INTERNATIONAL STANDARD

ISO 10637

First edition
1999-08-01

Dental equipment — High- and medium-volume suction systems

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

Reference number
ISO 10637:1999(E)

Contents

Page

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Printed in Switzerland

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.*

ISO 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

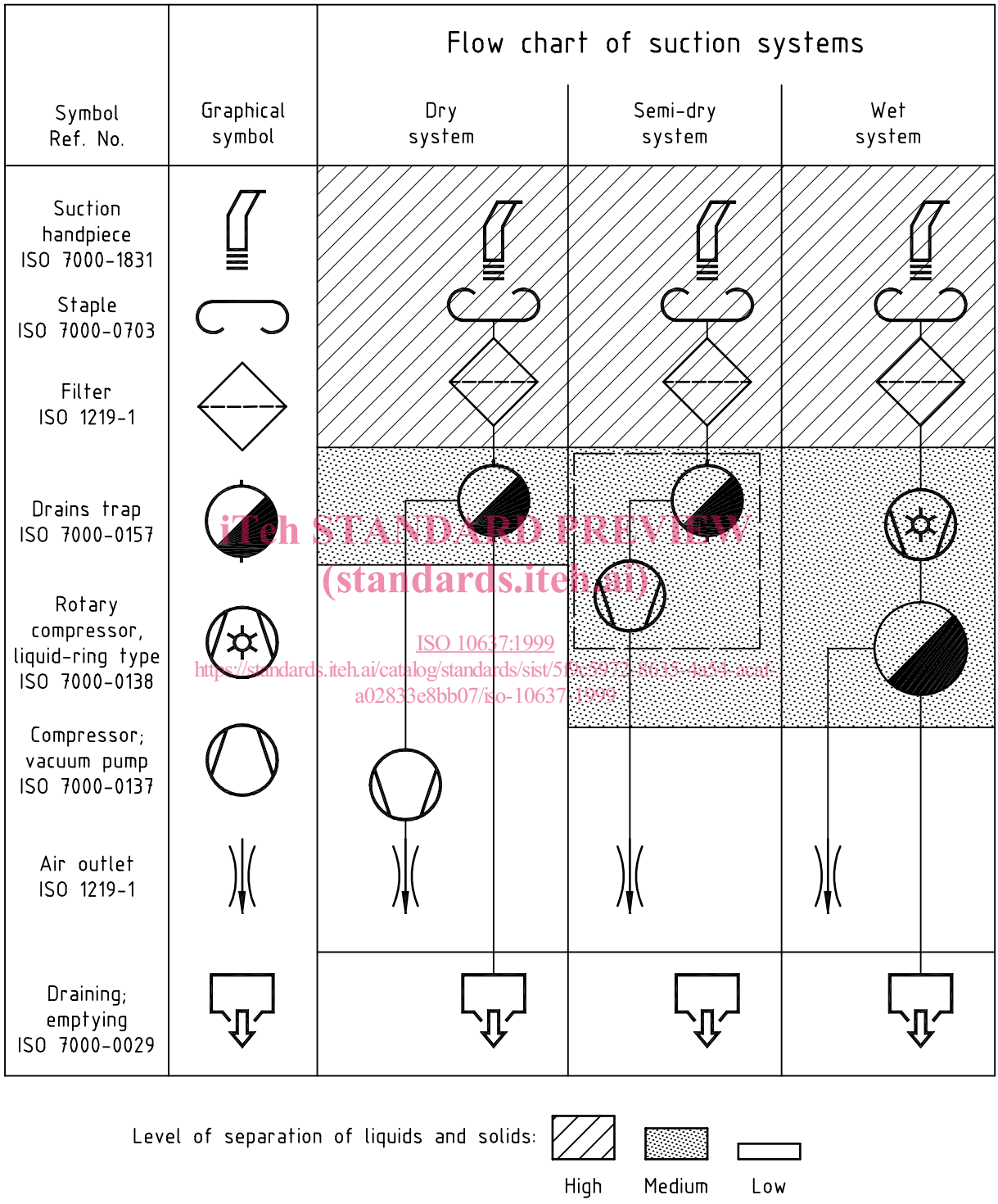

Figure 1 — Suction systems

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.