
British Standard

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.5 Specification for safety of ultrasonic therapy equipment

Appareils électromédicaux

Partie 2. Conditions particulières de sécurité

Section 2.5 Sécurité pour appareils à ultrasons pour thérapie — Spécifications

Elektromedizinische Geräte

Teil 2. Besondere Sicherheitsanforderungen

Abschnitt 2.5 Sicherheit von Ultraschall-Therapiegeräten

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee. It is identical with IEC Publication 601-2-5 'Medical electrical equipment' Part 2 'Particular requirements for the safety of ultrasonic therapy equipment', published in 1984 by the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724 : Part 1 hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over those of 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; the additional appendix is lettered AA and additional items 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.

A rationale for the most important requirements is given in appendix AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This appendix does not form part of the standard.

Terminology and conventions. The text of the international standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards. In particular the following print types are used.

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

Explanations, advice, general statements, exceptions and references: in small roman type

Test specifications: in italic type

Terms defined in clause 2 of the General Standard and this Particular Standard: small capitals.

Wherever page numbers are quoted, they are IEC page numbers.

Cross-reference

International standard	Corresponding British Standard
IEC 601-1 : 1977	BS 5724 Medical electrical equipment Part 1 : 1979 Specification for general safety requirements (Technically equivalent)

The Technical Committee has reviewed the provisions of CISPR Publication 11 and IEC Publication 150, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

It is the intention that IEC Publication 150 will be revised and, at that time, this Section of BS 5724 will be amended accordingly.

Textual error. When adopting the text of the international standard, the textual error given below was discovered. It has been marked in the text and has been reported to the International Electrotechnical Commission in a proposal to amend the text of the international standard.

Clause 35.2 'EFFECTIVE ACOUSTIC OUTPUT POWER' should read 'EFFECTIVE ULTRASOUND OUTPUT POWER'.

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

Amendment No.1
published and effective from 15 July 1992
to BS 5724 : Part 2 : Section 2.5 : 1985

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therapy equipment

NOTE. This amendment is being published to effect the implementation of CENELEC HD 395.2.5.

Revised text

AMD 7016
July 1992

Front cover

Underneath the title, insert the following.

‘(Implementation of CENELEC HD 395.2.5)’.

AMD 7016
July 1992

National foreword

Insert the following sentence at the end of paragraph 1.

‘This Section of BS 5724 is also in agreement with Harmonization Document HD 395.2.5, published by the European Committee for Electrotechnical Standardization (CENELEC).’

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*Only clauses with text differing from that given in BS 5724 : Part 1 are included in this list.

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SECTION ONE — GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

Addition:

This Particular Standard specifies the requirements for safety of **ULTRASONIC THERAPY EQUIPMENT** used in medical practice, as defined in Sub-clause 2.1.101, hereinafter referred to as **EQUIPMENT**.

This Particular Standard does not apply to **EQUIPMENT** in which a tool is driven by **ULTRASOUND** (for example **EQUIPMENT** used in surgery or dentistry) or in which focused **ULTRASOUND** pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotrites).

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Addition:

Radiating area and the other accessible parts of the **TREATMENT HEAD**, including any **ADAPTOR**.

Additional definitions:

2.1.101 *ULTRASONIC THERAPY EQUIPMENT*

EQUIPMENT for the generation and application of **ULTRASOUND** to a **PATIENT** for therapeutic purposes.

Essentially the **EQUIPMENT** comprises a generator of electric high-frequency power and a transducer for converting this to **ULTRASOUND**.

2.1.102 *ULTRASONIC TRANSDUCER*

Device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range.

2.1.103 *TREATMENT HEAD*

Assembly comprising one or more **ULTRASONIC TRANSDUCER(S)** and associated parts for local application of **ULTRASOUND** to the **PATIENT**.

A **TREATMENT HEAD** is also referred to as an applicator.