DOI: 10.11910/j.issn.2791-2043.2026.3.02

ICS 11.020
CCS C 05

Group standard

T/CRHA 273—2026

Management specifications for installation, use and maintenance of medical air compressors/units in central sterile supply departments

Issued on January 26, 2026 Implemented from January 30, 2026

Issued by **Chinese Research Hospital Association**

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1—2020, Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents.

Please note that some of the contents in this document may be patent related. The releasing organization of this document shall not be responsible for identifying patents.

This document was proposed by the Medical Quality Management and Evaluation Professional Committee of the Chinese Research Hospital Association.

This document is under the jurisdiction of the Chinese Research Hospital Association.

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Management Specifications for Installation, Use and Maintenance of Medical Air Compressors/Units in Central Sterile Supply Departments

Chinese Research Hospital Association

1 Scope

This document specifies the classification, basic requirements, basic components, installation requirements, use requirements, maintenance, and quality and testing requirements for compressed air used for device drying of medical air compressors/units in central sterile supply departments of medical institutions.

This document applies to the management of medical air compressors/units for drying reusable medical devices in central sterile supply departments of medical institutions at all levels and of all types.

2 Normative references

The following documents contain provisions which, through normative reference in this text, constitute provisions of this document. For dated references, subsequent amendments (excluding corrigenda) to or revisions of any of these publications do not apply. For undated references, the latest version of the referenced document (including any amendments) applies.

GB/T 13277.1 Compressed Air - Part 1: Contaminants and Purity Classes

GB/T 13277.2 Compressed Air - Part 2: Test Methods for Oil Aerosol Content

GB/T 13277.3 Compressed Air - Part 3: Test Methods for Measurement of Humidity

GB/T 13277.4 Compressed air - Part 4: Test Methods for Solid Particle Content

GB/T 13277.5 Compressed Air - Part 5: Test Methods for Oil Vapour and Organic Solvent Content

GB/T 13277.7 Compressed Air - Part 7: Test Method for Viable Microbiological Contaminant Content

GB/T 13277.8 Compressed Air - Part 8: Test Methods for Solid Particle Content by Mass Concentration

GB/T 13277.9 Compressed Air - Part 9: Test Methods for Liquid Water Content

TSG 21 Supervision Regulation on Safety Technology for Stationary Pressure Vessel

TSG ZF001 Safety Technical Supervision Regulations for Safety Valves

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

3.1 Medical Air Compressor

Equipment that generates medical compressed air by converting mechanical energy into gas pressure energy.

3.2 Medical Air Compressor Unit

An assembly composed of air compressors, air purification equipment, functional components, and other parts that provide sufficient and clean air for medical equipment requiring an air source.

3.3 Compressed Air for Instrument Drying

Compressed air that has undergone treatment including compression, drying and filtration, with limited contaminant concentrations, and is supplied through a medical pipeline system for drying reusable medical devices after cleaning and disinfection.

3.4 Aftercooler

Equipment that reduces the heat in compressed air after compression is completed.

3.5 Compressed Air Dryer

Equipment that can reduce the content of gaseous moisture in compressed air.

[Source: JB/T 7664—2020, 2.37]

3.6 Adsorption Dryer

A dryer that separates water vapor from compressed air by using the principle that water molecules in the gas or liquid phase can be adsorbed on the surface of an adsorbent, and that can regenerate the adsorbent by removing the water from its surface by various methods.

[Source: JB/T 7664—2020, 3.1]

3.7 Refrigeration Dryer

A dryer that cools the water vapor in compressed air by means of a refrigeration system, causing it to liquefy and be removed.

[Source: JB/T 7664—2020, 3.2]

3.8 Pressure Dew Point

The temperature at which water vapor in compressed air begins to condense at a specified pressure, used to evaluate the drying performance of compressed air.

Note: The unit is degrees Celsius (℃).

3.9 Compressed Air Filter

Equipment generally used for fine separation of small solid contaminants and micro-droplets in compressed air and used to separate small contaminants in compressed air.

Note: Based on the intended use of the filter, they are generally classified into coalescing filters, adsorption filters, dust removal filters, water removal filters, etc.

[Source: JB/T 7664—2020, 2.38, modified]

3.10 Compressed Air Contaminant

Solid particles, moisture, oil, viable microorganisms, etc. in compressed air.

4 Classification

4.1 According to the working principle, air compressors can be classified into piston air compressors, screw air compressors, scroll air compressors, etc.

4.2 According to the lubrication method, air compressors can be classified into oil-free air compressors and oil-lubricated air compressors.

4.3 According to the air supply mode, air compressor units can be classified into centralized air supply compressor units and single-unit air supply compressors. Among them, centralized air supply compressor units can be classified into hospital-level centralized air supply compressor units and department-level centralized air supply compressor units.

5 Basic requirements

5.1 Equipment operators, maintenance personnel, or management personnel shall receive professional training and master the relevant knowledge and skills.

5.2 Management systems and standard operating procedures for equipment, including air compressors, shall be established.

5.3 The medical air compressors/units in the central sterile supply department shall be installed in accordance with the requirements of Chapter 7.

5.4 The quality and testing of compressed air for drying shall comply with the requirements of Chapter 10.

5.5 Routine maintenance and periodic maintenance should be conducted in accordance with the manufacturer's instructions, and records shall be established.

5.6 Testing of safety valves, pressure gauges, air receivers, adsorption dryers, and other components shall be carried out in accordance with TSG 21 and TSG ZF001.

6 Basic components of medical air compressor units

A medical air compressor unit includes an air compressor, an aftercooler, a compressed air dryer, an air receiver, an air filtration system, a pressure-reducing device, connecting pipelines and valves (including check valves, etc.) between the above equipment, instruments and meters, and a control and monitoring system.

7 Installation requirements

7.1 The installation location shall be well ventilated, protected from dampness, with suitable ambient temperature and humidity, and far away from sources of contamination. Centralized air supply compressor units shall be installed in a dedicated equipment room meeting the installation conditions specified in the equipment manual. Adequate space shall be reserved around fixed air compressor units to facilitate necessary inspection, maintenance, and disassembly.

7.2 Oil-free air compressors/units should preferably be selected. An activated carbon filter shall be installed If oil-lubricated air compressors/units are used.

7.3 Noise-reduction designs such as soundproof enclosures, vibration damping devices, or low-speed motors should preferably be used. For centralized air supply compressors installed in independent rooms,

the noise level should preferably be ≤85 dB(A). The noise level of single-supply air compressors installed in work areas should preferably be ≤60 dB(A).

7.4 The types of compressed air dryer and the dew point classes should be selected in accordance with the highest annual temperature and humidity at the location of the medical institution and the required compressed air class. The pressure dew point shall meet the requirements. Common compressed air humidity classes and methods for achieving pressure dew point are shown in Annex A.

7.5 Medical air pressure-reducing devices shall be of the dual-line type incorporating safety valves. Each line shall meet the requirements for maximum flow and safe relief. Copper or stainless steel materials shall be selected.

7.6 In case of any pressure-reducing device used in the unit, the air filtration system shall be installed on the inlet side of the pressure-reducing device, and the filtration shall have no fewer than two stages, with each stage having a standby filter. The filtration accuracy of the final-stage filter of the system shall not be lower than 0.01 μm, and the filtration efficiency shall be greater than 99.9%. Measures for monitoring filter performance shall be taken at the air filter.

7.7 The final stage of the filtration system for compressed air used for drying shall be provided with a bacterial filter, and have a backup with the same flow capacity. The filtration accuracy of the system shall be 0.01 μm to 0.1 μm, and the filtration efficiency shall be greater than 99.995%. Measures for monitoring filter performance shall be taken for the bacterial filter.

7.8 The air receiver shall be made of corrosion-resistant materials such as 304 L or higher-grade stainless steel, or be subject to corrosion-resistant treatment, and automatic and manual drain valves shall be provided for condensate discharge.

7.9 Pressure regulators shall be installed at the points of use. The pressure regulators shall have a pressure indication function, with the indication accuracy ≤ 0.02 MPa. They shall have a pressure adjustment function, with an adjustable range of 0.15 MPa to 0.85 MPa. The pressure shall meet the pressure requirements for drying different devices.

7.10 Corrosion-resistant and easy-to-clean pipelines shall be selected, such as 316 L stainless steel or copper pipes, and flexible connections are recommended for the intake and exhaust pipes of the compressor. A gas sampling port shall be arranged at the gas source outlet.

7.11 The pipelines, valves, and fittings that come into contact with compressed air shall be cleaned before assembly and degreased to ensure that they are free of grease. During assembly, all components shall be kept clean.

7.12 Precautions for installation

a) The basic components and installation of a single-unit air supply compressor shall comply with the requirements hereof. In case of no compressed air drying and filtration systems, the compressed air generated shall not be used for drying reusable medical devices.

b) A standby air compressor should be provided so that the unit can continue to supply air in the event of any single failure (or maintenance) within the air compressor unit.

c) When the central sterile supply department uses the hospital-level centralized air supply, the quality of compressed air shall meet the requirements of 10.1. In case of non-independent configuration, the compressed air shall not be used for the maintenance or purging of various tools, or for driving non-medical pneumatic tools or sealing doors. For compressed air used for device drying in the central sterile supply department, a bacterial filter with a grade meeting the requirements of 7.7 shall be installed at the user end of the centralized air supply.

d) In case of department-level centralized air supply, if the same unit supplies compressed air for both equipment and device drying, a check valve shall be installed on the main supply pipe for equipment use.

e) Drainage pipes or condensate treatment devices should be preferably be arranged at the air compressors, air receivers and air

dryers.

f) Effective grounding measures shall be provided for special voltage and electrical components in accordance with the manufacturer's instructions.

g) The equipment shall not be modified without the manufacturer's authorization.

8 Use requirements

8.1 Pre-use inspection

8.1.1 The environment around the equipment shall be safe and free of flammable or explosive materials.

8.1.2 Check that the power connections of the air compressor and the compressed air dryer are intact, that the pressure gauge pointers are at the 0 position, and that special voltage and electrical components requiring grounding are effectively grounded.

8.1.3 Check that the external pipeline connections are intact with no looseness or gas leakage.

8.1.4 Confirm that there is no accumulated water in the air compressor and the air receiver. In case of manual drainage, close the drain valve.

8.1.5 If it is necessary to open the air valves, the opening sequence shall follow the manufacturer's instructions.

8.2 In-use management

8.2.1 Start the air compressor, compressed air dryer, and other equipment, and ensure that the system operates normally.

8.2.2 After startup and during operation, periodically observe and record the operating conditions of the air compressor and compressed air dryer, pressure gauge readings, and compressed air dryer dew point temperature. For records of the use and routine maintenance of the air compressord/unitd, see Annex B. If the air receiver is provided with automatic drainage, check whether the drainage is unobstructed.

8.2.3 During operation, observe that there is no air leakage and that pressure and temperature are normal. If abnormal vibration, unusual noise, or large pressure fluctuation is detected, the equipment shall be shut down immediately for troubleshooting. In case of an alarm or operation interruption, timely measures shall be taken, with records made.

8.3 Post-use handling

8.3.1 If it is necessary to close the air valves, the closing sequence shall follow the manufacturer's instructions.

8.3.2 Press the stop bitton to cut off the power supply to the air compressor and the compressed air dryer.

8.3.3 If the air receiver is equipped with a manual drain valve, condensate shall be drained.

8.3.4 When necessary, depressurize the air compressor to ensure system safety.

8.4 Precautions for use

8.4.1 The medical air compressors/units shall be used in accordance with the manufacturer's instructions.

8.4.2 Any independent compressed air dryer, if installed, shall be used in accordance with the manufacturer's instructions.

9 Maintenance

9.1 Routine maintenance

9.1.1 The display readings shall be checked daily to ensure they are normal.

9.1.2 The tightness of the pipelines shall be checked daily to ensure that there is no air leakage.

9.1.3 If the air receiver is equipped with an automatic drain valve, its drainage function shall be checked daily. If a manual drain valve is equipped, the condensate shall be completely discharged after the end of each day's work and the drain valve shall be closed, or the condensate shall be discharged at regular intervals according to the manufacturer's instructions.

9.1.4 For air compressors equipped with a refrigeration dryer, the dew point temperature and condensate drainage shall be checked daily to ensure they are normal.

9.1.5 Safety inspections and routine maintenance shall be carried out in accordance with the manufacturer's instructions, and records of use and routine maintenance shall be established, as shown in Annex B. Any detected faults and potential hazards shall be eliminated promptly, and fault records shall include the fault phenomenon, cause, corrective mea-

sures and results.

9.2 Regular maintenance

9.2.1 Air compressor

9.2.1.1 Regularly clean the surface of the equipment, the fan, the fan duct, and the main unit heat sinks.

9.2.1.2 Check the tension of the drive belts regularly, and carry out prompt replacement in case of any damage.

9.2.2 Compressed air filter

9.2.2.1 Inspect the compressed air filter element regularly for any foreign matter or blockage, or cleanliness and damage. Clean the dust on the compressed air filter regularly in accordance with the manufacturer's instructions. Any damaged compressed air filter element shall be replaced in time.

9.2.2.2 Replace the compressed air filter element regularly according to the requirements of the manufacturer's instructions.

9.2.3 Compressed air dryer

9.2.3.1 For the refrigeration dryer, regularly clean and wipe the fin surfaces of the condenser of the compressed air dryer. Inspect and clean the manual or automatic drain device regularly.

9.2.3.2 For the adsorption dryer, remove dust from the silencer regularly and replace the filter element or silencer when necessary. Replace the desiccant regularly.

9.2.4 Safety valve and pressure gauge

Check the functions of the safety valve and pressure gauge regularly and test them in accordance with TSG ZF001 and TSG 21.

9.2.5 Power supply lines and connecting pipelines

Inspect the power supply lines and connecting pipelines regularly for damage, loose connections or disconnection; tighten or replace them in time as appropriate.

9.2.6 Precautions for maintenance

9.2.6.1 A regular maintenance plan shall be formulated in accordance with the manufacturer's instructions and implemented on schedule. The maintenance cycle of air compressors/units is shown in Annex C.

9.2.6.2 Regular maintenance and repair of equipment shall be performed by professional personnel from the manufacturer.

9.2.6.3 Before equipment maintenance or repair, ensure that the power supply has been disconnected and the equipment is in standby and cooled down, so as to avoid live operation and approaching or touching high-temperature components (such as cylinders, exhaust pipes, etc.).

9.2.6.4 The area around the air receiver shall be kept away from open flames, and a dry powder fire extinguisher shall be provided.

9.2.6.5 Regularly start and check the standby air compressors to ensure that they can be put into use at any time.

9.2.6.6 When the pressure and temperature of the compressed air rise abnormally, the equipment shall be shut down immediately, either manually or automatically, the air source shall be closed, and the backup system shall be activated.

9.2.6.7 Regularly conduct emergency drill exercises for air leakage. In the event of air leakage, immediately cut off the air supply and power supply, evacuate on-site personnel to a safe area, notify the maintenance department to locate the leakage point, and handle leakage in time.

9.2.6.8 It is recommended that a professional electrician or the manufacturer test the grounding of the equipment and the insulation performance of the power lines every year.

10 Quality and testing requirements for compressed air for device drying

10.1 Quality and testing requirements for compressed air for device drying

The quality requirements for compressed air used for device drying shall comply with the provisions of Table 1.

10.2 Testing requirements for contaminants in compressed air used for device drying

10.2.1 Regularly test the oil content, water content, solid particles, total bacterial count, etc. in the compressed air.

10.2.2 Testing methods shall follow the relevant provisions of GB/T 13277.2, GB/T 13277.3, GB/T 13277.4, GB/T 13277.5, GB/T 13277.7, 13277.8,

Table 1 Quality Requirements for Compressed Air Used for Device Drying

Item	Oil[a] mg/Nm^3	Pressure dew point ℃	Particulate[b]	Odor
Compressed air Quality requirements	≤0. 1	≤−40	Class 2	None

[a] Mass of oil contained in each cubic meter of air at standard conditions (air temperature: 20℃, absolute air pressure: 0. 1 MPa, relative water vapor pressure: 0);

[b] Particulate classes are graded in accordance with GB/T 13277. 1

and 13277.9.

Annex A

（Informative）

Common Compressed Air Humidity Classes and Methods for Achieving Pressure Dew Point

Common compressed air humidity classes and methods for achieving pressure dew point are shown in Table A.1.

Table A.1 Common Compressed Air Humidity Classes and Methods for Achieving Pressure Dew Point

Humidity class[a]	Pressure dew point ℃	Common methods for achievement
1	≤−70	Aftercooler+combined (refrigeration+ adsorption) dryer
2	≤−40	Aftercooler+adsorption dryer
3	≤−20	
4	≤+3	
5	≤+7	Aftercooler+refrigeration dryer
6	≤+10	

[a] Humidity classes are graded in accordance with GB/T 13277. 1.

Annex B

（Informative）

Record of Use and Routine Maintenance of Air Compressors/Units

Records of the use and routine maintenance of the air compressors/units are provided in Table B.1, and specific use and routine maintenance shall follow the manufacturer's instructions for the equipment.

Table B.1 Record of Use and Routine Maintenance of Air Compressors/Units

Date	Startup time	Inspection time	Startup and inspection											Shutdown			
			Compressed air dryer inlet valve open/air bypass valve closed	Normal electrical system	No air leakage in pipelines	No abnormal noise from the equipment	Air compressor outlet pressure	Normal automatic drainage/ manual drain valve closed	Pressure gauge reading of the compressed air dryer	Compressed air dryer pressure dew point ℃	Pressure gauge reading of the air receiver	No alarm from the equipment	Signature	Close the intake valve of the compressed air dryer	Air receiver drainage (if equipped with a manual drain)	Shutdown time	Shutdown signature

Note: Based on the inspection during startup and operation, put a "√" in the appropriate column when the conditions are met, or specify the details in the appropriate column.

Annex C
（Informative）
Maintenance Schedule for Air Compressors/Units

The maintenance schedule for the air compressors/units is shown in Table C. 1, and the specific maintenance intervals and items shall follow the manufacturer's instructions for the equipment.

Table C.1 Maintenance Schedule for Air Compressors/units

Every day
1. Check the readings on the display.
2. Check the tightness of pipelines for any air leakage.
3. Check whether the condensate from air compressors and air receivers with automatic drainage is discharged automatically.
4. For air compressors and air receivers with manual drainage, manually discharge condensate every day, or discharge it periodically according to the instructions.
5. For air compressors with a refrigeration dryer, check whether the dew point temperature and condensate discharge are normal.
6. For compressors equipped with a built-in compressed air dryer, check the dew point.
Every week
1. Clean the surface of the equipment, the fan, the fan duct, and the main unit heat sinks.
2. Clean the compressed air filter.
3. Clean the cooler.
Every month
1. Adsorption dryer:
1) Check the desiccant.
2) Check the silencer.
3) Check the valves.
2. Refrigeration dryer:
Clean the condenser fins of the dryer.
3. Check the compressed air filter element.
Every 3 months
1. Check the prefilter pad on the cooling compressed air inlet (if installed).
2. Check the intake filter for cleanness and damage. In case of any dust, clean it. In case of any damage, replace it.
3. Clean the air compressor and the aftercooler.
Every 6 months
1. Operate the safety valve manually.
2. Check for damaged wires or loose connections.
3. Check for air leakage.
4. Check and clean the electronic drain device.
5. Check the pressure gauge.
Every year
1. Replace the intake filter and the pre-filter pad on the cooling compressed air intake (if installed).
2. Check the safety valve.
3. Test the temperature protection and motor overload.
4. Check for the tension of drive belts and any damage.
5. Replace the silencer (for adsorption dryer).
6. Replace the air filter element.
Every 2 years
1. Replace the drive belt.
2. Replacement the check valve.
3. Replace the main unit's compressed air outlet pipe.

续表

Every day
4. Clean the fan, fan duct and main unit heat sinks (the cleaning frequency shall be increased in dusty environments).
5. Apply grease to the drive scroll bearings and crank pin bearings, if any.
6. Replace the sealing device (the replacement frequency shall be increased for a dry environment).
At irregular intervals: Replace the valve components.
During each maintenance: All removed gaskets and washers shall be replaced.

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