

NEWLIFE[®]
elite

Patient Manual

Oxygen Concentrator

*Includes: Oxygen Monitor, Air Outlet,
Dual Flow, and Pediatric Flow
Options*

AIRSEP[®]

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0459





DO NOT OPERATE THIS EQUIPMENT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS AND INSTRUCTIONS, CONTACT YOUR EQUIPMENT PROVIDER BEFORE ATTEMPTING TO USE THIS EQUIPMENT; OTHER INJURY OR DAMAGE COULD OCCUR.



Smoking while using oxygen is the number one cause of fire, injury, and death. You must follow these safety warnings:

Do not allow smoking, candles, or open flames within the same room of the device or the oxygen-carrying accessories.

Smoking while wearing an oxygen cannula can cause facial burns and possibly result in death.

Removing the cannula and placing it on clothing, bedding, sofas, or other cushion material will cause a flash fire when exposed to a cigarette, heat source, spark or open flame.

If you smoke, you must always follow these 3 important steps first: **turn off** the oxygen concentrator, **take off** the cannula, and **leave the room** where this device is located.



“*No Smoking – Oxygen in Use*” signs must be prominently displayed in the home, or where oxygen is in use. Patients and their caregivers must be informed about the dangers of smoking in the presence of, or while using, medical oxygen.



Federal (USA) law restricts this device to sale or rental by order of a physician or other licensed health care provider.

English: A multilingual version of the manual is available through your equipment provider.

Español: Una versión multilingüe del manual está disponible a través de su proveedor de equipo.

Français: Une version multilingue du manuel est disponible par l'intermédiaire de votre fournisseur de matériel.

Deutsche: Eine mehrsprachige Version des Handbuchs ist in Ihrer Geräte-Anbieter.

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[Read the Important Safety Rules section before operating this equipment.]

AirSep® NewLife® Elite Oxygen Concentrator

This Patient Manual will acquaint you with AirSep's NewLife Elite Oxygen Concentrator. Make sure you read and understand all the information contained in this manual before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

Important Safety Rules

Carefully review and familiarize yourself with the following important safety information about the NewLife Elite Oxygen Concentrator.



“No Smoking – Oxygen in Use” signs must be prominently displayed in the home, or where oxygen is in use. Patients and their caregivers must be informed about the dangers of smoking in the presence of, or while using, medical oxygen.



This device supplies high-concentration oxygen that promotes rapid burning. **Do not allow smoking or open flames within the same room of (1) this device, or (2) any oxygen-carrying accessory.** Failure to observe this warning can result in severe fire, property damage and / or cause physical injury or death.

Do not use your oxygen concentrator in the presence of flammable gases. This can result in rapid burning causing property damage, bodily injuries or death.

Do not leave a nasal cannula on clothing, bed coverings or chair cushions. If the unit is turned on but not in use, the oxygen will make the material flammable. Set the I/O power switch to the 0 (Off) position when the Oxygen Concentrator is not in use.

Do not use oil, grease, or petroleum-based or other flammable products with the oxygen-carrying accessories or the Oxygen Concentrator. Oxygen accelerates the combustion of flammable substances. **Use only water based, oxygen compatible lotions or salves.**



This unit is not to be used for life-support. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this device may require additional monitoring. Patients with hearing and/or sight impairments may need assistance with monitoring the alarms.

If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.



Electrical shock hazard. Turn *Off* the unit and disconnect the power cord from the electric outlet before you clean the unit to prevent accidental electrical shock and burn hazard. **Only your Equipment Provider or a qualified service technician should remove the covers or service the unit.**

Care should be taken to prevent the Oxygen Concentrator from getting wet or allowing fluids to enter the unit. This can cause the unit to malfunction or shut down, and cause an increased risk for electrical shock or burns.

Do not use liquid directly on the unit. A list of undesirable chemical agents includes but is not limited to the following: alcohol and alcohol-based products, concentrated chlorine-based products (ethylene chloride), and oil-based products (Pine-Sol®, Lestoil®). These are **NOT** to be used to clean the plastic housing on the Oxygen Concentrator, as they can damage the unit's plastic.



Clean the cabinet, control panel, and power cord only with a mild household cleaner applied with a damp cloth (not wet) or sponge, and then wipe all surfaces dry. **Do not allow any liquid to get inside the device.**



The Oxygen Concentrator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is unavoidable, the device should be observed to verify normal operation.

No modification of this equipment is permitted.

Use of cables and adapters other than those specified, with the exception of cables and adapters sold by the manufacturer of the medical electrical equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the Oxygen Concentrator.

Use only electrical voltage as specified on the specification label affixed to the device.

Do not use extension cords with this unit or connect too many plugs into the same electrical outlet. The use of extension cords could adversely affect the performance of the device. Too many plugs into one outlet can result in an overload to the electrical panel causing the breaker/fuse to activate or fire if the breaker or fuse fails to operate.



Cet appareil produit de l'oxygène à concentration élevée, favorisant une combustion rapide. Ne pas permettre de fumer ou des flammes nues dans la même chambre: (1) cet appareil ou (2) tout accessoire contenant de l'oxygène. Ne pas utiliser de produits à base d'huile, de graisse ou de pétrole sur ou à proximité de l'unité.

Déconnecter le cordon d'alimentation de la prise électrique avant de nettoyer ou de faire l'entretien de l'unité.

Risque de choc électrique. Ne pas enlever les couvercles lorsque l'unité est branchée. Seuls votre fournisseur d'équipement ou un technicien de service qualifié devrait enlever les couvercles ou faire l'entretien de l'unité.



Federal (USA) law restricts this device to sale or rental by order of a physician or other licensed health care provider.



Do not position the unit so that it is difficult to access the power cord.

The concentrator should be located as to avoid smoke, pollutants or fumes.

Ensure concentrator is operated in an upright position.

Always place oxygen supply tubing and power cords in a manner that prevents a trip hazard.



Position the unit away from curtains or drapes, hot air registers or heaters. Be certain to place the unit on a flat surface and make sure all sides are at least 1 foot (30 cm) away from a wall or other obstruction. Do not place the unit in a confined area. Choose a dust and smoke free-location away from direct sunlight. Do not operate the unit outdoors unless the unit is plugged into a Ground Fault Circuit Interrupter (GFCI) protected outlet.

Do not operate this unit in a restricted or confined space where ventilation can be limited. This can cause the device to overheat and affect performance.

Do not allow either the air intake or the air outlet vents to be blocked. DO NOT drop or insert any object into any openings on the device. This can cause the Oxygen Concentrator to overheat and impair performance.



The Manufacturer recommends an alternate source of supplemental oxygen in the event of a power outage, alarm condition, or mechanical failure. Consult your physician or Equipment Provider for the type of reserve system required.

It is very important to select only the prescribed level of oxygen. Do not change the flow selection unless you have been directed to do so by a licensed clinician.

The Oxygen Concentrator may be used during sleep under the recommendation of a licensed clinician.



Operating or storing the Oxygen Concentrator outside of its normal operating temperature range can impair the performance of the unit. Refer to the specification section of this manual for storage and operating temperature limits.



In the event of an alarm or you observe the Oxygen Concentrator is not working properly; consult the troubleshooting section of this manual. If you cannot resolve the problem, consult your Equipment Provider.

If the audio alarm is weak or does not sound at all, consult your Equipment Provider immediately

For units equipped with the oxygen monitor option - Contact your Equipment Provider immediately if the amber OXYGEN MONITOR light remains on for more than 15 minutes and/or the audio alarm activates.



If the humidifier bottle tubing is not properly connected to the humidifier bottle fitting or to the oxygen outlet, an oxygen leak can occur.



Cannula must be non-kinking, which can be used for a total length of 25 ft. (7.6m) max.

Ensure the cannula is fully inserted and secure. You should hear or feel oxygen flow to the prongs of the nasal cannula. If oxygen does not seem to flow, first verify that the flow meter ball is registering a flow. Then, place the tip of the cannula into a glass of water; if bubbles come out of the cannula, oxygen is flowing. If bubbles do not appear, refer to the troubleshooting section of this manual.

Always follow the cannula manufacturer's instructions for proper use. Replace the disposable cannula as recommended by the cannula manufacturer or your Equipment Provider. Additional supplies are available from your Equipment Provider.



The use of some oxygen administration accessories not specified for use with this oxygen concentrator may impair its performance. Recommended accessories are referenced within this manual.

To Equipment Provider: The following oxygen administration accessories are recommended for use with the Oxygen Concentrator

- | | |
|--|-------------------|
| • Humidifier Bottle: | Part No. HU003-1 |
| • Nasal Cannula with 7 feet (2.1 m) of tubing: | Part No. CU002-1 |
| • Humidifier Adapter Extension: | Part No. HU002-1 |
| • Oxygen Outlet Adapter: | Part No. F0025-1 |
| • OxySafe Kit w/ Cannula & 7 ft. tube | Part No. 20628667 |
| • OxySafe Kit w/ DISS tubing adaptor | Part No. 20628668 |
| • Air Outlet Kit | Part No. KI365-1 |



NOTE

The Manufacturer does not recommend the sterilization of this equipment.

If the unit has not been used for an extended time period, it needs to operate for a minimum of minutes before power failure alarm can become activated.

For units equipped with the oxygen monitor option - When you turn the unit on, it's normal for the amber OXYGEN MONITOR light to turn on and remain on for up to five minutes.

For prescriptions levels below 1 lpm, you must operate the oxygen concentrator for at least 5 minutes at 2 lpm.



NOTE

The concentrator releases warm air out the bottom of the unit which can permanently discolor temperature sensitive flooring surfaces such as vinyl. The concentrator should not be used over flooring that is sensitive to heat staining. The Manufacturer is not responsible for flooring that becomes discolored.



NOTE

To prevent a void warranty, follow all manufacturers' instructions.

Do not attempt any maintenance other than the possible solutions listed within the manual.

Portable and mobile RF communications equipment can effect medical electrical equipment.

There is never a danger of depleting the oxygen in a room when you use your Oxygen Concentrator unit.



NOTE

The standard NewLife Elite Oxygen Concentrator accommodates prescriptions from 1 lpm minimum to 5 lpm maximum.



NOTE

AirSep offers the OxySafe as an optional accessory. This is intended to be used in conjunction with the NewLife Elite concentrator. For customers in regions requiring compliance to EN ISO 8359:1996-Ammendment1:2012, this accessory will meet this need.

The OxySafe is a thermal fuse to stop the flow of gas in the event that the downstream cannula or oxygen tubing is ignited and burns to the OxySafe. It is placed in-line with the nasal cannula or oxygen tubing between the patient and the oxygen outlet of the NewLife Elite.

For proper use of the OxySafe, always refer to the manufacturer's instructions (included with each OxySafe kit). AirSep offers an OxySafe kit that includes an OxySafe, 2" of tubing, and a DISS connector to connect to the oxygen outlet.; PN 20628668

[Read the Important Safety Rules section before operating this equipment.]

Why Your Physician Prescribed Oxygen

Many people suffer from a variety of heart, lung, and other respiratory diseases. A significant number of these patients can benefit from supplemental oxygen therapy at home, in the hospital, or at a medical facility.

Oxygen is a gas that makes up 21% of the room air we breathe. Our bodies depend on a steady supply to function properly. Your physician prescribed a flow or setting to address your particular respiratory condition.

Although Oxygen is a non-additive drug, unauthorized oxygen therapy can be dangerous. You must seek medical advice before you use this oxygen concentrator. The Equipment Provider who supplies your oxygen equipment will demonstrate how to set the prescribed flow rate.



It is very important to select the prescribed level of oxygen flow. Do not increase or decrease the flow until you first consult your physician.

[Read the Important Safety Rules section before operating this equipment.]

What is an Oxygen Concentrator?

Oxygen concentrators were introduced in the mid-1970's and have become the most convenient, reliable source of supplemental oxygen available today. Oxygen concentrators are the most cost-effective, efficient, and safest alternative to using high-pressure oxygen cylinders or liquid oxygen. An oxygen concentrator provides all the oxygen you need with no cylinder or bottle deliveries required.

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gases. In the NewLife Elite unit, room air passes through a regenerative, adsorbent material called "molecular sieve." This material separates the oxygen from the nitrogen. The result is a flow of high-concentration oxygen delivered to the patient.



There is never a danger of depleting the oxygen in a room when you use your NewLife Elite unit.



[Read the Important Safety Rules section before operating this equipment.]

How to Operate Your Oxygen Concentrator

First, become familiar with the important parts of your NewLife Elite Oxygen Concentrator (Figures 1a and 1b).

A. On/Off (I/O) Power Switch:

Starts and stops the operation of the unit.

B. Circuit Breaker Reset Button:

Resets the unit after electrical overload shutdown

C. Digital Hour Meter:

Records the unit's total hours of operation.

D. Flow meter/Adjustment Knob:

Controls and indicates the oxygen flow rate in liters per minute (lpm).

E. Oxygen Outlet :

Provides connections for a humidifier (if required) or nasal cannula.

F. Top and Side Handles:

Enables convenience in carrying the unit.

G. Operating Instructions:

Explains procedures to operate the unit.

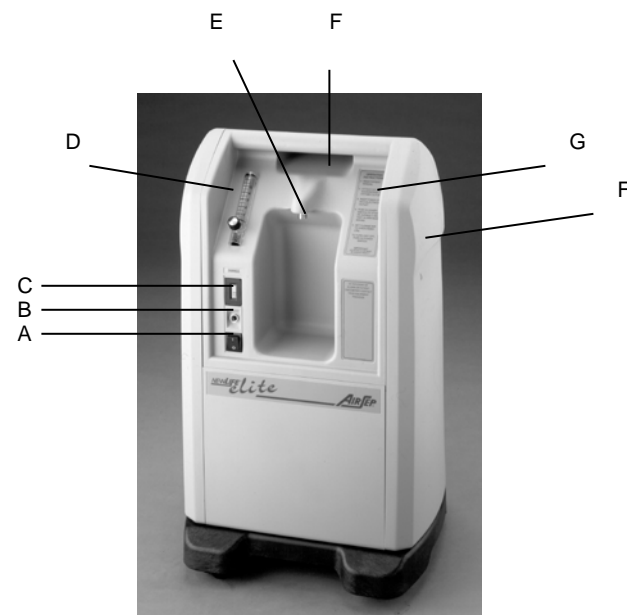


Figure 1a

[Read the Important Safety Rules section before operating this equipment.]

I. Air Intake Gross Particle Filter:

Prevents dust and other airborne particles from entering the unit.

J. Power Cord:

Allows connection of unit into electrical outlet.

	Do not use extension cords with this unit or connect too many plugs into the same outlet. Too many plugs in one outlet can result in an overload to the electrical panel causing the breaker/fuse to activate or fire if the breaker or fuse fails to operate.
--	--




Figure 1b


1. Locate the unit near an electrical outlet in the room where you spend most of your time.
2. Position the unit away from curtains or drapes, hot air registers, heaters, and fireplaces. Be certain to place the unit so all sides are at least 12 inches (30.5 cm) away from a wall or other obstruction. Do not place the unit in a confined area.
3. Turn the unit so that the operating controls are within easy reach and the air intake on the back of the unit is not obstructed.
4. Connect oxygen accessories such as a humidifier (if required), nasal cannula, and/or extension tubing to the oxygen outlet.
5. Completely unwrap the power cord (Figure 1b).

[Read the Important Safety Rules section before operating this equipment.]

6. Insert power cord into the electrical outlet.
7. Locate the power switch on the front of the unit, and switch it to the **I** position (on). (Figure 2.)

A battery-operated audible alarm must sound for a 5-second test to indicate a good battery and alarm.

 CAUTION	If the alarm is weak or does not sound at all, consult your Equipment Provider immediately.
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 NOTE	The standard NewLife Elite Oxygen Concentrator accommodates prescriptions from 1 to 5 lpm max.
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8. *Dual Flow and High Flow Applications:* Set the flow meter adjustment knob(s) to the prescribed lpm, in any combination of flows up to a total of 5 lpm for Dual 5 units (Figure 3).

or

Pediatric/Low Flow Applications: Set the flow meter adjustable knob(s) to the prescribed lpm up to 2 lpm in 1/8 liter (125 ccm) increments.

The concentrator is now ready for use.





Figure 2



Figure 3

[Read the Important Safety Rules section before operating this equipment.]

9. To turn the concentrator off, press the I/O switch to the 0 position.

 CAUTION	Ensure concentrator is operated in an upright position
 NOTE	For prescriptions levels below 1 lpm, you must operate the NewLife Elite unit for at least 5 minutes at 2 lpm.

10. If the NewLife Elite unit fails to operate properly, refer to the Troubleshooting section for a list of probable causes and solutions.

[Read the Important Safety Rules section before operating this equipment.]

Filters

Air enters the NewLife Elite unit through an air intake gross particle filter located on the back of the oxygen concentrator. This filter removes dust particles and other large particles from the air. Before you operate the NewLife Elite unit, make sure this filter is clean and positioned correctly (**Figure 4**).

The supplemental oxygen produced by the NewLife Elite unit receives additional filtration from a product filter located within the oxygen concentrator. Your Equipment Provider performs maintenance on the product filter in addition to other maintenance on the unit.



Figure 4



The use of some oxygen administration accessories not specified for use with this oxygen concentrator may impair its performance.

Oxygen Without Humidifier

1. If your physician did not prescribe a humidifier, connect the oxygen tubing directly to the unit's Oxygen outlet. A separate outlet fitting is supplied for this type of connection (**Figure 5**).



Figure 5

[Read the Important Safety Rules section before operating this equipment.]

Operating With Humidifier

Following these steps if your physician prescribed an oxygen humidifier as part of your therapy:

1. Remove or unscrew the reservoir bottle from the humidifier (If you have a pre-filled unit, do not perform this step. Proceed directly to step 4.)
2. Fill the reservoir with cool or cold water (distilled water is preferred) to the fill line indicated on the bottle. **DO NOT OVERFILL.**
3. Screw the reservoir bottle back together.
4. On the top of the humidifier, turn the thread nut counterclockwise while you connect the humidifier to the oxygen outlet, and tighten securely (Figure 6).
5. Connect oxygen tubing from the nasal cannula to the humidifier outlet fitting (Figure 7).



Figure 6



The use of certain humidifiers not specified for use with this oxygen concentrator may impair its performance.



To Equipment Provider: The following humidifier bottle is recommended for use with the NewLife Elite Oxygen Concentrator:
AirSep Part No. **HU003-1**



Figure 7

[Read the Important Safety Rules section before operating this equipment.]

Nasal Cannula

Your physician has prescribed either a nasal cannula, face mask, or other accessories (Figure 8). In most cases the manufacturer has already connected the oxygen supply tubing to the nasal cannula, face mask, or other accessory. If not, follow the manufacturer's instructions for proper connection. Connect the oxygen tubing to the oxygen outlet adapter or humidifier.



NOTE

To Equipment Provider: The following oxygen administration accessories are recommended for use with the NewLife Elite Oxygen Concentrator:

- | | |
|--|---------------------------------|
| • Nasal Cannula with 7 feet (2.1 m) of tubing: | AirSep Part No. CU002-1 |
| • Oxygen Outlet Adapter: | AirSep Part No. F0025-1 |
| • Humidifier Adapter Extension | AirSep Part No. HU002-1 |
| • Humidifier Bottle | AirSep Part No. HU003-1 |
| • OxySafe Kit w/ Cannula & 7 ft. tube | AirSep Part No. 20628667 |
| • OxySafe Kit w/ DISS tubing adaptor | AirSep Part No. 20628668 |



Figure 8

[Read the Important Safety Rules section before operating this equipment.]

Proper Setting of Oxygen Flow meter

To set the proper flow of supplemental oxygen, turn the flow meter adjustment knob left or right until the ball inside the flow meter centers on the flow line number prescribed by your physician (**Figure 9**).

To view the flow meter at the proper angle, note that the back line and the front numbered line must give the appearance of just one line.



It is very important to follow the prescribed level of oxygen. Do not increase or decrease the flow until you first consult your physician.



Normally, you should not need to adjust the flow meter on your unit. If you turn the flow meter adjustment knob clockwise, you will decrease and can shut off the flow of oxygen from your unit. For your convenience, the flow meter is marked in $\frac{1}{2}$ lpm increments from 1 to 5 lpm. For units with the pediatric flow meter option, the flow meter is marked in $\frac{1}{8}$ lpm increments for flow settings up to 2 lpm.








Figure 9

[Read the Important Safety Rules section before operating this equipment.]

Cleaning, Care, and Proper Maintenance

Cabinet

 WARNING	<p>Electrical shock hazard. Disconnect the power cord from the electric outlet before you clean the unit to prevent accidental electrical shock and burn hazard. Only your Equipment Provider or a qualified service technician should remove the covers or service the unit.</p> <p>Do not use oil, grease, or petroleum-based or other flammable products with the oxygen-carrying accessories or the Oxygen Concentrator. Oxygen accelerates the combustion of flammable substances.</p> <p>Use only water based, oxygen compatible lotions or salves.</p>
 CAUTION	<p>Do not use liquid directly on the NewLife Elite unit to clean it. A list of undesirable chemical agents includes but is not limited to, the following, according to the plastics manufacturer: alcohol and alcohol-based products, concentrated chlorine-based products (ethylene chloride), and oil-based products (Pine-Sol™, Lestoil™). These are NOT to be used to clean the plastic housing on NewLife Elite, as they can damage the unit's plastic.</p>
 CAUTION	<p>Clean the cabinet, control panel, and power cord only with a mild household cleaner applied with a damp cloth or sponge, and then wipe all surfaces dry. Do not allow any liquids to enter the concentrator.</p>
 NOTE	<p>To prevent a voided AirSep warranty, follow all manufacturers' instructions.</p>
 NOTE	<p>AirSep does not recommend the sterilization of this equipment.</p>

[Read the Important Safety Rules section before operating this equipment.]

Filters



Do not operate the unit without the air intake gross particle filter in place.

At least one time each week, wash the air intake gross particle filter, which is located in the back of the unit. Your Equipment Provider may advise you to clean it more often, depending upon your operating conditions. Follow these steps to properly clean the air intake filter:

1. Remove the filter and wash it in a warm solution of soap and water.
2. Rinse the filter thoroughly, and remove excess water with a soft, adsorbent towel. Ensure that the filter is dry before replacing it.
3. Replace the dry filter.


Reserve Oxygen Supply

Your Equipment Provider may recommend another source of supplemental oxygen therapy in case there is a mechanical failure or a power outage.

Troubleshooting

If your NewLife Elite Oxygen Concentrator fails to operate properly, refer to the chart on the following pages for possible causes and solutions and, if needed, consult your Equipment Provider.

If you cannot get the unit to operate, connect your nasal cannula, face mask, or other accessories to the reserve supplemental oxygen supply (if provided).

 NOTE	<p>Do not attempt any maintenance other than the possible solutions listed below.</p>
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Problem	Probable Cause	Solution
Unit does not operate. Power failure condition causes a continuous alarm to sound.	<p>Power cord not connected into electrical outlet.</p> <p>No power at electrical outlet.</p> <p>Oxygen concentrator circuit breaker is activated.</p>	<p>Check power cord plug at the electrical outlet for a proper connection.</p> <p>Check power source, wall switch, fuse, or circuit breaker in-house.</p> <p>Contact your Equipment Provider for service.</p>
Limited oxygen flow.	<p>Dirty or obstructed humidifier bottle.</p> <p>Defective nasal cannula, face mask, catheter, and/or oxygen delivery tube, or other accessory.</p> <p>Other leak or restriction.</p>	<p>Remove the humidifier bottle (if used) from the oxygen outlet. If flow is restored, clean or replace with a new humidifier bottle.</p> <p>Remove nasal cannula, face mask, or other accessories from oxygen tubing. If proper flow is restored, replace with new nasal cannula, face mask, or other accessories.</p> <p>Disconnect delivery tubing at oxygen outlet (front of unit). If proper flow is restored, check oxygen tubing for kinks or obstructions. Replace if needed.</p> <p>Contact your Equipment Provider.</p>

Troubleshooting Continued

Problem	Probable Cause	Solution
Condensation collects in the oxygen tubing when you use the humidifier bottle.	Unit not properly ventilated. Elevated operating temperature.	<p>Make sure unit is positioned away from curtains or drapes, hot air registers, heaters, and fireplaces. Be certain to place the unit so all sides are at least 12 inches (30.5 cm) away from a wall or other obstruction. Do not place the unit in a confined area.</p> <p>Allow oxygen tubing to dry out, or replace with new tubing. Refill humidifier bottle with COLD water. DO NOT OVERFILL.</p>
Intermittent alarm sounds at one second intervals.	Equipment malfunction.	Set I/O power switch to 0 position, use your reserve oxygen supply (if provided), and consult your Equipment Provider immediately.
Unit does not alarm, or weak alarm sounds for 5 seconds during start-up.	Weak 9-volt battery	Call your Equipment Provider to replace 9-volt battery.
All other problems.		Set I/O power switch to the 0 position, use your reserve oxygen supply (if provided), and consult your Equipment Provider immediately.


Product Specifications

* Based on an atmospheric pressure of 14.7 psi (101 kPa) at 70°F (21°C)

** Operating unit outside of operational temperature range can affect performance.

<p>Oxygen Concentration: * ISO 8359: 1.7 IEC 60601-7.9.3</p>	<p>1-3 lpm: 95.5% - 92.0% 4 lpm: 92% ± 3% 5 lpm: 90% ± 3%</p>	
<p>Physical Characteristics ISO 8359: 1.7 IEC 60601-7.9.2.5</p>	<p>Height: 72.4 cm (28.5 in.) Width: 40.0 cm (15.7 in.) Depth: 36.8 cm (14.5 in.) Weight: 24.5 kg (54.0 lb.)</p>	
<p>Electrical Power: ISO 8359: 1.8 IEC 60601-4.11</p>	<p>120 VAC, 60 Hz, 4.0 amps 350 watts – 5 lpm model Two-prong polarized plug Double insulated cabinet CSA-Approved to IEC 601-1</p>	<p><i>Export Models:</i> 230 VAC, 50 Hz, 2.0 amps 230 VAC, 60 Hz, 2.0 amps Double-insulated cabinet Approved to IEC 60601-1 3rd ed.</p>
<p>Alarms: ISO 8359: 11.1 ISO 9703-2. IEC 60601-12.3</p>	<p>Battery test Power failure High and low pressure Low oxygen concentration (with Oxygen Monitor option)</p>	
<p>Temperature: ** ISO 8359: 1.7 IEC 60601-7.9.3</p>	<p>Operational: 5°F to 104°F (-15°C to 40°C) Storage: -4°F to 140°F (-20°C to 60°C)</p>	
<p>Relief Pressure ISO 8359: 1.7 IEC 60601-7.9.3</p>	<p>45 Psig (310 kPa) @ Compressor</p>	

Product Specifications Continued

<p>O₂ Monitor Option ISO 8359: 1.7 IEC 60601-7.9.3</p>	<p>Yellow caution light Range: Below 85% +/- 3% O₂ Audible Alarm: After 15 min. +/- 2 min. below specified Range Max Pressure = 60 Psig (414kPa) Max Flow 8 LPM Operating temperature Range: -31°F to 158°F (-35°C to 70°C) Operational Humidity: 0 to 100%</p>
<p>Altitude ISO 8359: 1.7 IEC 60601-7.9.3</p>	<p>Sea level to 400 ft. 13,125 ft. (4000 m) 92% O₂ 87% O₂</p>
<p>Sound Pressure ISO 8359: 4.6 IEC 60601-1: 9.6</p>	<p>EUT: 53 dbA per ISO 3744 (Max 60 dbA allowed) Chamber Background Noise: 30dbA Max</p>
<p>Fire Prevention - System</p> 	<p>Read warnings and cautions on flammable cleaning solvents, grease, oil and “NO” smoking at the beginning of this manual. There are three legs of the thermal event triangle: Fuel, Oxidizer and Ignition source. Two of the three are present: Cotton fibre, skin lotion, facial hair and some plastics are hydrocarbon by nature. Oxygen of 90% level runs through the plastic tubing to cannula. Therefore, <u>DO NOT</u> allow sparking, flame from a lighter or match or other elevated temperatures beyond operational range to reduce risk of thermal event. To further improve safety, install OxySafe Kit Part No. 20628667 and 20628668.</p>
<p>Fire Prevention ISO 8359:7.2 IEC 60601-1: 11.2</p>	<p>O₂ level inside Concentrator at or below 25% and in combination with highest safety test temperature poses no threat to any thermal event. Further protection is double insulation of internal wiring and sufficient electrical safety testing to ensure equipment shutdown in overheat.</p>

Product Specifications Continued

Excessive Temperatures** ISO 8359:7.1 IEC 60601-1: 11.1	Maximum O ₂ Outlet Temperature Rise + 5.4°F (3°C)		
Flow Rate Range ISO 8359 Section 8_50.3 IEC 60601-1: 7.4	1% maximum difference in flow rate of allowable +/- 10%		
O ₂ Concentration at extreme voltage conditions ISO 8359 Section 8_50.4 IEC 60601-1: 7.4	Voltage extreme	% Volume	
	132V	94.6	
	103V	94.0	
	253V	91.0	
	195V	90.0	
ISO 8359 Section 8_50.5 Mean O ₂ Concentration IEC 60601-1: 7.4	Voltage extreme	% Mean O ₂	% Individual Deviation from mean (+/- 3% allowable)
	132V	94.6	0.6
	103V	94.0	0.6
	253V	91.0	0.6
	195V	90.0	1.4
ISO 8359 Section 8_50.6 Mean Flow Rate IEC 60601-1: 7.4	Voltage extreme	% Mean Flow	% Individual Deviation from mean (+/- 3% allowable)
	132V	4.87	0.8
	103V	5.11	0.8
	253V	4.99	1.4
	195V	5.00	1.4

Product Specifications Continued

ISO 8359 Section 8_50.7 Backpressure Effect Test IEC 60601-1: 7.4	Flow 5.00 lpm 4.75 lpm	Applied Pressure * @ 0 psig (0 kPa) @ 1 psig (7 kPa)
Outlet Pressure Test ISO 8359 Section 8_50.8 IEC 60601-1: 7.4	Actual Pressure 7.3 max psig	Max Allowable Limit 8.8 psig

EMC SUMMARY: IMMUNITY TEST RESULTS PERFORMANCE CRITERIA

Criteria	During Test	After Test
A	Operate as intended No Degradation of performance No loss of function	Operate as intended No degradation of performance No loss of function
B	Loss of function (one or more)	Operate as intended No degradation of performance Functions self-recoverable
C	Loss of function (one or more)	Operate as intended No degradation of performance Functions recoverable by the operator

*** Applicable to all life support equipment and any equipment with less than 1 kVA input power, equipment with input power above 1 kVA and below 16A per phase need only meet criteria B.**

Note (1)- N/A – No I/O Ports;

Note (2) - N/A – Power did not have ground

Note (3): IMMUNITY FAILURE CRITERIA TO BE APPLIED

(a) If O₂ concentration is above 87% and the alarm turns ON, this will be considered a nuisance alarm and not a failure, because the percent of concentrated oxygen being delivered to the patient is at or above specification.

(b) If the EUT resets during testing for EN61000-4 -2 thru -11 Immunity testing it is acceptable. The concentration (%O₂) will drop momentarily during the rest condition. The system should recover and return to its previous concentration level.

(c) A reset has occurred when the system restarts by turning on its 4 waste/feed valves, the O₂ alarm LED and the audible alarm for 4 seconds. The compressor may also turn off momentarily.

The EUT is expected to recover with no performance degradation

This device provides physician recommended oxygen therapy.

Source testing: ULTRATECH GROUP OF LABS File #: IEC 60601-1-2: 2007 (3rd EDITION) – Immunity for Medical Electrical Equipment AIR095 & 116-EN601-1-2 Elite 120v 60 Hz, January, 2014
AIR-116_EN 60601-1-2_Elite 230v 50Hz, January, 2014,

EMC SUMMARY: PART I IMMUNITY TEST RESULTS

Standard	Description	Severity Required	Performance Criteria Met	Performance Criteria Allowed(1)
IEC 61000-4-2 EN 61000-4-2	Electrostatic Discharge	±6kV contact ±8kV air	A	A
IEC 61000-4-3 EN61000-4-3 ENV 50204	Radiated RF Immunity	3V/m, 80-1000MHz, 2Hz, 80%AM modulation 3V/m, 1000-2500MHz, 2Hz 80%AM modulation	A	A
IEC 61000-4-4 EN 61000-4-4	Electrical Fast Transient	±2kV on AC ±1kV on I/O	A N/A (1)	A N/A
EN 61000-4-5 EN 61000-4-5	Surge Withstand	±2kV common mode ±1kV differential on AC lines (minimum 5 surges at each phase angle)	N/A (2) A (3)	A A
IEC 61000-4-6 EN 61000-4-6	Conducted RF Immunity	3 V, 0.15-80 MHz, 2Hz, 80% AM modulation	A	A
IEC 61000-4-8 EN 61000-4-8	Magnetic Field Immunity	50 Hz, 3A/m 60 Hz, 3A/m	A A	A A

EMC SUMMARY: PART I IMMUNITY TEST RESULTS Continued

Standard	Description	Severity Required	Performance Criteria Met	Performance Criteria Allowed(3)
IEC 61000-4-11 EN 61000-4-11 For 230V 50 Hz	Dips Dips Dips Interrupts	< 5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds * UT: a.c. mains voltage prior to application of the test level.	A A A C	A A A C
IEC 61000-4-11 EN 61000-4-11 For 120V 60 Hz	Dips Dips Dips Interrupts	30% - 25 cycles for 3 times 60% - 5 cycles or 3 times >95 - 0.5 cycles for 3 times >95 - 250 cycles for 3 times	A A A C	A A A C
<i>IEC 61000-3-2 EN61000-3-2</i>	<i>Harmonic Current Emissions</i>	<i>Class A</i>	<i>N/A</i>	<i>N/A</i>
IEC 61000-3-3 EN61000-3-3	Voltage Fluctuation and Flicker in Low- Voltage Supplies	Voltage Fluctuation Flicker	N/A N/A	N/A N/A
EN 60601-1-2 CLAUSE 36.202.14 (230V 50 Hz) (120V 60 Hz)	Variations of power frequencies	Variations of power frequencies at +/- 1Hz (49 Hz and 51Hz) at +/- 1Hz (59 Hz and 61Hz)	PASS PASS	PASS PASS

EMC SUMMARY: PART II EMC EMISSION TEST RESULTS

CISPR11: / EN 55011	TEST REQUIREMENTS	MARGIN LIMITS BELOW (-) / ABOVE (+)	COMPLIANCE (YES / NO)
Source Testing: ULTRATECH GROUP OF LABS File #: AIR095-CISPR11B (Elite 120v 60 Hz) 9Aug2010			
5.1.2 TABLE 2b, CLASS B (GROUP 1)	AC Mains Terminal Disturbance Voltage in the frequency band 150 kHz to 30 MHz	-28.1 dB @ 0.152MHz	YES
5.2.2 TABLE 3, CLASS B (GROUP 1)	Electromagnetic Radiation Disturbance in the frequency band 30 MHz to 1000 MHz	-2 dB @ 80.00MHz	YES
Source Testing: ULTRATECH GROUP OF LABS File #: AIR-116_CISPR11B_Elite 230v 50Hz 30Jan2014			
6.2.1.3, Table 3, Class B (Group1)	AC Mains Terminal Disturbance Voltage in the frequency band 150 kHz to 30 MHz	- 9.3 dB @ 0.156 MHz	YES
6.2.2.3, Table 5, Class B (Group 1)	Electromagnetic Radiation Disturbance in the frequency band 30 MHz to 1000 MHz	- 4.1 dB @ 112 MHz	YES

EMC SUMMARY: PART III FCC EMC EMISSION TEST RESULTS

FCC PART 15, SUBPART B	TEST REQUIREMENTS	MARGIN BELOW (-) / ABOVE (+) THE LIMITS	COMPLIANCE (YES / NO)
Source Testing: ULTRATECH GROUP OF LABS File #: AIR095-FCC15B (Elite 120V 60Hz) 9Aug2010			
15.107(a), CLASS B	AC Power Line Conducted Emissions Measurements	-28.3 dB @ 13.007 MHz	YES
15.109(a), CLASS B	Radiated Emissions from Unintentional Radiators (Digital Devices)	-1.5 dB @ 80.00MHz	YES
Source Testing: ULTRATECH GROUP OF LABS File #: AIR-116_FCC15B_Elite 230v 50Hz			
15.107(a), CLASS B	AC Power Line Conducted Emissions Measurements	- 9.3 dB @ 0.156 MHz	YES
15.109(a), CLASS B	Radiated Emissions from Unintentional Radiators (Digital Devices)	- 7.1 dB @ 112.00 MHz	YES

Classification

Type of protection against electric shock:

Class II Protection from electric shock is achieved by double insulation.
Protective earthing or reliance upon installation conditions are not required.

Degree of protection against electric shock:

Type BF Equipment providing a particular degree of protection against electric shock particularly regarding:
1) allowable leakage current;
2) reliability of protective earth connection (if present).
Not intended for direct cardiac application.

Degree of protection against harmful ingress of water:

Drip-proof equipment – IPX1.
Equipment provided with an enclosure preventing of such an amount of falling liquid as might interfere with the satisfactory and safe operation of the equipment.

Method of cleaning and infection control allowed:

Please refer to Maintenance section in the NewLife Elite Service Manual.

Degree of safety of application in the presence of flammable anesthetic gases:

Equipment not suited for such application.

Mode of operation:

Continuous duty.

[Read the Important Safety Rules section before operating this equipment.]

Oxygen Monitor Option

The following information will acquaint you with Oxygen Monitor option of the NewLife Elite Oxygen Concentrator. Make sure you read and understand all the information contained in this manual before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.



If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.



This unit is not to be used for life support. Geriatric, pediatric, or any other patients unable to communicate discomfort while using this machine may require additional monitoring. Patients with hearing and/or sight impairment(s) may need assistance with monitoring alarms.



Contact your Equipment Provider immediately if the amber OXYGEN MONITOR light remains on for more than 15 minutes.



When you turn the unit on, it's normal for the amber OXYGEN MONITOR light to turn on and remain on for up to five minutes.

Function of the Oxygen Monitor

The oxygen monitor is a small electronic device within the NewLife Elite Oxygen Concentrator that monitors the concentration of oxygen produced by the unit.

Alarm Signal

If oxygen concentration falls below the acceptable therapeutic level, an amber OXYGEN MONITOR light on the Oxygen Concentrator turns on (Figure 10). If the light remains on for more than 15 minutes, an intermittent alarm sounds.



Amber Light

Figure 10

[Read the Important Safety Rules section before operating this equipment]

Air Outlet Option

The following information will acquaint you with the Air Outlet option for the NewLife Elite Oxygen Concentrator. Make sure you read and understand all the information in this NewLife Elite Patient Manual before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.



If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.



This unit is not to be used for life support. Geriatric, pediatric, or any other patients unable to communicate discomfort while using this machine may require additional monitoring. Patients with hearing and/or sight impairment(s) may need assistance with monitoring alarms.

Operating the NewLife Elite Air Outlet

1. Read and understand all information contained in the NewLife Elite Patient Manual's How to Operate Your Oxygen Concentrator section before you operate your unit.

[Read the Important Safety Rules section before operating this equipment.]



The NewLife Elite Air Outlet option allows you to connect a hand held nebulizer

Figure 1: Nebulizer with tubing, valve and fitting shown

Figure 2: Valve and fitting shown included in Air Outlet Kit P/N KI365-1:

- Air Valve AirSep Part No. VA007-1
- Air Outlet Barb Fitting: AirSep Part No. F0032-1



You may continue to receive oxygen from the unit while you use the Air Outlet option.



Figure 1

Air Outlet option

* Shown with hand held nebulizer



Figure 2

Air Valve
Part No.
VA007-1

Air Outlet
Barb Fitting
Part No.
F0032-1

[Read the Important Safety Rules section before operating this equipment.]

2. Locate the air outlet barb fitting on the front of the unit (**Figure 2**). If a hand held nebulizer will be used, connect one end of the air supply tubing to the air outlet barb fitting and the other end to the bottom of the nebulizer.



NOTE

Oxygen-enriched air is not delivered at the air outlet.



NOTE

In high humidity environments or during extended period of non-use, open the air valve completely (**Figure 3**) to purge/flush the system.

3. Fill the nebulizer cup with medication as prescribed by your physician (Refer to the Nebulizer with Medication section for filling instructions).
4. Operate the NewLife Elite unit for at least five minutes, and then open the air valve completely (**Figure 3**).
5. Begin your treatment (Refer to the Inhaling Medication/Treatment Instruction sections). Nebulizer medication will now be visible as a fine mist.*




Figure 3

[Read the Important Safety Rules section before operating this equipment.]

- When treatment is complete, turn the air valve to the *OFF* position.
(Figure 4)




Figure 4


NOTE The NewLife Elite Air Outlet regulator is preset to deliver 6 liters per minute (lpm) at 12 psig (85 kPa).

- Disconnect the nebulizer and the air supply tubing from the air outlet barb fitting.
 - Clean the nebulizer. (Refer to the Cleaning the Nebulizer section).
- * If you think that your nebulizer is not operating properly, contact your Equipment Provider.

Filling the Nebulizer with Medication

- Wash your hands thoroughly.
- Use an eyedropper, syringe, or other measuring device to measure out the proper amount of medication, as prescribed by your physician.


NOTE Use only the amount of medication and frequency of treatment that your physician prescribed

[Read the Important Safety Rules section before operating this equipment.]

3. Remove or unscrew the medication cup on the nebulizer, and place your prescribed measured dosage into the medication cup (**Figure 5**).
4. Connect the medication cup to the nebulizer, and then connect the “T” piece or mouthpiece to the nebulizer (**Figure 6**).



Figure 5

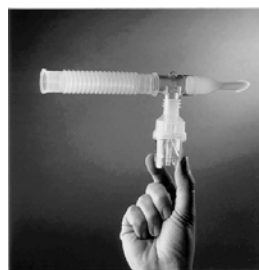


Figure 6

5. Connect one end of the air supply tubing to the air outlet barb fitting and the other end to the bottom of the nebulizer, and open the air valve completely as shown in **Figure 3**.
6. Begin your treatment. (Refer to the Inhaling Medication/Treatment Instruction section)

[Read the Important Safety Rules section before operating this equipment.]

Inhaling Medication/Treatment Instructions



NOTE

The following instructions for inhaling medication are often recommended. If your physician or health care professional has given you special instructions, make sure you follow them instead, as prescribed.

1. Close your mouth around the mouthpiece, but do not hold it with your teeth (**Figure 7**).
2. Take a slow, deep breath, and pause at the end of the inhalation for 1 -2 seconds, then exhale slowly and completely.
3. Repeat this procedure until the prescribed amount of medication nebulizes or the Prescribed amount of treatment time elapses (whichever occurs first).
4. If your physician or health care professional instructed you to take short rest periods During your treatment, make sure you turn the air valve to the *OFF* position, as shown in **Figure 4**. This will conserve your medication.

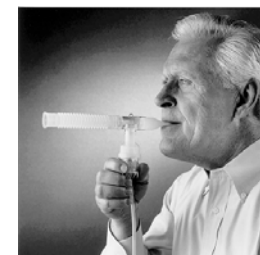


Figure 7



NOTE

Prolonged treatment time can indicate a defective nebulizer. Contact your Equipment Provider if this condition exists.

[Read the Important Safety Rules section before operating this equipment.]

Cleaning the Nebulizer



NOTE

Perform steps 1 and 2 below after each treatment to prevent medication from collecting and hardening inside the nebulizer parts.

1. After each treatment, separate the nebulizer and the “T” piece or mouthpiece assembly.
2. Remove or unscrew the nebulizer cup, and rinse each component thoroughly in warm water.
3. Once a day, clean all nebulizer parts (excluding air supply tubing) with a mild detergent or soap solution in warm water. Rinse thoroughly, and soak all parts in a solution of one (1) part white vinegar and three (3) parts water for 30 minutes to disinfect.
4. Rinse thoroughly in warm water to remove the disinfectant solution.
5. Place all nebulizer parts on a paper towel or soft absorbent material to air dry. **DO NOT WIPE DRY.**
6. When dry, store the nebulizer parts in a clean container or plastic bag.
7. Repeat the above procedure after each treatment/patient use.

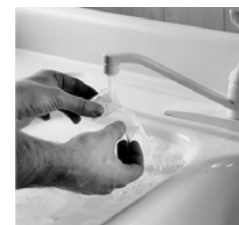


Figure 8



Federal (USA) law restricts this device to sale or rental by order of a physician or other licensed health care provider.

[Read the Important Safety Rules section before operating this equipment.]

Dual Flow and Pediatric/Low Flow Options

The following information will acquaint you with the 5 liter dual flow and pediatric/low flow options of the NewLife Elite Oxygen Concentrator (see **Figure 9**). Make sure you read and understand all the information contained in this manual before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.



“No Smoking – Oxygen in Use” signs must be prominently displayed in the home, or where the oxygen concentrator is in use. Patients and their caregivers must be informed about the dangers of smoking in the presence of, or while using, medical oxygen.



If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.



This unit is not to be used for life support. Geriatric, pediatric, or any other patients unable to communicate discomfort while using this machine may require additional monitoring. Patients with hearing and/or sight impairment(s) may need assistance with monitoring alarms.



Use no oil, grease, or petroleum-based or other flammable products on or near nasal end of cannula or the NewLife Elite unit. Oxygen accelerates the combustion of flammable substances.



This device supplies high-concentration oxygen that promotes rapid burning. Do not allow smoking or open flames within the same room of (1) this device, or (2) any oxygen-carrying accessory. Failure to observe this warning can result in severe fire, property damage and / or cause physical injury or death.

[Read the Important Safety Rules section before operating this equipment.]

Dual Flow Application

The NewLife Elite unit's dual flow option allows a single concentrator to meet the high flow requirements of one patient (**Figure 9**) or the needs of two patients, in any combination of flows up to the maximum capacity of the concentrator. Excellent for use in the home, extended care facility, hospital, or physician's waiting room.

Two Patients/
Dual Flow
Applications



Figure 9

Pediatric/Low Flow Application

The pediatric flow meter (available for use with the dual flow NewLife Elite unit) Meets low flow requirements up to 2 lpm in 1/8 liter (125 cc) increments (**Figure 10**).



Figure 10

[Read the Important Safety Rules section before operating this equipment.]

Setting the Pediatric Flow meter

When using the pediatric flow meter, the unit will not reach proper concentration at the pediatric setting (less than 2 lpm) until you bleed off a portion of the oxygen by opening the primary flow meter (on the left side of the unit). Follow the procedure below when using the pediatric flow meter.

1. Follow the start-up instructions 1-7 as outlined on page 9 & 10.
2. Set the pediatric flow meter to the prescribed flow.
3. Set the primary flow meter to 2 lpm to bleed off excess product, and allow the unit to achieve maximum concentration.



The NewLife Elite Oxygen Concentrator must be operated for at least five minutes at 2 lpm before using the unit.































The NewLife Elite is appropriate for usage by two patients, provided the combined flow is a minimum of 2 lpm and does not exceed the maximum capacity of the concentrator.

Symbols/Abbreviations

Symbols are frequently used on equipment and/or the manual in preference to words with the intention of decreasing the possibility of misunderstanding caused by language differences. Symbols can also permit easier comprehension of a concept within a restricted space.

The following table is a list of symbols and definitions that may be used with the NewLife Elite Oxygen Concentrator.

Symbol	Description	Symbol	Description
	ON (power switch on)		OFF (power switch off)
	No smoking		Do not disassemble
	Type BF equipment		Consult instructions for use
	Warning – Describes a hazard or unsafe practice that if not avoided can result in severe bodily injury, death or property damage		Class II Device
	Caution – Describes a hazard or unsafe practice that if not avoided can result in minor bodily injury or property damage		Complies with the 93/42/EEC directive drawn up by the approved organization No. 0459
	Note – Provides information important enough to emphasize or repeat		Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment

Symbol	Description	Symbol	Description
	Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment.		Oxygen concentration warning LED
	Keep unit and accessories dry		Consult the accompanying documents
	Use no oil or grease		Proper disposal of waste of electrical and electronic equipment required
	Oxygen outlet connection to the cannula		Do not expose to open flames
	Fragile – handle with care		Keep in the vertical position
	Caution: Federal law (USA) restricts this for sale or rental by or on the order of a physician or licensed health care provider.		Manufacturer
	Serial Number		Authorized Representative in the European Community
	Catalog Number		Date of Manufacture

For European representative:



Medical Product Services GmbH (MPS)

Borngasse 20

35619 Braunfels, Germany

Tel: +49 (0) 6442-962073

E-mail: info@mps-gmbh.eu



For service on your NewLife Elite Oxygen Concentrator, please contact your local Equipment Provider at:



CAIRE Inc.
2200 Airport Industrial Dr., Ste 500
Ball Ground, GA 30107
www.chartindustries.com/RespiratoryHealthcare

