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IEC 60601-2-16 Ed.4.0 (2012)

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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Australian and New Zealand College of Anaesthetists
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Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
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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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