26464 5

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Text of EN 60601-2-17/A1	3
Annex ZA (normative) Normative references to international publications with their corresponding European publications	7
List of references	Inside back cover

National foreword

This Supplement to BS EN 60601-2-17 has been prepared by Technical Committee CH/81 and is the English language version of amendment A1:1996 to 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 Amendment 1:1996 to IEC 601-2-17:1989, published by the International Electrotechnical Commission (IEC).

This Supplement amends and adds to the requirements specified in BS EN 60601-2-17:1996 (BS 5724-2.17:1990).

References to page numbers, and to the “foreword” and “preface”, should be ignored, as they related to the original IEC document.

Cross-references (see also Annex ZA)

Publication referred to	Corresponding British Standard
EN 60601-1:1990 (IEC 601-1:1988)	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i> BS EN 60601 <i>Medical electrical equipment</i> Part 1 <i>General requirements for safety</i>
EN 60601-1-2:1993 (IEC 601-1-2:1993)	Section 1.2:1993 <i>Collateral standard. Electromagnetic compatibility. Requirements and tests</i>
HD 501 S1:1988 (IEC 788:1984)	BS 6641:1985 <i>Glossary of medical radiology terms</i>
ISO 361:1975	BS 3510:1968 <i>Specification for a basic symbol to denote the actual or potential presence of ionizing radiation</i>

Additional information. The Technical Committee has become aware of the following inconsistency in the text of this Supplement, relating to the application of the Collateral Standard IEC 601-1-4. The additional subclause **1.5.104** given in the Supplement conflicts with the new text relating to **52.1** in SECTION 9 of the General Standard IEC 601-1:1988 (BS 5724-1:1989) which states:

“Amendment 2 to IEC 601-1 does not apply.

NOTE See **1.5.104**.”

Amendment 2 to IEC 601-1 adds the following text to **52.1**:

“The safety of EQUIPMENT incorporating P.E.Ss. shall be assessed against the requirements of (future) IEC Collateral Standard 601-1-4 (see Appendix L).”

To clarify this point, a proposal has been submitted to the IEC to amend the reference in IEC 601-2-17 to clause **52** of the General Standard.

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 and ii, the EN title page, pages 2 to 8, 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.

UDC 615.849.114:539.122:614.8
ICS 11.040.60

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/A1:1996)

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/A1:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit ferngesteuerter, automatisch
betriebener Afterloading-Geräte für
Gamma-Strahlung
(IEC 601-2-17:1989/A1:1996)

This amendment A1 modifies the European Standard EN 60601-2-17:1996; it 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 amendment 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 amendment 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