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## Dentistry — Central compressed air source equipment

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition cancels and replaces ISO/TS 22595-2:2008.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

Central compressed air source equipment is nearly universally present in modern dental treatment facilities. It consists of components located separate from treatment rooms used to compress air, prepare the air to meet quality requirements and to store the dental air for eventual use by treatment room pneumatic devices such as air powered hand pieces and air-water syringes as well as for cooling purposes.

Since the output of central compressed air source equipment is used in dental treatment, the equipment characteristics as well as the quality characteristics of the dental air becomes the subject of this document.

The requirements specified in this document have been developed with consideration for the dental air requirements specified in ISO 7494-2.

In medical applications the quality of “air for medical use” is carefully defined. For example, in the European Pharmacopeia and in other countries there are similar definitions. Air for medical use is used for artificial breathing, anaesthetic, endoscopic and other applications inside the human body, also for long term therapy. Also, it is used in sterile environments like operating rooms. For these applications it is necessary to have a precise definition of the quality of the air. The European Pharmacopeia gives values and limits for the contents of the air as well as limits for dangerous contaminants.

In dental applications, compressed air is used to supply driving power for treatment room pneumatic devices such as air powered hand pieces (“drills”) and for drying an operating site. Air used for these purposes intermittently enters a patient’s mouth and to a significant degree, can be quickly removed by dental suction equipment. As the ambient air in the dental treatment room is not sterile, there is no need for dental air to be sterile nor is there a need for the contents of dental air to be controlled beyond the requirements of normal ambient air.

Nevertheless, there are some essential quality characteristics for the air used in dentistry:

- a) to protect sensitive dental instruments and apparatus (from oil, water, particles);
- b) to provide clean and dry air and to avoid that dental procedures are compromised (because oil is a release agent that it affects e.g. dental adhesion systems);
- c) to protect against high humidity in the dental air that creates corrosion in the air receivers and air lines and that can result in technical difficulties in dental instruments; also to protect against the growth of microorganisms in the dental air system.

The test method in this document has been developed in response to the need for clear specification in determining the quality of the dental air.

Up to now, there is no international standard available which defines the quality of “air for dental use”.

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# Dentistry — Central compressed air source equipment

## 1 Scope

This document specifies requirements and test methods for central compressed air source equipment supplying dental air for dental units and various dental air consuming devices in the dental office.

It also specifies quality requirements and test methods for the dental air produced by the central compressed air source equipment, such as requirements for the purity level of dental air.

It also specifies requirements for information to be supplied by the manufacturer on the performance, installation, operation and maintenance of the central compressed air source equipment.

This document applies only to central compressed air source equipment located outside of the dental treatment room.

This document does not apply to central compressed air source equipment located in the dental treatment room and facility piping. This document does not include requirements for dental laboratory applications (e.g. CAD/CAM systems).

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 2151, *Acoustics — Noise test code for compressors and vacuum pumps — Engineering method (Grade 2)*

ISO 7494-2, *Dentistry — Dental units — Part 2: Air, water, suction and wastewater systems*

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

ISO 8573-2, *Compressed air — Contaminant measurement — Part 2: Oil aerosol content*

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

ISO 8573-4, *Compressed air — Contaminant measurement — Part 4: Particle content*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

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

IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Generic standards — Immunity for industrial environments*

IEC 61000-6-3, *Electromagnetic compatibility (EMC) — Generic standards — Emission standard for residential, commercial and light-industrial environments*

IEC 60417-1, *Graphical symbols for use on equipment — Part 1: Overview and application*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 7494-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1

##### **air cooler**

device designed to reduce the temperature of *compressed air* (3.9) to a desired level

#### 3.2

##### **air delivery flow rate**

performance of *central compressed air source equipment* (3.8) defined as Normal litres per minutes

#### 3.3

##### **air dryer system**

system designed to reduce the humidity of *compressed air* (3.9) to a desired level

EXAMPLE Adsorption dryer, membrane dryer, refrigeration dryer.

#### 3.4

##### **air filter**

air treatment system component used to lower *compressed air* (3.9) particulate content

#### 3.5

##### **air intake filter**

device designed to remove particles from intake air

#### 3.6

##### **air receiver**

component used to store *compressed air* (3.9)

#### 3.7

##### **bacterial filter**

device designed to restrict the passage of bacteria and to reduce bacteria in the *dental air* (3.14)

#### 3.8

##### **central compressed air source equipment**

all components located between air intake and the *central compressed air source equipment connection point* (3.17), excluding the *suction tube* (3.32) if present

#### 3.9

##### **compressed air**

ambient air compressed to a higher-pressure level than ambient pressure

#### 3.10

##### **compressed air filter**

device designed to remove solid particles from the *compressed air* (3.9) after the air dryer

#### 3.11

##### **compressor head**

collection of mechanical components used to compress ambient air

Note 1 to entry: Compressor heads may be of various mechanical types such as piston and rotary screw.



**3.12****compressor motor set**

collection of components including one or more *compressor heads* (3.11) along with one or more electrical drive motors

**3.13****condensate drain**

device to drain off condensed water from the *air receiver* (3.6), water separator, air dryer, *air filter* (3.4)

**3.14****dental air**

*compressed air* (3.9) for powering, controlling, and/or assisting various dental instruments and equipment, as well as for assisting practitioners with procedures in the oral cavity, but not for procedures requiring medical air or sterile air, such as endoscopy, oral surgery, analgesia, and life support

[SOURCE: ISO 7494-2, 2015, 3.7]

**3.15****dental air outlet**

location at *central compressed air source equipment* (3.8) where the *dental air* (3.14) lines or additional devices are connected to central compressed air source equipment

**3.16****dental compressor**

collection of components used to compress, treat and store air that meets *dental air* (3.14) specifications for dental procedures

**3.17****central compressed air source equipment connection point**

location where the *central compressed air source equipment* (3.8) is connected to the *main line for dental air* (3.25)

**3.18****dewpoint**

temperature at which water vapour begins to condense

**3.19****exhaust air outlet**

point where the cooling air exits *central compressed air source equipment* (3.8) location room

**3.20****fittings**

components that are used to connect the *dental compressor* (3.16), valves and devices with the pipes

**3.21****flexible tube**

hose or tube which connects the compressor with the remain *central compressed air source equipment* (3.8) or with the connection point to the *main line for dental air* (3.25) or, if applicable the quick release coupling device

**3.22****fresh air inlet**

location where *central compressed air source equipment* (3.8) can draw in the atmospheric air from a source, where appropriate located outside the building

**3.23****fresh air ventilation**

place, where fresh air can enter *central compressed air source equipment* (3.8) location for ventilation, cooling and compressing

**3.24**

**intake muffler**

device which reduces the noise level caused by the suction action of the compressor

**3.25**

**main line for dental air**

components of a piping installation in a dental facility used to transport *dental air* (3.14) from *central compressed air source equipment* (3.8) to the dental treatment room and other rooms with various dental air consuming devices

**3.26**

**oil separator**

device that is installed in oil-lubricated *central compressed air source equipment* (3.8) in order to reduce the oil content of the *compressed air* (3.9)

**3.27**

**central compressed air source equipment location**

area outside the dental treatment room in a dental facility where equipment which supplies *dental air* (3.14) to one or more treatment rooms are installed

**3.28**

**pressure dewpoint**

*dewpoint* (3.18) of the air at the specified pressure

**3.29**

**pressure-regulating valve**

device that controls the maximum air pressure delivered to the *main line for dental air* (3.25)

**3.30**

**quick-release coupling device**

device that is installed at the *central compressed air source equipment* (3.8) connection point to disconnect the central compressed air source equipment from the *main line for dental air* (3.25) for maintenance and measurement of *air delivery flow rate* (3.2), air humidity and noise level

**3.31**

**shut-off valve**

device that is used for maintenance to isolate *central compressed air source equipment* (3.8) from the *main line for dental air* (3.25) installed between the *air receiver* (3.6) and the *dental air outlet* (3.15)

**3.32**

**suction tube**

component for connecting the *fresh air inlet* (3.22) with the compressor fresh air inlet

**3.33**

**water separator**

component of the *air dryer system* (3.3) used to remove liquid water from *compressed air* (3.9)

## 4 Classification

Central compressed air source equipment shall be classified according to the type of compressor lubrication methods into the following two types:

### Type 1: oil-lubricated compressor heads

Compressor heads are oil-lubricated.

For typical central compressed air source equipment arrangements of oil-lubricated compressor, see [B.1](#) and [B.2](#), and [Figures B.1](#) and [B.2](#).

### Type 2: non-oil-lubricated compressor heads

Compressor heads are not oil-lubricated.

For typical central compressed air source equipment arrangements of non-oil-lubricated compressor, see [B.3](#) and [B.4](#), and [Figures B.3](#) and [B.4](#).

## 5 Requirements

### 5.1 Electrical safety

Dental compressors and other parts of the central compressed air source equipment are designed as stationary equipment to be installed in a location separate from dental treatment rooms.

To prevent electrical conduction between central compressed air source equipment and the main line for dental air in case of fault condition, hoses or tubes (flexible tubes), which connect the dental compressor with the central compressed air source equipment connection point or, if applicable the quick release coupling device, shall be made from an electrical insulating material.

For central compressed air source equipment, the safety requirements of IEC 60335-1 apply.

Testing shall be carried out in accordance with IEC 60335-1.

### 5.2 Electromagnetic compatibility

For electromagnetic compatibility (EMC), the following requirements shall apply.

Immunity requirements of IEC 61000-6-2 shall apply.

Testing shall be carried out in accordance with IEC 61000-6-2.

Emission requirements of IEC 61000-6-3 shall apply.

Testing shall be carried out in accordance with IEC 61000-6-3.

### 5.3 Quality of dental air

The dental air produced by the central compressed air source equipment shall conform to purity class [2:4:2] according ISO 8573-1.

Explanation of purity-class [2:4:2]:

**Particle class 2:** The numbers of particle in the dental air are as follows:

Particle size	Number of particles per cubic metre
$0,1 \mu\text{m} < d \leq 0,5 \mu\text{m}$	$\leq 400\ 000$
$0,5 \mu\text{m} < d \leq 1,0 \mu\text{m}$	$\leq 6\ 000$
$1,0 \mu\text{m} < d \leq 5,0 \mu\text{m}$	$\leq 100$

**Humidity class 4:** The pressure dewpoint is  $\leq +3 \text{ }^\circ\text{C}$  at  $20 \text{ }^\circ\text{C}$  medium temperature and at  $0,7 \text{ MPa}$  constant system pressure (this is equivalent to an atmospheric dewpoint of  $\leq -21 \text{ }^\circ\text{C}$ ).

**Oil content class 2:** The oil content of the dental air is  $\leq 0,1 \text{ mg/m}^3$ .

Testing shall be carried out in accordance with [7.2.3.1](#), [7.2.3.2](#), [7.2.3.3](#).

NOTE 1 In ISO 8573-1 the classification for humidity is defined in relation to the gas temperature.