TECHNICAL SPECIFICATION

ISO/TS 22595-1

First edition
2006-09-01

Dentistry — Plant area equipment —

Part 1: Suction systems

Art dentaire — Installation de la zone technique —

Partie 1: Systèmes d'aspiration

Reference number
ISO/TS 22595-1:2006(E)

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Published in Switzerland

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Foreword

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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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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.

5.2.6 Water line

The internal diametres of the pipes and fittings and the material shall be installed according to the manufacturer's instructions and shall be according to local regulations.

The suction equipment shall be connected by flexible tube at the water line.

5.2.7 Water line connection point

The material of the water line to the municipal water shall be in accordance with local regulations.

5.2.8 Backflow prevention device

A system using municipal water as procedural water for wet suction machines and for cleaning suction or waste water lines and air separators shall have a backflow prevention device at the connection point with the municipal water supply or an air gap of less than 20 mm.

Test in accordance with 6.7.

5.2.9 Waste water line

The internal diametres of the pipes and fittings selected shall be selected and installed according to the manufacturer's instructions.

Use pipes that are made of materials resistant to solutions such as corrosion agents. Between the end of the waste water line and the waste water connection point there should be a curve installed in the pipe like a siphon that will fill with liquid and form a seal against the upward passage of gasses.

5.2.10 Waste water connection point

The connection of the waste water 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.

5.2.11 Suction machines

For installations served by more than one suction machine, the system shall be designed so that adequate performance capability is maintained if one machine is inoperative. The various suction machines shall be automatically or manually switched on and off as demand rises and falls.

Test in accordance with 6.2, 6.3 and 6.4.

For the correct functioning of the multi-unit suction device, each component should have the same performance.

5.2.12 Indicator lights of the suction machine

If the manufacturer recommends an indicator light, it shall be green light and clearly visible to indicate when suction machine is running.

5.2.13 Suction machine alarm

When an optical or acoustic alarm to indicate when a suction machine is in a fault condition is installed in the systems with two or more suction machines, testing shall be carried out by visual inspection.

5.2.14 Changeover switch

An electrical changeover switch shall be installed so that at intervals the duty sequence of the suction machines can be alternated. This may be automatic or manually operated.

5.2.15 Non-return valve

Systems with two or more suction machines shall have a non-return valve on the outlet of each suction machine to prevent the system from aspirating through any suction machines that are at rest.

Testing shall be carried out in accordance with the requirements and recommendations of the manufacturer and by visual inspection.

5.2.16 Vacuum gauge

If a vacuum gauge is recommended by the manufacturer, a vacuum gauge (with an accuracy of 1 % full-scale pressure) or equivalent capable of measuring a vacuum gauge pressure of 500 hPa shall be positioned near the control panel in a clearly-visible location to indicate the available suction. The tapping point in the suction line shall be located in such a position so as not to be affected by the velocity of airflow in the pipeline.

Testing shall be carried out by visual inspection.

5.2.17 Relief valve

A relief valve shall be provided to limit the maximum vacuum to 25 kPa with all suction inlet points closed. This requirement is applicable for high- and medium-volume suction systems as defined in ISO 10637.

5.2.18 Overflow protection

Systems with dry or semi-dry air separators shall be designed to prevent equipment damage from air separator overfilling.

Test in accordance with 6.5.

5.2.19 Bacterial filter

If a bacterial filter is installed in the system it shall

a) be fitted before or after the suction machines in the exhaust air line on dry and semi-dry systems,

b) be fitted behind the air separator in the exhaust air line of wet-suction machines,

c) have a differential pressure gauge to indicate when the filter cartridge requires changing,

d) be equipped with a filter cartridge that shall be changed according to the manufacturer's instructions,

e) establish a pressure differential on the clean filter that shall be less than 50 mbar.

Testing shall be carried out by visual inspection in accordance with the requirements and recommendations of the manufacturer.

5.2.20 Amalgam separators

For suction systems which are fitted with an amalgam separator, the amalgam separator shall comply with the requirements of ISO 11143.

5.2.21 Suction machines

For suction machines and other devices, which are installed in a separate plant area away from the dental treatment rooms, the requirements of IEC 60335–1 or IEC 61010-1 apply.

NOTE If suction machines are installed in a cabinet and/or separate equipment components in an area within 1,5 m of the patient, IEC 60601-1 for medical devices can apply.

5.2.22 Suction machine connection point

At the suction machine connection point the shock absorbed installed suction machines shall be connected with a fixed installed measuring section line by a flexible tube to prevent transmission of vibration to the devices (such as air or condensate separator, filter, relief valve, tubes) and the main suction line connection point.

5.2.23 Measuring section line

The main suction line, the devices and the suction machines shall be connected at the measuring section line in accordance with the requirements and recommendations of the manufacturer given in the manufacturer's instructions in such a manner that the air flow at the tapping point of the measuring section line is not affected. The tapping point should be shaped like a Pitot tube or a restrictor. The length of measuring section line shall be in accordance with the requirements of the manufacturer.

After a factory test or maintenance and before putting the suction into operation the tapping point should be closed or a vacuum gauge should be installed in accordance with 5.2.16.

5.2.24 Electrical machines

For electrical machines (such as sewage lift pumps) in the plant room area, the requirements of IEC 60364-7-710 apply.

5.3 Performance

5.3.1 Performance of single dental units

The suction machines of a high-volume suction system (ISO 10637:1999, 5.3.1) shall have at the suction connection point an air flow rate which guarantees at least 250 l/min at each cannula connector of the dental unit, and the suction machines of a medium-volume suction system (ISO 10637:1999, 5.3.2) shall have at the suction connection point a flow rate which guarantees at least 90 l/min at each cannula connector of the dental unit, to which the system is designed to provide suction.

Test the performance rating as specified in 6.3.

5.3.2 Performance of multiple dental units

For clinics with more than six suction devices, an agreement between the parties concerned should specify the number of suction machines and dental units intended to be connected and the number of these dental units intended to be open simultaneously to calculate the flow rate required at the suction line connection point.

Test the performance rating as specified in 6.3.

5.3.3 Utilization factor

For one or two suction devices the utilization factor should be 100 %, for three to six suction devices the utilization factor should be at least 60 %.

Test in accordance with 6.2, 6.3 and 6.4.

5.4 Cleaning and disinfection

All interior parts of air separator and wet-suction machines and equipment in contact with liquids and/or solids from the mouth of the patient during dental treatment should be capable of withstanding, without damage, the cleaning and disinfection processes specified by the manufacturer of the suction system.

Testing of the disinfection shall be carried out in accordance with the requirements and recommendations of the manufacturer [see 8.2 e)].

5.5 Location of the suction machine

The suction machines and auxiliary equipment shall be in a well-lit and ventilated location. The installed equipment shall be conveniently accessible for maintenance purposes.

Testing shall be carried out by visual inspection [see 8.3 g) and j)].

5.6 System exhaust

5.6.1 General

Because of the possibility of the development of objectionable odour, where practical, discharge shall be vented outdoors, above the roof level of the plant area and buildings and away from the immediate vicinity of windows and other air intakes. The exit vent shall be so designed to prevent ingress of the elements. If discharge venting outdoors is not practical a bacterial filter shall be installed.

Notwithstanding the foregoing requirements, the method of discharging from the system shall comply with any relevant government regulations.

5.6.2 Exhaust line

The exhaust side of the suction machines and the exhaust line shall be piped to the exhaust line connection point to carry the exhaust air away from the plant area, the air intake of the compressor equipment and habitable areas.

If the exhaust line is installed upright across several floors above the roof, the pipes have to be installed in such a way as to prevent the entering of rain-water and the condensate in the suction machine and its accumulation at the lowest point of the exhaust pipeline, and to permit its draining by a hand or automatically-operated valve.

5.6.3 Exhaust line dimensions

The exhaust system shall be designed to minimise the effect of backpressure on the performance of the system. Preferably, the exhaust line should have at least the same diameter as the main suction line.

Testing of the complete exhaust system shall be carried out in accordance with 8.3 b), c), d), e) and f) and by visual inspection.

6 Testing procedures

6.1 Visual inspection

Visual inspections shall be carried out at normal visual acuity without magnification.

6.2 Achievement of normal use conditions

Before the suction system being tested has been set up for normal use, carry out tests under the following conditions:

a) run the suction system at sufficient flow to operate the agreed number of suction devices to be operated simultaneously as specified in 5.3; the compressor unit should have the capacity of air at a pressure as given in ISO/TS 22595-2;

b) ambient temperature, as specified in the manufacturer's instructions;

c) relative humidity as specified in the manufacturer's instructions;

d) atmospheric pressure as specified in the manufacturer's instructions.

6.3 Flow rate of the dental suction equipment

6.3.1 Apparatus

6.3.1.1 Pressure gauge (precision negative pressure gauge; vacuum gauge) capable of measuring a vacuum gauge pressure of 400 hPa.

6.3.1.2 Vaporized precision apparatus with an accuracy of 0,6 % of full-scale pressure.

6.3.2 Flow rate of dental suction equipment

Connect the precision negative pressure gauge to the connecting fitting at the tapping point of the measuring section line and activate the system. Operate the agreed number of cannula connectors of the dental units and read the negative pressure indicated by the gauge.

The system flow rate can be read from the suction machine characteristic curve given by the manufacturer as a function of the measured negative pressure. The determined system flow rate shall be at least the guaranteed air flow rate at the cannula connector (250 l/min or 90 l/min) multiplied by the number of cannula connectors of the dental units which are open simultaneously during the test.

Above an altitude of 1 000 m, the atmospheric pressure shall be considered.

If a high- and medium-volume suction system is installed according to the manufacturer's instructions, the air flow shall be as incompressible as possible.

6.3.3 Flow rate of dental suction equipment in case one suction machine is idle

Isolate electrically one of the suction machines. Connect the precision negative pressure gauge to the connecting fitting at the tapping point of the measuring section line and activate the system. Operate the agreed number of cannula connectors of dental units and read the negative pressure indicated by the gauge. Determine the system flow rate from the suction machine characteristic curve of the manufacturer.

The system flow rate shall be the flow rate of the whole system as given by the manufacturer reduced by the flow rate of one suction machine.

Above an altitude of 1 000 m, the atmospheric pressure shall be considered.

If a high- and medium-volume suction system is installed according to the manufacturer's instructions the air flow shall be as incompressible as possible.

Check by visual inspection whether all installed suction machines are the same type.

6.4 Operational test of the relief valve

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 cannula connector at each suction device for dental units (see ISO 10637:1999, 5.3.1.4 and 5.3.2).

Test by closing the suction connection point and running the suction machine. The pressure in the system should not exceed 25 kPa.

6.5 Overflow protection

If an overflow protection device is installed, overfilling of the air separator shall be prevented by the maximum possible liquid flow rate of the whole suction device as given by the manufacturer.

6.6 Measurement of noise level

6.6.1 Apparatus

6.6.1.1 Precision sound level meter, Type II instrument in accordance with IEC 61672-1.

6.6.2 Procedure

Operate the suction system as described in 6.2. After 1 h running, use the sound level meter and measure the maximum A-weighted sound pressure value in accordance with ISO 3746.

6.7 Backflow prevention device

Check by visual inspection whether a backflow prevention device or an air gap is installed at the connection point with the municipal water supply. Measure the distance of the air gap in accordance with national requirements.

7 Electrical tests

Equipment shall comply with all the requirements of this Technical Specification when operated in normal use under the least favourable combination of the conditions specified in IEC 60204-1, IEC 60335-1, IEC 60364-7-710 or IEC 61010-1 (if suction machines and/or separate equipment components are installed in an area within 1,5 m of the patient, IEC 60601-1 is applicable), according to 4.1 and 4.2.

8 Information to be supplied by the manufacturer

8.1 General

The requirements in IEC 60204-1 or IEC 60335-1 or IEC 60364-6 or IEC 60364-7-710 apply (if the suction machines and/or separate equipment components are installed in an area within 1,5 m of the patient, IEC 60601-1 for medical devices is usable).

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

8.2 Technical description

The following information shall be provided by the manufacturer:

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

b) technical data of the suction machines (suction machine characteristic curve, maximum negative pressure, noise level, diameter of the suction machine and the main suction line connection point and exhaust line connection point);

c) information for in-the-field assembly, installation and mounting of the suction equipment; additional information about the installation of the measuring section line and the flexible tube;

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

e) directions for cleaning and disinfecting the suction equipment;

f) attachments that the suction equipment is designed to accept;

g) schematic wiring diagrams;

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

i) minimum spare part requirements and recommendations for routine maintenance;

j) type of suction equipment (dry, semi-dry or wet);

k) maximum water flow rate of the amalgam separator and technical description according to ISO 11143;

l) operating and maintenance instructions;

m) typical diagnostic procedures for correcting problems;

n) if devices such as air separator or condensate separator, bacterial filter, filter are installed behind the suction machine connection point or integrated in the suction machine, their pressure losses shall be included in the suction machine characteristic curve;

o) detailed description as to how to measure the flow rate of the suction equipment.

8.3 Recommendations for the plant area

The following information shall be provided by the manufacturer.

a) The suction equipment exhaust line should be installed to discharge above the roof of the building. Only if this is impossible can the exhaust line be installed through the plant area wall to the outside atmosphere. The outlet must be away from windows, doors and habitable areas.

b) A bacterial filter shall be fitted if the exhaust line discharge is not above the roof or is near windows, doors or habitable areas.

c) The exhaust of the suction equipment shall not be discharged into the plant area.

d) The exhaust pipe outlet shall be designed to prevent liquids, solids and rain water from entering the system.

e) Provision shall be made to prevent the suction equipment exhaust air entering into the compressor air intake.

f) The exhaust pipeline should be a dedicated line from the exhaust line connection point to the discharge point outside the building. It should not be connected to any other pipeline, e. g. plumbing vent line.

g) Specify the minimum size of the doorway to allow placement and maintenance of the equipment.

h) The air in the plant area should be clean and free of dust.

i) The suction lines between the dental units and the plant room equipment shall be installed according to the manufacturer's instructions.

j) A temperature detector and alarm shall be installed.

k) If bacterial filters are used, the manufacturer shall give information about safe changing of the filter.

l) Specify minimum and maximum ambient temperatures for operation of equipment.

m) Specify ventilation requirements for cooling of the plant area. The temperature in the plant area should not exceed 40 °C.

9 Marking

9.1 Marking on the suction equipment

Mains-operated suction equipment, including separable components thereof which have a mains-operated part, shall be provided corresponding to IEC 60204-1 or IEC 60335-1 or IEC 60601-1 of the manufactured device with permanently affixed and clearly legible markings on the outside of the major part, giving at least the following information:

a) indication of origin;

b) model or type reference;

c) serial number;

d) year of manufacture;

e) supply voltage;

f) supply frequency (in hertz);

g) connection to the supply;

h) power input;

i) fuses;

j) motor driving speed;

k) mode of operation;

l) maximum vacuum pressure.

9.2 Marking of controls

IEC 60204-1, IEC 60335-1, IEC 60601-1 and IEC 61010-1 apply. The mains switch shall be clearly identified.

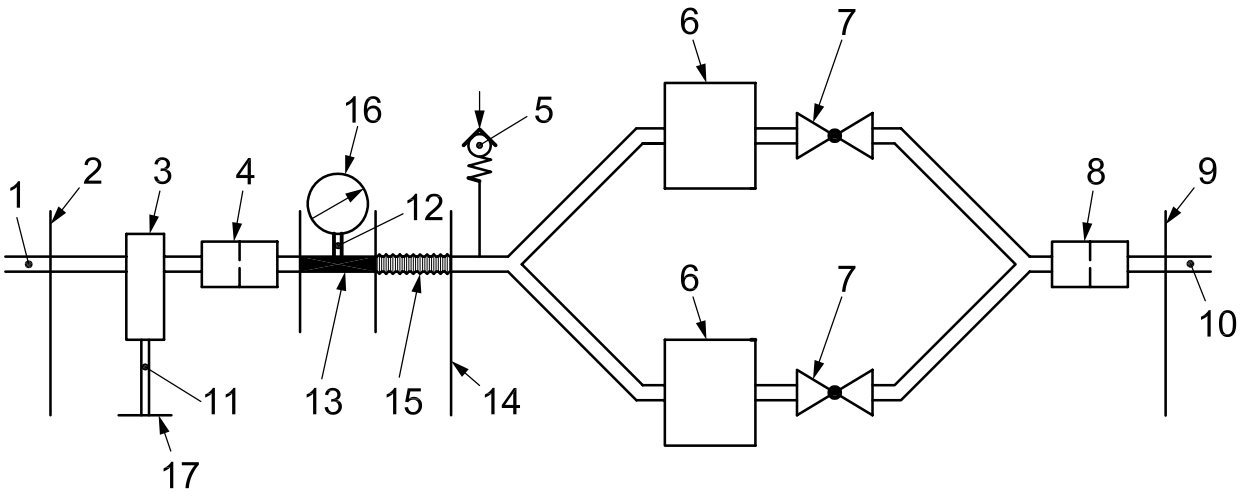
9.3 Graphical symbols

Graphical symbols used for controls and performances shall be in accordance with ISO 9687 and IEC 60601-1:2005, Annex D. Examples of schemas of typical suction systems using graphical symbols are given in Annex A.

Compliance shall be verified by visual inspection.

Annex A
(informative)

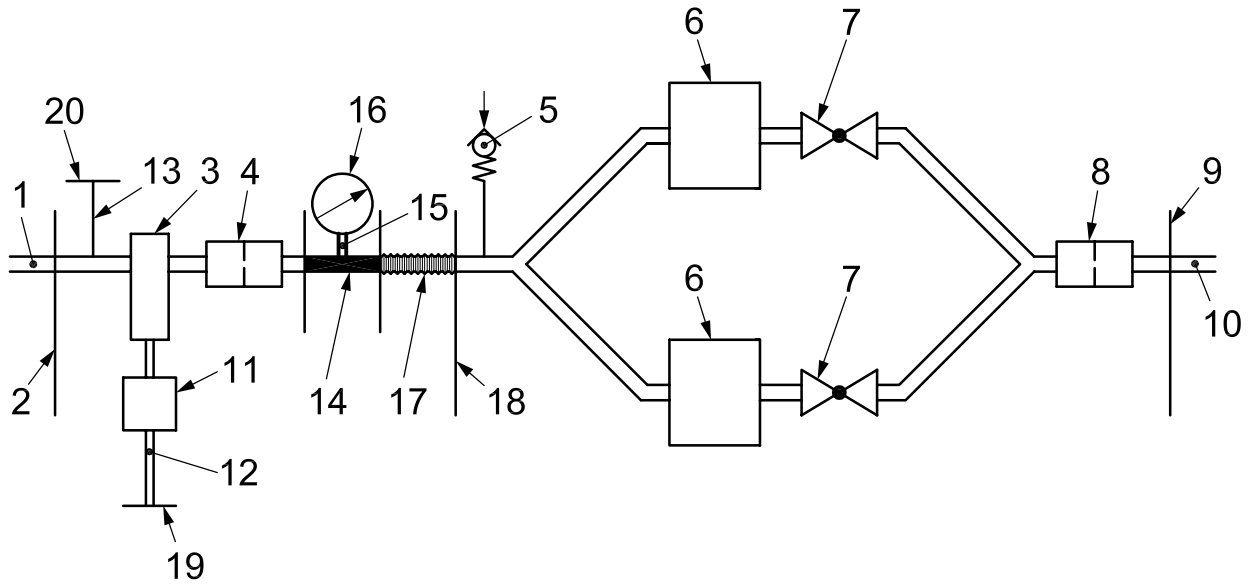
Schematic diagrams of typical suction plant equipment



Key

1 main suction line
2 main suction line connection point
3 condensate separator (optional)
4 bacterial filter (optional)
5 relief valve
6 suction machine
7 non-return valve
8 bacterial filter (optional)
9 exhaust line connection point
10 air exhaust line
11 waste water line
12 tapping point
13 measuring section line
14 suction machine connection point
15 flexible tube
16 pressure gauge (only for factory tests)
17 waste water connection point

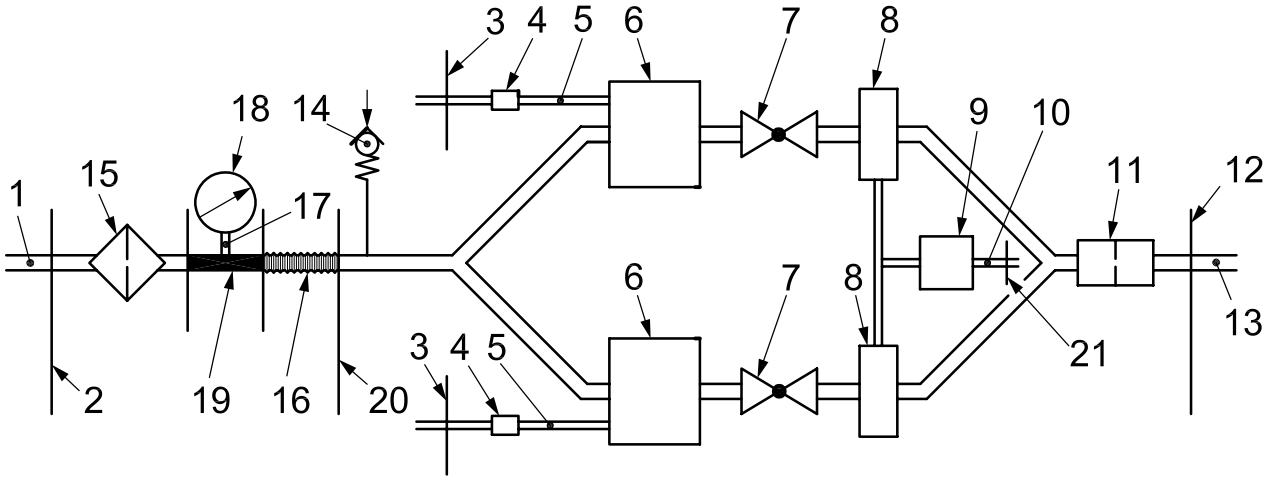
Figure A.1 — Dry-suction system



Key

1 main suction line
2 main suction line connection point
3 air separator
4 bacterial filter (optional)
5 relief valve
6 suction machine
7 non-return valve
8 bacterial filter (optional)
9 exhaust line connection point
10 air exhaust line
11 amalgam separator
12 waste water line
13 water line
14 measuring section line
15 tapping point
16 pressure gauge (only for factory tests)
17 flexible tube
18 suction machine connection point
19 waste water connection point
20 water line connection point

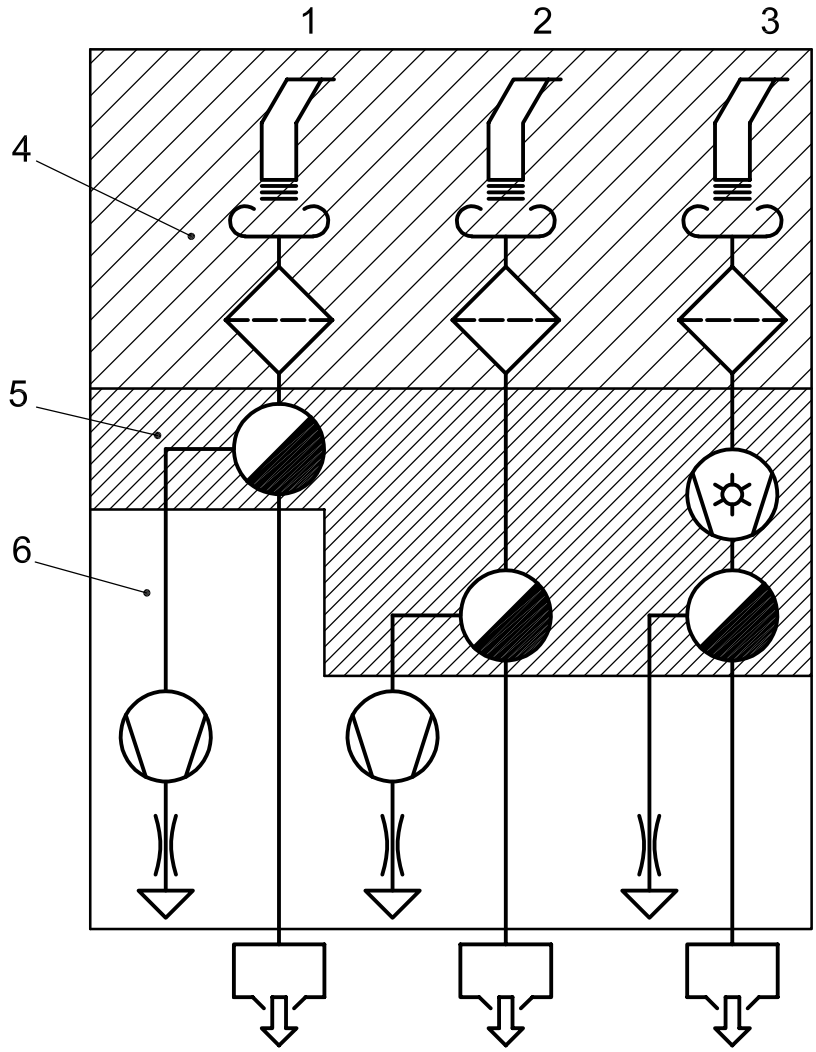
Figure A.2 — Semi-dry-suction system



Key

1 main suction line
2 main suction line connection point
3 water line connection point
4 filter
5 water line
6 suction machine
7 non-return valve
8 air separator
9 amalgam separator
10 waste water line
11 bacterial filter (optional)
12 exhaust line connection point
13 air exhaust line
14 relief valve
15 filter
16 flexible tube
17 tapping point
18 pressure gauge (only for factory tests)
19 measuring section line
20 suction machine connection point
21 waste water connection point

Figure A.3 — Wet-suction system

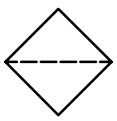


Key

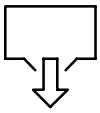
1	dry-suction system	4	wet zone
2	semi-dry-suction system	5	semi-dry zone
3	wet-suction system	6	dry zone


cannula connector (ISO 7000-1831)

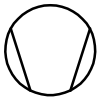
holder/manifold (ISO 7000-0703)


filter (ISO 1219-1:1991, 10.2.2.1)


separator (ISO 7000-0157)


waste (ISO 7000-0029)


liquid seal pump (ISO 7000-0138)


suction pump (ISO 7000-0137)

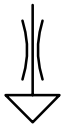

continuous air outlet (ISO 1219-1:1991, 6.2.2.1.1)

Figure A.4 — Suction systems

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[9] IEC 61672-2:2003, *Electroacoustics — Sound level meters — Part 2: Pattern evaluation tests*

1) To be published. (Revision of ISO 1219-1:1991)

2) Under preparation.

ICS 11.060.20

Price based on 18 pages