TECHNICAL SPECIFICATION

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Dentistry — Plant area equipment —

Part 2: Compressor systems

Art dentaire — Installation de la zone technique —

Partie 2: Systèmes de compression

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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

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ISO/TS 22595-2 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*

Introduction

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

The air compressor equipment consists of the compressor unit, compressed-air line, fittings and shut-off valve.

Ancillary equipment may include air conditioning, heating, hot water and equipment that may be installed in the plant area.

Dentistry — Plant area equipment —

Part 2:
Compressor systems

1 Scope

This Technical Specification applies to compressor units for dental air and specifies quality requirements for dental air, fittings, pipe lines and valves in the plant area, used to source compressed air for the dental units, dental instruments and technical dental lab equipment.

This Technical Specification gives recommended guidelines for performance as well as test procedures for compressor units for dental air with at least a compressor motor set including compressor head, air receiver, air dryer system, condensed water tap, pressure switch, valves, pipes, fittings and quality requirements for dental air.

The technical specifications of the compressor unit are limited to the compressed-air main 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 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods*

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

ISO 8573-1, *Compressed air — Part 1: Contaminants and purity classes*

ISO 8573-2, *Compressed air — Part 2: Test methods for oil aerosol content*

ISO 8573-3, *Compressed air — Part 3: Test methods for measurement of humidity*

ISO 9687, *Dental equipment — Graphical symbols*

ISO/TS 22595-1, *Dentistry — Plant area equipment — Part 1: Suction systems*

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, *Electroacoustics — Sound level meters — Part 1: Specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, ISO 1942, ISO 7494-1, ISO 7494-2, ISO/TS 22595-1 and the following apply.

3.1
air dryer system
device designed to reduce the humidity of compressed dental air and which is part of the compressor unit

3.2
air filter
device designed to remove solid particles from the compressed air

3.3
air receiver
device designed to store compressed air, which is a pressure vessel and part of the compressor unit

3.4
bacterial filter
device designed to minimize the content of bacteria in the dental air

3.5
compressed-air main line
pipeline through which compressed air from the compressor unit is carried via the compressed-air main line connection point to all consuming dental devices

3.6
compressed-air main line connection point
location where the air main line is connected to the pipes of all consuming dental devices

3.7
compressor motor set
device consisting of one or more electrically driven compressor heads

3.8
compressor unit
electrically driven device that creates dental air for dental surgeries and dental laboratory applications and which consists of one or more compressor motor sets

3.9
compressor unit connection point
location where the compressed-air main line is connected to the compressor unit

3.10
condensed water tap
device designed to drain off condensed water from the air receiver

3.11
compressor fresh air inlet
location where the compressor unit sucks in the atmospheric air

3.12
dental air
common ambient air available in the dental office, used in dental procedures in the oral cavity of the patient

NOTE This air is different from medical air used for anaesthetic purposes or for surgical purposes (e.g. during endoscopy).

[ISO 7494-2:2003, definintion 3.22]

3.13
fittings
materials that are used to connect the compressor unit, valves and devices with the pipes

3.14
flexible tube
device to connect the inlet muffler and the air inlet filter of the compressor unit or compressor motor sets with the fresh air connection point

3.15
fresh air inlet
location where the compressor unit or each compressor motor set can draw in the atmospheric air from a source located outside the plant area

3.16
fresh air ventilation
location where atmospheric air enters the plant area

3.17
inlet muffler and air inlet filter
device designed to protect the compressor unit against solid particles in atmospheric air and reduce the noise level of the intake of atmospheric air

3.18
oil separator
device that is installed in an oil-lubricated compressor unit in order to reduce the oil contamination of the compressed air

3.19
plant area fresh air connection point
location where the compressor unit or each compressor motor set and the ventilating pipe are connected

3.20
pressure-regulating valves
compressor unit components that limit the maximum air pressure delivered into the main air line by the compressor unit

3.21
quick-release coupling device
device that is installed behind the shut-off valve at the compressor unit connection point to disconnect the compressor unit from the compressed-air main line for maintenance and measurement of air flow rate, air humidity, ambient temperature and noise level

3.22
shut-off valve
device that is installed between the compressor unit and the compressor unit connection point and which is used for maintenance to isolate the compressor unit from the compressed-air main line

3.23
ventilating pipe
pipe from the fresh air connection point to the fresh air inlet

3.24
air outlet
location where the air exits the plant area

4 Classification

4.1 According to the type of compressor motor set

Compressor units are classified according to the type of compressor motor set into the following two types.

— **Type 1: oil-lubricated system**: the compressor heads are oil-lubricated.

— **Type 2: non-oil-lubricated system**: the compressor heads are designed and constructed so that there is no oil lubrication required.

4.2 According to the type of protection against electric shock

4.2.1 Class I equipment

Equipment in which protection against electric shock does not rely on basic insulation only, but includes an additional safety precaution that 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.

4.2.2 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.

4.3 According to mode of operation

Compressor units are classified as applicable for either intermittent or continuous operation.

5 Requirements

5.1 Electrical

For compressor units the requirements of IEC 60335-1, IEC 60204-1 or IEC 61010-1 apply.

5.2 Performance

5.2.1 Compressor unit

The compressor unit shall have a capacity of continuous flow at atmospheric pressure of at least 50 l/min at a nominal pressure of 5 bar at the incoming air connection point (see ISO 7494-2:2003, Figure 1, key item 11) for one dental unit.

For more than one dental unit, a clinic or a technical laboratory with more than three dental compressed-air devices, an agreement between the parties concerned shall specify the quantity of air at atmospheric pressure that is required to simultaneously operate a number of dental units and/or technical laboratory benches.

The manufacturer shall state the maximum number of units compatible with the compressor unit maintaining the correct air pressure.

NOTE All pressure data are pressures in excess of atmospheric pressure.

5.2.2 Ventilating pipe

If the pipe between the fresh air inlet and a fresh air connection point is necessary to supply the compressor unit with filtered air, the internal diameter of the pipes, the material and the fittings shall be installed according to the manufacturer's instructions.

The fresh air ventilation shall supply low-contaminated atmospheric air to the plant area.

If it is not possible to prevent the air of the plant area from being contaminated by other installed devices, the compressor unit shall be connected with the ventilating pipe at the fresh air connection point.

The coupling with each compressor motor set of the compressor unit at the fresh air connection point shall be achieved by a flexible tube according to the manufacturer's instructions.

Testing shall be carried out by visual inspection.

5.2.3 Inlet muffler and air inlet filter

If a fresh air inlet is installed and the compressor unit is connected with the ventilating pipe at the fresh air connection point, air inlet filters and inlet mufflers shall be fitted between the compressor unit or each compressor motor set and the fresh air connecting point.

The manufacturer’s instructions shall define the interval and method for changing the filter element.

Testing shall be carried out by visual inspection and by comparing the observations with the technical data of the manufacturer.

5.2.4 Oil separator/filter

The device of an oil-lubricated compressor shall remove oil and oil vapour from compressed air. The oil content shall be $< 0{,}1$ mg/m^3 by atmospheric pressure. ISO 8573-1, Class 2, applies.

Replacements for the filter elements shall be carried out in accordance with the requirements and recommendations of the manufacturer [see 7.2 j)].

Testing shall be carried out by comparing the technical data and the test results, in accordance with ISO 8573-2.

5.2.5 Air receiver

The device shall be internally coated to prevent corrosion or shall be made of corrosion-resistant materials.

Testing shall be carried out by visual inspection, if required, in accordance with national regulations.

5.2.6 Condensed water tap

If the dryer is located upstream of the receiver, the device shall be at the lowest point of the receiver to drain off condensed water in preparation for a fault condition and for maintenance purposes.

If the dryer is located downstream of the receiver and the receiver acts as a secondary after-cooler, an automatic condensed water trap shall be installed.

Testing shall be carried out by visual inspection and the possibility of manually opening and closing the water tap.

5.2.7 Air dryer system

The air dryer shall supply an air quality that complies with ISO 8573-1, Class 4, corresponding to a pressure dew-point $\leqslant$ +3 °C and a specified air flow according to 5.2.1 under normal conditions of use (see 6.2) by the method of compressor unit installation recommended by the manufacturer.

Under the worst conditions the device shall withstand a maximum ambient temperature of 40 °C.

NOTE The optimal range for ambient temperature of the device is from 10 °C to 25 °C and it shall be capable of withstanding a maximum of 40 °C.

Testing shall be carried out in accordance with 6.4.

5.2.8 Air filter

The device shall be fitted at the outlet of the air dryer system. The grade of filtration shall be $\leqslant$ 5 µm (nominal). ISO 8573-1, Class 3, applies.

If an air dryer is used with drying agents, the grade of filtration shall be $\leqslant$ 1 µm (nominal) to prevent drying agent dust from entering the compressed-air main line. ISO 8573-1, Class 2, applies.

The manufacturer shall specify the method and interval for the filter element replacement.

5.2.9 Bacterial filter

If a bacterial filter is fitted, it shall be installed downstream of the air filter. The grade of filtration shall be at least 0,01 µm with an efficiency of 99,99 %.

The manufacturer shall specify the method and interval for the filter element replacement.

5.2.10 Compressed-air main line

The compressed-air main line shall be installed in accordance with the instructions for use and maintenance provided by the manufacturer of the compressor.

The lines shall be installed in an area with a temperature which shall not fall below 10 °C.

The manufacturer shall specify the internal diameter and thickness of the pipe wall and fittings.

Testing shall be carried out by visual inspection.

5.2.11 Compressor unit connection point

A quick-release coupling device shall be installed at the connection point, which connects the compressor unit by a flexible and electrically earthed tube with the compressed-air main line, to prevent transmission of vibration and static electricity to the compressed-air main line connection point.

Testing shall be carried out by visual inspection.

5.2.12 Shut-off valve

The shut-off valve shall be installed on either the inlet or outlet sides of the pressure-regulating valve. The device is a part of the piping or compressor units. If the shut-off valve is installed on the inlet side, an additional valve may need to be installed on the outlet side by the tester for testing purposes.

Testing shall be carried out by visual inspection.

5.2.13 Fittings

Fittings that are used for compressed-air lines shall be manufactured from a material that does not reduce the air quality.

NOTE Examples of material are copper, stainless steel, brass, plastic.

5.2.14 Pressure-regulating valve

The pressure-regulating valve shall be capable of modulating outlet pressure at the flow rate and pressure stated by the manufacturer for the compressor unit, before the shut-off valve, as a part of the piping or compressor unit mainly for measurement purposes of air flow rate and air humidity.

Testing shall be carried out in accordance with the manufacturer's instruction [see 7.2 j)].

The reduction of pressure due to flow resistance in the compressed-air main line to all consuming dental devices shall be as high as possible due to high adjusted pressure.

5.2.15 Dental air

The dental air shall have a pressure which shall not fall below 0,55 MPa at the compressor unit connection point and at the incoming air connection point of the connected dental units (ISO 7494-2:2003; Figure 1, key item 11). The air humidity shall be according to ISO 8573-1, Class 4.

The oil content shall not exceed 0,1 mg/m^3 by atmospheric pressure. ISO 8573-1, Class 2, applies.

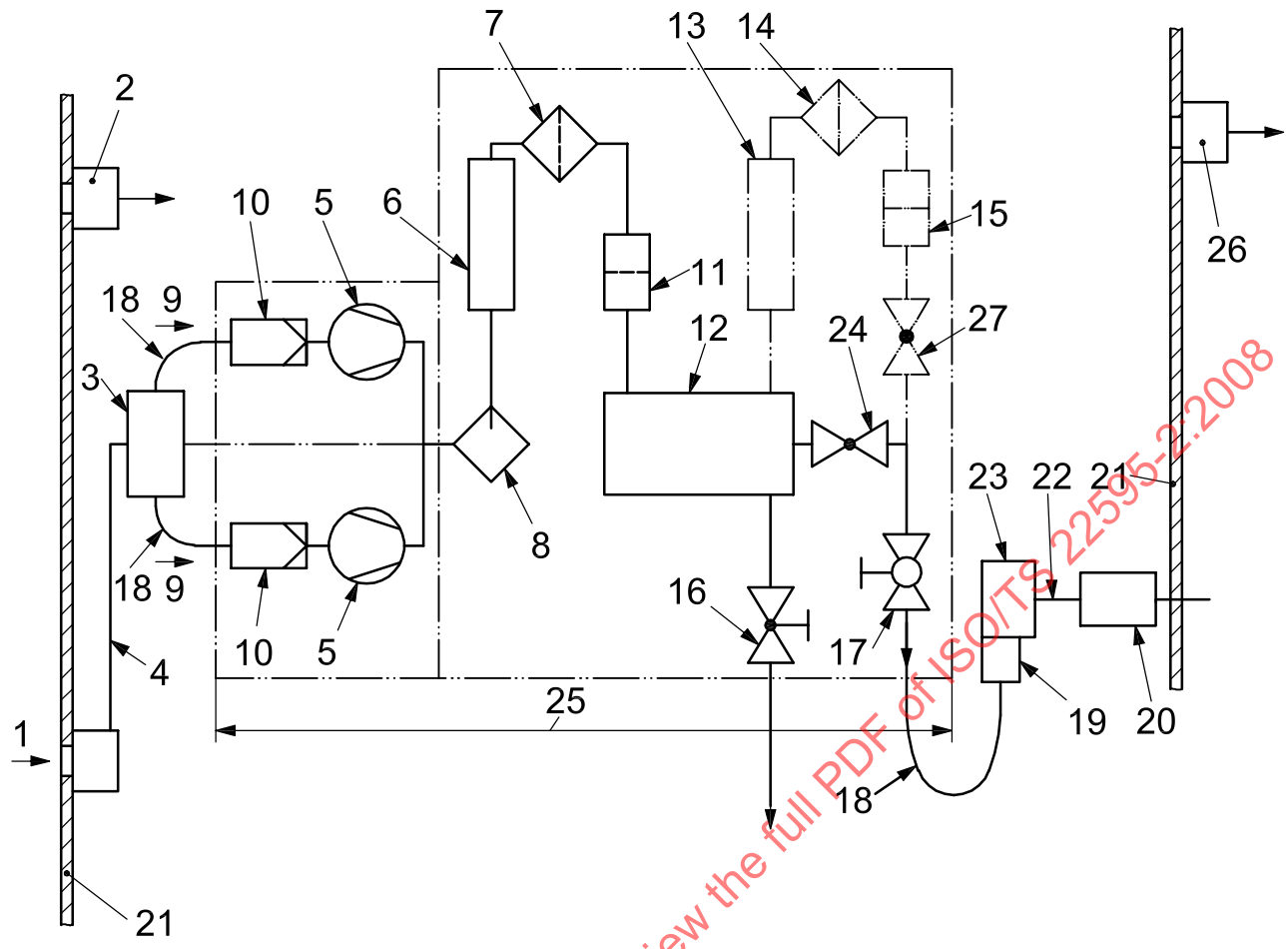
The particle size of solids in the compressed air shall not exceed 5 µm. To minimize the content of bacteria in the compressed air, a bacterial filter with a filtration grade of 0,01 µm and a filter performance $\geqslant$ 99 % can be fitted as an option.

Testing shall be carried out in accordance with 6.4.

5.2.16 Compressor unit ventilation

The compressor unit and auxiliary equipment shall be ventilated with the help of a sufficiently large fresh air ventilation and waste air outlet, according to manufacturer's instructions.

See Figure 1 for the compressor arrangement.



Key

1 fresh air inlet
2 fresh air ventilation
3 air filter
4 ventilating pipe
5 compressor motor set
6 air dryer system
7 air filter
8 oil separator/filter (if necessary)
9 compressor fresh air inlet (depending on plant air condition)
10 inlet muffler and air inlet filter
11 bacterial filter (alternate position and optional)
12 air receiver
13 air dryer system (alternate)
14 air filter (alternate)
15 bacterial filter (alternate position and optional)
16 condensed water tap
17 shut-off valve
18 flexible tube
19 quick-release coupling device
20 compressed-air main line connection point
21 plant area wall
22 compressed-air main line
23 compressor unit connection point
24 pressure-regulating valve
25 compressor unit
26 waste air outlet
27 pressure-regulating valve (alternate position)

Figure 1 — Schematic diagram of typical compressor arrangement

6 Testing procedures

6.1 Visual inspection

Visual inspection shall be carried out at normal visual acuity without magnification. If visibility is limited, additional illumination or an inspection device may be required (e.g. fibre optic).

6.2 Test conditions

Carry out tests under the following conditions:

a) the pressure in the compressor main line shall be set to the required pressure by using the pressure-regulating valve and shut-off valve, and the flow rate (continuous flow) shall be set as specified in 5.2.1;

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 Air flow rate at quick-release coupling device

Check the correct installation of the pressure-regulating valve and the shut-off valve behind the receiver according 5.2.14 and 5.2.16, connect a flowmeter behind the quick-release coupling device and activate the system. The measured quantity of air at a pressure given by the manufacturer takes into account the resistance of flow in the pipes between the compressor unit connection point and the incoming air connection point of the dental units (see ISO 7494-2:2003; Figure, key item 11) and shall guarantee at least the quantity of continuous air flow, as specified in 5.2.1, measured after achieving normal use conditions as specified in 6.2.

6.4 Air humidity at quick-release coupling device

Connect a pressure dew-point-measuring device behind the quick-release coupling device. Activate the compressor unit by setting the air consumption to the flow rate and the pressure according to 5.2.1. Measure the pressure dew-point in accordance with the test method of ISO 8573-3.

6.5 Measurement of noise level

6.5.1 Apparatus

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

6.5.2 Procedure

Operate the compressor unit as described in 6.2. After the normal condition of use is reached, use the sound level meter and measure the maximum A-weighted sound pressure value in accordance with ISO 3746.

7 Information to be supplied by the manufacturer

7.1 General

The requirements in IEC 60204-1, IEC 60335-1, IEC 60364-6-6 or IEC 60364-7-710 apply. IEC 60601-1 is applicable if compressor units are installed in a separate plant area, like a noise-reduced cabinet, within 1,5 m of the patient.

7.2 Technical description

The following information shall be provided by the manufacturer of the compressor unit:

a) overall dimensions and weight of the parts of the compressor unit;

b) technical data of the compressor unit (characteristic curve of quantity of air dependent upon the overpressure, noise level, fresh air connection point, compressor unit connection point and internal diameter of the compressed-air main line, flexible tubes, fittings, pipe materials, pipe diameters);

c) information on assembly in the field, installation and mounting of the compressor unit;

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

e) attachments that the compressor unit is designed to accept;

f) schematic wiring diagrams;

g) list of spare parts and consumables that would be required in general use;

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

i) type of compressor motor set (oil-lubricated system or oil-free system);

j) operating and maintenance instructions;

k) typical diagnostic procedures for correcting problems;

l) information for the installer regarding minimum temperature for the compressed-air line.

7.3 Information on the plant area

The following information shall be provided by the manufacturer:

a) design or layout of the fresh air inlet, to prevent liquids and solids from entering the ventilating pipe system;

b) location of the suction system for exhaust air, to prevent it from recirculating into the compressor intake;

c) minimum size of doorway and room clearance, to allow placement and maintenance of the equipment;

d) desired location of compressed-air piping between dental units and the plant area equipment;

e) recommendations and specifications for temperature alarms and ventilation for the plant area;

f) ventilation requirements for cooling of the plant area.