

Fig. I.1

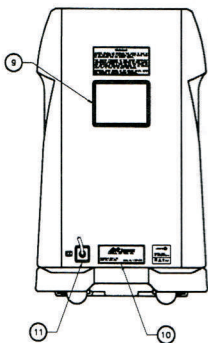


Fig. I.2



Western Surgical®

OXYGEN CON. AIRSEP

USER MANUAL

www.westernsurgical.in
 Email : westernsurgical@gmail.com
 Email : info@westernsurgical.in
 Ph. : +91-281-2232871 / 2243159

CONTENTS

GENERAL SAFETY GUIDELINES	1-GB
I. DESCRIPTION	2-GB
I. 1. Front panel (Fig. I. 1)	2-GB
I. 2. Rear panel (Fig. I. 2)	2-GB
II. STARTING-UP / INSTALLATION	3-GB
II. 1. Use in direct oxygen therapy	3-GB
III. CLEANING - MAINTENANCE	4-GB
III. 1. Cleaning	4-GB
III. 2. Everyday disinfection	4-GB
IV. USEFUL INFORMATION	5-GB
IV. 1. Accessories and spare parts	5-GB
IV. 2. Materials in direct or indirect contact with the patient	5-GB
IV. 3. Operating principle	5-GB
IV. 4. Alarms - Safety devices	6-GB
IV. 5. Oxygen Monitor function (optional - mandating for Europe and certain other countries)	6-GB
IV. 6. Technical characteristics	7-GB
IV. 7. Standards	8-GB
IV. 8. Symbols - Abbreviations	8-GB
IV. 9. Method for disposing of waste	8-GB
IV. 10. Method for disposing of device	8-GB
IV. 11. Troubleshooting	9-GB
APPENDICES	10-GB
Installation check list - before use	10-GB

Western Surgical
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

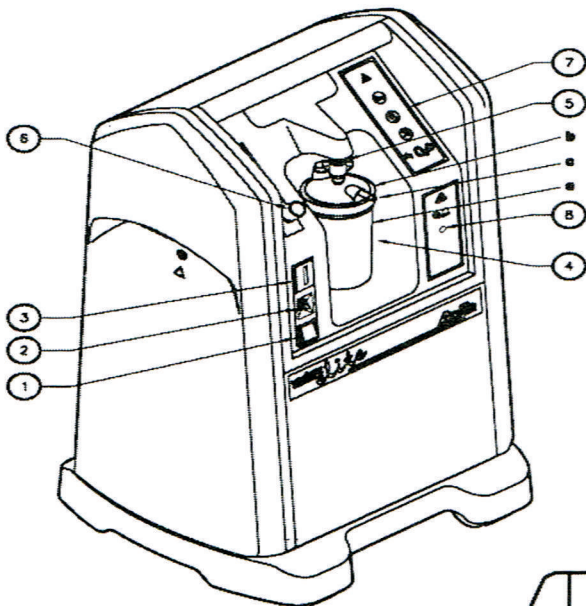


Fig. I.1

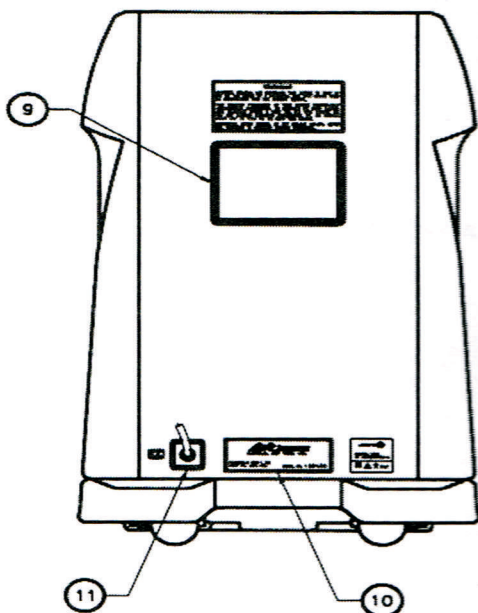


Fig. I.2

Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

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 **NEWLIFE ELITE** 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 0.5 meters 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 **NEWLIFE ELITE** 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's 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 NEWLIFE ELITE. The **NEWLIFE ELITE** 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.

Western Surgical Ltd.
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

- 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 **NEWLIFE ELITE** is an oxygen concentrator designed to satisfy oxygen therapy prescriptions at home or in the hospital. It provides a continuous flow of oxygen enriched air by separating the oxygen and nitrogen contained in ambient air. It can be used either to administer oxygen with nasal cannulas or another probe or mask type of device.

The **NEWLIFE ELITE** is easy to use and ergonomic. The single flow adjustment knob allows:

- the device to be easily adjusted to the prescribed flow rate,
- Technicians or medical staff to limit flows to a specific range of flow rates with an internal locking device. It has a mains alarm and an operating fault alarm (positive safety type).

Note: the performances described only concern the use of the NEWLIFE ELITE with the accessories recommended by the manufacturer.

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

- 1 Start/stop push button
- 2 Circuit breaker
- 3 Hour meter
- 4 Humidifier (space reserved)
 - a) Flask
 - b) Lid
 - c) Outlet connector
- 5 Oxygen enriched air outlet
- 6 Flow adjustment knob (l/min.)
- 7 Safety instructions
- 8 Oxygen Monitor

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

- 9 Dust filter
- 10 Manufacturer's label
- 11 Electrical power cable

Western Surgical Ltd
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

II. STARTING UP / INSTALLATION

II. 1. Use in direct oxygen therapy.

a - Ensure that the switch (1) 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 **NEWLIFE ELITE** should be less than 15 metres 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 switch to the start position - I . An alarm operating test is carried out automatically when the machine is switched on (this test lasts about 5 seconds).

g - Turn the flow adjustment knob (6) to the prescribed value. The prescribed valve line should appear to split the middle of the flowmeter knob.

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.

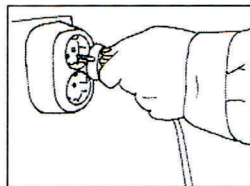
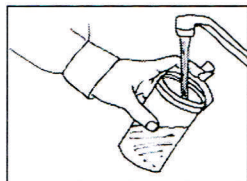
i - Adjust the nasal cannulas or mask to suit your face.

Remark: the 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, press the push button (1) to place it in the 0 position to stop the device. The oxygen enriched air flow continues for approximately 1 minute after the device is stopped.

For the technician or medical staff:

The flow adjustment knob may be locked to limit it to a given range of values or released. (See procedure in the maintenance manual).



Western Surgical
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

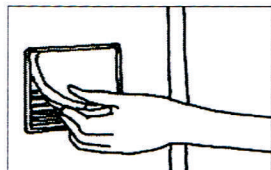
III. CLEANING - MAINTENANCE

III. 1. Cleaning

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



The removable dust filter (9) must be cleaned in soapy water after approximately 100 hours of use, or when required. Rinse and wipe dry. Fit a dry filter.



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, probes, nasal cannulas (refer to the respective instructions for use).

The use of alcohol based solutions means that the device must be switched off.

a - 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 slightly mineralised 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.

b - For each new patient:

The humidifier must be sterilised if possible or changed. The **NEWLIFE ELITE** must be cleaned and disinfected as per the above instructions. The dust filter and the product filter should preferably be changed. The entire oxygen administration circuit (oxygen therapy nasal cannulas, etc.) must be changed.

Western Surgical
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

IV. USEFUL INFORMATION

IV. 1. Accessories and spare parts

The accessories used with the **NEWLIFE ELITE** must:

- be oxygen compatible,
 - be biocompatible,
 - comply with the general requirements of the 93/42/EEC European Directive.
- The connectors, tubes, nasal cannulas, probes or masks 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 performances and void the manufacturer's responsibility (ISO 8359).

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

Concentrator casing	Valtra/ABS
Mains cable	PVC
Dust filter	Polyester
ON/OFF switch.....	Thermoplastic
Casters	Nylon
Flow adjustment knob	ABS/Polycarbonate
Gas outlet	Chrome Plated Brass
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 enriched air 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 enriched air 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 enriched air finally passes through a product filter situated prior to the oxygen therapy outlet.

Western Surgical Ltd.
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

IV. 4. Alarms - Safety devices

IV. 4. 1. Alarms

- No volt detection:

In the event of a mains power cut, a continuous audible alarm is tripped.

- Operating fault:

In the case of a distribution fault, an audible intermittent alarm is tripped.

IV. 4. 2. Safety devices

- **Compressor motor:**

Thermal safety is ensured by a thermostat situated in the stator winding (145 ± 5 °C).

- Electrical protection of the **NEWLIFE ELITE** :

A circuit breaker is located on the front panel I.1 (2).

- Safety valve:

This is fitted on the compressor outlet and is calibrated to 3 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 **NEWLIFE ELITE** 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 $85 \pm 3\%$.

When the LED is yellow for more than 15 minutes (± 2 minutes), an intermittent audible alarm is tripped.

Note: when the **NEWLIFE ELITE** is started, the Oxygen Monitor module operates as follows:

- 1) in addition to the normal **NEWLIFE ELITE** test, the Oxygen Monitor yellow LED lights up.
- 2) in principle, the LED remains lit for a few minutes (3 minutes at maximum) until the concentration of the gas supplied reaches and exceeds $85 \pm 3\%$ O₂.
- 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 to $85 \pm 3\%$, and there is no need to alter the settings.

Western Surgical
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

IV. 6. Technical characteristics

Dimensions: L x W x H: 368 x 400 x 724 mm.

Weight: 24.5 kg.

Noise level: ± 48 dBA

Flow values:

0 - 5 l/min.

Accuracy of flow supplied:

In compliance with the ISO 8359 standard, the flow supplied is equal to the flow set on the flow selector, accurate to within $\pm 10\%$ or 200 ml/min., whichever is the larger of the two.

Average oxygen content:

- at 2 l/min. 93 %.
- at 4 l/min. 91 %.
- at 5 l/min. 90%.

(values at 21 °C and at an atmospheric pressure of 1013 mbar). Max. recommended flow: 5 l/min. The variation of the maximum recommended flow does not exceed $\pm 10\%$ of the indicated value when a counter pressure of 7 kPa is applied to the output of the device. The maximum outlet pressure is 55 kPa.

Electrical power supply:

• **230 V - 50 Hz Europe / 115 V – 60 Hz / 230 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: 350 watts**

Class II

Type B

Protected by a 2.5 A circuit breaker switch (230 V).

Protected by an 8 A circuit breaker switch (115 V).

Filters:

At the rear of the device: a dust filter.

Before the oxygen outlet: a product filter $< 2.0\ \mu\text{m}$.

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 and 1013 mbar. They may change with temperature and altitude.

Western Surgical
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com














Ph. : +91-281-2232871 / 2243159

- 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 10 °C and 40 °C (operation).
- Storage temperature range from 0 °C to 50 °C.
- Relative humidity of between 0% and 95% (operation and storage).
- IPX1: Protected against dripping water (complies with the EN 60601-1 standard)

IV. 7. Standards

EN 60-601-1-2: Electromagnetic compatibility of electro-medical devices.
ISO 8359: Oxygen concentrators for medical use.

IV. 8. Symbols - Abbreviations

-  : ON
-  : Off (power switched off).
-  : Type B device
-  : Class II device
-  : Do not smoke.
-  : 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.
-  : Keep in the vertical position.
-  : Fragile - handle with care.
-  : Oxygen concentration warning LED
-  : Gas outlet, connection to the patient circuit.

IV. 9. Method for disposing of waste

All waste from the **NEWLIFE ELITE** (patient circuit, filter, etc.) must be disposed of using the appropriate methods.

IV. 10. Method for disposing of the device

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

Western Surgical Ltd.
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

IV. 11. Troubleshooting

Observations	Probable causes	Solutions
The 0-I button is in the ON position. The device does not operate. The continuous 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.
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 enriched 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.

Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

APPENDICES

INSTALLATION CHECK LIST / BEFORE USE

Each time after installation and before use, carry out the following sequence of operations

- Check that the device is in good condition generally (no traces of impacts, etc.)
- Check that the patient circuit is in good condition generally (flexible nasal cannulas, pipes clean, no cuts, etc.)
- If necessary, fill and fit the humidifier.
- Before plugging in the device, check that the mains fault alarm is working by placing the O/I switch in the I position for a few seconds. Switch back to the O position.
- Plug the device into the mains, after first checking that the electrical characteristics of the mains systems match those indicated on the manufacturer's label (rear panel of device).
- Switch on the device (switch in the I position) and check that the audible and visual alarms operate for 15 seconds at most.
- After a maximum of 5 minutes of operation, check that the yellow LED on the oxygen monitor module (8) is extinguished. The light remains on until the oxygen purity reaches $85\% \pm 3$ (approximately 2 minutes).

For the technician only:

- for each installation:
 - check that the mains fault alarm is working
 - at regular intervals and every time maintenance work is carried out:
 - check that the flow supplied matches the flow set within the respective tolerances (refer to § Technical Characteristics in this manual).
 - check that for the patient's prescribed flow, the oxygen concentration is equal to or higher than 90%.

The manufacturer's instructions for the **preventive maintenance** of the devices defined in the maintenance manual and any updates to it must be followed. The work must be carried out by suitably trained technicians.

Only use original spare parts. Upon request, the supplier can provide circuit diagrams, spare parts lists, technical details or any other information of use to qualified technical personnel for parts of the device whose repair is designated as being the manufacturer's responsibility.

European Representative:

Gavin Ayling
9 Bungham Lane
Penkridge Stafford
Staffordshire ST19 5NH England
Tel/Fax: 44-1785-712636

Western Surgical Ltd
Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

Date of Installation	Installed By
Model No.	Serial No.
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

**Marketed By: Western Surgical
Sign. With Stamps**

No Claim Warranty :

1) Any Defect Throught Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

Due to constant upgradation design, price and features are subject to change without prior notice.



Western Surgical

www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

[illegible]

Western Surgical

HAPPY HOME

Dr. G. L. GONDALIYA - HOSPITAL

ARIZOO A.C. RESTAURANT
PUNJABI & GUJARATI

R. K. PAN CENTER

CHANDRABAKANT MEDICAL STORE
SIRSI
JEE BHIMNATH
BHAIJI BHIMNATH

* www.westernsurgical.in *