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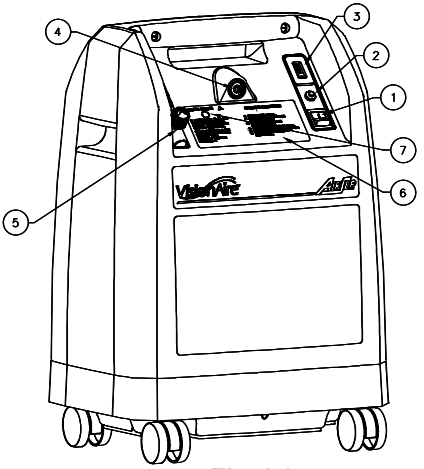


Fig. I.1

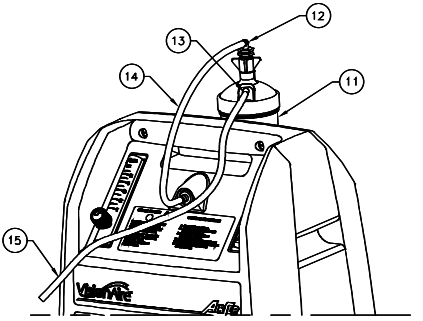


Fig. I.3

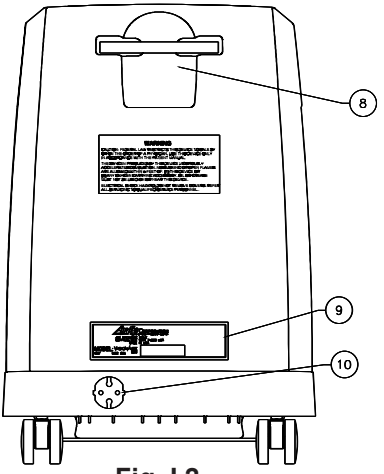


Fig. I.2

GENERAL SAFETY GUIDELINES

USE OF OXYGEN

• Oxygen is not a flammable gas, but it accelerates the combustion of materials. To avoid all risks of fire, the **VisionAire™** should be kept away from all flames, incandescent sources and sources of heat (cigarettes), as well as any combustible products such as oil, grease, solvents, aerosols, etc.
• Do not use in an explosive atmosphere.
• Avoid letting oxygen accumulate on an upholstered seat or other fabrics. In the event the concentrator is operating while not supplying oxygen to a patient, position it so that the gas flow is diluted in the ambient air.
• Place the device in a ventilated area free from smoke and atmospheric pollution, at least 30.5cm (1ft) from any other object.

USE AND MAINTENANCE OF THE DEVICE

• Use the cable provided, and check that the electrical characteristics of the mains socket used match those indicated on the manufacturer's plate on the rear panel of the machine.
• We recommend avoiding the use of extension cables or even adapters, as they are sources of sparks and therefore of fire.
• The **VisionAire™** must only be used for oxygen therapy and only on medical prescription. The indicated daily duration and flow must be followed, otherwise this may present a risk to the health of the patient.
• Do not use in a specifically magnetic environment (MRI, etc.).

This user manual reflects the instruction and safety guidelines for the "user" of the equipment, which AirSep acknowledges may be referred to as "patient," "client," or some other related term throughout various parts of the world.

Only persons who have read and understood this entire manual are authorised to use the VisionAire™. The **VisionAire™** has an audible alarm intended to warn the user of problems. The maximum distance that the user can move away from it must, therefore, be determined to suit the surrounding environment, in order that the alarm may be heard.

Conformity with EN 60-601 (§ 6.8.2 b):
"The manufacturer, assembler, installer or importer are not considered to be responsible themselves for the consequences on the safety, reliability and characteristics of a device unless:
- The assembly, fitting, extensions, adjustments, modifications or repairs have been performed by persons authorised by the party in question,
- The electrical installation of the corresponding premises complies with IEC regulations.

- The device is used in accordance with the instructions for use." If the replacement parts used for the periodic servicing by an approved technician do not comply with the manufacturer's specifications, the latter is absolved from all responsibility in the event of an accident. Do not open the device whilst in operation: risk of electrical shock. This device complies with the requirements of the 93/42/EEC European directive but its operation may be affected by other devices being used close by, such as diathermy and high frequency electro-surgical equipment, defibrillators, short wave therapy equipment, mobile telephones, CB and other portable devices, microwave ovens, induction plates or even remote control toys and more generally electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.

I. DESCRIPTION

The **VisionAire™** is an oxygen concentrator designed to satisfy oxygen therapy prescriptions at home or in the hospital. It provides a continuous flow of oxygen air by separating the oxygen and nitrogen contained in ambient air.
The **VisionAire™** is easy to use and ergonomic. The single flow adjustment knob allows the device to be easily adjusted to the prescribed flow rate.

Note: the performances described only concern the use of the VisionAire™ with the accessories recommended by the manufacturer.

I. 1. Front panel (Fig. I. 1)

1 Power switch
2 Circuit breaker
3 Hour meter
4 Oxygen air outlet
5 Flow adjustment knob (l/min.)
6 Safety instructions
7 Oxygen monitor LED

I. 2. Rear panel (Fig. I. 2)

8 Humidifier recess
9 Manufacturer's label
10 Electrical power cable

I. 3. Humidifier installation (optional) (Fig. I. 3)

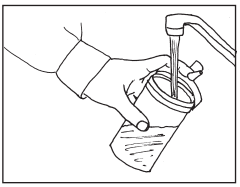
11 Humidifier
12 Humidifier fitting
13 Humidifier oxygen outlet
14 Humidifier tubing
15 Oxygen tubing/cannula

II. STARTING UP / INSTALLATION

II. 1. Use in direct oxygen therapy.

a - Ensure that the power switch is in the 0 position.

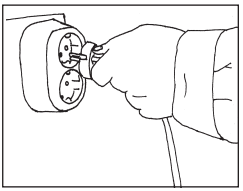
b - If used with a humidifier:
Unscrew the flask and fill it with water up to the line (see the humidifier instructions). Then screw the humidifier flask onto its lid until there are no leaks from it.



c - Connect the oxygen administration tube to the humidifier outlet nozzle or connect the administration nasal cannulas onto the concentrator. The tube between the patient and the **VisionAire™ should be less than 15 metres (50 ft) long**, in order to ensure that the oxygen flow rate remains satisfactory.

d - Ensure that all of the parts are connected correctly so as to avoid leaks.

e - Plug the power cable into a mains socket.



f - Press the power switch to the start position - I. An alarm operating test is carried out automatically when the machine is power switched on (this test lasts about 5 seconds). Note: If the unit has not been used for an extended period of time it needs to operate for several minutes before the mains power cut alarm can become activated.

g - Turn the flow adjustment knob (5) to the LPM setting. The LPM setting on the flowmeter should appear to split the middle of the flowmeter ball.

h - Check that the oxygen flows out of the administration device (nasal cannulas or other) by placing the orifice(s) on the surface of a glass of water. The flow should disturb the surface of the water.

i - Adjust the nasal cannula.

Remark: optimal oxygen concentration is obtained about ten minutes after the device is switched on (90% of the concentration is obtained after around 5 minutes).

At the end of the treatment, set the power switch to the 0 position to stop the device. The oxygen air flow continues for approximately 1 minute after the device is stopped.

III. CLEANING

III. 1. Cleaning

Only the outside of the **VisionAire™** is to be cleaned, with a dry cloth or, if necessary, a damp sponge and clean or soapy water, then thoroughly dried. Acetone, solvents or any other flammable products **must not be used**. Do not use abrasive powders.

III. 2. Everyday disinfection

Due to the presence of the product filter inside the device, everyday disinfection only concerns the external oxygen therapy accessories: humidifier, nasal cannulas (refer to the respective instructions for use).

The following minimum guidelines must be respected:

• Humidifier:
Daily:
- empty the water from the humidifier.
- rinse the humidifier flask under running water.
- Fill the humidifier up to the mark with water.

Regularly:
- Disinfect the equipment by immersing them in a disinfectant solution (in general, we recommend using water containing a small amount of chlorine bleach).
- Rinse and dry.
- Check that the humidifier lid seal is in good condition.

• Oxygen administration devices:
Follow the manufacturer's instructions.

IV. USEFUL INFORMATION

IV. 1. Accessories and spare parts

The accessories used with the **VisionAire™** must:
- be oxygen compatible,
- be biocompatible,
- comply with the general requirements of the 93/42/EEC European Directive.

The connectors, tubes, nasal cannulas, must be designed for oxygen therapy. Contact your distributor to obtain these accessories.

Remarks:

• The use of certain administration accessories which are not specified for use with this concentrator may reduce its performance and void the manufacturer's warranty.

IV. 2. Materials in direct or indirect contact with the patient

Concentrator casing ..... Valtra/ABS/Polystyrene
Mains cable ..... PVC
ON/OFF power switch ..... Thermoplastic
Casters ..... Nylon
Flow adjustment knob ..... ABS/Polycarbonate
Gas outlet ..... Polycarbonate
Printed labels ..... Lexan

IV. 3. Operating principle

The compressor sends filtered ambient air to a group of valves, which allows compressed air to pass to the column in production. The columns contain a molecular sieve, whose function is to adsorb the nitrogen and thus allow oxygen to pass. The oxygen is then directed to a pressure reducing valve through the flow control valve to the oxygen outlet fitting.

During this time, the column which is being "regenerated" is connected to the ambient air and a current of oxygen is passed through it (from the column "in production"). In this way, when one column is in production, the other is in a nitrogen desorption or "regeneration" phase. The oxygen air finally passes through a product filter situated prior to the oxygen therapy outlet.

IV. 4. Alarms - Safety devices

IV. 4. 1. Alarms

• No volt detection:
In the event of a mains power cut, an audible intermittent single alarm is tripped.

• Operating fault:
In the case of a distribution fault, an audible intermittent multiple alarm is tripped.

IV. 4. 2. Safety devices

• Compressor motor:
Thermal safety is ensured by a thermostat situated in the stator winding (135 ± 5°C (275°F)).

• Electrical protection of the **VisionAire™:**
A circuit breaker is located on the front panel Fig. I.1 (2).

• Safety valve:
This is fitted on the compressor outlet and is calibrated to 2.8 bar.

• Class II devices with insulated casings (IEC 601-1 standard).

IV. 5. Oxygen Monitor function (optional - mandating for Europe and certain other countries)

IV. 5. 1. Oxygen Monitor operating principle (oxygen concentration indication module)
The Oxygen Monitor is an electronic module capable of checking the effective oxygen concentration supplied by the **VisionAire™** concentrator.

The Oxygen Monitor detects any drop in the concentration below a pre-set level and activates an audible and visual alarm. A yellow LED indicates a concentration level of below specification.

When the LED is yellow for more than 15 minutes, an audiible intermittent multiple alarm is tripped.

Note: when the **VisionAire™** is started, the Oxygen Monitor module operates as follows:
1) in addition to the normal **VisionAire™** test, the Oxygen Monitor yellow LED lights up.
2) in principle, the LED remains lit for a few minutes (10 minutes at maximum) until the concentration of the gas supplied reaches and exceeds specification.
3) The yellow LED is extinguished after this period, showing that the concentrator is operating satisfactorily.

IV. 5. 2. Maintenance of the Oxygen Monitor module:

- No special maintenance is required, The alarm trigger is factory pre-set and there is no need to alter the settings.

IV. 6. Technical characteristics

Dimensions: D x W x H: 29.2 x 35.8 x 52.8 cm (11.5 x 14.1 x 20.8 in).
Weight: 13.6 kg (30 lbs).
Sound level: 40 dBA

Flow values:
1 - 5 l/min.

Average oxygen content:
• 90% +5.5%/-3%.
(values at 21°C (69.8ºF) and at an atmospheric pressure of 1013 mbar). Max. flow: 5l/min. The maximum outlet pressure is 55kPa.

Electrical power supply:
• 220 - 240 V - 50 Hz Europe / 115 V – 60 Hz / 220 - 240 V – 60 Hz (other countries, depending on version)
• Use the cable provided, and check that the electrical characteristics of the mains socket used match those indicated on the manufacturer's plate on the rear panel of the machine.

• Mean power rating: 290 watts
Class II
Type B
1.5 amps (220 - 240 V).
3.0 amps (115 V).

Filters:
Before the oxygen outlet: a product filter < 0.30 µm.

Air circulation:
A fan cools the compressor compartment.

Environmental limit conditions:
The performances of the device (especially the oxygen concentration) are quoted at 21°C (69.8ºF) and 1013 mbar. They may change with temperature and altitude.
- The device should preferably be stored and transported in the vertical position.
- The device must only be used in the vertical position.
- Ambient temperature of between 5°C and 40ºC (41ºF and 104ºF) (operation for 115 VAC units).
- Ambient temperature of between 5°C and 35ºC (41ºF and 95ºF) (operation for 220-240 VAC units).

- Storage temperature range from -20°C to 60°C (-4ºF and 140ºF) .
- Relative humidity up to 95% (non-condensing).

IV. 7. Symbols - Abbreviations

I : ON

O : Off (power switched off).

 : Type B device

 : Class II device

 : Do not smoke.

CE 0459 : Complies with the 93/42/EEC directive drawn up by the approved organization n° 0459.

 : Do not expose to open flames.

 : Do not grease.

 : Consult the accompanying documents

 : Do not disassemble.

 : Consult instructions for use.

$R_{x\ ONLY}$: Caution: federal law restricts this device to sale by or on the order of a licensed healthcare provider.

 : Keep in the vertical position.

 : Fragile - handle with care.

 : Oxygen concentration warning LED

 : WEEE Directive

IV. 8. Method for disposing of waste

All waste from the **VisionAire™** (patient circuit, etc.) must be disposed of using the appropriate methods.

IV. 9. Method for disposing of the device

In order to preserve the environment, the concentrator must only be disposed of using the appropriate methods.

IV. 10. Troubleshooting

Observations	Probable causes	Solutions
The 0-I button is in the ON position. The device does not operate. The intermittent single alarm sounds.	Power cable not plugged in correctly. Mains power failure.	Check the cable connection. Reset the circuit breaker (2) if necessary by pressing. Check the fuses or circuit breaker fitted on the premises.
Oxygen concentration indicator remains lit yellow.	Oxygen concentration is too low.	Contact your distributor.
The alarm test does not work.	Internal electrical fault.	Contact your distributor. Note: if the unit has not been used for an extended time period, it needs to operate for several minutes before the mains power cut alarm can become activated.
The 0-I button is ON and the compressor is operating but there is no flow. The audible alarm sounds.	Pneumatic connection broken or compressor problem.	Stop the device by pressing the 0-I button and contact your distributor.
The 0-I button is ON, the compressor is operating, there is a flow but the audible alarm sounds.	Internal electrical fault. Pneumatic circuit fault.	Stop the device and contact your distributor.
The compressor stops in mid-cycle, then starts again after a few minutes.	Compressor thermal safety device has been tripped. Fan not working.	Stop the device and wait for it to cool down. Check that the patient circuit is not obstructed. Start up again. If the device does not start, contact your distributor.
The oxygen air flow is interrupted at the nasal cannula outlet.	Tube disconnected or humidifier not tight.	Check the gas administration circuit.
The flow at the nasal cannula outlet is irregular.	Pneumatic circuit problem.	Contact your distributor.

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