

AS/NZS 3200.2.24:1999
IEC 60601-2-24:1998

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.24: Particular requirements for safety—Infusion pumps and controllers

[IEC title: Medical electrical equipment, Part 2.24: Particular
requirements for the safety of infusion pumps and controllers]

AS/NZS 3200.2.24:1999

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 Australian & New Zealand College of Anaesthetists
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 Australian Dental Association
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PREFACE

This Standard was prepared by the Joint Australian/New Zealand Standards Committee HE/3, Medical Electrical Equipment.

This Particular Standard is technically equivalent to and has been reproduced from IEC 60601-2-24:1998, *Medical electrical equipment, Part 2-24: Particular requirements for the safety of infusion pumps and controllers* which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998, hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-24. For the purposes of this Standard the IEC text is amended, supplemented or replaced as set out in Appendix ZZ. These changes are indicated by a rule in the margin against each clause affected.

In the text of this Standard, the following print types are used.

- (a) Requirements, compliance with which can be tested and definitions
..... in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
..... in smaller roman type
- (c) Headings of sub-clauses and text specifications in italic type
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

* An asterisk is placed before each Clause for which rationale is included in Annex AA.

The even numbered pages of the original publication are in French and are omitted from this version. Some other pages of the original, which relate to IEC administrative matters, are also omitted from this edition.

As this publication has been reproduced from an international Standard, the following modifications apply:

- (i) its number does not appear on each page of text and its identity is shown on the cover and title page.
- (ii) the words 'this Australian/New Zealand Standard' should replace the words 'this International Standard' wherever they appear.
- (iii) substitute a full point for a comma where it appears as a decimal marker.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

<i>Reference to International Standard or other publication</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS	
60521	Class 0.5, 1 and 2 alternating-current watthour meters	1284 1284.1	Electricity metering Part 1: General purpose induction watthour meters

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IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1-1	Part 1: General requirements for safety	32001.0	Part 1.0: General requirements for safety Parent Standard
60601-1-2	Part 1: General requirements for safety — 2. Collateral Standard: Electromagnetic compatibility — Requirements and tests	3200.1.2	Part 1.2: General requirements for safety Collateral Standard: Electromagnetic compatibility — Requirements and tests
60651	Sound level meters	AS 1259 1259.1	Acoustics—Sound level meters Part 1: Non-integrating
60801	Electromagnetic compatibility for industrial-process measurement and control equipment	—	
60801-1	Part 1: General introduction	—	
60801-2	Part 2: Electrostatic discharge requirements	—	
60804	Integrating-averaging sound level meters	1259.2	Part 2: Integrating—Averaging
61000	Electromagnetic compatibility (EMC)	—	
61000-4-3	Part 4: Testing and measurement techniques—Section 3: Radiated radio-frequency, electromagnetic field immunity test	—	
61000-4-4	Part 4: Testing and measurement techniques—Section 4: Electrical fast transient/burst immunity test	—	
ISO		—	
3696	Water for analytical laboratory use—Specification and test methods	—	
3744	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane	—	
7864	Sterile hypodermic needles for single use	—	
7886	Sterile hypodermic syringes for single use	—	
7886-2	Part 2: Syringes for use with power-driven syringe pumps	—	
IEC		—	
8536	Infusion equipment for medical use	—	
8536-4	Part 4: Infusion sets for single use	—	

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

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AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment**Part 2.24:****Particular requirements for safety—Infusion pumps and controllers**

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard and of this section of the Collateral Standard IEC 60601-1-2 apply, except as follows:

1 Scope and object

This clause of the General Standard and this clause of the Collateral Standard IEC 60601-1-2 apply, except as follows:

1.1* Scope*Addition:*

This Particular Standard specifies the requirement for INFUSION PUMPS, INFUSION CONTROLLERS, SYRINGE PUMPS and PUMPS FOR AMBULATORY USE, as defined in 2.101 to 2.110. These devices are intended for use by medical staff and home PATIENTS as prescribed and medically indicated. These particular requirements do not apply to devices:

- 1) specifically intended for diagnostic or similar use (e.g. angiography or other pumps permanently controlled or supervised by the OPERATOR),
- 2) enteral infusion,
- 3) extracorporeal circulation of blood,
- 4) implantable or disposable devices,
- 5) EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water);
- 6) EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography).

1.3 Particular standards*Addition:*

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995) and to the Collateral Standard IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*.

For brevity, Part 1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s) and IEC 60601-1-2 as the Collateral Standard.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa*), *bb*), etc.

The term “this Standard” is used to make reference to the General Standard, the Collateral Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a “General guidance and rationale” section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

1.5 Collateral Standards

Addition:

This Particular Standard also refers to IEC 60601-1-2, which is applicable unless otherwise stated in a particular clause or subclause.

2 Terminology and definitions

This clause of the General Standard and of the Collateral Standard IEC 60601-1-2 apply, except as follows:

2.1.3

ACCESSORY

Addition:

Separate programmers are regarded as accessories and therefore a component part of the EQUIPMENT

2.1.5**APPLIED PART***Replacement:*

entirety of all parts of the EQUIPMENT including the infusion liquid pathway that is intentionally in contact with the PATIENT being treated in NORMAL USE

2.2.18**PORTABLE EQUIPMENT***Replacement:*

TRANSPORTABLE EQUIPMENT intended to be moved from one location to another while in use or between periods of use, by one or more persons or by other means

*Additional definitions:***2.101****INFUSION PUMP**

EQUIPMENT intended to regulate the flow of liquids into the PATIENT under positive pressure generated by the pump

The INFUSION PUMP may be of:

- type 1: continuous infusion flow only,
- type 2: non-continuous flow only,
- type 3: discrete delivery of a BOLUS,
- type 4: type 1 combined with type 3 and/or type 2 in the same EQUIPMENT,
- type 5: PROFILE PUMP.

2.102**VOLUMETRIC INFUSION PUMP**

INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time, but excluding SYRINGE PUMPS

2.103**DRIP-RATE INFUSION PUMP**

INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT as a number of drops per unit of time

2.104**INFUSION CONTROLLER**

EQUIPMENT intended to regulate the flow of liquid into the PATIENT under positive pressure generated by gravitational force

2.105**VOLUMETRIC INFUSION CONTROLLER**

INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

2.106**DRIP-RATE INFUSION CONTROLLER**

INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT as a number of drops per unit of time

2.107**SPECIAL USE EQUIPMENT**

EQUIPMENT in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in units other than those defined in 2.101 to 2.106

2.108**SYRINGE PUMP**

EQUIPMENT intended for controlled infusion of liquids into the PATIENT by means of one or more single action syringe(s) or similar container(s) (e.g. where the cartridge is emptied by pushing on its plunger)) and in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

2.109**INFUSION PUMP FOR AMBULATORY USE**

EQUIPMENT intended for the controlled infusion of liquids into the PATIENT and intended to be carried continuously by the PATIENT

2.110**PROFILE PUMP**

EQUIPMENT intended for controlled infusion of liquids into the PATIENT by means of a programmed sequence of delivery rates

2.111**REGION OF CONTROL**

that part of the EQUIPMENT within which flow regulation, flow shut-off or air detection occurs, within the body of the EQUIPMENT or remotely

2.112**ADMINISTRATION SET**

device(s) that convey(s) liquid from the supply via the EQUIPMENT to the PATIENT

2.113**PATIENT LINE**

that part of the ADMINISTRATION SET between the EQUIPMENT and the PATIENT

2.114**SUPPLY LINE**

that part of the ADMINISTRATION SET between the liquid supply and the EQUIPMENT

2.115**OCCLUSSION ALARM THRESHOLD (PRESSURE)**

value of the physical quantity at which the occlusion alarm is activated

2.116**KEEP OPEN RATE (KOR)**

low predetermined rate(s) to which the EQUIPMENT reverts under specified conditions with the object of keeping the PATIENT LINE open

NOTE – The abbreviation KVO (Keep-Vein-Open Rate) is commonly used as a synonym of KOR.

2.117**FREE FLOW**

flow in an ADMINISTRATION SET which is not controlled by the EQUIPMENT, for example, due to the unintended effects of gravity by the removal of the ADMINISTRATION SET from the EQUIPMENT

2.118**ADMINISTRATION SET CHANGE INTERVAL**

time recommended by the manufacturer of the EQUIPMENT for using the ADMINISTRATION SET

2.119**BOLUS**

discrete quantity of liquid which is delivered in a short time

2.120

INTERMEDIATE RATE defined as follows:

- for volumetric infusion pumps and volumetric infusion controllers, set the rate to 25 ml/h;
- for drip-rate infusion pumps and drip-rate infusion controllers, set the rate to 20 drops/minute;
- for syringe pumps, set the rate to 5 ml/h;
- for special use equipment and infusion pumps for ambulatory use, set the rate specified by the manufacturer as typical for the equipment.

2.121**MINIMUM RATE**

lowest rate selectable by the OPERATOR, but not less than 1 ml/h

NOTE – For INFUSION PUMPS FOR AMBULATORY USE it is the lowest selectable rate.

2.122**MAXIMUM INFUSION PRESSURE**

maximum pressure which can be generated by the EQUIPMENT under conditions of total occlusion at the end of the PATIENT LINE

2.123**PATIENT END**

that end of the PATIENT LINE where connection to the PATIENT takes place

3 General requirements

This clause of the General Standard applies, except as follows:

3.6* Addition

SINGLE FAULT CONDITIONS occurring in those protective systems specified in 51.5 and 51.102 shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL. SINGLE FAULT CONDITIONS occurring in the protective system specified in clause 51.103 shall cause the cessation of delivery and the generation of an alarm within a time interval less than the volume of the ADMINISTRATION SET between the air detector and the venous cannula connected to it divided by the maximum flow rate of the pump.

NOTE – Acceptable methods of complying with this requirement are, for example:

- 1) a safety system check initiated and controlled by the EQUIPMENT, first at the beginning of the ADMINISTRATION SET CHANGE INTERVAL, and then repeated continuously as warranted;
- 2) one or more protective systems checks initiated by the OPERATOR and controlled by the EQUIPMENT within the ADMINISTRATION SET CHANGE INTERVAL, with the OPERATOR initiating checks before or during the infusion;
- 3) a safety system check carried out by the OPERATOR at least once within the ADMINISTRATION SET CHANGE INTERVAL (see 6.8.2 a) 24)).

The following are not regarded as SINGLE FAULT CONDITIONS, but are regarded as NORMAL USE CONDITIONS:

- leakage from the ADMINISTRATION SET and/or the liquid supply;
- depletion of the INTERNAL ELECTRICAL POWER SOURCE;
- mispositioning and/or incorrect filling of a drip chamber;

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- air in the SUPPLY LINE or the REGION OF CONTROL;
- pulling on the PATIENT LINE (see ISO 8536-4).

5 Classification

This clause of the General Standard applies, except as follows:

5.2 Amendment:

Delete TYPE B APPLIED PART;

5.6 Amendment:

Delete all except for CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard and this clause of the Collateral Standard IEC 60601-1-2 apply, except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

- aa) If detachable liquid reservoirs or PATIENT LINE(S) of specific sizes or brands, or containing specific concentrations of drugs need to be used to maintain safe NORMAL USE of the EQUIPMENT then relevant markings shall be fixed or indicated in a prominent place on the EQUIPMENT which either identify those conditions or provide location of such information.

Compliance is checked by inspection.

6.1 q) Physiological effects

Replacement:

The body of the EQUIPMENT shall be marked with the following:

- 1) symbol No. 14 of appendix D of the General Standard or a statement to refer the OPERATOR to the ACCOMPANYING DOCUMENTS;
- 2) an arrow or other appropriate symbol indicating the correct direction of flow if the ADMINISTRATION SET can be incorrectly loaded;
- 3) EQUIPMENT as defined in 2.103 and 2.106 shall additionally be marked as follows:
"Caution: this equipment controls the drip rate not the volume delivered."

Additional items:

6.1.201 of the Collateral Standard, IEC 60601-1-2

Addition:

Compliance is checked by inspection.

6.8 ACCOMPANYING DOCUMENTS

a) *Addition:*

The instructions for use shall also include the following:

- 1) a list of the recommended ADMINISTRATION SET(S) to be used;
 - 2) a warning of the consequences of the use of unsuitable ADMINISTRATION SET(S);
 - 3) a list of particular ACCESSORIES recommended by the manufacturer for use with the EQUIPMENT;
 - 4) permitted EQUIPMENT orientation and methods and precautions concerning its mounting, for example, stability on a pole;
 - 5) instructions regarding loading, priming, changing and reloading the ADMINISTRATION SET(S), and the ADMINISTRATION SET CHANGE INTERVAL to maintain the specified performance;
 - 6) instructions regarding the use of clamps on an ADMINISTRATION SET, the avoidance of FREE FLOW conditions and the procedure to be followed when changing liquid containers;
 - 7) where gravity is relevant to performance, the acceptable height range of the liquid container above the PATIENT's heart;
 - 8) the means provided to protect the PATIENT from air infusion;
 - 9) a statement of the MAXIMUM INFUSION PRESSURE generated and the OCCLUSION ALARM THRESHOLD (PRESSURE)(S) of the EQUIPMENT;
 - 10) a statement of the maximum time for activation of the occlusion alarm when the EQUIPMENT is operating at the MINIMUM RATE and the INTERMEDIATE RATE and at the minimum and maximum selectable OCCLUSION ALARM THRESHOLD (PRESSURE)(S);
 - 11) a statement of the BOLUS volume generated as a result of the EQUIPMENT operating at the INTERMEDIATE RATE and reaching the minimum and maximum OCCLUSION ALARM THRESHOLD (PRESSURE) (see also 51.5 b));
 - 12) a statement of the means provided (if any) to manage the BOLUS before occlusion release;
 - 13) a statement to indicate to the OPERATOR if the EQUIPMENT cannot be used as PORTABLE EQUIPMENT;
 - 14) precautions required with drop detectors, for example with respect to placement, cleanliness, liquid level, ambient light;
 - 15) recommendations on any specific method of cleaning and maintaining the EQUIPMENT;
 - 16) the typical operating time when the EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE;
 - 17) a statement of KEEP OPEN RATE(S), and when initiated;
 - 18) a list of alarms and their operating conditions;
 - 19)* a warning that under certain circumstances the specified accuracy may not be maintained.
- NOTE – The manufacturer must specify the parameters in which the device cannot maintain the specified accuracy; e.g. minimum/maximum viscosity of liquids, reaction time of the safety system, scope of the risk analysis, etc.
- 20)* reference to a guide on the SAFETY HAZARDS associated with the interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE;
 - 21) the rate obtained when the prime/purge or BOLUS control is operated, and a statement of any alarm disabled;
 - 22) a warning statement on the possible SAFETY HAZARDS associated with external radio-frequency interference (RFI) or electromagnetic radiation which may affect the safe operation of the EQUIPMENT. This statement should include examples of typical EQUIPMENT which may generate such radiation;
 - 23) the selectable rate range and the increments of selection;
 - 24) guidance on tests to permit the OPERATOR to check the correct functioning of alarm(s) and the operational safety of the EQUIPMENT;

- 25) data as evaluated by the test methods of 50.101 to 50.108 at the rates indicated in table 102, including an explanation for the OPERATOR of the data presentation;
- 26) the time for which the electronic memory is retained following switch-off;
- 27) for SPECIAL USE EQUIPMENT, the conversion factor(s) for volume divided by unit of time;
- 28)* the maximum volume that may be infused under SINGLE FAULT CONDITIONS;
- 29) guidance on the safe operation of the EQUIPMENT if it is connected operationally to a remote control device;
- 30) information concerning type(s) of battery to be used and where available;
- 31) a statement of the meaning of claimed IP-classification.

6.8.201 of IEC 60601-1-2

Addition:

6.8.3 Technical description

Addition:

The technical description shall also include the following:

- aa) the sensitivity of the air detector, if included to comply with 51.9, over the specified range of rates for a single bubble;
- bb) the units of measurement used for calibration of the EQUIPMENT;
- cc) a description of any battery charging system;
- dd) a functional description of the means provided to protect the PATIENT from EQUIPMENT error resulting in overinfusion and, where applicable, in underinfusion;
- ee) the manufacturer shall disclose the ADMINISTRATION SET(S) used for all the tests in this standard.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply, except as follows:

10 Environmental conditions

This clause of the General Standard applies, except as follows:

Replacement:

- 10.2.1 a) An ambient temperature between +5 °C and +40 °C.
- 10.2.1 b) A relative humidity between 20 % and 90 %.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of the General Standard apply, except as follows:

14 Requirements related to classification

This clause of the General Standard applies, except as follows:

Replacement:

14.6 b) EQUIPMENT shall be of Type BF or CF.

14.6 d) EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more APPLIED PARTS of TYPE CF may have one or more additional APPLIED PARTS of TYPE BF which may be applied simultaneously if the requirements of 6.1 l) and 19.3 for such EQUIPMENT have been met.

17 Separation

This clause of the General Standard applies, except as follows:

Item c) is not applicable.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies, except as follows:

19.4 Tests:

d) Measuring arrangement

Addition:

3) Measurement of the PATIENT LEAKAGE CURRENT shall be made from the APPLIED PART with the PATIENT LINE filled with saline solution (0,9 % NaCl), and with the PATIENT connection immersed in a container of saline solution (0,9 % NaCl) as indicated in figures 101 and 102.

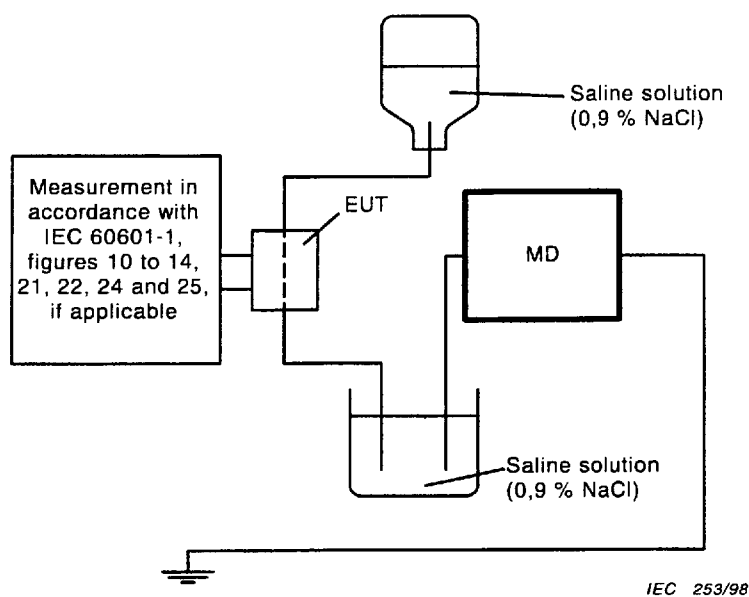


Figure 101 – PATIENT LEAKAGE CURRENT external power supply

(MD = Measuring device, EUT = EQUIPMENT under test)

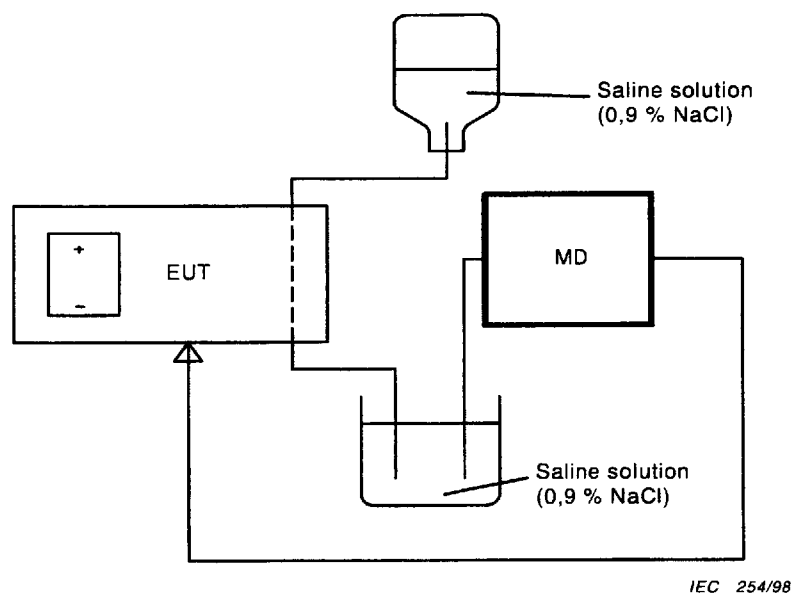


Figure 102 – PATIENT LEAKAGE CURRENT – INTERNAL ELECTRICAL POWER SOURCE

h) Measure of PATIENT LEAKAGE CURRENT

Addition:

- h) Measurement of PATIENT LEAKAGE CURRENT in a SINGLE FAULT CONDITION shall be performed utilizing the method described in 19.4 d) 3) of this Particular Standard.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

21 Mechanical strength

This clause of the General Standard applies, except as follows:

21.1 Replacement:

EQUIPMENT shall not present a safety hazard to the PATIENT as a result of external vibration. This requirement applies only to PORTABLE EQUIPMENT.

Compliance is checked by inspection and the following test:

Fit the EQUIPMENT with the manufacturer's recommended ADMINISTRATION SET and ACCESSORIES. Apply vibrations in a vertical direction and consecutively in two other directions perpendicular to each other in a horizontal plane and in accordance with the values given in table 101.

Table 101 – Vibration value

Frequency range Hz	Displacement or acceleration (peak value)	Number of sweep cycles in each direction
3 to 8	7,5 mm	4
8 to 300	2 g	4

Applied with a sweep rate of 1 octave/min.

21.4 Replacement:

Remote parts including MAINS OPERATED adapters and parts not specified in 21.5 shall not present a safety hazard as a result of a free fall from a height of 1 m onto a hard surface. Subsequent to the fall of the remote part, when the EQUIPMENT is turned on for use, it shall either:

- function normally, or
- cease delivery and activate an alarm.

Compliance is checked by the following test:

The sample to be tested is allowed to fall freely once from each of three different starting attitudes from a height of 1 m onto a 50 mm thick hardwood board (e.g. hardwood with a density greater than 700 kg/m³) which lies flat on a rigid base (concrete block). After this test, no LIVE parts shall become accessible. Cracks not visible to the naked eye and surface cracks in fibre reinforced mouldings and the like shall be ignored. If the EQUIPMENT is operational after the test a dielectric strength test and LEAKAGE CURRENT tests according to clauses 19 and 20 and FUNCTIONAL TESTS at the INTERMEDIATE RATE shall be carried out.

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21.6 Addition:

INFUSION PUMPS FOR AMBULATORY USE shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface.

Compliance is checked by the test of 21.4.

**SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED
OR EXCESSIVE RADIATION**

The clauses and subclauses of this section of the General Standard and of this section of the Collateral Standard IEC 60601-1-2 apply, except as follows:

36* Electromagnetic compatibility

This clause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

36.201* EMISSIONS**36.201.1 Radio frequency (RF) EMISSIONS**

36.201.1.3* This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply.

36.201.1.4* This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

Amendment:

Only paragraph 2 of the Collateral Standard IEC 60601-1-2 applies.

36.201.1.5* This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply.

36.201.1.6 High-frequency surgical equipment

This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply.

36.201.1.7***36.201.2.1* VOLTAGE FLUCTUATIONS and harmonic distortion****36.201.2.2* Magnetic field EMISSIONS****36.202* IMMUNITY**

Addition:

The safe functioning of the EQUIPMENT as specified by the manufacturer shall not be impaired by one or more of the immunity tests, or the EQUIPMENT shall fail without creating a SAFETY HAZARD by these tests. In the latter case, the (non-hazardous) failure mode and the failure level to worst case shall be specified by the manufacturer.

Compliance is checked by the following test:

Set up the EQUIPMENT in NORMAL USE according to the manufacturer's instructions for use. Switch on the EQUIPMENT and select the INTERMEDIATE RATE. Carry out the test as described in this Particular Standard according to the test conditions described in this Particular Standard. By inspection and functional tests determine compliance with the additional requirement formulated in the previous paragraph. (In case of doubt and if the EQUIPMENT still continues to infuse liquid, carry out a functional test without changing any of the previously selected parameters, for a period of 1 h). Switch the EQUIPMENT off and then on again. Select the INTERMEDIATE RATE and carry out another functional test for a period of 1 h.

36.202.1* ELECTROSTATIC DISCHARGE

This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows (see annex AA also):

Amendment:

A level of 8 kV shall apply for contact discharge and a level of 15 kV shall apply for air discharge.

36.202.2 Radiated radiofrequency electromagnetic field

This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

Amendment:

36.202.2.1 Requirements

a)* This item applies except as follows:

The applicable level is not 3 V/m but 10 V/m.

b)* This item does *not* apply

c)* This item does *not* apply

d)*

36.202.2.2* Test conditions

c) This item does *not* apply

e)* This item does *not* apply

36.202.4* VOLTAGE DIPS, short interruptions and voltage variations on power supply input lines

36.202.5* Conducted disturbances, induced by radio-frequency fields above 9 kHz

36.202.6* Magnetic fields

This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

Amendment:

Level: 400 A/m

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

This clause of the General Standard applies, except as follows:

44.3 Spillage

Replacement:

If an IPX1-classification or better is not claimed:

Replacement:

The EQUIPMENT shall be so designed that, taking into consideration ageing and rough handling of the EQUIPMENT, in the event of spillage (accidental wetting) no liquid is retained within the EQUIPMENT ENCLOSURE and the EQUIPMENT shall either continue to function normally or cease delivery and activate an alarm.

Compliance is checked by the following test:

Use the test in accordance with IEC 60529 with a test apparatus for DRIP-PROOF EQUIPMENT.

Place the EQUIPMENT in the position of NORMAL USE. Subject the EQUIPMENT to an artificial rainfall of 3 mm/min for 30 s, falling vertically from a height of 0,5 m above the top of the EQUIPMENT. Carry out the test using tap water. Covers and other parts, for example battery compartment covers, which can be removed without the aid of a TOOL are left in position during the test. Where carrying pouches are specified by the manufacturer as forming part of the protection against spillage then the test is carried out with the EQUIPMENT in the carrying pouch. Where no such specification exists then the carrying pouch is removed prior to the start of the test. Immediately after the 30 s exposure, remove visible moisture from the body of the EQUIPMENT. Immediately after the above test, determine by inspection that the water has not entered the EQUIPMENT. If water has entered the EQUIPMENT, repeat the test using saline solution (0,9 % NaCl). Carry out a functional test at the INTERMEDIATE RATE for a period of 1 h. Carry out the dielectric strength tests specified in 20.4.

44.4* Leakage*Replacement:*

EQUIPMENT shall be so constructed that liquid which might leak from containers, tubing, couplings and the like does not impair the safe functioning of the EQUIPMENT nor wet uninsulated LIVE parts or electrical insulation which is liable to be adversely affected by such a liquid.

Compliance is checked by the following test:

Set up the EQUIPMENT in NORMAL USE and according to the manufacturer's instructions for use. By means of a pipette apply drops of the test solution to couplings, tubing connectors, seals and to parts of the ADMINISTRATION SET which might rupture. Moving parts are in operation or at rest whichever is the most unfavourable.

Immediately after application of the test solution, carry out the test(s) from 50.102 to 50.108 according to the classification of the EQUIPMENT, at the INTERMEDIATE RATE only. If the EQUIPMENT does not fall into one of the defined categories then use the appropriate test from 50.102 to 50.108. Carry out the tests of 51.103 and 51.104. Switch off the EQUIPMENT and allow it to stand for a minimum of 12 h under normal conditions (20 °C ± 2 °C, 65 % ± 5 % RH). By means of functional tests determine that FREE FLOW does not occur. By inspection, check the function of controls and other parts which may have been adversely affected by the test solution.

Carry out the test with a test solution consisting of a 50 % dextrose solution.

44.6 Ingress of liquids*Addition:*

If an IPX1-classification is claimed:

Covers and other parts, for example, battery compartment covers, which can be removed without the aid of a TOOL are left in position during the test. Where carrying pouches are specified by the manufacturer as forming part of the protection against ingress of liquids, then the test is carried out with the EQUIPMENT in the carrying pouch. Where no such specification exists then the carrying pouch is removed prior to the test.

47 Electrostatic charges

Not used. Transferred to clause 36.

49 Interruption of the power supply

This clause of the General Standard applies, except as follows:

49.2*Additions:*

EQUIPMENT powered from the SUPPLY MAINS only shall give an audible alarm in the event of an accidental disconnection or a SUPPLY MAINS failure. Under such conditions, the audible alarm shall be maintained for at least 3 min or until power is restored, whichever is the less.

Compliance is checked by inspection and functional tests.

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