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

Part 1: General requirements

Médecine bucco-dentaire — Matériel dentaire portatif utilisable dans des environnements de soins de santé non permanents —

Partie 1: Exigences générales

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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).

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).

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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.

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.

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 healthcare 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.

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)

4 Classification

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.

5.2.2 Grips or other handling devices

When packed for transport, the equipment shall have grips or other handling devices which permit the equipment to be transported in accordance with IEC 62366-1 with consideration for its classification according to transport conditions in 4.5 and the number of persons intended to carry the equipment per 8.3. Compliance shall be checked in accordance with 7.1 and 7.2.

5.2.3 Maximum mass

The mass of each module of equipment when packed for transport shall not exceed 20 kg if the transport module is intended to be carried by one person. If a transport module is intended to be carried by multiple people (as indicated by the number of persons intended to carry the equipment per 8.3), the mass to be carried by each person shall not exceed 20 kg. Compliance shall be checked in accordance with 7.2.

5.2.4 Maximum dimensions

For portable dental equipment classified for indoor use per 4.3, each equipment module when packed for transport shall be able to fit through a door having a width of 0,8 m and a height of 2,0 m. Compliance shall be checked in accordance with 7.2.

NOTE This requirement is compatible with the minimum door sizes specified in the International Residential Code (IRC R311.4.2 Door Type and Size) and International Building Code (IBC 1008.1.1 Size of doors).

5.2.5 Environmental exposure

When packed for transport, each equipment module shall withstand exposure to the minimum and maximum storage/transport temperatures, atmospheric pressure (if applicable), and relative humidity levels specified by the manufacturer without malfunction and/or unacceptable risk when tested according to 7.2.

5.2.6 Impact

When packed for transport, IEC 60601-1:2005/Amd 1:2012, 15.3.3, shall apply to each equipment module.

5.2.7 Drop

When packed for transport, each equipment module shall withstand a free fall drop without malfunction and/or unacceptable risk when tested in accordance with IEC 60601-1:2005/Amd 1:2012 15.3.4.2.

5.2.8 Vibration

When packed for transport, each equipment module shall withstand vibration without malfunction and/or unacceptable risk when tested in accordance with IEC 60601-1:2005/Amd 1:2012, 15.3.4.2.

5.2.9 Particulate and liquid ingress during transport

5.2.9.1 General

This requirement applies to equipment which has components which can malfunction or lead to an unacceptable risk due to particulate or liquid ingress.

5.2.9.2 For portable dental equipment intended for use in exposed settings per 4.3

If the portable dental equipment is packed with the independent transport case regardless of the transport condition specified in ISO 4180:2009, Clause 11, the transport case and the enclosure(s) of the equipment shall conform to IP55 per IEC 60529:1989/Amd 1:1999/Amd 2:2013, Table 2 and Table 3.

5.2.9.3 For portable dental equipment intended for indoor use per 4.3

If the portable dental equipment is packed with the independent transport case and the portable dental equipment is intended to be transported under the condition level 1 or level 2 as specified in ISO 4180:2009, Clause 11, the transport case shall conform to IP55 and the enclosure(s) of the equipment shall conform to IP21 per IEC 60529:1989/Amd 1:1999/Amd 2:2013, Table 2 and Table 3.

5.2.9.4 If the portable dental equipment is intended to be transported under the condition level 3 as specified in ISO 4180:2009, Clause 11, the transport case and/or the enclosure(s) of the equipment shall conform to IP21 per IEC 60529:1989/Amd 1:1999/Amd 2:2013, Table 2 and Table 3.

5.2.10 Flammability

The equipment shall comply with the requirements for fire enclosures of medical-electrical equipment according to IEC 60601-1:2005/Amd 1:2012.

5.3 Assembly and disassembly requirements

The equipment should be designed in such a way that a safety check is possible without measurements. Electrical equipment should contain a self-test for electrical safety of the device. Compliance shall be checked in accordance with 7.2.

5.4 Utility requirements

If applicable, the manufacturer shall specify the electrical mains supply requirements of the equipment, including the voltage, frequency and power requirements. The manufacturer shall also specify the safety requirements for the power source, which may include, for example, fuses/circuit breakers, residual-current device (RCD), protective earth connection. If the equipment is designed to be electrically powered by battery, the manufacturer shall specify the type of battery or batteries which are required. Compliance shall be checked in accordance with 7.2.

5.5 Operational requirements

5.5.1 Ambient operating conditions

The equipment shall operate under the range of temperature and atmospheric pressure specified by the manufacturer in the technical description.

5.5.2 Usability

The usability requirements of IEC 62366-1 shall apply. The manufacturer shall address in a usability engineering process the risk of poor usability, including those associated with identification, marking and documents.

5.5.3 Applied parts not intended to supply heat to a patient

If the equipment is medical electrical equipment, for the patient side of portable dental equipment in normal and single fault condition the limits of IEC 60601-1:2005/Amd 1:2012, Table 24, shall apply. If the surface temperature of an applied part exceeds 43 °C, the maximum temperature shall be disclosed in the instructions for use. The clinical effects with respect to characteristics, such as body surface, maturity of patients, medications being taken or surface pressure, shall be determined and documented in the risk management file. Where 43 °C is not exceeded, no justification is required. Compliance shall be checked in accordance with 7.2.

5.5.4 Cleaning and disinfection of external surfaces

Manufacturers shall provide instructions for cleaning and disinfecting external equipment surfaces and connection interfaces. These instructions shall include guidance on appropriate chemical agents to use as well as cautionary notes regarding chemical agents that can damage the equipment.

All materials used for external and touchable surfaces of the portable dental equipment and the transport case which can be contaminated by aerosols, splatters and droplets in normal use, shall be capable of cleaning and disinfection without deterioration or discoloration when tested in accordance with ISO 21530 using the relevant cleaning agent(s) and disinfectant agent(s) recommended by the manufacturer.

Testing shall be carried out in accordance with ISO 21530.

NOTE As portable dental equipment for use in non-permanent healthcare environments is intended to be moved between treatment sites, and surfaces and connection interfaces on the equipment are likely to be touched than on stationary equipment, which can increase the probability of exposure to contamination for patients, operators and those involved in transporting the equipment. Similarly, because there can be less control over environmental conditions and available utilities as well as more frequent disassembly and reassembly of portable dental equipment for use in non-permanent healthcare environments, there can be an increased risk of contamination in the compressed air, water and/or suction systems, as well as an increased risk of mould contamination associated with prolonged storage and transport.

5.5.5 Noise

IEC 60601-1:2005/Amd 1:2012, 9.6.2.1, shall apply.

6 Sampling

All type tests shall be made on one representative sample of the equipment.

7 Measurement and test methods

7.1 Visual inspection of the device

Visually inspect the device to determine conformity with the requirements.

7.2 Visual inspection of the documentation

Visually inspect product documentation to determine conformity with the requirements.

8 Manufacturer's instructions

8.1 General

Printed instructions shall be durable and readable as necessary for their storage, transport and use environment. Printed instructions shall be located in a specific, obvious and secure storage location provided directly on/in the equipment or transport case to enhance storage and avoid loss. Whenever possible, the printed instructions shall be augmented, not replaced, by downloadable electronic instructions. Markings directly on the equipment shall inform users of the need to review the instructions.

EXAMPLES

— "Caution - consult accompanying documents"

— Graphical symbol ISO 7000-0434A, Caution

— Graphical symbol ISO 7000-1641, Operator's manual; operating instructions

— Graphical symbol ISO 7000-3500, Electronic instructions for use

— Graphical symbol ISO 7010-M002, Refer to instruction manual/booklet

8.2 Instructions for use

The following information shall be provided by the manufacturer in the instructions for use, if applicable:

a) instructions for unpacking and setting up the equipment after transport and before use;

b) instructions for disassembling and packing the equipment for transport or storage;

c) environmental conditions during use, including upper and lower limits for temperature, humidity, pollution, and atmospheric pressure;

d) environmental conditions during transport, including upper and lower limits for temperature, humidity, pollution, and atmospheric pressure;

e) supply requirements for electrical power (see 5.4);

f) maximum surface temperature of applied part if in excess of 43 °C (see 5.5.3);

g) cleaning and disinfection instructions for external equipment surfaces and connection interfaces (see 5.5.4.1);

h) Functional use and visual safety check prior to use;

i) troubleshooting guidance;

j) field service guidance.

8.3 Technical description

The following information shall be provided by the manufacturer in the technical description:

a) classification of the equipment (according to Clause 4);

b) mass and dimensions (length, width, height) of the equipment in its configurations for use and transporting, including any transport case (if the equipment is intended to be transported in separate modules, the mass and dimensions of each transport module shall be provided by the manufacturer);

c) number of persons intended to carry the equipment (per 5.2.2);

d) ambient operating condition (per 5.5.1).

9 Marking

9.1 Marking on the equipment

The usability requirements of IEC 60601-1:2005/Amd 1:2012, 12.2, shall apply, regardless of whether the equipment is a medical device or an ME device. The manufacturer shall address in a usability engineering process the risk of poor usability, including those associated with identification, marking, documents and any symbols not found in ISO 9687 and ISO 15223-1.

9.2 Marking of packaging

All packages shall be marked on the outside to facilitate the assembly and installation.

IEC 60601-1:2005/Amd 1:2012, 7.2.17, applies, regardless of whether the equipment is a medical device or an ME device.

Compliance is checked by visual inspection.

10 Packaging

Portable dental equipment shall be packaged for delivery from the manufacturer at the discretion of the manufacturer in such a way that no damage can occur during anticipated transport conditions.

IEC 60601-1:2005/Amd 1:2012, 7.2.17, applies, regardless of whether the equipment is a medical device or an ME device.

NOTE Requirements for enclosures provided for transporting the equipment between use locations after original delivery from the manufacturer are specified in 5.2.

