IS 13450-2-5 (2009): Medical Electrical Equipment, Part 2: Particular Requirements for the Safety, Section 5: Ultrasonic Physiotherapy Equipment [MHD 14: Hospital Planning]

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IS 13450 (Part 2/Sec 5) : 2009
IEC 60601-2-5 : 2005
[Superseding IS 13020 (Part 1) : 1991 and IS 13020 (Part 2) : 1990]

भारतीय मानक

चिकित्सीय विद्युत उपस्कर

भाग 2 सुरक्षा के लिए विशिष्ट अपेक्षाएँ

अनुभाग 5 अल्ट्रासोनिक फीजियोथेरेपी उपस्कर

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 5 Ultrasonic Physiotherapy Equipment

ICS 11.040.60

BUREAU OF INDIAN STANDARDS
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December 2009 **Price Group 7**

Electromedical Equipment Sectional Committee, MHR 15

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 5) which is identical with IEC 60601-2-5 : 2005 'Medical electrical equipment — Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was earlier published in two parts as IS 13020 (Part 1) : 1991 'Medical electrical equipment — Ultrasonic physiotherapy equipment: Part 1 Particular requirements for safety' and IS 13020 (Part 2) : 1990 'Medical electrical equipment — Ultrasonic physiotherapy equipment: Part 2 Constructional and performance requirements', as technically equivalent standards based on IEC 60601-2-5 : 1984. This adoption has been taken to harmonize with the latest IEC Publication. This standard incorporates both the safety requirements as well as constructional requirements. With the publication of this standard IS 13020 (Part 1) : 1991 and IS 13020 (Part 2) : 1990 shall be treated as superseded and hence withdrawn.

This particular standard specifies requirements and tests for the safety of ultrasonic physiotherapy equipment. This particular standard supplements the General Standard IS 13450 (Part 1) : 2008 'Medical electrical equipment — Part 1: General requirements for the basic safety and essential performance (*first revision*)'. The requirements of this particular standard take priority over those of the General Standard.

This standard incorporates additional clauses on electro-magnetic compatibility, homogeneity of the radiation field and output stability with time. The specified accuracy has been changed from ±30 percent to ±20 percent in order to provide an adequate degree of safety. Accuracy of the timer has been specified for timer settings of less than 5 min, 5 min to 10 min and more than 10 min. Additional items has been included in 'instructions for use' clause, for example, intervals for regular performance testing and calibration by the user, a list of conditions for which ultrasound treatment is contra indicated, a statement of intended use(s), information on available treatment head, method by which interchangeability is achieved, in case the treatment head has been designed for interchangeability.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

The text of IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker in the International Standard while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below, along with their degree of equivalence, for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1 : 1988[1)] Medical electrical equipment — Part 1: General requirement for safety	IS 13450 (Part 1) : 2008 Medical electrical equipment: Part 1 General requirement for the basic safety and essential performance (*first revision*)	Technically Equivalent

[1)]Since revised in 2005.

(*Continued on third cover*)

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 5 Ultrasonic Physiotherapy Equipment

SECTION ONE – GENERAL

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

1 Scope and object

1.1 Scope

Addition:

This Particular Standard specifies the requirements for safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

This Particular Standard does not apply to:

- EQUIPMENT in which a tool is driven by ULTRASOUND (for example EQUIPMENT used in surgery or dentistry);
- EQUIPMENT in which focused ULTRASOUND pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotrites) (for information refer to IEC 60601-2-36);
- ULTRASONIC PHYSIOTHERAPY EQUIPMENT in which focused ULTRASOUND pulse waves are used.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard as the "General Standard" .

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard 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 or figures 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 and Collateral Standards mentioned below.

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – Section 1 – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

2 Terminology and definitions

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Additional definitions:

2.1.101
ULTRASONIC PHYSIOTHERAPY EQUIPMENT (hereinafter referred to as EQUIPMENT)
EQUIPMENT for the generation and application of ULTRASOUND to a PATIENT for therapeutic purposes

NOTE 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 an ULTRASONIC TRANSDUCER and associated parts for local application of ULTRASOUND to the PATIENT

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

2.1.104
ATTACHMENT HEAD
ACCESSORY intended to be attached to the TREATMENT HEAD for the purpose of modifying the ultrasonic beam characteristics

2.12 MISCELLANEOUS

2.12.101
RATED OUTPUT POWER
maximum OUTPUT POWER of the EQUIPMENT at any RATED MAINS VOLTAGE

[IEC 61689, definition 3.32]

2.12.102
ULTRASOUND
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 16 kHz) (see 801-21-04 of IEC 60050(801))

[IEC 61689, definition 3.45]

2.12.103
EFFECTIVE RADIATING AREA
beam cross-sectional area extrapolated to the front face of the TREATMENT HEAD and multiplied by a dimensionless factor according to IEC 61689

[IEC 61689, definition 3.20, modified]

NOTE This may be thought of as the area of the face of the treatment head which contains 100 % of the total mean square acoustic power.

2.12.104
EFFECTIVE INTENSITY
ratio of the OUTPUT POWER to the EFFECTIVE RADIATING AREA. It is expressed in watts per square centimetre

[IEC 61689, definition 3.18, modified]

2.12.105
ACOUSTIC WORKING FREQUENCY
frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field. The signal is analysed using the zero-crossing frequency technique (see 3.4.1 of IEC 61102)

[IEC 61689, definition 3.3]

2.12.106
BEAM NON-UNIFORMITY RATIO
ratio of the square of the maximum r.m.s. acoustic pressure to the spatial average of the square of the r.m.s. acoustic pressure where the spatial average is taken over the EFFECTIVE RADIATING AREA, determined in accordance with IEC 61689

[IEC 61689, definition 3.9, modified]

2.12.107
BEAM TYPE
descriptive classification for the ultrasonic beam in one of three types: collimated, convergent or divergent

[IEC 61689, definition 3.11]

2.12.108
DUTY FACTOR
ratio of the PULSE DURATION to the PULSE REPETITION PERIOD (see 5.3.2.4 of IEC 60469-1)

[IEC 61689, definition 3.17]

2.12.109
OUTPUT POWER
time-average ultrasonic power radiated by a TREATMENT HEAD of EQUIPMENT into an approximately free field under specified conditions in a specified medium, preferably in water (see 3.5 of IEC 61161)

[IEC 61689, definition 3.31]

2.12.110
PULSE DURATION
time interval beginning at the first time the pressure amplitude exceeds a reference value and ending at the last time the pressure amplitude returns to that value. The reference value is equal to the sum of the minimum pressure amplitude and 10 % of the difference between the maximum and minimum pressure amplitude

[IEC 61689, definition 3.35]

NOTE The above definition from IEC 61689 differs from that of 3.30 of IEC 61102 to account for incomplete modulation.

2.12.111
PULSE REPETITION PERIOD
absolute value of the time interval after which the same characteristics of a periodic waveform recur (see 5.3.2.1 of IEC 60469-1)

[IEC 61689, definition 3.36]

2.12.112
TEMPORAL-MAXIMUM INTENSITY
in the case of an amplitude modulated wave, this is the ratio of the TEMPORAL-MAXIMUM OUTPUT POWER to the EFFECTIVE RADIATING AREA

[IEC 61689, definition 3.41, modified]

2.12.113
TEMPORAL-MAXIMUM OUTPUT POWER
in the case of an amplitude modulated wave, this is a function of the actual OUTPUT POWER, the temporal-peak acoustic pressure and the r.m.s. acoustic pressure and is determined as specified in IEC 61689

[conforms to 3.34 of IEC 61689]

*4 General requirements for tests

This clause of the General Standard applies, except as follows:

*4.1 Tests

Note addition to rationale (see Annex AA).

5 Classification

This clause of the General Standard applies, except as follows:

5.6

Amendment:

Delete all dashed items except "– CONTINUOUS OPERATION".

*6 Identification, marking and documents

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

p) Output

Replacement:

1. The generator of an EQUIPMENT shall additionally be provided with the following markings:
   - ACOUSTIC WORKING FREQUENCY in MHz (in kHz for frequencies below 1 MHz)
   - waveform (continuous, amplitude modulated (or pulsed))
   - if amplitude modulated (or pulsed), a description or picture of the output waveforms, along with values for the PULSE DURATION, PULSE REPETITION PERIOD, and DUTY FACTOR for each modulation setting.
2. The generator shall carry a nameplate, permanently attached, on which is given a unique serial number so that it is individually identified.
3. The treatment head shall be marked with its rated output power in watts, the effective radiating area in square centimetres, the beam non-uniformity ratio, the beam type, a designation of the specific generator (where applicable, see 6.8.2 aa) item 9) of the equipment for which the treatment head is intended and a unique serial number.

6.8.2 Instructions for use

Additional item:

aa) The instructions for use shall additionally contain the following:

1) Information on ACOUSTIC WORKING FREQUENCY or FREQUENCIES in kilohertz or megahertz and EFFECTIVE RADIATING AREA or AREAS in square centimetres of any TREATMENT HEAD or ATTACHMENT HEAD.
2) A recommendation calling the USER's attention to the need for periodic maintenance, especially:
   - INTERVALS FOR REGULAR PERFORMANCE TESTING AND CALIBRATION BY THE USER;
   - INSPECTION OF THE TREATMENT HEAD FOR CRACKS, WHICH MAY ALLOW THE INGRESS OF CONDUCTIVE FLUID;
   - INSPECTION OF THE TREATMENT HEAD CABLES AND ASSOCIATED CONNECTORS.

3) Advice on the procedures necessary for safe operation, drawing attention in the case of TYPE B APPLIED PARTS to the SAFETY HAZARDS which may occur as a result of an inadequate electrical installation.

4) Advice on the type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR.

5) Advice drawing the USER's attention to the need for care when handling the TREATMENT HEAD since rough handling may adversely affect its characteristics.

6) A list of conditions for which ULTRASOUND treatment is contraindicated.

7) A statement of intended use(s).

8) Information on available TREATMENT HEADS.

9) Where a TREATMENT HEAD has been designed for interchangeability, such that it is not possible to specify a particular generator unit, this shall be stated and the method by which interchangeability is achieved shall be described.

7 Power input

This clause of the General Standard applies with EQUIPMENT operated as specified in Clause 50.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

*13 General

Addition:

In the case of combined EQUIPMENT (e.g. EQUIPMENT additionally provided with a function or an APPLIED PART for electrical stimulation) such EQUIPMENT shall also comply with any Particular Standard specifying safety requirements for the additional function.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

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

21 Mechanical strength

21.5 *Compliance test:*

Additional paragraph:

After the test, the TREATMENT HEAD shall comply with 51.104 of this Particular Standard.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

*35 Acoustical energy (including ultrasonics)

Replacement:

The spatial-peak temporal-average intensity (see IEC 61102) of unwanted ULTRASOUND radiation from a TREATMENT HEAD intended for hand-held use shall be less than 100 mW/cm^2 when measured as described below.

Compliance shall be checked by the following test:

The front face of the TREATMENT HEAD is immersed in degassed water the temperature of which is 22 °C ± 3 °C. The EQUIPMENT is operated at the RATED OUTPUT POWER specified for the TREATMENT HEAD. The unwanted ULTRASOUND radiation is measured by scanning, by hand, the side walls of the TREATMENT HEAD by means of a calibrated hydrophone coupled to the side walls using a coupling gel.

NOTE For requirements concerning OUTPUT POWER and intensity distribution, see Section Eight.

*36 Electromagnetic compatibility

Replacement:

EQUIPMENT shall comply with the Collateral Standard 60601-1-2, except as follows:

36.202.2.1 d)

Additional sentence:

The value of 3 V/m is specified for the immunity tests.

36.202.2.2 d)

Replacement:

The following operating conditions apply during the test:

- *Maximum and half setting of the OUTPUT POWER, the TREATMENT HEAD being immersed in water.*
- *If the output circuit can be tuned with an accessible control, the measurement shall be made at resonance and also when detuned.*

SECTION SIX – PROTECTION AGAINST THE HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETHIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

42 Excessive temperatures

42.3

* *Compliance test*

Additional items:

6) *The radiating surface of a normally hand-held* TREATMENT HEAD *is immersed approximately 1 cm below the surface of 2 l of water having a total depth of not less than 20 cm and an initial temperature of 25 °C ± 1 °C. The* EQUIPMENT *is operated for 3 min at the* RATED OUTPUT POWER *for the* TREATMENT HEAD *concerned. The* TREATMENT HEAD *is then removed from the water for 15 s and then immediately reimmersed in the water and the above cycle repeated twice more (a total test time of 9 min 45 s). (See figure 101.)*

7) *A* TREATMENT HEAD *which is intended only for use under water, and which is not intended to be used as a hand-held device, shall be tested while completely immersed in not less than 2 l of water with the* EQUIPMENT *operating for 15 min at the* RATED OUTPUT POWER *specified for the* TREATMENT HEAD *concerned.*

NOTE Some form of mechanical stirrer may be necessary to ensure that the temperature is distributed evenly. (See Annex AA, Clause 42.)

8) *At no time during tests 101 or 102 above shall the temperature of the radiating surface exceed 41 °C.*

NOTE 1 During the measurement of temperature, it may be necessary to de-energize the TREATMENT HEAD in order to avoid direct heating of the temperature measuring device.

NOTE 2 To avoid additional heating caused by ULTRASOUND reflected from the sides or bottom of the water test tank, the walls and bottom of the test tank should be lined with acoustic absorbing material.

9) *The temperature-rise test for the generator is performed at* RATED OUTPUT POWER *with the* TREATMENT HEAD *immersed in a container filled with water at an initial temperature of 25 °C ± 1 °C for a period of time as specified in Item 3) "*DUTY CYCLE*" of the compliance test following 42.3 of the General Standard. The test shall be performed for each* TREATMENT HEAD *provided by the manufacturer in turn unless it can be shown that testing a specific* TREATMENT HEAD *ill produce worst case results.*

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

***44.6 Ingress of liquids**

Addition:

101) The TREATMENT HEAD of EQUIPMENT shall be rated IPX7 according to IEC 60529.

Compliance shall be checked by testing the TREATMENT HEAD *including the inlet of the connecting cord according to IEC 60529.*

102) A TREATMENT HEAD specified for ultrasonic therapy in combination with pressurized water massage shall withstand the maximum pressure occurring in this treatment.

Compliance shall be checked by the test mentioned under 44.6.101) above, but at 1,3 times the maximum pressure occurring in NORMAL USE.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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

* 50 Accuracy of operating data

50.1 Marking of controls and instruments

Replacement:

50.1.101 Quantitative indicators shall be provided on the control panel in the form of a meter or a calibrated output control. They shall be directly readable, and show

a) OUTPUT POWER and EFFECTIVE INTENSITY in the case of continuous wave mode of operation, and
b) TEMPORAL-MAXIMUM INTENSITY and TEMPORAL-MAXIMUM OUTPUT POWER in the amplitude modulated wave mode of operation.

Compliance shall be checked by measurement in accordance with Clause 8 of IEC 61689. The above measurements shall be made immediately after any warm-up period specified in the ACCOMPANYING DOCUMENTS.

50.1.102 Where any indicator described in 50.1.101 utilizes two or more different ranges of measurement, a clear and reliable indication of the range used shall be provided.

Compliance shall be checked by inspection.

50.1.103 Any power indication described in 50.1.101 shall not differ from the actual value by more than ±20 % of the actual value.

Compliance shall be checked by inspection and measurement of the TEMPORAL-MAXIMUM OUTPUT POWER *in amplitude modulated wave mode, and the* OUTPUT POWER *in continuous wave mode. The measurements shall be performed with an indicated value which is greater than 10 % of the maximum indicatable value.*

NOTE As the quotient of OUTPUT POWER to EFFECTIVE INTENSITY is the EFFECTIVE RADIATING AREA, the 20 % limitation specified above automatically applies to both types of indication.

*51 Protection against hazardous output

This clause of the General Standard applies, except as follows:

*** 51.5 Incorrect output**

Replacement:

The maximum EFFECTIVE INTENSITY shall not exceed 3 W/cm^2 with any TREATMENT HEAD or ATTACHMENT HEAD provided by the manufacturer. This requirement shall apply in NORMAL CONDITION and in any SINGLE FAULT CONDITION.

Compliance shall be checked by measurement of the EFFECTIVE RADIATING AREA and measurement of the RATED OUTPUT POWER as in 50.1.

Additions:

*** 51.101 Output control**

EQUIPMENT shall incorporate a means (an output control) to enable the OUTPUT POWER to be reduced to not more than 5 % of the RATED OUTPUT POWER.

Compliance shall be checked by measurement of OUTPUT POWER as in 50.1.

*** 51.102 Output stability with supply variations**

The OUTPUT POWER shall not vary by more than ±20 % for variations of the MAINS VOLTAGE of ±10 %. Manual readjustment of the EQUIPMENT for compliance with this requirement is not permitted.

Compliance shall be checked by measurement of the OUTPUT POWER as in 50.1 at 90 %, 100 % and 110 % of the RATED value of the MAINS VOLTAGE.

*** 51.103 Timer**

EQUIPMENT shall be provided with an adjustable timer which de-energizes the output after a preselected operating period. The timer shall have a range not exceeding 30 min and the following accuracy:

for timer settings of	accuracy
less than 5 min	±30 s
5 min to 10 min	±10 % of setting
more than 10 min	±1 min

*** 51.104 Homogeneity of the radiation field**

The BEAM NON-UNIFORMITY RATIO shall not exceed 8,0 with any TREATMENT HEAD or ATTACHMENT HEAD provided by the manufacturer.

Compliance shall be checked by measurement in accordance with Clause 8 of IEC 61689.

51.105 Output stability with time

During one hour of continuous operation at maximum OUTPUT POWER and at RATED MAINS VOLTAGE, in water at 22 °C ± 3 °C, the OUTPUT POWER shall remain constant within ±20 % of its initial value.

***51.106 Acoustic working frequency**

The ACOUSTIC WORKING FREQUENCY shall comply with IEC 61689.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

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

56 Components and general assembly

*** 56.3 Connections – General**

Additional item:

aa) The connecting cord of the TREATMENT HEAD shall be protected against excessive bending at the entries into the TREATMENT HEAD and into the EQUIPMENT or the pertaining connection plug, respectively.

Compliance shall be checked by application of the test for mains cords specified in 57.4 b) of the General Standard to the two ends of this connection cord.

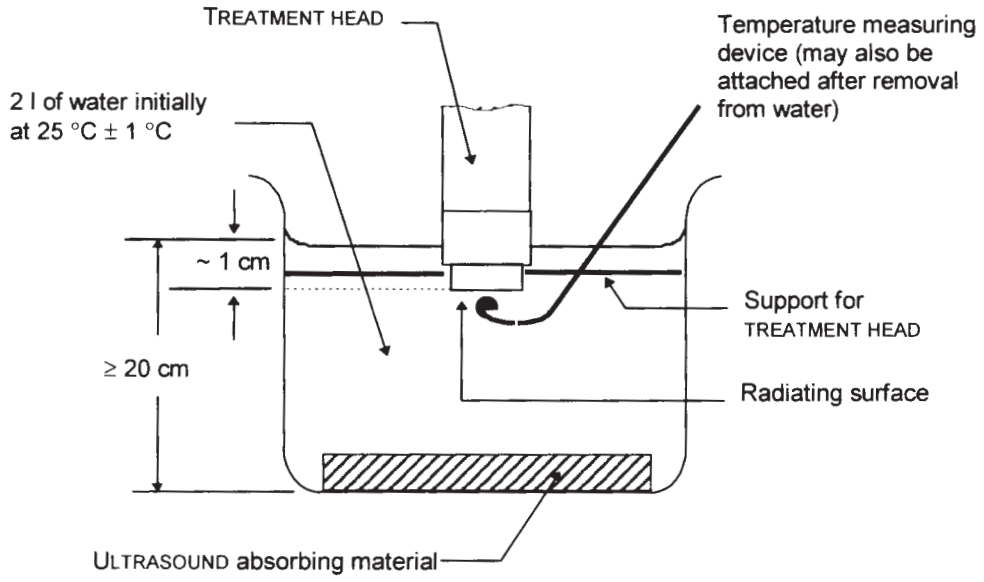

Figure 101 – Arrangement for testing the temperature of the radiating surface (see 42.3)

The Appendices of the General Standard apply, except as follows:

Appendix L

Additional IEC Standards:

IEC 60050(801):1994, *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

IEC 60469-1:1987, *Pulse techniques and apparatus – Part 1: Pulse terms and definitions*

IEC 60601-2-36:1997, *Medical electrical equipment – Part 2-36. Particular requirements for the safety of equipment for extracorporeally induced lithotripsy*

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range of 0,5 MHz to 15 MHz*

IEC 61161:1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*
Amendment 1 (1998)[1)]

IEC 61689:1996, *Ultrasonics – Physiotherapy systems – Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

[1)] There exists a consolidated edition 1.1 (1998) which includes IEC 61161 (1992) and its Amendment 1 (1998).

Annex AA
(informative)

General guidance and rationale

This annex provides a concise rationale for the important requirements of this Standard and is intended for those who are familiar with the subject of this Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of this Standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this Standard necessitated by these developments.

2.1.103 TREATMENT HEAD

Multi-element transducers are commonplace in diagnostic and hyperthermia applications, but are virtually unknown nowadays in EQUIPMENT. For this reason, and additionally because of the problems of applying suitable test methods for determination of the key acoustic parameters, the scope of IEC 61689 was restricted to "single plane circular transducers". This restriction has been maintained in this revision of IEC 60601-2-5.

4.1 Tests

The testing during manufacture (see rationale in 4.1 of the General Standard) should include verification of the RATED OUTPUT POWER according to the test method specified in 50.1, and a test for watertightness of the TREATMENT HEAD as specified in 44.6.

Since the test of 50.1 is inadequate for detection of hotspots, the manufacturer is recommended to perform the more extensive tests specified in Clause 9 of IEC 61689 on a sample basis.

6 Identification, marking and documents

The most important output characteristics, the knowledge of which may be important for safe use, shall be displayed on the EQUIPMENT. Other output parameters may be specified in the ACCOMPANYING DOCUMENTS. It is recommended that these include the estimated uncertainties at the 95 % confidence level for

(i) the indicated EFFECTIVE RADIATING AREA in 6.1 p) 3),

(ii) the indicated RATED OUTPUT POWER in 6.1 p) 3),

(iii) the ACOUSTIC WORKING FREQUENCY,

(iv) the BEAM NON-UNIFORMITY RATIO,

(v) the PULSE DURATION,

(vi) the PULSE REPETITION PERIOD,

(vii) the quantitative indication of OUTPUT POWER in 50.1.101 and

(viii) the quantitative indication of EFFECTIVE INTENSITY in 50.1.101.

In practice it is anticipated that manufacturers will declare nominal values of a range of parameters in accordance with Clause 5 of IEC 61689.

13 General

In combined EQUIPMENT, this Particular Standard is applicable only to the ultrasonic part.

However, in combined EQUIPMENT, for example where the TREATMENT HEAD forms one of the electrodes of an electric stimulator, earthing of the TREATMENT HEAD may not be allowed.

35 Acoustical energy (including ultrasonics)

The figure of 100 mW/cm^2 incorporates a reasonable safety factor due to the low efficiency of coupling to the OPERATOR's hand, in NORMAL USE, in comparison with the test conditions. If the OPERATOR's fingers were wet or covered in gel, then temperature rises of a few degrees Celsius could occur. In practice, this is an unlikely situation but remains an important issue for the OPERATOR.

Neither the principle of this method nor the arrangement used allow an exact determination of the intensity value, however the value as measured does give an indication of the energy available at the sides of the TREATMENT HEAD.

36 Electromagnetic compatibility

The EQUIPMENT is not allowed to cause electromagnetic interference above a certain level under any conditions of practical use nor to degrade in safety and performance in a "normal" electromagnetic environment. The test under half output power is necessary, since higher levels of interference may be produced under this operating condition.

42.3 Compliance test

Removal of the TREATMENT HEAD from contact with the PATIENT is likely during treatment and may result in an increase in the temperature of the radiating surface of the TREATMENT HEAD. A test with the TREATMENT HEAD radiating into air for short periods is therefore specified. The test method specified minimizes measurement errors due to the heating of the temperature measuring device by ULTRASOUND radiation.

This scenario will not arise with modern physiotherapy equipment which senses acoustic coupling and automatically switches OUTPUT POWER.

Regarding the test method, for typical systems generating 12 watts RATED OUTPUT POWER, a 15-minute insonnation will transfer almost 12 kJ of energy into the absorbing material, possibly giving rise to a high temperature rise in the material. There are two consequences of this: the absorber may become damaged and also, convection currents may be set-up which will carry the heat up to the TRANSDUCER. It is therefore advisable that some kind of mechanical stirrer is used to ensure the temperature is distributed evenly.

44.6 Ingress of liquids

Watertightness of the TREATMENT HEAD is necessary not only for the case of treatment under water, but also to prevent the ingress of oils or creams used for coupling of the TRANSDUCER face to the PATIENT'S skin during treatment outside of a water bath. The depth of immersion during the test covers methods used in clinical practice.

50 Accuracy of operating data

Actual OUTPUT POWER and EFFECTIVE INTENSITY are the most important quantities for safe treatment, hence their direct indication is considered necessary. Operators should be able to rely on the indicated values when treating PATIENTS. The specified accuracy is considered to provide an adequate degree of safety and also takes into account the errors inherent in ultrasound power measurements.

51 Protection against hazardous output

IEC 61689 uses the term *absolute maximum/minimum* to refer to a quantity which is the measured value plus/minus the uncertainty of the measurement. This Standard sets specific values and does not mention measurement uncertainty (apart from disclosure requirements); ability to demonstrate compliance with required values is considered to take such uncertainties into account in line with published IEC guidelines.

51.5 Incorrect output

The maximum value of 3 W/cm^2 specified is a well-established value taking clinical practice and safety considerations into account. However, lower values dependent on the clinical application used may be necessary for particular treatments.

51.101 All EQUIPMENT should be suitable for treatment of the PATIENT with low power.

51.102 Output stability with supply variations

This modest requirement should protect against excessive output variations with MAINS VOLTAGE fluctuations likely to be encountered in practical use.

51.103 Timer

The accuracy requirement for the timer is considered adequate in view of the accuracy requirement for the OUTPUT POWER.

51.104 Homogeneity of the radiation field

Excessive local peaks in the ULTRASOUND intensity could constitute a SAFETY HAZARD and should be avoided. See also Annex F of IEC 61689.

51.106 ACOUSTIC WORKING FREQUENCY

This requirement represents an accuracy of ±10 %, which is considered sufficient for therapeutic applications.

56.3 Connections – General

The connection cord of the TREATMENT HEAD is flexed continuously in practical use, consequently protection against excessive bending is necessary.

NATIONAL ANNEX A
(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

(*Continued from second cover*)

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1-1 : 1992[1)] Medical electrical equipment — Part1: General requirements for safety — Section 1 — Collateral Standard : Safety requirements for medical electrical systems	IS 13450 (Part 1/Sec 1) : 2006 Medical electrical equipment: Part 1 General requirement for safety, Section 1 Collateral Standard: Safety requirements for medical electrical systems	Technically Equivalent
IEC 60601-1-4 : 1996[1)] Medical electrical equipment — Part 1: General requirements for safety — 4. Collateral Standard: Programmable electrical medical systems	IS 13450 (Part 1/Sec 4) : 2008 Medical electrical equipment: Part 1 General requirements for safety, Section 4 Collateral Standard: Programmable electrical medical systems	do

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 60050 (801) : 1994	International Electrotechnical Vocabulary — Chapter 801: Acoustics and electroacoustics
IEC 60469-1 : 1987	Pulse techniques and apparatus — Part 1: Pulse terms and definitions
IEC 60601-1-2 : 1993[2)]	Medical electrical equipment — Part 1: General requirements for safety — Section 2 — Collateral Standard: Electromagnetic compatibility — Requirements and tests
IEC 60601-2-36 : 1997	Medical electrical equipment — Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy
IEC 61102 : 1991[3)]	Measurement and characterization of ultrasonic fields using hydrophones in the frequency range 0.5 MHz to 15 MHz
IEC 61161 : 1992[4)]	Ultrasonics — Power measurement — Radiation force balances and performance requirements
IEC 61689 : 1996[2)]	Ultrasonics — Physiotherapy systems — Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz

Only the English language text of the International Standard has been retained while adopting it in this Indian Standard, and as such the page numbers given here are not the same as in the IEC publication.

The standard also makes a reference to the BIS Certification Marking of the product, details of which is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

[1)] Since revised in 2000.
[2)] Since revised in 2007.
[3)] This IEC has been replaced by IEC 62127-1 : 2007, IEC 62127-2 : 2007 and IEC 62127-3 : 2007.
[4)] Since revised in 2006.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: MHR 15 (0092).

Amendments Issued Since Publication

Amendment No.	Date of Issue	Text Affected

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