SMART check

OXYGEN + FLOW + PRESSURE

Smart Check Oxygen Analyzer

REF : MA0236EN

User Manual

– English –

LIFESPARK MEDICAL

Document ID: MA0237EN, Revision E

Manufacturer

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Note: If you would like assistance with setting-up, operating or maintaining the Smart Check, contact Life Spark Medical

Classification Information

Protection against electric shock	Internally Powered ME Equipment
Ingress Protection Rating	IP22: Indicated the device is protected against: Solid foreign objects of 12.5mm and greater, and Water ingress of vertically falling water drops when device is tilted up to 15°
Method of Sterilization	Non-sterile. Do not sterilize. See Section 5.2: Cleaning
Mode of Operation	Continuous
Oxygen Compatibility	Suitable for use in oxygen rich environments
Anesthetic Mixtures	Not for use in the presence of flammable anesthetic mixtures.

Standards Conformance

ISO 80601-2-55:2018+AMD2023
ANSI/AAMI ES60601-1:2005 + A1: 2012 + A2:2021
IEC 60601-1:2005 Edition 3.2
ANSI/AAMI HA60601-1-11:2015/AMD1:2021
IEC 60601-1-11 Edition 2.1
IEC 60601-1-2:2014/AMD1:2020

Disposal Information

This device may contain electrical components that are hazardous to the environment. DO NOT dispose of device into standard trash. Contact your local waste management for disposal of electronic equipment.

Indications for use

The Smart Check is a tool used to measure oxygen purity, flow, and pressure at the outlet of an oxygen concentrator. The Smart Check is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers.

Essential Performance

The following are essential performance characteristics, loss, or degradation of which would result in an unacceptable risk. Refer to Section 3 Factors Affecting Accuracy, for stated accuracy values.

- Oxygen measurement accuracy
- Flow measurement accuracy
- Pressure measurement accuracy
- Pulse volume measurement accuracy

Warranty

Smart Check is designed for analyzing oxygen concentration. Under normal conditions, Life Spark Medical warrants the Smart Check Oxygen Concentrator Analyzer to be free from defects of workmanship or materials for a period of three (3) years from the date of purchase.

Life Spark Medical's sole obligation under the foregoing warranty is limited to making replacements, repairs, or issuing credit for equipment found to be defective provided the item is returned, shipping prepaid, to Life Spark Medical. Any and all transportation charges are the responsibility of the purchaser and are not included in this warranty. This warranty extends only to the original purchaser and is non-transferable. This warranty does not apply if the product has been damaged by abuse, misapplication, neglect, accident, transport, or misuse or has been serviced or modified by anyone other than Life Spark Medical Authorized Service Center. THESE WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING A WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. LIFE SPARK MEDICAL SHALL NOT BE LIABLE FOR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA ARISING FROM PRODUCT USE. This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. This warranty is limited to repairing the product to Life Spark Medical's specifications. For this warranty to remain valid, all operations and maintenance must be performed in accordance with this manual. Please read the manual thoroughly before use.

Description and Principles of Operation

The Smart Check is an ultrasonic oxygen analyzer, used to verify the performance of oxygen concentrators. The device uses ultrasonic time-of-flight measurements to determine the oxygen concentration and flow rate of the supplied gas. Ultrasonic pulses are sent/received both upstream and downstream through a long sensor body through which the sample gas is flowing. The microprocessor accurately measures the transit time both upstream and downstream and converts them to flow rate and oxygen concentration. These values are shown to the user on the display. The user may initiate a pressure check mode, during which the device measures and displays the pressure of the supplied gas. The user may select pulse or continuous mode to test traditional continuous flow concentrators or pulse-flow conserving concentrators. The device does not require field calibration; however, users may enter a calibration check mode and deliver pure oxygen to the device to verify performance.

Warnings ⚠

A **WARNING** identifies actions and conditions that pose hazards to the operator.

⚠ **Warning:** The Smart Check is not intended to be used by patients who are prescribed oxygen, nor is it intended to be used to monitor or confirm oxygen delivery to a patient. It is intended to verify performance of oxygen concentrators prior to their being placed into service.

⚠ **Warning:** Keep the sample tube away from children to avoid risk of strangulation.

⚠ **Warning:** Use of accessories other than those specified for use with the Smart Check, as described in this document, may result in degraded performance.

⚠ **Warning:** Do not physically connect the Smart Check to other devices not described in this document. Damage to internal parts could affect the safety or performance of the device.

⚠ **Warning:** Do not attempt to repair or modify the Smart Check. Damage to internal parts could affect the safety or performance of the device.

⚠ **Warning:** Use of this equipment adjacent to or stacked with other equipment, other than an oxygen concentrator, should be avoided because it could result in inaccurate measurements. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Smart Check system. Otherwise, degradation of the performance of this equipment could result.

⚠ **Warning:** Avoid storing in direct sunlight or hot cars. If the Smart Check has been stored at an extreme temperature, connect it to the concentrator with gas flowing for 5 minutes prior to taking readings, to ensure accuracy.

⚠ **Warning:** The Smart Check is calibrated to read the mixture of gas produced by oxygen concentrators. Measuring other sources of oxygen will result in inaccurate readings.

Cautions ⚠

A **CAUTION** identifies actions and conditions that may damage the Smart Check, or the concentrator being tested.

⚠ **Caution**: The Smart Check is for use by trained durable medical equipment technicians. Prior to use, thoroughly read this user manual, and the user/service manuals of any devices being tested with the Smart Check. Following the instructions herein is necessary for safe and effective use of the Smart Check.

Note: Additional cautions are provided throughout this user manual adjacent to their corresponding use instructions.

Symbol Guide

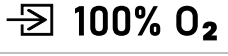
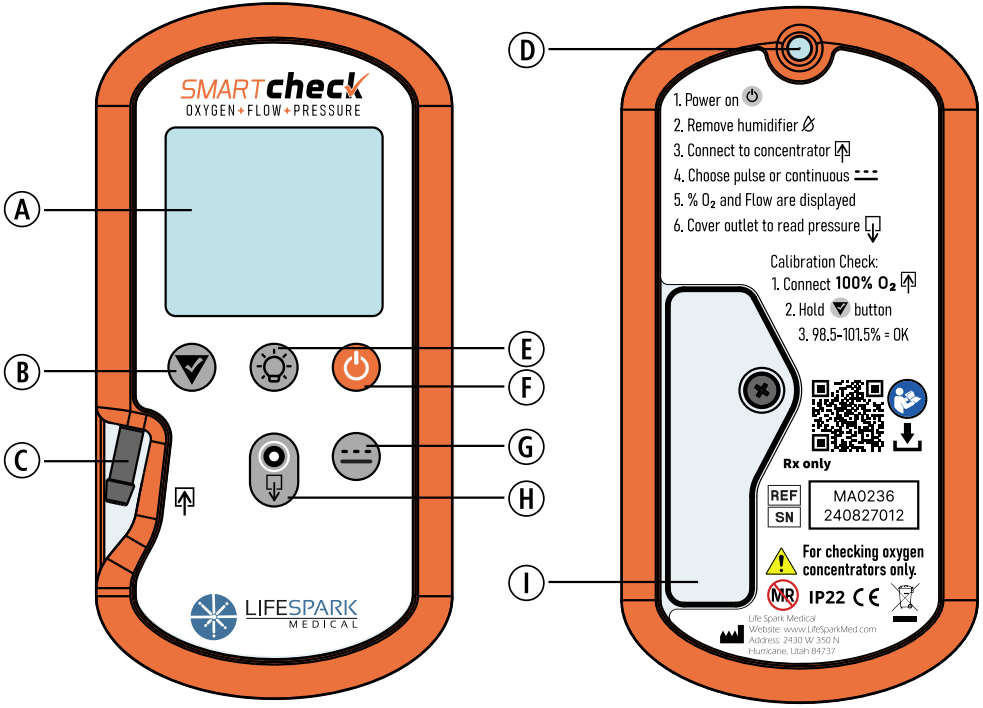
Symbol	Description	Symbol	Description
	Manufacturer	REF	Model Number
IP22	Liquid ingress protection rating		Do not throw away
	WARNING. RISK OF DANGER		Caution
SN	Serial number		Download user manual
	Read user manual	CE	Complies with requirements of the European Economic Area
	Sample inlet		Sample outlet
	Cal check button		Feed 100 percent oxygen
	Backlight/flashlight button		Pulse/continuous mode button
	ON/OFF button		Remove humidifier
PSI	Pressure: Pounds per square inch	%	Oxygen volume fraction
KPA	Pressure: Kilopascal		Battery charge level
cmH_2O	Pressure: Centimeters of water	LPM	Liters per minute – flow rate
	The Smart Check O_2 is MR Unsafe	ml	Milliliter – pulse volume
Rx only	Prescription Only (USA only)		

Table of Contents

1. Overview

1.1. Components

1.1.1. Front & Back



Ⓐ LCD Display

Ⓑ Calibration Check Button

Ⓒ Sample Inlet

Ⓓ Flashlight

Ⓔ Flashlight/Backlight Button

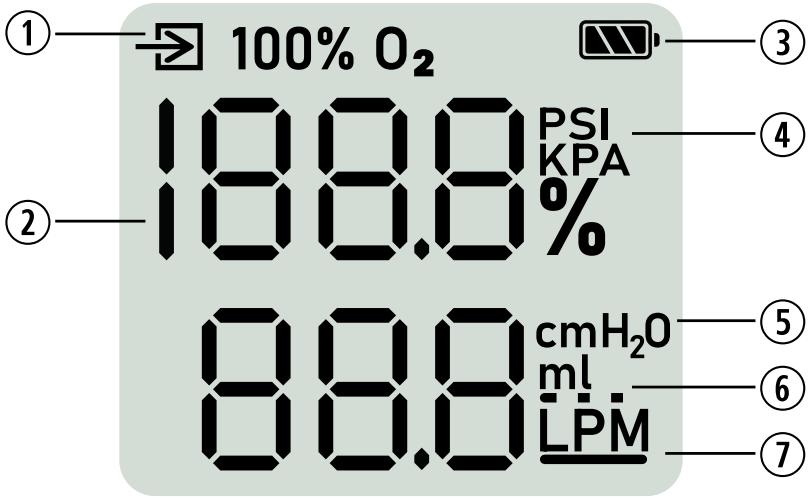
Ⓕ Power On/Off Button

Ⓖ Mode Button

Ⓗ Sample Outlet

Ⓘ Battery Cover

1.1.2. Display



① Feed 100% O_2 Indicator

② O_2 percent Display (%)

③ Battery Indicator

④ Pressure Unit (PSI or KPA)

⑤ Displaying Low Range Pressure (cmH_2O)

⑥ Displaying Pulse Volume (ml)

⑦ Displaying Continuous Flow Rate (LPM)

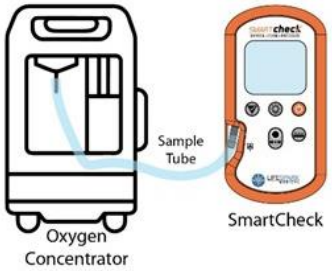
1.1.3. Controls

Control	Function	Additional Information
	**Power On/Off Button** Turns on/off the Smart Check	Device will turn off after 2 minutes of inactivity.
	**Flashlight/Backlight Button** Device off: Turn on flashlight Device on: Turn on backlight	Backlight will remain on for 30 seconds, or until turned off. Flashlight will remain on for 60 seconds, or until turned off. See Section 2.3 Backlight/Flashlight.
	**Calibration Check Button** Hold while delivering pure O_2 to verify O_2 calibration.	See Section 2.5 O2 Calibration
	**Mode Button** Switches between measuring continuous flow rate and pulse flow volume	See Sections 2.1.2 Measuring O2 and Flow Rate – Continuous Mode LPM 2.1.3 Measuring O2 and Flow Volume – Pulse Mode ml
	**Exhaust Port** Cover port outlet to measure pressure	See Section 2.1.4 Measuring Pressure – Pressure Mode KPA / PSI / cmH_2O

2. Operating Instructions

2.1. Getting Readings

2.1.1. Basic Setup



1) Power on the Smart Check device by pressing .
2) Remove humidifier (if connected).
3) Connect one end of the tube to the oxygen concentrator outlet. *
4) Ensure that the other end of the tube is securely connected to the Smart Check sample inlet .
5) Verify DUT is set to the OEM recommended mode and flow settings.

2.1.2. Measuring O_2 and Flow Rate – Continuous Mode LPM

This default mode is used to test continuous oxygen concentrators and pulse concentrators operating in continuous mode.

1) Verify oxygen concentrator is in Continuous Mode. NOTE: For Pulse Mode testing see Section 2.1.3.
2) Verify Smart Check is displaying LPM for Continuous Mode testing. If not, press .
3) Allow readings to stabilize for 10 seconds.
4) Read the O_2% and flow rate (LPM).

NOTE: Do not measure pure O_2 in this mode, see Section 2.5 for O_2 Calibration Verification.

2.1.3. Measuring O_2 and Flow Volume – Pulse Mode ml

This mode is used to test pulse oxygen concentrators in pulse mode.

1) Verify gas concentrator is in Pulse Mode and pulsing. NOTE: For Continuous Mode testing see Section 2.1.2.
2) Verify Smart Check is displaying ml for Pulse Mode testing. If not, press .
3) For accurate readings, wait a minimum of 12 pulse cycles.
4) Read the O_2% and flow volume (ml).

NOTE: Some pulse concentrator modes (like Sleep mode) deliver a continuous oxygen stream rather than pulses if not in use on a patient. The Smart Check will display E15 when testing a continuous source in Pulse Mode. Consult concentrator manuals.

* For best results, power on the Smart Check before connecting to the oxygen concentrator.

2.1.4. Measuring Pressure – Pressure Mode KPA / PSI / cmH_2O

This mode is used to test the pressure for both continuous and pulse gas concentrators. The Smart Check can also be used to test pressures on nebulizers, CPAPs and other devices.

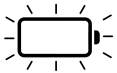
1) From either continuous or pulse mode, cover outlet with finger  .
2) Wait for pressure to be displayed.
   NOTE: When testing pressure from a pulse gas concentrator, wait several pulse cycles for values to stabilize.

See Section 2.6 to change default pressure units between PSI & KPA.

Low pressures, < 75 cmH_2O (~1 psi), will also be displayed in cmH_2O on the lower half of the display.

2.2. Reading Battery Level

The battery icon on the Smart Check screen indicates the remaining battery life. As the battery power decreases, the icon will show progressively lower levels. Under normal conditions the battery should last over one year of typical use. Note however, that the backlight consumes power 10X faster than the analyzer alone, so using it limits battery life.

Icon	Description
	Battery Level is full.
	Battery level is medium.
	Battery level is low.
	Battery level is very low.
	Battery level is critically low. Change the battery immediately (≈ 1 hour). NOTE: Calibration will not be affected when changing batteries.

If the battery level is too low for proper operation, the Smart Check will not power on.

2.3. Backlight/Flashlight

1) Backlight: With device on, press  . Backlight will remain on for 30 seconds or press  to turn off.
2) Flashlight: With the device off, press  . Flashlight will remain on for 60 seconds or press  to turn off.

2.4. Storing the Tube

Wrap tube around device and snap into embedded clips for storage.

2.5. O_2 Calibration Check

⚠ **CAUTION:** Calibration Check must be done using pure O_2 (bottle), not O_2 from a concentrator.

1) Deliver 2 to 4 LPM of Pure O_2  .
2) Press and hold  .
3) Pure O_2 reading will be displayed.
4) If reading is 98.5 – 101.5% calibration is OK. If out of spec, wait 15 minutes and re-test. If still out of spec contact Life Spark for service.

NOTE: If  is flashing, verify 100% O_2 is being delivered and not O_2 from a concentrator.

2.6. Changing pressure units

1) With the unit off, press and hold  .
2) While holding  , press and release  .
3) Release  .
4) New pressure unit will flash (**KPA** or **PSI**) for 4 seconds before resuming normal operation.

2.7. Manual Pressure Zero

The Smart Check auto zeros on startup. If the unit displays a pressure when none is applied, force the unit to zero the pressure as follows:

1) Ensure no gas is being supplied to the Smart Check.
2) With the unit off, press and hold  .
3) While holding  , press and release  , then  .
4) Release  .
5)  will flash for 4 seconds before resuming normal operation.

3. Factors Affecting Accuracy

3.1. High or Low flow

Oxygen concentrators have an optimal flow rate as specified by the concentrator manufacturer. Oxygen concentration may be low (85% to 91%) at flows outside the optimal flow. Oxygen concentration may be low on pulse concentrators set to higher volume pulses.

⚠ **Warning:** Always test oxygen concentrators at their optimal flow rate as specified by the concentrator manufacturer.

3.2. Temperature

Smart Check compensates for temperature across the operating range. Error codes are displayed if the device is outside the operating range. If this occurs, allow the temperature to stabilize before proceeding. Temperature will stabilize faster if connected to an operating oxygen concentrator.

3.3. Humidity

The Smart Check is accurate within the humidity operating range. High levels of humidity (> 95% relative) or condensing conditions can lead to inaccurate readings and device malfunction.

⚠ Caution**:** Always remove humidifiers from oxygen concentrators or other devices before testing.
Caution: Do not blow or breathe into the Smart Check as that can introduce excessive moisture.

3.4. Gas Mix

Smart Check is calibrated to measure gas from an oxygen concentrator composed of Oxygen, Nitrogen and Argon. It will also measure 100% Oxygen in Calibration Check mode. Measurement of any other gas mixes will result in inaccurate oxygen and flow readings.

4. Error Codes

Smart Check will display error codes under certain conditions. If error codes persist, contact customer support.

Error Code	Description	Action
E01	Error during self-check. Additional characters are a diagnostic code.	Turn Smart Check off and on - try again.
E02	Memory corruption error.	Verify flow is < 10 LPM.
E03 or E04	Sonic measurement error. Additional characters are a diagnostic code.	Contact customer support if issue continues.
E05 or E06	Read error. Additional characters are a diagnostic code.	Error will clear automatically when data is accurate.
E07	Data may be inaccurate.	Error will clear automatically when data is accurate.
E08	Unexpected pressure.	Zero Pressure. See Section 2.7.
E09 CLd	Smart Check is cold (< 5°C)	Allow Smart Check to warm up. Error clears when temperature is ok.
E 10 HOt	Smart Check is hot (> 40°C)	Allow the Smart Check to cool down. Error clears when temperature is ok.
E 11 LO	O_2 lower than expected	Check gas mix. Perform O_2 Calibration Check (see Section 2.5)
E 12 HI	O_2 higher than expected	Check gas mix*. Verify not using Pure O_2. Perform O_2 Calibration Check (see Section 2.5)
E 13	Exceeded pressure limit (> 45 PSI/310 kPa)	Lower pressure to clear the error code.
E 14	Exceeded flow rate limit (> 10.5 LPM)	Lower flow rate to clear the error code.
E 15	Exceeded flow volume limit (> 998 ml)	Verify test device is in pulse mode and not continuous flow mode.

5. Cleaning and Maintenance

The Smart Check has a stated service life of 5 years, but with proper care, cleaning, and maintenance, it can remain functional and accurate well beyond the stated service life. You may continue to use it as long as it is clean, physically undamaged and passes the O_2 calibration check described in this user manual.

Note: The sample tube may not last 5 years, depending on usage. Replace the sample tube if it appears to be damaged, leaking or has permanent kinks/twists. See Section 8 Replacement Parts.

5.1. What not to do when cleaning

DO NOT immerse Smart Check into liquid decontamination agents.

DO NOT spray cleaning agents directly on Smart Check.

DO NOT use strong solvent cleaners.

DO NOT allow liquids to ingress into the various ports.

DO NOT attempt to sterilize Smart Check.

5.2. Cleaning

Under normal use conditions, the surfaces of the Smart Check should not become contaminated. If you can see visible contamination, or you suspect that the external surface of the Smart Check has contacted infectious substances, the following cleaning procedures should be conducted.

Using Super Sani-Cloth® germicidal disposable wipes (or other similar medical grade 2-in-1 cleaning/disinfecting wipes) remove all visible contamination from the external surfaces of the device. Be sure to thoroughly clean, inspect, and remove all visible contamination from seams and recesses of the device that may trap contaminants. Use a new clean wipe to repeat cleaning once again after all visible contamination is removed, then allow device to air dry completely.

Note: If multiple cleanings over an extended use life result in the labels on front or back peeling at the edges, return to Life Spark Medical for repair.

5.3. Accidental Water Exposure

If your Smart Check is inadvertently exposed to water, it is crucial to take immediate action to prevent damage and ensure its continued accurate performance.

1) **Remove the batteries immediately.** Shake the Smart Check vigorously to remove as much water as possible. Do not use compressed air.
2) **Dry the exterior** with lint-free cloth. Leave the batteries out and the battery door off.
3) **Connect Smart Check** to an oxygen concentrator with a flow rate between 5-10 LPM. Allow oxygen to flow through the device for at least 2 hours after no visible moisture remains in the sample tube.
4) **Remove from concentrator** and allow Smart Check to sit for 24 hours with the battery door off at a temperature between 20° and 40° C.
5) **Reassemble the device** by reinstalling the batteries. Perform a calibration check using pure oxygen as described in Section 2.5 O2 Calibration Check.

5.4. Maintenance

The Smart Check should be stored in a clean, dry location when not in use. Remove the batteries from the Smart Check before storing for long-term storage (more than 2 months).

5.4.1. Changing Batteries

The Smart Check uses 2 replaceable AA Batteries (included). When replacing batteries, replace both at the same time with new batteries of the same type. Do **not** use rechargeable batteries.

1) Remove door using screwdriver.
2) Install batteries in correct orientation (see printed indication in battery compartment).
3) Reinstall the battery door and lightly tighten screw.
4) If Smart Check does not power on, verify batteries are oriented correctly.

5.4.2. Calibration

Routine O_2 and flow calibration is not required. If you have reason to question O_2 accuracy, calibration can be verified using 100% O_2 gas. See Section 2.5, O2 Calibration Check. Regular pressure calibration is not needed. In rare instances the pressure may need to be zeroed or tared. See Section 2.7 Manual Pressure Zero.

If you have reason to question the flow accuracy, you can check it against a suitable mass flow meter. The Smart Check reads volumetric flow rate, so be sure to set your reference flow meter to read volumetric rather than standard flow and minimize flow restriction between the reference meter and the Smart Check.

5.4.3. Firmware

Firmware cannot be updated in the field. Should an update be required, owners will be contacted by the OEM and provided instructions on how to receive the update.

6. Troubleshooting

Problem	Possible Causes	Actions
An error code(s) appears when testing nebulizers.	Variations in oxygen concentration and flow rate may trigger error codes due to pulsatility of the nebulizer pump. This is normal.	Cover the gas outlet to view pressure reading when testing a nebulizer.
The backlight/flashlight turns off on its own.	The backlight/flashlight is designed to stay on for only 30 seconds after the light button is pushed.	Press the light button to turn on the backlight/flashlight for 30 more seconds.
The user does not have the original sample tube needed for accurate readings.	The sample tube for the Smart Check has been lost.	You can use a similar size tubing as a temporary replacement, ensuring it is of similar length and fits tightly on the gas inlet without leaking. Order a replacement part as soon as possible, see Section 8 (Replacement Parts) for information on how to order.
Smart Check does not return to room air immediately after use.	Oxygen lingers inside the unit. This is normal.	No action required. The oxygen will diffuse out. NOTE: Do not breathe into unit.

Problem	Possible Causes	Actions
The Smart Check does not read accurately when connected to a pure oxygen source.	In its default concentrator mode, the Smart Check compensates for argon present in the output of an oxygen concentrator, which results in a false reading (typically around 91.8%) when connected to a pure oxygen source.	Press and hold the "cal check" button to remove the argon compensation, allowing the device to accurately measure the oxygen purity within ±1.5% of the actual value for compressed gaseous oxygen.
The Smart Check consistently shows an O_2 concentration reading of 96.0% on every concentrator tested.	Oxygen concentrators operate at maximum efficiency (96.0%) at lower flow rates. When the flow rate is increased, the concentrator's output typically decreases slightly, leading to a lower than 96.0% reading.	If you suspect the device may not be functioning properly, first stabilize it to room air. Then re-test with the concentrator, allowing it to stabilize at the higher flow rate before testing. This stabilization process may take up to 10 minutes.
The Smart Check shows pressure values even when no device is connected to it.	The pressure may need to be zeroed.	While disconnected from all devices, turn the Smart Check off and on. If it continues, manually zero pressure. See Section 0.

7. Specifications

General

Dimensions.....75 x 147 x 27 mm (2.95 x 5.79 x 1.06 in)
Weight .....0.23 kg (0.5 lbs.)
Battery Life.....1-year typical use (>16k read cycles) *
Battery Type .....2 replaceable AA batteries
Operating Temperature .....5° - 40° C (41° - 104° F)
Storage Temperature.....-25° - 70° C (-13° - 158° F)
Auto Shutoff ..... 2 minutes
Atmospheric pressure** .....700 – 1060 hPa absolute
Humidity..... 0 – 90% (non-condensing)
Pressure Units..... PSI, kPa, cmH_2O
Sample Rate ..... Continuous Mode: 1 Hz
.....Pulse Mode: 19.2 Hz
Response Time.....10 seconds
Start-up Time .....2.5 seconds

Concentration Mode

Range (concentrator) .....20.9 – 96%
Range (pure O_2) .....20.9 – 100%
Accuracy..... ±1.5% full scale
Resolution 0.10%

Flow Mode

Range .....0 – 10 LPM volumetric
Resolution ..... 0.1 LPM
Accuracy ..... ±0.2 LPM

Pulse Mode

Range ..... 3-200 ml
Resolution ..... 0.1 ml up to 100 ml, 1 ml above 100 ml
Accuracy .....±3 ml

Pressure Mode

Range ..... High: 0 -40 PSI (0-275 kPa)
..... Low: 3 – 70 cmH_2O
Resolution .....PSI and cmH_2O: 0.1
..... kPa: 0.1 up to 200, 1 above 200
Accuracy .....High: ±0.5% of reading
..... Low: ±0.3 cmH_2O

*Read cycle estimate is without backlight use. 1 year estimate includes occasional use of the backlight/flashlight. The backlight and flashlight consume power 10x faster than the analyzer alone. Using the backlight constantly will significantly reduce battery life.
**The Smart Check automatically compensates for changes in barometric pressure to maintain accuracy.

8. Replacement Parts

Contact Life Spark if the following replacement parts are needed:

REF MA0231, Battery door

REF MA0239, Sample tube

REF MA0238, Quick Start Guide

Replacement of any other components must be performed by Life Spark or an authorized service center.

9. Electromagnetic Compatibility

The Smart Check meets the applicable requirements of IEC 60601-1-2:2014/AMD1:2020 including the amendments provided in ISO 80601-2-55:2018+AMD2023 and IEC 60601-1-11:2015/AMD1:2020 for electromagnetic compatibility. During the following immunity testing the Smart Check continued to function normally and meet measurement accuracy specifications.

⚠ **Warning:** Use of this equipment adjacent to or stacked with other equipment, other than an oxygen concentrator, should be avoided because it could result in inaccurate measurements. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Smart Check system. Otherwise, degradation of the performance of this equipment could result.

⚠ **Warning:** Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances. Note that the Smart Check is not to be used within 1 meter of any Electrosurgical Cut and Coagulate device.

ELECTROMAGNETIC EMISSIONS		
Emissions Test	**Compliance**	**EMC Environmental Guidance**
RF Emissions	CISPR 11 Group 1	The Smart Check 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.
Classification	CISPR 11 Class B	The Smart Check 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	N/A	Internally powered only.
Voltage fluctuations / flicker emissions, IEC 61000-3-3	N/A	Internally powered only.

The Smart Check was tested for radiated immunity to RF wireless communication equipment at the test levels below.

Frequency (Hz)	Modulation	Level V/m
385	Pulse, 18 Hz, 50% DC	27
450	FM, 1 kHz Sine, ±5 Hz deviation	28
710, 745, 780	Pulse, 217 Hz, 50% DC	9
810, 870, 930	Pulse, 18 Hz, 50% DC	28
1720, 1845, 1970	Pulse, 217 Hz, 50% DC	28
2450		28
5240, 5500, 5785		9

ELECTROMAGNETIC IMMUNITY		
Immunity Test	**Compliance**	**EMC Environmental Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 2, 4, 8, 15kV air	The relative humidity should be at least 5 %
Radiated RF IEC 61000-4-3	10 V/m from 80 MHz to 2.7 GHz	The Smart Check is suitable for the RF electromagnetic environment of typical residential, hospital and commercial settings.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields from common appliances in the home are not expected to affect the device. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical residential, commercial or hospital environment. Keep the Smart Check away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.
IEC 61000-4-39 Immunity to proximity magnetic fields	30 kHz 8 A/m 134.2 kHz 65 A/m 13.56 MHz 7.5 A/m	Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the Smart Check is not to be used within 1 meter of any Electrosurgical Cut and Coagulate device. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

10. Cybersecurity Statements

This device has no electrical or wireless connections. Hence, the cybersecurity threat is very low, and the device can be used in any electronic environment safely. The best way to protect the device's integrity is to securely store the device in a controlled environment to minimize unauthorized handling.

User settings cannot alter the cybersecurity of the device. The device does not log or track sensitive, confidential, or proprietary data, so no data sanitation is required.

Should the calibration be tampered with, an error message will appear indicating the calibration data has been corrupted. Use the Cal Check procedure to verify the calibration is accurate.

Firmware cannot be updated in the field. Should an update be required (as determined by the OEM), owners will be contacted by the OEM and provided instructions on how to receive the update.