



USER'S GUIDE

VITAL-LITE

OXYGEN CONCENTRATOR



Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. This oxygen concentrator should be used only under the supervision of a licensed physician.



Danger: Do not smoke when using oxygen or when near this device.

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GLOSSARY OF SYMBOLS

- : ON (power switched on)
- : Off (power switched off)
- : Type B device
- : Class II protection
- : Do not expose to open flames.

- : Do not use oil or grease.
- : Technical information
- : Consult the accompanying documents.
- : Keep in the vertical position.
- : Fragile - handle with care

GENERAL SAFETY GUIDELINES

Only persons who have read and understood this entire manual should be allowed to operate the *VITAL-LITE*.

USE OF OXYGEN



Oxygen is not a flammable gas, but it accelerates the combustion of materials. To avoid all risks of fire, the *VITAL-LITE* 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. If 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 (rear filter unobstructed).



The *VITAL-LITE* must only be used for oxygen therapy and only on medical prescription. The indicated daily duration and flow must be followed, otherwise it may present a risk to the health of the patient.



Do not use in a specifically magnetic environment such as (MRI, X-ray, etc.)

USE AND MAINTENANCE OF THE DEVICE



Do not open the device while in operation: risk of electrical shock.



Use the power cord provided, and check that the electrical characteristics of the power socket used match those indicated on the manufacturer's plate on the rear panel of the machine.



We recommend against the use of extension cords or adapters, as they are potential sources of sparks and fire.



The *VITAL-LITE* has an audible alarm to warn the user of problems. In order that the alarm may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level.

CONFORMITY WITH IEC60601-1 (§ 6.8.2 B):

"The manufacturer, assembler, installer or distributor 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 authorized by the party in question,
- The electrical installation of the corresponding premises complies with local electrical codes. (e.g. IEC / NEC).
- 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 manufacturer is not responsible in the event of an accident.

This device complies with the requirements of the FDA Quality System Regulation but its operation may be affected by other devices being used near by, such as diathermy and high frequency electro-surgical equipment, defibrillators, short wave therapy equipment, mobile telephones, CB and other portable devices, microwave ovens, television, induction plates or even remote control toys or any other electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.

I. DESCRIPTION

The *VITAL-LITE* is intended to supply supplemental oxygen to persons requiring low flow oxygen therapy. It is not intended to be life supporting or life sustaining. It produces oxygen enriched product by concentrating the oxygen contained in room air. It can be used either to administer oxygen with nasal cannulas or another probe or mask type of device.

The *VITAL-LITE* is easy to use.

The single flow adjustment knob allows:

- the device to be easily adjusted to the prescribed flow rate,
- the equipment supplier or medical staff to limit flows to a specific flow rate with a built-in locking device.

It has a power failure alarm and an operating fault alarm.

Note: the performances described pertain to the use of the *VITAL-LITE* with the accessories recommended by Merits Health Products, Inc.



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

- 1 - I/O (ON/OFF) Switch
- 2 - Indicator Lights
- 3 - Oxygen enriched air outlet
- 4 - Flow adjustment knob (l/min.)
- 5 - Circuit Breaker



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

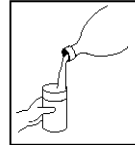
- 6 - Humidifier
- 7 - Filter
- 8 - Power Cord
- 9 - Hour meter
- 10 - Technical Label

II. STARTING UP / INSTALLATION

II. 1. Use in direct oxygen therapy

a - Ensure that the switch (1) is in the O/(OFF) position.

b - If used with a humidifier:

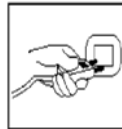


Unscrew the flask and fill it with water up to the line (see humidifier instructions). Then screw the lid on the humidifier flask until there are no leaks.

c - Connect the oxygen tube to the humidifier outlet nozzle or to the concentrator outlet if a humidifier has not been prescribed. The tube between the cannula and the **VITAL-LITE** should be limited to 60 feet (20 meters) long, in order to ensure that the oxygen flow rate remains within specification values.

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

e - Plug the power cable into a power outlet of the correct voltage and frequency as defined on the manufacturer's technical label (Fig I2-10).



f - Press the power switch (I/O) to the ON position (I). The red indicator will light and the audible alarm will sound for a few seconds until system pressure rises to the accepted level.

g - Turn the flow adjustment knob (4) to the prescribed value. This knob may have already been locked in the medically prescribed position. In this case, do not force it. Only the technician or medical personnel are authorized to release it.

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 to suit your face.

Remark: the required oxygen concentration is normally obtained within five minutes after the unit is started.

At the end of the treatment, press the I/O switch to place it in the (O) [OFF] position to stop the device. The oxygen enriched air flow continues for approximately 1 minute after the device is stopped.

For the equipment supplier or medical staff:

The flow adjustment knob may be locked to limit it to a specific predetermined value.

III. CLEANING - MAINTENANCE

III.1. Cleaning

Only the outside of the **VITAL-LITE** is to be cleaned, with a soft, dry cloth or, if necessary, a damp sponge, then thoroughly dried with wipes and an alcohol based solution. Acetone, solvents or any other inflammable products **must not be used**. Do not use abrasive powders.

The removable dust filter (2) must be cleaned weekly in warm water and household detergent or after approximately 100 hours of use. More frequent cleaning is recommended in dusty environments.



1. Filter / Silencer
2. Dust filter
3. Ventilation grill

III.2. Daily disinfection

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

The device must be switched off when alcohol based solutions are used.

a. The following minimum guidelines must be observed:

- Humidifier: (If prescribed by a physician)

Daily:

- Empty the water from the humidifier.
- Rinse the humidifier flask under running water.
- Fill humidifier up to the mark with distilled water.

Regularly:

- Disinfect the humidifier parts 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 tubing and nasal cannula:

Follow the manufacturer's instructions.

b. For each new patient:

The humidifier must be sterilized if possible or changed. The **VITAL-LITE** must be cleaned and disinfected as per the above instructions. The bacterial filter inside the device should be changed. The cabinet air filter may be changed as well. The entire oxygen administration circuit (oxygen therapy nasal cannulas, etc.) must be changed.

III.3. Maintenance

No special maintenance needs to be carried out by the patient. Your equipment supplier performs periodic maintenance operations to assure continued reliable service from the **VITAL-LITE**.

IV. USEFUL INFORMATION

IV.1. Accessories and spare parts

The accessories used with the **VITAL-LITE** must:

- be oxygen compatible,
- be biocompatible,
- comply with the general requirements of the FDA Quality System Regulation.

The connectors, tubes and nasal cannulas must be designed and approved for oxygen therapy usage.

The accessories with a **Merits Health Products** part number reference, or included in the set of accessories supplied with the device, comply with these requirements. Contact your dealer 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 responsibility.

AVAILABLE ACCESSORIES IF PRESCRIBED BY A PHYSICIAN

Humidifier:	P/N 9012-8774
Cannula with 2 m (7 ft) tubing:	P/N 9012-8780
Extension Tubing 7.7 m (25ft):	P/N 9012-8781
Tubing Adapter:	P/N 9012-8783

The above items are available from
Merits Health Products, Inc.

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

Concentrator casing	ABS
Mains cable	PVC
Dust filter	Polyester
ON/OFF switch	Nylon
Casters	Nylon
Flow adjustment knob	ABS
Gas outlet	Stainless Steel
Printed labels	Polycarbonate
Pipe/Tubing	Aluminium, PVC, polyurethane or silicone
Humidifier	Polypropylene
Filter	Polypropylene

IV.3. Operating Principle

The compressor sends filtered ambient air to a solenoid valve, which allows compressed air to pass to the column in production. The columns contain a molecular sieve that function to adsorb the nitrogen and thus allow oxygen to pass.

The oxygen enriched product is then directed to a pressure reducing valve through the adjustable flow meter to the oxygen outlet fitting.

During this time, the column which is being "regenerated" is connected to the ambient air and flow of oxygen enriched product 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 product finally passes through a bacterial filter located prior to the oxygen outlet fitting.

IV.4. Alarms - Safety Devices

IV.4.1 Alarm:

- No voltage detection:

In the event of a loss of mains power, an intermittent audible alarm is activated. Test alarm by activating **I/O [On/Off]** switch with power cable unplugged from wall outlet.

•Power Quality:

A rapidly pulsing alarm is indicative of a power quality problem, this will normally not effect the machines output, if the problem persist contact your power provider.

• Process fault:

In the case of a process fault, a visible and audible alarm is activated (continuous red light and audible alarm, see p. 7).

IV.4. 2. Safety devices

• Compressor motor:

Thermal safety is ensured by a thermal switch situated in the motor winding (145 ± 5 °C).

- Electrical protection of the **VITAL-LITE**

A 5A circuit breaker is incorporated into the front cabinet of all 230V models. A 10 A circuit breaker is included with 115V models.

• Safety valve:

This is fitted on the compressor outlet and is calibrated to 2.7 bar (40 psig).

- Class II devices with insulated casings (EN60601-1 standard).

IV.5. Indicator Light Function

IV. 5.1 Green Indicator

The green (LED) indicator light indicates that power is applied to the concentrator and that it is ready to provide oxygen enriched air to the patient. To be lighted, it is necessary that the concentrator power plug be inserted into the wall outlet and that the **ON/OFF (I/O)** switch be actuated.

IV. 5.2 Red Indicator

The red (LED) indicator light is utilized to warn the patient of a system fault. The two events that can cause the red (LED) indicator to be lighted are abnormal system pressure and loss of mains power. The abnormal system pressure warning red (LED) will light and an audible alarm will sound when product pressure is outside of normal operating range. The same red (LED) and audible alarm will sound intermittently on loss of mains power. Call the equipment supplier to service the device.

IV. 5.3. Maintenance of the system alarms:

- No special maintenance is required.
- The equipment supplier checks that the unit is still operating correctly when the routine checks are performed on the **VITAL-LITE**.

IV. 6. Technical characteristics

Dimensions: L x W x H:36x23x58.5cm (14 x 9 x 23 in.)

Caster diameter: 3.8 cm (1.5 in.).

Tilt angle (transport with humidifier fitted): 30°.

Weight: 13 kg. 30 lbs (depends on model)

Noise level: 45 to < 40 dBA (depends on model)

Flow values:

12 position adjustable flow valve 0.125-5 liters/minute. (Some models may have other values)

Accuracy of flow supplied:

The flow supplied is equal to the flow set on the flowmeter, accurate to within ± 10 % or 200 ml/min, whichever is the larger of the two.

Oxygen Concentration:

- at 2 l/min: > 90%.
- at 5 l/min: 90%. (+6.5%/-3%)

(Values at 21°C and at one atmosphere pressure).

Max. recommended flow: 5 l/min.

The variation of the maximum recommended flow does not exceed ± 10 % of the indicated value when a back pressure of 7 kPa (1 psig) is applied to the output of the device. The maximum outlet pressure is 50 kPa (7 psig).

Electrical power supply:

	115 V Units	230 V Units
Frequency:	60Hz	50 & 60Hz
Average Power:	330 W (avg)	300W(avg)
Protection Class:	Class IIb	Class IIb
Mains Protection:	10A	5A

Filters:

At the rear of the device: a dust filter.
 At the compressor input: a filter cartridge behind cabinet dust filter.
 Before the oxygen outlet: a bacterial filter < 0.3 µm. (technician only)

Air circulation:

A tubeaxial fan cools the compressor compartment

Environmental limit conditions:

The performances of the device (especially the oxygen concentration) are quoted at 21°C (70°F) and one atmosphere. They may change with temperature and altitude. For further information, please consult the maintenance manual.

- The device must be stored, transported and used in the vertical position only.
- Ambient temperature of between 5°C and 40 °C (40°F and 104 °F) (operation).
- Storage temperature range -20 °C to 60°C. (-4°F to 140°F).
- Relative humidity of between 15 % and 95 % operation and less than 95% storage, both non-condensing.
- Altitude(21°C): Up to 2,286 m (7,500 ft) without degradation;

Consult your equipment provider for further information regarding 2,286 m to 4000 m (7,500 to 13000 ft).

- Complies with EN60601-1 standard; spilling of a glass of water.

IV. 7. Standards

EN 60601-1[UL60601-1:2003],CAN/CSA-C22.2 No.601.1-M90 w/A1&A2: Electrical Safety- Medical Devices.

EN60601-1-2:2001 Electromagnetic Compatibility

IV. 8. Method for disposing of waste

All waste from the **VITAL-LITE** (patient circuit, filter, etc.) must be disposed of using the methods appropriate to the civil authority of the location where used.

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. All materials of construction are recyclable.

VITAL-LITE Serial No. _____

Date first used: _____

Maintained by: _____

Your distributor: _____

Address : _____

Telephone : _____

PREVENTIVE MAINTENANCE:

- a. Wash cabinet filter weekly
- b. Replace air inlet filter annually
- c. Check oxygen concentration every three months.

The manufacturer’s instructions for the **preventive maintenance** of the devices are defined in the maintenance manual and any updates to it must be followed.

The work must be carried out by suitably trained technicians.

Use original spare parts only (see Pg. 7).

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 which are designated as being the manufacturer’s responsibility or by the manufacturer as repairable.

IV. 10. Troubleshooting.

Observations	Possible Causes	Solutions
The I-O (ON/OFF) button is in the ON position but the device does not operate.	Power cable is not correctly plugged in.	Check the cable connection.
The intermittent alarm sounds.	Power failure.	Check the circuit breaker on the front of the unit under the flowmeter.
Red light remains lighted.	Product pressure is too low or too high.	Contact your equipment supplier.
A rapidly pulsing alarm.	Power Quality	If the problem persists contact your power provider
The alarm test does not work. See IV. 4.1	Capacitor is not charged Internal electrical fault.	Backup Capacitor has discharged operate unit for approximately 10 minutes and retest. Contact your equipment supplier.
The compressor operates and the I-O (ON/OFF) button is in the ON position but the green light is not lighted.	Faulty indicator.	Contact your equipment supplier.
The I-O (ON/OFF) button is ON and the compressor is operating but there is no flow. The audible alarm sounds (continuously).	Pneumatic connection broken or other pressure problem.	Stop the device by pressing the I-O (ON/OFF) button and contact your equipment supplier.
The I-O (ON/OFF) button is ON, the compressor is operating, there is a flow but the audible alarm sounds continuously.	Internal electrical fault. Pneumatic circuit fault.	Stop the device and contact your equipment supplier.
The compressor stops in mid-cycle, then starts again after a few minutes.	Compressor thermal safety device has been activated. Fan is not working. Dirty Filters.	Stop the device and wait for it to cool down. Clean cabinet filter. Start up again. Reset the circuit breaker. Contact your equipment supplier. If the device does not start, contact your equipment supplier.
The oxygen enriched air flow is interrupted at the nasal cannula outlet.	Tube disconnected or humidifier not tight.	Check that tubing connections are secure and that the tubing is not kinked.
The flow at the nasal cannula outlet is irregular.	Cannula tubing is kinked.	Straighten the tubing; contact your equipment supplier if damaged.



Maintenance Items

Cabinet Air Filter- Part Ref: 8400-1025; Replace annually, wash in warm water every week.

Inlet Air Filter- Part Ref: 8400-1180; Replace annually, more often in dusty environment.

APPENDIX A: EMC Information


Important: Failure to follow these guidelines listed may result in increased emissions and/or decreased immunity of the **VITAL-LITE** concentrator.

- * Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- * Portable and mobile RF communications equipment can affect Medical Electrical Equipment
- * The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the **VITAL-LITE**
- * The **VITAL-LITE** should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the **VITAL-LITE** should be observed to verify normal operation in the configuration in which it will be used.
- * Use only Merits replacement electrical parts.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions: The VITAL-LITE is intended for use in the electromagnetic environment specified below. The user of the VITAL-LITE should assure that it is used in such an environment.		
Emission tests	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The VITAL-LITE 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 VITAL-LITE 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 or domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity: The VITAL-LITE is intended for use in the electromagnetic environment specified below. The user of the VITAL-LITE should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Levels	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines Not applicable. No I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 70% U_T (30% dip in U_T) for 25 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VITAL-LITE requires continued operation during power mains interruptions, it is recommended that the VITAL-LITE be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 the test level			

Guidance and manufacturer's declaration – electromagnetic immunity: This VITAL-LITE is intended for use in the electromagnetic environment specified below. The user of this VITAL-LITE should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Levels	Compliance Level	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the VITAL-LITE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance $d = 1.2 \sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			w here P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.:

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electro-magnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VITAL-LITE as used exceeds the applicable RF compliance level above, the VITAL-LITE should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VITAL-LITE

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the VITAL-LITE device: The VITAL-LITE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VITAL-LITE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VITAL-LITE as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (M)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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**MERITS HEALTH PRODUCTS, INC.
730 N.E. 19TH PLACE
CAPE CORAL, FL 33909**

(800) 963-7487

www.meritshealth.com