



CSA Z7001:24
National Standard of Canada



Safe use of energy-based medical and surgical devices in health care



Legal Notice for Standards

Canadian Standards Association (operating as “CSA Group”) develops standards through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA Group administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document’s fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party’s intellectual property rights. CSA Group does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA Group makes no representations or warranties regarding this document’s compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA GROUP, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA GROUP HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA Group is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA Group accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA Group is a private not-for-profit company that publishes voluntary standards and related documents. CSA Group has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA Group and the users of this document (whether it be in printed or electronic form), CSA Group is the owner, or the authorized licensee, of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. Without limitation, the unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA Group’s and/or others’ intellectual property and may give rise to a right in CSA Group and/or others to seek legal redress for such use, modification, copying, or disclosure. To the extent permitted by treaty or by law, CSA Group reserves all intellectual property rights in this document.

Patent rights

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. CSA Group shall not be held responsible for identifying any or all such patent rights. Users of this standard are expressly advised that determination of the validity of any such patent rights is entirely their own responsibility.

Authorized use of this document

This document is being provided by CSA Group for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:

- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document if it is in PDF form.

Limited copies of this document in print or paper form may be distributed only to persons who are authorized by CSA Group to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to

- alter this document in any way, or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA Group; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents hereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.



Standards Update Service

CSA Z7001:24

December 2024

Title: *Safe use of energy-based medical and surgical devices in health care*

To register for e-mail notification about any updates to this publication go to updates.csagroup.org.

The **List ID** that you will need to register for updates to this publication is **2431687**.

If you require assistance, please e-mail techsupport@csagroup.org or call 416-777-2233.

Visit CSA Group's policy on privacy at www.csagroup.org/legal to find out how we protect your personal information.

Canadian Standards Association (operating as “CSA Group”), under whose auspices this National Standard has been produced, was chartered in 1919 and accredited by the Standards Council of Canada to the National Standards system in 1973. It is a not-for-profit, nonstatutory, voluntary membership association engaged in standards development and certification activities.

CSA Group standards reflect a national consensus of producers and users — including manufacturers, consumers, retailers, unions and professional organizations, and governmental agencies. The standards are used widely by industry and commerce and often adopted by municipal, provincial, and federal governments in their regulations, particularly in the fields of health, safety, building and construction, and the environment.

More than 10 000 members indicate their support for CSA Group’s standards development by volunteering their time and skills to Committee work.

CSA Group offers certification and testing services in support of and as an extension to its standards development activities. To ensure the integrity of its certification process, CSA Group regularly and continually audits and inspects products that bear the CSA Group Mark.

In addition to its head office and laboratory complex in Toronto, CSA Group has regional branch offices in major centres across Canada and inspection and testing agencies in fourteen countries. Since 1919, CSA Group has developed the necessary expertise to meet its corporate mission: CSA Group is an independent service organization whose mission is to provide an open and effective forum for activities facilitating the exchange of goods and services through the use of standards, certification and related services to meet national and international needs.

For further information on CSA Group services, write to
CSA Group
178 Rexdale Boulevard
Toronto, Ontario, M9W 1R3
Canada

A National Standard of Canada is a standard developed by a Standards Council of Canada (SCC) accredited Standards Development Organization, in compliance with requirements and guidance set out by SCC. More information on National Standards of Canada can be found at www.scc.ca.

SCC is a Crown corporation within the portfolio of Innovation, Science and Economic Development (ISED) Canada. With the goal of enhancing Canada’s economic competitiveness and social wellbeing, SCC leads and facilitates the development and use of national and international standards. SCC also coordinates Canadian participation in standards development, and identifies strategies to advance Canadian standardization efforts.

Accreditation services are provided by SCC to various customers, including product certifiers, testing laboratories, and standards development organizations. A list of SCC programs and accredited bodies is publicly available at www.scc.ca.

Standards Council of Canada
600-55 Metcalfe Street
Ottawa, Ontario, K1P 6L5
Canada



Cette Norme Nationale du Canada n’est disponible qu’en anglais.

Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users to judge its suitability for their particular purpose.

®A trademark of the Canadian Standards Association, operating as “CSA Group”

National Standard of Canada

CSA Z7001:24

***Safe use of energy-based
medical and surgical devices in
health care***



*®A trademark of the Canadian Standards Association,
operating as "CSA Group"*



*Published in December 2024 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3*

*To purchase standards and related publications, visit our Online Store at
www.csagroup.org/store/ or call toll-free 1-800-463-6727 or 416-747-4044.*

*ICS 11.040.01
ISBN 978-1-4883-5271-3*

*© 2024 Canadian Standards Association
All rights reserved. No part of this publication may be reproduced in any form whatsoever
without the prior permission of the publisher.*

Contents

Technical Committee on Perioperative Safety	4
Subcommittee on Energy-Based Medical and Surgical Devices	7
Preface	9
Sustainable Development Goals (SDG) Foreword	10
0 Introduction	11
0.1 General	11
0.2 Copyright permissions	11
1 Scope	11
1.1 Safety guidance for use of energy-based medical and surgical devices	11
1.2 Application	11
1.3 Inclusions	11
1.4 Controls for safe use of energy-based medical and surgical devices	12
1.5 Control measures	12
1.6 Exclusions	12
1.7 Terminology	12
2 Reference publications	12
3 Definitions and abbreviations	14
3.1 Definitions	14
3.2 Abbreviations	19
4 Risk assessment — Hazards, risks, and control measures	20
4.1 Risk assessment	20
4.2 Infection prevention and control	20
5 Policies and procedures	20
5.1 General	20
5.2 Policies	20
5.3 Procedures	21
6 Administrative controls	21
6.1 General	21
6.1.1 Hazard controls	21
6.1.2 Personnel responsible for review and revision of policies and procedures	21
6.1.3 Incident and exposure reporting	21
6.2 Documentation	21
6.3 Audit	22
6.4 Heating, ventilation, and air conditioning considerations	22
7 Responsibilities, education, training, and credentials	22
7.1 General	22

7.2	Administrative personnel	22
7.2.1	Relevant safety committee	22
7.2.2	Education programs	24
8	Hazards and controls	24
8.1	Fire prevention	24
8.2	Fire control measures	24
8.3	Control measures for shared airway procedures	25
9	Evaluation and purchase of energy-based medical and surgical devices	25
9.1	General	25
9.1.1	Evaluation and purchasing procedures	25
9.1.2	Reusable medical devices or equipment	26
9.1.3	New equipment information	26
9.2	Manufacturer's instructions for use (IFU)	26
10	Acquisition, installation, and maintenance of energy-based medical and surgical devices	27
10.1	Acquisition	27
10.1.1	Equipment safety requirements	27
10.1.2	Documentation	27
10.1.3	Acquisition factors	27
10.1.4	Department labelling	27
10.1.5	Equipment evaluation trials	27
10.2	Installation of energy-based medical and surgical devices	28
10.3	Maintenance of energy-based medical and surgical devices	28
10.3.1	Maintenance and servicing	28
10.3.2	Operating manual	28
10.3.3	Service personnel	28
10.3.4	Inspection, testing, and maintenance	28
10.3.5	Equipment malfunctions	28
10.3.6	Reports and records	28
10.3.7	Inspection and maintenance provisions	28
10.3.8	Protective housing or beam enclosure requirements	29
11	Laser management and equipment	29
11.1	Classification of lasers	29
11.2	Risk assessment	30
11.2.1	General requirements for controlling exposure	30
11.2.2	Laser beam-related hazards, risks, and control measures	30
11.2.3	Fire control measures	31
11.2.4	Hazardous materials	32
11.3	Administrative controls	32
11.3.1	Documentation	32
11.3.2	Indications for laser system shutdown	33
11.3.3	Controlled access to laser area	34
11.3.4	Responsibilities, education, training, and credentials	34
11.4.1	Personnel verification and education	34
11.4.2	Instructor criteria and qualifications	35
11.4.3	Education and training	35
11.4.4	Laser-specific personnel	35

11.4.5	Allied health personnel — Health care personnel, observers, and trainees	38
11.5	Engineering and procedural controls	39
11.5.1	Engineering controls	39
11.5.2	Laser equipment	39
11.5.3	Laser delivery devices	40
11.5.4	Laser instruments	40
11.5.5	Warning signs	40
11.6	Acquisition, installation, and maintenance of lasers	42
11.6.1	Availability of safety equipment and accessories	42
11.6.2	Acceptance and installation of lasers including third-party systems	42
11.6.3	Maintenance of health care lasers	43
12	Electrosurgical management and equipment	43
12.1	Equipment, instruments, and accessories	43
12.1.1	Ground-referenced generators	43
12.1.2	Return electrodes	43
12.1.3	Return electrode contact quality monitoring (RECQM)	44
12.1.4	Single-use return electrodes	44
12.1.5	Capacitively coupled return electrodes	45
12.1.6	Active electrodes	46
12.2	Implanted electronic devices (IEDs)	48
12.2.1	Patient safety hazard awareness and protection	48
12.2.2	General principles	48
12.2.3	Cardiac IEDs	48
13	Plume management and equipment	49
13.1	Control measures	49
13.1.1	Ventilation	49
13.1.2	Personal protective equipment	49
13.1.3	Routine practices	49
13.2	Operational requirements	49
13.2.1	General	49
13.2.2	Central PES requirements	49
13.2.3	PES maintenance instructions	49
13.2.4	PES maintenance schedule	49
<hr/>		
Annex A (informative)	Biological effects during the use of energy-based medical and surgical devices	54
Annex B (normative)	Documentation	56
Annex C (normative)	Audits	58
Annex D (informative)	Fire risk	64
Annex E (informative)	Calculation of the NOHA	65
Annex F (normative)	Education and training of laser personnel	71
Annex G (informative)	Laser engineering controls	73
Annex H (informative)	Additional patient safety considerations when using electrosurgery	74
Annex I (informative)	Types of plume evacuation systems	75
Annex J (informative)	Typical plume capture devices and transfer tubing	81

Technical Committee on Perioperative Safety

C. Stark	City of London London, Ontario, Canada <i>Category: User Management</i>	<i>Chair</i>
B. W. McLeod	Maple Ridge, British Columbia, Canada <i>Category: Health Care Professional</i>	<i>Vice-Chair</i>
P. Nellis	Canadian Hospital Specialties Ltd. Oakville, Ontario, Canada <i>Category: Producer Interest</i>	<i>Vice-Chair</i>
A. Bialachowski	St. Joseph's Healthcare Hamilton Hamilton, Ontario, Canada <i>Category: User Management</i>	
K. Bowden	O-Two Systems Ltd. Mississauga, Ontario, Canada	<i>Non-voting</i>
L. D. Boyer	Public Health Ontario Sudbury, Ontario, Canada <i>Category: Government and/or Regulatory Authority</i>	
K. Brown	The Montreal Children's Hospital Montreal, Quebec, Canada	<i>Non-voting</i>
G. D. Burrill	Tegeror Consulting Inc. Fredericton, New Brunswick, Canada <i>Category: General Interest</i>	
S. Dain	University of Waterloo London, Ontario, Canada <i>Category: Health Care Professional</i>	
M. B. Dochow	St. Joseph's Healthcare Hamilton/McMaster University Hamilton, Ontario, Canada	<i>Non-voting</i>
B. Hunt	Ontario, Canada <i>Category: General Interest</i>	

R. Khotar	Providence Health Care Vancouver, British Columbia, Canada <i>Category: Health Care Professional</i>	
N. Z. Kolozetti	St. Michael's Hospital — Unity Health Toronto Toronto, Ontario, Canada <i>Category: Health Care Professional</i>	
L. Ladouceur	University Health Network Ottawa, Ontario, Canada <i>Category: User Management</i>	
K. LeDez	Memorial University of Newfoundland St. John's, Newfoundland and Labrador, Canada <i>Category: Health Care Professional</i>	
J. Levett	College of Physicians and Surgeons of British Columbia Vancouver, British Columbia, Canada <i>Category: Government and/or Regulatory Authority</i>	
T. Martire	GE Healthcare Mississauga, Ontario, Canada <i>Category: Producer Interest</i>	
G. J. Mendes	GCOMM Consulting Mississauga, Ontario, Canada	<i>Non-voting</i>
C. Over	Class 1 Inc. Cambridge, Ontario, Canada	<i>Non-voting</i>
F. Qureshi	Class 1 Inc. Cambridge, Ontario, Canada	<i>Non-voting</i>
K. Ratnayake	Burlington, Ontario, Canada	<i>Non-voting</i>
R. Sethi	Medtronic Vancouver, British Columbia, Canada	<i>Non-voting</i>
R. C. Shantz	Parkin Architects Ltd. Vancouver, British Columbia, Canada <i>Category: General Interest</i>	
P. J. Smalley	Technology Concepts International Elk Grove Village, Illinois, USA <i>Category: General Interest</i>	

J. Smith	Alberta Health Services Calgary, Alberta, Canada <i>Category: User Management</i>	
A. Sun	Amico Patient Care Corp. Richmond Hill, Ontario, Canada <i>Category: Producer Interest</i>	
A. Y. Yancheshmeh	BD San Diego, California, USA	<i>Non-voting</i>
O. Croxall	CSA Group Toronto, Ontario, Canada	<i>Project Manager</i>

Subcommittee on Energy-Based Medical and Surgical Devices

P. J. Smalley	Technology Concepts International Elk Grove Village, Illinois, USA	<i>Chair</i>
G. Bruce	AMT Surgical Kitchener, Ontario, Canada	<i>Vice-Chair</i>
W. Li	Fraser Health Vancouver, British Columbia, Canada	<i>Vice-Chair</i>
S. Taylor	Laser Teaching Services Canada London, Ontario, Canada	<i>Vice-Chair</i>
M. Balcom	CONMED Canada Mississauga, Ontario, Canada	
S. Bekai	University of Alberta Hospital Edmonton, Alberta, Canada	
A. Bialachowski	St. Joseph's Healthcare Hamilton Hamilton, Ontario, Canada	
C. Bonke	Alberta Health Services Calgary, Alberta, Canada	
T. El-Cheikh	London Health Sciences Centre London, Ontario, Canada	
R. Gullekson	Public Health Ontario Ottawa, Ontario, Canada	
J. Hill	Interior Health — Professional Practice Office Kelowna, British Columbia, Canada	
E. Hood	H. H. Angus & Associates Ltd. Consulting Engineers Toronto, Ontario, Canada	
R. Hribljan	Halton Healthcare Oakville, Ontario, Canada	

A. Jaber	Insight Health Tech Planning (IHP) Inc. Mississauga, Ontario, Canada	
S. K. Kelso	Shared Health Manitoba Winnipeg, Manitoba, Canada	
V. Kot	Clarion Medical Technologies Cambridge, Ontario, Canada	
A. M. Majewski	University Health Network Toronto, Ontario, Canada	
K. Monteiro	Smith + Andersen Toronto, Ontario, Canada	
M. R. Ramirez	The Hospital for Sick Children Toronto, Ontario, Canada	
J. Rao	University of Alberta Edmonton, Alberta, Canada	
E. Robertson	Operating Room Nurses Association of Canada (ORNAC) Toronto, Ontario, Canada	
M. Samiee	MB Shared Health Services Winnipeg, Manitoba, Canada	<i>Non-voting</i>
C. Stark	City of London London, Ontario, Canada	<i>Non-voting</i>
M. Y. Teo	WorkSafe BC Vancouver, British Columbia, Canada	
R. Vortman	University of Illinois Chicago – College of Nursing Springfield, Illinois, USA	
T. Zarhi	WSP Markham, Ontario, Canada	
O. Croxall	CSA Group Toronto, Ontario, Canada	<i>Project Manager</i>

Preface

This is the first edition of CSA Z7001, *Safe use of energy-based medical and surgical devices in health care*. It supersedes CSA Z386, *Safe use of lasers in health care*; CSA Z387, *Safe use of electrosurgical medical devices and systems in health care*; and CSA Z305.13, *Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings*.

CSA acknowledges that the development of this Standard was made possible, in part, by the financial support of the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Québec, Saskatchewan, and Yukon, as administered by the Canadian Agency for Drugs and Technologies in Health (CADTH).

This Standard was prepared by the Subcommittee on Energy-Based Medical and Surgical Devices, under the jurisdiction of the Technical Committee on Perioperative Safety and the Strategic Steering Committee on Health and Well-Being, and has been formally approved by the Technical Committee.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

Notes:

- 1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*
- 2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*
- 3) *This Standard was developed by consensus, which is defined by CSA Policy governing standardization — Code of good practice for standardization as “substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity”. It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*
- 4) *To submit a request for interpretation of this Standard, please send the following information to inquiries@csagroup.org and include “Request for interpretation” in the subject line:*
 - a) *define the problem, making reference to the specific clause, and, where appropriate, include a graphical image;*
 - b) *provide an explanation of circumstances surrounding the actual field condition; and*
 - c) *where possible, phrase the request in such a way that a specific “yes” or “no” answer will address the issue.*

Committee interpretations are processed in accordance with CSA Directives and guidelines governing standardization and are available on the Current Standards Activities page at standardsactivities.csagroup.org.

- 5) *This Standard is subject to review within five years from the date of publication. Suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include “Proposal for change” in the subject line:*
 - a) *Standard designation (number);*
 - b) *relevant clause, table, and/or figure number;*
 - c) *wording of the proposed change; and*
 - d) *rationale for the change.*