STANDARDS AUSTRALIA

Amendment No. 2
to
AS 3200.1—1990
Approval and test specification—Medical electrical equipment
Part 1: General requirements for safety

CORRECTION

The 1990 edition of AS 3200.1 is amended as follows; the amendment(s) should be inserted in the appropriate place.

SUMMARY: This Amendment applies to the number of the Standard only. The change is to facilitate consistency in following the IEC numbering system from the parent series of Standards

Published on 5 December 1995.

AMDT No. 2 DEC. 1995

Page Front cover Standard Number *Add* '0' to the designation.

Change number to AS 3200.1.0 *Add* 'parent Standard' to title which becomes:
Approval and test specification—Medical electrical equipment
Part 1.0: General requirements for safety—Parent Standard.

AMDT No. 2 DEC. 1995

Page 1 Standard Number *Add* '0' to the designation.

Change number to AS 3200.1.0 *Add* 'parent Standard' to the title which becomes:
Approval and test specification—Medical electrical equipment
Part 1.0: General requirements for safety—Parent Standard.

AMDT No. 2 DEC. 1995

Page 7 Part Number *Add* '0' to the designation.

Change Part 1 to Part 1.0 *Add* 'parent Standard' to the title which becomes:
Approval and test specification—Medical electrical equipment
Part 1.0: General requirements for safety—Parent Standard.

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Amendment No. 3
to
AS 3200.1.0—1990/NZS 6150:1990
Approval and test specification—Medical electrical equipment
Part 1.0: General requirements for safety—Parent Standard

REVISED TEXT

The 1990 edition of AS 3200.1.0/NZS 6150 is amended as follows; the amendment(s) should be inserted in the appropriate place.

SUMMARY: This Amendment comprises three parts.

The first part incorporates amendments to the main body of text and a corrigendum to one of those changes that are based on and reproduced from Amendment 2 (1995) and Corrigendum (1995), respectively, to IEC 601-1:1988.

The second part replaces Appendix L.

The third part replaces Appendix Z with the new Appendix ZZ.

Published on 5 June 1998.
Approved for publication in New Zealand on behalf of the Standards Council of New Zealand on 16 March 1998.

PART ONE

Replace existing text as specified below.

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– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. electromagnetic compatibility).

If a Collateral Standard applies to a Particular Standard, then the Particular Standard takes priority over the Collateral Standard.

2 Terminology and definitions

Replace the existing definitions by the following:

*2.1.5 *APPLIED PART*

A part of the EQUIPMENT which in NORMAL USE:

– necessarily comes into physical contact with the PATIENT for the EQUIPMENT to perform its function; or

– can be brought into contact with the PATIENT; or

– needs to be touched by the PATIENT.

2.1.7 *F-TYPE ISOLATED (FLOATING) APPLIED PART*
(hereinafter referred to as *F-TYPE APPLIED PART)*

APPLIED PART isolated from other parts of the EQUIPMENT to such a degree that no current higher than the PATIENT LEAKAGE CURRENT allowable in SINGLE FAULT CONDITION flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the APPLIED PART and earth.

F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

*2.1.15 *PATIENT CIRCUIT*

Any electrical circuit which contains one or more PATIENT CONNECTIONS.

PATIENT CIRCUITS include all conductive parts which are not insulated from the PATIENT CONNECTIONS to the extent necessary to comply with the dielectric strength requirements (see clause 20) or which are not separated from the PATIENT CONNECTIONS to the extent necessary to comply with the CREEPAGE DISTANCE and AIR CLEARANCE requirements (see 57.10).

Add the following definitions:

*2.1.23 *PATIENT CONNECTION*

Every individual part of the APPLIED PART through which current can flow between the PATIENT and the EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.