



New Standards & Editions

CAN/CSA-ISO 5841-2-01, 2nd edition
Implants for Surgery—Cardiac Pacemakers—Part 2: Reporting of the Clinical Performance of Populations of Pulse Generators or Leads (Adopted ISO 5841-2:2000, second edition, 2000-10-15) \$75

This standard specifies requirements for reports on the clinical performance in humans of population samples of pulse generators or leads, intended for long-term implantation as cardiac pacemakers. It includes general requirements for all reports; it also includes supplementary requirements for reports on cumulative experience with devices and estimates of future clinical performance for devices, when appropriate.

The standard's Annexes provide requirements for categorizing devices, guidelines for statistics (including a discussion of application of the results obtained), and the rationale for this part of ISO 5841.

CAN/CSA-ISO 14971-01, 1st edition
Medical Devices—Application of Risk Management to Medical Devices (Adopted ISO 14971:2000, first edition, 2000-12-15) \$95

This standard specifies a procedure that a manufacturer can use to identify the hazards associated with medical devices and their accessories (including *in vitro* diagnostic medical devices), estimate and evaluate the risks, control these risks, and monitor the effectiveness of the control. This standard's requirements apply to all stages of the life cycle of a medical device.

This standard does not apply to clinical judgements relating to the use of a medical device. Nor does it specify acceptable risk levels.

Z317.2-01, 2nd edition
Special Requirements for Heating, Ventilation, and Air Conditioning (HVAC) Systems in Health Care Facilities \$85

This standard provides criteria for the aspects of HVAC systems that are particular to health care facilities. These criteria lead to more stringent requirements that are above and beyond those generally applied in planning, designing, constructing, commissioning, maintaining, and operating HVAC systems.

This standard sets values for certain parameters; identifies the suitability of possible design options;

establishes recommendations for zoning, controls and monitoring; and sets targets for energy conservation. This standard is not intended to dictate the design concepts, construction procedures, or operating and maintenance procedures, but rather to provide guidance that prompts discussion and helps in the formulation of rational, practical decisions.

Nouvelles parutions en français

B355-00, 4^e édition
Appareils élévateurs pour personnes handicapées . . . 75 \$

Cette norme énonce les exigences minimales de conception, de construction, d'installation, de fonctionnement, d'inspection et de mise à l'essai des appareils élévateurs conçus spécialement pour le transport des personnes handicapées entre les divers niveaux d'un bâtiment ou d'une structure, dans le but d'assurer la protection contre le risque d'accidents associés au fonctionnement de ces appareils.

Les appareils élévateurs visés par cette norme sont les suivants :

- a) plates-formes verticales à gaine fermée ;
- b) plates-formes verticales à gaine non fermée ;
- c) fauteuils élévateurs d'escalier ;
- d) plates-formes d'escalier à gaine protégée ; et
- e) plates-formes d'escalier à gaine non protégée.

CAN/CSA-ISO 5841-2-01, 2^e édition
Implants chirurgicaux—Stimulateurs cardiaques—Partie 2 : Établissement d'un rapport concernant le fonctionnement clinique de populations de générateurs d'impulsions ou de fils-électrodes (norme ISO 5841-2:2000 adoptée, deuxième édition, 2000-10-15) 75 \$

Cette norme spécifie les exigences que doivent remplir les rapports concernant le fonctionnement clinique chez l'homme, pour des échantillons de population de générateurs d'impulsions ou de fils-électrodes destinés à une implantation à long terme. Elle comprend les exigences générales qui concernent tous les rapports et les exigences supplémentaires qui concernent les rapports sur l'expérience cumulée avec les appareils ainsi que les estimations sur le fonctionnement clinique futur des appareils, le cas échéant.

Les annexes énoncent des critères de classification des appareils, des lignes directrices pour l'étude statistique (et présentent une discussion des résultats) et les motifs de la présente partie de l'ISO 5841.



Modifications publiées en français

CAN/CSA-B622-98

Sélection et utilisation des citernes routières, des citernes de wagon-citerne à éléments multiples et des citernes amovibles pour le transport des marchandises dangereuses de la classe 2

Des modifications ont été apportées à la table des matières, aux articles 4.4, 5.5 et 6.3, ainsi qu'aux tableaux 1 et 2. L'article 5.2.5 a été ajoutée.

Proposed New Projects

For more information about the proposed development of the following new edition, contact Cathryn Cortissoz at 416-747-2594 or cathryn.cortissoz@csa.ca:

- **Z364.2.2, 3rd edition**
Water Treatment Equipment and Water Quality for Haemodialysis

For more information about the proposed development of the following new edition, contact Ron Meyers at 416-747-2687 or ron.meyers@csa.ca:

- **Z795, 2nd edition**
Coding of Work Injury or Disease Information

For more information about the proposed development of the following new edition, contact Dave Shanahan at 416-747-2586 or dave.shanahan@csa.ca:

- **Z91, 5th edition**
Health and Safety Code for Suspended Equipment Operations
- **Z611, 2nd edition**
Riot Helmets

Proposed Adoption of Standards

Please note: Public comments about proposed adoptions listed in this issue are due by January 7, 2002.

For more information about the proposed adoption of the following ANSI and IEC standards, or to offer comments, contact Ron Meyers at 416-747-2687 or ron.meyers@csa.ca:

- **ANSI/RIA R15.06-1999** (to be published by CSA as the 2nd edition of Z434)
Robot Safety

- **IEC 73 (1996)** (to be published as the 2nd edition of Z431)
Basic and Safety Principles for Man-Machine Interface, Marking and Identification—Coding Principles for Indication Devices and Actuators

For more information about the proposed adoption of the following IEC standards, contact Michael Wilson at 416-747-2532 or michael.wilson@csa.ca:

- **IEC 60601-2-23 (1999-12)**
Medical Electrical Equipment—Part 2-23: Particular Requirements for the Safety, Including Essential Performance, of Transcutaneous Partial Pressure Monitoring Equipment
- **IEC 60601-2-25-am1 (1999-05)**
Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Electrocardiographs. Amendment 1
- **IEC 60601-2-30 (1999-12)**
Medical Electrical Equipment—Part 2-30: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-invasive Blood Pressure Monitoring Equipment
- **IEC 60601-2-34 (2000-10)**
Medical Electrical Equipment—Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment

Drafts

Please note: Public comments about draft standards and proposed amendments listed in this issue are due by January 7, 2002.

To receive copies of the following draft standards, or to offer comments, contact Dave Shanahan at 416-747-2586 or dave.shanahan@csa.ca:

- **Z94.3, 6th edition**
Selection, Use and Care Guide for Eye and Face Protection
- **Z195, 5th edition**
Protective Footwear

To receive copies of the following draft standards, or to offer comments, contact Paul Levine at 416-747-4172 or paul.levine@csa.ca:

- **B620, 3rd edition**
Highway Tanks and Portable Tanks for the Transportation of Dangerous Goods



- **B621, 3rd edition**
Selection and Use of Highway Tanks, Portable Tanks, Cargo Compartments, and Containers for the Transportation of Dangerous Goods, Classes 3, 4, 5, 6.1, 8, and 9
- **B622, 3rd edition**
Selection and Use of Highway Tanks, Multi-Unit Tank Car Tanks and Portable Tanks for the Transportation of Dangerous Goods, Class 2

To receive copies of the following draft standards, or to offer comments, contact Nancy Bestic at 416-747-2710 or nancy.bestic@csa.ca:

- **Z900.1, 1st edition**
Safety of Cells, Tissues, and Organs for Transplantation
- **Z900.2.1, 1st edition**
Safety of Tissues for Assisted Reproduction (Note: This title has been changed from "Safety of Reproductive Tissues for Transplantation," as listed in *Info Update 2001 Volume 1*)
- **Z900.2.2, 1st edition**
Safety of Tissues for Transplantation
- **Z900.2.3, 1st edition**
Safety of Perfusable Organs for Transplantation
- **Z900.2.4, 1st edition**
Safety of Ocular Tissues for Transplantation

To receive copies of the following draft standards, or to offer comments, contact Ron Meyers at 416-747-2687 or ron.meyers@csa.ca:

- **B335, 2nd edition**
Industrial Lift Truck Operator Training
- **B354.4, 2nd edition**
Boom-Type Elevating Work Platforms
- **Z142, 4th edition**
Code for Punch Press and Brake Press
- **Z248, 2nd edition**
Code for Tower Cranes

Proposed Reaffirmation of Standards

For more information about the proposed reaffirmation of the following standard, contact Ron Meyers at 416-747-2687 or ron.meyers@csa.ca:

- **CAN/CSA-Z615-87**
Code for Hot Forging Producers, Health and Safety Requirements

Reaffirmed Standards

- CAN/CSA-ISO 5841-1-97 (R2001)**
Cardiac Pacemakers—Part 1: Implantable Pacemakers
- CAN/CSA-ISO 9703-1-97 (R2001)**
Anaesthesia and Respiratory Care Alarm Signals—Part 1: Visual Alarm Signals
- CAN/CSA-ISO 9703-2-97 (R2001)**
Anaesthesia and Respiratory Care Alarm Signals—Part 2: Auditory Alarm Signals
- CAN/CSA-ISO 10993-2-97 (R2001)**
Biological Evaluation of Medical Devices—Part 2: Animal Welfare Requirements
- CAN/CSA-ISO 10993-3-97 (R2001)**
Biological Evaluation of Medical Devices—Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- CAN/CSA-ISO 10993-4-97 (R2001)**
Biological Evaluation of Medical Devices—Part 4: Selection of Tests for Interactions with Blood
- CAN/CSA-ISO 10993-6-97 (R2001)**
Biological Evaluation of Medical Devices—Part 6: Tests for Local Effects After Implantation
- CAN/CSA-Z364.1.1-94 (R2001)/CAN/CSA-Z364.1.2-94 (R2001)**
Haemodialyzers, Haemofilters, and Haemoconcentrators/ Extracorporeal Blood Circuit for Haemodialyzers, Haemofilters, and Haemoconcentrators
- Z364.2.1-94 (R2001)**
Fluid Supply and Monitoring Systems for Haemodialysis

Withdrawn Standards

CSA has withdrawn its endorsement of the following endorsed ISO standards:

- **ISO 668:1979**
Series 1 Freight Containers—Classification, External Dimensions and Ratings
- **ISO 830:1981**
Freight Containers—Terminology
- **ISO 1161:1984**
Series 1 Freight Containers—Corner Fittings—Specification



Certification Notices

Please note: ▶ Notices marked with an arrowhead are new in this issue.

Effective Date	Subject	Title
▶ February 21, 2003	Publication of Technical Information Letter (TIL) No. MHC-08, covering interim certification requirements for electromechanical lifting devices for persons.	Health Care Equipment No. 12

Status of CSA Standards Projects

TYPE: ns *new standard*; ne *new edition*; spec *special publication*; p *preliminary standard*.

STATUS: 1 *The project is under initial evaluation.*

2 *The technical content is being drafted.*

3 *The draft is undergoing an internal quality audit by CSA.*

4 *The publication is being processed for formal letter-ballot approval.*

5 *The approved publication will be for sale within 2–3 months.*

H *The publication is on hold.*

C *The publication has been cancelled. It will be removed from the next status report.*

SUBJECT	NUMBER	TYPE	STATUS
Health Care Technology			
Implants for Surgery—Cardiac Pacemakers—Part 3: Low-Profile Connectors (IS-1) for Implantable Pacemakers	ISO 5841-3	ne	5
Application of Auditory and Visual Medical Devices	ISO 9703-3	ns	3
Biological Evaluation of Medical Devices—Part 15: Identification and Quantification of Degradation Products from Metals and Alloys	ISO 10993-15	ns	3
Medical Devices—Symbols to Be Used with Medical Device Labels, Labelling and Information to Be Supplied	ISO 15223	ns	H
Metered Dose Inhaler Spacer Device	Z264.1	ns	5
Medical Electrical Equipment—Particular Requirements for Safety of Medical Supply Units	Z305.8	ns	4
Disinfectants	Z314.11	ns	H
Selection and Use of Rigid Sterilization Containers	Z314.14	ne	3
Area Measurement for Health Care Facilities	Z317.11	ne	3
Water Treatment Equipment and Water Quality Requirements for Haemodialysis	Z364.2.2	ne	3
Transportable Mobility Aids	Z604	ne	5
Mobility Aid Securement and Occupant Restraint Systems	Z605	ne	5
Safety of Tissues and Organs for Transplantation	Z900.1	ns	2
Safety of Tissues for Assisted Reproduction	Z900.2.1	ns	2
Safety of Tissues for Transplantation	Z900.2.2	ns	2
Safety of Perfusable Organs for Transplantation	Z900.2.3	ns	2
Safety of Ocular Tissues for Transplantation	Z900.2.4	ns	2
Safety of Hematopoietic Cells for Transplantation	Z900.2.5	ns	2
Nonflammable Medical Gas Pipeline Systems—Part 1: Pipelines for Compressed Medical Gases and Vacuum	Z7396.1	ns	3



SUBJECT	NUMBER	TYPE	STATUS
Nonflammable Medical Gas Pipeline Systems–Part 2: Pipelines for Anaesthetic Gas Scavenging Disposal Systems	Z7396.2	ns	5
Pressure Regulators and Pressure Regulators with Flow-Metering Devices for Medical Gas Systems	Z10524	ns	5
Flow-Metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems	Z15002	ns	5
Mechanical Industrial Equipment			
Elevator and Escalator Electrical Equipment	B44.1	ne	4
Safety Code for Manlifts	B311	ne	4
Cylinders, Spheres and Tubes for the Transportation of Dangerous Goods	B339	ne	4
Selection and Use of Cylinders, Spheres, Tubes, and Other Containers for the Transportation of Dangerous Goods, Class 2	B340	ne	4
Community and Personal Issues			
Barrier-Free Design	B651	ne	1
Design for Aging	B659	ns	5
Motor Vehicles for the Transportation of Physically Disabled Persons	D409	ne	4
Transit Vehicles for the Transportation of Persons with Physical Disabilities	D435	ns	2
Over-the-road Buses for the Transportation of Persons with Physical Disabilities	D436	ns	2
Dimensions for Facially-Featured Headforms	Z262.6	ns	4
Racquet Sports Eye Protection	Z400	ns	1
Occupational Health and Safety			
Industrial Lift Truck Operator Training	B335	ne	3
Elevating Rolling Work Platforms	B354.1	ne	2
Boom-Type Elevating Work Platforms	B354.4	ne	4
Mast Climbers	B354.5	ns	2
Lighting and Marking of Agricultural Field Equipment on Highways	M669	ne	1
Agricultural Tractors–Operator's Seating Accommodation–Dimensions	M4253	ns	H
Chain Saws	Z62.1	ne	2
Health and Safety Code for Suspended Equipment Operations	Z91	ne	3
Hearing Protection	Z94.2	ne	4
Eyewear User Guide	Z94.3.1	spec	2
Selection, Use, and Care of Respirators	Z94.4	ne	3
High-Visibility Safety Apparel	Z96	ns	2
Code for Punch Press and Brake Press Operation: Health, Safety, and Guarding Requirements	Z142	ne	3
Protective Footwear	Z195	ne	4
Footwear User Guide	Z195.1	spec	4
Design of Double Girder Electric Overhead Travelling Cranes	Z202	ns	H
Code for Tower Cranes	Z248	ne	4
Flexible Horizontal Lifelines	Z259.13	ns	2
Fall Restrict Equipment for Wood Pole Climbing	Z259.14	ns	5
Hyperbaric Facilities	Z275.1	ne	2
Safety Code for Diving Operations	Z275.2	ne	2
Competency Standard for Diving Operations	Z275.4	ne	2
Riot Helmets and Faceshields	Z611	ne	2