NewLife® Intensity 10

User Manual (US)

CAIRE®

User Controls & System Status Indicators

ISO 7000	
	Read user's manual before operation. Reg. # 1641
	Storage or operating temperature range. Reg. # 0632
	Storage humidity range. Reg. # 2620
	Keep away from rain, keep dry. Reg. # 0626
	Name and address of manufacturer. Reg. # 3082
	The country and date of manufacture. The "CC" identifies the two letter country code of the country of manufacture. The date of manufacture is in YYYY-MM-DD format. Reg. # 6049
	Caution, consult accompanying documents. Reg. # 0434A
	Catalog Number. Reg. # 2493
	Serial Number. Reg. # 2498
	This way up. Reg. # 0623
	Fragile, handle with care. Reg. # 0621
	Stacking limit by number, where "n" indicates the maximum number of units allowed. Reg. # 2403
	Contains hazardous substances. Reg. # 3723
	Importer. Reg. # 3725
ISO 7010	
	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	
EC REP	Authorized representative in the European Community
CE ####	If the product unique device identifier (UDI) label has the CE#### symbol on it, the device complies with the requirements of Directive 93/42/EEC concerning medical devices. The CE#### symbol indicates notified body number.
Additional Symbols	
	Keep away from flammable materials, oil and grease.
	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)
CH REP	Authorized representative in Switzerland.
UK CA	If the device bears the UKCA mark as shown with UKCA#### indicating the notified body number, this device complies with UKCA regulations.
IEC 60417	
	Class II equipment
21 CFR 801.15	
RX ONLY	Federal law restricts this device to sale by or on the order of a physician.
IEC 60601-1	
IP21	Drip Proof Equipment - IP21

Council Directive 2012/19/EU	
	WEEE This symbol is to remind the equipment owners to return it to a recycling 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.
ISO 15223-1	
MD	Medical Device. Reg. # 5.7.7
UDI	Unique device identifier # 5.7.10
QPS Electrical Safety Certification	
	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.

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.: www.caireinc.com/corporate/patents/.

NewLife® Oxygen Concentrator

This user manual will acquaint you with the NewLife oxygen concentrator. Make sure you read and understand all the information contained in this manual before you operate your unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

What is the Oxygen Concentrator

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gasses. In the NewLife oxygen concentrator, room air is drawn into the machine through the air intakes. It then passes through an adsorbent material called molecular sieve. This material separates the oxygen from the nitrogen and allows only the oxygen to pass through. The result is a flow of high-concentration oxygen delivered to the user.

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

Why Your Physician Prescribed Oxygen

Many people suffer from a variety of heart, lung, and other respiratory diseases. A significant number of these people can benefit from supplemental oxygen therapy at home, when traveling, or while participating in daily activities away from home.

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

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

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: IN THE EVENT THERE IS A SERIOUS INCIDENT OCCURRING WITH THIS DEVICE, THE USER SHOULD IMMEDIATELY REPORT THE INCIDENT TO THE PROVIDER AND/OR THE MANUFACTURER. A SERIOUS INCIDENT IS DEFINED AS AN INJURY, DEATH, OR POTENTIAL TO CAUSE INJURY/DEATH SHOULD THERE BE A REOCCURRENCE OF THE INCIDENT. THE USER CAN ALSO REPORT THE INCIDENT TO THE COMPETENT AUTHORITY IN THE COUNTRY WHERE THE INCIDENT OCCURRED.

Operator Profile

Concentrators are intended to supply supplemental oxygen to users suffering from discomfort due to ailments which effect the efficiency of one's lungs to transfer oxygen in the air to their bloodstream. Stationary oxygen concentrators (SOCs) do not store or contain oxygen. They do not need to be refilled, and can operate at any location where AC power source is available. Oxygen concentrator use requires a physician's prescription and is not intended for life support use.

Although oxygen therapy can be prescribed for users of all ages, the typical oxygen therapy user is older than 65 years of age and suffers from a variety of respiratory diseases, including Chronic Obstructive Pulmonary Disorder (COPD). Users typically have good cognitive abilities and must be able to communicate discomfort. If the user is unable to communicate discomfort, or unable to read and understand the concentrator labeling and instructions for use, then use is recommended only under the supervision of one who can. If any discomfort is felt while using the concentrator, users are advised to contact their healthcare provider. Users are also advised to have back-up oxygen available (i.e. cylinder oxygen) in the event of a power outage or concentrator failure. There are no other unique skills or user abilities required for concentrator use.

Unpacking Your NewLife

Verify that all of the components listed and shown below are included in the package. If any items are missing, contact your oxygen provider immediately.

• Stationary Oxygen Concentrator

Getting to Know Your NewLife Oxygen Concentrator

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

A. On/Off (I/0) 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: Controls and indicates the oxygen flow rate in liters per minute (lpm).
E. Oxygen Outlet: Provides connections for a humidifier (if required), nasal cannula, face mask, or catheter.
F. Top and Side Handles: Enables convenience in carrying the unit.
G. Operating Instructions: Explains procedures to operate the unit.
H. Air Intake Gross Particle Filter: Prevents dust and other airborne particles from entering the unit.
I. Power Cord: Allows connection of unit into electrical outlet.

Figure 1a

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 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.

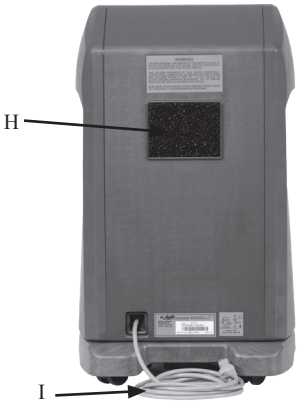


Figure 1b

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 Intensity 10.

Note: Information needing special attention.

Indications for Use

Intended Use

The CAIRE NewLife oxygen concentrator is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

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

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 ELECTRICAL POWER INTERRUPTION, OR THE NEED TO HAVE THE OXYGEN CONCENTRATOR SERVICED 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.

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.

Safety Guidelines

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

WARNING: IF YOU FEEL DISCOMFORT OR ARE EXPERIENCING A MEDICAL EMERGENCY, SEEK MEDICAL ASSISTANCE IMMEDIATELY.

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

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: 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 AND POWER CORDS IN A MANNER THAT PREVENTS TRIP HAZARD OR POSSIBLE ACCIDENTAL STRANGULATION.

WARNING: NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED.

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.

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

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

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

WARNING: USE OF DEVICE OUTSIDE OF SPECIFIED OPERATING CONDITIONS IS EXPECTED TO ADVERSELY AFFECT THE FLOWRATE AND PERCENTAGE OF OXYGEN AND CONSEQUENTLY THE QUALITY OF THE THERAPY.

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 SPECIFICATION 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: Ensure concentrator is operated in an upright position.

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

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

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 performance.

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.

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 (30 cm) away from a wall or other obstruction. Do not place the unit in a confined area. Choose a dust and smoke free-location away from direct sunlight. Do not operate the unit outdoors unless the unit is plugged into a Ground Fault Circuit Interrupter (GFCI) protected outlet.

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 can shut off the flow of oxygen from your unit. For your convenience, the flowmeter is marked in ½ 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: 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 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 Intensity Oxygen Concentrator must be operated for at least five minutes at 2 LPM before using the unit.

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

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

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

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

• Nasal Cannula: CAIRE Part Number CU002-1

• Humidifier Adaptor Tubing: CAIRE Part Number 20843882

• Humidifier Bottle: CAIRE Part Number HU003-1

• Firebreak: CAIRE Part Number 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).

• Additional recommended accessories information is available online at www.caireinc.com.

WARNING: KEEP OUT OF THE REACH OF CHILDREN UNTIL INSTALLED.

WARNING: THIS PRODUCT CAN EXPOSE YOU TO CHEMICALS INCLUDING NICKEL, WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER. FOR MORE INFORMATION, GO TO WWW.P65WARNINGS.CA.GOV.

Specifications

	NewLife Intensity 10
Flow Rates*	2–10 LPM ±10% of indicated setting, or 200 mL, whichever is greater**
Dimensions	27.5 x 16.5 x 14.5 in (69.9 x 41.9 x 36.8 cm)
Weight	58 lbs (26.3 kg)
Sound Pressure Level	58 dB(A) at flow rates of 2 to 10 LPM
Power Consumption	600 watts–2-10 LPM model Two-prong polarized plug Double insulated cabinet 120 VAC, 60 Hz, 6.0 amps 230 VAC, 50 Hz, 3.0 amps
O2 Concentration	90% +5.5 -3
Output Pressure	20 psig (138 kPA)
Operating Environment*	50°F to 104°F (10°C to 40°C), 15–90% humidity
Altitude	-1250 to 10,000 ft (-381 to 3048 m) (tested to 700 – 1060 hPa)
Storage Environment	-25° C to 70° C (-13° F to 158° F), 0-90% Humidity (non-condensing)
Warranty	3 Years
Maintenance Schedule	Felt Filter – 1 Year Replacement, Intake Filter – Clean Weekly
Max Tubing	200 ft (61 m)

* Based on an atmospheric pressure range of 700 hPa to 1060 hPa at 70°F (21°C)

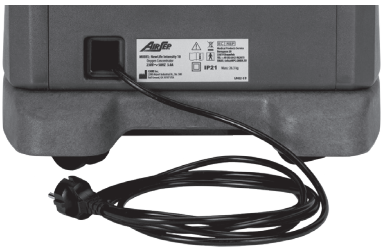
** At altitudes below sea level and higher than 8,000 ft (2438 m) above sea level, flow meter accuracy may be affected up to 13%.

The expected service life of this device is a minimum of five years.

See technical manual (PN MN240-1) for sound power level.

Operating Instructions

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



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

   An audible and visual alarm must sound for a short test to indicate proper alarm function.

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

8. Set the flowmeter adjustment knob to the prescribed LPM. The concentrator is now ready for use.

9. To turn the concentrator off, press the I/0 switch to the 0 position.
10. If the NewLife unit fails to operate properly, refer to the Troubleshooting section for a list of probable causes and solutions.

WARNING: 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.

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. ONLY WATER BASED, OXYGEN COMPATIBLE LOTIONS OR SALVES SHOULD BE USED. OXYGEN ACCELERATES THE COMBUSTION OF FLAMMABLE SUBSTANCES.

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

CAUTION: Always operate the unit in an upright position.

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.

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: 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 ½ 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.

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

Filters

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

The supplemental oxygen produced by the NewLife unit receives additional filtration from a product filter (for particle size 10 micron or greater) located within the oxygen concentrator. Your equipment Provider performs maintenance on the product filter in addition to other maintenance on the unit.

Operating 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.

Operating With Humidifier

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

1. Remove or unscrew the reservoir bottle from the humidifier (If you have a pre-filled unit do not perform this step. Proceed directly to step 4.)
2. Fill the reservoir with cool or cold water (distilled water is preferred) to the fill line indicated on the bottle. DO NOT OVERFILL.
3. Screw the reservoir bottle back together.

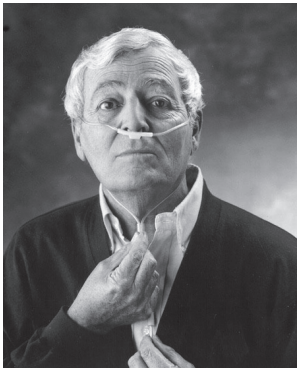
4. On the top of the humidifier, turn the thread nut counterclockwise while you connect the humidifier to the oxygen outlet, and tighten securely.
5. Connect oxygen tubing from the nasal cannula, face mask, or other accessories to the humidifier outlet fitting.

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

Note: To Equipment Provider: The following humidifier bottles are recommended for use with the NewLife Oxygen Concentrators:
Part No. HU014-1

Nasal Cannula

Your physician has prescribed either a nasal cannula, face mask, or other accessories. In most cases the manufacturer has already connected the oxygen supply tubing to the nasal cannula, face mask, or other accessory.



If not, follow the manufacturer's instructions for proper connection. Connect the oxygen tubing to the oxygen outlet adapter or humidifier.

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

- Nasal Cannula with 7 feet (2.1 m) of tubing (6 LPM max): Part No. CU002-1
- Oxygen Outlet Adapter (6 LPM max) (Not for use with Intensity 10 LPM): Part No. F0025-1
- Face Mask with 7 feet (2.1 m) of tubing (10 LPM Max)*: Part No. MS013-1
- Humidifier Adapter Extension: Part No. HU002-1
- Humidifier Bottle for Intensity models: Part No. HU014-1

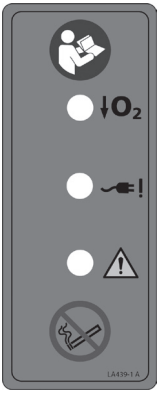
*Face mask should only be used with Intensity 10 models.

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 section of this manual.

Safety Features

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

- Compressor Motor: A pressure relief valve is fitted to the compressor outlet and is calibrated to 360 kPa (52 psig). Thermal safety is ensured by a thermal safety switch which will cause the compressor to shut down (65 °C / 149 °F).
- 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



Device warning label and alarm display.

Note: 10 LPM Single Flow Meter Only

  - High device product tank pressure condition of greater than 38 psig (±1)
  - Low device product tank pressure condition of less than 15 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)
- 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 O2 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.
- Product Filter: ≥ 10 µm filter

Note: Dual Flow New Life Intensity—Obstruction to the flow of oxygen such as a pinch or kink in the delivery cannula will cause the flow meter ball to drop to zero as an indicator of no flow.

Oxygen Monitor

The oxygen monitor is a small electronic device within the NewLife Oxygen Concentrator that monitors the concentration of oxygen produced by the unit. If oxygen concentration falls below the acceptable therapeutic level, a yellow oxygen monitor light on the Oxygen Concentrator turns on. If the light remains on for more than 15 minutes, an intermittent alarm sounds.

⚠ **CAUTION: Contact your Equipment Provider immediately if the yellow oxygen monitor light remains on for more than 15 minutes.**

Note: When you turn the unit on, it is normal for the yellow oxygen monitor light to turn on and remain on for up to five minutes.

Operating Instructions—Dual Flow

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 or the needs of two patients, in any combination of flows up to 10 lpm. Excellent for use in the home, extended care facility, hospital, or physician's waiting room.

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 Intensity Oxygen Concentrator accommodates high pressure/high flow prescriptions.

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

Filling the Nebulizer with Medication

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

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

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

Figure 4: Medicine into cup

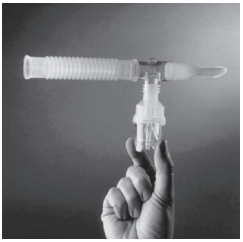


Figure 5: Nebulizer mouthpiece

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

Inhaling Medication/Treatment Instructions

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

1. Close your mouth around the mouthpiece, but do not hold it with your teeth (Figure 6).

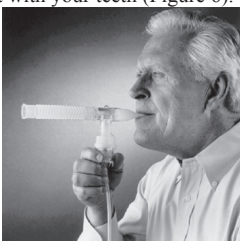


Figure 6: Mouthpiece

2. Take a slow, deep breath, and pause at the end of the inhalation for 1-2 seconds, then exhale slowly and completely.
3. Repeat this procedure until the prescribed amount of medication nebulizes or the Prescribed amount of treatment time elapses (whichever occurs first).
4. If your physician or health care professional instructed you to take short rest periods During your treatment, make sure you turn the air valve to the OFF position. This will conserve your medication.

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

Cleaning the Nebulizer

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

1. After each treatment, separate the nebulizer and the "T" piece or mouthpiece assembly.
2. Remove or unscrew the nebulizer cup, and rinse each component thoroughly in warm water.
3. Once a day, clean all nebulizer parts (excluding air supply tubing) with a mild detergent or soap solution in warm water. Rinse thoroughly, and soak all parts in a solution of one (1) part white vinegar and three (3) parts water for 30 minutes to disinfect.

Figure 7

4. Rinse thoroughly in warm water to remove the disinfectant solution.
5. Place all nebulizer parts on a paper towel or soft absorbent material to air dry. DO NOT WIPE DRY.
6. When dry, store the nebulizer parts in a clean container or plastic bag.
7. Repeat the above procedure after each treatment/patient use.

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

Materials in Direct or Indirect Contact with Operator

NewLife Intensity 10:

Concentrator casing ..... Valtra/ABS/Polystyrene
Mains cable ..... PVC
Dust filter ..... Polyester
ON/OFF switch ..... Thermoplastic
Casters ..... Nylon
Flow adjustment ..... ABS/Polycarbonate
Gas outlet ..... Chrome Plated Brass
Printed labels ..... Lexan

Cleaning, Care, and Proper Maintenance

WARNING: CLEAN THE CABINET, CONTROL PANEL, AND POWER CORD ONLY WITH A MILD HOUSEHOLD CLEANER APPLIED WITH A DAMP (NOT WET) CLOTH OR SPONGE, AND THEN WIPE ALL SURFACES DRY. DO NOT ALLOW ANY LIQUID TO GET INSIDE THE CONCENTRATOR. PAY SPECIAL ATTENTION TO THE OXYGEN OUTLET FOR THE CANNULA CONNECTION TO MAKE SURE IT REMAINS FREE OF DUST, WATER, AND PARTICLES.

Cabinet

Turn OFF the unit and disconnect from power before any cleaning or disinfection. DO NOT spray the outer case directly. Use a damp (not wet) cloth or sponge. Spray the cloth or sponge with a mild detergent solution to clean the cabinet. Proceed as directed by the cleaner manufacturer. Device cabinet should be cleaned at minimum between users.

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

WARNING: DO NOT USE LIQUID DIRECTLY ON THE UNIT. A LIST OF UNDESIRABLE CHEMICAL AGENTS INCLUDES BUT IS NOT LIMITED TO THE FOLLOWING: ALCOHOL AND ALCOHOL-BASED PRODUCTS, CONCENTRATED CHLORINE-BASED PRODUCTS (ETHYLENE CHLORIDE), AND OIL-BASED PRODUCTS (PINE-SOL®, LESTOIL®). THESE ARE NOT TO BE USED TO CLEAN THE PLASTIC HOUSING ON THE OXYGEN CONCENTRATOR, AS THEY CAN DAMAGE THE UNIT'S PLASTIC. CLEAN THE CABINET, CONTROL PANEL, AND POWER CORD ONLY WITH A MILD HOUSEHOLD CLEANER APPLIED WITH A DAMP CLOTH (NOT WET) OR SPONGE, AND THEN WIPE ALL SURFACES DRY. DO NOT ALLOW ANY LIQUID TO GET INSIDE THE DEVICE.

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.

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

Filters

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

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

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

Reserve Oxygen Supply

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

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.

Cannula Replacement

Always follow the cannula manufacturer's instructions for proper use. Replace the nasal cannula or oxygen tubing as recommended by the cannula manufacturer or your oxygen provider. Your physician or oxygen provider will provide you with cleaning and replacement instructions.

Additional supplies for replacement are available through your oxygen provider.

Alarm Conditions

All alarms are low priority alarms.

Alarm	Indicates	Action
General malfunction yellow light  and intermittent audible alarm	High Product Tank Pressure OR Low Product Tank Pressure OR High Device Temperature OR No Flow (10 LPM Single Flow Meter Only)	Ensure flowmeter is open to minimum flow rate or higher. Ensure cannula is not kinked or obstructed. Remove any devices connected downstream of the outlet of the device. Ensure device has at least 12" of clearance on all sides and intakes are not obstructed. Ensure external gross particle intake filter is clean and not clogged. Ensure unit is within operating temperature range. If issue persists, contact equipment provider for service.
Oxygen monitor yellow light  and intermittent audible alarm	Low Oxygen Concentration	Contact equipment provider for service.
Power failure yellow light  and intermittent audible alarm	Power Failure	Ensure device is plugged into a known, working outlet. Ensure breaker switch is pushed in. If issue persists contact equipment provider for service.

Troubleshooting

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

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

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

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

Problem	Probable Cause	Solution
Unit does not operate. Power failure condition causes an 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.	Contact your Equipment Provider for service.

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, face mask, catheter, and/or oxygen delivery tube, or other accessory.	Remove nasal cannula, face mask, or other accessories from oxygen tubing. If proper flow is restored, replace with new nasal cannula, face mask, or other accessories.
	Other leak or restriction.	Disconnect delivery tubing at oxygen outlet (front of unit). If proper flow is restored, check oxygen tubing for kinks or obstructions. Replace if needed. Contact your Equipment Provider.
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 (30.5 cm) away from a wall or other obstruction. Do not place the unit in a confined area. Allow oxygen tubing to dry out, or replace with new tubing. Refill humidifier bottle with COLD water. DO NOT OVERFILL.
Intermittent alarm sounds.	Equipment malfunction.	Set I/0 power switch to 0 position, use your reserve oxygen supply and consult your Equipment Provider immediately.
NewLife Intensity 10 displays alarm and produces intermittent beep.	Refer to Alarm Conditions table.	Refer to Alarm Conditions table.
Oxygen concentrator does not turn on.	Not connected to external power. General malfunction.	Power the unit through the outlet. Ensure that external connects are secure. Contact your Equipment Provider, and change to another source of oxygen as necessary.
All other problems.		Set I/0 power switch to the 0 position, use your reserve oxygen supply and consult your Equipment Provider immediately.

Accessories

For proper performance and safety, use only these listed accessories supplied by CAIRE through your oxygen provider. Use of accessories not listed below could adversely affect the performance and/or safety of the concentrator. The following oxygen administration accessories are recommended for use with the NewLife Oxygen Concentrator.

NewLife Intensity 10 Standard Accessories	
Nasal Cannula with 7 feet (2.1 m) of tubing (6 LPM max)	CU002-1
Oxygen Outlet Adapter	F0025-1
Face Mask with 7 feet (2.1 m) of tubing (10 LPM max)*	MS013-1
Humidifier Adapter Extension	HU002-1
Humidifier Bottle for Intensity models (6-15 LPM)	HU014-1
SureFlow	FM069

*Face mask should only be used with NewLife Intensity 10 models.

Note: Additional options may be available for country-specific power cords where noted above. Contact CAIRE or your oxygen provider if alternate options are needed for order.

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

EMC Testing

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

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
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.		
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	±8 kV contact ±15 kV air	±8 kV contact ±15 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	± 2kV common mode on AC lines ± 1kV differential on AC lines ±- 2kV common mode on outdoor I/O lines	N/A ± 1kV differential on AC lines N/A	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	0% U_T for 0.5 cycles (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0°) 70% U_T (30% dip in U_T) for 25/30 cycles (0°) 0% U_T for 250/300 cycles (0°)	0% U_T for 0.5 cycles (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0°) 70% U_T (30% dip in U_T) for 25/30 cycles (0°) 0% U_T for 250/300 cycles (0°)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NewLife Intensity 10 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	30 A / m	30 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, 1 kHz or 2 kHz, 80% AM modulation (6V in ISM and amateur radio band in this range for home environment)	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
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz, 1 kHz 80% modulation for home environment	10 V/m	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ from 800 MHz to 2.5 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: 

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.

NOTE 3 Under some radiated immunity conditions the concentrator may shut down and automatically restart.

NOTE 4 Under some radiated immunity conditions the concentrator low oxygen concentration warning light may activate due to interference.

[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 Intensity 10 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 Intensity 10.

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

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHZ deviations 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4.25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAM, 802.11 b/g/n. RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT OR ME SYSTEM may be reduced to 1m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only uplink frequencies are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The manufacturer should consider reducing the minimum separation distance, based on risk management, and using higher immunity test levels that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher immunity test levels should be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum distance in m, and E is the immunity test level in V/m.

If the ME EQUIPMENT or ME SYSTEM complies with higher immunity test levels or this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher immunity test levels.

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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

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.

Notes

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