NEWLIFE® inTENSity10

Patient Manual

for NewLife 10-Liter Oxygen Concentrator

includes *Oxygen Monitor, Dual Flow, and Pediatric/Low Flow Options*

AIRSEP®

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AirSep® NewLife® Intensity 10 Oxygen Concentrator

This Patient Manual will acquaint you with AirSep's NewLife Oxygen Concentrator with Intensity10/ 10-Liter option. Make sure you read and understand all the information contained in this guide before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

	In the event of an alarm or if you are experiencing any signs of patient discomfort, consult your Equipment Provider and/or your physician immediately.
	This unit is not a life-support device. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this oxygen concentrator may require additional monitoring. Patients with hearing and/or sight impairments may need assistance with monitoring the alarms. Consult your physician immediately if you are experiencing any signs of discomfort.
	This device manufactures high concentration oxygen, which promotes rapid burning. Do not allow smoking or open flames within 5 feet of: (1) this device or (2) any oxygen- carrying accessory. Use no oil, grease, or petroleum-based products on or near the unit. Disconnect the power cord from the electrical outlet before you clean or service the unit.

Why Your Physician Prescribed Oxygen

Many people today suffer from a variety of heart, lung, and other respiratory diseases. A significant number of these patients can benefit from supplemental oxygen therapy for respiratory care 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 has prescribed supplemental oxygen therapy because your body is not able to get enough oxygen from room air. Oxygen is a non-addictive drug, and your physician prescribed a flow sufficient to improve your condition.

Please keep in mind that unauthorized oxygen therapy can be dangerous. You must seek medical advice before you use this unit. The Equipment Provider who supplies your oxygen equipment will demonstrate how to set the prescribed flow rate.

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

What is an Oxygen Concentrator?

Oxygen concentrators were introduced in the mid-1970s and have become the most convenient, reliable source of supplemental oxygen available today. Without an oxygen concentrator, the average patient would require a delivery of 12 bottles/cylinders of oxygen each month. Your oxygen concentrator produces all the oxygen you need, with no deliveries required.

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gases.

In the NewLife Intensity 10 unit, room air passes through a regenerative adsorbent material called molecular sieve. This material separates the oxygen from the nitrogen and other gases. The result is a constant supply of concentrated high purity supplemental oxygen that is delivered to the patient.

NOTE

There is never a danger of depleting the oxygen in a room when you use your NewLife Intensity 10 unit.

Important Safety Rules

Carefully review and familiarize yourself with the following important safety information about the NewLife Intensity 10 Oxygen Concentrator:

	In the event of an alarm or if you are experiencing any signs of patient discomfort, consult your Equipment Provider and/or your physician immediately.
	This unit is not a life-support device. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this oxygen concentrator may require additional monitoring. Patients with hearing and/or sight impairments may need assistance with monitoring the alarms. Consult your physician immediately if you are experiencing any signs of discomfort.
	Do not leave a nasal cannula under 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 O (off) position when the NewLife Intensity 10 unit is not in use.
	Electrical shock hazard. Do not remove covers while the unit is plugged in. Only your Equipment Provider should remove the covers.

	This device manufactures high concentration oxygen, which promotes rapid burning. Do not allow smoking or open flames within 5 feet of: (1) this device or (2) any oxygen-carrying accessory. Use no oil, grease, or petroleum-based products on or near the unit. Disconnect the power cord from the electrical outlet before you clean or service the unit.
	Do not use extension cords with this unit.
	AirSep 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.
	U.S. Federal law restricts this device to sale by or on order of a physician. Use unit in accordance with the manufacturer's Patient Manual.

How to Operate Your Oxygen Concentrator

First, become familiar with the important parts of your NewLife Intensity 10 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. Flowmeter/Adjustment Knob (Primary on Dual Option):
Controls and indicates the oxygen flow rate in liters per minute (lpm). Main flowmeter (left side) on units with dual flow option.

E. Oxygen Outlet (Primary on Dual Option):
Provides connections for a humidifier (if required), cannula, or catheter. On units with dual flow option, controlled by primary flowmeter.

F. Top and Side Handles:
Enables convenience in carrying the unit.

G. Operating Instructions:
Explains procedures to operate the unit.

H. Secondary Flowmeter (Dual Option):
Flowmeter (right side) on units with dual flow option.

I. Secondary Oxygen Outlet (Dual Option):
Oxygen outlet (right side) on units with dual flow option. Controlled by secondary flowmeter.

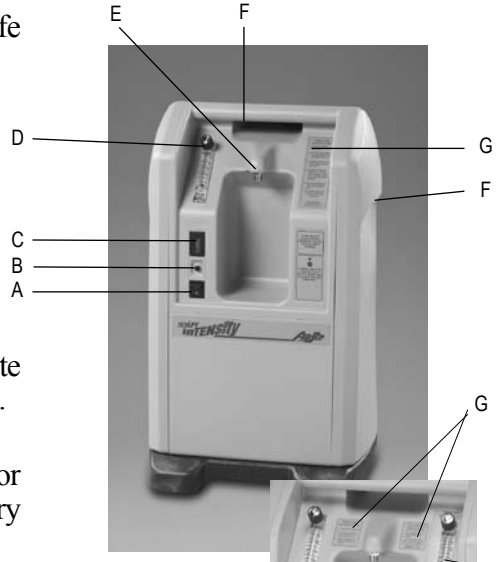

Figure 1a

Dual Flow Option

J. Air Intake Gross Particle Filter:
Prevents dust and other airborne particles from entering the unit.

K. Storage Pocket:
Handy accessory pocket with Velcro attachments to hold user manual, extra air intake filter, and oxygen adapter.

L. Power Cord:
Allows connection of unit into an electrical outlet.

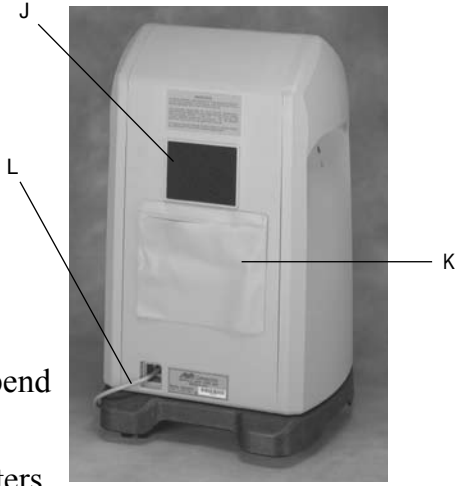

Figure 1b

> **CAUTION** Do not use extension cords with this unit.

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 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), cannula, catheter, and/or extension tubing to the oxygen outlet.

5. Remove the power cord *completely* from around the concentrator, if wrapped around **(Figure 1b)**.

6. Insert the 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 loudly sound for a 5-second test to indicate a good battery and alarm.

Figure 2

CAUTION	If the alarm is weak or does not sound at all, consult your Equipment Provider immediately.
NOTE	The standard NewLife Intensity 10 Oxygen Concentrator accommodates high pressure/high flow prescriptions from 2 to 10 lpm.

8. *Dual Flow and High Flow Applications:* Set the flowmeter adjustment knob(s) to the prescribed lpm, in any combination of flows up to a total of 10 lpm for 10 liter dual flow units. **(Figure 3).**

   or

   Pediatric/Low Flow Applications: See page B-3 for details.

Figure 3

The concentrator is now ready for use.

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

Always operate the unit in an upright position.

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

For easier reference, store this Patient Manual and the additional air intake gross particle filter (if provided) in the pocket.

Filters

Air enters the NewLife Intensity 10 unit through an air intake gross particle filter located on the back of the oxygen concentrator. This filter removes dust particles and other impurities from the air. Before you operate the NewLife Intensity 10 unit, make sure this filter is clean and positioned correctly **(Figure 4).**

Figure 4

The supplemental oxygen produced by the NewLife Intensity 10 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.

NOTE

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

Oxygen With Humidifier

Follow 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 threaded nut counterclockwise while you connect the humidifier to the oxygen outlet, and tighten securely **(Figure 6).**
5. Connect oxygen tubing from the cannula or catheter to the humidifier outlet fitting **(Figure 7).**

Figure 6

Figure 7

NOTE

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

NOTE

To Equipment Provider: The following humidifier bottle is recommended for use with the NewLife Intensity 10 Oxygen Concentrator:

•AirSep Part No. **HU003-1.**

Nasal Cannula

Your physician has prescribed either a nasal cannula or catheter **(Figure 8).**

In most cases, the manufacturer has already connected the oxygen supply tubing to the cannula or catheter. If not, follow the manufacturer's instructions for proper connection. Connect the oxygen tubing to the oxygen outlet adapter or humidifier.

Figure 8

NOTE

To Equipment Provider: The following oxygen administration accessories are recommended for use with the NewLife Intensity 10 Oxygen Concentrator:

•Nasal Cannula with 7 feet of tubing: AirSep Part No. **CU002-1.**

•Oxygen Outlet Adapter: AirSep Part No. **F0025-1.**

Proper Setting of Oxygen Flowmeter

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

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

CAUTION	It is very important to follow the prescribed level of oxygen flow. Do not increase or decrease the flow until you first consult your physician.
CAUTION	Normally, you should not need to adjust the flowmeter on your unit. If you turn the flowmeter adjustment knob clockwise, you will decrease and can shut off the flow of oxygen from your unit. For your convenience, the flowmeter is marked in 1/2 lpm increments from 2 to 10 lpm flow settings. For units with the pediatric flowmeter option, the flowmeter is marked in 1/8 lpm increments for flow settings up to 2 lpm.

Figure 9

Cleaning, Care, and Proper Maintenance

Cabinet

WARNING	Disconnect the power cord from the electrical outlet before you clean the cabinet.
CAUTION	Do not use liquid directly on the unit. Do not use any petroleum-based solvents or cleaning agents.
CAUTION	Clean the cabinet and power cord only with a mild household cleaner applied with a damp cloth or sponge, and then wipe them dry **(Figure 10)**.

Figure 10

Filters

NOTE

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

On a weekly basis, wash the air intake gross particle filter, located on the back of the unit. Your Equipment Provider may advise you to clean it more often depending on your operating conditions.

Follow these steps to properly clean the air intake gross particle filter:

1. Remove the filter and wash in a warm solution of soap and water **(Figure 11).**
2. Rinse the filter thoroughly, and remove excess water with a soft absorbent towel.
3. Replace the filter.

Figure 11

AirSep does not recommend the sterilization of this equipment.

Reserve Oxygen Supply

Your Equipment Provider should provide or suggest an alternative source for supplemental oxygen therapy in case there is a mechanical failure or a power outage. During a power outage, alarm condition, or mechanical failure, use your reserve oxygen supply (if provided), and consult your Equipment Provider immediately.

Troubleshooting

If your NewLife Intensity 10 Oxygen Concentrator fails to operate properly, consult your Equipment Provider, and then refer to the troubleshooting chart on the following pages for probable causes and solutions.

NOTE

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

If you cannot get the unit to operate, connect your cannula or catheter to the reserve supplemental oxygen supply (if provided).

Problem	Probable Cause	Solution
Unit does not operate. Power failure condition causes a continuous alarm to sound.	Power cord not connected into electrical outlet.	Check power cord plug at the electrical outlet for a proper connection.
	No power at electrical outlet.	Check power source, wall switch, fuse, or circuit breaker in-house.
	Oxygen concentrator circuit breaker is activated.	Press **(Do not hold in)** the circuit breaker reset button on the front of the unit.
		Contact your Equipment Provider for service.

Problem	Probable Cause	Solution
Limited oxygen flow.	Dirty or obstructed humidifier bottle.	Remove the humidifier bottle (if used) from the oxygen outlet. If flow is restored, clean or replace with a new humidifier bottle.
	Defective nasal cannula, catheter, and/or oxygen delivery tube.	Remove nasal cannula or catheter from oxygen tubing. If proper flow is restored, replace with new cannula or catheter. Disconnect delivery tubing at oxygen outlet (front of unit). If proper flow is restored, check oxygen tubing for kinks or obstructions. Replace if needed.
Condensation collects in the oxygen tubing when you use the humidifier bottle.	Unit not properly ventilated. Elevated operating temperature.	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 away from a wall or other obstruction. Do not place the unit in a confined area.
		Refill humidifier bottle with COLD water. DO NOT OVERFILL. Allow oxygen tubing to dry out, or replace with new tubing.

Problem	Probable Cause	Solution
Intermittent alarm sounds at one second intervals.	Equipment malfunction.	Set I/O power switch to O 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 O position, use your reserve oxygen supply (if provided), and consult your Equipment Provider immediately.

Product Specifications

Oxygen Concentration:*	2-9 lpm: 92% ±3% 10 lpm: 90% ±3%

Dimensions:	27.5 in. high x 16.5 in. wide x 14.5 in. deep (69.9 cm high x 41.9 cm wide x 36.8 cm deep)
Weight:	58 lb (26.4 kg)
Electrical:	120 VAC, 60 Hz, 6.0 amps Two-prong polarized plug Double-insulated cabinet *Export Models:* 220–240 VAC, 50 Hz, 3.0 amps 220 VAC, 60 Hz, 3.0 amps Double-insulated cabinet
Alarms:	Power failure High and low pressure Battery test Low oxygen concentration (Oxygen Monitor)
Operating Temperature:	41°F to 95°F (5°C to 35°C)
Storage Temperature:	-4°F to 140°F (-20°C to 60°C)

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

CE 0459

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 authorized by the party in question,

- The electrical installation of the corresponding premises complies with IEC regulations.

- The device is used in accordance with the instructions for use." If the replacement parts used for the periodic servicing by an approved technician do not comply with the manufacturer's specifications, the latter is absolved from all responsibility in the event of an accident.
Do not open the device while 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.

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 B 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 entry 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 the Maintenance section in the NewLife Service Manual.

Degree of safety of application in the presence of flammable anesthetic gases:
Equipment not suitable for such application.

Mode of operation: Continuous duty.

Symbols/Abbreviations

Symbols are frequently used on equipment in preference to words with the intention of lessening any 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 Intensity 10 Oxygen Concentrator. These symbols are referenced from the appropriate International Electrotechnical Commission (IEC) standards:

Symbol	Description
	ON
0	Off (power switched off).
	Type B device
	Class II device
	Do not smoke.
CE 0459	Complies with the 93/42/EEC directive drawn up by the approved organization n° 0459.
	Do not expose to open flames.
	Do not grease.

Symbol	Description
	Consult the accompanying documents.
	Keep in the vertical position.
	Fragile - handle with care.
	Oxygen concentration warning LED
	Gas outlet, connection to the patient circuit.
	Proper disposal of waste of electrical and electronic equipment required.
	Keep unit and accessories dry.
	Do not disassemble

Method for disposing of waste: All waste from the **NEWLIFE INTENSITY 10** (patient circuit, filter, etc.) must be disposed of using the appropriate methods.

Method for disposing of the device: In order to preserve the environment, the concentrator must only be disposed of using the appropriate methods.

Oxygen Monitor Option

The following information will acquaint you with the Oxygen Monitor option for the NewLife Intensity 10 Oxygen Concentrator. Make sure you read and understand the information in this NewLife Intensity 10 Patient Manual before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

WARNING	In the event of an alarm or if you are experiencing any signs of patient discomfort, consult your Equipment Provider and/or your physician immediately.
WARNING	This unit is not to be used for or with any life-supporting applications. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this machine may require additional monitoring. Consult your physician immediately if you are experiencing any signs of patient discomfort.

Figure 1

WARNING

This device manufactures high concentration oxygen, which promotes rapid burning. Do not allow smoking or open flames within 5 feet of: (1) this device or (2) any oxygen-carrying accessory. Use no oil, grease, or petroleum-based products on or near the unit. Disconnect the power cord from the electrical outlet before you clean or service the unit.

Function of the Oxygen Monitor

The Oxygen Monitor is a small electronic device within the NewLife Intensity 10 Oxygen Concentrator that monitors the concentration of oxygen produced by the unit.

Alarm Signal

If oxygen purity falls below the acceptable therapeutic level, an amber OXYGEN MONITOR light on the front of the Oxygen Concentrator turns on **(Figure 2)**. If the light remains on for more than 15 minutes, an intermittent alarm sounds.

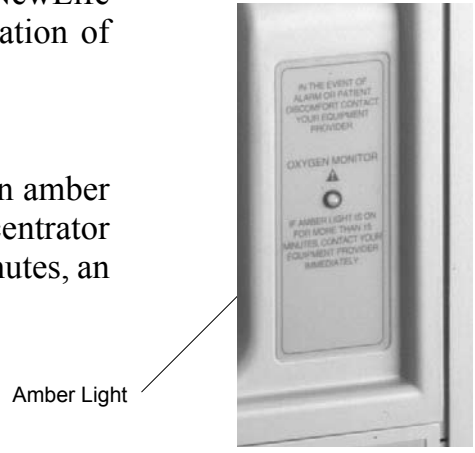

Figure 2

 CAUTION	Contact your Equipment Provider immediately if the amber OXYGEN MONITOR light remains on for more than 15 minutes.
 NOTE	When you turn the unit on, it's normal for the amber OXYGEN MONITOR light to turn on and remain on for up to 5 minutes.
 CAUTION	U.S. Federal law restricts this device to sale by or on order of a physician. Use unit in accordance with the manufacturer's patient manual.

Dual Flow and Pediatric/Low Flow Options

The following information will acquaint you with the 10 liter dual flow and pediatric/low flow options for the NewLife Intensity 10 Oxygen Concentrator. Make sure you read and understand all the information in this NewLife Intensity 10 Patient Manual before you operate the unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

WARNING	In the event of an alarm or if you are experiencing any signs of patient discomfort, consult your Equipment Provider and/or your physician immediately.
WARNING	This unit is not to be used for or with any life-supporting applications. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this machine may require additional monitoring. Consult your physician immediately if you are experiencing any signs of patient discomfort.

Figure 1 — Front

Two Patients/
Dual Flow
Applications

WARNING

This device manufactures high concentration oxygen, which promotes rapid burning. Do not allow smoking or open flames within 5 feet of: (1) this device or (2) any oxygen-carrying accessory. Use no oil, grease, or petroleum-based products on or near the unit. Disconnect the power cord from the electrical outlet before you clean or service the unit.

Dual Flow Application

The NewLife Intensity 10 unit's 10-liter dual flow option allows a single concentrator to meet the high flow requirements of a 10 lpm patient **(Figure 2)** or the needs of two patients, in any combination of flows up to 10 lpm **(Figure 3)**. Excellent for use in the home, extended care facility, hospital, or physician's waiting room.

Figure 2

Figure 3

Pediatric/Low Flow Application

The pediatric flowmeter (available for use with the dual flow NewLife Intensity 10 unit) meets low flow requirements up to 2 lpm in 1/8 liter (125 ccm) increments **(Figure 4)**.

Setting the Pediatric Flowmeter

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

1. Follow the start-up instructions 1-7 as outlined on page 7 & 8.
2. Set the pediatric flowmeter to the prescribed flow.
3. Set the primary flowmeter to 2 lpm to bleed off excess product, and allow the unit to achieve maximum concentration.

NOTE	The NewLife Intensity 10 Oxygen Concentrator must be operated for at least five minutes at 2 lpm before using the unit.
CAUTION	Federal law restricts this device to sale by or on order of a physician. Use unit in accordance with the manufacturer's patient manual. *United States Federal Requirement.
NOTE	The NewLife Intensity 10 is appropriate for usage by two patients, provided that the combined flow is a minimum of 2 lpm and does not exceed 10 lpm.

Figure 4

European Representative:

eurorepcontact@airsep.com

Gavin Ayling
9 Bungham Lane
Penkridge Stafford
Staffordshire ST19 5NH England

For service on your NewLife Intensity 10 Oxygen Concentrator, please contact:

Manufactured by:
AirSep Corporation
Buffalo, NY 14228-2085 USA