

Australian Standard™

**Sterilizers—Steam—
Downward-displacement**



This Australian Standard was prepared by Committee ME-003, Sterilizing Equipment. It was approved on behalf of the Council of Standards Australia on 21 June 2002 and published on 25 July 2002.

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Australian Standard™

Sterilizers—Steam— Downward-displacement

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PREFACE

This Standard was prepared by the Standards Australia Committee ME-003, Sterilizing Equipment, to supersede AS 2192—1991.

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

Technical changes from the previous edition include the following:

- (a) Clause 1.4 includes some definitions.
- (b) Clause 2.8 includes amended requirements for wheels of carriages.
- (c) Clause 3.6 amends the requirements for surface finish.
- (d) Clause 3.18 includes requirements to prohibit the introduction of superheated steam and amendments to requirements for steam separation.
- (e) Clause 3.23.1 for temperature indicators has been amended.
- (f) Clause 3.25.2 includes amended requirements for colours of stage indicators.
- (g) Section 6 on testing has been amended.
- (h) Paragraphs H1 and H2, which prescribe standard fabric and instrument test packs, have been amended.
- (i) Requirements and advice regarding the sterilization of fluids are included in Clauses 3.12.1, 3.24.3, Table 4 and Appendix G.

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— Downward-displacement

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies requirements for horizontal downward-displacement steam sterilizers (including jacketed types and non-jacketed types) that are intended for use in hospitals and other non-industrial applications.

NOTES:

- 1 Downward-displacement-type steam sterilizers should not be used to sterilize any instrument or equipment that is lumened or blind lumened, as specified in AS 4187 (Clause 4.2.2 in the 2002 edition).
- 2 Steam sterilizers require an independently generated saturated steam supply that has a dryness value of not less than 0.97 and an adequate steam quality. Information on steam quality is provided by HTM 2031.
- 3 Steam sterilizers should not be installed in any location where flammable anaesthetics or volatile liquids may be used, unless the location and the sterilizer comply with the relevant requirements of AS 1169, AS 2380.2 and AS 2380.7.
- 4 Guidance on information that should be supplied with enquiries and orders is given in Appendix A.
- 5 Information on quality of water is given in Appendix B.
- 6 Information on steam supplies is given in Appendix C.
- 7 Standards for machines that wash, sterilize or dry medical equipment in health care facilities are listed in Appendix D.

1.2 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 third-party proof that the innovation is not inferior to that of the intent of this Standard.

1.3 REFERENCED DOCUMENTS

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

1.4 DEFINITIONS

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

1.4.1 Air removal

Removal of air from the sterilizer chamber and sterilizer load, sufficient to facilitate steam penetration.

1.4.2 Autoclave

Colloquial term for steam-under-pressure sterilizer.

1.4.3 Automatic process controller

A device that, in response to pre-determined cycle variables, operates a sterilizer sequentially through the required stages of the cycle.

1.4.4 Biological indicator

A population of calibrated bacterial spores on, or in, a carrier that is packaged in such a manner that the integrity of the inoculated carrier is maintained.

1.4.5 Calibration

Comparison of a measurement system or device of unknown accuracy with a measurement system or device of a known accuracy, to detect, correlate, report or eliminate by adjustment any variation from the required performance limits of the unverified measurement system or device.

1.4.6 Chamber

The part of a sterilizer that receives a sterilizer load.

1.4.7 Commissioning

A series of checks and tests performed after installation of a sterilizer in its place of use.

1.4.8 Cycle complete

An indication that a sterilization cycle has been satisfactorily completed, and the sterilized load is ready for removal from the sterilizer chamber.

1.4.9 Cycle fault

Recognition by an automatic controller that the pre-set cycle variables for a sterilization cycle have not been attained.

1.4.10 Door

A device that closes and seals a sterilizer chamber.

1.4.11 Double-ended sterilizer

A sterilizer with a door at each end of the sterilizer chamber.

1.4.12 Drain

An outlet situated at the lowest part of a sterilizer chamber, to control the discharge of condensate, air and non-condensable gases from the sterilizer chamber.

1.4.13 Dry saturated steam

Steam with a temperature and pressure corresponding to the vaporization curve of water.

NOTE: This is an ideal condition, which can deviate towards either superheated steam or wet steam. This deviation is quantified by the determination of the dryness value for the steam.

1.4.14 Dryness value

The ratio of the mass of pure steam to the total mass.

1.4.15 Holding time

The minimum time at a given temperature that has been established to destroy all microorganisms.

1.4.16 Independent steam supply

A supply of steam produced by a dedicated generator, for a sterilizer or group of sterilizers.

1.4.17 Inoculated carrier

A carrier on which a defined number of test organisms has been deposited.

1.4.18 Non-condensable gas

Air and other gases that will not condense under the conditions of steam sterilization.

1.4.19 Penetration time

The time required for every part of a load to reach the selected sterilizing temperature after that temperature has been reached in the sterilizing chamber.

1.4.20 Pressure vessel

A vessel consisting of a sterilizer chamber, a jacket (if fitted), the door and the components that are permanently connected with a sterilizer chamber.

1.4.21 Shall

Indicates that a statement is mandatory.

1.4.22 Should

Indicates a recommendation.

1.4.23 Sterile

A state of being free of viable microorganisms.

NOTE: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

1.4.24 Sterilization

A validated process used to render a product free of all forms of viable microorganisms.

NOTE: In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

1.4.25 Sterilization cycle

A defined sequence of operational steps, designed to achieve sterilization, that are carried out in a sealed chamber.

1.4.26 Sterilization time

The total time of a sterilization stage after a sterilizing chamber has reached the sterilizing temperature (i.e., penetration time plus holding time plus safety factor).

1.4.27 Sterilizer load

Goods that are to be sterilized simultaneously in the same sterilizer chamber.

1.4.28 Sterilizing temperature

The minimum temperature of the sterilization temperature band.

1.4.29 Sterilizing temperature band

A range of temperatures, expressed as the sterilization temperature and the maximum allowable temperature that may prevail throughout the load during the holding time.

NOTE: These temperatures are usually stated in whole degrees Celsius.

1.4.30 Superheated steam

- (a) Steam that is able to cool to a lower temperature at the same pressure, before it condenses into water.
- (b) Steam that is hotter than would be dry saturated steam at the same pressure.
- (c) Steam that is too hot at the prevailing pressure to be able to immediately condense.

1.4.31 Type test

A series of tests to establish the working data for a sterilizer type.

1.4.32 Usable space

Space inside the sterilizer chamber that is not restricted by fixed parts and is consequently available to accept a sterilizer load.

NOTE: The usable space is expressed in terms of chamber height, chamber width and chamber depth.

1.4.33 Work test

A series of tests on a sterilizer, performed at the manufacturer's factory, to demonstrate compliance of the sterilizer with its specification.

1.5 EXPRESSION OF PRESSURE VALUES

Pressure values are taken to be gauge pressure at sea level, unless otherwise specified.

SECTION 2 MATERIALS

2.1 WELDING AND BRAZING CONSUMABLES

Electrodes and filler metal used in welding and brazing processes, and other welding consumables and their application, shall comply with AS 1167.1, AS 1858.1, AS 1858.2, AS 2203.1, AS 2717.2, AS/NZS 1167.2, AS/NZS 1553.1, AS/NZS 1553.2, or AS/NZS 2717.1, as appropriate.

2.2 MATERIALS FOR CONNECTIONS WELDED TO THE CHAMBER OR JACKET

Materials for connections welded to the chamber or jacket should be one of the combinations listed in Table 1.

TABLE 1
MATERIALS FOR CONNECTIONS WELDED TO THE CHAMBER OR JACKET

Chamber (see Table 2)	Connections (see Note)
Stainless steel	Stainless steel of equivalent type to the material of the chamber
Stainless-steel-clad carbon steel	Stainless steel of equivalent type to the cladding material of the chamber
Nickel-clad carbon steel	Nickel or copper-nickel alloy

NOTE: Carbon steel connections may be made to carbon steel jackets.

2.3 CLADDING

Where clad carbon steel plate is used, the thickness of the cladding shall be not less than 8% of the total thickness of the plate.

2.4 GALVANIZING

Any galvanizing shall be of a Z350 Class as specified by AS 1627.5, to give a smooth non-corroding finish.

2.5 CHAMBERS, JACKETS, CLOSURE HOLDING ELEMENTS AND DOORS

Chambers, jackets, closure holding elements and doors shall be of one of the combinations of materials given in Table 2.

Pressure-retaining portions that are fabricated from stainless steel shall comply with the requirements for cleanliness and descaling specified in ASTM A380.

TABLE 2
MATERIALS FOR CHAMBERS, JACKETS, CLOSURE HOLDING ELEMENTS
AND DOORS

1	2	3	4	5
Combination designation	Chamber	Jacket	Closure holding elements	Door
A	Stainless steel	Stainless steel	Stainless steel	Stainless steel
B	Stainless-steel-clad (on internal face) carbon steel	Carbon steel	Stainless steel	Stainless-steel-clad (on internal face) carbon steel
C	Nickel-clad carbon steel	Carbon steel	Stainless steel or Copper-nickel alloy or Carbon steel	Nickel-clad (on internal face) carbon steel or Copper-nickel alloy or Gunmetal or Aluminium
D	Aluminium	Aluminium	Stainless steel or Chromium plated carbon steel	Stainless steel or Aluminium

2.6 FRAMEWORK

Where a fixed frame is provided, the framework shall be of—

- (a) stainless steel; or
- (b) carbon steel that, after fabrication, has been pickled in accordance with AS 1627.5 and then either—
 - (i) galvanized with a Z350 Class coating by a hot dip process in accordance with AS 1627.5; or
 - (ii) powder coated.

Adjustable support brackets, levelling bolts and feet shall be of stainless steel or suitable plastic material.

2.7 EXTERNAL PANELS

Freestanding sterilizers and through-wall sterilizers shall be fully enclosed. Built-in sterilizers shall have a front panel.

External panels should be of satin finish stainless steel having a thickness of not less than 0.9 mm. Where the purchaser requires another material, the type of material and its thickness should be specified at the time of order.

2.8 LOADING EQUIPMENT

Carriages, baskets and other equipment used within the chamber, except for trays, shelves, wheels and loading equipment, shall be of stainless steel.

Trolleys shall be of stainless steel, aluminium or powder-coated carbon steel.

Trays shall be of stainless steel or aluminium.

Wheels of carriages shall be of aluminium, brass, bronze, stainless steel or suitable plastics.

Wheels of trolleys shall be non-marking.

SECTION 3 DESIGN AND CONSTRUCTION

3.1 GENERAL

Where practicable, the design should allow for an easy replacement of parts and fittings, so that maintenance of the sterilizer can be carried out without unnecessary delays.

The design should also accommodate the requirements given with enquiries and orders, which should include those listed in Appendix A.

3.2 WELDING

Where chambers are constructed of nickel-clad or stainless-steel-clad carbon steel, the sealing welds on the clad side shall be compatible with the cladding material. Electrodes used in the welding of connections to the vessel shall be compatible with the materials of the connections and chamber.

Welds in the chamber and external welds visible from operating positions shall not be pitted, nor have any crevice that may lead to corrosion or roughness, nor any projecting roughness that could cause catching or snagging of material. Grinding shall not penetrate below the surface of clad materials.

NOTE: Welds may be ground to blend with the parent material but need not be ground flush.

3.3 CORROSION

Any adjacent dissimilar metals shall be protected against galvanic corrosion.

3.4 NOISE

Sterilizers, external panelling and auxiliary equipment shall be designed and constructed to minimize the emission of noise. The noise level of each machine, while it is correctly loaded with metal articles, shall be not more than 75 dB(A), measured in accordance with AS 1217.7.

NOTES:

- 1 Testing authorities may require sterilizers to be installed and operated without exceeding a specified limit of noise level.
- 2 The noise level of a sterilizer is a function of both the equipment and its location. The machine may need to be installed in a room that meets the requirements of AS 1081.2.

3.5 THERMAL INSULATION

Exterior surfaces of the pressure vessel, other than exterior surfaces of doors, shall be thermally lagged, to provide a thermal insulation of not less than $0.8 \text{ m}^2 \cdot \text{K/W}$. Where practicable, steam supply piping shall be lagged.

Prior to lagging, exterior surfaces of carbon steel pressure vessels shall be coated with a compatible heat-resistant paint.

Sliding doors that are not lagged shall be fitted with a heat shield or designed to protect the operator against contact with any hot surface.

NOTE: AS 4426 gives advice on the use of thermal insulating materials.

3.6 EXTERNAL PANELS

External panels shall be easily cleanable, readily removable for maintenance purposes and free from scratches, blemishes, burrs and sharp edges. Where external panels are of stainless steel, their exterior surfaces shall have a finish of 4, as designated by AS 1449.

Where any panel is constructed from more than one section of stainless steel, visible joints shall be neat, flush and supported by a backing plate or covered by a stainless steel strip.

Freestanding sterilizers and through-wall sterilizers shall be fully enclosed. Built-in sterilizers shall have a front panel.

For freestanding models, external panels having a length equal to the full length of the frame shall be fitted. The panels shall not cover the feet.

3.7 VENTILATION

Ventilation openings shall be provided in the panelling to eliminate any build-up of temperature or humidity around the controls.

3.8 SUPPORT FRAME

The support frame shall be—

- (a) where applicable, constructed in accordance with the requirements of AS 4100; and
- (b) where necessary, mounted on adjustable feet drilled for holding bolts.

3.9 PRESSURIZED COMPONENTS

Pressurized components shall comply with AS 1210.

Design pressures shall be not less than the following:

- (a) For the jacket, 235 kPa.
- (b) For the jacketed portions of the chamber, 335 kPa (that is, the difference between the jacket pressure and a vacuum in the chamber).
- (c) For the unjacketed portions of the chamber, 235 kPa.

3.10 JACKET

Where the purchaser specifies that a load-drying function is required, a jacketed space shall be provided, to permit preheating of the chamber walls in order to prevent excessive condensate formation and assist the drying process.

NOTE: This space should extend to within 90 mm of the open end of the chamber shell.

For fluid sterilizing, jacket isolation shall be provided.

3.11 CHAMBERS

3.11.1 Internal dimensions

Useable internal dimensions of sterilizers should be restricted to the preferred sets of dimensions given in Table 3.

The minimum internal dimensions of door openings are taken to be the height and the width of the chamber, as appropriate.

NOTES:

- 1 The whole of the internal space of chambers is not available for use because of the space taken up by loading racks or rails, baffle plates and clearances required for loading equipment.
- 2 Chambers with dimensions of 500 mm × 500 mm × 900 mm or larger should be provided with carriages and transfer trolleys (see Clause 3.13).

TABLE 3
PREFERRED INTERNAL DIMENSIONS OF
RECTANGULAR CHAMBERS

millimetres		
Width	Height	Depth
280	280	400
350	350	400
400	400	600
500	500	900
600	600	900
600	600	1200

3.11.2 Cleaning

The internal surfaces of chambers shall be readily accessible for cleaning purposes.

3.11.3 Baffle plate

Each sterilizer shall be provided with a baffle plate that will minimize wetting of the load by distributing incoming steam.

3.11.4 Guide rails

Any guide rails shall—

- (a) guide the carriage into and out of the chamber;
- (b) be capable of supporting a full load in the chamber;
- (c) minimize the retention of condensate; and
- (d) be removable, to allow a thorough cleaning of the chamber.

NOTE: Suitable guide rails should be fitted, to correctly guide the trolley.

3.12 DOORS

3.12.1 General

Doors shall open by sliding or by swinging on a hinge to the left or to the right.

Doors shall fit the vessel in a way that will not cause uneven wear of or damage to the door gasket.

The internal and external surfaces of doors and closure holding elements shall be able to be cleaned.

Sterilizers that are intended to sterilize fluids should be fitted with a thermal door lock, to ensure that when glass containers are being processed, the door cannot be opened until the temperature inside every container has fallen below 80°C.

3.12.2 Door gasket

Doors shall be sealed by a gasket against the internal and external design pressures while the door is in the closed and locked position.

Gaskets shall not be affected adversely by steam.

Any recess for a gasket in the shell, door or closure holding elements shall be machined or fabricated, but shall not penetrate any cladding.

3.12.3 Locking mechanisms

Handwheels and handles shall be easy to operate.

Door-locking mechanisms shall not project in a way that could cause a hazard to operators.

3.12.4 Door operation

Each door shall be interlocked so that it cannot be opened by the operator until the cycle is complete.

NOTE: Where required, a means should be provided to enable the door to be brought to a closed position without the door joint contacting the door holding element.

The following additional requirements for the relevant type of door also apply:

- (a) *Power-operated doors* Power-operated doors shall be fitted with—
 - (i) a safety device that will return the doors to the fully open position immediately an obstruction is encountered; and
 - (ii) a readily accessible means of operating the door manually in an emergency that will not override any interlock that has been fitted to comply with AS 1210.
- (b) *Hinged doors* The door mechanism of hinged doors shall be provided with a stop to limit their opening to not more than 140°. Hinged doors shall remain at any selected position.
- (c) *Sliding doors* Sliding doors shall be designed to prevent damage to the face of the door, the door ring and the door joint, while the door is opening and closing.

3.12.5 Doors at both ends

Where doors are provided at both ends, means shall be provided to ensure that at, all times, one door at least is closed and locked, to allow for adequate contamination control.

NOTE: Other special facilities for contamination control may also be necessary.

3.13 LOADING EQUIPMENT

3.13.1 Baskets

Any baskets shall allow a free passage of steam, minimize the retention of condensate, and be readily removable from the sterilizer by being supported by a carriage.

3.13.2 Carriages

Any carriages shall be—

- (a) provided with a bottom shelf;
- (b) other than the bottom shelf, provided with adjustable shelves having adjustment increments of not more than 75 mm;
- (c) designed to carry a full load, so that it will not contact the chamber;
- (d) designed to direct condensate in a way that will not interfere with the drying of the load; and.
- (e) designed to allow for easy placement and removal of packages, without changing the load.

Each carriage shall be provided with a device that will enable the carriage to be locked onto a trolley during transit. A means shall be provided to indicate when the carriage is locked onto a trolley or the sterilizer.

A means shall be provided to indicate when the carriage is correctly located in the sterilizer.

Carriage wheels shall operate quietly, operate with low friction, not require lubrication and not damage the floor of the sterilizer.

3.13.3 Trolley

Any trolleys shall be—

- (a) stable, to minimize the possibility of overbalancing;

- (b) provided with adequate buffers;
- (c) provided with four rubber-tyred castor-mounted wheels having a diameter of not less than 100 mm; and
- (d) provided with a locking means to hold the trolley onto the sterilizer, while transferring a carriage between the trolley and the sterilizer.

NOTES:

- 1 Wheel locks may be required to retain the position of a trolley on an uneven floor.
- 2 Trolleys may be provided with a vertical height adjustment.
- 3 Where a trolley services more than one sterilizer, the heights of these sterilizers above the floor need to be the same.
- 4 Other automated or semi-automated systems may be used.

3.14 PIPEWORK AND PIPE FITTINGS

Pipework and pipe fittings visible from the operating position and not normally enclosed shall have a bright polished finish and, if not of stainless steel, be polished and bright nickel-chromium plated to not less than Service Condition 3, as specified in AS 1192.

Pipework and pipe fittings shall be easily accessible for maintenance and, where involved with or affecting drainage, neatly arranged with a fall so that liquids will not be trapped. Pipe joints shall be neat and allow for an easy removal of each section of pipework, fittings and related components, for inspection or repair. Piping for service connections to sterilizers shall terminate in unions.

NOTE: Pipework should be laid out to minimize the possibility of injury during maintenance from operating safety valves, hot pipework and hot fittings.

3.15 VALVES

Valves shall comply with AS 1271 and the handles of steam valves that are controlled by the operator shall be insulated against heat and be easy to operate. Safety valves for jackets and chambers shall be fitted in accordance with AS 1210.

3.16 MECHANICAL AIR REMOVAL

Laboratory sterilizers should be provided with a means to connect the chamber to a mechanical air removal system, for the removal of air from containers, contaminated bags, buckets and other loads, prior to the sterilizing stage.

Where sterilizers are used to decontaminate soiled hospital supplies (e.g., operating theatre waste, pathology laboratory waste), it is important that users recognize that exhaust filters and filter housings are likely to become contaminated and need to be handled with care.

3.17 AIR FILTERS

Air inducted into the chamber shall be passed through filters complying with the following:

- (a) The main filters shall be high efficiency particulate air (HEPA) Grade 1 filters as specified in AS 4260.
- (b) Filter materials shall be resistant to corrosion and rotting.
- (c) Filter materials shall be firmly supported to prevent distortion or movement during operation.
- (d) Filter supports shall be adequately constructed of material that will not corrode under normal operating conditions.
- (e) Filter units shall be mounted outside the chamber in a readily accessible location.