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Dental equipment — High- and medium-volume suction systems

Matériel dentaire — Systèmes d'aspiration à haut et moyen volume

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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 3.

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.

International Standard ISO 10637 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

Annex A forms a normative part of this International Standard.

Introduction

This International Standard contains specifications for high- and medium-volume suction systems which are used in the dental surgery as part of the dental equipment.

The aim of this International Standard is to ensure the reliable function of suction systems and the necessary safety in common usage and within normal ambient conditions.

Any item of dental equipment recommended by the manufacturer for use in connection with suction systems should not render the equipment unsafe.

Dental equipment — High- and medium-volume suction systems

1 Scope

This International Standard applies to high- and medium-volume suction systems which are items of dental equipment. They are usually an integral part of a dental unit.

This International Standard specifies performance and safety requirements as well as test procedures for high- and medium-volume suction systems. It also contains specifications on manufacturer's instructions, marking and packaging.

This International Standard takes priority, where applicable, over IEC 60601-1, as specified in the individual clauses of this International Standard.

This International Standard is not applicable to low-volume suction systems.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942-4, *Dental vocabulary — Part 4: Dental equipment.*

ISO 7494, *Dental units.*

lSO 9687, *Dental equipment — Graphical symbols.*

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 60651, *Sound level metres.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in IEC 60601-1:1988, clause 2, and the following apply.

3.1
suction system
active entity of dental equipment, including a suction machine, which enables an air flow to be induced which is designed to remove spray, liquids and solids from the mouth of the dental patient during dental treatment

See Figure 1.

NOTE It is a combination of apparatus and accessories. Some components are described in 3.2 to 3.7.

3.2
suction device
passive entity which can only induce an air flow when connected to a suction machine

3.3
air separator
apparatus which separates liquids and solids from the suction air

3.4
filter
apparatus which retains solids from the air and liquids passing through it

3.5
central system
vacuum system having at least one suction machine which serves more than one device

3.6
accessories
cannula, manifold, filter and/or mobile support

3.7
cannula connector
cartridge, at the end of the hose part of the suction system, intended for fitting of cannulae and for placement in the mobile support

NOTE Also called a suction handpiece.

3.8
low-volume suction system
suction system with an air intake of less than 90 l/min

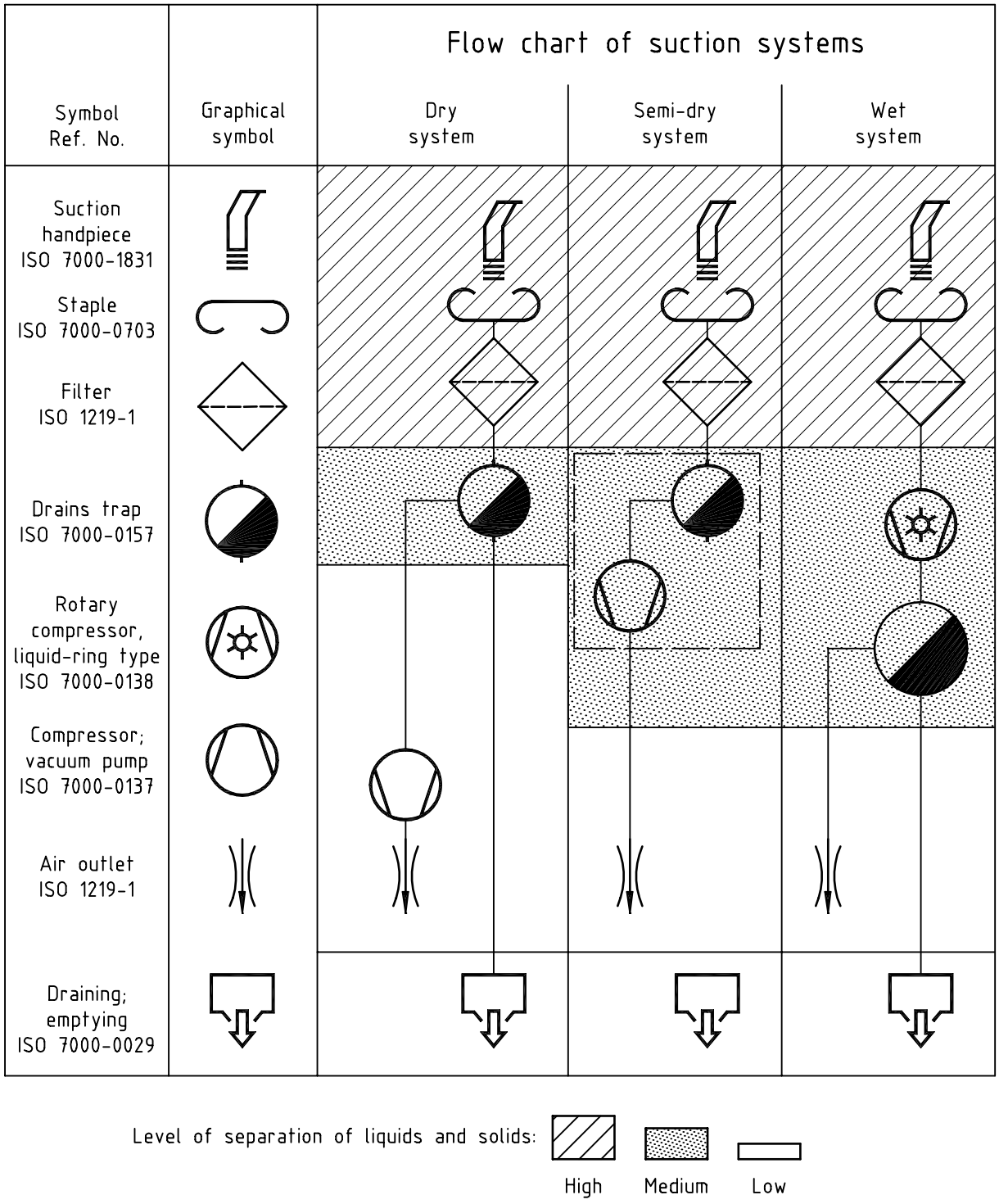

Figure 1 — Suction systems

4 Classification

4.1 According to the air volume flowrate provided

Suction systems to which this International Standard is applicable are classified according to the air volume flowrate provided as follows:

a) High-volume suction system

Suction system with an air intake of more than 250 litres per minute (l/min) in each suction device.

b) Medium-volume suction system

Suction system with an air intake between 90 l/min and 250 l/min in each suction device.

4.2 According to the type of suction

Suction systems are classified according to the type of suction as follows:

a) Dry system

Suction system in which, with an air separator, liquids and solids have been removed from the air flow before the air enters the suction machine and in which the separator and the suction machine are two different devices. See Figure 1.

b) Semi-dry system

Suction system in which, with an air separator, liquids and solids have been removed from the air flow before the air enters the suction machine and in which the separator and the suction machine are combined into one device. See Figure 1.

c) Wet system

Suction system in which solids have been removed from the air flow by a filter before air and liquid enter the suction machine, where they in turn are separated. See Figure 1.

4.3 According to the type of protection against electric shock (see IEC 60601-1)

Suction systems are classified according to the type of protection against electric shock by classes as follows:

a) 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.

b) 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 degree of protection against electric shock (see IEC 60601-1)

Suction systems are classified according to the degree of protection against electric shock by type as follows:

a) Type B equipment (see IEC 60601-1:1988, 2.2.24)

Class I or II equipment or equipment with an internal electrical power source providing an adequate degree of protection against electric shock, particularly regarding:

— allowable leakage current;

— reliability of the protective earth connection, if present.

NOTE Type B equipment is, for example, suitable for intentional external and internal application to the patient, excluding direct cardiac application.

b) Type BF equipment (see IEC 60601-1:1988, 2.2.25)

Type B equipment with an F-type isolated (floated) applied part.

4.5 According to the mode of operation (see IEC 60601-1:1988, 2.10)

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

5 Requirements

5.1 General

This clause contains requirements relevant to high- and medium-volume suction systems. Many of these requirements are quantitatively verifiable as detailed in clause 7.

Some requirements are objectively verifiable by visual inspection.

Compliance with some requirements, however, involves a subjective decision of qualified testing personnel. It is envisaged to include in these cases quantitative tests as soon as results of relevant research work are available.

Electrical requirements are only applicable to electrically powered high- and medium-volume suction systems and high- and medium volume suction devices intended for use in powered suction systems. However, the general requirements in IEC 60601-1 which are referred to are applicable to nonelectrical suction systems and devices as well.

5.2 General requirements

5.2.1 Design

5.2.1.1 High- and medium-volume suction systems shall be designed, constructed and manufactured so that when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they cause no danger which could reasonably be foreseen to the patient, to the operating personnel, or to the surroundings in normal use and in single fault condition.

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

5.2.1.2 High- and medium-volume suction systems 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.

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

5.2.1.3 Dry systems shall include a suction machine, an air separator, a suction pipeline and appropriate accessories.

5.2.1.4 Semi-dry systems shall include a suction machine with an air separator before the suction machine, an interconnecting pipeline and appropriate accessories.

5.2.1.5 Wet systems shall include a suction machine, an interconnecting pipeline and appropriate accessories.

5.2.1.6 Edges and corners of components and parts accessible to the patient or dental personnel shall be finished so as to avoid injury to the patient or the dental personnel. Compliance shall be checked by visual inspection.

5.2.1.7 For suction machines, the requirements of IEC 60335-1 apply.

5.2.2 Cleaning and disinfection

All exterior parts shall be cleanable and disinfectable, without deteriorating the surface or markings, by using agents recommended by the manufacturer of the suction system.

Testing shall be carried out in accordance with 7.2.

All interior parts should be cleanable and disinfectable, without deteriorating the surface or markings, by using agents recommended by the manufacturer of the suction system.

5.3 Performance requirements

5.3.1 High-volume suction systems

5.3.1.1 High-volume suction systems with integral suction machine

The suction system shall ensure an air suction volume flowrate of at least 250 l/min into the cannula connector of the largest-bore operating hose, when operated at full power and in accordance with the manufacturer’s instruction for use.

The maximum vacuum at the cannula connector shall not exceed 25 kPa under worst case normal operating conditions, including zero-suction volume into all available cannulae.

An agreement between the parties concerned should specify the number of suction devices intended to be connected and the number of these dental units to be open when the flowrate is tested.

Testing shall be carried out in accordance with 7.3.1.2

5.3.1.2 High-volume suction systems for single surgery use and with separate suction machine

The suction system shall ensure an air suction volume flowrate of at least 250 l/min into the cannula connector of the largest-bore operating hose, when operated at full power and in accordance with the manufacturer’s instruction for use and when the suction device is connected to the suction machine through a pipeline of the smallest diameter and maximum length recommended by the manufacturer.

The maximum vacuum at the cannula connector shall not exceed 25 kPa under worst-case normal operating conditions, including a zero-suction volume by closed-cannulae connector.

Testing shall be carried out in accordance with 7.3.1.3

5.3.1.3 High-volume suction systems with central suction machine

The suction system shall ensure an air suction volume flowrate of at least 250 l/min into the cannula connector of the largest-bore operating hose, when operated at full power and in accordance with the manufacturer's instruction for use.

The maximum vacuum at the cannula connector of any operating hose shall not exceed 25 kPa under worst-case normal operating conditions, including a zero-suction volume by closed-cannulae connector.

Testing shall be carried out in accordance with 7.3.1.4.

5.3.1.4 High-volume suction device with vacuum specified by the manufacturer

The suction device shall admit an air suction volume flowrate of at least 250 l/min into the cannula connector of the largest-bore operating hose when the vacuum specified by the manufacturer is applied and maintained at the connection part and the suction device is operated according to the manufacturer's instructions for normal use.

The maximum vacuum at the cannula connector shall not exceed 25 kPa under worst-case normal operating connections, including a zero-suction volume by closed-cannulae connector.

Testing shall be carried out in accordance with 7.3.1.5

5.3.2 Medium-volume suction systems

The medium-volume suction system shall ensure an air suction volume flowrate of at least 90 l/min at the cannula connection without cannulae.

The maximum vacuum at the cannula connector shall not exceed 25 kPa under worst-case normal operating conditions, including a zero-suction volume by closed-cannulae connector.

In case of central suction systems, these requirements shall be ensured at each connection when all connected devices are functioning.

An agreement between the parties concerned should specify the number of dental units intended to be connected and the number of these dental units to be open when the flowrate is tested.

Testing shall be carried out in accordance with the appropriate subclauses of 7.3.1.

5.4 Air separators

Air separators should require minimal and easy maintenance.

5.5 Requirements for accessories

5.5.1 Cannula connectors

Cannula connectors for high-volume suction systems shall have a nominal inside diameter of (15 ± 1) mm or (11 ± 1) mm at the narrowest dimension. The dimensions for the fittings are given by the manufacturer.

Cannula connectors for medium-volume suction systems shall have a nominal inside diameter of at least 9 mm at the narrowest dimension.

Compliance shall be verified using readily available measuring instruments.

Cannula conectors should allow easy access of the cannula to every part of the patient's mouth without causing distortion of the hoses.

5.5.2 Operating hoses

Operating hoses should be internally smooth, flexible and noncollapsible. Operating hoses shall withstand a vacuum of 25 kPa. They should be cleanable, disinfectable and easy to handle for hygenic treatment by methods and with agents recommended by the manufacturer of the suction systems.

Compliance shall be verified by visual inspection.

5.5.3 Filters

5.5.3.1 Filters for dry and semi-dry systems

Where the manufacturer prohibits the entry of solid waste above a specified size into the separator, the suction system shall include a filter, placed between the operating hoses and the separator. The filter shall have a mesh size determined by the manufacturer and specified in the accompanying documents.

Filters for dry and semi-dry systems shall be located before the air separator and in such a way to allow easy removal for maintenance.

Compliance of the filter location shall be verified by visual inspection.

5.5.3.2 Filters for wet systems

Filters for wet systems shall be located before the suction machine and in such a way to allow easy removal for maintenance.

The filters shall have a mesh size determined by the manufacturer and specified in the accompanying documents.

Compliance of the filter location shall be verified by visual inspection.

5.6 Noise level

The A-weighted noise level generated by high- and medium-volume suction systems through the connected cannula shall not exceed 60 dB at a distance of 0,5 m from the cannula connector and with the cannula recommended by the manufacturer of the dental unit.

Testing shall be carried out in accordance with 7.3.2.

5.7 Waste disposal

Any waste generated by suction systems shall be disposed of in accordance with relevant national regulations.

5.8 Electrical requirements

5.8.1 Power input

IEC 60601-1:1988, clause 7 applies.

5.8.2 Single fault conditions

IEC 60601-1:1988, 3.6 applies.

5.8.3 Protection against electric shock hazards

IEC 60601-1:1988, clause 13 applies.

5.8.4 Requirements related to classification

5.8.4.1 Class I equipment

IEC 60601-1:1988, 14.1 applies.

5.8.4.2 Class II equipment

IEC 60601-1:1988, 14.2 applies.

5.8.4.3 Equipment classes I and II

IEC 60601-1:1988, 14.4 applies, Iimited to classes I and II.

5.8.4.4 Equipment types B and BF

IEC 60601-1:1988, 14.6 applies.

5.8.5 Limitation of voltage and/or energy

IEC 60601-1:1988, clause 15 applies.

5.8.6 Enclosures and protective covers

IEC 60601-1:1988, clause16 applies.

5.8.7 Spillage and ingress of liquids

IEC 60601-1:1988, 44.3 and 44.6 apply.

5.8.8 Leakage

IEC 60601-1:1988, 44.4 applies.

5.8.9 Separation

IEC 60601-1:1988, clause 17 applies.

5.8.10 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, clause 18 applies.

5.8.11 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, clause 19 applies.

Testing shall be carried out in accordance with 7.4.1.3

5.8.12 Dielectric strength

IEC 60601-1:1988, clause 20 applies.

Testing shall be carried out in accordance with 7.4.2.

5.8.13 Stability in normal use

IEC 60601-1:1988, clause 24 applies.

5.8.14 Excessive temperatures

IEC 60601-1:1988, clause 42 applies.

5.8.15 Interruption of the power supply

IEC 60601-1:1988, 49.1 to 49.3 apply.

5.8.16 Abnormal operation and fault conditions

IEC 60601-1:1988, clause 52 applies.

5.8.17 Components and general assembly

IEC 60601-1:1988, clause 56 applies.

5.8.18 Mains parts, components and layout

IEC 60601-1:1988, clause 57 applies.

5.8.19 Protective earthing — Terminals and connections

IEC 60601-1:1988, clause 58 applies.

5.8.20 Construction and layout

IEC 60601-1:1988, clause 59 applies.

6 Sampling

One representative sample of the suction system being tested shall be selected.

7 Test procedures

7.1 General

7.1.1 General provisions for tests

Conduct tests in the sequence specified in IEC 60601-1:1988, Appendix C (for further information see annex A).

All tests described in this International Standard are type tests made on one representative sample (see clause 6).

Unless otherwise specified, do not repeat tests. This applies specifically to the dielectric strength tests, which shall be made only on the manufacturer's premises or in independent test laboratories.

Since some of the tests described are destructive tests, do not afterwards install the high- and medium-volume suction systems tested in a dental unit.

Inspect the rating of components to check that it is appropriate for the application intended.

Where a component or equipment part has specified ratings exceeding those appropriate to its use in the equipment, it does not have to be tested for such a wider range.

Compliance is considered to be achieved if all relevant tests of this International Standard are passed successfully.

High- and medium-volume suction systems, or parts thereof, using materials or having forms of construction different from those detailed in this International Standard are acceptable if it can be demonstrated that an equivalent degree of safety is obtained.

7.1.2 Atmospheric conditions

After the high- and medium-volume suction system 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 860 hPa to 1060 hPa (645 mmHg to 795 mmHg).

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

7.1.3 Other conditions

IEC 60601-1:1988, 4.6 a), b) and d) apply.

7.1.4 Supply and test voltages, type of current, nature of supply, frequency

IEC 60601-1:1988, 4.7 applies.

7.1.5 Preconditioning

IEC 60601-1:1988, 4 8 applies.

7.1.6 Repairs and modifications

IEC 60601-1:1988, 4.9 applies.

7.1.7 Humidity preconditioning treatment

IEC 60601-1:1988, 4.10 applies.

7.2 Cleaning and disinfection

Carry out tests for cleaning and disinfection in accordance with IEC 60601-1:1988, 44.7.

7.3 Performance tests

7.3.1 Measurement of flowrate

7.3.1.1 General

Measure the flowrate for the high- and medium-volume suction systems at the cannula connector using commonly used devices, such as a flowmeter or other equivalent, with a measurement tolerance of ± 5 %.

The flowrate measuring devices shall have a full-scale reading greater than 500 l/min.

7.3.1.2 High- and medium-volume suction systems with integral suction machine

Operate the suction system at maximum power. Measure the flowrate by connection of the flowrate meter to the cannula connector of the largest-bore operating hose, with any flow control set fully open. Any additional operating hoses shall be either unobstructed or closed off, according to the manufacturer's instruction for normal use.

Measure the maximum vacuum at maximum power and, in turn, at the cannula connector of each available operating hose, all other operating hoses being blanked off so that they do not admit air. Connection of the measuring instrument to the cannula connector shall be leakfree.

Allow any vacuum-limiting device incorporated in the suction system to operate normally.

7.3.1.3 High- and medium-volume suction systems for single surgery use and with separate suction machine

Connect the suction device to the suction machine according to the manufacturer's instructions and by a pipeline of the minimum diameter and maximum length recommended by the manufacturer.

Operate the suction system at maximum power. Measure the flowrate by connection of the flowrate meter to the cannula connector of the largest-bore operating hose, with any flow control set fully open. Any additional operating hoses shall be either unobstructed or closed off, according to the manufacturer's instructions for normal use.

Measure the maximum vacuum at maximum power and, in turn, at the cannula connector of each available operating hose, all other operating hoses being blanked off such that they do not admit air. Connection of the measuring instrument to the cannula connector shall be leakfree.

Allow any vacuum-limiting device incorporated in the vacuum system to operate normally.

7.3.1.4 High- and medium-volume suction systems with central suction machine

Connect the suction machine to a single suction device according to the manufacturer's instruction and through a pipeline of diameter appropriate to that of the connection part of the suction device. The length of the pipeline should be sufficient only to allow the practical implementation of the test. Install any vacuum-limiting device supplied as part of the system according to the manufacturer's instructions. With the exception of air normally admitted by any vacuum limiting device, the connections and pipeline shall be leakfree.

Allow any vacuum-limiting device incorporated in the suction device to operate normally.

Connect a vacuum-measuring instrument in such a way as to measure the vacuum existing at the connection part of the suction device.

Connect the flowrate meter to the cannula connector of the largest-bore operating hose, with any flow control set fully open. Any additional operating hoses shall be either unobstructed or closed off, according to the manufacturer's instructions for normal use.

7.3.1.5 High- and medium-volume suction systems with specified vacuum

Connect the suction device to a suitable suction source.

Connect a vacuum-measuring instrument in such a way as to measure the vacuum existing at the connection part of the suction device.

Connect the flowrate meter to the cannula connector of the largest-bore operating hose, with any flow control set fully open. Any additional operating hoses shall be either unobstructed or closed off, according to the manufacturer's instructions for normal use.

With air being admitted into the operating hose through the flowmeter, adjust the suction source until the vacuum measured at the connection part is equal to the specific vacuum stated by the manufacturer in the accompanying documents.

7.3.2 Measurement of noise level

7.3.2.1 Apparatus

7.3.2.1.1 Precision sound level meter, type I instrument in accordance with IEC 60651.

7.3.2.1.2 Non-rigid suspension system.

7.3.2.2 Procedure

Operate the suction system at the specified air flowrate of 250 l/min for high-volume and 90 l/min for medium-volume suction systems. Using the sound level meter, measure the maximum A-weighted sound pressure value generated from the cannula connector in its holder placed at a distance of 0,5 m from the suction system.

7.4 Electrical tests

7.4.1 Environmental conditions

7.4.1.1 Operation

Equipment shall comply with all the requirements of this International Standard when operated in normal use under the least favourable combination of the conditions specified in IEC 60601-1:1988, 10.2.1.

7.4.1.2 Power supply

High- and medium-volume suction systems shall be designed to have a mains supply with the following characteristics:

a) maximum internal impedance of 0,1 Ω for permanent devices and of 0,3 Ω for plug-in devices;

b) voltage fluctuations generally not exceeding ±10 % of the nominal voltage, not including short-time fluctuations (for example, duration less than 1 s) at irregular intervals such as caused by operation of X-ray generators or similar equipment;

c) voltages which are practically sinusoidal in waveform and provide a practically symmetrical supply system in case of polyphase supply;

d) frequency which does not deviate by more than 1 Hz from the nominal value up to 100 Hz and by more than 1 % from 100 Hz to 1 kHz.

Testing shall be carried out using readily available measuring instruments.

NOTE Protective measures will be specified in a future International Standard on electrical installations in hospitals and in rooms used for medical purposes outside hospitals.

7.4.1.3 Continuous leakage currents and patient auxiliary currents

Test the earth leakage current, the enclosure leakage current, the patient leakage current and the patient auxiliary current

a) after the high- or medium-volume suction system has been brought up to normal operating temperature in accordance with the requirements of IEC 60601-1:1988, clause 7;

b) after the moisture preconditioning treatment as described in IEC 60601-1:1988, 4.10.

Carry out the measurements with equipment located outside the humidity cabinet and commence 1 h after the equipment has been taken out of this cabinet and has been placed in an environment with a temperature less than or equal to the temperature of the humidity cabinet.

During testing, make first those measurements which do not energize equipment.

7.4.2 Dielectric strength

Apply the test voltage for a single-phase equipment and for three-phase equipment (to be tested as single-phase equipment) to the insulation parts as described in IEC 60601-1:1988, 20.1 and 20.2, for 1 min and in accordance with IEC 60601-1:1988, table V:

a) immediately after warming up to operating temperature and switching off the equipment and

b) immediately after the moisture preconditioning treatment (as described in IEC 60601-1:1988, 4.10) with the equipment de-energized during the test and kept in the humidity cabinet, and

c) after any required disinfection procedure with the equipment de-energized (see IEC 60601-1:1988, 44.7).

Initially, apply not more than half the prescribed voltage, then raise the voltage over a period of 10 s to the full value and maintain for 1 min.

7.4.3 Creepage distance and air clearances

IEC 60601-1:1988, 57.10 d) applies.

8 Information to be supplied by the manufacturer

8.1 General

IEC 60601-1:1988, 6.8.1 applies.

Information should be available in the language of the country in which the product is to be used.

High- and medium-volume suction systems shall be accompanied by documents containing at least the relevant information specified in 8.2 and 8.3.

8.2 Instructions for use

IEC 60601-1:1988, 6.8.2 applies.

Instructions for use shall also include warning statements on the use of the high- or medium-volume suction system in conjunction with other equipment that may move.

8.3 Technical description

IEC 60601-1:1988 , 6.8.3 applies.

In addition, the following information shall be provided by the manufacturer:

a) overall dimensions of the parts of the suction system;

b) overall dimensions of the baseplate and service location interfaces, if applicable;

c) details of interface surfaces and methods of retention (bolts, etc.) and electrical supplies and other services;

d) information on the field assembly and mounting of the suction system;

e) electrical characteristics (voltage, frequency, fuse values);

f) directions for cleaning and disinfecting the suction device;

g) attachments that the suction system is designed to accept;

h) list of spare parts that would be required in general use;

i) schematic wiring diagrams;

j) minimum spare requirements and recommendations for the dental unit installation within the dental surgery;

k) specified vacuum, where applicable;

l) type of suction system (high- or medium-volume).

9 Marking

9.1 Marking on outside of mains-operated high- and medium-volume suction systems

Mains-operated high- and medium-volume suction systems, including separable components thereof which have a mains part, shall be provided at least with permanently affixed and clearly legible markings on the outside of the major part, giving the following:

a) indication of origin

IEC 60601-1:1988, 6.1 e) applies.

b) model or type reference

IEC 60601-1:1988, 6.1 f) applies.

c) connection to the supply

IEC 60601-1:1988, 6.1 g) applies. Not applicable for permanently installed equipment if marked on the inside.

d) supply frequency (in hertz)

IEC 60601-1:1988, 6.1 h) applies. Not applicable for permanently installed equipment if marked on the inside.

e) power input

IEC 60601-1:1988, 6.1 j) applies. Not applicable for permanently installed equipment if marked on the inside.

f) classification

4.3 and 4.4 of this International Standard apply.

g) mode of operation

IEC 60601-1:1988, 6.1 m) applies.

h) fuses

IEC 60601-1:1988, 6.1 n) applies.

9.2 Marking on inside of high- and medium-volume suction systems or their parts

IEC 60601-1:1988, 6.2 a), e), f), h), j), k) and l) apply.

Compliance shall be checked in accordance with IEC 60601-1:1988, 6.1 z) except the rubbing test.

9.3 Marking of controls

IEC 60601-1:1988, 6.3 a), b), c) and f) apply. The mains switch shall be clearly identified.

9.4 Symbols

Symbols used for controls and performance shall be in accordance with ISO 9687.

Symbols used for marking in accordance with 9.2 and 9.3 shall conform to IEC 60601-1:1988, Appendix D, where applicable.

Compliance shall be verified by visual inspection.

9.5 Colours of the insulation of conductors

IEC 60601-1:1988, 6.5 applies.

9.6 Indicator lights and push-buttons

IEC 60601-1:1988, 6.7 applies.

10 Packaging

High- and medium-volume suction systems shall be packaged for transportation in such a way that no damage can occur during anticipated transport conditions.

If several packages exist, they shall be marked on the outside to facilitate assembly and installation.

Annex A
(normative)

Sequence of testing

This sequence of testing is essentially aligned to IEC 60601-1:1988, annex C. It is adjusted to the particular requirements of dental suction systems.

Tests, if applicable, should be carried out in the sequence indicated below. The sequence of the tests marked by an asterisk (*) is mandatory.

However, this does not preclude the possibility of conducting a test which preliminary inspection suggests might cause failure.

	Test	Reference in this International Standard
1	General	See 5.1
2	General requirements	See 5.2
3	Markings	See clause 9
4	Power input	See 5.8.1
5	Classification	See clause 4 and 5.8.4
6	Limitation of voltage and/or energy	See 5.8.5
7	Enclosures and protective covers	See 5.8.6
8	Separation	See 5.8.9
9	Protective earthing, functional earthing and potential equalization	See 5.8.10 and 5.8.19
10	Mechanical strength	See 5.2
11	Moving parts	See 5.2.1.1
12	Surfaces, corners and edges	See 5.2.1.5
13	Stability and transportability	See 5.2.1.1
14	Expelled parts	See 5.2.1.1
15	Suspended masses	Not used
16	Radiation hazards	Not used
17	Electromagnetic compatibility	See 5.1
18	Pressure vessels and parts subject to pressure	Not used
19	Human errors	Not used
20	Temperatures — Fire prevention	See 5.8.14

21	Interruption of the power supply	Not used
22	Accuracy of operating data and protection against incorrect output	Not used
*23	Abnormal operation, fault conditions, environmental tests	See 5.8.2
*24	Continuous leakage currents and patient auxiliary currents at operating temperature	See 5.8.11
*25	Dielectric strength at operating temperature	See 5.8.12
*26	Humidity preconditioning treatment	See 7.1.7
*27	Dielectric strength test (cold condition)	See 5.8.12
*28	Leakage current after humidity preconditioning treatment	See 5.8.11
*29	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	See 5.2.2
30	Enclosures and covers	See 5.8.6
31	Components and general assembly	See 5.8.17
32	Mains parts, components and layout	See 5.8.18
33	Not used, covered by 9	Not used
34	Construction and layout	See 5.8.20
35	Category AP and APG equipment	Not used
36	Verification of markings	See clause 9

ICS 11.060.20

Price based on 18 pages