

ICS 11.060.20
CCS C 33

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0905-2023

Replacing YY/T 0905.2-2013

Dentistry - Central compressed air source equipment

牙科学 中央压缩空气源设备

(English Translation)

Issued on: September 5, 2023

Implemented on: March 15, 2025

Issued by: State Drug Administration

Table of Contents

Preface

Introduction

1 Scope

2 Normative reference documents

3 Terms and Definitions

4 Category

5 Requirements

6 Sampling

7 Test method

8 Information provided by the manufacturer

9 Mark

Appendix A (informative) Central compressed air source equipment design example

Appendix B (informative) Suggested template for test report

Appendix C (informative) Typical arrangements and construction and installation
recommendations for central compressed air source equipment in dental facilities

Reference

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting.

This document replaces YY/T 0905.2-2013 "Dental Site Equipment Part 2: Compressor System" and is the same as YY/T 0905.2-Compared with 2013, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

---Changed the scope of the standard (see Chapter 1, Chapter 1 of the 2013 edition), terms and definitions (see Chapter 3, Chapter 3 of the 2013 edition), Classification (see Chapter 4, Chapter 4 of the 2013 edition), electrical safety (see 5.1, 5.1 of the 2013 edition), dental air quality (See 5.3, 5.2.4, 5.2.7, 5.2.8, 5.2.15 of the 2013 edition), air delivery flow rate of central compressed air source equipment (see 5.4.1, 5.2.1 of the 2013 edition), condensate discharge (see 5.4.2, 5.2.6 of the 2013 edition), bacterial filter (see 5.4.3, 5.2.9 of the 2013 edition), information provided by the manufacturer (see Chapter 8, Chapter 7 of the 2013 edition), marking (see Chapter 9, 2013 version of Chapter 8);

---Added electromagnetic compatibility requirements (see 5.2), sound level of central

compressed air source equipment (see 5.4.4), sampling (see Chapter 6) Require;

---Deleted the breather pipe (see 5.2.2 of the 2013 version), air intake silencer and air intake filter (see 5.2.3 of the 2013 version), air Gas storage tank (see 5.2.5 of the 2013 edition), compressed air main pipe (see 5.2.10 of the 2013 edition), compressor unit connection point (see 5.2.11 of the 2013 edition), stop valve (see 5.2.12 of the 2013 edition), connectors (see 5.2.13 of the 2013 edition), pressure the requirements for force regulating valves (see 5.2.14 of the 2013 edition) and compressor unit vents (see 5.2.16 of the 2013 edition) will be relevant the content has been adjusted to informative appendix C.

This document is modified to adopt ISO 22052:2020 "Dental Central Compressed Air Source Equipment".

Compared with ISO 22052:2020, this document has made the following structural adjustments.

---Adjust Appendix B of ISO 22052:2020 to Appendix C; adjust Appendix C of ISO 22052:2020 to Appendix B.

The technical differences between this document and ISO 22052:2020 and their reasons are as follows.

---Replaced ISO 1942 (see Chapter 3) with normatively cited GB/T 9937 to adapt to my country's technical conditions and increase operability work nature;

---Replaced ISO 8573-2 (see 7.2.3.3) with normatively cited GB/T 13277.2 to adapt to my country's technical conditions, adding Operability;

---Replaced ISO 8573-3 (see 7.2.3.2) with normatively cited GB/T 13277.3 to adapt to my country's technical conditions, adding Operability;

---Replaced ISO 8573-4 (see 7.2.3.1) with normatively cited GB/T 13277.4 to adapt to my country's technical conditions, adding Operability;

---Replaced ISO 2151 (see 7.2.4) with normatively cited GB/T 21271 to adapt to my country's technical conditions and increase operability work nature;

---Replaced IEC 60335-1 (see 5.1) with normatively quoted GB 4706.1 to adapt to my country's technical conditions and increase operability work nature;

---Replaced IEC 60417 (see 9.3) with normatively quoted GB/T 5465.2 to adapt to my country's technical conditions and increase operability work nature;

---Replaced IEC 61000-6-2 [see 5.2a)] with the normatively cited GB/T 17799.2 to adapt to my country's technical conditions, adding Increase operability;

---Replaced IEC 61000-6-3 [see 5.2a)] with the normatively cited GB 17799.3 to adapt to my country's technical conditions, adding Operability;

- Replaced ISO 9687 (see 8.2) with normatively cited YY/T 0628 to adapt to my country's technical conditions and increase operability work nature;
- Replaced ISO 7494-2 (see Chapter 3) with normatively cited YY/T 1043.2 to adapt to my country's technical conditions, adding Operability;
- Added GB 4793.1 and GB/T 18268.1 (see 5.1, 5.2, 8.2, 8.3, 9.1, 9.2), taking into account the actual implementation of standards within the country;
- Changed the auxiliary verb in the clause expression in the classification, changing "central compressed air source equipment should be divided into the following two types" to "central Compressed air source equipment can be divided into the following two types" (see Chapter 4) to adapt to technological development;
- Electrical safety has been changed, changing "should comply with the requirements of GB 4706.1" to "should comply with the requirements of GB 4706.1 or GB 4793.1" "Requirements", change "should be tested according to GB 4706.1" to "should be tested according to GB 4706.1 or GB 4793.1" (see 5.1), Because taking into account the actual situation of the implementation of domestic standards for medical devices;
- Changed the electromagnetic compatibility requirements and added "If the safety requirements comply with GB 4793.1, then the requirements of GB/T 18268.1 shall comply with combine. The test should be carried out in accordance with GB/T 18268.1" [see 5.2b)], and 5.2 in the original clause ISO 22052:2020 is listed as 5.2a), Because considering the actual situation of domestic implementation standards of medical devices;
- Changed the instructions for use, changing "h) technical data in compliance with GB 4706.1" to "h) in compliance with GB 4706.1 or GB 4793.1 "Technical data" (see 8.2), because the actual implementation of standards for medical devices in the country is considered;
- The technical description has been changed, changing "v) technical data in compliance with GB 4706.1" to "v) in compliance with GB 4706.1 or GB 4793.1 "Technical data" (see 8.3), because the actual implementation of standards for medical devices in the country is considered;
- Changed the mark on the central compressed air source equipment, changing "according to GB 4706.1" to "according to GB 4706.1 or GB 4793.1" (see 9.1), because of considering the actual situation of the implementation of standards for medical devices in China;
- Changed the marking of the control device, changing "GB 4706.1 applicable" to "GB 4706.1 or GB 4793.1 applicable" (see 9.2), Because considering the actual situation of domestic implementation standards of medical devices;
- Deleted the 5.5 test report to adapt to the specific domestic conditions.

The following editorial changes have been made to this document.

---Deleted the introductory words about the ISO and IEC terminology database URLs in "Terms and Definitions" (see Chapter 3).

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

Introduction

Central compressed air source equipment is almost universally found in modern dental treatment facilities. It consists of components independent of the treatment room and is used to Compress air, prepare air that meets quality requirements and store dental air for pneumatic devices in the treatment room (such as pneumatic handpieces and three-way nozzles) gun) end use, as well as for cooling purposes.

Since the output of a central compressed air source device is used for dental treatment, the performance of the device as well as the quality characteristics of the air supplied to the dentistry are important.

is the subject of this document.

The requirements specified in this document are developed taking into account the requirements for air for dental use specified in YY/T 1043.2.

In medical applications, the quality of "medical air" is well defined. For example, there are similar definitions in the European Pharmacopoeia and other countries.

Medical air is used for artificial respiration, anesthesia, endoscopy and other in vivo applications, as well as for long-term treatment. In addition, it is used for sterile environment, such as the operating room. For these applications, a more precise definition of air quality is necessary. The European Pharmacopoeia gives airborne substances Content values and limits, as well as limits for hazardous pollutants.

In dental applications, compressed air is used to power treatment room pneumatic equipment such as pneumatic handpieces (drills) and to dry hands.

surgical site. The air used for these purposes is intermittently introduced into the patient's mouth and can, to a large extent, be rapidly expelled through dental suction equipment.

Since the ambient air in a dental treatment room is not sterile, there is no need to sterilize the dental air or to the substance content of the air used is controlled beyond the requirements of normal ambient air.

However, air used in dentistry has some basic quality characteristics.

- a) Protect sensitive dental instruments and instruments (from oil, water, particles);
- b) Provide clean and dry air to prevent dental surgery from being affected (because oil is a release agent and will affect oral adhesion systems such as system, etc.);