

# **Australia and New Zealand Electricity Standards and Home Dialysis 2015 update**

**AS/NZS 3003:2011/Amdt 1:2015**

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### Appendix 1: Amended clauses

### Appendix 2: Prior standard

### Acknowledgements for contribution:

Brian Lester

Chair of AS/NZS 3003 Committee

### Disclaimer

The intent of this document is to provide information to renal units. All information presented is an interpretation of the relevant Australian Standards Legislation, as at February 2015. KHA hold no responsibility for changes to the legislation. The legislation does not necessarily reflect the views of KHA. Electrical installers must obtain original copies of all legislation.

## Introduction

Dialysis equipment has been used in homes since the 1970s. Dialysis equipment is also used in hospitals, and has been subject to regulations and standards for many years.

The national standard for electricity installations in patient areas has been in place since 2003. It was expanded, with consultation, and became mandatory in Australia and New Zealand in April 2011. The standard is AS/NZS 3003: Electrical installations; Patient areas. In 2013 an application for review was accepted leading to amendments to the standard that were approved in April 2014.

This standard applies to all current and future home haemodialysis and peritoneal dialysis machines. It applies to Baxter Home-Choice PD machines<sup>1</sup>, Fresenius Staysafe PD machines, 2008, 4008, 5008 HD machines<sup>2</sup>, Gambro HD machines, and Nxstage HD machines.

## Rationale for Standards

Electrical standards are designed to protect the individual from harm. Harm, related to any medical equipment, may occur by electrocution or failure of power to the machine.

## Application of Standards

The qualified electricians who perform the electrical installation must be cognisant with all relevant clauses of these standards. The dialysis technicians should also know how the standards apply to home dialysis installations given that this group may inspect properties prior to the decision to perform home dialysis. Often the dialysis technician is the main communication source for the electrician. Inspections and testing must also be completed annually as per the standards.

Standards are also referenced within each other and these must also be adhered to. AS/NZS 3000:2007: Australian New Zealand Wiring Rules also applies to home dialysis. Standard 3351. It also applies when a machine is installed in a temporary location.

## Role of Kidney Health Australia and Health Services

The role of Kidney Health Australia, related to standards and legislation, is to support the safety of the consumer by notifying all relevant stakeholders who administer home dialysis programmes regarding relevant safety information. The role of each health service is to alter policy and implement any legislated standard. Kidney Health Australia also support consumer access to all modalities of dialysis and may advocate on behalf of the consumer if a standard is considered not to be in consumer best interests.

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<sup>1</sup> Baxter Healthcare Australia. APD classification confirmed by Ben Yerbury, ANZ Commercial Director Baxter Healthcare

<sup>2</sup> Fresenius Medical Care., Australia. APD classification confirmed by Margot Hurwitz, Managing Director Fresenius Medical Care.

## General Information and Definitions:

### Medical Equipment

Home haemodialysis (HHD) and automated home peritoneal (APD) machines are classified as medical equipment within Australian and New Zealand. As such they must meet any standards that pertain to the use of medical equipment in the home.

### Medical Equipment classification

The Therapeutic Goods Administration classification of dialysis equipment is Class IIb.<sup>3</sup> All machines are additionally classified depending on how the circuitry is designed, and how it is earthed. Machines have applied parts that are classified as Type B, Type BF or Type CF. The type determines the risk of electrocution. Type BF and type CF are cardiac protected. Those with Type B parts may require additional protection for the patient.

Fresenius, Gambro, and Baxter HHD and APD machines are all classified as HD machines or home care medical electrical equipment having Type B parts and are therefore subject to AS/NZS:3003, clause 5.1 -5.2. Nxstage is classified Type BF.

### Standards Australia

Standards Australia is an independent, not-for-profit organisation, recognised by the Australian Government as the peak non-government Standards body in Australia. Standards Australia develops internationally aligned Australian Standards® that deliver Net Benefit to Australia and is the Australian member of ISO and IEC.<sup>4</sup> All standards are available in Australia from Standards Australia's distributor of Australian Standards, SAI Global at [www.saiglobal.com/shop](http://www.saiglobal.com/shop) or 131 242 and in New Zealand from Standards New Zealand at [www.standards.co.nz](http://www.standards.co.nz)

Within the standards that apply to medical equipment are specific electrical installation regulations for patient areas with a sub-clause related to home.

### Development of and Options to request updates to a Standard

Standards are developed by specially convened working parties, governed by Standards Australia. Consultation is sought from relevant stakeholders. The working party are disbanded on completion of a standard. Standard review can be requested in writing. This process, if agreed upon, can take up to two years.

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<sup>3</sup> Australian regulatory guidelines for medical devices (ARGMD) 2011, v1.1. p 100

<sup>4</sup> Standards Australia <http://www.standards.org.au/> Accessed May 2014

## **Electrical Standards specifically applying to Home Dialysis AS/NZS 3003:2011; Electrical Installations – Patient areas**

This joint Australian/New Zealand standard was prepared by Joint Technical Committee HT-021, Electrical Energy Networks, Construction and Operation. It was approved on 2 March 2011 and published on 1 April 2011 (appendix 2). An amendment was approved on 20th February 2015 (appendix 1). Current relevant clauses are:

Clause 5.1 Responsibility of the organisation

Clause 5.2.1 Compliance not required

Clause 5.2.2 Compliance required

Clause 5.2.3 Temporary installations

**Standard AS/NZS 3003 has mandatory application to all new home dialysis installations from 1 April 2011. The amendments apply to all machines installed from February 20 2015. It is recommended all installations at minimum meet the latest amendment.**

### **AS/NZS 3000:2007; Australian New Zealand Wiring Rules**

All electrical wiring including home dialysis installations in Australia and New Zealand must also meet standard AD/NZS 3000.

#### **Terminology in Standard**

**RCD** – Residual Current device. Different ratings are used for different circumstances. 10mA and 30mA are applicable to home dialysis. Type 1 RCDs have a residual tripping current below 10mA and a tripping time <40ms. This is recommended for medical equipment.

**LPD** – Leakage Protection Device. A device to detect current leakage. These can be low-voltage isolation transformers complying with AS/NZS 4510 or type 1 RCDs complying with AS/NZS 3190

**Body Protected Area** – The area around the patient that is protected, specified in metres. A specific area has been removed from the new amendment for home installations.

**Cardiac Protected** – The area around the patient that is cardiac protected. This only applies when the medical device has direct access to the heart.

## Standard Amendment Summary February 2015:

See appendix 1 for official wording.

All medical equipment used at home, regardless of purpose, is now within the same clause of the standard. Haemodialysis is no longer managed differently.

### Clause 5.1 Managing the Risk – key points

The organisation is responsible for development of protocols and procedures to ensure the integrity and safety of the equipment.

The new standard has removed the need for additional circuits for dialysis in all circumstances. However overload of any electricity circuit can cause fires. Standard haemodialysis machines including water treatment are estimated to use 2.5kWh, Nxstage and APD use 0.1kWh. Standard haemodialysis machines **should not be** on a circuit that supplies other equipment that also has a high power usage. It is the responsibility of the organisation to ensure that electrical installations are safe.

Clause 2 of the standards indicate that an inspection should be completed by a skilled person (electrician or trained technician) regarding safety and compliance.

### Clause 5.2.1 Compliance not required – key points

If a dialysis machine meets the specified criteria then compliance is not required. To date the dialysis machines in Australia do not meet the criteria so compliance is required. Check with the manufacturers if you have any queries regarding compliance of a machine.

### Clause 5.2.2 Compliance required – key points

The options for protection are:

Socket outlets protected by an LPD (10mA)

An RCD (rated at 10mA). The RCD can be at the location of the equipment or at the switchboard – due to the complexity of options for this please see standard amendment wording for details.

A skilled person must determine whether each individual home requires an additional electricity supply circuit, specifically for the haemodialysis machine or not. Where there are no adequate sub-circuits to power the machine a new sub-circuit must be installed. Sockets should be labelled as suitable for medical equipment and all socket-outlets must be tested according to usual practice and using the inspection check list in clause 2.1 (minus the first paragraph).

### Clause 5.2.3 Dialysis away from Home/temporary installations

Specific information regarding travel is provided within standard ASNZS 3551. At minimum a portable LPD/RCD is used between the machine and the wall socket. It must trip at 10mA.

Examples of RCD suppliers can be found at: [www.alibaba.com/showroom/portable-rcd-10ma.html](http://www.alibaba.com/showroom/portable-rcd-10ma.html).

## Electricity usage of Dialysis Machines

Usage varies dependent on the machine and type of water equipment. Standard Fresenius and Gambro HD machines and water equipment machinery combined use in total approximately 2.5kWh. The Nxstage uses 0.1kWh. APD machines use 0.1kWh.

## Calculating cost of electricity usage

To determine the usage and costs of electricity it is necessary to know the hourly unit cost for the individual jurisdiction which of note may also vary by time of day.

To calculate the weekly usage (and costs):

**kW per hour X Hours on dialysis per week X Cost per hr**

Dialysing at different times can alter costs. It may be necessary to perform 2 or 3 calculations related to each time period and add these together.

## Electricity subsidies

The home dialysis electricity subsidies vary by state. Concession holders are eligible for more subsidies but in some states subsidies may apply for all home dialysis patients. Visit [www.homedialysis.org.au](http://www.homedialysis.org.au) for information related to each state.