

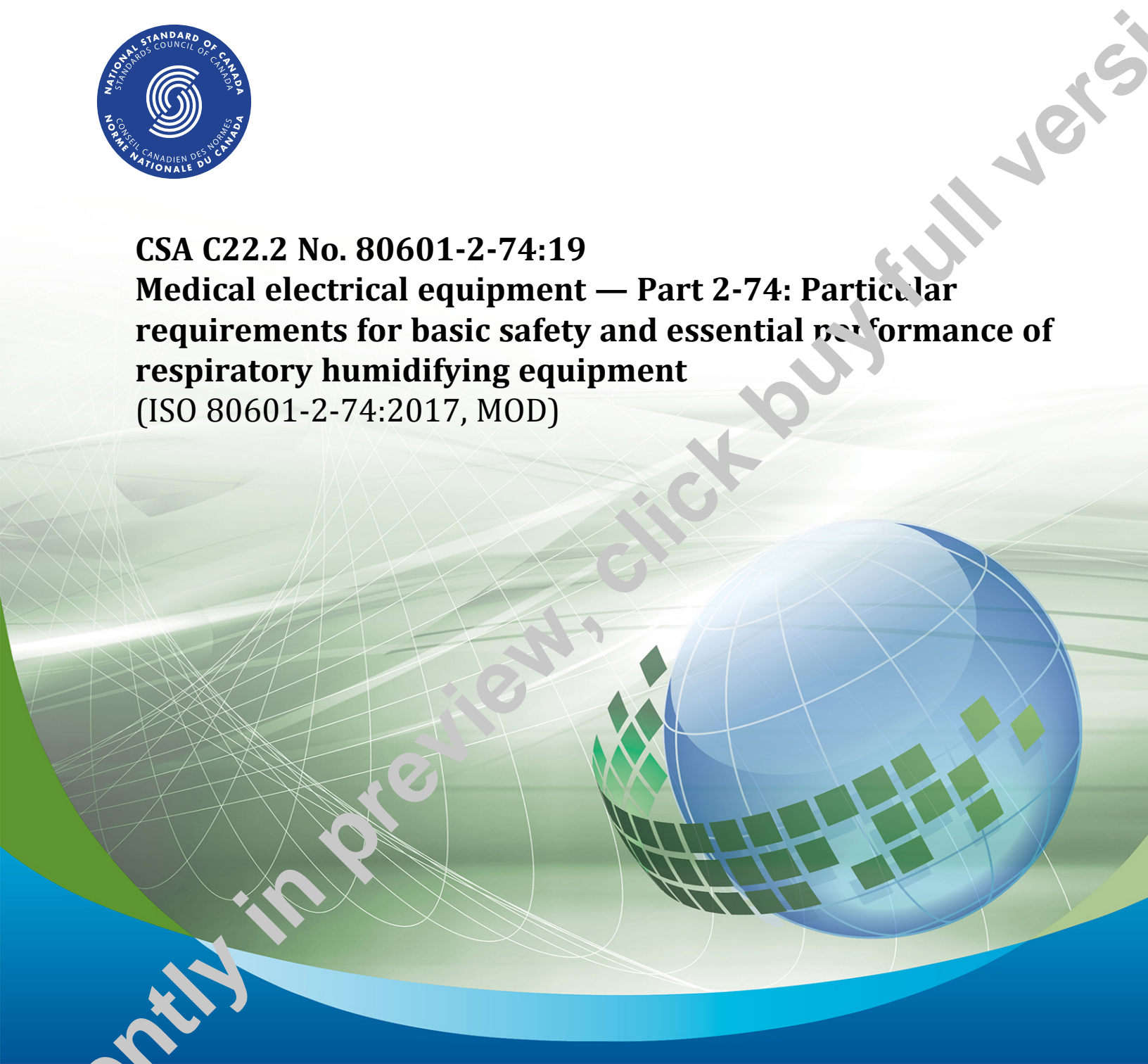


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CSA C22.2 No. 80601-2-74:19
(ISO 80601-2-74:2017, MOD)
National Standard of Canada



CSA C22.2 No. 80601-2-74:19
Medical electrical equipment — Part 2-74: Particular
requirements for basic safety and essential performance of
respiratory humidifying equipment
(ISO 80601-2-74:2017, MOD)



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CSA C22.2 No. 80601-2-74:19

Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:2017, MOD)

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Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

(ISO 80601-2-74:2017, MOD)

CSA Preface

This is the first edition of CSA C22.2 No. 80601-2-74, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*, which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 80601-2-74 (first edition, 2017-05). It replaces CAN/CSA-Z8185:08, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems* (adopted ISO 8185:2006). It is one in a series of Standards issued by CSA Group under Part II of the *Canadian Electrical Code*.

For brevity, this Standard will be referred to as “CSA C22.2 No. 80601-2-74” throughout.

This Standard is intended to be used in conjunction with CAN/CSA-C22.2 No. 60601-1:14, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance* (adopted IEC 60601-1:2005, including Amendment 1:2012, with Canadian deviations).

This Standard is considered suitable for use for conformity assessment within the stated scope of the Standard.

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Consumer and Commercial Products, under the jurisdiction of the CSA Strategic Steering Committee on Requirements for Electrical Safety, and has been formally approved by the Technical Committee. Due to the medical content of this Standard, it was also approved by the CSA Technical Committee on Application of Electricity in Health Care, under the jurisdiction of the CSA Strategic Steering Committee on Health Care Technology & Systems.

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.

Interpretations: The Strategic Steering Committee on Requirements for Electrical Safety has provided the following direction for the interpretations of standards under its jurisdiction: “The literal text shall be used in judging compliance of products with the safety requirements of this Standard. When the literal text cannot be applied to the product, such as for new materials or construction, and when a relevant CSA committee interpretation has not already been published, CSA Group’s procedures for interpretation shall be followed to determine the intended safety principle.”

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- a) Standard designation (number);
- b) relevant clause, table, and/or figure number;
- c) wording of the proposed change; and
- d) rationale for the change.

Canadian deviations

The following deviations are intended to meet product requirements and to align with the *Canadian Electrical Code, Part I*.

International Standard ISO 80601-2-74:2017 (first edition) forms the basis for CSA C22.2 No. 80601-2-74, which contains the following deviations in addition to those shown in CAN/CSA-C22.2 No. 60601-1:14.

[Replace all references to “IEC 60601-1” with “CAN/CSA-C22.2 No. 60601-1”]

201.1 Scope, object and related standards

201.1.1 *Scope

[Add the following paragraph]

This Standard applies to ME EQUIPMENT and ME SYSTEMS that are intended to be installed or used in accordance with CSA C22.1, *Canadian Electrical Code, Part I*.

201.2 Normative references

[Add the following to the list of IEC references]

Any reference to International Standards that are adopted as National Standards of Canada subsequent to the publication of CSA C22.2 No. 80601-2-74 shall be replaced by the relevant National Standard of Canada.

[Delete the following entry]

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

[Add the following note]

NOTE 1A: *Symbol for use in the labelling of medical devices containing phthalates can refer to the requirements of EN 15986-1:2011.*

[Add the following]

Any reference in CSA C22.2 No. 80601-2-74 to International Standards that have been adopted as National Standards of Canada shall be replaced by the relevant National Standard of Canada. Where reference is made to CSA Group publications, such reference shall be considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following publications, and the years shown indicate the latest editions available at the time of printing:

CSA Group

C22.1-18

Canadian Electrical Code, Part I

CAN/CSA-C22.2 No. 0-10 (R2015)

General requirements — Canadian Electrical Code, Part II

CAN/CSA-C22.2 No. 60601-1:14

Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

201.4 General requirements

[Add the following clause]

201.4.1A General

General requirements applicable to these products are provided in CAN/CSA-C22.2 No. 0.

Bibliography

[Add the following entry]

[50A] EN 15986:2011, *Symbol for use in the labelling of medical devices -- Requirements for labelling of medical devices containing phthalates*

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Medical electrical equipment —
Part 2-74:
Particular requirements for basic
safety and essential performance of
respiratory humidifying equipment

Appareils électromédicaux —

Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire





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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*.

This first edition of ISO 80601-2-74 cancels and replaces the third edition of ISO 8185:2007^[1], which has been technically revised. It also incorporates the third edition of IEC 60601-1, including amendment 1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, including amendment 1, the second edition of IEC 60601-1-8, including amendment 1, and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

- extending the scope to include the HUMIDIFIER and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the HUMIDIFIER, and thus not only the HUMIDIFIER itself;
- identification of ESSENTIAL PERFORMANCE for a HUMIDIFIER and its ACCESSORIES;
- modification of the humidification test PROCEDURE and the disclosure of humidification performance;

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- more fully dimensioning the removable temperature sensor port and sensor;
- removal of requirements for so-called “bubble” HUMIDIFIERS as a separate document is being prepared for them^[8];

and the following additions:

- requirements for mechanical strength (via IEC 60601-1-11);
- new symbols;
- requirements for a HUMIDIFIER as a component of an ME SYSTEM;
- requirements for ENCLOSURE integrity (water ingress via IEC 60601-1-11);
- requirements for cleaning and disinfection PROCEDURES (via IEC 60601-1-11);
- requirements for BIOCOMPATIBILITY;
- requirements for USABILITY.

Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on PATIENTS in HOME HEALTHCARE ENVIRONMENT and in healthcare facilities. HUMIDIFIERS are used to raise the water content of gases delivered to PATIENTS. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of PATIENTS whose upper airways have been bypassed. Inadequate humidity at the PATIENT-CONNECTION PORT can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway^{[19][20]}. Heat is employed to increase the water output of the HUMIDIFIER.

In addition, many HUMIDIFIERS utilize heated BREATHING TUBES in order to increase operating efficiency and reduce water loss (condensate) as well as heat loss in the BREATHING TUBE. Ventilator and anaesthesia BREATHING TUBES in common use might not withstand the heat generated by HUMIDIFIERS and BREATHING TUBE heating mechanisms.

Many HUMIDIFIER MANUFACTURERS use off-the-shelf electrical connectors for their electrically heated BREATHING TUBES. However, since different MANUFACTURERS have used the same electrical connector for different power outputs, electrically heated BREATHING TUBES can be physically, but not electrically, interchangeable. Use of improper electrically heated BREATHING TUBES has caused overheating, circuit melting, PATIENT and OPERATOR burns and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between HUMIDIFIERS and BREATHING TUBES produced by different MANUFACTURERS.

Since the safe use of a HUMIDIFIER depends on the interaction of the HUMIDIFIER with its many ACCESSORIES, this document sets total system performance requirements up to the PATIENT-CONNECTION PORT. These requirements are applicable to ACCESSORIES such as BREATHING TUBES (both heated and non-heated), temperature sensors and equipment intended to control the environment within these BREATHING TUBES.

Humidification can also be used by respiratory support ME EQUIPMENT to increase PATIENT comfort and compliance with the therapy. Examples are obstructive sleep apnoea and nasal high flow therapy equipment. The HUMIDIFICATION OUTPUT requirements of such ME EQUIPMENT is less demanding as the PATIENT'S upper airway is not bypassed.

HUMIDIFIERS are commonly used with air and air-oxygen mixtures and any HUMIDIFIER should be able to operate with these gases. Care should be taken if using other gas mixes such as helium-oxygen mixtures, as the different physical and thermal properties of these gases may disturb the operation of the HUMIDIFIER.

In this document, the following print types are used:

- Requirements and definitions: roman type;
- *Test specifications: italic type;*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- Terms defined in CLAUSE 3 of the general standard, in this document or as noted: small capitals;

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In referring to the structure of this document, the term

- “clause” means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Medical electrical equipment —

Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1 applies, except as follows.

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a HUMIDIFIER, also hereafter referred to as ME EQUIPMENT, in combination with its ACCESSORIES, the combination also hereafter referred to as ME SYSTEM.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a HUMIDIFIER where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER.

EXAMPLE 1 Heated BREATHING TUBES (heated-wire BREATHING TUBES) or ME EQUIPMENT intended to control these heated BREATHING TUBES (heated BREATHING TUBE controllers).

NOTE 1 Heated BREATHING TUBES and their controllers are ME EQUIPMENT and are subject to the requirements of IEC 60601-1.

NOTE 2 ISO 5367 specifies other safety and performance requirements for BREATHING TUBES.

This document includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy PATIENTS.

NOTE 3 A HUMIDIFIER can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the HUMIDIFIER.

EXAMPLE 2 Heated HUMIDIFIER incorporated into a critical care ventilator where ISO 80601-2-12^[12] also applies.

EXAMPLE 3 Heated HUMIDIFIER incorporated into a homecare ventilator for dependent PATIENTS where ISO 80601-2-72^[14] also applies.

EXAMPLE 4 Heated HUMIDIFIER incorporated into sleep apnoea therapy equipment where ISO 80601-2-70^[13] also applies.

This document also includes requirements for an ACTIVE HME (HEAT AND MOISTURE EXCHANGER), ME EQUIPMENT which actively adds heat and moisture to increase the humidity level of the gas delivered from the HME to the PATIENT. This document is not applicable to a passive HME, which returns a portion of the expired moisture and heat of the PATIENT to the respiratory tract during inspiration without adding heat or moisture.