AS/NZS ISO 15004: 2002
ISO 15004:1997

Australian/New Zealand Standard™

Ophthalmic instruments—Fundamental requirements and test methods

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 26 June 2002 and on behalf of the Council of Standards New Zealand on 20 June 2002. It was published on 28 June 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 Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
Canterbury District Health Board
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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™

Ophthalmic instruments—Fundamental requirements and test methods

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PREFACE

This Joint Australian/ New Zealand Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as a Joint Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-003 on Medical Electrical Equipment.

This Standard is identical with and has been reproduced from ISO 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods.*

The objective of this Standard is to specify requirements for non-invasive, active and non-active ophthalmic instruments.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the International Standards referenced herein:

Reference to International Standard or other publication		*Equivalent Australian/New Zealand Standard*	
IEC		AS/NZS	
60601-1	Medical electrical equipment: Part 1: General requirements for safety	3200.1.0	Medical electrical equipment — Part 1.0: General requirements for safety — Parent Standard
60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	3200.1.1	Approval and test specification - Medical electrical equipment - General requirements for safety - Collateral Standard: Safety requirements for medical electrical systems

As this Standard is reproduced from an international Standard, the following applies:

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

(b) In the source text ‘this International Standard' should read ‘this Australian/New Zealand Standard’.

(c) A full point substitutes for a comma when referring to a decimal marker.

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NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Ophthalmic instruments—Fundamental requirements and test methods

1 Scope

This International Standard specifies Fundamental requirements for non-invasive, active and non-active ophthalmic instruments. This International Standard is also applicable to low-vision aids and tonometers, but not to other ophthalmic instruments which are used in contact with the globe of the eye.

This International Standard takes precedence over the corresponding requirements of the other general standards cited in clause 2, if differences exist.

This International Standard does not apply to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

2 Normative references

The following standards 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 standards 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 standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9022-2:1994, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat, humidity.*

ISO 9022-3:1994, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

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

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 non-invasive ophthalmic instrument
Ophthalmic instrument which does not in whole or in part penetrate inside the body, either through a body orifice or through the surface of the body.

3.2 active ophthalmic instrument
Any ophthalmic instrument connected with a permanently installed source of electrical power energy.

3.3 manufacturer (of an ophthalmic instrument)
Natural or legal person who places the ophthalmic instrument on the market.

3.4 optical radiation hazard
Possibility of damage to the retina by optical radiation.

NOTE — The effect of the radiance of a source (see 3.6) will decrease as the light beam passes through an optical system due to filtering, absorption or other loss mechanisms. Thus, basing the optical radiation hazard on the source radiance ensures that the radiance at the retina cannot exceed the source radiance.