Electricity Standards and Home Dialysis 2012

Australia and New Zealand

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Electricity and Home Dialysis

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Home Dialysis Advisory Committee (HDAC)

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 2012. KHA and the HDAC hold no responsibility for changes to the legislation. The legislation does not necessarily reflect the views of KHA or the HDAC. 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.

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

In many States the 2003 regulations have been applied at varying levels for home haemodialysis (HHD). Anecdotally they have not been applied at the same level to automated peritoneal dialysis (APD).

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 sections 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.

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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[1] Baxter Healthcare Australia. APD classification confirmed by Ben Yerbury, ANZ Commercial Director Baxter Healthcare

[2] 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.[3] 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, section 5.2.1or2 Nxstage is a HD machine which indicates a requirement for compliance with section 5.2.1 although the parts are 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.[4] All standards are available in Australia from Standards Australia's distributor of Australian Standards, SAI Global at www.saiglobal.com/shop or 131 242 and in New Zealand from Standards New Zealand at www.standards.co.nz

Within the standards that apply to medical equipment are specific electrical installation regulations for patient areas with a sub-section 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. The Home Dialysis Advisory Committee is seeking advice regarding this process and may submit an application regarding AS/NZS 3003:2011.

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[3] Australian regulatory guidelines for medical devices (ARGMD) 2011, v1.1. p 100

[4] Standards Australia http://www.standards.org.au/ Accessed Nov 2011

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.

Section 5.2 Home Care Installations

Section 5.2.1 Home Haemodialysis installations (standard page 45-46)

Section 5.2.2 Home care installations other than for haemodialysis (standard page 46)

Standard AS/NZS 3003 has mandatory application to all new home dialysis installations from 1 April 2011
It is also recommended that consideration is given to its application for existing installations.

Pertinent details of this standard are summarised on page 6 and 7 of this document.

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

All electrical wiring including home dialysis installations in Australia and New Zealand must also meet this standard.

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. For home dialysis it is 3 metres. All sockets in this area are subject to the legislation.

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

Home Haemodialysis (5.2.1) - Summary

Technicians and electricians should refer to AS/NZS 3003 for detail re these main points[5]:

The body protected area applies up to 3m from the patient

1. A dedicated sub-circuit to the dialysis room must be provided that is not protected by a 30 mA residual current devices (RCD) at the switchboard. No other household sockets or outlets can be supplied by this circuit. The dialysis machine must use this circuit and the water treatment units can optionally use this circuit.
2. At least one socket-outlet marked 'DIALYSIS MACHINE ONLY' and 'RCD PROTECTED' must be provided. If more than 1 location is used in the home they can be linked to the same circuit. If more than 1 person dialyses at the location a separate circuit shall be used.
3. At least one socket-outlet marked 'REVERSE OSMOSIS MACHINE ONLY' or 'WATER TREATMENT UNIT ONLY' and 'RCD PROTECTED' must be provided, wherever the water treatment unit is housed
4. The above sockets must have power-available indicator lights and be at least 300 mm above the floor
5. Protection by a leakage protective device (LPD) or type 1 RCD sensitive to 10mA must be provided for each of the above sockets in the body protected area. The LPD/RCD shall be positioned such that it can be reset by the patient dialysing.
6. The socket and RCD shall be marked to identify association with each other.
7. Compliance is checked by inspection and testing of the above. Sample forms are provided in AS/NZS 3003.
8. Body protected electrical area signs and cleaning purpose only signs are not required (as would be in dialysis units)
9. Other sockets and outlets in the body protection zone and for the water treatment if in another room must be protected at minimum by an RCD rated at 30mA.

It is the responsibility of the health care provider to warn the patient re the electrical safety requirements and the risks of use of other equipment in the body protected area.

Rationale

Point 1 is to prevent accidental loss of power to the dialysis machine.

Points 2 -9 are to related to protection from electrocution

[5] AS/NZS 3003:2011

Home Automated Peritoneal Dialysis (and other medical equipment) 5.2.2

5.2.2 applies to all home care medical equipment that is class II and has type B parts.

Technicians and electricians should refer to AS/NZS 3003 for detail re these main points[6]:

1. A dedicated sub-circuit to the dialysis room must be provided that is not protected by a 30 mA residual current devices RCD at the switchboard.
2. At least one socket-outlet marked 'DIALYSIS MACHINE ONLY' and 'RCD PROTECTED' must be provided. If more than one location is used in the home they can be linked to the same circuit. If more than one person dialyses at the location a separate circuit shall be used for each machine.
3. The above sockets must have power-available indicator lights and be at least 300 mm above the floor
4. Protection by a leakage protective device (LPD) or type 1 RCD sensitive to 10mA must be provided for the above sockets. No other household sockets or outlets can be supplied by this circuit.
5. The LPD/RCD shall be positioned such that it can be reset by the patient dialysing
6. The socket and RCD shall be marked to identify association
7. Compliance is checked by inspection and testing of the above.
8. Body protected electrical area signs and cleaning purpose only signs are not required (as in dialysis units)
9. Other sockets and outlets should be protected at minimum by an RCD rated at 30mA.

It is the responsibility of the health care provider to warn the patient re the electrical safety requirements and the risks of use of other equipment in the body protected area

Rationale

Point 1 is to prevent accidental loss of power to the dialysis machine.

Points 2-9 are to related to protection from electrocution

Dialysis away from Home

No specific information regarding travel is provided within the legislation. It is suggested that 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.

6 AS/NZS 3003:2011

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 calculates the weekly usage (and costs)

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

If the individual dialyses at times that attract different 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.kidney.org.au for information related to each state.

References:

AS/NZS 3003:2011 Australian/New Zealand standard Electrical installations-Patient Areas

AS/NZS 3000:2007 Australian New Zealand Wiring Rules

Australian Regulatory Guidelines for Medical Devices (ARGMD) 2011, v1.1. Therapeutic Goods Administration, Commonwealth of Australia

Clipsal product information - http://www.clipsal.com.au/trade/__data/page/81/A88.pdf

ESV guidelines, Electrical installations for home dialysis – interim arrangements (Victoria) – 2009. Energysafe Victoria