saros™

Oxygen System

OPERATOR MANUAL

MODEL 4000

CAIRE®

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

MN255-1 E

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 MAY RESULT.

DEFINITION OF SYMBOLS PAGE / WARNING PAGE

WARNING: INDICATES A HAZARDOUS SITUATION THAT, IF NOT AVOIDED, COULD RESULT IN DEATH OR SERIOUS INJURY.

CAUTION: Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTE: Indicates information considered important, but not hazard-related (e.g. messages relating to property damage).

SYMBOLS USED IN THE OPERATION OF SAROS

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

ISO 7000	
	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
	Atmospheric pressure limitation. Reg. # 2621
	This way up. Reg. # 0623

	Fragile, handle with care. Reg. # 0621
	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.
O_2	Oxygen Output
A	Amperes
	Alert (Yellow) Indicator*: When illuminated, this indicates an awareness condition or Caution.
	ON/OFF (Standby); Powers the device ON or OFF, but does not directly disconnect the main power.
	Increase Flow Setting; Increases the flow setting by 1.0 LPM increments or by 1 pulse setting each time the button is pressed.
	Decrease Flow Setting; Decreases the flow setting by 1.0 LPM increments or by 1 pulse setting each time the button is pressed.
	Activates either Continuous Flow Mode or Pulse Flow Mode Operation.
	Utility; The Button that activates a utility menu to access information or to change settings.
	External Power is Present Indicator; Indicates the presence of external power.
	Battery Status Indicator; Shows the amount of charge remaining in the battery. When charging, battery displays as a "Waterfall" Effect.
	"Alarm Off" indicator displayed during Tactical Mode.
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, Double Insulated Reg. # 5172
	Alternating Current Reg. # 5032
	Direct Current Reg. # 5031
21 CFR 801.15	
RX ONLY	Federal law restricts this device to sale by or on the order of a physician.
IEC 60601-1	
IP33	Protected from tools and wires greater than 2.5 millimeters, Protected from water spray less than 60 degrees from vertical.
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.

*Alarms for the SAROS are considered information-only signals.

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/.

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ILLUSTRATIONS

TABLES

INDICATIONS FOR USE

SAROS oxygen system is indicated for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities. The SAROS can be used in the Military Medical Service that is operationally used for medical assemblages, such as the Expeditionary Medical Support (EMEDS) and En-Route Patient Staging System (ERPSS), in deployed scenarios, including wartime operations, deterrence and humanitarian and contingency operations.

The SAROS is used by patients suffering from discomfort due to ailments which affect the efficiency of one's lungs to transfer the oxygen in air to their bloodstream. The device will be operated by a trained medical technician or clinician with a working knowledge of oxygen concentrators. A physician has prescribed a specific oxygen flow setting to meet an individual's needs. Oxygen flow should be adjusted only under the direction of a physician.

The SAROS uses a vacuum pressure adsorbent process to separate oxygen from the air and deliver oxygen rich gas to a patient through a nasal cannula.

	**WARNING: FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

INDICATIONS

	**WARNING: IN CERTAIN CIRCUMSTANCES, THE USE OF NON-PRESCRIBED OXYGEN CAN BE HAZARDOUS. THIS DEVICE SHOULD ONLY BE USED UNDER THE DIRECTION OF A PHYSICIAN OR QUALIFIED CLINICIAN.** **NOT FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.** **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 SAROS SERVICED BY A QUALIFIED TECHNICIAN. SAROS IS NOT APPROPRIATE FOR ANY PATIENT WHO WOULD EXPERIENCE ADVERSE HEALTH CONSEQUENCES AS THE RESULT OF SUCH TEMPORARY INTERRUPTION.** **USE OF AN OXYGEN MASK IS CONTRAINDICATED DUE TO THE POSSIBILITY OF REBREATHING EXHALED CARBON DIOXIDE.**
	**WARNING: EXHAUST GAS MAY REACH HIGH TEMPERATURES DURING NORMAL OPERATIONS. USE CAUTION TO AVOID TOUCHING THE EXHAUST PORT OF THE SAROS WHILE IN USE.**
	**WARNING: THERE IS A RISK OF FIRE ASSOCIATED WITH OXYGEN THERAPY. DO NOT USE CONCENTRATOR OR ACCESSORIES NEAR SPARKS OR OPEN FLAMES.**
	**WARNING: SMOKING DURING OXYGEN THERAPY IS DANGEROUS AND IS LIKELY TO RESULT IN SERIOUS INJURY OR DEATH OF THE PATIENT AND OTHERS FROM FIRE.**
	**WARNING: OPEN FLAMES DURING OXYGEN THERAPY ARE DANGEROUS AND IS LIKELY TO RESULT IN FIRE OR DEATH. DO NOT ALLOW OPEN FLAMES WITHIN 2 METERS OF THE OXYGEN CONCENTRATOR OR ANY OXYGEN CARRYING ACCESSORIES.**
	**WARNING: SMOKING DURING OXYGEN THERAPY IS DANGEROUS AND IS LIKELY TO RESULT IN FACIAL BURNS OR DEATH. DO NOT ALLOW SMOKING WITHIN THE SAME ROOM WHERE THE OXYGEN CONCENTRATOR OF ANY OXYGEN CARRYING ACCESSORIES ARE LOCATED. IF YOU INTEND TO SMOKE, YOU MUST ALWAYS TURN THE OXYGEN CONCENTRATOR OFF, REMOVE THE CANNULA AND LEAVE THE ROOM WHERE EITHER THE CANNULA OR MASK OR THE OXYGEN CONCENTRATOR IS LOCATED. IF UNABLE TO LEAVE THE ROOM, YOU MUST WAIT 10 MINUTES AFTER YOU HAVE TURNED THE OXYGEN CONCENTRATOR OFF BEFORE SMOKING.**

NOTE: Auditory alarms may not be heard in noisy environments and/or in tactical mode. Care providers must rely on visual indications to determine if there are any alarms or other system malfunctions. Care providers should monitor the SAROS for any alarm conditions.

CONTRAINDICATIONS

SAFETY GUIDELINES

These are Warnings and Cautions that apply to hazards or unsafe practices that could result in serious injury or property damage.

	WARNING: FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
	WARNING: DO NOT USE SAROS IF IT HAS A DAMAGED POWER CORD OR PLUG.
	WARNING: DO NOT DROP OR INSERT ANY OBJECTS INTO ANY OPENING ON THE DEVICE.
	WARNING: DO NOT BLOCK THE AIR INLET OR THE EXHAUST VENT OF THE SAROS WHEN IT IS ON A SOFT SURFACE, SUCH AS A LITTER, BED, CHAIR, CARPET, COUCH OR VEHICLE SEAT.
	WARNING: DO NOT COVER THE DEVICE WITH A BLANKET, TOWEL OR SHEET, ETC.
	WARNING: DO NOT STORE THE SAROS WITH THE BATTERY INSTALLED IN THE UNIT.
	WARNING: DO NOT REMOVE THE COVER. THERE ARE NO USER-SERVICEABLE PARTS INSIDE THE DEVICE. ONLY QUALIFIED SERVICE PERSONNEL SHOULD REMOVE THE COVER OF THE DEVICE.
	WARNING: DO NOT MODIFY THIS EQUIPMENT WITHOUT AUTHORIZATION OF THE MANUFACTURER.
	WARNING: DO NOT OPERATE THE DEVICE, COMPONENTS OR ACCESSORIES ON WET SURFACES OR IN STANDING WATER AND DO NOT SUBMERSE IN WATER.
	WARNING: GERIATRIC, PAEDIATRIC OR ANY OTHER PATIENT UNABLE TO COMMUNICATE DISCOMFORT CAN REQUIRE ADDITIONAL MONITORING AND OR A DISTRIBUTED ALARM SYSTEM TO CONVEY THE INFORMATION ABOUT THE DISCOMFORT AND OR THE MEDICAL URGENCY TO THE RESPONSIBLE CARE GIVER TO AVOID HARM.
	WARNING: OXYGEN MAKES IT EASIER FOR A FIRE TO START AND SPREAD. DO NOT LEAVE THE NASAL CANNULA OR MASK ON BED COVERINGS OR CHAIR CUSHIONS, IF THE OXYGEN CONCENTRATOR IS TURNED ON, BUT NOT IN USE; THE OXYGEN WILL MAKE THE MATERIALS FLAMMABLE. TURN THE OXYGEN CONCENTRATOR OFF WHEN NOT IN USE TO PREVENT OXYGEN ENRICHMENT.
	WARNING: IF YOU FEEL DISCOMFORT OR ARE EXPERIENCING A MEDICAL EMERGENCY WHILE UNDERGOING OXYGEN THERAPY, SEEK MEDICAL ASSISTANCE IMMEDIATELY TO AVOID HARM.
	WARNING: WIND OR STRONG DRAUGHTS, INCLUDING AN OPEN WINDOW OR FAN, CAN ADVERSELY AFFECT ACCURATE DELIVERY OF OXYGEN THERAPY.
	WARNING: THE SETTINGS OF OTHER MODELS OR BRANDS OF OXYGEN THERAPY EQUIPMENT DO NOT CORRESPOND WITH THE SETTINGS OF THE SAROS MODEL 4000.
	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: 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.

	**CAUTION: INDICATES A HAZARDOUS SITUATION THAT, IF NOT AVOIDED, COULD RESULT IN MINOR OR MODERATE INJURY.**
	**CAUTION: KEEP SAROS AND THE POWER CORD AWAY FROM HOT SURFACES OR OPEN FLAMES.**
	**CAUTION: SAROS SHOULD BE LOCATED IN A WELL-VENTILATED AREA TO ALLOW FOR ADEQUATE AIR INTAKE.**
	**CAUTION: AVOID THE INTAKE OF AIRBORNE POLLUTANTS, SMOKE AND FUMES.**
	**CAUTION: ONLY USE THIS DEVICE WITH ACCESSORIES SPECIFIED BY, OR RECOMMENDED BY CAIRE INC.**
	**CAUTION: IF SAROS HAS BEEN DROPPED, DAMAGED OR EXPOSED TO WATER, PLEASE CONTACT A QUALIFIED TECHNICIAN FOR INSPECTION OR POSSIBLE REPAIR OF THE DEVICE.**
	**CAUTION: WHEN USING SAROS IN ANY VEHICLE, BE SURE IT IS PROPERLY SECURED, BELTED OR RESTRAINED.**
	**CAUTION: LOCATE OXYGEN SUPPLY TUBING AND ALL POWER CORDS IN A MANNER TO PREVENT TRIPPING HAZARDS.**
	**CAUTION: DO NOT PLACE THE SAROS IN A SMALL, ENCLOSED SPACE, SUCH AS A BATHROOM, CLOSET, BAG OR BOX WITH THE OXYGEN CANNULA OR TUBING LEADING OUT OF THE ENCLOSED SPACE.**
	**CAUTION: DO NOT EXPOSE THE DEVICE TO TEMPERATURES OUTSIDE OF THE SPECIFIED RANGE OF OPERATING OR STORAGE TEMPERATURES AS THIS MAY DAMAGE THE DEVICE.**

NOTE: THIS DEVICE MUST COOL FROM THE MAXIMUM STORAGE TEMPERATURE BETWEEN USES UNTIL IT IS READY FOR TEMPERATURES FOR INTENDED USE.
NOTE: SAROS UNIT MUST BE CONSTRAINED OR MOUNTED TO PREVENT DAMAGE TO UNIT OR INJURY TO USER WHILE IN USE.
NOTE: THIS DEVICE DOES EXHAUST NITROGEN GAS. HOWEVER, THIS EXHAUST IS NOT SUFFICIENT TO DISPLACE OXYGEN IN THE OPERATING ENVIRONMENT. NO ADDITIONAL SAFETY PRECAUTIONS NEED TO BE TAKEN TO ACCOUNT FOR THE NITROGEN EXHAUST.
NOTE: PROTECT ELECTRICAL POWER CORDS FROM SHARP EDGES OR ELECTRICAL SHOCK AND SERIOUS PHYSICAL INJURY MAY OCCUR.
NOTE: ONLY USE THE CAIRE INC. SUPPLIED AC POWER ADAPTER AND 24 VDC CABLE WITH THE SAROS. USE OF ANY OTHER AC POWER ADAPTER OR DC CABLE MAY BE HAZARDOUS, CAUSE SERIOUS DAMAGE TO THE SAROS AND WILL VOID THE WARRANTY.
NOTE: AVAILABILITY OF AN ALTERNATE, OR BACK-UP, SOURCE OF SUPPLEMENTAL OXYGEN IS RECOMMENDED IN CASE OF A POWER OUTAGE OR A MECHANICAL FAILURE OF THE DEVICE.

BATTERY SAFETY

	**WARNING: DO NOT DISASSEMBLE, PUNCTURE, OR CRUSH THE BATTERY. BATTERY ELECTROLYTES MAY BE TOXIC IF SWALLOWED AND CAN BE HARMFUL TO SKIN AND EYES. KEEP THE BATTERY AWAY FROM CHILDREN.**
	**WARNING: DO NOT SHORT-CIRCUIT THE BATTERY'S METAL CONTACTS WITH METALLIC OBJECTS, SUCH AS KEYS OR COINS. THIS MAY CAUSE SPARKS OR EXCESSIVE HEAT TO BE GENERATED.**
	**WARNING: USE OF A DAMAGED BATTERY MAY CAUSE PERSONAL INJURY.**

	**WARNING: THE BATTERY MAY EXPLODE AND CAUSE POTENTIAL INJURY IF EXPOSED TO A FIRE, OR DISPOSED OF IN A FIRE.**
	**WARNING: EXPOSING THE BATTERY TO WATER OR OTHER LIQUIDS MAY CAUSE PERSONAL INJURY.**

	**CAUTION: DO NOT EXPOSE THE BATTERY TO TEMPERATURES ABOVE 140° F (60°C), SUCH AS IN A VEHICLE PARKED IN THE SUN ON A HOT DAY.**
	**CAUTION: IT IS NOT RECOMMENDED THAT THE BATTERY IS CHARGED BELOW 41° F (5° C) OR ABOVE 104° F (40° C).**
	**CAUTION: ONLY USE THE BATTERY FOR ITS INTENDED PURPOSE.**
	**CAUTION: PUSH LOCKING/UNLOCKING BUTTON BEFORE BATTERY INSTALLATION.**

1.0 INTRODUCTION

1.1 GENERAL INFORMATION

This manual will familiarize you with information regarding the SAROS Oxygen System, Model 4000.

INTRODUCTION
The SAROS Oxygen System, Model 4000 with autoSAT® Technology (hereafter referred to as SAROS) is a portable medical device used to extract oxygen from the atmosphere, concentrate it to greater than 90% and flow it through the oxygen outlet port. The device will operate in Continuous flow or Pulse flow modes. In Continuous Flow Mode the oxygen is provided at a constant flow rate of 1, 2, or 3 LPM. In Pulse flow Mode, oxygen is supplied in a bolus at the beginning of each inspiration, providing a selectable range setting of flow between 16 ml and 96 ml, in increments of 16 ml.

SAROS is BTP (Body, Temperature, and Pressure) compensated. It delivers oxygen by accounting for difference between ambient conditions and those found in the patient's lungs (37°C).

SAROS operates from external AC power, 24VDC or from a rechargeable Battery. The system includes a "Smart Battery" charger that recharges the Battery whenever the SAROS is connected to external power. The system monitors and controls both the power source and the Battery Charger.

SAROS has a recommended five minute warm up/stabilization period.

INTENDED USE
The CAIRE SAROS oxygen system is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

1.2 SAROS OXYGEN SYSTEM SPECIFICATIONS

Dimensions **• With Battery / • Without Battery**	26.80" long x 4.375" diameter (68.1 cm long x 11.1 cm diameter) / 23.25" long x 4.375" diameter (59.1 cm long x 11.1 cm diameter)	
Weight **• With Battery / • Without Battery**	12.25 pounds (5.56 kg) / 10.00 pounds (4.54 kg)	
Flow Settings **• Continuous Flow / • Pulse flow**	1, 2, 3 LPM / 16, 32, 48, 64, 80, 96 ml	
Continuous Flow Accuracy	1LPM: +/- 0.2 LPM / 2LPM: +/- 10% / 3LPM: +/- 10%	
Oxygen concentration	93% +/- 3% for all flow settings	
Maximum System Pressure	15 psig (103.4 kPa)	
Oxygen Output Pressure	4.0 psig (27.5 kPa) nominal	
Nominal Sound Level	<59 dB(A) at 3LPM	
Operating Environment **• Temperature** **• Humidity**	32ºF to 109ºF (0° to 43°C) 10% to 90%, Non-condensing, 82.4°F (28°C) Maximum Dew point	
Storage Environment **• Temperature / • Humidity**	-4ºF to 140ºF (-20° to 60°C) / Up to 90% Non-condensing	
Transient Environmental Operating Conditions **• Temperature / • Humidity**	32ºF to 109ºF (0° to 43°C) / Up to 90% Non-condensing	
Ambient Pressure Range	(506 hPa to 1060 hPa) or (-1253ft [-381m] to 18000ft [5486m])	
Nominal Power **3 LPM Continuous Flow**	≤130 Watts	
Nominal Battery operating time at 3 LPM Continuous Flow	30 Minutes	
Battery Life	80% Nominal Capacity after 200 Charge/Discharge cycles	
Continuous Flow Indication	Expressed in liters per minute (LPM)	
Audible Alarm Indicators	• Loss of Power/Hot Battery • Low Battery/Warm Battery • Low Oxygen Concentration	• No breath detection • O2 Flow Outside Normal Limits • Low 9V battery • Unit Malfunction
Audible Signal Characteristics	Alarms Signal - 200 msec Beep Info Signal - 100 msec Beep (Occurs as power-up confirmation, button push confirmation). Volume of all signals is fixed and are both the same volume.	
Visual Alarm Indicators	Yellow LED: Constant ON during alarm state / OFF when not in alarm state	
Back-Up Alarm Power	9V Internal Battery	
Filters	Air Inlet Filter, HEPA and Exhaust Filter	
Device Classification	IEC Class II, Type BF Applied Part, IP33	

Table 1-1. SAROS Specifications

Pulse Settings	16, 32, 48, 64, 80, 96 ml
autoSAT Technology	Servo-control to maintain consistent FiO2
Trigger Sensitivity	Adjustable settings of 1 (most sensitive), 2 and 3 (least sensitive)
Trigger Criteria	Cannula pressure has dropped below the trigger point (typically between 0.15 – 0.45 cm of H2O of negative pressure with a MAX trigger point of .50 cm H2O)
Minimum time between breaths	1.25 seconds (max 3 consecutive breaths)
Response to Missing Breaths	Switch to Continuous Mode if no inspiration has been detected for 60 seconds with an audible alarm.

Table 1-2. Pulse Mode Specifications

Bolus Size ml (± 15%)	**Max Breath Rate with Full Bolus Size**	**Max Breath Rate with Full Bolus Size within delivered oxygen capture time per ISO 80601-2-67:2014**
16	40	40
32	40	40
48	40	35
64	40	30
80	37	25
96	31	20

NOTE: At breath rate above Max Breath Rate, bolus size will be reduced proportionally.

Table 1-3. Bolus Volume and Breath Rates

	AC Power Supply	**24 VDC Cable**
Input Voltage	100- 240 VAC, 50 – 60 Hz 115V at 400Hz	20 – 28 VDC; 24VDC (Nominal)
Input Current	2.5- 1.3A	10 A
Output Voltage	24 VDC	-
Output Power	200 W	-

Table 1-4. Power Accessory Specifications

Output Voltage	14.4 VDC
Capacity	84.2 W-Hr
Battery Life	80% Nominal Capacity after 200 Charge/Discharge cycles
Battery Recharge Time	1.5 hours typical (3 hours max) to achieve 80% capacity from a fully discharged battery while operating at 3 lpm

Table 1-5. Battery Specifications

List of Items Furnished

Concentrator	Standard Power Sources	
		AC Power Adapter (9726-1-SEQ)
		AC Power Adapter Cord (North America) (4997-SEQ)
		AC Power Adapter Cord (EU) (4998-SEQ)
		24 VDC Cable (9727-SEQ)
		Battery (9723-SEQ; reorder PN 20952897)

Table 1-6. SAROS

Also includes: Nasal Cannulas (2), Operator Manual, a spare HEPA and air intake filter.
No additional parts required for standard operation.

2.0 INTRODUCTION TO YOUR SAROS OXYGEN SYSTEM

This operator manual will inform you about the use and care of the SAROS and its standard components. Please read thoroughly all of the information in this manual before operating the SAROS and receive proper training on the use and care of this device.

A PHYSICIAN HAS PRESCRIBED SUPPLEMENTAL OXYGEN AS PART OF A TREATMENT PLAN TO MEET AN INDIVIDUAL'S CLINICAL NEEDS. OXYGEN FLOW MODES AND SETTINGS SHOULD BE ADJUSTED ONLY UNDER THE ADVICE OF A PHYSICIAN OR CLINICIAN. THESE SHOULD BE PERIODICALLY REASSESSED FOR THE EFFECTIVENESS OF THE THERAPY.

A representation of the major features of the SAROS hardware interface are shown below:

- Membrane Panel containing:
  - Five tactile buttons allow control of all user controllable settings
  - Four variable intensity LED indicators provide overall status
  - An 8-character LCD display shows settings
- 9V Battery
- Oxygen Outlet Port
- External Power Connector
- Battery
- Simplified User Instructions Label
- Main / Rating Label
- Air Inlet Filter
- HEPA Filter

2.1 DESCRIPTION OF THE SAROS ASSEMBLY—SHIPPABLE

Become familiar with the key features of the SAROS and the user control panel.

ADDITIONAL PARTS

24 VDC Cable: 9727-SEQ
AC Power Supply 9726-1-SEQ and Power Cord 4997-SEQ (North America) or 4998-SEQ (EU)
Carry Strap 21495456

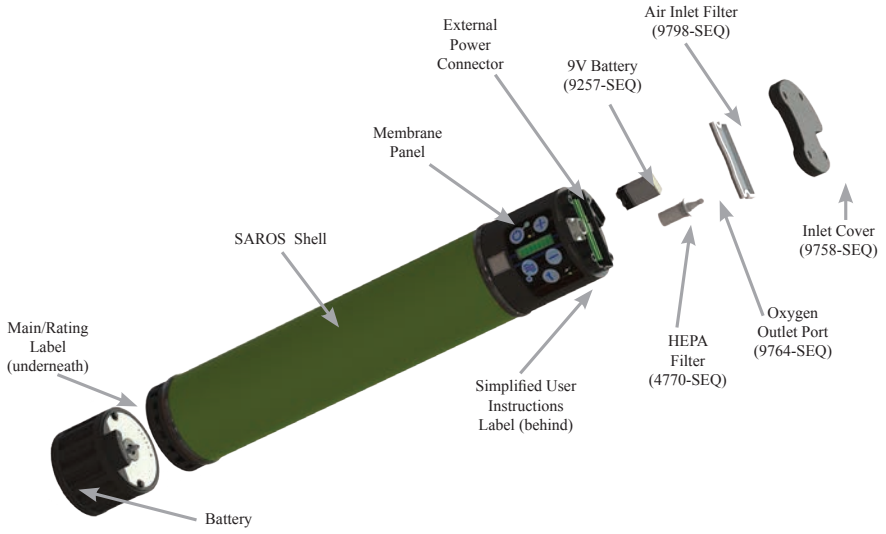
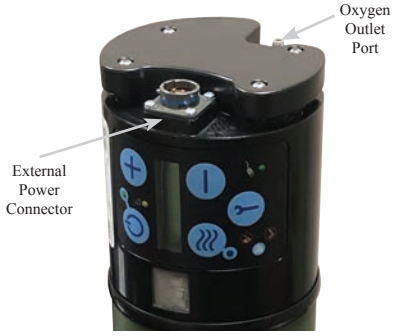


Figure 2-1. SAROS Components

FRONT – CONTROL PANEL

BACK – SIMPLIFIED INSTRUCTIONS

TOP



BOTTOM – WITHOUT BATTERY

BOTTOM WITH BATTERY

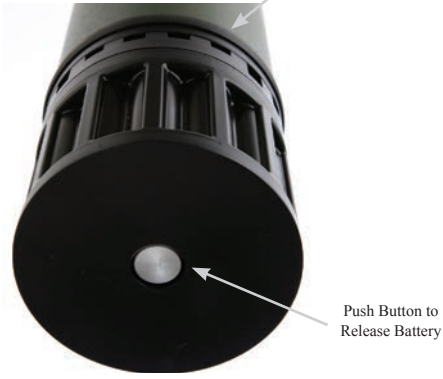


Figure 2-2. SAROS Components

Input/Output Connections

Oxygen Outlet Port: Oxygen supply tubing or a cannula is attached to this port.

Air Inlet Filter: Ambient air is drawn into the device through the air inlet located at the top of the device. This air inlet filter prevents dust / debris from entering the SAROS and should be cleaned regularly.

External Power Connector: The SAROS AC Power Adapter or 24 VDC Cable connects to this receptacle.

Exhaust Vent: Exhaust air from the SAROS leaves the device from this vent.

2.2 USER CONTROLS AND SYSTEM STATUS INDICATORS

The SAROS User Control Panel displays important operating information. This section will help you understand this operating information.

The SAROS has two modes: Normal and Tactical. To switch between these modes, depress Utility Button, and then the Decrease Button to switch between TACT=ON and TACT=OFF.

Normal Mode provides all LED indications with full brightness, full audio indicator sound and LCD backlight. The system always starts up in Normal Mode. Normal Mode is indicated by TACT=OFF.

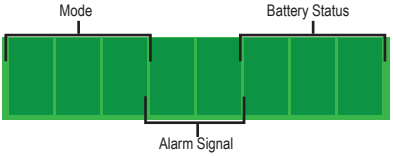
Tactical Mode is provided for operation where noise and light may compromise a situation. In these situations, the LED indicators will be off. Tactical Mode is indicated by TACT=ON.

Green and Yellow Indicators on the front panel indicate the operating condition of the device. For additional information on these indicators see the Alerts, Alarms and Troubleshooting Table in this manual.

	ON/OFF (Standby) and Power Indicator (Green): This button powers the device ON or powers it OFF. The Power Indicator is illuminated when the device is powered ON and operating in the Normal Mode and off when operating in Tactical Mode. If Power Indicator is blinking, there may be an issue with the power source. Check Alarm Section for more details.
	Increase or Decrease Flow Setting Button: Use these buttons to set the flow or to make selections in the Utility Menu.
	Delivery Mode Button and Indicator (Blue): The SAROS contains a button to toggle between Continuous Flow and Pulse Flow mode. The Pulse Flow mode activates autoSAT Technology – as breath rate changes, the system adjusts to provide a consistent bolus size. The Pulse Flow Mode allows a significant increase in operating time when powered by a Battery. When the Pulse Flow Mode is activated, the blue Flow Mode Indicator illuminates and a pulse of oxygen is delivered with each inspiratory effort. When the pulse of oxygen is delivered, the flow mode indicator turns off.
	ALERT (Yellow) Indicator: In Normal Mode, when illuminated, this indicates a low priority awareness condition or Caution. Continue to use your system and refer to the Alerts, Alarms, and Troubleshooting Table for the proper response.
N/A	Buzzer: An audible alarm (or buzzer) is used to alert you to the operating condition of the device, including Alarm and Info signals.
	Flow Setting Indicator: This is the main focus on your control panel. A clinician will correctly set the prescribed flow for either the CY - Continuous Flow Mode at Y LPM (1, 2 or 3) and/or the PXXX - Pulse Flow Mode XXX ml (16, 32, 48, 64, 80, 96) settings. Each time the device is turned ON, it will operate at C3 (3 LPM) continuous flow in the Normal Display Mode.
	Battery Status Gauge: This indicator displays the charge remaining in the Battery. When the Battery is fully charged all 5 gray bars are illuminated. Each gray bar represents approximately 20% of the total Battery charge. When the Battery is being charged, the charge indicator bars will waterfall. If the Battery is not installed, or if it is improperly installed, the Battery Status Gauge will not be illuminated and Time on Battery is not displayed.
	External Power is Present Indicator (green): When the SAROS is properly plugged in and is using the AC or 24 VDC Cable, this indicator will illuminate on the User Control Panel in Normal Mode.
	“Alarm Off” indicator displayed during Tactical Mode.

Table 2-1. User Controls and Indicators

Definition of LCD display screen.



Mode

Normal mode, Pulse Dose. P indicates Normal mode. XX is the Pulse Dose value 16 to 96.

Tactical mode, Pulse dose. Symbol indicates Tactical mode. XX is the Pulse Dose value 16 to 96.

Normal mode, Continuous Flow. C indicates Continuous Flow. Y is flow level 1 to 3.

Tactical mode, Continuous Flow. Symbol indicates Tactical mode. Y is flow level 1 to 3.

Alarm Signal

Blank fields indicate no alarm conditions present.

ZZ indicates an alarm condition is present. See Alarm Table for alarm definitions.

Battery Status

Blank fields indicate no battery attached.

Symbol indicates battery. TT is time remaining on battery.

Battery icon indicates battery is present and discharging and current battery charge level. TT is time remaining at the current battery consumption level.

Battery icon indicates battery is present and discharging and current battery charge level. T indicates hour of remaining battery at current setting, and .t indicates the tens of minutes, with 1=10 minutes, 2=20 minutes, through 5=50 minutes.

Animated (waterfall) battery icon with any charge level and no time displayed indicates battery charging. Animation will pause on one charge level, which indicates current battery charge level.

Blinking battery icon indicates a battery error condition or a battery charge level of less than 15 minutes remaining at the current setting.

Battery at full charge.

Battery at 80% charge.

Battery at 60% charge.

Battery at 40% charge.

Battery at 20% charge.

Battery at 0% charge.

Examples of LCD display during Normal Mode with Continuous Flow

Example of LCD Display indicates the following information: Normal mode, Continuous Flow at 1 LPM, no alarm, battery installed, estimated time remaining 28 minutes.

Example of LCD display during Normal Mode with Pulse Flow

Example of LCD Display indicates the following information: Normal mode in pulse flow setting, 96 is Pulse Dose 96 mL, BL indicates low battery alarm, battery installed, time remaining.

Example of LCD display during Tactical Mode with Continuous Flow

Example of LCD Display indicates the following information: Tactical mode, continuous flow is 3 LPM, no alarm, no battery installed.

Example of LCD display during Tactical Mode with Pulse Flow

Example of LCD Display indicates the following information: Tactical mode, 96 is Pulse Dose 96mL, no alarm, no battery installed.

2.3 RECOMMENDED OPERATING ENVIRONMENTS

The following chart provides important information concerning the recommended operating environments, or operating conditions, for optimum use of the device.

Operating Temperature	See Table 1-1
Operating Humidity	See Table 1-1
Transport/Storage Temperature	See Table 1-1
Electrical	Use no extension cords or electrical outlets controlled by a switch.
Altitude	0 to 18,000 feet [0-5,486 meters]
Placement	DO NOT block the air inlet or the exhaust vent. Place device a minimum of 3 inches (7.5 cm) away from walls, draperies, furniture, other equipment, etc.
Environment	Must be smoke, pollutant, and fume free. Pollution Protection Degree 3 for EMS Environments.
Operating Time	24-hours per day when connected to an external AC Power Adapter or 24 VDC Cable.

Table 2-2. Recommended Operating Environments

	**WARNING: OPERATING THE SAROS OUTSIDE OF THE RECOMMENDED OPERATING ENVIRONMENT MAY NEGATIVELY IMPACT DEVICE PERFORMANCE, MAY CAUSE DAMAGE TO THE DEVICE AND WILL VOID THE WARRANTY IF THIS OCCURS.**
	**WARNING: OPERATING THE SAROS UNDER HIGH AMBIENT TEMPERATURE CONDITIONS MAY RESULT IN HIGH PRODUCT GAS TEMPERATURE.**
	**WARNING: USE OF THIS EQUIPMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.**

NOTE: When moving the SAROS from an extreme temperature environment, please allow time for your device to acclimate to the recommended operating temperature environment.

OPERATION CHARACTERISTICS AT EXTREME TEMPERATURES

SAROS has been designed to optimally operate at temperatures between 0ºC – 43ºC. When operating the system in environments outside these temperatures, the system performance is characterized as follows:

The conditions below are not part of IEC60601-1 Compliance Testing.

While operating in temperatures between 0ºC to 43ºC, SAROS is capable of maintaining flow and purity in continuous and pulse flow modes, while operating on all power sources with the exception of Battery charging.

While operating in temperatures above 43ºC the purity of the oxygen may fall below 90% and the operating time on the battery may be reduced. If SAROS is operating on external power at this temperature, the system may not transition to battery operation due to the safety circuit in the Battery being too hot. During discharge, the SAROS software will shut the system down if internal battery cell temperature exceeds 59°C. While the Battery is charging, software will interrupt charger operation when the internal battery temperature exceeds 40°C or temperature is less than 5°C.

THE PROPER LOCATION

Select a location for the device that avoids the intake of smoke, fumes and pollutants. Correct placement of the device should allow intake of air through the air inlet filter at the top and allow exhaust air to freely leave the exhaust vent at the bottom of the device.

Locate the device such that the alarms can be heard and position the oxygen supply tubing in such a way that it does not kink or occlude. Keep the SAROS at least five (5) feet (1.5 m) away from hot, sparking objects or open flames.

DO NOT locate the device near flammable materials or cleaning agents or in the direct path of any heat source, such as a stove, range, heat register or vehicle heater.

AIRCRAFT USAGE

SAROS 4000 was vibration tested according RTCA DO-160G Section 8 Categories S and U. CAIRE recommends using the SAROS in the below configurations for fixed and rotary wing aircraft.
For fixed wing aircraft, a battery connected to the SAROS can be charged and discharged during operation.
For rotary wing aircraft, battery usage is application-dependent and not recommended by CAIRE.

Excess vibrations not captured as part of the above DO-160G testing may negatively impact usage and performance of the SAROS device.

3.0 PREPARATION FOR USE AND INSTALLATION

Pre-Delivery Check List

Before delivering the device, check and log the status of the following:
Parts Inventory – Verify that each SAROS is provided with the following items:

- SAROS Concentrator
- AC Power Cord
- AC Power Adapter
- 24 VDC Cable
- Battery
- Nasal Cannulas (2)
- Operator Manual
- Spare Filter Set

3.1 BATTERY INSTALLATION ONTO SAROS

1. Remove connector and pin caps.
2. Press the Latching Pin Release Button inward on the bottom of the Battery prior to installing onto the SAROS.

NOTE: It is important to depress the latching pin release button prior to installation.

3. Insert the Battery onto the SAROS by aligning the Battery Connector of the Battery into the connector opening at the bottom of the unit. Battery is properly engaged when the latch pin is snapped into place.

Figure 3-1. Battery Installation

3.2 LOCATING THE SAROS

Place the SAROS in a well-ventilated area. Be sure the air inlet and exhaust vent are not obstructed.

Position the SAROS so all audible and visual indicators or alarms can be easily seen and heard.

Connect the AC Power Adapter to External Power Receptacle located on top of the device and plug the device into a grounded AC Power outlet, connect to a DC Power source with the 24 VDC Cable, or be sure there is a fully charged Battery installed.

4.0 OPERATING INSTRUCTIONS

BEFORE OPERATING

This Operator & Service Manual serves as your reference to help you operate and maintain the device. If you have any questions or concerns please contact a qualified representative, or CAIRE Inc.

	**WARNING: PROTECT THE SAROS AND THE AC POWER ADAPTER AND 24 VDC CABLE FROM ALL FLUID SPILLS OR FLUID DRIPS TO AVOID POSSIBLE SHOCK HAZARDS.**
	**WARNING: USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.**
	**WARNING: DO NOT LUBRICATE FITTINGS, CONNECTIONS, TUBING, OR OTHER ACCESSORIES OF THE OXYGEN CONCENTRATOR TO AVOID THE RISK OF FIRE AND BURNS.**

	**CAUTION: Always check that the air inlet and the exhaust vent of the device are not blocked and the air inlet filter is clean before using your device.**

POWERING ON YOUR SAROS

The SAROS comes complete with the concentrator, AC Power Adapter, power cord, 24 VDC Cable, Battery, and extra filters. The SAROS is a lightweight portable and stationary source of supplemental oxygen. The device is capable of being operated directly from three different power sources: AC power adapter, DC power supply, and battery. To power the SAROS on, connect a source of power and press and hold the ON/OFF button for 2–3 seconds.

GENERAL CHARGING INFORMATION

The SAROS charges the Battery when external power (AC or DC) is present and when the Battery temperature is below a safe charging temperature. When external power is disconnected, the device will automatically switch over to the Battery, if installed and charged. When external power is restored, by plugging into an AC or DC outlet, the device will accept power from the external power source and recharge the Battery while operating the device if adequate AC or DC power is available.

	**WARNING: DO NOT TOUCH THE POWER CONNECTOR ON THE BOTTOM OF THE UNIT WITH THE BATTERY REMOVED AND WHEN THE DEVICE IS CONNECTED TO AN EXTERNAL AC OR DC POWER SOURCE.**

AC POWER ADAPTER

The SAROS includes a universal AC Power Adapter for use wherever standard AC power is available. To connect to an AC power source, be sure the AC Power Adapter device cord is securely inserted into the recessed power receptacle on the top of the device and that the AC power cord from the AC Power Adapter is plugged into an AC outlet. When the device is plugged in properly, the External Power is Present Indicator will appear on the user control panel in Normal Mode.

	**CAUTION: The AC power cords used with the SAROS must meet the electrical requirements of the country where the device is used.**
	**CAUTION: Use only with CAIRE Inc. supplied power cords.**

DC POWER SUPPLY

A 24 VDC Cable allows the system to operate from DC outlets, such as those found in vehicles. Start the vehicle. Insert the 24 VDC cable into the power receptacle on the top of the device. Next, insert the 24 VDC Cable plug into the DC power outlet in your vehicle. When the device is properly connected and receiving power from the DC power source, a green indicator light on the External Power is Present Indicator, on the control panel will illuminate in Normal Mode.

	**WARNING: SECURE THE SAROS AND THE DC POWER SUPPLY IN YOUR VEHICLE AND BE SURE THERE IS ADEQUATE AIR FLOW TO THE DEVICE AND THAT THE AIR INLET AND EXHAUST VENTS ARE NOT BLOCKED. BLOCKING OF THE AIR INLET OR EXHAUST VENT MAY IMPAIR DEVICE PERFORMANCE.**
	**WARNING: DO NOT LEAVE THE SAROS OR 24 VDC CABLE PLUGGED INTO THE VEHICLE WITHOUT THE ENGINE RUNNING OR ATTEMPT TO START THE VEHICLE WHILE THE DC CABLE IS CONNECTED TO THE VEHICLE. DOING SO WILL DRAIN THE VEHICLE'S BATTERY.**
	**WARNING: IF THE VEHICLE'S DC POWER SOURCE DROPS BELOW 20.0 VOLTS (BROWNOUT CONDITION) THE SAROS WILL REVERT TO BATTERY OPERATION IF THE BATTERY IS PRESENT.**

TYPICAL NEW BATTERY OPERATING TIME

Battery Operating Time: The remaining operating time of the Battery is displayed on the user control panel when in Battery mode. A variety of factors, such as flow setting, Pulse or Continuous Flow Mode, temperature or age will impact the operating time. The following table provides operating time estimates for the SAROS operating on a fully charged Battery given certain flow settings and nominal operating conditions.

CONTINUOUS FLOW SETTING (LPM)	CONTINUOUS FLOW BATTERY OPERATING TIME	PULSE FLOW BATTERY OPERATING TIME	PULSE FLOW MODE SETTING (ML)
1.0	1.1 hours	1.2 hours	16
2.0	45 min	1.1 hours	32
3.0	30 min	53 min	48
		47 min	64
		46 min	80
		37 min	96

Table 4-1. Typical New Battery Operating Time

NOTE: Battery run time will degrade under high temperature use and as the battery cells age.

	**CAUTION: Store the battery in a cool and dry location. This will help to assure the longevity of the battery.**
	**CAUTION: U.S. Department of Transportation (DOT) and United Nations (U.N.) regulations require the removal of the battery from the device for all international airline travel when the SAROS is checked as luggage. When shipping the SAROS, the battery must also be removed from the device and packaged properly.**
	**CAUTION: Only replace the CAIRE Inc. battery supplied with the device with a CAIRE Inc. battery.**

	**WARNING: DO NOT ATTEMPT TO OPEN THE BATTERY; THERE ARE NO SERVICEABLE PARTS INSIDE THE BATTERY.**
	**WARNING: DO NOT STORE THE SAROS WITH THE BATTERY INSTALLED IN THE UNIT. RETURN THE BATTERY TO AN AUTHORIZED SERVICE CENTER OR CAIRE INC. FOR PROPER DISPOSAL.**
	**WARNING: DO NOT DISASSEMBLE, INCINERATE, OR HEAT THE BATTERY ABOVE 140° F (60° C). THE BATTERY, USED IN THIS DEVICE, MAY PRESENT A RISK OF FIRE OR CHEMICAL BURN IF MISTREATED.**

TYPICAL BATTERY RECHARGE TIME

The typical time to recharge your Battery, in order to achieve 80% capacity, from a fully discharged Battery is 1.5 hours, while operating at 3 LPM continuous flow.

If the Battery becomes too warm during discharging, recharging will not begin until the Battery sufficiently cools. Removing the Battery and allowing it to cool may expedite this cooling process.

INITIAL BATTERY CHARGING

The new Battery supplied with the SAROS is not fully charged when it is shipped from the factory. Pushing the Test Button on the Battery will indicate the level of charge within. Before using the SAROS for the first time, fully charge the Battery.

Attach the Battery by aligning the connector on the battery to the mating part on the bottom of the SAROS. The Battery will click into place. Depress latching pin button prior to connecting battery.

Power the SAROS ON, with the AC Power Adapter plugged in, and the Battery correctly installed. With the device powered ON, allow the Battery to completely charge. The Battery is fully charged when the Battery Status Gauge Indicator on the Control Panel is completely illuminated or the device has been charging for a minimum of 5 hours.

	**WARNING: If out of operating specifications, allow SAROS and SAROS accessories to return to normal operating range specifications prior to use.**

CAUTION: Do not leave the SAROS, or battery, in the seating area of a motor vehicle or in the trunk of a motor vehicle during a hot day.

NOTE: The SAROS can be used when either discharging or recharging of the Battery is taking place.

In the event of an external power interruption, the SAROS will automatically switch to the Battery operation. When external power is restored, the Battery will automatically start recharging. If the Battery is not present, or fully discharged, during an external power interruption, the SAROS will shut down.

LOW BATTERY ALERTS

The table below describes the LCD Display and Alarm for Low Battery Conditions.

MINIMUM REMAINING TIME ON BATTERY

	< 6 Minutes	7 Minutes < X < 15 Minutes	> 15 Minutes
Time Remaining (Min)	Flash	Flash	Solid
Battery Icon	Flash	Solid	Solid
Alarm	ON	OFF	OFF

Table 4-2. Minimum Remaining Time on Battery

When replacing the Battery without the device being externally powered, push the ON/OFF (Standby) to restart the SAROS.

BATTERY INSTALLATION ONTO SAROS

1. Remove connector and pin caps.
2. Press the Latching Pin Release Button inward on the bottom of the Battery prior to installing onto the SAROS.

NOTE: It is important to depress the latching pin release button prior to installation.

3. Insert the Battery onto the SAROS by aligning the Battery Connector of the Battery into the connector opening at the bottom of the unit. Battery is properly engaged when the latch pin is snapped into place.

Figure 5-1. Battery Installation

4.1 OPERATING THE SAROS FOR THE FIRST TIME

Step 1: Locating the SAROS.
Place the SAROS in a well-ventilated area. Be sure the air inlet and exhaust vent are not obstructed.

Position the SAROS so all audible and visual indicators or alarms can be easily seen and heard. SAROS is operable in both vertical and horizontal orientations. Although capable of operating in a vertical orientation, the device is more stable operating in the horizontal orientation when freestanding. The user or technician must secure the device firmly to the either the patient stretcher (horizontal orientation), or to an appropriate permanent mount in a vehicle that prevents the device from moving or coming loose during all driving conditions. CAIRE can also offer a carrying strap P/N 21495456 to allow secure carrying of the SAROS while outside the vehicle.

Connect the AC Power Adapter to External Power Receptacle located on top of the device and plug the device into an AC Power outlet, connect to a DC Power source with the 24 VDC Cable, or be sure there is a fully charged Battery installed.

Step 2: Power ON the Device and allow it to Warm Up
Oxygen Monitoring – The SAROS has an oxygen concentration status indicator (OCSI) built-in to the device. The OCSI continually monitors the oxygen output of the device.

Press and hold the "ON/OFF" Button to power ON your SAROS. The SAROS will start up in Normal Mode and Continuous Flow of 3 LPM. Allow five (5) minutes minimum for the device to reach its performance specifications. The five (5) minute warm-up time is a stabilization period during which no alerts or codes are to be expected. If the device fails to reach its performance specifications after five (5) minutes, the unit will alarm according to the mode it is in.

Step 3: Connect the oxygen supply tubing to the SAROS

Figure 4-2. Cannula Installation

Clean and Replace the cannula and oxygen supply tubing regularly, as recommended by the cannula manufacturer's instructions.

Step 4: Select the flow delivery mode
Press the Flow Mode button to select the desired flow mode – Continuous or Pulse. Pressing this button repeatedly will toggle you back and forth between the flow modes.

When operating in the Continuous Flow Mode, a continuous supply of oxygen measured in liters per minute (LPM) will flow from the Oxygen Outlet Port.

⚠	**WARNING: DO NOT USE SUPPLY TUBING OR CANNULA EXTENSIONS THAT ARE MORE THAN 50' (15.2M) IN LENGTH IN THE CONTINUOUS FLOW MODE. IN PULSE MODE, USE ONLY THE CANNULA WITHOUT EXTENSIONS.**
⚠	**WARNING: USE ONLY WATER-BASED LOTIONS OR SALVES THAT ARE OXYGEN-COMPATIBLE PRIOR TO AND DURING OXYGEN THERAPY. NEVER USE PETROLEUM OR OIL-BASED LOTIONS OR SALVES TO AVOID THE RISK OF FIRE AND BURNS.**

PULSE FLOW MODE OPERATION:
When operating in Pulse Flow Mode and there is no inspiratory effort detected by the device after 60 seconds total time, the device will switch to the Continuous Flow Mode and will produce at the last equivalent setting. The alert will cease at this time.

When operating in Pulse Flow Mode, a bolus of oxygen measured in mL will be delivered from the Oxygen Outlet Port, each time an inspiratory effort, or negative pressure, is detected.

PULSE FLOW MODE FEATURES:
The SAROS Pulse Flow Mode delivers a high flow oxygen bolus at the beginning of each inspiration. Your SAROS Pulse Flow Mode has a feature, called autoSAT Technology and a Pulse Flow Mode Sensitivity Setting to easily trigger the oxygen bolus delivery.

These features are provided to ensure that patients can easily trigger a delivery of an oxygen bolus and that the oxygen bolus maintains consistency over higher breath rates.

autoSAT Technology provides a consistent bolus volume of oxygen as a patients' breath rate increases or decreases.

Pulse Setting Bolus Size (+/- 15%)	Maximum Breath Per Minute (bpm)
16	40
32	40
48	40
64	40
80	37
96	31

Table 4-3. Pulse Settings

NOTE: Bolus volume decreases as breath rate exceeds published range.

The Pulse Flow Sensitivity (P SENS) can be adjusted in the Utility Menu from 1–3. A setting of 1 is the most sensitive and a setting of 3 is the least.

	**WARNING: PULSE FLOW MODE SETTINGS MUST BE DETERMINED FOR EACH PATIENT INDIVIDUALLY. SETTINGS USED IN THE CONTINUOUS FLOW MODE MAY NOT APPLY, OR BE APPROPRIATE, IN THE PULSE FLOW MODE AND VICE VERSA.**
	**WARNING: AS WITH ALL OXYGEN-CONSERVING TYPE DEVICES, THE SAROS MAY NOT BE ABLE TO DETECT ALL INSPIRATORY EFFORTS IN THE PULSE FLOW MODE.**

Step 5: ADJUST THE FLOW SETTING TO THE PRESCRIBED LEVEL
Using the Flow Setting Buttons, adjust the flow setting to the prescribed setting.

Step 6: SELECT USER DEFINABLE SETTINGS USING THE UTILITY MENU
The Utility Menu has the features that can be adjusted by the user or information for the user or Service Technician. Below are the features of the Utility Button and the Utility Menu:

- The Utility Menu mode can be entered whenever the unit has power (Standby or ON) or 9V Battery.
- Each time the Utility Button is pressed, the Utility menu will advance to the next option.
- The options within the Utility Menu can be changed by using the Increase and Decrease buttons.
- Pressing the Flow Mode button in the Utility Menu goes back to the previous Utility menu item.
- The Utility Menu will revert back to the previous display mode after 5 seconds.

The following sequence of screens shall be displayed on the LCD when the Utility Menu is displayed.

Alarm Codes	Format: AC=XXXX See Alarm Code Table definitions. When more than one alarm code is present, pressing the Increase key will show the next highest priority code and pressing the Decrease key will show the next lowest priority code.
Pulse Sensitivity	Format: P SENS = X (where X is the value of 1 thru 3)
LCD Contrast	Format: LCD CT = X (where X is the value from 1 thru 6)
Normal Mode Brightness	Format N BRT = X (where X is 1 thru 6) Selects the LED and LCD backlight Light intensity used in Normal Mode.
Tactical Mode Brightness	Format T BRT= X (where X is 0 thru 6) Selects the LED and LCD backlight Light intensity used in Tactical Mode.
Tactical Buzzer Volume	Format: TVOL=ON Format: TVOL=OFF
Tactical Mode On / Off selection	Format: TACT=ON Format: TACT=OFF
9V Battery Status	Format: 9V = GOOD Format: 9V = RPLC
Hours of Operation	Format: HR= XXXXX
System Software Part Number and Revision	Format: FW-1 x.y (x = Major Version, and y = minor Version)
Motor Software Part Number and Revision	Format: FW-2 x.y (x = Major Version, and y = minor Version)

Table 4-4. Utility Menu Screens

Step 7: Begin using the SAROS
NOTE: You will achieve longer operating time on the Battery if you operate in the Pulse Flow Mode.

Step 8: Power off the Device
Press and hold the "ON/OFF" Standby Button for two (2) seconds to power OFF the SAROS.

5.0 OPERATOR MAINTENANCE & SERVICE

5.1 CLEANING THE SAROS

Use mild detergent solution to clean the sleeve, control panel and power supplies. Turn OFF the SAROS and disconnect from AC or DC power before any cleaning or disinfection activity. DO NOT spray the sleeve, control panel or power supplies. Use a damp (not soaking wet) cloth or sponge. Spray the cloth or sponge with mild detergent solution to clean the sleeve, control panel or power supplies. To disinfect the SAROS, use only Lysol Brand II disinfectant (or equivalent). Proceed as directed by the manufacturer.

WARNING: USE ONLY SPARE PARTS RECOMMENDED BY THE MANUFACTURER TO ENSURE PROPER FUNCTION AND TO AVOID THE RISK OF FIRE AND BURNS.

Cleaning the SAROS Battery

The Battery in the SAROS requires special care to assure a longer life and the highest level of performance. The CAIRE Inc. Battery is the only approved Battery recommended for use with the SAROS.

Use a damp (not soaking wet) cloth or sponge. First spray the cloth or sponge with a mild detergent and then clean the Battery case and the latch.

Cannula Replacement

Replace your supply tubing and cannula on a regular basis as recommended by the cannula manufacturer's instructions.

5.2 ROUTINE MAINTENANCE

Maintenance Step	Frequency	Performed By
Clean Air Inlet Filter	weekly (If in use, not required if in storage.)	User
Run device and fully drain SAROS battery	3 months*	User, Distributor, or Authorized Service Center
Replace 9-volt battery	as needed	User, Distributor, or Authorized Service Center
Air Inlet Filter Replacement	6 months, or as needed	User, Distributor, or Authorized Service Center
HEPA Filter	6 months, or as needed	User, Distributor, or Authorized Service Center
Performance Verification Check**	6 months, or when a problem is suspected	Distributor or Authorized Service Center

Table 5-1. Routine Maintenance

*Three month recommendation is based on a climate-controlled storage environment.
** Contact Distributor to schedule

Tools Required

The following section lists procedures that are necessary to maintain the SAROS. Service should only be performed by a qualified technician. To perform periodic maintenance, the only tools that should be necessary are:

- #1 Phillips Screwdriver
- 3/8" open end wrench
- Oxygen Analyzer that includes the capability to measure both flow rate (LPM and mL) and Oxygen concentration/purity %.
- Tubing to connect the SAROS to the Oxygen Analyzer for testing.

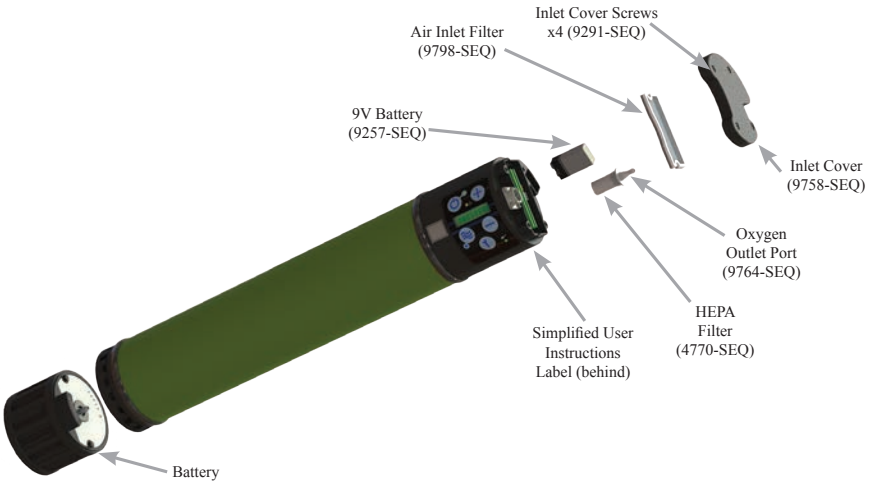


Figure 5-1. SAROS Components

5.3 CLEANING OR REPLACING AIR INLET FILTER

5.3.1 Removing the air inlet cover.

5.3.2 Disconnect power supplies and remove the battery if connected.

5.3.3 Using a Phillips #1 screwdriver, loosen the four captive screws.

5.3.4 Remove cover.

Figure 5-2. Remove Cover

5.3.5 REMOVING AND CLEANING/REPLACING THE AIR INLET FILTER

5.3.6 Gently remove the filter shown in figure 6-3.

5.3.7 If the filter is damaged, replace.

5.3.8 For cleaning, gently wash with warm soapy water. Allow filter to completely dry before re-installing.

5.3.9 Re-install Air Inlet Filter.

5.3.10 Using a Phillips #1 screwdriver, re-attach the Cover with screws.

5.3.11 Initial and date the Service and Maintenance Record.

Figure 5-3. Filter

CAUTION: Operating the SAROS with a clogged air inlet filter may reduce performance and lead to system damage or premature failure.

5.4 REPLACING THE HEPA FILTER

5.4.1 Disconnect all power supplies including external Battery if connected.

5.4.2 Using a 3/8" open end wrench, remove the O2 Fitting/HEPA Filter shown in figures 6-4.

5.4.3 Unscrew the HEPA Filter from the O2 Fitting as shown in figure 6-4.

5.4.4 Replace with new HEPA Filter. Do not over tighten.

NOTE: Ensure that the O-Rings shown in figure 6-4 are positioned correctly before re-installation.

5.4.5 Re-install the O2 Fitting/HEPA Filter. Do not over tighten.

5.4.6 Initial and date the Service and Maintenance Record.

Figure 5-4. Reinstall O2 Fitting/HEPA Filter

5.5 RUN DEVICE AND FULLY DRAIN SAROS BATTERY

Operate the device once every 3 months by running the device on battery power until drained. This is required if the device is in storage and unused. If the device is not run regularly per this recommendation there is a risk it will not perform to specification when removed from storage.

1) Turn on the SAROS and run at any continuous flow setting until the battery is completely drained and the SAROS powers off.

2) Once the SAROS powers off, immediately connect to AC external power to begin re-charging the battery. You may either continue to run the SAROS or leave it powered off during re-charge.

3) Once the battery is fully charged, disconnect the battery, power off the unit if still running, and return the SAROS to proper storage conditions.

5.6 REPLACING THE 9V BATTERY

5.6.1 Disconnect power supplies and remove external battery if connected.

5.6.2 Using a Phillips #1 screwdriver, loosen the four captive screws shown in figure 5-2.

5.6.3 Remove cover.

5.6.4 Remove 9V battery from where shown in figure 5-5.

5.6.5 Disconnect and replace battery as shown in figure 5-5.

5.6.6 Using a Phillips #1 screwdriver, replace the Air Inlet Cover.

5.6.7 Initial and date the Service and Maintenance Record.

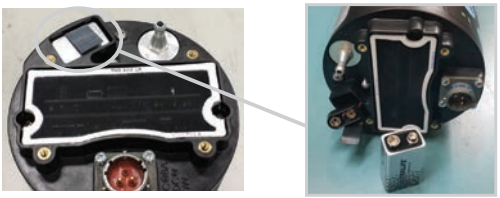


Figure 5-5. Replacing 9V battery

6.0 ALERTS, ALARMS, AND TROUBLESHOOTING TABLE

The tables show the possible audible and visual alerts and alarms, their conditions and suggest appropriate troubleshooting responses. The SAROS runs functional verification on alarm system as part of its operation. If you are unsure about any alerts or alarm conditions, or responses please contact an authorized service technician or go to www.caireinc.com.

Alarm levels

Type	Level	Yellow LED	Audio Alarm	LCD	Description
Alarm	1	ON	1 beep 200ms only or repeats every 20 seconds	Displays Alarm Signal	Attention is required
Status	0	OFF	OFF	NC (No Change)	All OK

Table 6-1. Alarm Levels

⚠	**WARNING: AVAILABILITY OF A BACK-UP SOURCE OF OXYGEN IS RECOMMENDED IN CASE OF POWER OUTAGE OR A DEVICE FAILURE. CONSULT YOUR PROVIDER FOR BACK-UP OXYGEN SYSTEM.**
⚠	**WARNING: DO NOT Ignore Alarms. System will attempt to produce oxygen under fault condition but may not be at purity or flow.**

6.1 SYSTEM TROUBLESHOOTING GUIDE

SYMPTOM	PROBABLE CAUSE	REMEDY
SAROS does not power on when ON/OFF button is pressed (constant tone)	No Battery installed	Install Battery or plug into external power
	Battery is discharged or no external power is present	Plug into external power
	Other	Contact an authorized Service Technician
No Oxygen	Air Inlet or HEPA Filter Blocked	Clean Air Inlet Filter or replace HEPA Filter
	SAROS not ON	Power SAROS ON
	Tubing or cannula is not properly connected or is kinked	Check tubing, cannula and connections
	Other	Contact an authorized Service Technician
Low Oxygen Concentration	Restriction in tubing	Repair or replace tubing.
	Air Inlet or HEPA Filter restricted	Clean air inlet filter or replace HEPA Filter. Place your SAROS so there is adequate air flow.
	Inadequate Ventilation	Place your SAROS so that there is adequate air flow, i.e. not covered by a blanket or a poncho.
	Hot environment	Allow SAROS to cool
	Other	Contact an authorized Service Technician
Low Oxygen Flow	Restriction tubing	Repair or replace tubing.
	Air Inlet or HEPA Filter Blocked	Clean Air Inlet Filter or replace HEPA Filter
	Other	Contact an authorized Service Technician
No Oxygen delivered in Pulse Flow Mode	Tubing/cannula longer than 7 feet (2.1m)	Attach 7 foot (2.1m) tubing/cannula
	No inspiration detected	Contact an authorized Service Technician
Battery Status Gauge never indicates fully charged	Battery is aging	Contact an authorized Service Technician to replace Battery
Heat related failures, i.e. Compressor too hot	Ambient condition is too hot	Place unit in cool environment or out of direct sunlight, if possible.
Battery will not latch onto SAROS	Battery Latching Pin Release is stuck in the wrong position	Press the Latching Pin Release Button inward to free the latch mechanism and re-install Battery
Oxygen production is limited due to power limitations	External power source cannot supply enough power	Check air inlet filter and check the external power source

Table 6-2. System Troubleshooting Guide

6.2 ALARM INDICATIONS AND CODES

Priority #	Alarm Signal	Alarm Type	Alarm Code	Alarm Description	Buzzer
1	PN	Power None	4000	Loss of Power	1 beep only
2	HU	Hot Unit	9510	Battery Too Hot	1 beep every 20 seconds for 120 seconds; LCD Battery Icon blinking
3	HB	Hot Battery	9300	Motor Driver Board Too Hot	1 beep every 20 seconds for 120 seconds
4	HU	Hot Unit	9200	Power Board Too Hot	1 beep every 20 seconds for 120 seconds
5	HU	Hot Unit	9100	Compressor Too Hot	1 beep every 20 seconds for 120 seconds
6	HU	Hot Unit	9110	Compressor Temperature Sensor Failure	1 beep only
7	SM	Shutdown Mechanical	A500	Unable to Achieve or Maintain Product Tank Pressure	1 beep every 20 seconds for 120 seconds
8	SE	Shutdown Electrical	AC00	External Voltage Too High	1 beep every 20 seconds for 120 seconds; Power LED blinking
9	SE	Shutdown Electrical	8000	Invalid Reset	1 beep every 20 seconds for 120 seconds
10	SM	Shutdown Mechanical	9194	Compressor Stall	1 beep every 20 seconds for 120 seconds
11	SE	Shutdown Electrical	9195	Compressor Driver Fault	1 beep every 20 seconds for 120 seconds
12	SE	Shutdown Electrical	A300	Ultrasonic Sensor Failure	1 beep every 20 seconds for 120 seconds
13	SE	Shutdown Electrical	A000	IPC Failure	1 beep every 20 seconds for 120 seconds
14	SE	Shutdown Electrical	A010	Board Communication Failure	1 beep every 20 seconds for 120 seconds
15	SE	Shutdown Electrical	9000	Watchdog Time out	1 beep every 20 seconds for 120 seconds
16	PN	Power None	4010	Missing Power POST	1 beep only
17	SE	Shutdown Electrical	FD00	Motor Controller Fault	1 beep every 20 seconds for 120 seconds
18	TN	Trigger None	B000	No Breath Detected for 15-59 seconds	1 beep every 20 seconds for 120 seconds
19	TN	Trigger None	B010	No Breath Detected for 60 seconds	1 beep only; Automatically switches to continuous mode
20	BL	Battery Low	9540	Low Battery ≤ 6 minutes	1 beep every 20 seconds for 120 seconds; LCD Battery Icon blinking
21	OL	Oxygen Low	0800	Oxygen Concentration Low (< 85% nominal)	1 beep every 20 seconds for 120 seconds
22	XF	Malfunction Flow	2000	Flow Rate Error	1 beep every 20 seconds for 120 seconds
23	XB	Malfunction Battery	9500	Battery Communication Error	1 beep every 20 seconds until condition clears
24	XK	Malfunction Keypad	8110	Key Stuck On	1 beep every 20 seconds until condition clears

Priority #	Alarm Signal	Alarm Type	Alarm Code	Alarm Description	Buzzer
25	TN	Trigger None	A200	Pulse Mode Disabled due to Sensor Failure	1 beep every 20 seconds until condition clears
26	XB	Malfunction Battery	952C	Cannot Charge Battery	1 beep every 20 seconds until condition clears
27	9L	9V Low	1020	Low 9 Volt Battery POST	1 beep only
28	9L	9V Low	1000	Low 9 Volt Battery	1 beep only
29	XB	Malfunction Battery	1030	Battery Too Hot to Charge	1 beep every 20 seconds until condition clears
30	XB	Malfunction Battery	95C0	Battery Too Cold to Use	1 beep every 20 seconds until condition clears
31	XB	Malfunction Battery	95CC	Battery Too Cold to Charge	1 beep every 20 seconds until condition clears
32	XB	Malfunction Battery	9550	Battery Thermistor Failure	1 beep every 20 seconds until condition clears; LCD Battery Icon blinking
33	XB	Malfunction Battery	9560	Battery Chip Thermistor Failure	1 beep every 20 seconds until condition clears; LCD Battery Icon blinking
34	BL	Battery Low	1040	Low Battery ≤ 15 Minutes	1 beep only
35	XP	Malfunction Pressure	A210	Breath Pressure Sensor Failure	1 beep only
36	XE	Malfunction Electrical	A600	Purity Calibration Data Failure	1 beep only
37	XE	Malfunction Electrical	A700	Flow Calibration Data Failure	1 beep only
38	XP	Malfunction Pressure	AB00	Ambient Pressure Sensor Failure	1 beep only
39	XT	Malfunction Temperature	AB10	Ambient Temperature Sensor Failure	1 beep only
40	XE	Malfunction Electrical	8300	Run Log Storage Failure	1 beep only
41	XE	Malfunction Electrical	8320	Event Log Storage Failure	1 beep only
42	XE	Malfunction Electrical	8400	EEPROM Data Write Failure	1 beep only
43	XT	Malfunction Temperature	8900	ATF Temperature Sensor Failure	1 beep only
44	XT	Malfunction Temperature	9210	Power Board Temperature Sensor Failure	1 beep only
45	XT	Malfunction Temperature	9310	Motor Driver Board Temperature Sensor Failure	1 beep only
46	XP	Malfunction Pressure	A400	Ambient Pressure Error	1 beep only

Table 6-3. Alarm Indications and Codes

7.0 REPROGRAMMING/CALIBRATION

All reprogramming of the circuit boards shall be performed by CAIRE, Inc or by a factory authorized service center. Flow calibration is required whenever replacing an ATF, control board, compressor, or proportional valve. Flow calibration can be done at a CAIRE authorized service center or in the field using item T-10560. See manual MN053 for details on performing flow calibration and firmware updates in the field using item T-10560.

8.0 SHIPPING AND TRANSPORTING THE SAROS

When shipping the SAROS use original packaging if possible. Always remove the Battery from the SAROS before shipping.

If original packaging material is available repack the SAROS, Battery and power supplies in the designated packaging area.

If original packaging material or other CAIRE Inc. authorized shipping container is not available, contact CAIRE Inc. for replacement shipping container.

9.0 STORING AND DISCARDING THE SAROS

WARNING: Do not expose the SAROS to water. The SAROS enclosure does not provide protection against the harmful effects of liquid ingress. Electrical shock or damage to the unit may result.

STORING THE SAROS

Heat and humidity may degrade the performance or severely damage the SAROS. Store the device in a cool, dry protected area away from high temperatures, moisture and humidity. Remove the Battery when storing the device.

Ensure that all recommended maintenance procedures in section 5.0 are performed while the device is in storage. It is especially important that the 3-month requirement to run the device and fully drain the SAROS battery be performed while the unit is in storage to ensure proper operation.

Discarding the SAROS

Battery Disposal: Your Battery is rechargeable and can be recycled. Always return it to an authorized service center or CAIRE Inc. for proper disposal. You can also contact your local city or town offices for instructions on proper disposal of the Battery.

SAROS: Local environmental laws may prohibit disposal of electrical and/or electronic equipment such as the SAROS and AC Power Adapter. Contact the local city, town or country offices for instructions on proper disposal of electrical or electronic equipment. Alternately, CAIRE Inc. may be contacted for disposal information at 1-800-482-2473.

10.0 EMC TESTING

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

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The SAROS is intended for use in the electromagnetic environment specified below. The customer or the user of the SAROS 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 discharge	±8 kV contact ±15 kV air discharge	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 professional healthcare facility and home healthcare environments.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2kV common mode on AC lines ±1kV differential on AC lines ±2kV common mode on outdoor I/O lines	±1 kV line(s) to line(s)	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0^0) 70% U_T (30% dip in U_T) for 25/30 cycles (0^0) 0% U_T for 250/300 cycles (0^0)	0% U_T for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0^0) 70% U_T (30% dip in U_T) for 25/30 cycles (0^0) 0% U_T for 250/300 cycles (0^0)	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments. If the user of the SAROS requires continued operation during power mains interruptions, it is recommended that the SAROS is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a professional healthcare facility and home healthcare environments.
NOTE U_T is the A.C. mains voltage prior to application of the test level. NOTE In some cases, the SAROS may reset after a significant Electrostatic Discharge, and may require a Full Power Cycle to resume normal operation. See Troubleshooting section for more details.			

Guidance and Manufacturer's Declaration–Electromagnetic Immunity			
The SAROS is intended for use in the electromagnetic environment specified below. The customer or the user of the SAROS 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	10 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SAROS, 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 2700 MHz 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	10 V/m 80 MHz to 2700 MHz	10 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 SAROS is used exceeds the applicable RF compliance level above, the SAROS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SAROS. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the SAROS

The SAROS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SAROS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SAROS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.2\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Classification

Type of protection against electric shock:
Class II Protection from electric shock is achieved by double insulation.

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.

Independent testing for Medical Electrical Equipment Standard:
Tested to be in compliance with
- IEC 60601-1 edition 3.1: Medical Electrical equipment - Part 1 General Requirements for safety.

Protection against potential electromagnetic or other interference between the equipment and other devices.
- Tested to be in compliance with EN 60601-1-2/IEC 60601-1-2: 4th Edition.
- Tested to be in compliance with RTCA/DO160 Section 21 Category M.
- CISPR 11 / EN 55011 Class B Group 1, "Industrial, Scientific, and Medical (ISM) Equipment"
- FCC Part 15, Subpart B – Class B Unintentional Radiators

IP33 – Protection against ingress of tools, thick wires, etc. > 2.5mm. Water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect.

Method of cleaning and infection control allowed: Please refer to cleaning section of this SAROS manual.

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

Mode of operation: Continuous duty.

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14 March 2025 MN255-1 E