

Australian Standard™

**Clinical thermometers**

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

This Australian Standard was prepared by Committee CH-030, Temperature Measurement. It was approved on behalf of the Council of Standards Australia on 7 April 2004 and published on 25 May 2004.

---

The following are represented on Committee CH-030:

Australian Chamber of Commerce and Industry  
Australian Electrical and Electronic Manufacturers Association  
Australian Institute of Physics  
CSIRO Manufacturing & Infrastructure Technology  
CSIRO National Measurement Laboratory  
Electricity Supply Association of Australia  
Institute of Instrumentation and Control Australia  
National Association of Testing Authorities Australia

---

### **Keeping Standards up-to-date**

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Web Shop at [www.standards.com.au](http://www.standards.com.au) and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

Australian Standards™ and other products and services developed by Standards Australia are published and distributed under contract by SAI Global, which operates the Standards Web Shop.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at [mail@standards.org.au](mailto:mail@standards.org.au), or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

---

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

Australian Standard™

## Clinical thermometers

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

First published as AS EN 12470.3—2004.

#### **COPYRIGHT**

© Standards Australia International

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

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:

<i>Reference to International Standard</i>		<i>Australian or Australian/New Zealand Standard</i>	
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.

## CONTENTS

1	Scope	1
2	Normative references	1
3	Definitions	1
4	Unit	2
5	Types of thermometers	2
6	Performance requirements	2
7	Test methods	6
8	Information supplied by the manufacturer	11
	Annex B (informative) Bibliography	15
	Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	16

NOTES

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

### 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.