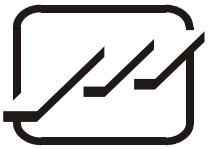
Pooyandegan Rah Saadat Co.

User Manual of Compressor

Code: D01014-V11



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Manual Purpose

This manual provides the instructions necessary to operate the compressor based on its intended use. This manual is a complete description of the capabilities of the RESPIAIR A1 compressor and how it works properly.

Observance of this manual is a prerequisite for proper operation and assures patient and operator safety. If you have any question about the compressor, please contact our customer service department. This manual is an essential part of and should always be kept close to the compressor system, so that it can be obtained conveniently when necessary.

Version Information

This manual has a version number. The version number changes whenever the manual is revised due to software or technical specification changes. The version information of this manual is as follows:

Version number	Release date
O49-L06-V11	September 2024

Table of content

1. GENERAL INFORMATION

1.1 INTENDED USE

The RESPIAIR A1 is a medical air compressor that provide a source of clean, oil-free pressurized air for use with medical ventilators.

1.2 OPERATOR'S RESPONSIBILITY FOR PATIENT SAFETY

The Installation, Operation and Maintenance Manual is an integral part of the device and must be kept with the unit. Careful review of this manual will provide the information necessary for correct operation of the device.

1.3 CE MARKING

Products marked with CE mark of compliance meet the safety guidelines of the European Union (93/42/EEC).

1.4 WARNINGS

The safety of operating personnel and trouble-free operation of the device are ensuring only if original parts are used. Only accessories and spare parts specified in the technical documentation or expressly approved by the manufacturer can be used.

If any other accessories or consumable materials are used, the manufacturer cannot be held responsible for the safe operation and functionality of the device.

The manufacturer's warranty does not cover damages originating from the use of accessories or consumable material other than those specified or recommended by the manufacturer.
Device only if:

- Installation, calibration, amendments, extensions and repairs are performed by the manufacturer or its representative, or a service provider authorized by the manufacturer
- The device is used in accordance with the Installation, Operation and Maintenance Manual

The Installation, Operation and Maintenance Manual describes the device and all relevant safety and technical standards for its use.

1.5 General safety warnings

The device is designed to operate safely when used correctly. Please observe the following safety measures to avoid damage and risk.

- Operation of the device must be in compliance with all local codes and regulations.
- The original packaging should be kept for the possible return of the unit.
- Only the original packaging ensures optimal protection of the device during transport. If it becomes necessary to return the device during the warranty period, the manufacturer is not liable for damages caused by incorrect packaging.
- If any problem occurs during use of the device, the user must inform supplier immediately.
- Do not use the compressor in any area where there is risk of explosion.

- Never operate the compressor in the presence of flammable anesthetics.
- Never put oxygen or nitrous oxide into the compressor. The electrical components are not approved for oxygen or nitrous oxide use.
- This device can be used only with ventilators equipped with a low pressure alarm.

1.6 Electrical system safety warnings

The device must be connected to a power source that has correct grounding.

If the power supply is lost, transfer of compressed air to the ventilator will be disrupted. To prevent it, make sure a suitable backup power supply is available.

Before the device is plugged in, verify that the mains voltage and frequency specified on the apparatus are in accordance with the local supply.

Before use, check for possible damage to the device and the air connectors. Damaged cables and sockets/plugs must be replaced immediately.

In case of emergency, immediately disconnect the device from the mains.

During all repairs and maintenance:

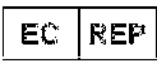
- Ensure that the mains plug is removed from the power socket.

-Pressure pipes must be air vented.

Only a qualified technician can install this device.

1.7 WARNING NOTICES AND SYMBOLS

In the Installation, Operation and Maintenance Manual and on the device and its packaging, the following symbols are used for important information.

	General warning
	Refer to instruction manual
S/N: xxxxxx	Device serial number
	FRAGILE
	This side up
	Keep dry
	Temperature limitation
	Humidity limitation
	Manufacturer
 **20XX**	Date of manufacture
IPX1	Device is protected against touch by fingers and water condense
	Authorized representative in the European Community
220 VAC, 50 Hz 2.5 A	Input Power Information
3 bar, 50LPM	Air Outlet
Max 8 bar	Air Inlet

1.8 CAUTIONS

- The device must be installed and operated in a dry, ventilated, dust- free area. Climatic conditions for operation see Technical data.
- The compressor must stand on a flat, sufficiently stable base.
- The compressor must not be exposed to rain nor be used in humid or wet environments. Never use the compressor in the presence of flammable liquids or gases.
- Before connecting the compressor to respiratory equipment, ensure that it meets the requirements for its intended use. Refer to the Technical data for this purpose.
- Any use other than that described in this manual is not covered by warranty and the manufacturer is not responsible for any damages that may result. The operator/user assumes all risk.
- This product is not intended for use in areas where there is a risk of an explosion.
- Never feed oxygen or nitrous oxide into the compressor. Compressor component are not approved for oxygen or nitrous oxide use.
- Restriction of air flow throw suction front filter (cabinet filter) will cause unit to overheat, causing the thermal reset to shut down compressor.
- Perform preventive maintenance at minimum recommend intervals.
- The air compressor is of the oil-less type and do not lubricate any of parts with oil, grease or petroleum products.

1.9 STORAGE AND TRANSPORT

The compressor is delivered in transport packaging with the pump stabilized, protecting it from damage during transport.

Always use the original packaging when transporting the compressor. Always transport the compressor upright.

During transport and storage, protect the compressor from humidity, contamination and extreme temperatures. A compressor in its original packaging can be stored in a dry and dust-free area.

The compressor can only be transported pressure-free. It is necessary to release the pressure from the circuit and pressure hoses prior to transport, and to release any possible condensate. Secure motor inside before transportation.

Prior to transport it is necessary to fix motor inside the compressor.

1.10 Contraindications

It is strongly recommended NOT to use the compressor in the following situations:

- **If there is no alternative compressed air source that can be used as a backup.**
- **If the compressor is connected to an inadequate electric mains power (e.g. without earth connection).**
- **If compressed air system connected to the compressor input port does not meet medical grade specifications.**

In the following conditions the use of compressor is forbidden:

- **In the presence of flammable anesthetic gases.**
- **Using nitric oxide, helium or mixtures containing helium as input.**
- **If the compressor is located in the vicinity of MRI equipment or any sources of considerable electromagnetic radiation.**
- **Failure to strictly comply with the instructions for use.**

1.11 Side effects

Compressor only prepares the compressed air for the ventilator and it could not have any side effects on the patient. However, output air pressure drop may cause negative effects of the performance of the ventilator which should be observed and managed by the ventilator itself (ventilator must be equipped with a low pressure alarm).

1.12 Accessories

The list of device accessories is given in the table below. Use only accessories approved by the compressor manufacturer.

Accessory	Part Number
Power cable	P03018
Drained water container	P44038
Cabinet filter	P44033
Hoses (central to compressor and compressor to ventilator)	P26516

2. EQUIPMENT DESCRIPTION

The device consists of an oil-free piston compressor driven by a single- phase electric motor, filtering and drying equipment, pressure reliefs and a pressure regulator. The compressor is contained in a box lined with noise reducing material. The compressor produces dried, filtered compressed air without any trace of oil.

The air compressor has an input air fitting labeled Air Inlet for connection to an outside air source. When an outside compressed air source connected to the Air Inlet fitting delivers air above a specified pressure, the air pump will not be activated even though the power switch is in the ON position. Instead, the air from the outside source will flow through to the compressor's air output. When the outside air source pressure is less than the adjusted output pressure (or is not connected) and the power switch is in the ON position, the air pump is activated and supplies compressed air through the air output.

The air pump draws atmospheric air through the air intake filter. Compressed air is cooled in the cooler and continues through the filter where condensed liquid from the water trap is automatically released to the evaporative tray. The air continues through the pressure regulator to the Air Outlet. Three safety valves prevent the pressure exceeding allowable limits.

A cooling fan system is located in the compressor motor portion such that the fans cools the compressor motor and exhaust out to the hot air. Cooling fans draw cool air and throws it on the

compressor pump head, so as to cool down the temperature of the motor portion of the unit.

The air taken by the motor is compressed and is circulated through the cooling coil. The cooling coil helps in reducing the temperature of hot compressed air. Air is passed through the series of water traps (40 and 5 microns), which remove the water and any particles larger than 5 microns present in the air. Thereby giving clean, dry and medical grade compressed air in the output is achieved.

From the water trap, compressed air is passed through main regulator which regulates the output pressure at 3.5 bar or as calibrated. The excess pressure along with moisture formed is released out through two pressure reliefs.

The motor is mounted on motor Hanging O-ring assembly to reduce the noise. The inside of the cabinet has acoustic pads, which reinforces noise reduction.

3. TECHNICAL SPECIFICATION

1	Nominal Voltage and Frequency	220V AC, ±10%, 50 Hz
2	Output Flow at 3 bar	>50 LPM
3	Peak Flow	>200 LPM
4	Outlet pressure	3.5 bar (Maximum 4.0 bar)
5	Removal of Condensed Water	Automatic
6	Operating Pressure of Safety Valve	8 ± 0.5 bar
7	Filtration of Air	40 µm and 5 µm
8	Dew point depression at 3 bar, 20 °C	>5 °C under the ambient temperature
9	Outlet Connection	Hose
10	Mode of Operation	Continuous
11	Wall Connection	DISS 1160-A
12	Noise Level	<50 dB(A)
13	Implementation according to EN 60601-1, EN12021	Class I, Type B
14	Classification according to MDD 93/42 EEC,2007/47 EC	II b
15	Operating Temperature	5° to 35°C
16	Storage and transport temperature	-10° to 60°C
17	Operating humidity	15% to 95%
18	Storage and transport humidity	5% to 95%
19	Operating altitude	11,000 ft (3,500 m) above sea level
20	Rating	IPX1
21	Dimensions (L×W×H)	≈ 48 × 45 × 48 cm
22	Weight	≈ 32 kg

Free output flow correction table:

Elevation (mamsl)	0-1500	1501-2500	2501-3500	3501-4500
Free output flow (LPM)	×1	×0.8	×0.7	×0.6

Free output flow refers to conditions at an elevation of 0 mamsl:
Temperature: 20°C
Atmospheric pressure: 101325 Pa
Relative humidity: 0%

4. OPERATION

4.1 INSTALLATION AND FIRST OPERATION

Prior to start-up the air pump must be unsecuring inside. The compressor cannot be switched ON with secured air pump. Unsecuring the compressor should be performed by the qualified service personnel of the manufacturer.

Note that the ON/OFF switch is located on the back side of the device.

4.1.1 Removal of transport stabilizers

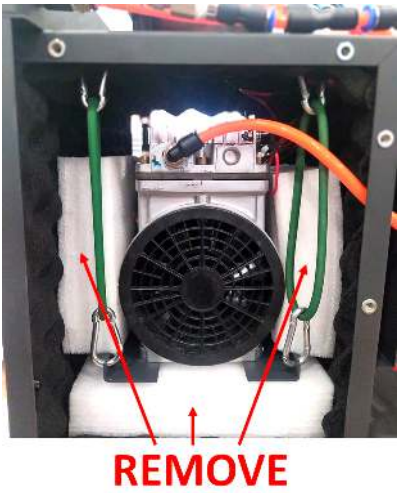
After unpacking do the following respectively

1. Remove the cover of compressor by unscrewing the nine screws on the sides and back of the cover.
2. Unscrew the screws and open the motor portion gate.
3. Remove all stabilizers (foams) around the air pump.

   *** In new version only unscrew the stabilizing bolts and there is no need to open the motor box doors.**
4. There is a female thimble disconnected from ON/OFF switch inside the compressor, reconnect it.

   *** In new version only remove the warning label and there is no need to open the compressor cover.**
5. Check compressor operation by switching ON the unit.
6. Replace the motor portion cover with its screws, replace cover.

Retain the stabilizers for future transportation of the compressor.



4.1.2 Compressed air connection

The medical compressor is equipped with couplings **Air Inlet (WALL)** and **Air Outlet** on the back of the cabinet.

To the coupling **Air Outlet** (output compressed air) connect the pressure hose leading to the applicable device/respiratory apparatus.

To the coupling **Air Inlet** (input compressed air) connect pressurized air from a central distribution system, if applicable. The air from the distribution system is automatically connected through the compressor to the Air Inlet port. In this configuration, the compressor serves as a backup source of compressed air. If the air pressure from the central distribution system is reduced, the compressor automatically switches on and there is no interruption of continuously pressurized air at the output from the compressor.

Please note that air entering the compressor from central distribution must be medical grade air (particulate size, humidity). The compressor delivers the air from central distribution to the output directly.

The hose connecting the compressor to the respiration equipment must be as short as possible with no links. Hose should be reinforced with though nylon and should be kink resistance.

4.1.3 First operation

1. Ensure that all stabilizers used during transport were removed.
2. Check that the connection to the compressed air supply is correct.
3. Check for proper connection to the main supply.
4. Ensure that the ON/ OFF switch cable is connected.
5. During operation, the device automatically releases condensed water from the filter to the evaporator tray.

4.2 CLEANING THE COMPRESSOR

- Do not pour or spray water or other liquids directly on the compressor.
- Do not use strong solvents such as acetone or ammonia.
- Do not use rough material, such as steel wool, etc.

- Before disinfecting the ventilator, make sure that the equipment is switched off and disconnected from the power line.
- Do not let the cleaning agent enter into the housing of the system.
- Dry out the cleaning agents on any part of the device.
- It is recommended to use water and soap for cleaning and isopropyl alcohol for disinfecting all parts of compressor.

4.3 SHUT DOWN

If the compressor is not going to be used for a long period of time, disconnect it from the mains supply.

4.4 DISPOSAL OF THE DEVICE

Disconnect the device from the mains supply.

Release the pressure in the pneumatic circuit.

Dispose of the device according to local regulations.

The parts used in this product have no negative impact on the environment when disposed of properly.

4.5 COMPRESSOR INDICATORS

POWER: There is a green indicator which is on while the ON/OFF switch is in ON position.

WALL: There is a yellow indicator which is active while the WALL is connected and its pressure is in the appropriate range.

OVERHEAT: There is a red indicator, when the motor becomes overheated, the indicator activates and the buzzer sounds.

5. MAINTENANCE

5.1 REPAIRS AND SERVICE

Warranty and extended warranty repairs are to be completed by the manufacturer or a service provider authorized by the manufacturer.

Manufacturer will make available on request information that will assist service personnel to repair of medical device.

The manufacturer reserves the right to modify the device in any way that will not alter the function or the operation of the device.

Only a qualified technician or the Customer Service Department of the manufacturer may perform repairs that go beyond routine maintenance. Use only spare parts and accessories approved by the manufacturer.

Prior to any maintenance or repairs, switch OFF the compressor and disconnect it from the mains (pull out the mains plug.) Remove cover by unscrewing the screws on the cover.

There is a hour-counter placed in the backside of compressor which displays the amount of working time. All maintenance operations should be done based on mentioned working time.

5.2 MAINTENANCE SCHEDULE

Maintenance	Time Interval	To be performed by
Clean air intake filter (cabinet filter)	**At least once a week**	Staff
Check water tray	**At least once a week**	Staff
Calibration	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company
Safety valve operation inspection	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company
Replace water trap filter cartridge (40 micron)	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company
Replace water trap filter cartridge (5 micron)	**Every 10000 hours or 24 months (whichever comes first)**	Qualified expert from the company
Replace relief valves set	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company
Motor overhauling	**Every 3000 hours or 6 months (whichever comes first)**	Qualified expert from the company
Replace suction filter	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company
Check cooling fans	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company
Check tightness of joint	**Every 5000 hours or 12 months (whichever comes first)**	Qualified expert from the company

5.2.1 Clean air cabinet filter

Air intake filter should be cleaned at least once a week located on the front side of unit. Wash the filter in warm soapy water, rinse thoroughly and allow it to dry.

5.2.2 Inspect water tray

The water tray should be checked at least once a week. It is located on the back side of unit.

6. TROUBLESHOOTING

Before beginning any repairs, reduce the pressure to zero and disconnect the device from the mains supply.

Only qualified service personnel can perform the activities listed in the troubleshooting guide.

PROBLEM	POTENTIAL CAUSE	SOLVING PROBLEMS
Compressor does not turning on	No main power voltage	Switched OFF mains breaker in distribution system
		Check power supply
		Replace defective fuse
		Loose wire terminal – tighten it
		Replace the power cord
	Interrupted winding of motor, damaged thermal protection	Contact service provider
	Defective capacitor	Contact service provider
	Jammed motor or other part	Switch OFF the compressor and Switch it ON again after 5 seconds (at least).
		Contact service provider
	Solenoid valve not working	Check power connection, if proper voltage is there, Contact service provider.

Compressor is noisy (knocking metal noise)	Damaged motor piston or bearing	Contact service provider
	Fan(s) is(are) making noise	Contact service provider
	Low pressure at pressure gauge and leakage in the pneumatic circuit can cause loud noise.	Contact service provider
	Voltage fluctuation	Check the input supply. If there is voltage fluctuation, use a voltage stabilizer preferably 2 KVA
	Loose (cracked) air pump hanger	Contact service provider
High temp. Audio alarm	Non-functioning of fans	Contact service provider
	Alarm malfunctioning	Contact service provider
	Dirty air intake filter	Clean or replace dirty air intake filter
	Unit is hot, unventilated area	Relocate unit
	Malfunctioning relief valves	Contact service provider
Water coming out of outlets	Malfunctioning water trap	Contact service provider

Low pressure	Pressure gauge not working	Contact service provider
	Compressor pump not making enough pressure due to wear and tear of piston rings or bearing	Contact service provider
	Leakage in pneumatic circuit	Contact service provider.
	Pressure regulator/Pressure relief valve not working	Recalibrate the unit. Check the working for some time. If again calibration is out, contact service provider.
	Dirty air suction filter	Contact service provider
	Pressure switch not working	Contact service provider.
	Solenoid valve not working.	First check the wire connection. If connection is ok, contact service provider.

7. GUIDANCE AND MANUFACTURER'S DECLARATIONS

Guidance and manufacturer's declaration – RESPIAIR A1 Compressor emissions		
The RESPIAIR A1 compressor is intended for use in the electromagnetic environment specified below. The customer or the user of the RESPIAIR A1 compressor, should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The RESPIAIR A1 compressor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RESPIAIR A1compressor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The RESPIAIR A1 compressor is intended for use in the electromagnetic environment specified below. The customer or the user of the RESPIAIR A1 compressor should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling		
	Signal input/output parts		
Electrical fast transient/burst IEC 61000-4-4	Input A.C. power	± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 1 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	Input A.C. power	± 0,5 kV, ± 1 kV Line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 2 kV Line-to ground	
Voltage dips, IEC 61000-4-11	Input A.C. power	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	Input A.C. power	0 % U_T; 250/300 cycle	

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the A.C. mains voltage prior to application of test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The RESPIAIR A1 compressor is intended for use in the electromagnetic environment specified below. The customer or the user of the RESPIAIR A1 compressor should assures that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>Port</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td rowspan="3">Conducted RF
IEC 61000-4-6</td><td>Input A.C. power</td><td>3 V
0,15 MHz – 80 MHz</td><td rowspan="4"></td></tr>
<tr><td>PATIENT coupling</td><td rowspan="2">6 V
in ISM bands between 0,15 MHz and 80 MHz

80 % AM at 1 kHz</td></tr>
<tr><td>Signal input/output parts</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>ENCLOSURE</td><td>3 V/m

80 MHz – 2,7 GHz

80 % AM at 1 kHz</td></tr>
<tr><td>Proximity fields from RF wireless communications equipment
IEC 61000-4-3</td><td>ENCLOSURE</td><td>Refer to the following table (table 9 of EN 60601-1-2: 2015)</td></tr>
</table>

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380- 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430- 470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704- 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.