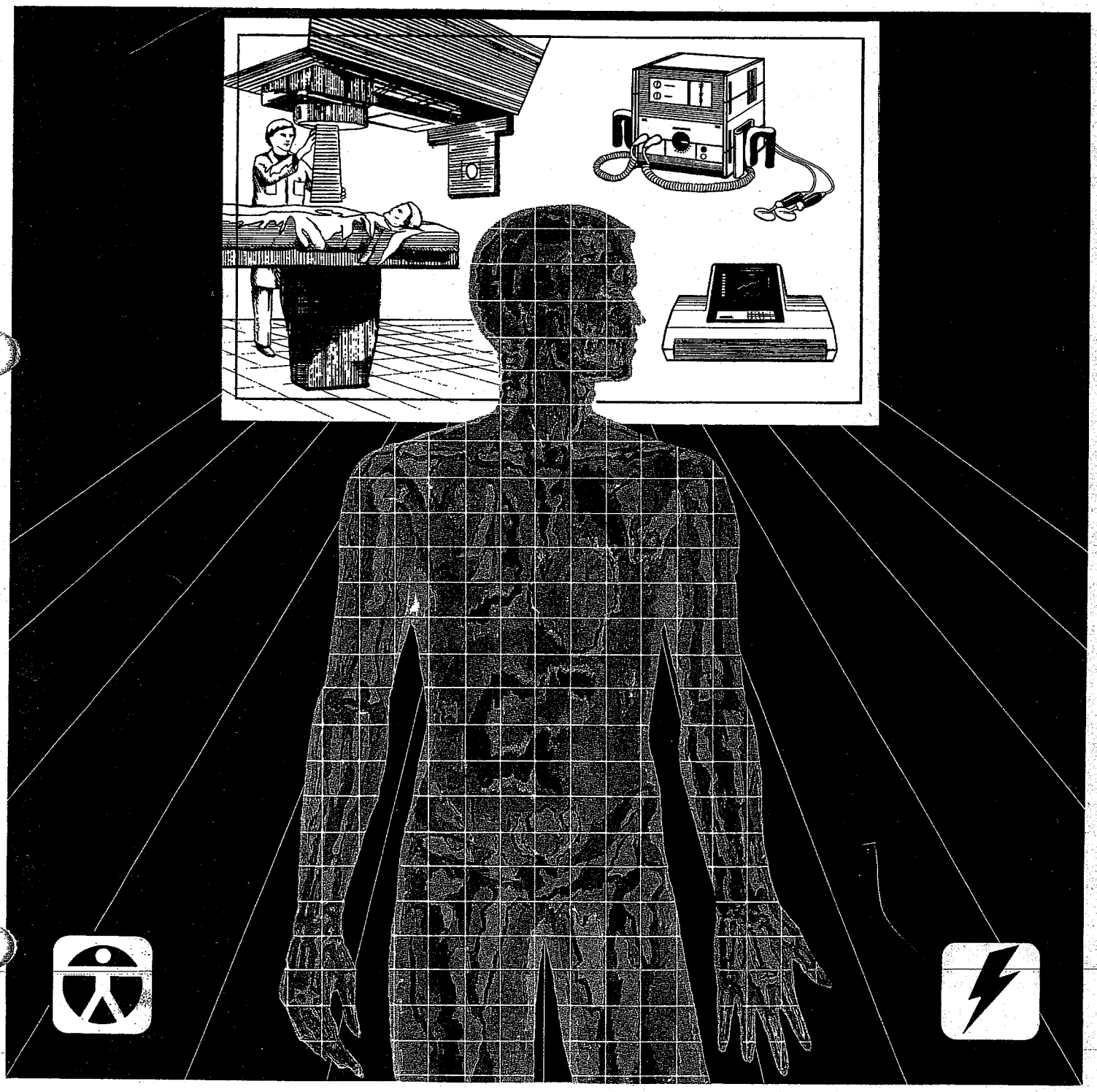
CAN/CSA-C22.2 No.601.1-M90

Medical Electrical Equipment

Part 1: General Requirements for Safety

A National Standard of Canada



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For further information on CSA services, write to
Canadian Standards Association
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The principal objects of the Council are to foster and promote voluntary standardization as a means of advancing the national economy, benefiting the health, safety, and welfare of the public, assisting and protecting the consumer, facilitating domestic and international trade, and furthering international cooperation in the field of standards.

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350 Sparks Street
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K1R 7S8

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National Standard of Canada CAN/CSA-C22.2 No. 601.1-M90

Medical Electrical Equipment
Part 1: General Requirements for Safety

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CSA Preface

This is the first edition of CSA Standard CAN/CSA-C22.2 No. 601.1, *Medical Electrical Equipment, Part 1: General Requirements for Safety.* It is based upon the identically titled second edition of IEC (International Eletrotechnical Commission) Standard 601-1 and supplements the existing CSA Standard C22.2 No. 125, *Electromedical Equipment,* as one of the National Standards of Canada for medical electrical equipment.

The preparation and publication of this Standard mark an important step forward in the harmonization of Canadian medical electrical equipment standards with those developed and used internationally. This Standard, in contrast to C22.2 No. 125, is more comprehensive and addresses more aspects of device design and specification than the one it supplements. Through the process of international harmonization, guidance for manufacturers is provided on a global scale which allows fairer competition in a larger market, with consequent economic advantage to the user, manufacturer, and diverse national interests. Care has been taken during the preparation of this Standard to avoid the inclusion of requirements which constitute technical non-tariff barriers to trade.

Some compromises have been made in order to integrate special national needs and this has been achieved within a context of concern for patient safety. Overall, the Standard provides an enhanced level of specification where needed but has also simplified manufacture in many areas. Deviations to the original IEC requirements are presented in the pages preceding the bulk of this Standard and constitute what are considered to be the "Canadian Deviations". Most of the deviations reflect the requirements of the *Canadian Electrical Code, Part I,* while others are based on issues relating to improved patient safety. Items of medical electrical equipment used and offered for sale in Canada must meet the requirements of these deviations, insofar as they apply.

The Canadian Standards Association has always taken a leadership role in promulgating Standards which provide the very highest level of protection for the end-user of the product. Every effort has been made to ensure that the harmonization of an existing Canadian Standard with international practice maintains that concern for the welfare of the patient.

This Standard contains its own rationale for many of the requirements. An appendix has been prepared and is included to provide detailed explanations where they are considered necessary.

This Standard was prepared by the CSA Subcommittee on Medical Electrical Equipment under the jurisdiction of

(a) the CSA Standards Steering Committee on the Canadian Electrical Code, Part II, and was formally approved by its Technical Committee on Environmental Products; and

(b) the CSA Standards Steering Committee on Health Care Technology, and was formally approved by its Technical Committee on Medical Electrical Equipment.

This Standard has been approved as a National Standard of Canada by the Standards Council of Canada.

November 1990

Notes:

(1) *Use of the masculine gender in this Standard is not meant to exclude the feminine gender when applied to persons. Similarly, use of the singular does not exclude the plural (and vice versa) when the sense allows.*

(2) *Altough the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the user of the Standard to judge its suitability for his particular purpose.*

(3) *CSA Standards are subject to periodic review, and suggestions for their improvement will be referred to the appropriate committee.*

(4) *All enquiries regarding this Standard, including requests for interpretation, should be addressed to Canadian Standards Association, Standards Division, 178 Rexdale Boulevard, Rexdale, Ontario M9W 1R3.*

Requests for interpretation should

(a) define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;

(b) provide an explanation of circumstances surrounding the actual field condition; and

(c) be phrased where possible to permit a specific "yes" or "no" answer.

Interpretations are published in CSA Information Update. *For subscription details and a free sample copy, write to CSA Sales Promotions or telephone (416) 747-4116.*

CSA Foreword

Certification organizations, as accredited by the Standards Council of Canada, have their own criteria and procedures for certification services. The following paragraphs define CSA Certification policies.

The Canadian Standards Association provides certification services for manufacturers who, under license from CSA, wish to use the appropriate registered CSA Marks on certain products of their manufacture to indicate conformity with CSA Standards.

CSA Certification for a number of products is provided in the interest of maintaining agreed-upon standards of quality, performance, interchangeability and/or safety, as appropriate. Where applicable, certification may form the basis for acceptance by inspection authorities responsible for enforcement of regulations. Where feasible, programs will be developed for additional products for which certification is desired by producers, consumers or other interests.

In performing its functions in accordance with its objectives, CSA does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of the Association represent its professional judgement given with due consideration to the necessary limitations of practical operation and state of the art at the time the Standard is processed.

Products in substantial accord with this Standard but which exhibit a minor difference or a new feature may be deemed to meet the Standard providing the feature or difference is found acceptable utilizing appropriate CSA Certification Division Operating Procedures. Products which comply with this Standard shall not be certified if they are found to have additional features which are inconsistent with the intent of this Standard. Products shall not be certifiable if they are discovered to contravene applicable Federal laws or regulations.

Testing techniques, test procedures and instrumentation frequently must be prescribed by the CSA Certification Division in addition to the technical requirements contained in Standards of CSA. In addition to markings specified in the Standard the CSA Certification and Testing Division may require special cautions, markings and instructions that are not specified by the Standard.

Some tests required by CSA Standards may be inherently hazardous. The Association neither assumes nor accepts any responsibility for any injury or damage that may occur during or as the result of tests, wherever performed, whether performed in whole or in part by the manufacturer or the Association, and whether or not any equipment, facility or personnel for or in connection with the test is furnished by the manufacturer or the Association.

Manufacturers should note that, in the event of the failure of the CSA Certification and Testing Division to resolve an issue arising from the interpretation of requirements, there is an appeal procedure: the complainant should submit the matter, in writing, to the Secretary of the Canadian Standards Association.

If this Standard is to be used in obtaining CSA Certification please remember, when making application for certification, to request all current Amendments, Bulletins, Notices and Technical Information Letters that may be applicable and for which there may be a nominal charge. For such information or for further information concerning details about CSA Certification please address your inquiry to the Applications and Records Section, Canadian Standards Association, 178 Rexdale Boulevard, Rexdale (Toronto), Ontario M9W 1R3. It has been approved as a National Standard of Canada by the Standards Council of Canada.

Publication Date — *November 30, 1990.*
(ie, the date on or after which this Standard may, at the discretion of the applicant, be used for certification).

Effective Date — *January 1, 2000.**
(ie, the date on which this Standard shall be applicable to equipment being submitted for certification and to equipment already certified and manufactured on or after that date).
* *Unless otherwise noted in the text or General Instruction.*

Glossary of Equivalent Terms

The following is a list of terms used within IEC Standard 601-1 for which equivalent North American terms are presented.

IEC Term	Equivalent North American Term
AUXILIARY MAINS SOCKET OUTLET	auxiliary supply receptacle
BASIC INSULATION	functional insulation
CLASS I EQUIPMENT	grounded equipment
CLASS II EQUIPMENT	double-insulated equipment
DETACHABLE POWER SUPPLY CORD	cordset
earth	ground
earthing	grounding
FUNCTIONAL EARTH CONDUCTOR	functional ground conductor
FUNCTIONAL EARTH TERMINAL	functional ground terminal
MAINS	supply
MAINS PART	primary part
MAINS PLUG	attachment plug
MAINS VOLTAGE	supply voltage
OVER-CURRENT RELEASE	overcurrent protective device
PROTECTIVE EARTH CONDUCTOR	protective ground conductor
PROTECTIVE EARTH TERMINAL	protective ground terminal
PROTECTIVELY EARTHED	protectively grounded
socket outlet	receptacle
SUPPLY MAINS	source of supply

Note: *As a result of the introduction of CSA Standard C22.2 No. 601.1, equipment Risk Classes have been replaced by Equipment Types. In order to assist users in making the transition from Risk Class to Equipment Type designations, the following equivalencies are presented:*

Old Risk Class	New Equipment Type
1, 2G	B
2	BF
3	CF

Reference Publications

Where reference is made to CSA Standards of the *Canadian Electrical Code, Parts I and II,* such reference shall be considered to refer to the latest edition and revision thereto, unless otherwise specified. This Standard refers to the following Standards and the years shown indicate the latest editions available at the time of printing:

CSA Standards

C22.1-1990,
Canadian Electrical Code, Part I;

C22.2 No. 0.4-M1982,
Bonding and Grounding of Electrical Equipment (Protective Grounding);

C22.2 No. 0.6-M1982,
Flammability and Testing of Polymeric Materials;

C22.2 No. 21-M1984,
Cord Sets and Power Supply Cords;

C22.2 No. 42-M1984,
General Use Receptacles, Attachment Plugs, and Similar Wiring Devices;

C22.2 No. 49-1989,
Flexible Cords and Cables;

C22.2 No. 125-M1984,
Electromedical Equipment;

C22.2 No. 151-M1986,
Laboratory Equipment;

Electrical Bulletin No. 1402C (April 11, 1989),
Requirements for Component Type Power Supplies Intended for Use With Information Processing and Business Equipment.

Where reference is made to the following publications, such reference shall be considered to refer to that edition listed below:

CSA Standards
B51-M1986,
Boiler, Pressure Vessel, and Pressure Piping Code.

CAN/CSA-Z32.2-M1989,
Electrical Safety in Patient Care Areas;

Z305.1-M1984,
Nonflammable Medical Gas Piping Systems;

Z305.2-M1988,
Low-Pressure Connecting Assemblies for Medical Gas Systems;

CAN/CSA-Z305.3-M87,
Pressure Regulators, Gauges, and Flow-Metering Devices for Medical Gases;

CAN3-Z305.4-M85,
Qualification Requirements for Agencies Testing Nonflammable Medical Gas Piping Systems;

CAN/CSA-Z305.5-M86,
Medical Gas Terminal Units.

CGA* Pamphlets
V-5-1978,
Diameter Index Safety System.

NEMA†Standard
WD1-1979,
General-Purpose Wiring Devices.

**Compressed Gas Association.*
†*National Electrical Manufacturers Association.*

CAN/CSA-C22.2 No. 601.1-M90
Medical Electrical Equipment, Part 1: General Requirements for Safety

Canadian Deviations

Sub-clause 1.1 Scope

Add the following text to this sub-clause:

This Standard applies to the safety of MEDICAL ELECTRICAL EQUIPMENT (as defined in Sub-Clause 2.2.15) designed to be installed and used in accordance with the rules of the *Canadian Electrical Code, Part I.*

Sub-clause 2.4.1 High Voltage

Replace the existing definition with the following definition reflecting the requirements of the *Canadian Electrical Code, Part I:*

Any voltage in excess of 750 V a.c. rms, 1050 V peak, or in excess of 750 V d.c.

Sub-clause 2.4.3 Safety Extra-Low Voltage (SELV)

Add the following explanatory information to this sub-clause:

Note: *Users of this Standard should recognize that this definition for SELV differs significantly from the definition for extra-low voltage presented in the* Canadian Electrical Code (*CEC*), Part I, *ie, extra-low voltage - a voltage not exceeding 30 V rms and 42.4 V peak.*

Sub-clause 2.12.4 Patient

Add the following explanatory information to this sub-clause:

Note: *The IEC definition for PATIENT includes both animals and humans. Neither Section 24 of the CEC, Part I (dealing with hospital electrical installations), nor CSA Standard CAN/CSA-Z32.2,* Electrical Safety in Patient Care Areas, *includes animals in their definition of patient. For the purposes of this Standard, the IEC definition is retained so that MEDICAL ELECTRICAL EQUIPMENT destined for use in veterinary medical practice can continue to be evaluated by CSA.*

Clause 6 Identification, Marking and Documents

Reflecting Canada's bilingual status, add the following requirement to this clause:

Where written safety warnings appear as EQUIPMENT markings, they should appear in both the French and English languages.

Sub-clause 6.5 Colours of the Insulation of Conductors

In item (c), replace the 4th dash with the following text:

— Functional earth conductors as specified in Sub-clause (18 (l)).

Sub-clause 6.6 (b) Identification of Medical Gas Cylinders and Connections

Replace this Sub-clause with the following requirement:

(b) The point of connection of gas cylinders to EQUIPMENT shall be
   (i) gas specific;
   (ii) non-interchangeable; and
   (iii) identified

so that errors are avoided when a replacement is made.

Sub-clause 6.7 Indicator Lights and Push-Buttons

Add the following explanatory information to Table III:

Note: *Users of this Standard are reminded that the colour red is to be used exclusively to indicate a warning of danger and/or a need for urgent action.*

Sub-clause 10.1 Transport and Storage

Add the following explanatory information to this Sub-clause:

Note: *Assessment of equipment to this Sub-clause will be performed as follows:*

(a) if the EQUIPMENT manufacturer specifies transportation and storage requirements, compliance with these requirements will be verified; or
(b) if the EQUIPMENT manufacturer does not specify any transportation and storage requirements, the EQUIPMENT will be assessed using the following IEC Standards:

(1) 68-1 Environmental Testing, Part 1: General and Guidance;
(2) 68-2 Part 2: Tests;
(3) 68-3 Part 3: Background Information; and
(4) 68-4 Part 4: Information for Specification Writers - Test Summaries.

Sub-clause 10.2.2 (a)

Replace the requirement accompanying the last dash with the following text:

— protective measures as described in the *Canadian Electrical Code, Part 1.*

Sub-clause 19.3 Table IV

Add the following information to this Table:

PATIENT LEAKAGE CURRENT limits are based upon the following assumptions:

(1) The probability of PATIENT LEAKAGE CURRENTS causing ventricular fibrillation is equal to the probability of mechanical stimulation causing ventricular fibrillation.

(2) Patient sensation, including muscular contraction, without causing physiological harm, is accepted under the SINGLE FAULT CONDITION because of the probability of such a SINGLE FAULT CONDITION arising.

Readers are encouraged to review Appendix A of this Standard and the following report:

Tan, K.S., Johnson, D.L. Threshold of Sensation for 60-Hertz Leakage Current: Results of a Survey. *Biomedical Instrumentation and Technology,* 1990, volume 24, pp. 207-211.

Sub-clause 19.4 Tests

Editorial

In Part (a), Subsection (1), replace the text accompanying the first dash with the following text:

— after the EQUIPMENT has been brought up to operating temperature in accordance with the requirements of Section Seven (refer to the compliance information accompanying Sub-clause 42.3 in particular), and

Sub-clause 20.2 Requirements for Equipment with an Applied Part

Under the Item B-b, add the following explanatory information:

Note: *From the point of view of device evaluation, Particular Standards should be referred to for test voltages whether or not those standards have been adopted by CSA.*

Sub-clause 21.3 Mechanical Strength

Editorial

In the second to last paragraph, replace the first sentence with the following text:

Foot rests and chairs shall be tested by the same procedure, but the test force shall be twice the specified maximum normal load or, if such a load is not specified, the test force shall be 27 kN.

Clause 37 Locations and Basic Requirements

Add the following explanatory information to this Clause:

Note: *A study of present anaesthetizing practice in human and veterinary medicine has revealed conclusively that flammable anaesthetics are no longer used in clinical practice in Canada. As a result, the requirements of this Section of the Standard are optional and thus manufacturers, at their discretion, may seek to have their EQUIPMENT marked as AP or APG.*

Sub-clause 37.5

Editorial

Replace the first sentence with the following text:

Where a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs because of a leakage or dischage of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

from an ENCLOSURE, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm from such a point.

Clause 43 Fire Prevention

Replace this Clause with the following requirements:

EQUIPMENT shall be designed and built to prevent PATIENTS and OPERATORS from being exposed to a fire hazard.

Compliance is checked by subjecting the EQUIPMENT to the abnormal tests.

Note: *The flammability tests described in CSA Standard C22.2 No. 125 and previously applied to enclosures need no longer be performed. They have been replaced by the abnormal tests presented in this Standard.*

Clause 45 Pressure Vessel and Parts Subject to Pressure

Add the following explanatory information to this clause:

Note: *At the present time in Canada, there is no single national regulation dealing with pressure vessels. Each province has its own requirements, these being based upon CSA Standard B51,* Boiler, Pressure Vessel, and Pressure Piping Code. *Depending upon the Provincial jurisdiction, Standard B51 is referred to in whole or in part. In order to clarify whether Standard B51 applies to a particular item of EQUIPMENT, the term pressure vessel is defined as follows:*

Pressure vessel - a closed vessel in which the pressure exceeds 103 kPa (15 psi), used for containing, storing, distributing, transferring, distilling, processing, or otherwise handling any gas, vapour, or liquid under pressure where one of the following limits is exceeded:
(a) an internal capacity of 0.0425 m^3 (1.5 ft^3); or
(b) an internal diameter of 152 mm (6 in);
except for those vessels defined elsewhere in Standard B51 or in a Provincial Act.

Sub-clause 45.2

Editorial

Replace the first sentence with the following text:

If a pressure vessel is not covered by a national regulation, with or without an inspection procedure, and has a PRESSURE x volume content greater than 200 kPa.L, and PRESSURE greater than 50 kPa, it shall withstand the HYDRAULIC TEST PRESSURE.

Sub-clause 52.4.1

The sentence following the third dash refers to Table XII. This is incorrect; the reference should be to Table XI.

Editorial

Replace the second paragraph with the following text:

The requirements of Sub-clause 52.1 and the corresponding tests shall not be applied to components when their construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to 15W or less.

Sub-clause 52.4.2

Editorial

Delete the word "of" in the first line.

Sub-clause 52.5.8

The final sentence of this sub-clause refers to Table XI. This is incorrect; the reference should be to Table XII.

Editorial

In Table XII, the second row, replace the first dash with the following:

— if impedance-protected, maximum value.

Clause 54 General

Editorial

Replace the second sentence of the third paragraph with the following text:

The requirements of this Section are not to be considered the only means of achieving the required degree of safety and the term "shall", where used, should be understood accordingly.

Sub-clause 56.3 (a) Construction of Connectors

Replace the requirement accompanying the third dash with the following:

Medical gas inlet connectors on EQUIPMENT shall be
(a) gas specific;
(b) non-interchangeable;
(c) of the Diameter Index Safety System (DISS) type, complying with the requirements described in the Compressed Gas Association (CGA) publication, Pamphlet V-5; and
(d) configured to permit the supply of medical gases from low pressure connecting assemblies complying with CSA Standard CAN/CSA-Z305.2.
Note: *Users of this Standard should consult the Z305 Series of CSA Standards for further information regarding inlet connectors, and ISO Recommendation 407 for requirements addressing yoke-type valve connections.*

Sub-clause 56.6 (a) Application

Replace the requirement accompanying the fourth dash with the following:

Where the consequent loss of function of EQUIPMENT caused by operation of a THERMAL CUT-OUT presents a SAFETY HAZARD, both visible and audible warnings shall be given.

Sub-clause 57.2 (g)

Add the following new item to this sub-clause:

(g) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall
(i) if of the moulded-on type, comply with the requirements for a hospital grade attachment plug (mains plug) as specified in CSA Standard C22.2 No. 21;

(ii) comply with the requirements for a hospital grade disassembly type attachment plug (mains plug), as specified in CSA Standard C22.2 No. 42; or

(iii) for Class II (double-insulated) equipment, be constructed using CSA Configuration 1-15P with polarized blades (see NEMA Standard WD1 for blade dimensions) and meet all applicable requirements for hospital grade in CSA Standards C22.2 No. 21 and C22.2 No. 42.

Sub-clause 57.3 (b) Power Supply Cords - Types

Replace this sub-clause with the following requirements:

(b) Types

A DETACHABLE POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected EQUIPMENT) shall be of a type that

(i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety hazard to a patient or operator;

(ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a SAFETY HAZARD to a PATIENT or OPERATOR; and

(iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a DETACHABLE POWER SUPPLY CORD which could make the EQUIPMENT hazardous.

A DETACHABLE POWER SUPPLY CORD shall comply with the following requirements:

(i) it shall comply with the applicable requirements of CSA Standard C22.2 No. 21;

(ii) the flexible cord shall be not smaller than No. 18 AWG, and the mechanical serviceability shall be

(a) not less than that of Type SJ for MOBILE EQUIPMENT such as hospital beds and instrument carts; and

(b) not less than that of Type SV (or Type HPN, if required because of temperature) for other EQUIPMENT.

Note: *See CSA Standard C22.2 No. 49 for requirements on the cord types mentioned in item (ii).*

Sub-clause 57.9 Mains Supply Transformers

Add the following requirement to this sub-clause:

Switching mode power supplies shall conform to the requirements of *CSA Electrical Bulletin 1402C.*

Sub-clause 57.9.4 (f)

Editorial

Replace the text accompanying the second dash, second dot, with the following:

- or the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot penetrate the joint.

Sub-clause 57.10 (a) Creepage Distances and Air Clearances-Values

Replace the third sentence of the text accompanying the second dash with the following:

Table V shall be used to determine those values of test voltages to be applied to parts at reference voltage in excess of 1000 V a.c. or 1200 V d.c.

Sub-clause 58.2

Add the following explanatory information to the Sub-clause:

Users of this Standard should refer to CSA Standard C22.2 No. 0.4 which presents suitable methods of assuring the integrity of the protective earth connection.

Sub-clause 59.1 Internal Wiring

Replace the requirement contained in Sub-section (f) with the following:

Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I,* as applicable.

Clause 60 Test for Defibrillator-Protected Equipment of Type BF and CF

Add the following new Clause 60 to the Standard as follows:

EQUIPMENT marked with symbols 02-04 or 02-06 of IEC Standard IEC 878 (see Table DII of this Standard) shall have minimum 4 mm creepage and clearance spacings between isolated and non-isolated parts and be so designed to isolate PATIENT connections from other parts of the EQUIPMENT that, during the discharge of a defibrillator to a PATIENT connected to these PATIENT connections, hazardous electrical energies are excluded from the following:

(1) the body of the EQUIPMENT;

(2) any SIGNAL INPUT PART and/or SIGNAL OUTPUT PART;

(3) metal foil on which the EQUIPMENT is placed and which has an area at least equal to the base of the EQUIPMENT (CLASS II EQUIPMENT or EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE is subject to this metal foil testing requirement).

Compliance shall be checked by the following test:

The above requirement is met when, after operation of switch S1 (see Figure 50), the peak voltage between points Y1 and Y2 does not exceed 1 volt. This voltage corresponds to a charge of 100 µC from the part under test.

CLASS I EQUIPMENT shall be tested while connected to the protective earth.

CLASS I EQUIPMENT which is capable of operation without a SUPPLY MAINS, eg, having an internal battery, shall also be tested without the protective earth connection.

Any connection to a functional earth shall be removed.

The test shall be repeated with the polarity of V reversed.

Note: *EQUIPMENT is presently being manufactured which incorporates defibrillator protection but for which no particular standard exists to evaluate this degree of protection. This test is provided in order to permit the evaluation of such EQUIPMENT.*

Figures - General

Add the following information to this section of the Standard:

Note: *In reviewing schematic diagrams, users of this Standard are reminded that*
(a) lines crossing do not constitute a connection unless a dot appears over the intersection (see Figure 11); and
(b) lines shown as making a T-junction do constitute a connection although no dot is present.

Figure 18 Measuring Circuit for the ENCLOSURE LEAKAGE CURRENT

Editorial

In order to be consistent with Figure 19, replace the script "5" at the top of the Figure with "9".

Figures 18, 19, and 20

Editorial

The voltmeter appearing in the lower half of these figures is to be labelled as V_1.

Legends of Symbols for Figures 10 to 27

Editorial

Add to the list of legends the following text:

R Impedance for protection of user of test apparatus.

Appendix A1

Sub-clause A1.1

Add the following explanatory information to this Sub-clause:

Users of this Standard should refer to CSA Standard CAN/CSA-Z32.2 *Electrical Safety in Patient Care Areas.*

Sub-clause A1.6.3

Add the following explanatory information to this Sub-clause:

A study of present anaesthetizing practice in human and veterinary medicine has revealed conclusively that flammable anaesthetics are no longer used in clinical practice in Canada. As a result, this Clause of the Appendix does not apply in Canada and the requirements of Clause 37 of this Standard are optional; manufacturers may, at their discretion, seek to have their EQUIPMENT marked as AP or APG.

Appendix A2

Clause 1

Replace the text of the third sentence of this Clause with the following:

Laboratory equipment, while not addressed by this Standard, must meet the requirements of CSA Standard C22.2 No. 151-M1986, *Laboratory Equipment.*

Sub-clause 2.7.6

Replace the text of this Sub-clause to read as follows:

Users of this Standard should refer to Sub-clause 57.3 of the Canadian Deviations.

Sub-clause 6.1 (f)

Editorial

Replace the first sentence of this sub-clause with the following text:

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it may not denote the exact construction, including the applied components and materials.

Sub-clause 6.1 (z)

Add the following requirement to this Sub-clause:

In order to perform the rubbing test with repeatability, the term methylated spirit is to consist of the following components by volume:

Ethanol	90.0%
Methanol	9.5%
Pyridine	0.5%

Sub-clause 16 (c)

Editorial

Replace the first sentence with the following text:

The compliance test for the protective earthing of ACCESSIBLE METAL PARTS of EQUIPMENT (Sub-clause 18(f)) is conducted with a current between 10 A and 25 A provided by a source with a sufficiently low voltage (not exceeding 6 V).

Sub-clause 19.4 Table IV

Editorial

The reference to a voltage of 220 V is incorrect. Replace the sentence with the following text:

The current flowing from the APPLIED PART, due to an external voltage on the APPLIED PART, to earth in BF TYPE EQUIPMENT of 5 mA is allowed because the risk of harmful physiological effects is small and the appearance of the mains voltage on the PATIENT is very unlikely.

Clause 26

Add the following sentence to this clause:

Appropriate Canadian sources should be consulted regarding aspects of the prevention and control of noise and vibration.

Clause 45

Replace the two sentences of this Clause with the following text:

At the present time in Canada, there is no single national regulation dealing with pressure vessels. Each province has its own requirements, these being based upon CSA Standard B51 *Boiler, Pressure Vessel, and Pressure Piping Code*. Depending on the province, B51 is referred to in whole or in part.

Sub-clause 45.2

Editorial

Replace the first sentence with the following text:

It is assumed that if the PRESSURE × volume is equal to or smaller than 200 kPa/L or the PRESSURE is equal to or smaller than 50 kPa, a hydraulic test is not necessary.

Clause 48

Add the following additional information to this Clause:

At this time, Canada continues to adopt ISO implant material standards as National Standards of Canada.

Sub-clause 55.1

Add the following additional information to this Sub-clause:

For additional information regarding the flammability testing of enclosures, readers should consult CSA Standard C22.2 No. 0.6.

Sub-clause 59.2 (b)

Add the following additional information to this Sub-clause:

For additional information regarding the flammability testing of enclosures, readers should consult CSA Standard C22.2 No. 0.6.

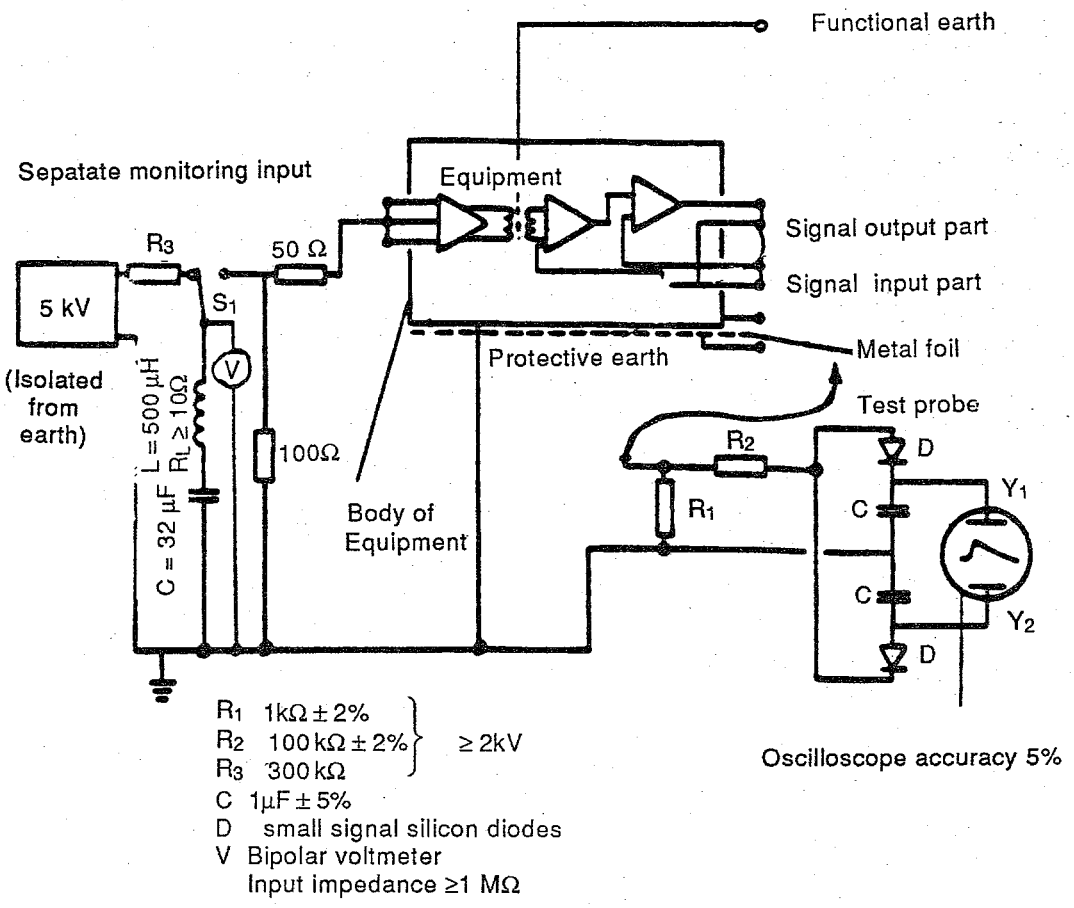

Figure 50
Dynamic Test for Limitation of Energy
From Different Parts of the Equipment
(See Clause 60)

Source: IEC Standard 601-2-4, Fig. 103

Table DII

No.	Symbol	IEC publication	Description
1		878-02-02	Type B equipment
2		878-02-03	Type BF equipment
3		878-02-05	Type CF equipment
4		878-02-07	Category AP equipment
5		878-02-08	Category APG equipment
6		878-03-01	Dangerous voltage
7			Not used
8		878-03-04	Nonionizing radiation

02-04		Defibrillator-proof type BF equipment

0206		Defibrillator-proof type CF equipment

Source: IEC Standard 878

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

It forms the second edition of IEC Publication 601-1 (1977), entitled "Safety of medical electrical equipment, Part 1: General requirements".

The text of this Standard is based on the following documents:

Six Months' Rule	Report on Voting	Two Months' Procedure	Report on Voting
62A(CO)24	62A(CO)25	62A(CO)27	62A(CO)33

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

The list of IEC, ISO and other publications quoted in this Standard will be found in Appendix L.

In this Standard, the following print types are used:

Requirements, compliance with which can be tested and definitions: in roman type.

Explanations, advice, introductions, general statements, exceptions and references: in smaller type.

Test specifications: in italic type.

TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: SMALL CAPITALS.

* Rationale (Appendix A).

INTRODUCTION

Aware of the need and the urgency for a General Standard covering electro-medical equipment, the majority of National Committees voted in 1977 in favour of the first edition of IEC Publication 601-1, based on a draft which at the time represented a first approach to the problem.

The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, had required years of effort in order to prepare this first Standard, which can now be said to have served as a universal reference since its publication.

However, its frequent application has revealed room for improvement, all the more desirable in view of the considerable success that this Standard has enjoyed since its publication. In fact it is now available in a dozen languages and forms an integral part of the National Standards of several countries.

The careful work of revision subsequently undertaken and continued over a number of years has finally resulted in this second edition. This incorporates all the improvements which can be reasonably expected at the present time, taking into account the level of current scientific knowledge. Further developments will remain under constant study.

The change of the title from "Safety of medical electrical equipment, Part 1: General requirements" in the first edition, to "Medical electrical equipment, Part 1: General requirements for safety", allows for subjects other than safety to be dealt with in other parts of IEC Publication 601.

This General Standard contains requirements of safety which are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of EQUIPMENT, these requirements are to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Standards exist, the General Standard should not be used alone. Special care is required in applying the General Standard to EQUIPMENT for which no Particular Standard exists.

In some countries EQUIPMENT may only be certified as complying with this Standard if either a Particular Standard or an authorized document based on the General Standard is available stating which clauses are applicable for the EQUIPMENT concerned.

An appendix on "General guidance and rationale" is added (see Appendix A). It is not a part of this Standard and only gives additional information; it can never be the subject of testing.

Clauses and sub-clauses to which there is a rationale are marked with an asterisk *.

The statement "Not used" refers to clauses and sub-clauses in the first edition that have not been retained in this second edition.