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SERVICE BULLETIN

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MODEL: SAROS

ISSUE: SAROS Performance Verification Test and Updated Routine Maintenance Schedule

NOTES: The below performance verification test procedure and updated routine maintenance schedule are being released as an addendum to the SAROS Maintenance Manual (PN 9735 rev F).

The performance verification test is intended to verify overall functionality of the SAROS system upon initial receipt, any time a problem is suspected, and at regular maintenance intervals. The routine maintenance schedule is intended to help ensure proper performance of the device.

See also the SAROS Technical Manual (PN 9705 rev K) and SAROS Maintenance Manual (PN 9735 rev F) for more detailed information on maintenance and operation of the SAROS Oxygen System.

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SAROS PERFORMANCE VERIFICATION TEST

Verify functionality of the SAROS using the following procedures. The performance verification test shall be performed upon initial receipt of the SAROS, any time a problem is suspected, and at regular 6 month intervals. It may be performed at more frequent intervals if required by the equipment provider. It is suggested that these steps be performed in the order listed for efficiency and accuracy.

A. General Operation Test

1) Install the SAROS battery.

2) Use an external (AC or DC) power cord to connect the SAROS to external power. Verify the power cord connects securely to the receptacle on the SAROS.

NOTE: The battery is not fully charged upon initial receipt of the SAROS. If testing a new unit, this will begin the battery charging process. Reference steps 7-8 to verify proper battery charging.

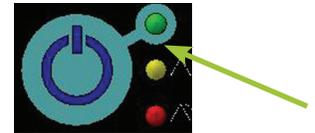
3) Press and hold the "ON/OFF" button for 3 seconds to power on the SAROS.

NOTE: Before powering on, ensure the SAROS is in a well-ventilated area and that the air inlet and exhaust vent are not obstructed.



4) Verify the audible alarm sounds upon start-up and the screen defaults to display a flow setting of C3.

5) Allow the unit to run for a minimum of 5 minutes to reach its performance specifications. After the warm-up period, verify that only the green light remains illuminated and there are no audible alarms.



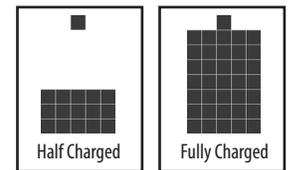
6) Press the utility button once and verify that there are no active alarms. The display screen will read "AC = NONE" if no alarms are active.



7) Verify that the battery icon is visible on the right side of the screen.



8) Verify that the battery is charging. The battery icon bars will move in a waterfall fashion while charging. If the battery icon is not moving, verify if the battery is already fully charged. A fully charged battery will have a completely dark icon with all bars filled.



9) Verify the functionality of the increase and decrease flow buttons. Starting at flow setting C3, press the decrease flow button and verify the screen reads C2. Press the increase flow button and verify the screen changes back to C3.

NOTE: It is normal for the motor to speed up or slow down with each flow adjustment.



Decrease flow button



Increase flow button



10) Verify the functionality of the pulse flow mode button. Press the button and verify the device toggles between a continuous flow setting (C) and pulse flow setting (P). The C & P are displayed on the far left side of the screen.

11) Verify the functionality of the no breath alarm. Switch to a pulse flow setting and do not attach any tubing to the outlet. Within 60 seconds of no breath detected, verify the system automatically changes to continuous flow. This is a patient safety measure.

12) Verify the unit runs on battery power. Disconnect the AC power supply and allow the SAROS to run for approximately 60 seconds. Verify the unit continues to run without interruption and that the battery icon is still displayed on the screen.

13) Verify the no battery alarm. Remove the battery with the AC power still disconnected and verify that an audible alarm sounds and the red light is visible.

14) Within 5-10 seconds, reinstall the battery and verify the SAROS restarts automatically. Once the SAROS restarts, re-connect the external power as well to resume battery charging.

B. Flow and O₂ Concentration Test

Connect the SAROS to a testing station per the diagram shown below:



NOTE: If testing concentration or flow rate at multiple settings, allow a 5 minute stabilization period between changing the flow rate prior to taking any test readings.

NOTE: The SAROS is BTP compensated. If measuring concentration and/or flow with a device that is non-Argon compensated and non-BTP compensated, an additional 0.10 LPM should be added to the flow rate recorded by the testing equipment. The VT PLUS HF Gas Flow Analyzer manufactured by FLUKE Biomedical is not BTP or Argon compensated.

NOTE: Be sure to use standard oxygen-compatible tubing. The tubing from SAROS to the testing device should be a single continuous piece with no restrictions in line.

1) Verify continuous flow settings C3 and C2 using the following procedure:

a) Turn on the SAROS and set the flow to C3 (3.0 LPM). Allow the unit to run for a minimum of 5 minutes to stabilize before testing.

b) Verify the O₂ concentration is within 90-96% and record the reading.

c) Record a 60 second running average for the flow rate. Verify the 60 second average is within 2.70 - 3.30 LPM. If using a non-Argon or Non-BTP compensated measuring device, verify the 60 second average is within 2.60 – 3.20 LPM.

d) Adjust the flow setting to C2 (2.0 LPM). Allow the unit to run for a minimum of 5 minutes to stabilize before testing.

e) Verify the O₂ concentration is within 90-96% and record the reading.

f) Record a 60 second running average for the flow rate. Verify the 60 second average is within 1.80 - 2.20 LPM. If using a non-Argon or Non-BTP compensated measuring device, verify the 60 second average is within 1.70 - 2.10 LPM.

Note: it is not required to test flow and concentration at 1 LPM for performance verification. This is not a typical clinical use case.

2) Verify functionality of the device in pulse flow mode using the following procedure:

a) Adjust the SAROS to a setting of P48 (48mL).

b) Trigger a simulated breath by folding and pinching the tubing* running from the SAROS to the testing device. Verify that a breath is triggered by the light blinking adjacent to the pulse flow mode button.

* Other acceptable procedures to trigger a breath may include connecting a tee to a breath simulator (syringe, jet venturi, nasal cannula, etc.). If you are using a tee, the tubing to the breath simulation device should not exceed 2 inches in length.

c) Note and record the bolus size in mL of each breath. Repeat five times. Average the five bolus measurements and record the average reading. You may need to "ZERO" the testing device between triggering a simulated breath.

d) Adjust the SAROS to a setting of P96 (96 mL).

e) Repeat steps B & C for the P96 setting.

C. Battery Run Time Test

1) Test battery run time using the following procedure:

a) Fully charge the battery via AC power by leaving it connected to AC power for a minimum of 1 hour. After 1 hour, verify the power cartridge status indicator is fully illuminated and no longer displays a waterfall motion.

b) Disconnect the AC power. Power the SAROS on at C3 (3.0 LPM) and start a timer.

c) Allow the unit to continue to run until it shuts off.

d) Once the unit shuts off completely, stop the timer and record the battery duration.

e) Verify that the time recorded is >24 minutes

NOTE: The nominal capacity of a new battery is 30 minutes at setting C3. A battery is considered within its useful life if its duration is 80% of the nominal capacity of a new battery (24 minutes at C3).



SAROS PERFORMANCE VERIFICATION CHECKLIST

| | | | | | | | | | |
|---|---|---|--|-------------------------|----|----|----|----|------|
| SAROS Serial Number: | | | | | | | | | |
| Hours of Operation: | | | | Date of Testing: | | | | | |
| A. General Operation Test | Pass | | | Fail | | | | | |
| 1) Battery installs properly | | | | | | | | | |
| 2) External power cord (AC or DC) connects securely | | | | | | | | | |
| 3) Unit powers on after holding ON/OFF button for 3 seconds | | | | | | | | | |
| 4) Audible alarm sounds upon start-up | | | | | | | | | |
| 5) 5-minute warm up period complete with no audible alarm | | | | | | | | | |
| 6) Utility Mode shows no active alarms after 5-minute warm up | | | | | | | | | |
| 7) Battery icon visible on screen | | | | | | | | | |
| 8) Battery is charging or already fully charged | | | | | | | | | |
| 9) Increase and decrease flow buttons are functional | | | | | | | | | |
| 10) Pulse flow mode button is functional | | | | | | | | | |
| 11) No breath alarm is functional | | | | | | | | | |
| 12) Unit runs on battery power | | | | | | | | | |
| 13) No battery alarm is functional | | | | | | | | | |
| 14) Automatic re-start when power is reconnected | | | | | | | | | |
| B. Flow and O₂ Concentration Test | Acceptable Range | | | Recorded Reading | | | | | |
| 1) Continuous Flow Setting Verification | | | | | | | | | |
| C3 (3.0 LPM)) O ₂ Concentration | 90 - 96 % | | | | | | | | |
| C3 (3.0 LPM) flow -- 60 second average reading ¹ | Argon-Compensated Testing Device: 2.70 - 3.30 LPM | Non Argon-Compensated Testing Device: 2.60 - 3.20 LPM | | | | | | | |
| C2 (2.0 LPM)) O ₂ Concentration | 90 - 96 % | | | | | | | | |
| C2 (2.0 LPM) flow -- 60 second average reading ¹ | Argon-Compensated Testing Device: 1.80 - 2.20 LPM | Non Argon-Compensated Testing Device: 1.70 - 2.10 LPM | | | | | | | |
| 2) Pulse Flow Mode Verification | | | | | | | | | |
| P48 (48 mL) -- 5 bolus average reading | 40.8 - 55.2 mL | | | 1: | 2: | 3: | 4: | 5: | Ave: |
| P96 (96 mL) -- 5 bolus average reading | 81.6 - 110.4 mL | | | 1: | 2: | 3: | 4: | 5: | Ave: |
| C. Battery Run Time Test | Acceptable Range | | | Recorded Reading | | | | | |
| C3 (3.0 LPM) | > 24 min | | | | | | | | |

Footnotes:

(1) The SAROS is BTP compensated. If measuring concentration and/or flow with a device that is non-Argon compensated and non-BTP compensated, the acceptable range of the device readings will be reduced by 0.1 LPM.

Technician Name (print): _____

Technician Signature: _____ Date: _____

ROUTINE MAINTENANCE

Below is the acceptable schedule for routine maintenance recommended by the manufacturer.

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

*Three month recommendation is based on a climate-controlled storage environment. For other storage conditions, contact CAIRE Technical Support at 1-800-482-2473.