Australian Standard®

# Medical suction equipment

## Part 1: Electrically-powered suction equipment—Safety requirements

This Australian Standard was prepared by Committee HT/4, Medical Gases and Pipeline Services. It was approved on behalf of the Council of Standards Australia on 22 July 1992 and published on 16 November 1992.

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The following interests are represented on Committee HT/4:

Association of Consulting Engineers, Australia
Australian Society of Anaesthetists
Confederation of Australian Industry
Department of Health, Housing and Community Services (Commonwealth)
Department of Health, N.S.W.
Health Department, W.A.
Institute of Hospital Engineering, Australia
Medical Industry Association of Australia
Metal Trades Industry Association of Australia
Public Works Department, N.S.W.
Royal Australasian College of Surgeons
South Australian Health Commission

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# PREFACE

This Standard was prepared by the Standards Australia Committee on Medical Gases and Pipeline Services, under the direction of the Multitechnics Standards Policy Board, to supersede, in part, AS 2120—1977, *Suction systems for medical use in hospitals.*

This Standard is the first in a series of Standards for medical suction equipment, and deals only with safety requirements for electrically-powered suction equipment. Part 2 deals with manually-powered suction equipment. Part 3 deals with suction equipment powered from a vacuum or pressure source.

The clauses of this Standard supplement or modify the corresponding clauses in AS 3200.1/NZS 6150, *Approval and test specifications—Electromedical equipment—General requirements*, Part 1: *General requirements for safety*. Where the reference in the text of this Standard includes an 'addition', 'replacement', 'substitution' or 'modification' of the relevant requirements, tests or explanatory notes of AS 3200.1/NZS 6150, these changes are made to the relevant text which then become part of that Standard. It will be observed that when no such change is necessary, the words 'the requirements given in (the relevant) clause of AS 3200.1/NZS 6150 apply' are used.

Where the requirements of AS 3200.1/NZS 6150 do not apply, the words 'not used' are used. Although this Standard closely follows AS 3200.1/NZS 6150 in format and technical content, some of the requirements of that publication have been modified to take account of local conditions.

Where this Standard deviates technically from ISO 10079-1:1991, *Medical suction equipment*, Part 1: *Electrically powered suction equipment—Safety requirements*, by way of additional or different requirements, such deviations are indicated by a rule in the margin against the Clause or part thereof, affected. Minor changes are not indicated. An Annex to the Standard lists the variations from ISO 10079-1.

This Standard has been prepared in response to a need for a safety and performance Standard for suction systems. Suction is used to clear the airway and remove unwanted material from body cavities. Suction is also used to assist drainage and decompress body cavities. Suction and vacuum systems are used widely both in health care facilities such as hospitals, for domiciliary care of patients who are nursed at home, and in emergency situations both outside hospitals in field conditions, and during transport in ambulances.

In this Standard, vacuum readings are specified as gauge (relative) pressures to assist clinical personnel. However, this is not intended to prevent engineering groups from using absolute vacuum in their design process. The specifications in this Standard assume an ambient pressure of 1 atmosphere at sea level.

Test methods other than those specified in this Standard, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this Standard are to be used as the reference methods.

This Standard requires reference to Australian and ISO Standards. These are listed in Appendix L.

A rationale for the most important requirements is given in Appendix O. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the Standard, but will expedite any subsequent revision.

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## SECTION 1 GENERAL

**1 SCOPE*** This Standard is based on AS 3200.1/NZS 6150. As stated in Clause 1.3 of AS 3200.1/NZS 6150, the requirements of this Standard take precedence over those of AS 3200.1/NZS 6150.

The Scope and Object given in Clause 1 of AS 3200.1/NZS 6150 applies except that Clause 1.1 shall be replaced by the following:

This Standard specifies minimum safety and performance requirements for medical and surgical suction equipment (see Figure 1) in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use. Although equipment may be driven by centrally-powered, piped vacuum systems, compressed gases, electricity or be manually powered for a variety of applications, this Standard addresses only transportable equipment powered electrically.

Excluded from this Standard are the following:

(a) Central power source (vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors.
(b) Catheter tubes, drains, curettes and suction tips.
(c) Syringes.
(d) Dental suction equipment, complying with AS 2686.2.
(e) Waste gas scavenging systems.
(f) Laboratory suction.
(g) Autotransfusion systems.
(h) Passive urinary drainage.
(i) Closed systems for wound drainage.
(j) Gravity gastric drainage.
(k) Orally-operated mucous extractors.
(l) Suction equipment where the collection container is downstream of the vacuum pump.
(m) Equipment marked as suction unit for permanent tracheostomy.
(n) Ventouse (obstetric) equipment.
(o) Neonatal mucous extractors.
(p) Suction equipment marked for endoscopic use only.

**1.4 Environmental conditions** The requirements given in Clause 1.4 of AS 3200.1/NZS 6150 apply except that the following modification shall be made to Clause 1.4(b)(i):

Substitute '+5°C' for '+10°C' and '+35°C' for '40°C'.

For field and transport use, environmental conditions shall be as specified in Clause 53.

**2 TERMINOLOGY AND DEFINITIONS** For the purposes of this Standard, the definitions given in Clause 2 of AS 3200.1/NZS 6150 apply except for the following variations:

(a) The definition given in Clause 2.1.5 shall be replaced by the following:

Applied part—all parts in the liquid pathway.

(b) The following shall be added to the definition given in Clause 2.4.3:

Safety extra-low voltage (SELV)—includes the electrical sources which are isolated (e.g. car battery) and do not require a separate transformer or converter with separate windings.

For the purpose of this Standard, the definitions below also apply.

**2.1 Breast pump**—vacuum pump for the collection of breast milk.

**2.2 Collection container**—container in which fluids or solid particles are collected.

**2.3 Collection container assembly**—collection container and its closure.

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* See also Appendix O (of this Standard).