AS EN 12470.3—2004
EN 12470-3:2000

Australian Standard™

Clinical thermometers

Part 3: Performance of compact electrical thermometers (non-predictive and predictive, with maximum device

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Australian Electrical and Electronic Manufacturers Association

Australian Institute of Physics

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This Standard was issued in draft form for comment as DR 03510.

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First published as AS EN 12470.3—2004.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5937 8

PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee CH-030, Temperature Measurement. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from EN 12470-3:2000, *Clinical thermometers*—Part 3: *Performance of compact electrical thermometers (non-predictive and predictive) with maximum device.*

The objective of this Standard is to specify the performance requirements for compact clinical electrical thermometers with maximum device (non-predictive and predictive).

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

As this Standard is reproduced from a European 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 European Standard' and 'this Part of EN 12470' should read 'this Australian Standard'.

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

References to International Standards and European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian or Australian/New Zealand Standard*	
ISO		AS	
2859	Sampling procedures for inspection by attributes	1199	Sampling procedures for inspection by attributes
2859-2	Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection	1199.2	Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-2	Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests

Only International or European references that have been adopted as Australian Standards have been listed.

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AUSTRALIAN STANDARD

Clinical thermometers

Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device

1 Scope

This Part of EN 12470 specifies the performance requirements for compact clinical electrical thermometers with maximum device (non-predictive and predictive).

This European Standard applies to devices that, when taking temperatures, are powered by an internal power supply and that provide a digital indication of temperature.

This European Standard does not apply to clinical electrical thermometers for continuous measurement and thermometers intended to measure skin temperature.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 980	*Graphical symbols for use in the labelling of medical devices*
EN 1041	*Information supplied by the manufacturer with medical devices*
prEN 12470-1: 1998	*Clinical thermometers* *Part 1: Metallic liquid-in-glass thermometers with maximum device*
EN 60601-1	*Medical electrical equipment -* *Part 1: General requirements for safety*
EN 60601-1-2	*Medical electrical equipment -* *Part 1: General requirements for safety - 2: Collateral Standard - Electromagnetic compatibility - Requirements and tests*
ISO 2859-2: 1985	*Sampling procedures for inspection by attributes -* *Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*

3 Definitions

For the purposes of this Part of EN 12470 the following definitions apply:

3.1 compact electrical thermometer: Contact thermometer that consists of a temperature probe and an indicating unit permanently connected together.

3.2 compact predictive thermometer: Device which calculates the maximum temperature of a probe in contact with a body cavity, without waiting for thermal equilibrium to occur, by
heat transfer data and a mathematical algorithm and maintains the calculated maximum temperature value for a specified time or until reset by its user.