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**Dentistry — Portable dental  
equipment for use in non-permanent  
healthcare environment —**

**Part 1:  
General requirements**

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*Médecine bucco-dentaire — Matériel dentaire portatif utilisable dans  
des environnements de soins de santé non permanents —  
Partie 1: Exigences générales*

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# Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Classification</b> .....	<b>2</b>
4.1 General.....	2
4.2 For electrically operated devices.....	2
4.3 According to intended use environment.....	2
4.4 According to supply sources.....	3
4.5 According to transport conditions.....	3
<b>5 Requirements</b> .....	<b>3</b>
5.1 General.....	3
5.2 Transport requirements.....	3
5.2.1 General.....	3
5.2.2 Grips or other handling devices.....	4
5.2.3 Maximum mass.....	4
5.2.4 Maximum dimensions.....	4
5.2.5 Environmental exposure.....	4
5.2.6 Impact.....	4
5.2.7 Drop.....	4
5.2.8 Vibration.....	4
5.2.9 Particulate and liquid ingress during transport.....	4
5.2.10 Flammability.....	5
5.3 Assembly and disassembly requirements.....	5
5.4 Utility requirements.....	5
5.5 Operational requirements.....	5
5.5.1 Ambient operating conditions.....	5
5.5.2 Usability.....	5
5.5.3 Applied parts not intended to supply heat to a patient.....	5
5.5.4 Cleaning and disinfection of external surfaces.....	6
5.5.5 Noise.....	6
<b>6 Sampling</b> .....	<b>6</b>
<b>7 Measurement and test methods</b> .....	<b>6</b>
7.1 Visual inspection of the device.....	6
7.2 Visual inspection of the documentation.....	6
<b>8 Manufacturer's instructions</b> .....	<b>6</b>
8.1 General.....	6
8.2 Instructions for use.....	7
8.3 Technical description.....	7
<b>9 Marking</b> .....	<b>7</b>
9.1 Marking on the equipment.....	7
9.2 Marking of packaging.....	7
<b>10 Packaging</b> .....	<b>8</b>
<b>Annex A (informative) Applicable testing methodology from IEC 60601-1:2005/Amd 1:2012</b> .....	<b>9</b>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 23402 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

Transportable dental equipment is used by dental professionals to provide care to patients in a variety of settings. Because the intended use applications and intended means for transporting such equipment vary considerably, a wide variety of transportable dental equipment is commercially available. For example, certain transportable equipment is designed and constructed to be carried or rolled on its own wheels between rooms within a healthcare facility, while other transportable dental equipment is made to be folded and packed to carry over terrain which can be rugged and used in transient dental care settings which can have only limited shelter and utility services.

Transportable equipment that can be moved from one location to another while being carried by one or more persons is referred to as portable equipment. The term, portable equipment, applies to equipment that can be carried from room to room in a given facility or to remote parts of the world. This document focuses on portable dental equipment which is specifically designed and constructed to be transported between non-clinical environments and used by dental professionals to provide dental care in such settings, including temporary field clinics.

Such portable dental equipment for use in non-permanent healthcare environments enables dental professionals to provide a high standard of care to patients who do not have access to, or are not able to, travel to traditional health care facilities. Settings in which this equipment is commonly used include military field environments, humanitarian aid field clinics, public health outreach clinics, patient residences, long-term care facilities, prisons, schools and workplaces.

A number of trends in health care have driven increased utilization of portable dental equipment in non-permanent healthcare environments. Military forces use portable dental equipment in support of mobilized forces or for humanitarian outreach. A variety of government and non-government organizations are increasingly providing humanitarian dental care to underserved populations and populations affected by disasters. Civilian health care workers are also increasingly providing dental services to a growing population who are simply unable to visit traditional dental clinics due to age, disability, or income. Academic and research bodies regularly conduct dental education programs, particularly at external/off-site locations (including dentistry, dental hygiene, dental assisting).

The transport and end-use conditions for portable dental equipment used in non-permanent healthcare environments drive certain unique requirements which generally do not apply to portable, mobile or stationary dental equipment used in traditional dental clinics or hospitals. Because portable equipment used in non-permanent healthcare environments is intended to be moved between venues, and in some cases carried over rugged terrain or in inclement conditions, it needs to be designed and constructed to be safely transported by humans without damage, be efficiently assembled and disassembled, and deliver reliable service at the point of use. Special consideration is given to the austerity of the environment in which the equipment can be used and the availability and quality of utility supplies (such as electrical power, water, compressed air). In order for the equipment to be sufficiently portable and capable of operating in extreme conditions, certain requirements for dental equipment intended for use in traditional clinical settings may not be practical and is to be reconsidered for portable dental equipment for use in non-permanent healthcare environments. There can also be unique safety and infection control concerns to consider.

This document is one in a series with the objective of standardizing requirements for portable dental equipment for use in non-permanent healthcare environments.

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# Dentistry — Portable dental equipment for use in non-permanent healthcare environment —

## Part 1: General requirements

### 1 Scope

This document specifies general requirements and test methods for portable dental equipment for use in non-permanent healthcare environments.

Portable dental equipment within the scope of this document includes portable dental units, portable patient chairs, portable operator's stools, portable operating lights, portable suction source equipment, portable air compressors and other portable dental equipment in instances where these devices are designed and constructed to be transported for use in non-permanent healthcare environments.

NOTE Particular requirements for specific types of portable dental equipment for use in non-permanent healthcare environments are specified in subsequent parts of this document.

This document does not apply to stationary dental equipment, wearable equipment (such as headlamps and loupes), mobile dental equipment or portable dental equipment that is not intended to be used in non-permanent healthcare environments or not designed to be disassembled, folded or packed for human transport between non-permanent healthcare environments. Also, requirements for stationary dental equipment that can be installed in a dental mobile medical facility (e.g. vehicular or containerized mobile dental clinic) are not considered in this document.

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 4180:2019, *Packaging — Complete, filled transport packages — General rules for the compilation of performance test schedules*

ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

IEC 60529:1989/Amd 1:1999, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005/Amd 1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005/Amd 1:2012, ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1 dental equipment

device or combination of devices for use in providing dental treatment and/or associated procedures, including machines, apparatus, furniture and accessories

#### 3.2 portable dental equipment

transportable dental equipment intended to be moved from one location to another while being carried by one or more persons

#### 3.3 non-permanent healthcare environment

setting for temporarily providing dental or medical treatment

#### 3.4 transport case

packaging container intended to be used for transport and for protection of the *portable dental equipment* (3.2)

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### 4 Classification

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#### 4.1 General

The following classifications pertain to electrical characteristics, end-use facility provisions, supply provisions and portability considerations applicable to portable dental equipment for use in non-permanent healthcare environments.

#### 4.2 For electrically operated devices

If the equipment is electrically operated, classification according to IEC 60601-1:2005/Amd 1:2012 and 80601-2-60 shall apply.

#### 4.3 According to intended use environment

Portable dental equipment for use in non-permanent healthcare environments is classified according to the intended use environment as follows.

##### a) For indoor use

Equipment of this class is intended to be used in indoor environments, such as residential settings, long-term care facilities (e.g. nursing homes, assisted living communities), offices, schools, convention centres, corrections facilities (e.g. prisons), and other permanent building facilities providing protection against weather elements.



- b) For use in exposed settings

Equipment of this class is intended to be used in outdoor environments where only rudimentary shelter, such as a tent or tarpaulin, can be available for limiting exposure to weather elements. Examples include military or humanitarian field operations.

#### 4.4 According to supply sources

Portable dental equipment for use in non-permanent healthcare environments is classified according to the supply sources (e.g. electrical power, water, compressed air, suction) required to operate the equipment as follows.

- a) Externally supplied source: equipment of this class requires connection to a specified supply source during use.
- b) Self-contained source: equipment of this class relies on a self-contained, internally supplied source (e.g. battery, air compressor, suction source equipment, water reservoir) and does not require connection to an external supply source during use.

Different classifications can apply to different supplies for a given piece of equipment. For example, the equipment can have a self-contained source for compressed air but require an externally supplied source for electrical power.

#### 4.5 According to transport conditions

Portable dental equipment for use in non-permanent healthcare environments is classified according to transport conditions as follows.

- a) Limited outdoor exposure and limited carrying distance: equipment of this class is intended to be transported under conditions which limit outdoor exposure and carrying distance (e.g. carried from a vehicle into a nearby building).
- b) Rugged outdoor exposure and extended carrying distance: equipment of this class is intended to be transported under conditions which can include exposure to extreme outdoor conditions and be carried over extended distances (e.g. carried for several kilometres over rugged terrain in inclement weather).

## 5 Requirements

### 5.1 General

IEC 60601-1:2005/Amd 1:2012 and IEC 80601-2-60 shall apply regardless of whether the equipment is a medical device or an ME device.

NOTE [Annex A](#) includes a list of tests associated with IEC 60601-1:2005/Amd 1:2012 which often apply to portable dental equipment for use in non-permanent healthcare environments.

### 5.2 Transport requirements

#### 5.2.1 General

The requirements in this subclause shall apply to the equipment when packed for transport according to the manufacturer's instructions. Any storage/transport case or other devices provided by the manufacturer to be used when transporting the equipment shall be included. Any disassembly, adjustment or other measures specified by the manufacturer before transporting the equipment shall be performed prior to evaluating these requirements.