

Australian Standard™

Sterilizers—Steam—Pre-vacuum

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This Australian Standard was prepared by Committee ME-003, Sterilizing Equipment. It was approved on behalf of the Council of Standards Australia on 13 December 2002 and published on 21 January 2003.

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Australian Standard™

Sterilizers—Steam—Pre-vacuum

Originated as AS 1410—1973.
Previous edition AS 1410—1987.
Fourth edition 2003.

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

ISBN 0 7337 5002 8

PREFACE

This Standard was prepared by the Standards Australia Committee ME-003, Sterilizing Equipment, to supersede AS 1410—1987.

The objective of this Standard is to provide users with equipment that will perform safely as intended.

This edition is a major revision of the previous edition. Wherever possible, it was changed to harmonise with relevant ISO and EN Standards.

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

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STANDARDS AUSTRALIA

Australian Standard Sterilizers—Steam—Pre-vacuum

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies requirements for fully-automatic jacketed pre-vacuum steam sterilizers that operate at a sterilizing temperature of 134°C and are intended for use in hospitals and other non-industrial applications for the sterilization of porous loads, and instruments and utensils wrapped in porous material.

The sterilizers are not intended for—

- (a) sterilization of fluids;
- (b) installation in areas associated with the use of flammable anaesthetics or volatile liquids (see AS 1169); or
- (c) downward-displacement cycles, unless the sterilizer also complies with AS 2192.

NOTES:

- 1 A sterilizer may be required to operate at a minimum of 121°C for a specific purpose. Refer to AS 4187 for sterilizer time/temperature relationships.
- 2 Guidance on information to be supplied with enquiries and orders is given in Appendix A.
- 3 Information on quality of water is given in Appendix B.
- 4 Information on steam supplies is given in Appendix C.
- 5 Standards for machines that wash, sterilize or dry medical equipment in health care facilities are listed in Appendix D.

1.2 APPLICATION

This Standard is intended to apply only to sterilizers that are installed with both a mechanical means to remove air and a supply of saturated steam with a very high dryness value, to assure consistently dry loads. Saturated steam with a dryness value of not less than 97% is required. Unless saturated steam with a dryness value of not less than 97% is provided, it is not normally possible to produce dry loads. To ensure a suitable steam supply, it may be necessary to provide a dedicated source of steam, such as an electric steam generator. (See Appendix C.)

1.3 INNOVATION

Any use of new or unusual materials or methods to achieve the intent of this Standard is encouraged. Manufacturers employing innovative materials or methods shall show documented proof that the innovation is not inferior to that of the intent of this Standard.

1.4 REFERENCED DOCUMENTS

The documents referred to in this Standard are listed in Appendix E.

1.5 DEFINITIONS

For the purpose of this Standard, the definitions in AS 4187 and those below apply.