AS/NZS IEC 60601.2.16:2015
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AS/NZS IEC 60601.2.16:2015

Australian/New Zealand Standard™

# Medical electrical equipment

# Part 2.16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 20 August 2015 and on behalf of the Council of Standards New Zealand on 21 August 2015.
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Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
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Originally in Australia as AS 3207—1981.
Previous and first New Zealand edition AS/NZS 3200.2.16:1999.
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# PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HE-003 Medical Electrical Equipment, to supersede AS/NZS 3200.2.16:1999, *Medical electrical equipment,* Part 2.16: *Particular requirements for safety—Haemodialysis, haemodiafiltration and haemofiltration equipment.*

The objective of this Standard is to establish basic safety and essential performance requirements for haemodialysis, haemodiafiltration and haemofiltration equipment. It does not take into consideration the dialysis fluid control system of haemodialysis equipment using regeneration of dialysis fluid and central delivery systems. It does however take into consideration the specific safety requirements of such haemodialysis equipment concerning electrical safety and patient safety.

The particular requirements of this Standard make reference to IEC 60601-1, which has been adopted as AS/NZS IEC 60601, *Medical electrical equipment*, Part 1: *General requirements for basic safety and essential performance*. Reference to the general requirements is essential for the application of this Standard.

This Standard is identical with, and has been reproduced from IEC 60601-2-16, Ed.4.0 (2012), *Medical electrical equipment*, Part 2-16: *Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian/New Zealand standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

| *Reference to International Standards* | | *Australian/New Zealand Standards* | |
|---|---|---|---|
| ISO | | AS | |
| 594 | Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment | 1600 | Medical equipment—Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment |
| 594-2 | Part 2: Lock fittings | 1600.2 | Part 2: Lock fittings |

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

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

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# IEC FOREWORD

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (* ) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

# INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

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AUSTRALIAN/NEW ZEALAND STANDARD

# Medical electrical equipment

## Part 2.16:
## Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

### 201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

#### 201.1.1 Scope

*Addition*:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT, hereafter referred to as HAEMODIALYSIS EQUIPMENT.

This International Standard does not take into consideration the DIALYSIS FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID and CENTRAL DELIVERY SYSTEMS. It does however take into consideration the specific safety requirements of such HAEMODIALYSIS EQUIPMENT concerning electrical safety and PATIENT safety.

This International Standard specifies the minimum safety requirements for HAEMODIALYSIS EQUIPMENT. These devices are intended for use either by medical staff or for use by the PATIENT or other trained personnel under the supervision of medical expertise.

This International Standard includes any ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT suffering from kidney failure.

The particular requirements in this International standard do not apply to:

– EXTRACORPOREAL CIRCUITS;
– DIALYSERS;
– DIALYSIS FLUID CONCENTRATES;
– water treatment equipment;
– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39).

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-1.

NOTE See also 4.2 of IEC 60601-1:2005.

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1 The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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