TECHNICAL SPECIFICATION

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Dentistry — Plant area equipment —

Part 1: Suction systems

Art dentaire — Installation de la zone technique —

Partie 1: Systèmes d'aspiration

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 22595-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

ISO/TS 22595 consists of the following parts, under the general title *Dentistry — Plant area equipment*:

— *Part 1: Suction systems*

Part 2, *Compressor systems*, is under preparation.

Introduction

This Technical Specification applies to the plant area environment, dental suction equipment, compressor equipment and their working conditions, and other machines installed in the plant area.

Other machines may include air conditioner, heating, hot water and equipment that may be installed in the plant area.

Dentistry — Plant area equipment —

Part 1:
Suction systems

1 Scope

This Technical Specification is applicable to dental suction equipment in the plant area, used to source suction for the dental equipment specified in ISO 10637.

This Technical Specification gives recommended guidelines for performance as well as test procedures for dental suction equipment including suction machines, amalgam separators, filters, valves, pipes, fittings and exhaust requirements.

This Technical Specification is limited to the performance of the suction system at the suction line connection point.

2 Normative references

The following referenced documents are indispensable for the application 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 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 7494-2:2003, *Dentistry — Dental units — Part 2: Water and air supply*

ISO 9687, *Dental equipment — Graphical symbols*

ISO 10637:1999, *Dental equipment — High- and medium-volume suction systems*

ISO 11143:1999, *Dental equipment — Amalgam separators*

IEC 60204-1, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

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

IEC 60364-6, *Low-voltage electrical installations — Part 6: Verification*

IEC 60364-7-710, *Electrical installations of buildings — Part 7-710: Requirements for special installations or locations — Medical locations*

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

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

IEC 61672-1:2002, *Electroacoustics — Sound level meters — Part 1: Specifications*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 1942, ISO 7494-2, ISO 10637, IEC 60601-1 and the following apply.

3.1
air separator
apparatus which separates liquids and solids from the suction air

[ISO 10637:1999, definition 3.3]

3.2
amalgam separator
item of dental equipment designed to remove amalgam particles from the waste water from the dental treatment centre, so as to reduce the number of amalgam particles and therefore the mass (amount) of amalgam entering the sewage system

[ISO 11143:1999, definition 3.1]

3.3
backflow prevention device
device to prevent backflow

EXAMPLE Pipe disconnector or air gap.

[ISO 7494-2:2003, definition 3.15]

3.4
bacterial filter
device designed to remove fine particles from dry air with a grade of filtration of 0,01 µm or less and an efficiency of 99,99 %

3.5
central system
vacuum system having at least one dry-, semi-dry- or wet-suction machine, which serves more than one suction device or dental unit

3.6
condensate separator
device fitted prior to the dry-suction machine in dry-suction systems to remove condensation from the air to protect the suction machine

3.7
exhaust line
air line between the exhaust line connection point and the pipe ending outside the building

3.8
exhaust line connection point
location that connects to the exhaust of plant area suction equipment

3.9
filter
apparatus which retains solids from the air and liquids passing through it

[ISO 10637:1999, definition 3.4]

3.10
fittings
parts which are used to connect the suction machines with the main suction line and exhaust line

3.11
flexible tube
facility which provides a movable connection between the suction machine and the fixed installed lines and devices

3.12
flow rate
volume of air per minute that is taken in at the suction line connection point and is determined by measuring the statically-negative pressure at the tapping point of the measuring section line by use of the suction machine characteristic curve

3.13
main suction line connection point
location where the suction line connects with the plant area suction equipment

3.14
measuring section line
facility of piping system with a tapping point shaped as a connecting fitting in the middle of the length of the piping system with one termination of the piping system in the direction of the main suction line connection point and the other termination in front of the suction machines

3.15
plant area
location in a treatment room or in another room or bay of the building in which utility equipment used to support dental treatment is placed

3.16
relief valve
device to allow the introduction of air to limit the maximum vacuum in the system

3.17
suction line
pipeline in which all pipes from the suction devices enter and through which only air or air together with liquids and solids is aspirated from each suction device and is carried across the suction line connection point to the suction machine in the plant area

NOTE The suction line is a facility of piping system with one termination at the suction line connection point and the other termination with vacuum devices in one or more treatment locations.

3.18
suction machine
collection of devices used to lower pressure within a pipeline to below atmospheric for the purpose of transporting materials from a dental operating location to a disposal location and which has an electrically-driven device, which creates the suction and evacuates the main suction line

3.19
suction machine characteristic curve
characteristic curve of the flow rate of the suction machine dependant upon the negative pressure

3.20
suction machine connection point
location where the suction machine is connected with the measuring section line

3.21
utilization factor
maximum percentage of suction devices that is likely to have open suction points simultaneously

3.22
water line
pipelines between the suction devices and the water line connection point

3.23
water line connection point
location where the water line is connected with the municipal water supply

3.24
waste water connection point
location where the waste water line of the plant room or building is connected to the discharge of the condensate and/or the amalgam separator

3.25
waste water line
pipelines between suction devices and/or dental units and the waste water line connection point in which discharged liquids are carried

4 Classification

4.1 Suction machines

For suction machines and other devices IEC 60204-1 or IEC 60335–1 or IEC 61010–1 applies.

NOTE Suction machines are installed in a separate plant area away from the dental treatment area.

If a suction machine is installed in a cabinet and/or separable equipment components in an area within 1,5 m of the patient, IEC 60601-1 (for medical devices) applies.

4.2 Amalgam separators

For amalgam separators IEC 60601-1 or IEC 61010-1 applies.

If an amalgam separator is installed in a cabinet and/or separable equipment components in an area within 1,5 m of the patient, IEC 60601-1 (for medical devices) applies.

4.3 According to the type of protection against electric shock (see 4.1 and 4.2)

4.3.1 Class I equipment

Equipment in which protection against electric shock does not rely on basic insulation only, but includes an additional safety precaution which provides means for the connection of accessible conductive parts to the protective (earth) conductor in the fixed wiring of the installation such that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

4.3.2 Class II equipment

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

4.4 According to the mode of operation (see 4.1 and 4.2)

Suction systems and amalgam separators are classified as applicable for either intermittent or continuous operation.

5 Requirements

5.1 General

This clause contains requirements relevant to suction systems and amalgam separators. Many of these requirements are quantitatively verifiable as detailed in Clause 6. Some requirements are objectively verifiable by visual inspection.

The requirements in IEC 60335-1 or IEC 61010-1 or IEC 60204-1 or IEC 60601-1 to which reference is made, are applicable to non-electrical devices as well.

5.2 General requirements

5.2.1 Suction machines

Suction machines shall be designed, constructed and manufactured so that when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they will cause no danger which could reasonably be foreseen to the operating personnel and service personal, or to the surroundings in normal use and in single fault condition.

Suction machines shall have the strength and rigidity necessary to resist the stresses to which they may be subjected in normal dental practice without risk of introducing fire, electrical shock or accident hazard.

Suction machines shall comply with local plumbing, electrical and fire-safety regulations.

These requirements cannot be objectively assessed. They are considered as fulfilled if all of the applicable requirements of Clause 5 are fulfilled.

5.2.2 Suction equipment

The complete suction equipment should be capable of withstanding without collapse at least 1,5 times the allowed maximum vacuum of 250 hPa, as specified in ISO 10637:1999, 5.3.2.

5.2.3 Main suction line

The main suction line shall be sized in accordance with the manufacturer's instructions.

Use pipes that are made of materials resistant to corrosion agents.

Testing shall be carried out at maximum reachable vacuum closure of the main suction line and subsequent visual inspection in accordance with the requirements and recommendations of the manufacturer (see 8.3).

5.2.4 Main suction line connection point

The main suction line connection point and the main suction line shall have the same internal diameter as the lines and the entrance of the devices in the plant area to avoid pressure loss and disturbance of the air flow in the measuring section.

The connection of the suction line to the suction machine shall be made with materials that protect the suction line from damage due to movement and vibration of the suction machine.

Testing shall be carried out by visual inspection.

5.2.5 Exhaust line connection point

The connection of the exhaust line to the suction machine shall be made with materials that protect the suction line from damage due to movement and vibration of the suction machine.

Testing shall be carried out by visual inspection.

