

VisionAire® 5

User Manual (EN)

CAIRE®

User Controls & System Status Indicators

ISO 7000	
	Read user's manual before operation. Reg. # 1641
	Keep away from rain, keep dry. Reg. # 0626
	Stacking limit by number. Reg. # 2403
	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
	Storage or operating temperature limitation range Reg. # 0632
	Storage humidity range Reg. # 2620
	This way up. Reg. # 0623
	Fragile, handle with care. Reg. # 0621
	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.
	2018 Labeling: When present on the device alarm panel indicates low oxygen concentration in device output.
	ON (power switch on)
	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 Reg. # 5.7.10
QPS Electrical Safety Certification	
c PS us	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/.

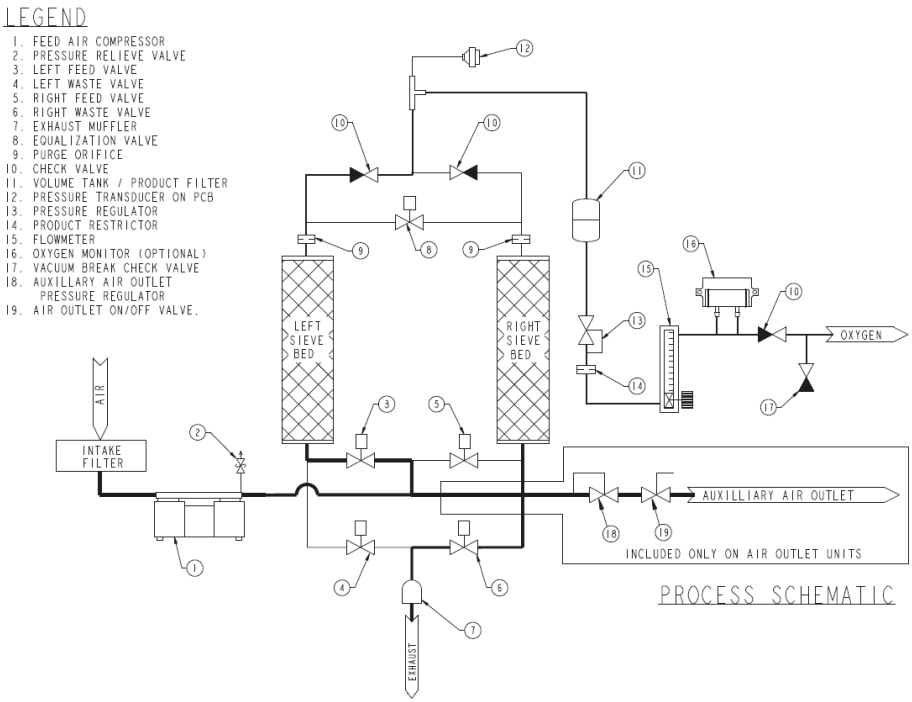
VisionAire Oxygen Concentrator

This User Manual will acquaint you with CAIRE's VisionAire 5 Oxygen Concentrator and all variations available. Make sure you read and understand all of the information contained in this guide before operating your concentrator. 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 VisionAire 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.



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.

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

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

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 recharge anywhere AC or DC power. 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 Disease (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.

Safety Features

The following information will acquaint you with safety features of the VisionAire 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.



Device warning label and alarm display.

- Compressor Motor: 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).

- 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 33psig (±1)
  - Low device product tank pressure condition of less than 5psig (±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: The oxygen monitor detects any drop in concentration below 82%. If this occurs the low oxygen concentration warning light (O_2) will illuminate. If the low O2 condition persists, an audible intermittent alarm will also activate in addition to the alarm light.
- 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. See label image.
- Product Filter: ≥ 10 µm filter

Unpacking Your VisionAire

Verify that all of the components listed are included in the package. If any items are missing, contact your oxygen provider immediately.
• Stationary Oxygen Concentrator

Getting to Know Your VisionAire Oxygen Concentrator

First, become familiar with the important parts of your VisionAire Oxygen Concentrator.

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. 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 connection for a humidifier (if required) or cannula.
F. Top and Side Handles: Enables convenience in carrying the unit.
G. Warning and Alarms Label
H. Specification Label: Displays electrical specifications and serial number.
I. Power Cord: Allows connection of unit into electrical outlet.
J. Casters: Four casters enable unit to be easily moved, as needed.
K. Humidifier Bottle Recess: Area to place the optional humidifier bottle.
L. Humidifier Bottle (optional)
M. Humidifier Bottle Oxygen Outlet: Connection for oxygen tubing/cannula.
N. Humidifier Bottle Oxygen Outlet
O. Humidifier Bottle Tubing
P. Humidifier Bottle Fitting
Q. Oxygen Tubing / Cannula



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 1a

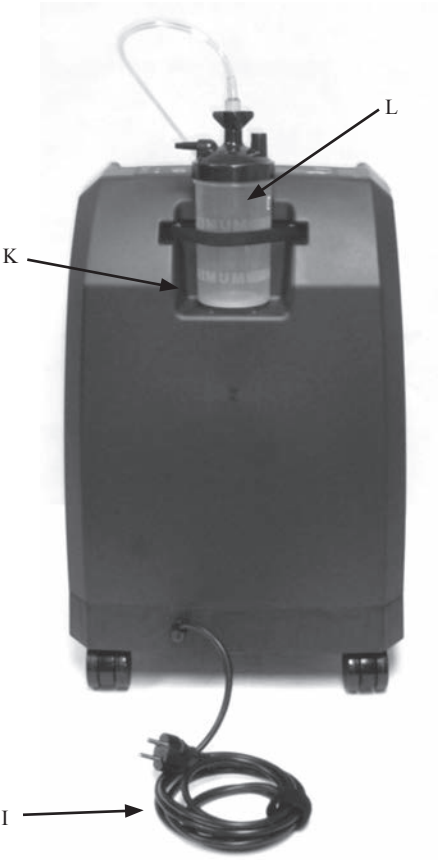
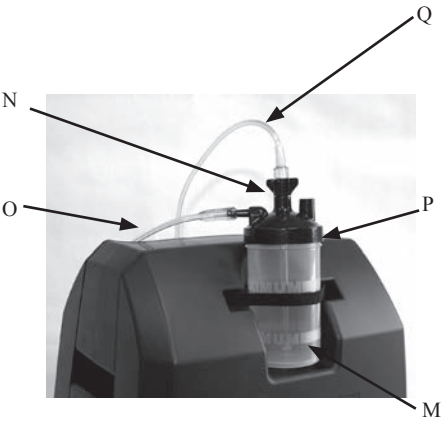




Figure 1b



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 VisionAire Family.

Note: Information needing special attention.

Indications for Use

Intended Use

The CAIRE VisionAire 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 VISIONAIRE INTENSITY OXYGEN CONCENTRATOR.

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

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

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 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.

WARNING: CLEAN THE CABINET, CONTROL PANEL, AND POWER CORD ONLY WITH A MILD DISINFECTANT 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 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: ENVIRONMENTAL CONDITIONS CAN AFFECT PERFORMANCE OF DEVICE. LOCATE IN CLEAN, PEST-FREE ENVIRONMENT.

WARNING: DEVICE SHOULD ONLY BE OPERATED BY END USERS, TRAINED CARE-GIVERS OR TRAINED TECHNICIANS. CHILDREN SHOULD NOT OPERATE DEVICE.

WARNING: TO ENSURE RECEIVING THE THERAPEUTIC AMOUNT OF OXYGEN DELIVERY ACCORDING TO YOUR MEDICAL CONDITION THE VISIONAIRE 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.

WARNING: USE OF THIS DEVICE AT AN ALTITUDE, TEMPERATURE, OR RELATIVE HUMIDITY OUTSIDE OF THE SPECIFIED VALUES LISTED IN THIS MANUAL CAN ADVERSELY AFFECT THE FLOWRATE AND THE OXYGEN CONCENTRATION, AND CONSEQUENTLY THE QUALITY OF THE THERAPY.

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.

WARNING: DO NOT TOUCH THE OXYGEN OUTLET LONGER THAN 10 SECONDS DURING OPERATION TO PREVENT THERMAL INJURY. DO NOT TOUCH THE BOTTOM OF THE CONCENTRATOR LONGER THAN 10 SECONDS DURING OPERATION. DO NOT TOUCH OTHER PLASTIC PARTS LONGER THAN 1 MINUTE DURING OPERATION. THE OXYGEN OUTLET CAN REACH TEMPERATURES UP TO 43°C IN NORMAL AND COVERED VENTILATION CONDITIONS.

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 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.

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

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

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

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

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 VisionAire Oxygen Concentrator must be operated for at least five minutes at 2 LPM before using the unit.

The VisionAire 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.

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

- Humidifier Bottle: Part No. HU003-1
- Nasal Cannula with 7 feet (2.1 m) of tubing (6 LPM max): Part No. CU002-1

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

Note: To Equipment Provider: A firebreak is recommended/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 VisionAire. 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: 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.



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.

Operating Instructions

Review the following information before you operate your oxygen concentrator.

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.

Humidifier Bottle (Optional)

If additional humidification is required with your oxygen therapy, perform the following steps each time you fill or clean the humidifier, which may have been initially set up for your use.

1. Remove the humidifier bottle from the humidifier bottle recess.
2. Open the humidifier bottle. If you have a prefilled bottle, do not perform this step. Proceed to step 5.
3. Fill the humidifier bottle with cool or cold water (distilled water is preferred) to the fill line indicated on the bottle. DO NOT OVERFILL.
4. Re-connect the top cover to the humidifier bottle.
5. Place the humidifier bottle in the humidifier bottle recess on the back of the concentrator and connect the humidifier bottle tubing to the oxygen outlet and the humidifier bottle fitting.

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.

Cannula Connection

Connect the tubing and cannula to the unit's oxygen outlet, or to the optional humidifier's oxygen outlet.

Note: Cannula must be non-kinking, which can be used for a total length of 50 ft. (15,2 m) max.

Ensure the cannula is fully inserted and secure. You should hear or feel oxygen flow to the prongs of the nasal cannula. If oxygen does not seem to flow, first verify that the 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.

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.

Starting the Concentrator

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: 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.

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: 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

CAUTION: Oxygen Concentrator to overheat and impair performance.

1. Locate the unit near the electrical outlet in the room where you spend most of your time.
2. Insert the power cord plug into the electrical outlet.
3. Set the I/0 power switch to the "I" position to turn the unit on. An audible alarm will loudly sound for approximately 1 seconds.
4. The low oxygen concentration indicator remains on for a few minutes and until the oxygen concentration reaches minimum concentration requirements, (only pertains to unit equipped with an Oxygen Monitor)
5. To set the 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 number line must give appearance of one line.
6. The concentrator is now ready for use.



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: Ensure concentrator is operated in an upright position.

Note: Optimal oxygen concentration is obtained within 10 minutes after the device is switched on (90% of the concentration is obtained after approximately 5 minutes).

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.

Turning the Concentrator Off

Set the I/0 power switch to the "0" position to turn off the unit.

Cleaning, Care, and Proper Maintenance

Cabinet

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 AND DURING THERAPY. NEVER USE PETROLEUM OR OIL-BASED LOTIONS OR SALVES TO AVOID THE RISK OF FIRE AND 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 DISINFECTANT 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: CLEAN THE CABINET, CONTROL PANEL, AND POWER CORD ONLY WITH A MILD DISINFECTANT 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.

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.

Use a mild disinfectant applied with a damp cloth or sponge to clean the exterior of the concentrator, and then wipe all surfaces dry. Do not allow any liquid to get inside the device. Device cabinet should be cleaned at a minimum between users.

Humidifier Bottle (optional)

- Check water level daily and add water as needed
- To clean and disinfect the humidifier, follow your Equipment Provider's instructions, or the instructions included with the humidifier bottle.

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	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 VisionAire 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. Maintenance is the responsibility of the provider and will be tracked by the provider.

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

Note: If the unit has not been used for an extended time period, it needs to operate for a minimum of 15 minutes before power failure alarm can become activated.

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.	Press (do not hold in) the circuit breaker reset button in the front of the unit. If the circuit breaker trips again or the alarm continues to sound after the unit is turned on, contact your Equipment Provider.
Limited oxygen flow.	Dirty or obstructed humidifier bottle.	Remove the humidifier bottle 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 and check accessories for kinks or obstructions. Replace if needed.
	Cannula tubing loose.	Check cannula tubing connection at control panel.
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. Refill humidifier bottle with COLD water. DO NOT OVERFILL. Allow oxygen tubing to dry out, or replace with new tubing.
Intermittent alarm sounds.	See 'Safety Features' section for a description of auditory indicators.	Set I/0 power switch to 0 position, use your reserve oxygen supply and consult your Equipment Provider immediately.

Problem	Probable Cause	Solution
Oxygen monitor light remains lit (yellow).	Oxygen concentration is ≤ 82%.	Set I/0 power switch to the 0 position, use your reserve oxygen supply (if provided), and consult your Equipment Provider immediately.
All other problems.		Set I/0 power switch to the 0 position, use your reserve oxygen supply and consult your Equipment Provider immediately.

Specifications

	VisionAire 5
Outlet Pressure	9 PSIG Max.
Flow Rates*	1 LPM – 5 LPM ±10% of indicated setting, or 200 mL, whichever is greater*
Dimensions	14.1 in. W x 11.5 in. D x 20.8 in. H (35.8 cm W x 29.2 cm D x 52.8 cm H)
Weight	30 lbs (13.6 kg)
Sound Pressure Level**	39,53 dB(A) ± 0,41 dB(A) @ 3 LPM
Power Consumption	290 Watts
O2 Concentration	90% (5.5% to / -3%)
Maximum Output Pressure	9 PSIG (62 KPa)
Electrical Requirements	230VAC /50 Hz, 1.5A 230VAC / 60 Hz, 1.5A
Operating Environment*	5–40° C (41–104° F) at altitudes from up to 10,000 ft (3048 m) above sea level. 15 - 90% relative humidity (non-condensing)
Altitude	-1250 to 10,000 ft (-381–3048 m) (tested to 700–1060 hPa)
Storage Environment	-25–70° C (-13–158°F). 0–90% relative humidity (non-condensing)

* Based on an atmospheric pressure range of 700 hPa to 1060 hPa at 70°F (21°C)
** Sound level measured per test method Nr. 14-1 10/2018 MDS-Hi.

The expected service life of the equipment is a minimum of five years.

See Technical Manual (PN MN138-1) for Sound Power Level.

WARNING: USE OF THIS DEVICE AT AN ALTITUDE, TEMPERATURE, OR RELATIVE HUMIDITY OUTSIDE OF THE SPECIFIED VALUES LISTED IN THIS MANUAL CAN ADVERSELY AFFECT THE FLOWRATE AND THE OXYGEN CONCENTRATION, AND CONSEQUENTLY THE QUALITY OF THE THERAPY.

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

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.

VisionAire Family Standard Accessories	
Humidifier Bottle (6-15 LPM)	Part Number – HU003-1
Cannula, 25 feet (7.6 m) (6 LPM max)	Part Number – CU002-4
Humidifier Bottle Tubing	Part Number – TU255-1
Humidifier Bottle Fitting	Part Number – F0655-1
Oxygen Tubing, 25 feet	Part Number – CU004-3
Tubing/Cannula Connector	Part Number – CU009-1

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.

Note: Replace all disposable accessories such as cannula, humidifier bottle, tubing, and connector as recommended by the accessory manufacturer or your home care provider.

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The VisionAire 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 VisionAire 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	

Recommended separation distances between portable and mobile RF communications equipment and the VisionAire Units

The VisionAire is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VisionAire can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VisionAire 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		
	from 150 kHz to 80 MHz $d = 1.2\sqrt{P}$	from 80 MHz to 800 MHz $d = 1.2\sqrt{P}$	from 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.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The VisionAire is intended for use in the electromagnetic environment specified below. The customer or the user of the VisionAire 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 earth	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) 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 VisionAire requires continued operation during power mains interruptions, it is recommended that the VisionAire is powered from an uninterruptible power supply (UPS).
Power frequency 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 VisionAire is intended for use in the electromagnetic environment specified below. The customer or the user of the VisionAire 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 VisionAire, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ = 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ = 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 metres (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 VisionAire is used exceeds the applicable RF compliance level above, the VisionAire should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VisionAire.

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

Method of Disposal

Disposal of Waste

All waste from CAIRE's VisionAire Oxygen Concentrator must be disposed using the appropriate methods specified by local authorities

Disposal of Device

In order to preserve the environment, the concentrator must be disposed using the appropriate methods specified by local authorities.

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

Method of cleaning and infection control allowed:

Please refer to Maintenance section in the VisionAire 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.

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.

Warranty

Limited Warranty Statement and Liability Disclaimer for CAIRE VisionAire (“Equipment”)

CAIRE Inc. (“CAIRE”) provides limited warranty coverage for its equipment. The specific terms, conditions, and duration of any applicable warranty are documented separately and may vary by product, region, or purchase agreement (the “Warranty Statement”). A copy of the Warranty Statement is provided with the user manual. For additional copies or questions, please contact CAIRE Customer Service by e-mail at customerservice.europe@caireinc.com.

Except as expressly stated in the applicable Warranty Statement, CAIRE makes no other warranties, express or implied, including any implied warranties of merchantability or fitness for a particular purpose.

TO THE FULLEST EXTENT PERMITTED BY LAW, CAIRE SHALL NOT BE LIABLE FOR, AND PURCHASER SHALL INDEMNIFY, DEFEND AND HOLD CAIRE HARMLESS FROM ANY CLAIMS ARISING OUT OF THE USE, SALE, OR LEASE OF THE EQUIPMENT, CAIRE’S COMPLIANCE WITH PURCHASER’S DESIGNS, SPECIFICATIONS OR INSTRUCTIONS, OR MODIFICATION OF ANY EQUIPMENT BY PARTIES OTHER THAN CAIRE, PURCHASER’S FAILURE TO COMPLY WITH THE APPLICABLE WARRANTY STATEMENT, OR USE OF THE EQUIPMENT IN COMBINATION WITH OTHER EQUIPMENT. PURCHASER’S RECOVERY FROM CAIRE FOR ANY CLAIM SHALL NOT EXCEED PURCHASER’S PURCHASE PRICE FOR THE EQUIPMENT GIVING RISE TO SUCH CLAIM, AND PURCHASER SHALL NOT IN ANY EVENT BE ENTITLED TO, AND PURCHASER SHALL INDEMNIFY, DEFEND AND HOLD CAIRE HARMLESS FROM, ANY CLAIMS FOR, INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY NATURE. THE FOREGOING SHALL APPLY IRRESPECTIVE OF THE NATURE OF THE CLAIM, WHETHER BASED ON CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE. THE REMEDIES AND WARRANTIES STATED IN THE WARRANTY STATEMENT ARE EXCLUSIVE AND IN LIEU OF ALL OTHER REMEDIES AND WARRANTIES GRANTED UNDER APPLICABLE LAW, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF QUALITY, PERFORMANCE AND DESIGNS, AND ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR ARISING FROM COURSE OF DEALING OR USAGE OF TRADE, ALL OF WHICH ARE HEREBY EXPRESSLY DISCLAIMED BY CAIRE.

Contact Information

Questions about VisionAire?

Please contact CAIRE at:
customerservice@caireinc.com
800-482-2473
2200 Airport Industrial Drive, Suite 500,
Ball Ground, GA 30107

Questions about your condition or prescription?

Please contact your prescribing physician or healthcare provider.

North America: Adverse Events

Healthcare Professionals and Consumers:

To report an adverse event experienced while using your VisionAire 5, please contact CAIRE customer service at customerservice@caireinc.com

Or report directly to:

- US: United States Food and Drug Administration (FDA) at MedWatch: www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or 1-800-FDA-1088.
- Canada: Visit Health Canada at www.canada.ca/en/health-canada to Report a medical device problem.
- In an emergency, please dial 911.

Europe: Serious Incidents

Healthcare Professionals and Consumers:

To report a serious incident experienced while using the VisionAire 5, please report the serious incident to your service provider and CAIRE customer service at customerservice.europe@caireinc.com.

The serious incident may also be reported directly to the Member State's national competent authority for medicinal products.

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