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Dentistry — Central suction source equipment

Médecine bucco-dentaire — Systèmes d'aspiration centrale

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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).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment.*

This second edition cancels and replaces the first edition (ISO 10637:1999), which has been technically revised.

The main changes compared to the previous edition are as follows:

— clarification of the scope;

— addition of the classification according to the air flow rate (Type 1, Type 2 or Type 3);

— addition of measurement and test methods;

— addition of diagrams for different suction source equipment in the Annexes.

Introduction

Dental suction systems evacuate solids, liquids, aerosols and gases from the oral cavity and immediate surrounding area for the purpose of improving operating effectiveness and efficiency during oral treatment procedures and limiting the contamination of the immediate environment. In central suction systems the equipment that generates suction and performs other supporting functions is located in a central location outside of the dental treatment room to isolate this equipment from the immediate vicinity of patient treatment and often to provide suction to multiple treatment rooms.

A central suction system consists of four basic elements:

1) dental treatment room suction components (e.g. dental unit suction system);

2) facility suction pipeline;

3) central suction source equipment;

4) exhaust pipeline.

The central suction source equipment consists of all the components from the facility suction pipeline connection point (i.e. discharge end of the facility suction pipeline) to the exhaust pipeline connection point (i.e. inlet to the exhaust pipeline). In addition to the equipment that generates air flow, centrally located amalgam separators and air water separators (if present) are also component parts of the central suction source equipment.

Dentistry — Central suction source equipment

1 Scope

This document specifies requirements and test methods for stationary, electrically powered central suction source equipment, including centrally located amalgam separators and air water separators.

It also specifies requirements for information to be supplied by the manufacturer on the performance, installation, operation and maintenance of the central suction source equipment as part of the complete dental suction system.

This document specifies requirements for central suction source equipment used to provide vacuum pressure and flow at the facility pipeline connection point.

This document does not apply to portable suction source equipment, air/water venturi suction source equipment, or to suction source equipment located in the treatment room. It also does not apply to suction source equipment used for life support or for scavenging halogenated anaesthetic gases.

This document does not include requirements for facility and exhaust piping systems or treatment room equipment.

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 5167-1, *Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full — Part 1: General principles and requirements*

ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 7494-2, *Dentistry — Dental units — Part 2: Air, water, suction and wastewater systems*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 11143, *Dentistry — Amalgam separators*

ISO 29463-1:2017, *High efficiency filters and filter media for removing particles from air — Part 1: Classification, performance, testing and marking*

IEC 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements*

IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Part 6-2: Generic standards — Immunity standard for industrial environments*

IEC 61000-6-3, *Electromagnetic compatibility (EMC) — Part 6-3: Generic standards — Emission standard for residential, commercial and light-industrial environments*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 7494-2 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
air separator
apparatus which separates liquids and solids from the *suction system air flow* (3.11)

3.2
cannula connector
component at the inlet end of the dental suction operating hose, which joins the cannula to the operating hose

3.3
central suction source equipment
assembly of components located between the *facility suction pipeline* (3.8) connection point and the *exhaust pipeline connection point* (3.7) which, when activated creates reduced air pressure capable of inducing an air flow at the *facility suction pipeline connection point* (3.9)

Note 1 to entry: Centrally located amalgam separators and air water separators are both component parts of the central suction source equipment.

3.4
central suction system
assembly of equipment, including dental treatment room suction equipment, *facility suction pipeline* (3.8), *central suction source equipment* (3.3) and *exhaust pipeline* (3.6) which can induce an air flow to evacuate solids, liquids, aerosols and gases from the oral cavity and immediate surrounding area during oral treatment procedures

3.5
dental unit suction system
dental suction system components that are part of the dental unit

Note 1 to entry: When a dental unit suction system is an element of a *central suction system* (3.4), it extends from the atmospheric inlet to the dental unit suction source connection point [i.e. the connection to the *facility suction pipeline* (3.8)].

3.6
exhaust pipeline
grouping of pipes and fittings used to carry the air and other gases with entrained substances discharged by the *central suction source equipment* (3.3)

3.7
exhaust pipeline connection point
port on the *central suction source equipment* (3.3) for connection to the *exhaust pipeline* (3.6)

3.8
facility suction pipeline
grouping of pipes and fittings that connect the dental unit suction system to the *central suction source equipment* (3.3)

3.9
facility suction pipeline connection point
location within the *central suction source equipment* (3.3) where connection is made to the *facility suction pipeline* (3.8)

3.10
suction machine
central suction source equipment (3.3) component that produces pressure lower than atmospheric

EXAMPLE Pump, side channel blower.

3.11
suction system air flow
movement of air along a pipeline induced by a pressure difference

4 Classification

4.1 Classification according to separation of solids and liquids from air flow

Dental suction systems are classified according to the location where liquids and solids carried by the suction system air flow are separated from the air flow.

A schematic diagram showing the three types of suction system is shown in Figure A.1.

a) Dry-suction system

Suction system in which liquids and solids are removed from the air flow before the air enters the facility suction pipeline. A schematic diagram of dry suction system for central suction source equipment is shown in Figure B.1.

b) Semi-dry suction system

Suction system in which liquids and solids are removed from the air flow after the flow passes through the facility suction pipeline and before the flow enters the suction machine. A schematic diagram of semi-dry suction system for central suction source equipment is shown in Figure C.1.

c) Wet-suction system

Suction system in which liquids and solids are removed from the air flow after passing through the suction machine. A schematic diagram of wet suction system for central suction source equipment is shown in Figure D.1.

4.2 Classification according to air flow rate

Dental suction systems are classified according to the minimum air flow rate intended to be produced by the suction system under normal use conditions.

NOTE 1 This classification is intended to facilitate communication between parties involved in the specification, design, procurement, installation, operation and maintenance of suction systems.

NOTE 2 Reference conditions for normal litres (NL) are specified in 7.1.2.

— Type 1: Suction system intended to supply a minimum air flow rate of 250 NL/min at one suction cannula connector on the dental unit.

NOTE 3 Type 1 suction systems are often commercially referred to as “High-volume suction systems” in certain regions.

— Type 2: Suction system intended to supply a minimum air flow rate of 170 NL/min at one suction cannula connector on the dental unit.

— Type 3: Suction system intended to supply a minimum air flow rate of 90 NL/min at one suction cannula connector on the dental unit.

NOTE 4 Type 3 suction systems are often commercially referred to as “Medium-volume suction systems” in certain regions.

These specified classifications do not restrict other specifications for minimum air flow rate that may be deemed appropriate in certain applications, regions or markets. In instances where none of the specified classifications are applicable, an alternative value may be specified for the minimum air volume flow rate to be supplied by the manufacturer.

NOTE 5 There are many factors that affect whether the performance target is achieved; some are specific to the central suction source equipment and others are not. The target performance indicated for each of these Types of suction systems is intended to assist in communicating the performance requirements of a complete dental suction system when installed in a particular facility.

5 Requirements

5.1 Characterization of central suction source equipment flow rate performance

Manufacturers of central suction source equipment shall measure and report the flow rate of their products at various pressures. The report shall be in the form of a performance curve or table.

Measurements shall be carried out in accordance with 7.2.1.

5.2 Maximum suction pressure

The maximum suction pressure under no air flow conditions shall not exceed the value specified by the central suction source equipment manufacturer when the pressure limiting valve (if included as a part of the central suction source equipment) is operating as intended by the manufacturer.

Testing shall be carried out in accordance with 7.2.2.

If the maximum potential suction pressure under no air flow conditions, and without the mitigating effects of the pressure limiting valve, exceeds 40 kPa, the manufacturer shall include in “Technical Description” how to implement measures to prevent the static suction pressure at the suction machine connection point from exceeding 40 kPa under no air flow conditions when the central suction source equipment is installed in a central suction system.

Testing shall be carried out in accordance with 7.2.3.

5.3 Safety requirements

For central suction source equipment, the requirements of IEC 60335-1 shall apply.

Testing shall be carried out in accordance with IEC 60335-1.

5.4 Electromagnetic compatibility (EMC)

For electromagnetic compatibility (EMC), the following requirements shall apply.

Immunity requirements of IEC 61000-6-2 shall apply.

Emission requirements of IEC 61000-6-3 shall apply.

Testing shall be carried out in accordance with IEC 61000-6-2 and IEC 61000-6-3.

5.5 Other requirements as applicable

5.5.1 Amalgam separator

If the central suction source equipment includes an amalgam separator as an integral part, it shall conform to ISO 11143.

Testing shall be carried out in accordance with ISO 11143.

5.5.2 Bacterial filter

If included, the bacterial filter shall be rated to restrict the passage of contaminants larger than 0,3 µm and have an efficiency of at least 99,95 %. The central suction source equipment manufacturer shall provide maintenance instructions and schedule for the bacterial filter.

Testing shall be carried out in accordance with 7.3.

6 Sampling

One representative sample of the central suction source equipment being tested shall be selected.

7 Measurement and test methods

7.1 General

7.1.1 General provisions for tests

All tests described in this clause are conformance tests made on one representative sample. Unless otherwise specified, do not repeat tests.

Where a component or equipment part has specified ratings exceeding those appropriate to its use in the equipment, it may be tested for such a wider range.

Conformity is considered to be achieved if all relevant tests of this document are passed successfully.

7.1.2 Reference conditions (air flow rates)

Air flow rates shall be reported as normalized air flow rates using the following reference conditions:

— air temperature: 20 °C

— absolute air pressure: 100 kPa = [1 bar](a)

— relative water vapour pressure: 65 %

Air flow rate unit: normal litres per minute (NL/min).

7.1.3 Atmospheric conditions

After the central suction source equipment being tested has been set up for normal use, carry out tests under the following atmospheric conditions:

a) ambient temperature within the range from 15 °C to 35 °C;

b) relative humidity within the range from 45 % to 75 %;

c) atmospheric pressure within the range from 860 hPa to 1 060 hPa.

Protect the equipment from draughts which might affect the validity of the tests.

After the measurement all values shall be calculated to reference conditions as specified in 7.1.2.

7.1.4 Other conditions

Conditions specified in IEC 60335-1 shall apply.