CAIRE®

NewLife® Family

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1.0 Introduction

1.1 Important Notice and Symbol Explanations

As you read the manual, pay special attention to the WARNING, CAUTION, and NOTE messages. They identify safety guidelines or other important information as follows:

	Describes a hazard or unsafe practice that can result in severe bodily injury or death.
	Describes a hazard or unsafe practice that can result in minor bodily injury or property damage.
	Provides information important enough to emphasize or repeat.

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 Oxygen Concentrator. These symbols are referenced from the appropriate International Electro-technical Commission (IEC) standards:

ISO 7000; Graphical symbols for use on equipment—Index and synopsis	
	Read user's manual before operation. Reg. # 1641
	Keep away from rain, keep dry. Reg. # 0626
	Name and address of manufacturer. Reg. # 3082
	Caution, consult accompanying documents. Reg. # 0434A
REF	Catalog Number. Reg. # 2493
SN	Serial Number. Reg. # 2498
	This way up. Reg. # 0623
	Fragile, handle with care. Reg. # 0621
ISO 7010: Graphical symbols—Safety colors and safety signs—Registered safety signs	
	The instruction manual must be read. Reg. # M002
	Keep away from open flame, fire, sparks. Open ignition source and smoking prohibited. Reg. # P003
	Do not smoke near unit or while operating unit. Reg. # P002
	Type BF applied part (degree of protection against electric shock). Reg. # 5333
	Warning. Reg. # W001
Council Directive 93/42/EEC; concerning medical devices	
EC REP	Authorized representative in the European Community
CE 0459	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. It bears the CE marking as shown. NewLife Elite and NewLife Intensity 8 units manufactured Jan 1st, 2018 or later do not bear a CE mark. NewLife Intensity 10 units manufactured after Jan 1st, 2018 continue to bear a CE mark.

Internal Symbols	
	Keep away from flammable materials, oil and grease.
	Safety agency for CAN/CSA C22.2 No. 60601-1-14 for medical electrical equipment. Certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.
	Do not disassemble.
	When present on the device alarm panel indicates external power interruption has been detected.
$\downarrow O_2$	When present on the device alarm panel indicates low oxygen concentration in device output.
I	ON (power switch on)
O	OFF (power switch off)
	Date of Manufacture
	Class II equipment
21 CFR 801.15: Code of Federal Regulations Title 21	
RX ONLY	Federal law restricts this device to sale by or on the order of a physician.
IEC 60601-1: Medical electrical equipment Part 1 General requirements for basic safety and essential performance	
IP21	Drip Proof Equipment - IP21
Council Directive 2012/19/EU: waste electrical and electronic equipment (WEEE)	
	WEEE This symbol is to remind the equipment owners to return it to a recy-cling facility at the end of its life, per Waste Electrical and Electronic Equipment (WEEE) Directive. Our products will comply with the restriction of Hazardous Substances (RoHS) directive. They will not contain more than trace amounts of lead or other hazardous material content.

This product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents. Pat.: patents.gtls.io.

Important!

Safety Instructions are defined as follows:

WARNING: IMPORTANT SAFETY INFORMATION FOR HAZARDS THAT MIGHT CAUSE SERIOUS INJURY
CAUTION: Important information for preventing damage to the NewLife Family.
Note: Information needing special attention.

Indications for Use

WARNING: 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.

WARNING: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE OF RENTAL BY ORDER OF A PHYSICIAN OR OTHER LISCENSED HEALTH CARE PROVIDER.

WARNING: THIS UNIT IS NOT TO BE USED FOR LIFE SUPPORT. GERIATRIC, PEDIATRIC, OR ANY OTHER USER UNABLE TO COMMUNICATE DISCOMFORT WHILE USING THIS DEVICE MAY REQUIRE ADDITIONAL MONITORING. USERS WITH HEARING AND/OR SIGHT IMPAIRMENT(S) MAY NEED ASSISTANCE WITH MONITORING ALARMS. IF YOU FEEL DISCOMFORT OR ARE EXPERIENCING A MEDICAL EMERGENCY, SEEK MEDICAL ASSISTANCE IMMEDIATELY.

Contraindications for Use

WARNING: IN CERTAIN CIRCUMSTANCES, THE USE OF NON-PRESCRIBED OXYGEN CAN BE HAZARDOUS. THIS DEVICE SHOULD ONLY BE USED WHEN PRESCRIBED BY A PHYSICIAN.

WARNING: NOT FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

WARNING: AS WITH ANY ELECTRICALLY POWERED DEVICE, THE USER MAY EXPERIENCE PERIODS OF NON-OPERATION AS A RESULT OF ELECTICAL POWER INTERRUPTION, OR THE NEED TO HAVE THE OXYGEN CONCENTRATOR SERVICE BY A QUALIFIED TECHNICIAN. THE OXYGEN CONCENTRATOR IS NOT APPROPRIATE FOR ANY USER WHO WOULD EXPERIENCE ADVERSE HEALTH CONSEQUENCES AS THE RESULT OF SUCH TEMPORARY INTERRUPTION.

Safety Guidelines

WARNING: CAREFULLY REVIEW AND FAMILIARIZE YOURSELF WITH THE FOLLOWING IMPORTANT SAFETY INFORMATION ABOUT THE NEWLIFE INTENSITY OXYGEN CONCENTRATOR.

WARNING: 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; OTHERWISE INJURY OR DAMAGE COULD OCCUR.

WARNING: SMOKING WHILE USING OXYGEN IS THE NUMBER ONE CAUSE OF FIRE INJURIES AND RELATED DEATHS. YOU MUST FOLLOW THESE SAFETY WARNINGS.

WARNING: DO NOT ALLOW SMOKING, CANDLES, OR OPEN FLAMES IN THE SAME ROOM WITH THE DEVICE OR THE OXYGEN-CARRYING ACCESSORIES.

WARNING: SMOKING WHILE WEARING AN OXYGEN CANNULA CAN CAUSE FACIAL BURNS AND POSSIBLY RESULT IN DEATH.

WARNING: 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.

WARNING: IF YOU SMOKE, YOU MUST ALWAYS FOLLOW THESE THREE (3) IMPORTANT STEPS. FIRST: TURN OFF THE OXYGEN CONCENTRATOR, TAKE OFF THE CANNULA, AND LEAVE THE ROOM WHERE THIS DEVICE IS LOCATED.

WARNING: "NO SMOKING – OXYGEN IN USE" SIGNS MUST BE PROMINENTLY DISPLAYED IN THE HOME, OR WHERE OXYGEN IS IN USE. USERS AND THEIR CAREGIVERS MUST BE INFORMED ABOUT THE DANGERS OF SMOKING IN THE PRESENCE OF, OR WHILE USING, MEDICAL OXYGEN.

WARNING: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE OR RENTAL BY ORDER OF A PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER.

WARNING: THIS DEVICE SUPPLIES HIGH-CONCENTRATED 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 FIRE, PROPERTY DAMAGE, AND/OR CAUSE PHYSICAL INJURY OR DEATH.

WARNING: 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.

WARNING: 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/0 POWER SWITCH TO THE 0 (OFF) POSITION WHEN THE OXYGEN CONCENTRATOR IS NOT IN USE.

WARNING: USE NO 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.

WARNING: 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 THIS UNIT.

WARNING: 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.

WARNING: DO NOT USE LIQUID DIRECTLY ON THE UNIT. A LIST OF UNDESIRABLE CHEMICAL AGENTS INCLUDE, BUT NOT LIMITED TO THE 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.

WARNING: 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.

WARNING: 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.

WARNING: ALWAYS PLACE THE OXYGEN SUPPLY TUBING AS POWER CORDS IN A MANNER THAT PREVENTS TRIP HAZARDS OR POSSIBLE ACCIDENTAL STRANGULATION.

WARNING: NO MODIFICATION OF THIS EQUIP-MENT IS PERMITTED.

WARNING: USE ONLY WATER-BASED LOTIONS OR SALVES THAT ARE OXYGEN COMPATIBLE PRIOR TO OR DURING OXYGEN THERAPY. NEVER USE PETROLEUM OR OIL-BASED LOTIONS OR SALVES TO AVOID THE RISK OF FIRE OR BURNS.

WARNING: DO NOT LUBRICATE FITTINGS, CONNECTIONS, TUBING, OR OTHER ACCESSORIES OF THE OXYGEN CONCENTRATOR TO AVOID THE RISK OF FIRE AND BURNS.

WARNING: PREGNANT OR NURSING WOMEN SHOULD NOT USE ACCESSORIES RECOMMENDED IN THIS MANUAL. THEY MAY CONTAIN PHTHALATES.

WARNING: USE ONLY ELECTRICAL VOLTAGE AS SPECIFIED ON THE SPECIFICATION LABEL AFFIXED TO THE DEVICE.

WARNING: DO NOT USE EXTENSION CORDS WITH THIS UNIT OR CONNECT TOO MANY PLUGS INTO THE SAME ELECTRICAL OUTLET. THE USE OF EXTENSION CORDS COULD AD-VERSELY AFFECT THE PERFORMANCE OF THE DEVICE. TOO MANY PLUGS INTO ONE OUTLET CAN RESULT IN AN OVERLOAD TO THE ELECT-RICAL PANEL CAUSING THE BREAKER/FUSE TO ACTIVATE OR FIRE IF THE BREAKER OR FUSE FAILS TO OPERATE.

WARNING: ENVIRONMENTAL CONDITIONS CAN AFFECT THE PERFORMANCE OF DEVICE. LOCATE IN CLEAN, PEST-FREE ENVIRONMENT.

WARNING: DEVICE SHOULD ONLY BE OPERAT-ED BY END USERS, TRAINED CAREGIVERS, OR TRAINED TECHNICIANS. CHILDREN SHOULD NOT OPERATE THE DEVICE.

WARNING: USE OF THIS DEVICE AT AN ALTITUDE ABOVE 3048 METERS (10,000 FEET) OR OUTSIDE A TEMPERATURE OF 50°F TO 104°F OR A RELATIVE HUMIDITY ABOVE 95% IS EXPECTED TO ADVERSELY AFFECT THE FLOW-RATE AND THE PERCENTAGE OF OXYGEN AND CONSEQUENTLY THE QUALITY OF THE THERAPY.

WARNING: THE USE OF SOME OXYGEN ADMIN-ISTRATION ACCESSORIES NOT SPECIFIED FOR USE WITH THIS OXYGEN CONCENTRATOR MAY IMPAIR ITS PERFORMANCE. RECOMMENDED ACCESSORIES ARE REFERENCED WITHIN THIS MANUAL.

WARNING: 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 OF DECREASED IMMUNITY OF THE OXYGEN CONCENTRATOR.

CAUTION: Ensure concentrator is operated in an upright position.

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

CAUTION: If the audible alarm is weak or does not sound at all, consult your Equipment Provider immediately.

CAUTION: 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.

CAUTION: 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.

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

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

CAUTION: 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 perform-ance.

CAUTION: 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.

WARNING: TO ENSURE RECEIVING THE THERAPEUTIC AMOUNT OF OXYGEN DELIVERY ACCORDING TO YOUR MEDICAL CONDITION, THE NEWLIFE UNIT MUST BE USED WITH THE SPECIFIC COMBINATION OF PARTS AND ACCESSORIES THAT ARE IN LINE WITH THE SPECIFICIATION OF THE CONCENTRATOR MANUFACTURER AND THAT WERE USED WHILE YOUR SETTINGS WERE DETERMINED.

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

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

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

CAUTION: 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.

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

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 shut off the flow of oxygen from your unit. For your convenience, the flowmeter is marked in 1/2 LPM increments. For units equipped with the 2 LPM flowmeter option, the flowmeter is marked in 1/8 LPM increments for flow settings up to 2 LPM.

Note: 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 flowmeter 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 secion of this manual.

Note: 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.

CAUTION: 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 (30cm) 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.

Note: Allow the unit to run for at least 5 minutes at 2 LPM or above before use.

Note: The Manufacturer does not recommend the sterilization of this equipment.

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

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: The NewLife Intenisty Oxygen Concentrator must be operated for at least five minutes at 2 LPM before using the unit.

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

Note: The standard NewLife Elite Oxygen Concentrator accomodates prescriptions from 1 LPM minimum to 5 LPM maximum.

Note: The standard NewLife Intenisty 10 Oxygen Concentrator accommodates prescriptions from 2 LPM to 10 LPM maximum.

Note: To prevent a void warranty, follow all manufacturer's instructions.

Note: Do not attempt any maintenance other than the possible solutions listed in this manual.

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

Note: Portable and mobile radio frequency (RF) communications equipment can effect medical electrical equipment.

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

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

- **Nasal Cannula with 7 feet (2.1m) of tubing: CU002-1**
- **Humidifier Bottle: Caire PN HU003-1**
- **Firebreak: Caire PN 20629671**

A firebreak is required for use with any cannula.

CAIRE offers a firebreak intended to be used in conjunction with the oxygen concentrator. The firebreak 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 firebreak. It is placed in-line with the nasal cannula or oxygen tubing between the patient and the oxygen outlet of the NewLife.

For proper use of the firebreak, always refer to the manufacturer's instructions (included with each firebreak kit).

For any additional recommended accessories, please see the Accessories Catalog (PN ML-LOX0010) available on www.caireinc.com.

1.2 Equipment Provider Responsibility

All Equipment Providers of the NewLife® Oxygen Concentrator must assume responsibilities for handling, operational check-out, patient instruction, and oxygen concentration checks. These responsibilities are outlined below and throughout this manual.

As an Equipment Provider, you must do all of the following:

- Inspect the condition of each NewLife unit immediately upon delivery to your business location. Note any sign of damage on the delivery receipt, and report it directly to both the, freight company and CAIRE, Inc. immediately.
- Check the operation of each NewLife before delivery to a patient. Confirm the oxygen concentration level is within specifications.
- Deliver NewLife units only to patients authorized by a licensed health care provider or physician's prescription. The NewLife must not be used as a life-supporting device. A backup supply of oxygen must be available.
- Instruct users how to use the NewLife in conjunction with the User Manual.
- Instruct users to notify their licensed health care provider/physician if they experience any signs of discomfort.
- Instruct each user how to perform routine maintenance of the air intake gross particle filter (Refer to Section 3.2.1.)
- Be available to provide service to each user at any time.
- Maintain the NewLife in accordance with Section 4.0.
- Establish and implement a protocol to check oxygen concentration.
- Repair components and replace parts only as outlined in this manual. Use only CAIRE parts for replacement in NewLife Oxygen Concentrators.

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.

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.

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

1.3 Product Specifications

	5 Liter Concentrators	10 Liter Concentrators
Oxygen Concentration: (1)	90% +5.5%/-3%	90% +5.5%/-3%
Physical Characteristics	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.)	Height: 69.9 cm (27.5 in.) Width: 41.9 cm (16.5 in.) Depth: 36.8 cm (14.5 in.) Weight: 26.3 kg (58.0 lb.) Shipping Weight: 29.9 kg (66.0 lb.)
Electrical Power:	350 Watts – 5 LPM model Two-prong polarized plug Double insulated cabinet *North American Models*: 120 VAC, 60 Hz, 4.0 amps *Export Models:* 230 VAC, 50 Hz, 2.0 amps 230 VAC, 60 Hz, 2.0 amps Double-insulated cabinet	600 Watts – 10 LPM model Two-prong polarized plug Double insulated cabinet *North American Models:* 120 VAC, 60 Hz, 6.0 amps *Export Models:* 230 VAC, 50 Hz, 3.0 amps
Alarms:	Power Failure General Malfunction Low oxygen concentration (with Oxygen Monitor option)	
Temperature: (2)	Operational: 41°F to 104° (5°C to 40°C) 15-90% humidity Storage: -13 to 158°F (-25 to 70°C) 0-90% humidity	Operational: 41°F to 104°F (5°C to 40°C) 15-90% humidity Storage: -13 to 158°F (-25 to 70°C) 0-90% humidity

Product Specifications Continued

Relief Pressure	45 PSIG (310 kPa) @ Compressor
O_2 Monitor	Yellow caution light Range: Below 82% O_2 Audible Alarm: After several minutes below specified Range Max Pressure = 60 PSIG (414kPa) Operating temperature Range: -31°F to 158°F (-35°C to 70°C) Operational Humidity: 0 to 100%
Altitude	Tested all models at -381 m to 3,048 m (-1,250 ft to 10,000 ft) (700-1060hPa) (87% O_2 for the Elite) (85% for Intensity 10)
Sound Pressure Level	**Elite:** EUT: 53 dB(A) Chamber Background Noise: 30dB(A) Max **Intensity:** EUT: 58 dB(A) Chamber Background Noise: 30dB(A) Max
Sound Power Level	**Elite:** 60.2 dB(A) **Intensity 10:** 69 dB(A)
Fire Prevention System 	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 fiber, skin lotion, facial hair and some plastics are hydrocarbon by nature. Oxygen of 90% level runs through the plastic tubing to cannula. Therefore, DO NOT 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.**
Fire Prevention	O_2 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

Product Specifications Continued

	5 Liter Concentrators	10 Liter Concentrators
Excessive Temperatures – Outlet (2)	Maximum O_2 Outlet Temperature Rise + 3 ^{O}C (5.4 ^{O}F)	Maximum O_2 Outlet Temperature Rise + 4.5 ^{O}C (8.1^{O}F)
Flow Rate Range	± 10% of indicated setting, or 200 mL, whichever is greater**	± 10% of indicated setting, or 200 mL, whichever is greater**
O_2 Concentration at Extreme Voltage Conditions	Voltage Extreme / % Volume 132 V / 94.6 103 V / 94.0 253 V / 91.0 195 V / 90.0	Voltage Extreme / % Volume 132 V / 88.0 to 91.0 103 V / 87.5 to 90.5 253 V / 88.0 to 91.0 195 V / 87.1 to 90.0
Mean O_2 Concentration	Voltage Extreme / Mean O_2 / % Individual Deviation from Mean (± 3% allowable) 132 V / 94.6 / 0.6 103 V / 94.0 / 0.6 253 V / 91.0 / 0.6 195 V / 90.0 / 1.4	Voltage Extreme / % Individual Deviation from Mean (± 3% allowable) 132 V / 0.6 103 V / 0.6 253 V / 0.6 195 V / 1.4
Mean Flow Rate	Voltage Extreme / Mean Flow / % Individual Deviation from Mean (± 10% allowable) 132 V / 4.87 / 0.8 103 V / 5.11 / 0.8 253 V / 4.99 / 1.4 195 V / 5.00 / 1.4	Voltage Extreme / % Individual Deviation from Mean (± 10% allowable) 132 V / 1.8 103 V / 3.7 253 V / 0.6 195 V / 0.4

** At altitudes below sea level and higher than 8,000 ft (2438 m) above sea level, flow meter accuracy may be affected up to 13%

Product Specifications Continued

	5 Liter Concentrators	10 Liter Concentrators
Backpressure Effect Test	Flow / Applied Pressure * 5.00 LPM @ 0 PSIG (0 kPA) 4.75 LPM @ 1 PSIG (7 kPA)	Flow / Applied Pressure * 10.00 LPM @ 0 PSIG (0 kPA) 9.65 LPM @ 1 PSIG (7 kPA)
Outlet Pressure Test	Actual Pressure / Max Allowable Limit 7.3 PSIG (50.3 kPA) / 8.8 PSIG (60.7 kPA)	Actual Pressure / Max Allowable Limit 21.9 PSIG (151 kPA) / 22.0 PSIG (151.7 kPA)
	(1) Based on 21ºC (70°F) at a nominal operating pressure range of 0-7 kPa (0-1 PSIG back pressure) and 14.7 PSI (101 kPa). (2) Operating outside of these operational specifications can affect performance. Accuracy: ±10% of indicated flow setting or ±200 mL, whichever is greater. Based on an atmospheric pressure range of 700 kPa to 1060 kPa at 70°F (21°C).	

2.0 Operational Check and Oxygen Concentration Test

2.1 Description of Operation

Air is drawn into the NewLife Oxygen Concentrator through an external air intake gross particulate filter. Before this air enters the compressor, it passes through the unit's suction resonator which, quiets the compressor's suction sound. Pressurized air then exits the compressor and passes through a heat exchanger. The heat exchanger reduces the temperature of the compressed air. Next, a two-way solenoid feed valve directs the air into one of two sieve beds that contain molecular sieve. The unique property of molecular sieve enables it to physically attract (adsorb) nitrogen when air passes through this material, thus producing high concentrated oxygen.

There are two sieve beds: while one produces high concentration oxygen, the other is purged of the nitrogen it adsorbed (collected) during this pressure swing adsorption (PSA) cycle. Each adsorber produces oxygen and delivers it to the product tank. Oxygen exits the product tank through a pressure regulator, flow control valve, and flowmeter.

2.2 Operation Check

CAIRE tests every NewLife Oxygen Concentrator thoroughly after manufacture. You must perform the following test to ensure that no damage occurred in shipping or handling.

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.

1. Open and inspect all cartons (that contain units) upon delivery. Unpack the unit and remove it from the carton. Inspect the unit itself for damage. If the exterior of a unit's carton is damaged, or the unit itself is damaged, note it on the freight bill signed by the driver.

2. Connect unit to power and set the ON/OFF power switch to the ON position. Check to see that the following occurs:
    a. An alarm that sounds for approximately one second with all display lights illuminated. See the troubleshooting chart in Section 6.3 of this manual if the unit's alarm does not sound or display illuminates.
    b. The compressor runs and flow is indicated in flowmeter.
    c. Perform an oxygen concentration test, as described in Section 2.3.5.

2.3 Safety and Alarm Features and Alarm Test Procedures

The NewLife Oxygen Concentrator is equipped with an audible and visual alarm system. There are alarms for power failure, general malfunction, and low oxygen concentration. The alarm will remain on until the alarm condition is corrected, or until the power is switched off. Refer to Section 6.3 for a list of probable alarm causes.
A pressure relief valve is fitted to the compressor outlet and is calibrated to 280 kPA (40 PSIG). Thermal safety is ensured by a thermostat situated in the stator winding of the compressor (135°C / 275 °F).

Three LED NewLife Units:

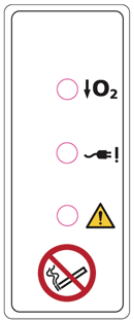


Figure 1: *Device warning label and alarm display. Note this is valid for units manufactured January 1st, 2019 and later.*

Oxygen Monitor: In the event the oxygen monitor detects an oxygen concentration below 82% the low oxygen concentration warning light (O_2) will illuminate. If the low O_2 condition persists an audible intermittent alarm will also activate.

Power Failure: In the event the unit is operating, and a loss of power occurs, the power warning light ( ) will illuminate and an audible intermittent alarm will activate.

General Malfunction: If any of the conditions listed below occurs, the general malfunction light ( ) will illuminate and an audible intermittent alarm will activate. This includes:

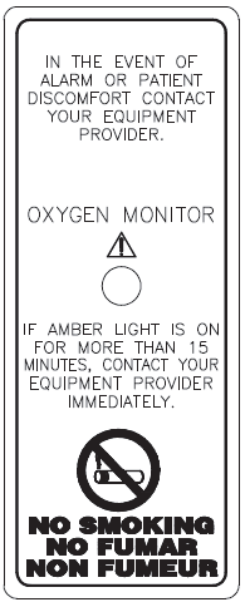
- Obstruction to the flow of oxygen such as a pinch or kink in the delivery cannula, triggered by high product tank pressure **
- High device product tank pressure condition of greater than 33 PSIG (±1)
- Low device product tank pressure condition of less than 5 PSIG (±1)
- High device temperature of greater than 135°C (275 °F), triggered by low product tank pressure if the thermal switch located within the compressor trips (shutting down the compressor)

** Note: The indication for a “no flow” condition on the NewLife Elite and Dual Flow NewLife Intensity 10 models is the flow ball dropping to zero. There is no audible alarm indication for the “no flow” alarm condition on the NewLife Elite manufactured with 3 LEDs. The Single Flow NewLife Intensity 10 model will display the general malfunction visual and audible alarm in the event of a “no flow” condition, caused by an obstruction to the outlet port.

Product Filter: ≥ 10 µm filter

One/Zero LED NewLife units:

Device warning label



Oxygen Monitor Label

Figure 2: *Device warning label and oxygen monitor label. Note this is valid for units manufactured before January 1st, 2019.*

Oxygen Monitor (Oxygen Monitor Unit Only): In the event the oxygen monitor detects an oxygen concentration below 82%, the oxygen monitor will illuminate. The unit needs approximately two minutes for warm up.

Battery Test: Each time the NewLife unit is turned on, a five-second audible alarm sounds to indicate the condition of the battery.

NOTE The audio alarm must sound loudly for approximately five seconds each time the unit is turned to ON to indicate the battery is in good condition.

Power Failure Alarm Test: To test the power failure alarm, take the following step: Unplug the unit, and set the ON/ OFF switch to the ON position. This should immediately activate the audio alarm. If it does not, refer to the troubleshooting chart in Section 6.0 of this manual.

Product Filter: ≥ 10 μm filter

2.3.1 Start Up

Each time the NewLife unit is turned on, an audible signal should sound.

NOTE

If the unit has not been used for an extended period of time, it needs to operate for several minutes to recharge the alarm capacitor.

2.3.2 Power Failure Alarm Test

1. Connect the unit to external power.
2. Set the ON/OFF switch to the "ON" position.
3. While the machine is still operating, disconnect from external power.
4. Verify that the power loss alarm LED illuminates on the front panel and audible alarm activates. The audible alarm will beep approximately once every 20 seconds.

If the unit has not been used for an extended period of time, it needs to operate for several minutes to recharge the power failure alarm.

2.3.3 General Malfunction Alarm Test

1. Disconnect the unit from external power.
2. Disconnect the compressor.
3. Connect unit to power and turn it on.
4. Verify that the general malfunction alarm LED illuminates on the front panel and audible alarm activates after the warm-up period.
5. Turn off the unit and disconnect it from power.
6. Reconnect compressor.
7. Connect unit to power and turn it on.
8. Verify the alarm ceases once the compressor is re-connected.

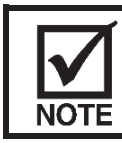
2.3.4 Low O_2 Alarm Test

1. Prior to performing this test procedure, ensure the unit has been turned off for at least 1 hour.
2. Disconnect the unit from external power.
3. Remove zip tie from inlet side of O_2 monitor assembly.
4. Disconnect inlet tubing from O_2 monitor assembly.
5. Connect unit to power and turn it on to the highest flow setting.
6. Verify that O_2 monitor LED illuminates and audible alarm activates after warm-up period.
7. Turn off the unit and disconnect it from power.
8. Reconnect tubing and re-install zip tie on the O_2 monitor.
9. Connect unit to power and turn it on to the highest flow setting.
10. Verify the alarm ceases once the tube is re-attached.

2.3.5 Oxygen Concentration Test and Specification

To ensure that the unit's output of oxygen is within specification, you must perform a test of the oxygen concentration. Test the unit upon delivery to a patient, and at periodic intervals. Equipment Providers need to establish and implement a protocol to check oxygen concentration.

1. If a humidifier bottle is used, disconnect it.
2. Connect a calibrated oxygen concentration analyzer to the oxygen outlet.
3. Verify that the product flow rate delivered by the unit matches the patient's prescription and does not exceed the capacity of the unit.
4. Set the unit's ON/OFF power switch to the ON position. Allow approximately five minutes for the oxygen concentration to stabilize. Take oxygen concentration readings and verify levels are within specification at the liter flow being tested.
5. Disconnect the oxygen analyzer and reconnect the humidifier bottle (if used).



Do not measure oxygen concentration output after the product stream passes through a humidifier bottle, or erroneous readings will result.

CAIRE NewLife Concentration Specifications

Model	Specification
Elite	90% +5.5%/-3%
Intensity 10	90% +5.5%/-3%

3.0 User Instructions

3.1 Instructions

It is important that patients thoroughly understand how to operate the CAIRE NewLife unit. This enables proper treatment, as prescribed by a licensed health care provider/physician. If users experience any discomfort or the unit alarms, they must notify their licensed health care provider/physician immediately.

You, as the Equipment Provider, are responsible to see that each user receives the User Manual. Explain each step in the operation of the unit to the user in reference to this manual.

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.

3.2 Routine Maintenance by the User

To ensure accurate output and efficient operation of the unit, the user must perform two simple routine maintenance tasks:

- Clean the air intake gross particle filter

3.2.1 Cleaning the Air Intake Gross Particle Filter

The user must clean this filter weekly, as described below. The filter may require daily cleaning if the NewLife unit operates in a harsh environment such as a house heated by wood, kerosene, or oil, or one with excessive cigarette smoke.

1. Remove the dirty air intake gross particle filter from the back of the NewLife unit, and install a clean filter, as described above.
2. Wash the dirty filter in warm soapy water, and rinse.
3. Use a soft absorbent towel to remove excess water.

4.0 Provider Instructions

4.1 Routine Maintenance

To ensure that the unit's output of oxygen is within specification, you must perform a test of the oxygen concentration. Test the unit upon delivery to a user and at periodic intervals. Equipment Providers need to establish and implement a protocol to check oxygen concentration.

CAIRE does not require preventative maintenance on the concentrator. You do not need to perform any maintenance as long as the NewLife unit remains within specifications at the desired flow rate.

4.1.1 Air Intake Gross Particle Filter/GPF

The external air intake gross particle filter is located on the back of the unit. You can easily remove it by hand. Instruct the user to clean this filter weekly. (Refer to Section 3.2.1.)

The Filter may require more frequent cleaning if the NewLife unit operates in a harsh environment, such as a house heated by wood, kerosene, oil, or one with excessive cooking or cigarette smoke.

4.1.2 Product Filter

The product filter is designed to last for the life of the unit. Whether inside the product tank or an external component to this tank, there is no required or scheduled replacement needed for this part.

Optional Felt Intake Filter Replacement (First Stage Resonator Filter)
The optional internal felt filter is required to be changed annually. See below for instructions for changing the filter. **This first stage resonator filter is standard on Intensity 10 units.**

1. Set the unit's ON/OFF switch to the OFF position and unplug the power cord.
2. Remove the right-side panel to locate the felt intake filter.
3. Remove the filter in the unit and replace with new filter.
4. Reconnect side panel.

1. Set the ON/OFF power switch to the ON position to test the alarm.
2. Reconnect the side panel.

4.1.3 Recording Maintenance

As the Equipment Provider, you can record all routine maintenance and repairs performed on the NewLife unit, including hours and dates of service.

	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.
	Care should be taken to prevent the NewLife from getting wet or allowing water 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. Clean the exterior of unit and power cord only with a mild household cleaner applied with a damp cloth or sponge, and then wipe all surfaces dry.

4.2 Preparing for New User Use/Method of Cleaning and Infection Control

When you remove NewLife unit from a user's home or a facility, always dispose of the used nasal cannula and humidifier bottle. Clean the exterior of the NewLife unit with a soapy water solution or mild household cleaner applied with a damp cloth or sponge to remove any gross debris. Do not use liquid directly on unit and be careful not to get liquid into the interior of the unit.

Next, following the same guidelines above, clean the exterior with either a common chemical disinfectant or a bleach solution*, while wearing eye and skin protection. After using the disinfecting solution, wipe entire unit with a cloth or sponge applied with water only, then wipe dry. Make sure unit is completely dry and then retest it before you return it to inventory.

Clean the air intake gross particle filter with warm soapy water between each user's use. Clean this filter at least once per week, depending on the environment, during normal operation.
The product filter is designed to last the life of the unit. It is not necessary to change this filter between users, even if the previous user had a communicable disease or infection.

*** The manufacturers of sodium hypochlorite products recommend various strengths of a bleach solution for killing bacteria, etc., based on the type of germ to disinfect; however, a generally recommended solution is ¾ cups (177mL) of household bleach per gallon (3.79 liters) of water.**

5.0 Main Components

5.1 Components

The design of the CAIRE NewLife Oxygen Concentrator allows for easy access and removal of most components. This allows you to perform repair and replacement of parts with minimal time and effort.

To prevent accidental electrical shock or burn, be sure to set the unit's ON/OFF power switch to the OFF position and disconnect the power cord of the unit from the electrical outlet before you service the NewLife Oxygen Concentrator.

Ensure unit is depressurized prior to repairs on internal components. This can be done by opening the black pressure tubing, or allowing the flowmeter to drop to zero after powering down

Record all scheduled maintenance. (Refer to Section 4.0.)

Before reattaching tubing connections using a tie-wrap, remove 1/8 inch (0.32 cm) from end of tubing to assure a proper seal. Tubing should be cut evenly across width.

5.2 Cabinet Removal

5.2.1 Removing Side Panel(s)

To remove one or both side panels, unscrew the 1/4 turn fastener(s) and remove the panel(s).

5.2.2 Removing Back Panel

Remove both side panels and lift off the back panel. Make sure the power cord can pass freely through the power cord cutout.

5.2.3 Removing Lower Front Panel

Firmly grasp panel with both hands, and slightly bow panel outward to remove.

5.2.4 Removing Control Panel

Four screws hold the control panel in place. Remove them and the control panel to re-install or replace if necessary.

5.2.5 Superstructure

The weight and forces of the internal components rest solely on three parts: the superstructure, compressor plate, and the base. These parts were specially designed and formed. They should never require replacement under normal use.

5.2.6 Caster Replacement

1. Remove the cabinet panels to expose the caster nut.
2. Remove the caster nut with a 9/16-inch socket. Use an extension for the two front caster nut removals.
3. Install the new caster with original washer and securing nut.
4. Reconnect the cabinet panels.

5.3 Compressor

The compressor is the "pump" within the oxygen concentrator that pushes the room air into the bottom of the sieve beds. This allows oxygen to flow out of the top of the sieve beds in the NewLife unit.
Two different aspects of the compressor cause concern: the output and the sound level.

Output

Compressor output refers to how much compressed air the compressor can produce. This depends upon the model of the compressor, stroke size, bore size, and cup seal condition. The cup seals form the seal between the piston and the cylinder wall. As the cup seals wear, the compressor's output begins to gradually decrease. This reduction in compressor output results in less air for the sieve beds. Therefore, the production of oxygen decreases.

Since this drop in oxygen production occurs over a long period of time, preventative maintenance on the compressor is not required. You can continue a patient's therapy on the NewLife unit as long as that unit's oxygen concentration level at the prescribed liter flow rate is within CAIRE's specifications.

Sound Level

The condition of the compressor's cup seals, bearings, and other components can result in an increased sound level. If the compressor's cup seals or bearings wear to the point that they become noisy, the concentrator may become noticeably louder; therefore, compressor service or exchange may be required.

The total acoustical energy emitted by a source per unit time is the sound power.

Sound pressure is the atmospheric pressure disturbance depending on the distance from the source, strength of the source, and the environment.

Sound power is the cause of the unit emitting sound pressure waves (and does not change with the distance from the unit), whereas sound pressure is the effect of the unit emitting sound on the surrounding air as sound pressure waves (and does vary with distance).

The sound power level for the Elite is 60.2 dB(A) and 69 dB(A) for the Intensity 10.

The sound pressure level for the Elite is approximately 53 dB(A) and 58 dB(A) for the Intensity 10.

5.3.1 Compressor Replacement

Compressor Assembly Removal

To remove the compressor assembly, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and lower front panels of unit.
3. Disconnect the suction tube.
4. Disconnect the blue compressor lead at the terminal strip and the brown lead at the temperature switch.
5. Disconnect the two leads to the capacitor and remove if necessary.
6. Disconnect the compression fitting for the heat exchanger located at the bottom center of the compressor.
7. Remove the two screws that connect the compressor plate to the base of the unit and slide the compressor assembly up and out.

Compressor Assembly Installation

To install compressor assembly, follow the steps below:

1. Perform the compressor removal procedure in reverse order.
2. Make sure to position the compressor's blue and brown lead wires behind the braided suction tube.
3. Leak test all connections.

5.3.2 Capacitor Replacement

The capacitor starts the compressor. If the compressor cannot start, the capacitor may be defective and require replacement. To replace the capacitor, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and lower front panels.
3. Disconnect the two leads to the capacitor and slide capacitor out of the tie-wrap holding it in place.
4. To install the new capacitor, connect the leads and slide the capacitor into the tie-wrap holding it in place.

5.4 Solenoid Valves

The NewLife uses five two-way solenoid valves: two feed, two waste, and one equalization. Each valve has an open (energized) and closed (de-energized) position. As the NewLife operates, two valves are always energized.

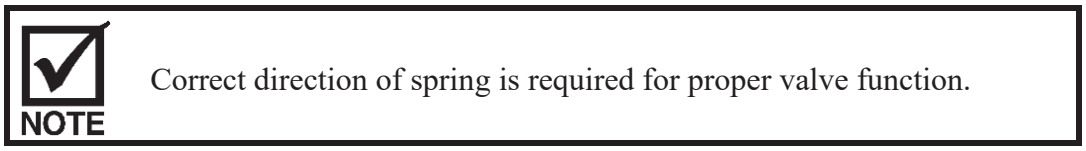
The solenoid valves of the NewLife unit require no scheduled maintenance. If a valve becomes noisy, you can easily replace the internal valve parts.

5.4.1 Feed/Waste Valve Replacement

Feed/Waste Valve Removal

To remove the feed or waste valves, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Remove the red cap from the appropriate valve with a slotted-head screwdriver.
4. Lift off the solenoid coil.



5. Loosen and remove the valve using a one-inch deep well socket. Be sure to also remove and discard valve o-ring.

Feed/Waste Valve Installation

To install a feed or waste valve, follow the feed/waste valve removal procedure in reverse order. Make sure to install new o-ring and test for leaks.

5.4.2 Solenoid Valve Coil Replacement

An ohmmeter can be a useful tool in determining the condition of a valve coil. When using and ohmmeter in the NewLife unit, valve coil readings should be as indicated below:

1. Elite 120VAC units
    a. EQ coil = 800ohms ± 10%
    b. Feed/waste coil = 800ohms ± 10%
2. Intensity 120VAC units
    a. EQ coil = 1,000ohms ± 10%
    b. Feed/waste coil = 800ohms ± 10%
3. Elite and Intensity 220-240VAC units
    a. EQ coil = 4,400ohms ± 10%
    b. Feed/waste coil = 3,220ohms ± 10%

You can also determine which coil is not operating by checking each valve to see if it becomes energized (magnetized) during unit operation.
To check for coil operation, follow the steps below:

1. Remove plastic cap securing the valve coil to the valve stem. (Do not remove coil).
2. With unit operating, hold a paperclip or the metal tip of a screwdriver slightly over the top of the valve stem located in the center of the coil.
3. When the coil becomes energized (magnetized) the paperclip or tip of the screwdriver will be pulled down onto valve stem, indicating the valve coil is operating.
4. If a coil is faulty, it will not become energized and require replacement.

To replace a solenoid valve coil, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Remove the red cap with a slotted-head screwdriver.
4. Disconnect the solenoid leads and lift off the solenoid coil.
5. Replace with the new coil.
6. Press the red cap back on top of the coil, and reconnect the solenoid leads.
7. Reconnect the back and side panels.

5.5 Sieve Beds

The NewLife unit utilizes two sieve beds, each containing molecular sieve. The unique property of molecular sieve enables it to physically attract nitrogen when air passes through this material, thus producing highly concentrated oxygen.

While one sieve bed produces high concentration oxygen, the other is purged of the nitrogen it adsorbed (collected) while it concentrates oxygen. Each adsorber (sieve bed) produces oxygen and delivers it to the product tank

5.5.1 Sieve Bed Replacement

Temporarily seal sieve bed openings with tape to prevent the sieve material from being exposed to the moisture in room air. Prolonged exposure to room air results in contamination and permanent damage to the sieve material.

Leaks can be so small in air loss that oxygen concentration is not affected immediately. The sieve material can become contaminated gradually. Careful leak testing is important as the sieve material can become contaminated gradually with very small leaks.

If replacement is necessary, you must replace both sieve beds at the same time.

Sieve Bed Removal

To remove sieve beds, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Cut the tie-wrap and disconnect green tubing at each elbow fitting located on the top of the sieve beds.
4. Remove the 9/16-inch compression fitting from the bottom of each sieve bed.
5. Cut the tie-wraps securing the sieve beds to the superstructure and remove the sieve beds.

Sieve Bed Installation

To install the sieve beds, follow the sieve bed removal procedure in reverse order. Do not over tighten fittings.

To check for leaks, take the following steps:

1. Connect the unit to power and set the unit's ON/OFF switch to the ON position.
2. Allow unit to run for three minutes.
3. Apply soapy water solution around tubing connections on both sieve beds and check for leaks.

5.6 Cabinet Fan

The cabinet fan pulls ambient air into the NewLife unit. As this air is drawn in, the air cools internal components (including the compressor) and exits out the bottom of the unit. The cabinet fan for NewLife is located in the back of the unit. Refer to the troubleshooting chart in Section 6.0 of this manual for instances where replacement of the fan may be required.

5.6.1 Cabinet Fan Replacement

To replace the cabinet fan, follow the steps below

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Remove the two screws that hold the fan to the superstructure and remove the fan.
4. Disconnect the fan leads.
5. Position the new cabinet fan so that the air flow arrow points toward the compressor and the electrical connections are in the bottom right corner.
6. Connect the fan leads and install the cabinet fan screws.
7. Reconnect the back and side panels.

5.7 Circuit Board

The solid-state printed circuit board controls the timing operation of the five solenoid valves and the alarm system functions.

Consult the troubleshooting chart in Section 6.0 to determine when to replace the printed circuit board.

The Printed Circuit Boards (PCBs) contain components that are sensitive to electrostatic discharge (ESD) and can damage the board if not handled properly. As when handling any ESD-sensitive PCB, observe standard ESD safety procedures.

5.7.1 Circuit Board Replacement

Circuit Board Removal

To remove the circuit board, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Disconnect all connections from the circuit board.
4. Cut the tie-wrap at the circuit board pressure transducer and disconnect the green tube from transducer.

Care must be taken when removing and installing tubing to circuit board sensor to prevent damaging sensor.

5. Push in on the circuit board support tabs while you lift each area of the circuit board to remove circuit board from the control panel.

Circuit Board Installation

To install the circuit board, follow the steps below:

1. Push the circuit board on to the support tabs.
2. Install green tubing to the top barb of transducer located on the circuit board. Secure with the tie-wrap.
3. Carefully align and firmly install all connections to the circuit board so that the connector's tab locks securely into place.
4. Reconnect the back and side panels.

5.8 Product Tank Replacement

Product Tank Removal

To remove the product tank, follow the steps below:

1. Set the unit's ON/OFF power switch to the OFF position and disconnect the power cord.
2. Remove the sides, lower front, and back panels.
3. Remove the compressor. (Refer to Section 5.3.)
4. Remove the intake resonator, which is held in place by Velcro.
5. Remove the securing nut that holds the product tank to the superstructure. (This securing nut is located in the top right area of the compressor compartment).
6. Remove the screws that hold the control panel to the superstructure. It is not necessary to fully remove the control panel. It is only necessary to create enough room to allow the product tank to be removed from the unit.
7. Remove the green tubing located at the regulator outlet and at the bottom of the product tank assembly.
8. Cut the tie wrap securing the product tank to the superstructure.
9. Lift the product tank with regulator attached from the mounting hole and remove from the unit.
10. Carefully remove regulator from product tank.

Product Tank Installation

To install the product tank assembly, follow the steps below:

1. Perform the product tank removal procedure in reverse order.
2. Apply sealant or sealant tape to threads of product tank fitting before reinstalling regulator onto product tank.
3. Perform the procedure from Section 5.9.1 to set the regulator to 20 PSIG (138 kPa). Leak test all connections.

5.9 Product Regulator Check and Setting

The product regulator is factory-set at 7 PSIG (48kPa) for the Elite, 20 PSIG (138 kPa) for the Intensity 10 and should not require adjustment. To check for proper adjustment of the product regulator, take the following steps:

Procedure A: NewLife Elite

1. Set the ON/OFF switch to the ON position.
2. Allow the unit to run for five minutes.
3. Turn the flowmeter adjustment knob counterclockwise until it stops (wide open).
4. The flowmeter ball centers itself on the 5.5 LPM line. If not, the product regulator needs to be adjusted.

Procedure B: NewLife Intensity 10

1. Install outlet pressure test kit (TU131-1) to the outlet of the NewLife unit.
2. Set the unit's ON/OFF power switch to the ON position.
3. Allow the unit to run for five minutes.
4. Turn the flowmeter adjustment knob counterclockwise until it stops (wide open).
5. The outlet pressure should measure 20 PSIG for the Intensity 10. If the outlet pressure is not at 20 PSIG the product regulator needs to be adjusted.

5.9.1 Setting Product Regulator for Normal Operation

Procedure A: NewLife Elite

Use the following procedure to set the product regulator to 7 PSIG (48kPa):

1. Disconnect the humidifier bottle, if used, and the tubing from the oxygen outlet.
2. Plug in the unit.
3. Set the unit's ON/OFF switch to the ON position, and allow the unit to run at least five minutes to build up pressure.
4. Remove the right-side panel.
5. Turn the flowmeter adjustment knob counterclockwise until it stops (wide open).
6. Pull outward on the regulator knob to unlock it.
7. Turn the regulator knob or set screws until the flowmeter ball centers on the 5.5 LPM line (clockwise to increase).
8. Push in the regulator knob to lock it.
9. Reconnect the side panel.

Procedure B: NewLife Intensity 10

Use the following procedure to set the product regulator to 20 PSIG (138 kPa):

1. Disconnect the humidifier bottle, if used, and the tubing from oxygen outlet.
2. Remove the side panels and back panel.
3. Connect unit to power.
4. Install outlet pressure test kit (TU131-1) to the outlet of the NewLife Intensity.
5. Set the unit's ON/OFF switch to the ON position, and allow unit to run at least five minutes to build up pressure.
6. Turn the flowmeter adjustment knob counterclockwise until it stops (wide open).
7. Pull outward on the regulator knob to unlock it.
8. Turn the regulator knob until the outlet pressure is 20 PISG (138 kPa) on the gauge of the pressure test kit.
9. Push in the regulator knob to lock it.
10. Reconnect the back and side panels.

5.9.2 Product Regulator Cleaning or Rebuilding

Clean or rebuild the product regulator if the regulator cannot be adjusted for lockout.

1. Set the unit's ON/OFF switch to the ON position and disconnect the power cord.
2. Remove the right-side panels and back panels.
3. Use large pliers to unscrew the bonnet of the product regulator, which contains a large spring.

Adjust the product regulator fully counterclockwise to unload the spring. This makes disassembly and reassembly easier.

4. Remove the diaphragm. (Clean or replace it.)
5. Using a Phillips-head screwdriver, unscrew the diaphragm stem guide located in the center of the regulator body to gain access to the seat.
6. Remove the seat. Be careful not to lose the spring located behind the seat.
7. Clean or replace the seat.
8. With the spring behind the seat, screw the diaphragm stem guide back into the body of the regulator. (Do not over tighten.)
9. Install a clean or replacement diaphragm.
10. Put the large spring and slip ring into the bonnet and screw the bonnet onto the regulator body.
11. Reset the product regulator as described in Section 5.9.1.

5.10 Circuit Breaker Replacement

Circuit Breaker Removal

To remove the circuit breaker, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the left side panel.
3. Cut the heat shrink to expose the circuit breakers leads.
4. Disconnect the circuit breakers leads.
5. Unscrew the circuit breaker while you apply pressure to the circuit breaker retaining ring.

Circuit Breaker Installation

Follow the removal procedure for the circuit breaker in reverse order to install the new circuit breaker. Wire connections on circuit breaker can be made to either terminal.

5.11 ON/OFF Power Switch Replacement

ON/OFF Power Switch Removal

To remove the ON/OFF power switch, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove both side panels and back panel.
3. Cut the heat shrink to expose the ON/OFF switch's leads.
4. Disconnect the ON/OFF power switch's leads.
5. Push on the back of the power switch, while holding in its upper and lower retaining tabs, and remove the switch through the front panel.

ON/OFF Power Switch Installation

Follow the removal procedure for the ON/OFF power switch in reverse order to install a new power switch.

1. Be sure to reinstall the new switch properly with the orientation of the OFF on the switch located on the bottom when finished.
2. Same side wire connections of power switch can be made to either terminal.

5.12 Buzzer Replacement

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the left side panel.
3. Unscrew the two Phillips-head screws that hold the buzzer to the superstructure.
4. Unplug the buzzer's connection from the board.
5. Plug in the new buzzer's connection to the board.
6. Screw the two Phillips-head screws that hold the new buzzer to the superstructure.
7. Reconnect the side panel.

5.13 Hour Meter Replacement

NOTE

HM009-2 is a dual function hour meter. It has a selection switch accessible by a pinhole in the upper right corner of the hour meter.
To toggle between display modes - press in the switch once using a small paperclip.

1. 'TMR1' mode displays accumulated hours, which can be reset to zero hours by pressing and holding the switch in until 0.0 is displayed (approximately 3 seconds).
2. If 'TMR1' is not displayed, then total operating hours of unit is displayed.

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the left side panel.
3. Cut the heat shrink to expose the hour meter's leads.
4. Disconnect the hour meter's leads.
5. Push hour meter mounting tabs inward from the hour meter.
6. Remove the hour meter through the control panel.
7. Install the new hour meter into the control panel, making sure the hours are displayed on top. (Hourglass icon should be located on bottom of hour meter when properly installed).
8. Reconnect the hour meter leads.
9. Reconnect the side panel.

5.14 Flowmeter Replacement

Flowmeter Removal

To remove the flowmeter, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side panel.
3. Cut the tie-wraps and remove the ¼-inch green oxygen tubing from the flowmeter fittings.
4. Unscrew the flowmeter nuts with a wrench.
5. Remove the flowmeter through the control panel.

Flowmeter Installation

To install a new flowmeter, follow the flowmeter removal procedure in reverse order. Leak test the tubing connections.

5.15 Power Cord Replacement

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Open the plastic twist clamps.
4. Cut the tie-wraps (located near the power cord push-on connectors).
5. Disconnect the white power cord lead from the ON/OFF switch lead.
6. Disconnect the black power cord lead from the top terminal on the circuit breaker.
7. Locate strain relief inside power cord receptacle. Press both ends together with pliers while pushing power cord from the back to remove power cord. Pull the power cord through the opening on the power cord receptacle.
8. Using the same length of installation for the strain relief from the original power cord, slide the strain relief onto the new power cord so that the larger lip of the strain relief faces the power cord plug end.
9. Insert and install the new power cord through the opening of the receptacle squeezing the strain relief together with pliers to secure in place.
10. Reconnect the power cord leads, close the plastic twist clamps, and reattach the tie-wraps.
11. Reconnect the side and back panels.

5.16 Oxygen Monitor Circuit Board Replacement

Oxygen Monitor Circuit Board Removal

To remove the circuit board, follow the steps below:

1. Set the unit's ON/OFF switch to the OFF position and disconnect the power cord.
2. Remove the side and back panels.
3. Locate oxygen monitor circuit board and carefully disconnect the 4-pin wire harness from circuit board.
4. Using Phillips-head screwdriver, remove screws and spacers securing circuit board to superstructure.
5. Disconnect tubing connections from circuit board sensor. (Note: depending on unit, there may be one or two tubing connections on the sensor). Review of tubing connection position(s) should be made prior to disconnecting.

Oxygen Monitor Circuit Board Installation

To install a new circuit board, follow the circuit board removal procedure in reverse order.

1. Be sure to reinstall tubing connection(s) to correct position on sensor of new circuit board.
2. Spacers are installed between circuit board and superstructure.

6.0 Troubleshooting

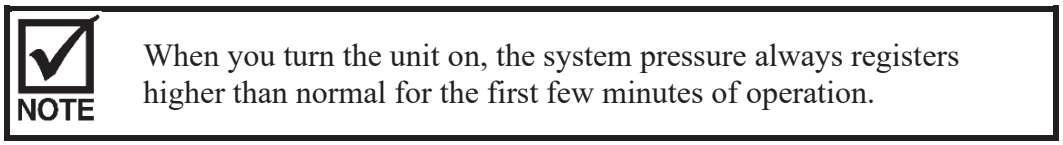
6.1 Operating Pressure Test

Testing the operating pressure is a useful diagnostic tool when a concentrator produces low oxygen concentration and requires servicing. Units functioning normally do not require operating pressure tests.

Use the following procedure to test the operating pressure of the unit:

1. Set the unit's ON/OFF power switch to the OFF position and disconnect the power cord.
2. Remove the right-side panel.
3. Locate the pressure test port location (black tube with plug in the end). Remove plug and using a pressure test port adapter (KI257-1), connect the pressure gauge to the test port.
4. Connect the unit to power and set the unit's ON/OFF power switch to the ON position. Set the flowmeter to indicated maximum flow setting and allow the unit to run five minutes.
5. Observe the maximum and minimum readings on the pressure test gauge.

Elite units:
The maximum reading should not exceed 32 PSIG (220.6 kPa).
The minimum reading should not exceed 10 PSIG (69 kPa).
Intensity 10 units:
The maximum reading should not exceed 34 PSIG (234 kPa).
The minimum reading should not be less than 10 PSIG (69 kPa).



6.1.1 High Operating Pressure

Higher than normal operating pressure may indicate any of the following:

- A restrictive exhaust muffler, which does not allow the waste (purge) gas to exit the system freely.
  Operate the unit with the exhaust muffler disconnected to see if the operating pressure returns to normal.
- An improperly operating circuit board or solenoid valve.
  Confirm that the circuit board and solenoid valves function properly.
- Contaminated sieve beds.
  Change the sieve beds.

6.1.2 Low Operating Pressure

If the oxygen concentration level at the desired liter flow is within CAIRE's specifications, no service is required, even if operating pressure is low. If concentration is below specifications at the desired liter flow rate with low operating pressure, this may indicate any of the following:

- A restriction in the intake resonator, which limits the amount of room air available to the compressor.
  Disconnect the braided tube at the compressor and allow the unit to operate without the intake resonator to see if normal operating pressure returns.
- A compressor with reduced output.
  If it is below specifications, replace or repair the compressor.
- An improperly operating circuit board or solenoid valve.
  Confirm that the circuit board and solenoid valves function properly.
- A leak in the unit, which allows system pressure to escape.
  Leak test unit.

6.2 General Troubleshooting

Before reviewing the troubleshooting chart, the following steps may be useful to isolate any malfunctions:

1. Turn on the concentrator. If the unit does not turn on, refer to the troubleshooting chart.
2. For Intensity units verify the outlet pressure is 20 PSIG (138 kPa). If the outlet pressure is not at 20 PSIG (138 kPa), the product regulator needs to be reset. Refer to Section 5.9. For Elite units verify the flowmeter tops out at 5.5LPM. If the flowmeter ball goes lower or higher than 5.5LPM, the product regulator needs to be reset. Refer to Section 5.9.
3. Make sure the unit is cycling properly by:
   a. Observing the flowmeter ball is stable in flowmeter. (Flowmeter ball does not move up and down more than ¼ of a liter.)
   b. Checking the operating pressure, please refer to section 6.1.
4. Place your thumb over outlet of unit. The flowmeter ball should drop to the bottom of the flowmeter. If the ball does not drop completely to the bottom, there is a leak present between the top of the flowmeter and the outlet of the unit.
5. If concentrator is not meeting specifications, make sure that the unit is leak-free by testing all tubing connections and fittings with leak testing solution. Protect circuit board(s) from solution and start leak test at the heat exchanger, following air flow of unit to oxygen outlet. Repair all leaks by tightening connections and fittings.
6. Set the concentrator at indicated maximum flow setting and connect pressure test gauge to unit. Determine pressure parameters by observing high and low pressure points on the gauge. If pressures are high or low, refer to Section 6.1.
7. Review troubleshooting chart to isolate and repair any other malfunctions.

6.3 Troubleshooting Chart

Problem	Probably Cause	Solution
Compressor does not run. Power failure light ( ) and intermittent audible alarm.	No power to unit from electrical outlet.	Check or restore power to outlet.
	Unit circuit breaker tripped or faulty.	Reset or replace circuit breaker.
	Faulty electrical connections.	Check electrical connections.
	Faulty ON/OFF power switch.	Replace ON/OFF power switch.
	Faulty circuit board.	Replace circuit board
Compressor runs and shuts down periodically.	Restricted air flow.	Remove obstruction.
	Unit overheating due to improper location. Compressor thermally cut off due to excessive heat. *Note: Unit will not restart until it cools down*.	Locate unit away from heating source, providing adequate ventilation on all sides. *Note: Do not run multiple units next to each other.*
	Faulty high temperature switch.	Replace high temperature switch.
	Faulty cabinet fan.	Replace cabinet fan.
Compressor does not start. ON/OFF power switch is in the ON position, intermittent alarm, and cabinet fan turns.	Extreme cold start.	Allow unit to reach room temperature.
	Faulty electrical connection for the compressor.	Check electrical connections for compressor.
	Faulty capacitor.	Replace capacitor.
	Faulty high temperature switch.	Replace high temperature switch.
	Faulty circuit board.	Replace circuit board.
Compressor runs with low O_2 concentration, general malfunction light ( ), and intermittent audible alarm.	Leak.	Leak test and repair leak.
	Reduced air intake (suction).	Check compressor intake path for obstruction. Clean or remove obstruction.
	Weak capacitor.	Replace capacitor.
	Faulty circuit board.	Replace circuit board
	Weak compressor.	Replace compressor.
	Restriction in exhaust muffler.	Replace or clean muffler.
	Faulty solenoid valve.	Repair or replace solenoid valve.
	Faulty circuit board.	Replace circuit board.
	Contaminated sieve beds.	Replace sieve beds.

Problem	Probable Cause	Solution
Compressor relief valve releases (popping sound).	Faulty electrical connection at waste valve.	Repair electrical connection.
	Faulty solenoid valve coil. *Refer to section 5.4.2 for acceptable ohm rating*.	Replace valve coil. *Use of an ohmmeter can be used to easily determine a faulty coil.*
	Faulty relief valve.	Replace relief valve or compressor.
	Faulty circuit board.	Replace circuit board.
	Contaminated sieve beds.	Replace sieve beds.
Power failure light ( ) and intermittent audible alarm with ON/OFF switch in the "ON" position. Circuit breaker trips repeatedly.	Faulty electrical connection.	Repair electrical connection.
	Faulty capacitor.	Replace capacitor.
	Faulty circuit breaker.	Replace circuit breaker.
	Faulty circuit board.	Replace circuit board.
	Faulty compressor.	Replace compressor.
Alarm does not sound.	Faulty electrical connection.	Repair electrical connection.
	Faulty buzzer.	Replace buzzer.
	Faulty ON/OFF power switch.	Replace ON/OFF power switch.
	Faulty circuit board.	Replace circuit board.
Flowmeter fluctuates.	Leak.	Leak test and repair leak.
	Reduced air intake (suction).	Check compressor intake path for obstruction. Clean/remove obstruction.
	Improperly set or faulty product regulator.	Check regulator setting. Repair or replace regulator.
	Faulty flowmeter.	Replace flowmeter.
	Worn compressor.	Replace compressor.
	Faulty circuit board.	Replace circuit board.
	Faulty solenoid valve.	Repair or replace solenoid valve.
Cabinet fan does not turn.	Faulty electrical connections.	Check electrical connections.
	Faulty cabinet fan.	Replace cabinet fan.

Problem	Probable Cause	Solution
Limited or low flow	Restriction in humidifier/tubing.	Replace humidifier or tubing.
	Product regulator set too low.	Adjust regulator setting.
	Leak.	Leak test and repair leak.
	Reduced air intake (suction).	Check compressor intake path for obstruction. Clean/remove obstruction.
	Faulty solenoid valve.	Repair or replace solenoid valve.
	Restriction in product tank.	Replace product tank.
	Faulty circuit board.	Replace circuit board.
	Weak compressor.	Check system pressure and rebuild or exchange compressor.
Low oxygen concentration	Outlet pressure not set to 20 PSIG.	Reset outlet pressure.
	Leak.	Leak test and repair leak.
	Ambient or unit's temperature is too high. Unit operating above temperature range specifications. Obstructed air intake or exhaust.	Locate unit away from heating source, providing adequate ventilation on all sides. (Do not run multiple units next to each other). Replace cabinet fan.
	Reduced air intake (suction).	Check compressor intake path for obstruction. Clean/remove obstruction.
	Restriction in exhaust muffler.	Replace or clean exhaust muffler.
	Faulty solenoid valve.	Repair or replace solenoid valve.
	Faulty circuit board.	Replace circuit board.
	Contaminated sieve beds.	Replace sieve beds.
	Weak compressor.	Check system pressure and rebuild or replace compressor.

6.4 Tool Kit and Pressure Test Gauge

The tools needed for you to properly service the NewLife units are listed below:

Multi-adjustable pliers, wire cutters, needle-nose pliers, slotted-head screwdriver, Phillips-head screwdriver, ratchet, adjustable wrench, 1-inch deep well socket, 9/16-inch socket, 2-inch extension, 7/16-inch combination wrench, 9/16-inch combination wrench, and 5/8-inch combination wrench.

Pressure test adapter: (KI057-1).
Outlet pressure test kit: (TU131-1 for Intensity 10 only)

A pressure test gauge (KI036-1) to read operating system pressures and outlet pressures on the NewLife unit should always be kept available.

7.0 EMC Testing

7.1 EMC Testing Tables

Medical equipment needs special precautions regarding EMC and needs to be installed an put into service according to EMC information provided in this Section.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The NewLifeis intended for use in the electromagnetic environment specified below. The customer or the user of the NewLife should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The NewLife 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 NewLife 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 for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration± Electromagnetic Immunity			
The NewLife is intended for use in the electromagnetic environment specified below. The customer or the user of the NewLife should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment ± guidance**
Electromagnetic environment – guidance IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to line(s)	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 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NewLife Family requires continued operation during power mains interruptions, it is recommended that the NewLife is powered from an uninterruptible power supply (UPS) 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

The NewLife is intended for use in the electromagnetic environment specified below. The customer or the user of the NewLife should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment ± guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the NewLife, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ from 800 MHz to .5 GHz where 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NewLife Family is used exceeds the applicable RF compliance level above, the NewLife should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NewLife Family.

[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 NewLife Units

The NewLife is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NewLife can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NewLife 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.2\sqrt{P}$
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 metres (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.

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 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 – IP21.
Protection against ingress of solid foreign objects greater than 12.5 mm diameter, and protection against vertically falling drops of water.

Method of cleaning and infection control allowed:

Please refer to Maintenance section in the NewLife Service Manuals.

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

Equipment not suited for such application.

Mode of operation:

Continuous duty.

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Please consult the applicable product instructions for use for product indications, contraindications, warnings, precautions, and detailed safety information.

MN240-1 Rev E