AS EN 12470.2—2004
EN 12470-2:2000

Australian Standard™

Clinical thermometers

Part 2: Phase change type (dot matrix) thermometers

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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 12470-2:2000, *Clinical thermometers*—Part 2: *Phase change type (dot matrix) thermometers.*

The objective of this Standard is to specify performance requirements and test methods for phase change-type (dot matrix) thermometers for measuring temperature in body cavities.

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 or European Standard		*Australian 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
EN		AS EN	
556	Sterilization of medical devices—Requirements for terminally sterilized medical devices to be labelled 'STERILE'	556	Sterilization of medical devices—Requirements for medical devices to be designated 'STERILE'
		556.1	Part 1: Requirements for terminally sterilized medical devices

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

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AUSTRALIAN STANDARD

Clinical thermometers

Part 2: Phase change type (dot matrix) thermometers

1 Scope

This Part of EN 12470 specifies performance requirements and test methods for phase change-type (dot matrix) thermometers for measuring temperature in body cavities.

NOTE: A body cavity can be the mouth, rectum or armpit.

This European Standard does not apply to clinical thermometers designed for special applications (e.g. thermometers for hypothermia) which owing to their measurement range, scale interval or maximum permissible error do not meet the requirements specified in this Standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publication. 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 (including amendments).

EN 980	*Graphical symbols for use in the labelling of medical devices*
EN 1041	*Information supplied by the manufacturer with medical devices*
EN 556+A1	*Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "Sterile"*
ISO 2859-2:1985	*Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*

3 Terms and definitions

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

3.1
measurement time
length of time required to measure body temperature.

3.2
phase change (dot matrix) thermometer
device utilising a change in state of chemical components designed to measure and indicate human body temperature.

3.3
retention time
duration of time for which the optimal signal for reading persists.

3.4
sensor matrix
temperature measuring area consisting of temperature dots.

NOTE: The dots contain different chemical mixtures, which change their state at specific temperatures. This change is accompanied by a change in appearance, e. g. change of colour. When in contact with the temperature site being measured, the change of state takes place in the sequence of dots up to and including the dot corresponding to the temperature of the site. This dot indicates the site temperature.

3.5
temperature offset
designed difference between preadjusted thermometer reading and water bath temperature after reaching thermal equilibrium.

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