Australian/New Zealand Standard™

Ultrasonics—Physiotherapy systems—Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz (IEC 61689:1996, MOD)

Standards Australia

STANDARDS NEW ZEALAND
Paerewa Aotearoa

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 22 October 2002 and on behalf of the Council of Standards New Zealand on 15 October 2002. It was published on 20 December 2002.

The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Canterbury District Health Board, New Zealand
Australian and New Zealand College of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Ageing
Department of Defence (Australia)
Masterton Hospital, New Zealand
Medical Industry Association of Australia
Ministry of Economic Development, New Zealand
Royal Australian and New Zealand College of Radiologists

Additional interests participating in the preparation of this Standard:

CSIRO National Measurement Laboratory
CSIRO Telecommunications and Industrial Physics
National Radiation Laboratory, New Zealand
N.S.W. Department of Public Works and Services
University of Queensland
University of Sydney

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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

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Australian/New Zealand Standard™

Ultrasonics—Physiotherapy systems—Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz (IEC 61689:1998 MOD)

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

This Standard modifies, and has been reproduced from, IEC 61689:1996, *Ultrasonics—Physiotherapy systems—Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz.*

Appendix ZZ lists the variations between this Standard and IEC 61689. These changes are indicated by a rule in the margin against each clause affected.

As this publication has been reproduced from an international Standard, the following modifications apply:

(a) Its number does not appear on each page of text and its identity is shown on the cover and title page.

(b) The words 'this Australian/New Zealand Standard' should replace the words 'this International Standard' wherever they appear.

(c) Substitute a full point for a comma where it appears as a decimal marker.

In the text of this Standard, the following print types are used:

(i) Requirements, compliance with which can be tested and definitions ..... in large roman type

(ii) Explanations, advice, introductions, general statements, exceptions and references ..... in smaller roman type

(iii) Headings of sub-clauses and test specifications ..... *in italic type*

(iv) Terms used throughout the Standard which have been defined in Clause 3 and which are also in the index ..... IN SMALL CAPITALS

Some pages of the original, which relate to IEC administrative matters, are omitted from this edition.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard[*]		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety systems	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-2-5	Part 2-5: Particular requirements for the safety of ultrasonic therapy equipment	3200.2.5	Part 2.5: Particular requirements for safety—Ultrasonic therapy equipment

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix or annex to which they apply. A 'normative' appendix or annex is an integral part of a Standard, whereas an 'informative' appendix or annex is only for information or guidance.

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[*]Only IEC Standards adopted in Australia/New Zealand appear in this list.

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Annexes

NOTES

INTRODUCTION

Ultrasound at low megahertz frequencies is widely used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of high-frequency electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** consists of a transducer, usually a disk of piezoelectric material, for converting the electrical energy to ultrasound and is often designed for contact with the human body.

AUSTRALIAN/NEW ZEALAND STANDARD

Ultrasonics—Physiotherapy systems—Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz (IEC 61689:1996, MOD)

1 Scope

This International Standard is applicable to **ultrasonic equipment** designed for physiotherapy consisting of an **ultrasonic transducer** generating continuous or quasi-**continuous wave** ultrasonic energy in the frequency range 0,5 MHz to 5 MHz.

This standard only relates to **ultrasonic physiotherapy equipment** employing a single plane circular transducer per **treatment head**, producing static beams perpendicular to the face of the **treatment head** in accordance with present practice.

This standard specifies:

- methods of measurement and characterization of the output performance of **ultrasonic physiotherapy equipment** based on reference testing methods;
- characteristics to be declared by manufacturers of **ultrasonic physiotherapy equipment** based on reference testing methods;
- requirements for performance and safety of the ultrasonic field generated by **ultrasonic physiotherapy equipment;**
- methods of measurement and characterization of the output performance of **ultrasonic physiotherapy equipment** based on routine testing methods;
- acceptance criteria for aspects of performance of **ultrasonic physiotherapy equipment** based on routine testing methods.

Therapeutic value and method of use of **ultrasonic physiotherapy equipment** are not covered by the scope of this standard.

2 Normative reference

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 50(801): 1994, *International Electrotechnical Vocabulary (IEV) – Chapter 801: Acoustics and electroacoustics*

IEC 469-1: 1987, *Pulse techniques and apparatus – Part 1: Pulse terms and definitions*

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*