Operating Manual



WARNING
For a full understanding of the performance characteristics of this medical device, the user should carefully read this manual before use.

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This manual is Dynasthetics part number SAM5300

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Chapter 1: Manual Overview

Purpose

This manual contains instructions to safely operate the Sovant™ according to its function and intended use.

Intended Audience

This manual is intended for clinical professionals who have a working knowledge of supplemental oxygen delivery and related terminology.

Revision History

Each page of the manual has the manual part number and revision letter at the bottom of the page. The revision letter changes whenever the manual is updated.

Revision	Date	Comments
A	2024	Initial release of this manual
B	2025	Updated version
C	2026	Updated version, Firmware 1.0.6

Indications for Use

The Sovant is intended for prescription use only for patients that require supplemental oxygen.

Environment of use: hospital, clinic settings

Patient population: any patient for whom supplemental oxygen is indicated

Manual Terminology

The terms danger, warning, and caution are used throughout this manual to indicate hazards and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

HAZARD is defined as a source of potential injury to a patient or user.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor-to-moderate personal injury or product/property damage.

Manual Symbols

Symbol	Meaning
	Indicates important clarifications and additional information
	Indicates crucial warnings for patient and operator safety

Device Safety

The safety statements presented in this chapter refer to the equipment in general and, in most cases, apply to all aspects of the device.



NOTE: The order in which safety statements are presented in no way implies order of importance.

General Dangers, Warnings and Cautions

Dangers

There are no dangers that refer to the equipment in general. Specific "Danger" statements may be given in the respective sections of this manual.

Warnings



Before operating the Sovant, the operator must verify that it is in correct working order and operating condition.



No modification of this equipment is allowed.



Whenever the integrity of the product is in doubt, test all functions of the device.



Observe the applicable waste control regulations and keep packaging out of children's reach.



Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.



Do not use in a magnetic resonance (MR) environment.



A patient must be assisted if ambulating with this product placed on a roll-stand mounted device.



Use of an incompatible power adapter will not power the device and may lead to permanent damage of the instrument.



The Sovant has finite battery life. Use caution and monitor battery life when not connected to a power supply.



Batteries should be replaced only by trained service personnel. Replacement of lithium batteries by inadequately trained personnel could result in serious injury.



The Sovant should not be serviced or maintained while in operation with a patient.



There is a risk of fire associated with oxygen equipment and therapy. Do not operate the Sovant near sparks or open flames. Exercise extreme caution if operating near electrocautery or other ignition source.



Smoking during oxygen therapy is dangerous and is likely to result in serious injury or death of the patient and others from fire.



Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking or open flames within the same room as the Sovant or any oxygen-carrying accessories.



The settings of the Sovant may not correspond with continuous flow oxygen.



The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the Sovant.



During setup and oxygen therapy, use only water-based lotions or salves that are safe for use with supplemental oxygen delivery. Never use petroleum-based or oil-based lotions or salves to avoid risk of fire and burns.



Do not lubricate replaceable fittings, connections, tubing, or other accessories of the Sovant to avoid risk of fire and burns.



Use only Smart Oxygen accessories (i.e. SmartProngs™ cannula, Veyo™ mask, etc.) manufactured by Dynasthetics to ensure proper function and to avoid risk of fire and burns.



Wind or strong draughts can adversely affect accurate delivery of oxygen therapy.



Operation of the Sovant at an altitude above 10,000 ft. (3048 meters) or outside a temperature range of 39.2 and 100.4 ˚F (4 and 38 ˚C) may adversely affect the quality of the oxygen therapy.



Oxygen increases the risk of fire ignition and spread. Do not leave the nasal cannula on bed coverings or chair cushions if the Sovant is turned on, but not in use; the oxygen will make the materials more flammable. Turn the Sovant off when not in use.



If the patient feels discomfort or is experiencing a medical emergency, the patient should seek medical assistance immediately.



Geriatric, pediatric, or any other patients unable to communicate discomfort may require additional monitoring to avoid harm.



The Sovant should be operated only with Smart Prongs cannulas and Veyo masks manufactured by Dynasthetics specifically for use with the Sovant.



Monitoring of patient oxygen levels is recommended while operating the Sovant.



The Sovant Smart Oxygen accessories are indicated for single patient use. Do not reuse to avoid risk of performance degradation or patient contamination.



The proper placement and positioning of the nasal cannula accessory in the nose or oxygen mask on the face is critical to the consistent operation of the Sovant.



Failure of the Sovant may interrupt oxygen delivery to the patient.



When administering oxygen therapy with the Sovant, do not use a humidifier.

Cautions

ACCESSORIES — To ensure patient safety, use only parts and accessories (i.e., cannulas, masks, etc.) manufactured or recommended by Dynasthetics.

DISPOSABLES — Smart Oxygen accessories (i.e., cannulas, masks, etc.) are disposable and intended for single patient use only. They should not be reused as performance could degrade or contamination could occur.

INSTRUCTIONS FOR USE — To ensure safe operation of the Sovant, follow the listed instructions. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

MAINTENANCE — Preventive maintenance should be performed regularly. The user is responsible for any requirements specific to their country.

NEGLIGENCE — Dynasthetics does not assume responsibility for damage to the equipment caused by, and not limited to, use with an incorrect power supply, connection to a gas source that exceeds the maximum input pressure of 55 PSI (380 kPa), damage caused by dropping, submersion, or other abuse.

OPERATOR — This medical device must only be operated by clinical healthcare professionals who have received adequate training in the use of such equipment and who are capable of applying it properly.

POWER REQUIREMENTS — Before connecting the power adapter to the Sovant, ensure that it is compatible. Power adapters should provide 9 VDC and be capable

of providing 36 watts of power. The barrel connector is 2.1mm positive lead in the center contact of the connector.

RESTRICTED SALE — U.S. federal law restricts this device to sale to or on the order of a physician.

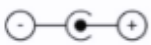
SUPERVISED USE — This equipment is intended for use under the direct supervision of a licensed clinical healthcare professional.

VENTILATION REQUIREMENTS — The Sovant should be set up in a location which affords sufficient ventilation. The ventilation openings of the Sovant must not be obstructed. The ambient conditions specified in the technical specifications must be ensured at all times.

MAGNETIC RESONANCE (MR) INCOMPATIBILITY — The Sovant is not intended to enter the MR environment. Keep the Sovant outside of the MR imaging scanner room.

Explanation of Symbols

The following is a table of symbols used in the Sovant labeling.

Symbol	Meaning
	Read operating instructions before using
	External power is connected
	Power on/off button
	Direct current power in
	Direct current barrel connector jack, center pin is positive voltage
	Type BF applied part
	Warning
℞ ONLY	Device is labeled for prescription use only

Symbol	Meaning
	Location of manufacture
	Date of manufacture
	Store between temperatures
	Store between relative humidity range
SN	Serial number
REF	Catalog number
LOT	Batch code

Chapter 2: Introduction

Sovant Background and Description

Oxygen therapy, or supplemental oxygen, is given to increase the amount of inhaled oxygen by infusing oxygen in the patient's nostrils or into an oxygen mask. The Sovant controls the flow of supplemental oxygen given to patients. The Sovant has two oxygen delivery modes:

1. **Continuous Flow mode**, where the Sovant delivers oxygen at a constant rate, or
2. **Synchronized Flow mode**, where the Sovant detects a patient's breath and synchronizes oxygen delivery with the start of each inhalation, pausing during exhalation.

Continuous Flow mode delivers oxygen to the patient at a constant rate set by the operator.

Synchronized Flow mode improves oxygen delivery to the alveoli, improves patient comfort and safety, reduces distortion of the capnogram, gives a secondary monitor of respiration and decreases oxygen waste. While in Synchronized Flow mode, the Sovant delivers a higher flow of oxygen at the beginning of inhalation when it is more likely to reach the patient's alveoli where it is needed. Synchronized Flow mode pauses the delivery of oxygen during exhalation, reducing drying of the nasal cavities and nasal discomfort. Oxygen flow during exhalation dilutes the CO_2 signal, leading to inaccurate capnometry. Excess oxygen given during exhalation can be uncomfortable for the patient and can build up under patient drapes and increase fire hazard. Because oxygen is only delivered during inhalation and not during exhalation, Synchronized Flow mode significantly reduces oxygen waste, improves patient comfort, and facilitates more accurate capnometry.

Theory of Operation

The Sovant has a sensitive air pressure sensor connected to its internal computer system. The Smart Prongs cannula and the Veyo mask have separate pressure monitoring tubes through which the pressure is monitored by the Sovant. As the patient inhales, a slight negative pressure is created. When the pressure sensor in the Sovant senses this negative pressure, the system responds by activating an electronic oxygen valve, giving the patient as much oxygen as they can inhale until

the set volume has been delivered. The volume of oxygen given for each breath is calculated by the Sovant based on the set oxygen flow rate and the patient's respiration rate (see the table of nominal oxygen bolus volumes by breath rate in Appendix A2). If no negative pressure events are detected after 15 seconds, the Sovant delivers automatic continuous oxygen flow at the set flow rate until breathing has resumed. The message "Auto Apneic O_2 Flow" is shown while continuous automatic oxygen flow is being given.

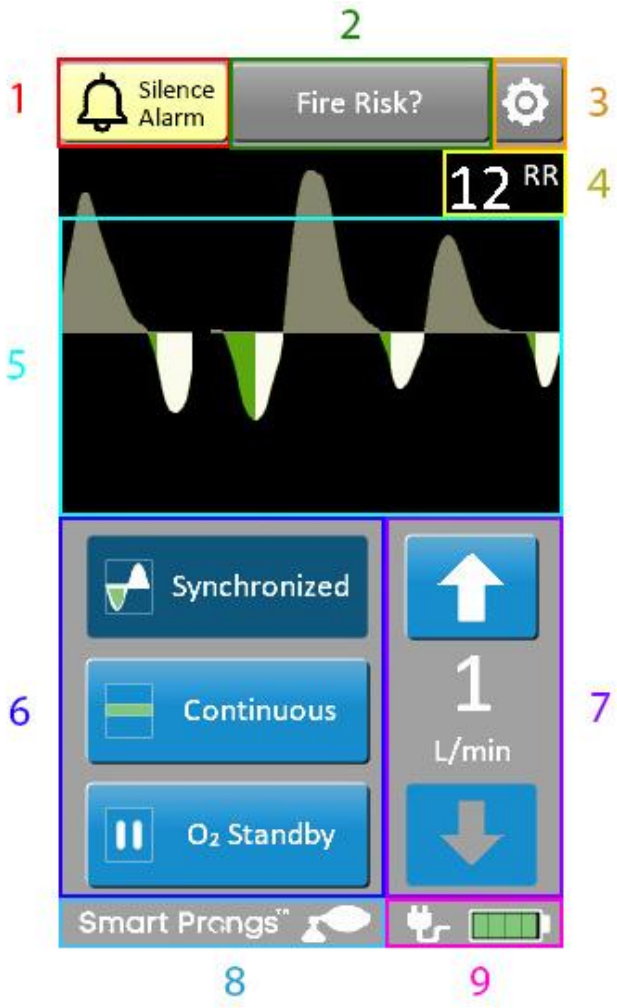
The Sovant can also deliver oxygen in Continuous Flow mode. In Continuous Flow mode, oxygen flows at the set flow rate throughout the breath phase. The flow of oxygen in this mode is controlled by the electronic valve in the Sovant.

Chapter 3: Description of Sovant Screens

User Interface Screens

The Sovant user interface is comprised of a single on/off button, LED light indicators and a graphical touchscreen display. The touch screen is divided into functional screen areas that are consistent across all modes of the main user interface. The options within each area of the main screen will change based on the Smart Oxygen accessory connected to the Sovant via the Smart Oxygen Port. The figures and tables below identify and describe the functional screen areas and functions of the main operational screens.

Screen Area Descriptions



Screen area	Function
1. Silence Alarm button	Each single press of this button silences the alarm sounds for 2 additional minutes up to a maximum of 10 minutes. Pressing and holding this button will silence alarm sounds until the device is powered off and back on. Pressing and holding this button again while alarms are permanently silenced will cause alarms to be audible again.
2. Fire Risk button	Unintended continuous flow oxygen or high oxygen flow rates could contribute to increased risk of fire. Pressing this button provides the user with the option to disable automatically giving continuous flow oxygen, or Auto Apneic O_2 Flow, in Synchronized Flow mode if no breaths are detected, and also prevents the user from selecting flow rates greater than 1 L/min without secondary confirmation.
3. Settings Adjustment button	Press this button to access device settings including adjustment of alarm volume and screen brightness.
4. Respiration Rate indicator	This area displays the patient's respiration rate (RR) in breaths per minute.
5. Waveform Display area	The Respiration Waveform is a graphical display of the breathing pressure observed by the Sovant. The vertical scale of the waveform is adjusted automatically to account for variability in patient anatomy as well as cannula/mask fit/insertion/positioning. Full description of the waveform area is detailed in Chapter 5.
6. Delivery Mode Selection area	The buttons in this area are used to select the oxygen delivery mode. Oxygen delivery mode descriptions are outlined in Chapter 5. Tap the desired mode to select it. A darker background color indicates which mode is active.
7. Flow Rate Selection buttons	Press these buttons to increase or decrease the set oxygen flow rate by 1 L/min. Pressing and holding the up arrow will set the flow to the maximum rate. Pressing and holding the down arrow will set the flow to the minimum rate.
8. Accessory Type indicator	This area indicates the type of Smart Oxygen accessory (i.e., Smart Prongs, Veyo, etc.) that is currently connected.
9. Power Status indicator	This indicates whether the Sovant external power supply is connected and the charge status of the internal battery.

Chapter 4: System Setup

1. **Perform pre-use device check.** Inspect the Sovant for signs of obvious damage or obstruction. Ensure that the inlet pressure is within specification. Use only genuine Dynasthetics Smart Oxygen accessories.
2. **Connect oxygen source.**
    a. First connect your oxygen source hose to the oxygen input port located on the back of the Sovant.



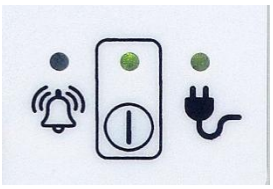
NOTE: Always connect the oxygen hose to the Sovant *before* connecting to the oxygen source.

    b. Second, connect the Sovant to a source of compressed pure oxygen. The oxygen pressure should be consistent with pressure found in medical gas pipeline systems (50-55 psi). If an oxygen tank is used, the outlet pressure of the tank regulator should be adjusted to between 50 and 55 pounds per square inch (PSI) prior to connection to the Sovant.

3. **Connect power supply.** Connect the power supply provided to the DC power input jack located on the back of the Sovant. Then connect the plug to an external power source.



During normal operation the Sovant should be connected to the external DC power supply. The power supply provides voltage at 9 volts DC. When the power supply is connected correctly, the LED above the wall plug icon (to the right of the power button) on the front of the device will be illuminated.



The Sovant has an internal backup battery. This battery is intended to power the device for up to 30 minutes to allow patient transport or other brief period when external power is interrupted. The internal battery is not designed to power the device for long periods without external power. The Sovant battery is being charged anytime external power is connected. The battery level is displayed in the Power Status indicator identified in Chapter 3.

> **NOTE:** If the battery has been completely drained, the Sovant will not turn on even when external DC power is applied. Please allow time for the battery to begin charging before moving to the next step to power on the device.

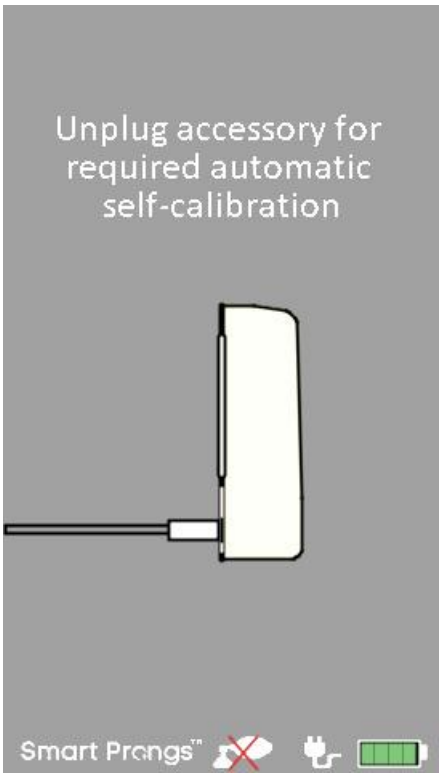
4. **Power on.** Power on the Sovant by pressing the on/off button located on the front of the device.

   At start-up, the Sovant performs a brief, automatic self-calibration. This test will check for the presence of a compressed oxygen source. The Sovant will also calibrate its patient pressure sensor. Any accessory must be disconnected during the pressure sensor calibration.

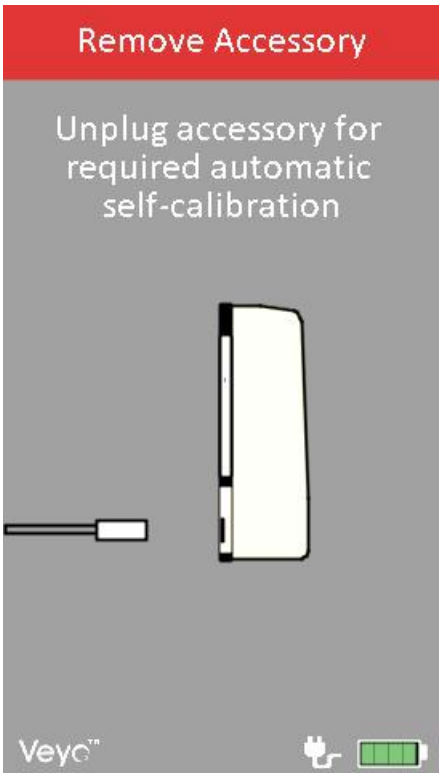


If the operator is unsure if the device is working properly, turning the device off and on again will reinitiate a self-calibration.

If an accessory is connected to the Sovant while calibration is required, the user will be prompted to remove the accessory to allow for calibration. The screen will display a message as shown below, indicating that the accessory must be removed to allow for automatic self-calibration of the patient pressure sensor.

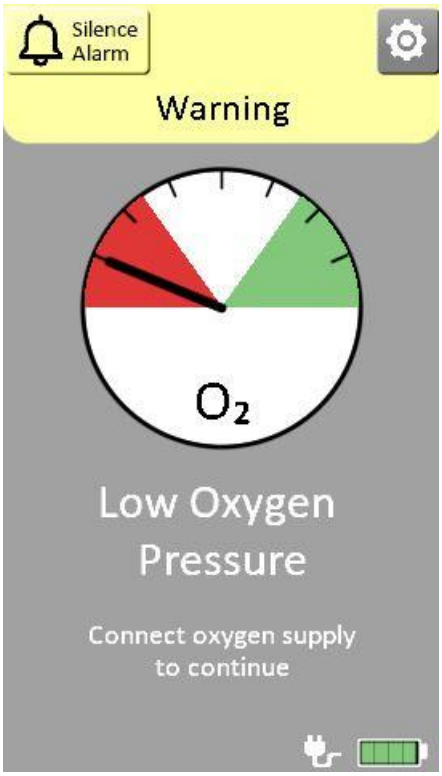


If the Smart Oxygen accessory has not been removed for two minutes, an audio and visual alarm will appear as shown below.



The self-calibration should only last a few seconds once any accessories are removed. If the self-calibration lasts more than one minute, ensure an adequate oxygen source is connected, check that the Smart Oxygen Port is clear of Smart Oxygen accessories and debris, and then power cycle the device.

When the Sovant is powered on, it will check for a connected oxygen source with sufficient inlet pressure. If it senses that sufficient oxygen supply is not available, the screen below will appear. Sufficient oxygen is needed before you can proceed to use the Sovant.

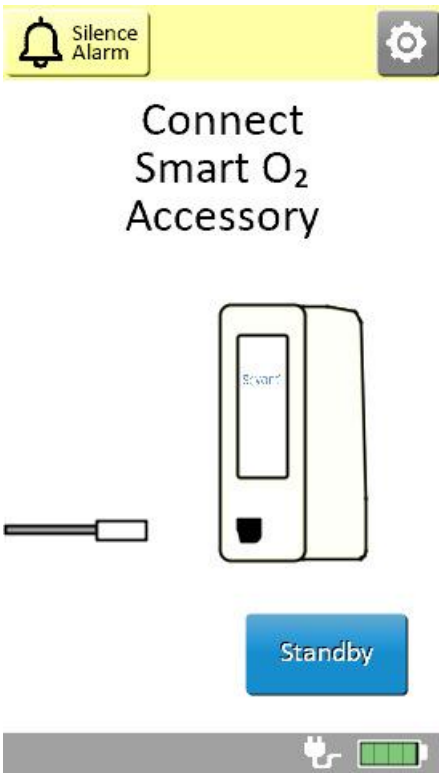


After connecting an oxygen source, the Sovant should detect it within 30 seconds or less, and the above screen should no longer be shown. If you notice the Sovant giving brief pulses of oxygen, but the warning screen above persists for longer than 30 seconds, check that the supplied pressure is at the required 50-55 PSI level.

5. **Connect Smart Oxygen accessory.** Connect the Smart Oxygen accessory (i.e., Smart Prongs, Veyo, etc.) by plugging the connector into the Smart Oxygen Port located on the front lower left corner of the Sovant.



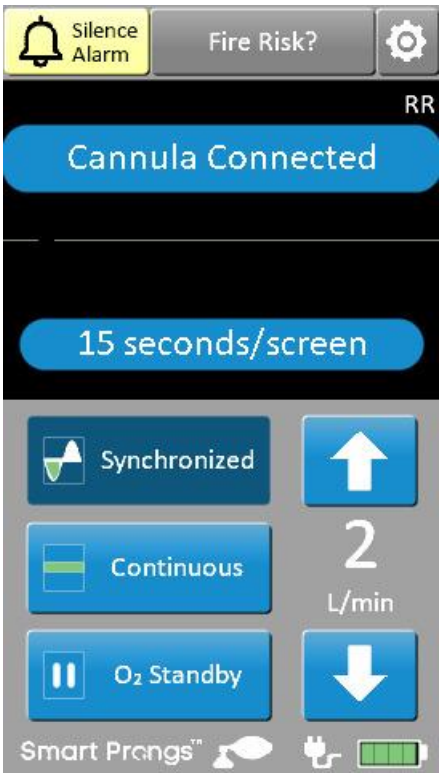
If sufficient oxygen supply is present, the Sovant will identify the current Smart Oxygen accessory connected. If no Smart Oxygen accessory is present, the screen below will appear. No oxygen delivery options are accessible until an accessory has been connected.



NOTE: The responsible organization should ensure the compatibility of the Sovant and all parts and accessories used to connect to the patient before use.

NOTE: The Sovant is only for use with genuine Dynasthetics Smart Oxygen accessories.

After the accessory (mask or cannula) has been connected, the message acknowledging what has been connected will appear as shown in the image below.



6. **Place Smart Oxygen accessory on patient.** Refer to the directions that come with each Smart Oxygen accessory (i.e., Smart Prongs, Veyo, etc.) for instructions on how to correctly place it on the patient.

7. **Select delivery mode.** Once sufficient oxygen supply and Smart Oxygen accessory connection have been verified, the Sovant will display the main user interface screen. The default oxygen delivery mode for the Smart Prongs and Veyo is Synchronized Flow mode. From this screen a desired mode may be selected by the operator in the Delivery Mode Selection area. The available modes are Synchronized Flow mode, Continuous Flow mode, and O_2 Standby. For detailed descriptions of each mode, please refer to Chapter 5.



8. **Select flow rate.** Press the up or down arrow to increase or decrease the oxygen flow rate. Each button press will increase or decrease the set flow rate by 1 L/min. Pressing and holding the up arrow will increase the rate to the maximum possible flow and pressing and holding the down arrow will decrease the rate to the minimum flow. When holding a flow rate button, the button will turn green after being held for one second or more, indicating that the flow rate will jump to the maximum or minimum flow rate (for the increase and decrease buttons respectively) after the button is released. The default oxygen flow rate upon startup is 2 L/min for the Smart Prongs cannula and 6 L/min for the Veyo mask. The maximum flow rate for the Smart Prongs cannula is 15 L/min and the minimum flow rate is 1 L/min. The maximum flow rate for the Veyo mask is 20 L/min and the minimum flow rate is 2 L/min. When the flow rate is set to the maximum level in Synchronized Flow mode, this is indicated with the word “MAX” in place of the up arrow, and in this case the Sovant will give oxygen the entire duration of inhalation.

Chapter 5: Operating Modes

Overview

The table below gives a brief introduction to each of the Sovant operating modes. Descriptions of each mode, its features, and intended purpose are detailed in subsequent sections.

Mode	Description
Synchronized Flow mode	Oxygen delivery is synchronized with patient inhalation and adjusted according to respiration rate and negative inspiratory pressure; no oxygen is delivered during exhalation
Continuous Flow mode	Oxygen is delivered constantly at a set flow rate
O_2 Standby	Oxygen delivery is paused
Mask Assist mode	Oxygen is delivered during ventilation with a bag-valve mask to compensate for leakage around the Smart Prongs cannula

NOTE: The Mask Assist mode is not available if you are using Veyo mask, when the Fire Risk button is active, or when there is insufficient space at the tip of the nasal prongs to allow high oxygen flows.

Synchronized Flow Mode

When the Sovant is powered on, the default mode is Synchronized Flow mode. This mode delivers high-flow oxygen synchronized with the start of inhalation as indicated by negative inspiratory pressure. The flow of oxygen is automatically adjusted according to the patient's inspiratory flow and the time since the prior breath. When more time has elapsed since the previous breath, a larger boost volume of oxygen is given to compensate for the oxygen not inhaled while respiration was paused. Conversely, smaller oxygen pulses are given at high breath rates (see Appendix A2 for specific oxygen pulse volumes at typical breath rates).

When in Synchronized Flow mode the Sovant uses only 40% of the user-set oxygen flow rate (i.e. when 2 L/min is selected, 0.8 L/min is used). This has been demonstrated to result in a similar volume of inhaled oxygen as continuous flow

oxygen when patients are breathing at normal or high rates. By disabling flow during exhalation, Synchronized Flow mode allows for more accurate end-tidal CO_2 measurements, improved patient comfort, and reduced oxygen waste.

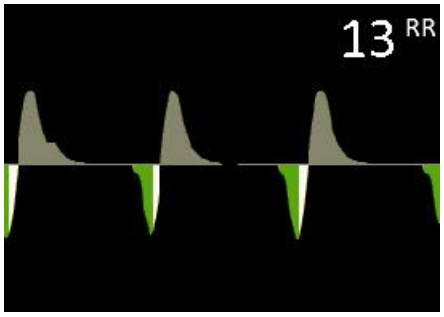
While in Synchronized Flow mode, if the flow rate is set to the maximum level (15 L/min for Smart Prongs and 20 L/min for Veyo Mask), oxygen will be delivered for the entire duration of inhalation instead of only delivering a set volume of oxygen at the start of the breath. This helps to ensure the maximum amount of oxygen possible is being delivered to the patient. Note that oxygen savings will be less than the normal 60% under these conditions, and that maximum oxygen delivery does not occur in this manner when the Fire Risk button is activated.



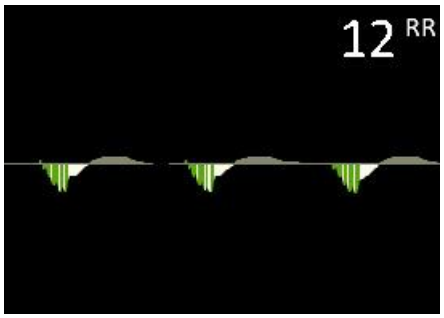
The Respiration Waveform shows the pressure in the nares or mask depending on the accessory used. The width of the plot represents 15 or 30 seconds of data (user selectable). The vertical scale of the waveform is adjusted automatically according to the pressure change observed in response to periodic test pulses of oxygen. These test pulses allow the Sovant to compensate for differences in the area of the nostrils or the tightness of the mask fit so that changes in depth of respiration can be observed in the plot. When using Synchronized Flow mode, the breath rate is displayed in the upper right corner of the graph area.

Respiration Waveform in Synchronized Flow Mode

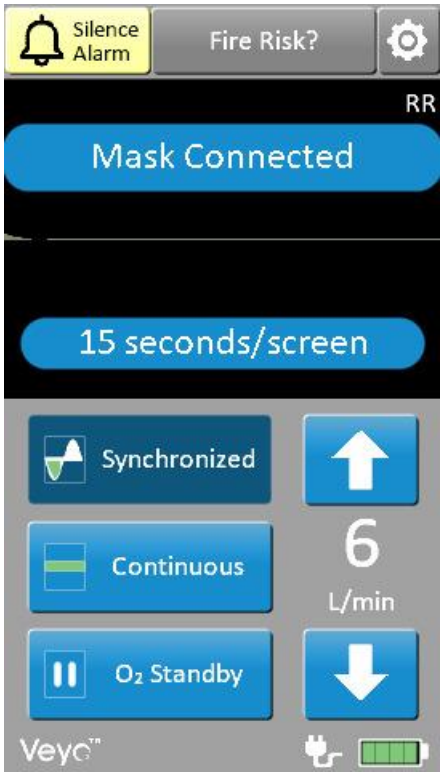
When Synchronized Flow mode is active, the Respiration Waveform is shaded green while oxygen is being delivered. The waveform is in white after the specified volume of oxygen for each breath has been delivered as shown below.



When the patient's airflow is restricted so that the full volume of oxygen cannot be immediately delivered, the green and white areas of the waveform will be intermixed showing that multiple attempts to deliver the oxygen are needed during the inspiratory phase of a single breath as shown below.



The Respiration Waveform will show the measured oxygen flow rate for the previous 15 or 30 seconds. Tap the screen in the plot area to change between the 15 second and 30 seconds per screen view. After changing the plot time, or connecting a new accessory, a message showing the duration of the waveform is briefly shown on the screen.



The option to change the display duration of the Respiration Waveform is available in all oxygen delivery modes.

Automatic Apneic O_2 Flow

When in Synchronized Flow mode and no breaths are detected for 15 seconds or longer, the Sovant triggers an audible and visual alarm message indicating that no breath has been detected. As a precaution, Sovant will automatically transition to give continuous flow oxygen at the automatic apneic flow rate until a breath is detected. The display screen will display the alarm condition along with a message of "Apneic O_2" indicating that continuous flow oxygen will be given until a breath is detected.

The default automatic apneic flow rate is the maximum flow rate of 15 L/min of oxygen for the SmartProngs cannula and 20 L/min for the Veyo Mask. The

automatic apneic flow rate can be increased using the up arrow and decreased using the down arrow while the automatic apneic flow rate is active. The selected automatic apneic flow rate will be given when needed until the Sovant is used for a new patient as detected by replacing the Smart Oxygen Accessory.

See Chapter 6 for a detailed description of this alarm.

NOTE: Automatic Apneic O_2 Flow will not be given when the Fire Risk button is active. When the Fire Risk button is active, a flame icon is added to the button.



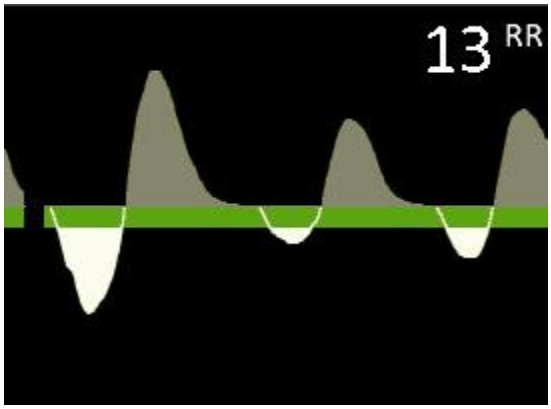
NOTE: The Sovant periodically gives a brief pulse of oxygen to automatically assess cannula placement in the nares or quality of the mask seal.

Continuous Flow Mode

Continuous Flow mode delivers a set volume of oxygen at a constant flow rate. This can be used when the patient's breathing is too shallow to trigger Synchronized Flow delivery.

Respiration Waveform in Continuous Flow Mode

The Respiration Waveform is active during Continuous Flow mode. The thickness of the green bar on this plot is indicative of the set oxygen flow rate. The waveform appears in white below the green bar to show negative pressure for inhalation and grey above the green bar to show positive pressure for exhalation.


13 RR

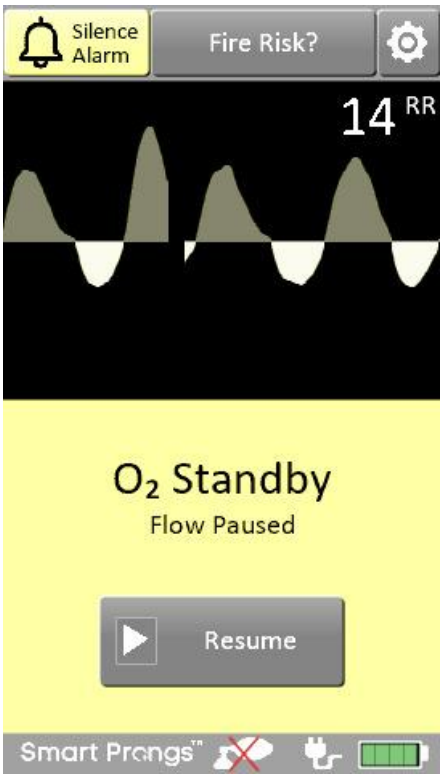
NOTE: As a fire safety measure, the Sovant will automatically discontinue oxygen flow for a quarter of a second every 5 seconds while the flow of oxygen is continuous and less than 10 L/min. This pause in oxygen flow is very brief and will not cause a significant decrease in the volume of oxygen inhaled by the patient.

The option to change the display duration of the Respiration Waveform is available in all oxygen delivery modes. Changing the duration is described in the above section “Respiration Waveform in Synchronized Flow Mode”.

O_2 Standby Mode

O_2 Standby pauses oxygen delivery until manually resumed. This is used when no oxygen flow is desired for either a brief or extended period. When this mode is selected the Respiration Waveform is still active. Press the “Resume” button to continue oxygen flow.

Upon entering O_2 Standby, the user interface will indicate O_2 Standby: Flow Paused status and a button to resume the previous delivery mode will appear in the Flow Rate Selection area. The Sovant will remain in O_2 Standby status until this button is selected.



Respiration Waveform in O_2 Standby Mode

The Respiration Waveform will continue to show the respiration pressure while Sovant is in O_2 Standby mode. No green areas are shown since no oxygen is being given.

The option to change the display duration of the Respiration Waveform is available in all oxygen delivery modes. Changing the duration is described in the above section “Respiration Waveform in Synchronized Flow Mode”.

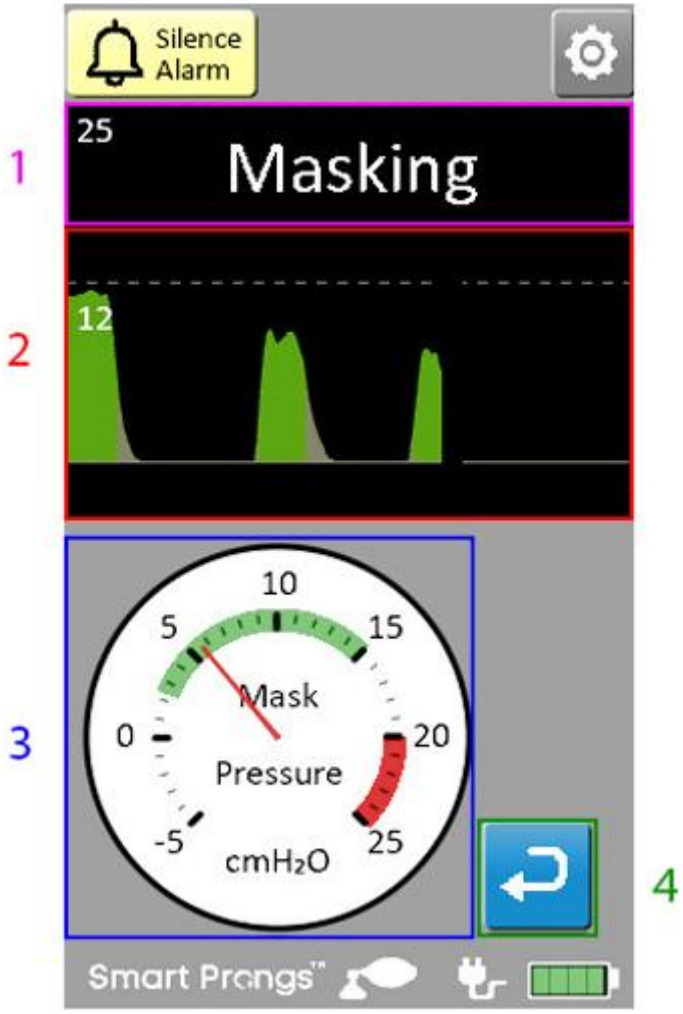
NOTE: Even though the Respiration Waveform is shown during O_2 Standby mode no patient monitoring alarms are active. The “No Breath, Check Patient” and “No breath, Check Cannula” alarms are not triggered while Sovant is in O_2 Standby mode.

Mask Assist Mode

When manual positive pressure ventilation is given using a bag-valve mask placed over the Smart Prongs cannula, the Sovant detects the elevated pressure and will automatically enter Mask Assist mode. This feature is used when manual ventilation breaths are given using a bag-valve-mask (BVM) or an anesthesia bag on an anesthesia workstation to give manual positive pressure breaths to the patient by placing a mask on their face over the Smart Prongs nasal cannula. Normally, without the Sovant, placing a BVM over cannula tubes and ventilating with positive pressure creates an uncompensated air leak, making it more difficult to ventilate the patient. When this feature is active, the Sovant will deliver higher flows of supplemental oxygen through the nasal canula to compensate for any leakage while the mask is applied and the bag is being squeezed. Mask Assist is activated automatically when mask pressures over 5 cmH_2O are detected.

When Mask Assist has already been activated, high-flow oxygen is given automatically when the bag is squeezed as detected by an increase in mask pressure. Mask Assist oxygen flow is reduced automatically for pressures above 15 cmH_2O. Mask Assist is turned off completely when pressure reaches 20 cmH_2O or when the bag is released. Release of the bag is detected by a sudden drop in mask pressure as is observed when the bag is allowed to refill.

When Mask Assist is active, it will be indicated on the Sovant. A screen displaying a pressure gauge which shows the current mask pressure. The region of the pressure gauge highlighted in green is the range of pressure for which the Sovant will deliver supplemental oxygen.



Screen area	Function
1. Active Mode area	"Masking" message indicates that the current mode is Mask Assist.
2. Mask Pressure Waveform area	This displays a waveform of the pressure in the mask during the previous 15 or 30 seconds as selected by the user.

3. Pressure Gauge area	This indicates the current mask pressure. The range highlighted in red indicates pressures that are usually too high for patient safety. Oxygen flow is diminished for pressures in the range between green and red on the gauge.
4. Return button	Pressing this allows the user to exit Mask Assist mode.

When the bag is squeezed, the screen will change and a message on the screen will appear to indicate that the Sovant is actively delivering oxygen.

Alternatively, if negative pressure is detected indicating the patient is breathing spontaneously or if the return button is pressed, the system will exit Mask Assist mode and return to the previous mode selected. If no breaths are detected (manual or spontaneous) while in mask assist mode for 15 seconds, automatic apneic oxygen flow will be given.

NOTE: Mask Assist is only available when using the Smart Prongs cannula. It is not available when using other Smart Oxygen accessories, such as the Veyo mask.

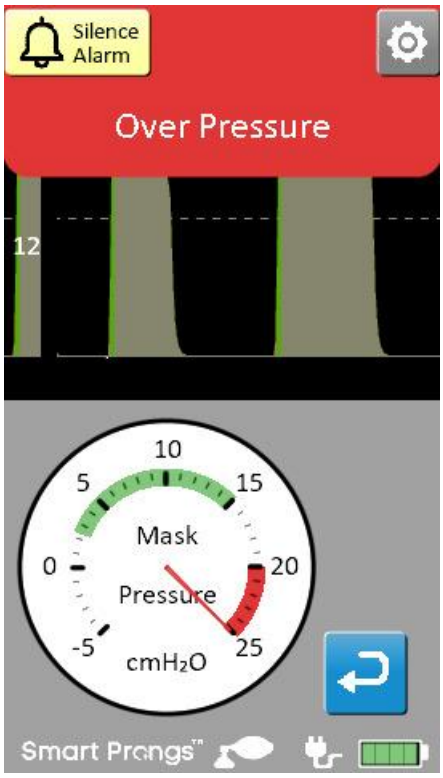
NOTE: Mask Assist Mode is not available when any of the three conditions listed below are met:

1. Fire Risk Button is active,
2. Sovant is in O_2 Standby mode, or
3. When space at the tip of the nasal prongs is insufficient for high oxygen flows.

The BVM icon in the status bar on the bottom of the screen will have a red "x" over it if any of these conditions are present, indicating that Mask Assist is not available.

Over Pressure Alarm

When using Mask Assist mode and the system detects a mask pressure of 20 cmH_2O or greater, the Over Pressure alarm will be triggered. When triggered the alarm sound is activated and an alarm screen similar to that shown below will be displayed.


Silence Alarm
Over Pressure
12
10
5
15
Mask
0
Pressure
20
-5
25
cmH2O
Smart Prongs™

Chapter 6: Alarms, Prompts, Buttons and Indicators

The Sovant includes an alarm system.

The functionality of the alarm system can be verified upon startup by visually observing the alarm LED indicators and listening to the alarm speaker. During the startup process, all alarm LED indicators are illuminated and a tone is generated by the alarm speaker.

Alarms are indicated visually and audibly. A red alarm indicator light represents a high-priority alarm, and a yellow indicator light represents a low-priority alarm. The audio alarm sequence for high-priority alarms consists of five tones- a series of three distinct tones followed by a pause after which two additional tones are heard. The audio alarm sequence for low-priority alarms is a series of two distinct tones. Visual indicators of alarm conditions are also displayed on the screen in the Warnings/Alarms area. Red is used for high-priority alarms. Yellow is used for low-priority alarms.

When multiple alarms are active, the Sovant will display the alarm with higher priority until it has been resolved. Alarm priority is determined using an internal ranking. Once the higher priority alarm has been resolved, the lower priority alarm will be displayed.

Alarms

Alarms given by the Sovant are listed below in order of ranking priority, beginning with highest priority and ending lowest priority.

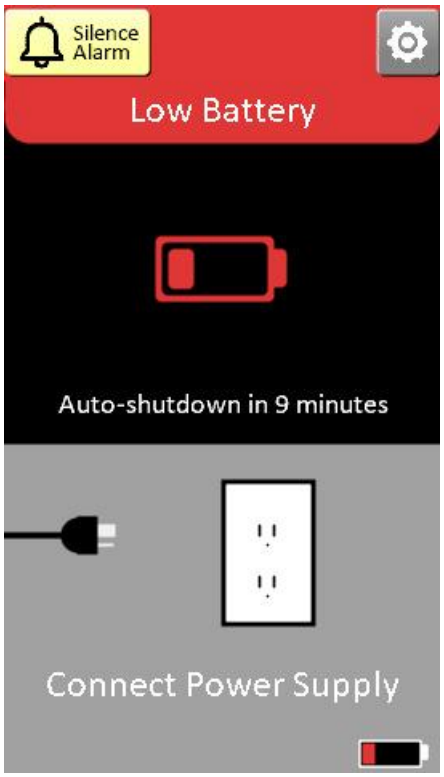


NOTE: Characteristics of the alarms alarm limits are set at the factory and cannot be adjusted by the user.

NOTE: Audio alarm sound level can be adjusted in the settings page

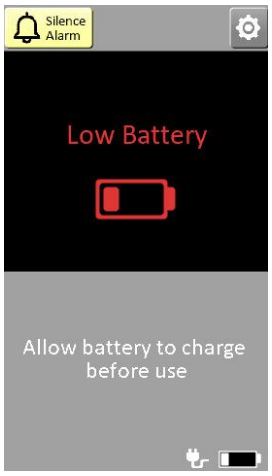
Low Battery (High Priority)

This alarm will appear with the screen shown below if no power supply is connected and the battery level becomes critically low.



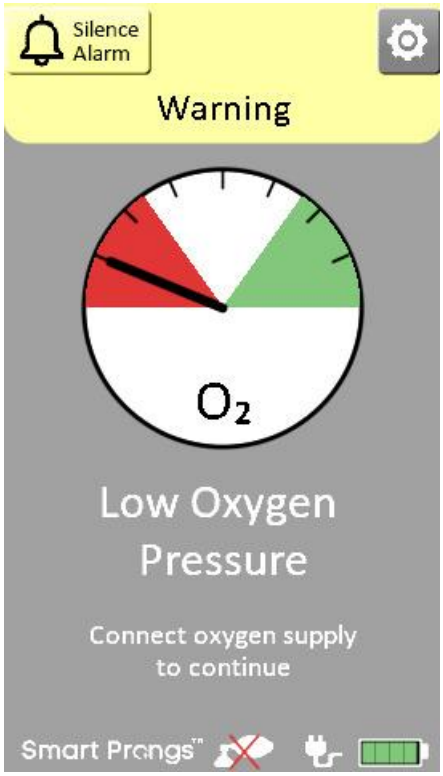
The screen will prompt the user to connect a power supply to charge the battery. This alarm screen is shown for 10 minutes before the device powers down automatically due to lack of power. The screen will give the time remaining until the device automatically powers down. This alarm is resolved by plugging in the power supply and charging the battery. The Silence Alarm button to pause the audio associated with the alarm for two minutes is available in the upper left corner of the screen. The audio alarm sequence for this alarm is the high-priority (five-tone) alarm sound.

NOTE: If the battery level is below the minimum operable threshold the display will show that the battery must be charged sufficiently before the device can be operated.

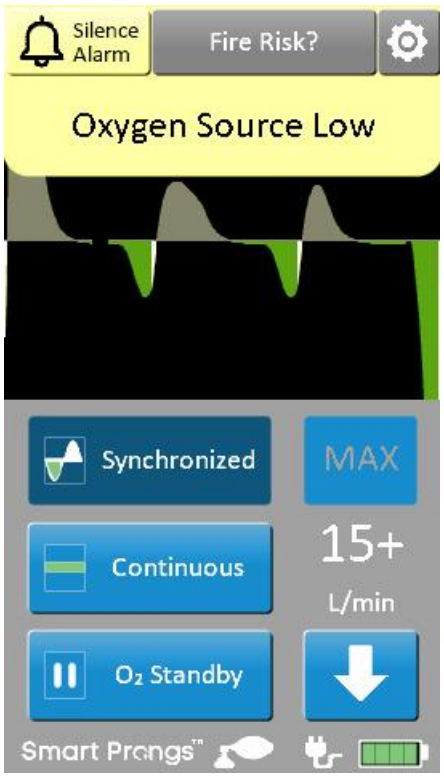


Low Oxygen Pressure (Low Priority)

The Sovant will display the screen below if the oxygen supply is insufficient for the Sovant to operate adequately.



If the oxygen pressure is low but the Sovant is still capable of operating, a warning message will be shown at the top of the screen, while the Sovant continues to operate, as shown below.

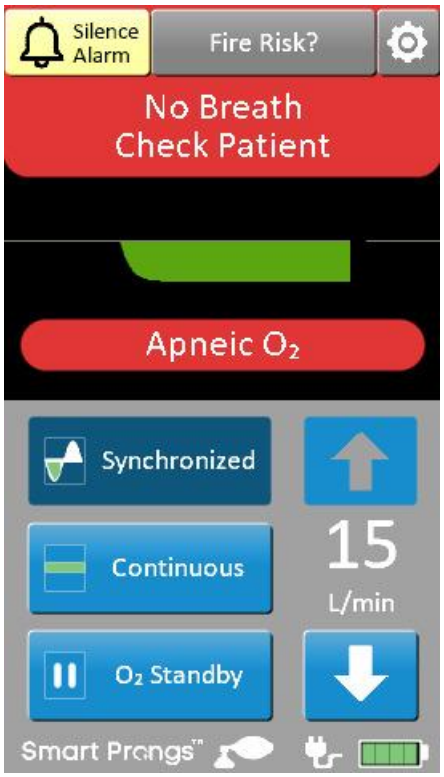


To resolve this alarm, the operator should check all pneumatic connections for leaks and check the pressure level of the compressed oxygen source to ensure it meets device requirements. This alarm may appear in Synchronized Flow mode, Continuous Flow mode, and Mask Assist mode. The audio alarm sequence for this alarm is the low-priority (two-tone) alarm sound. If this alarm is a warning and the Sovant can still operate, the alarm can be silenced by pressing the alarm silence button.

NOTE: The accuracy of oxygen delivery flow rates and volumes cannot be guaranteed while this alarm is active.

No Breath, Check Patient (High Priority)

In Synchronized Flow mode, if no breaths are detected after 15 seconds, this alarm and recommended action will appear on the screen as shown below.



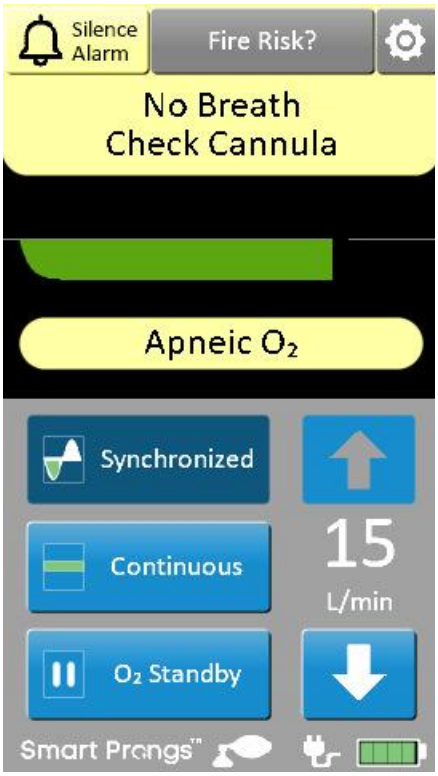
When this alarm is triggered, the Sovant will deliver continuous flow oxygen at 15 L/min when using the SmartProngs Cannula and 20 L/min when using the VeyO_2 mask. The Automatic Apneic O_2 Flow rate can be adjusted up or down by the user with the up and down arrows on the screen while the Automatic Apneic O_2 Flow is active. , . The Sovant will continue to give continuous flow oxygen until a breath is detected, at which point it will automatically return to Synchronized Flow mode. To resolve this alarm, the operator should check the patient's breathing and clinically intervene if necessary. A button to silence the audio alarm sequence for two minutes is available in the upper left corner of the screen. This audio alarm sequence for this alarm is the high priority (five tone) alarm sound.

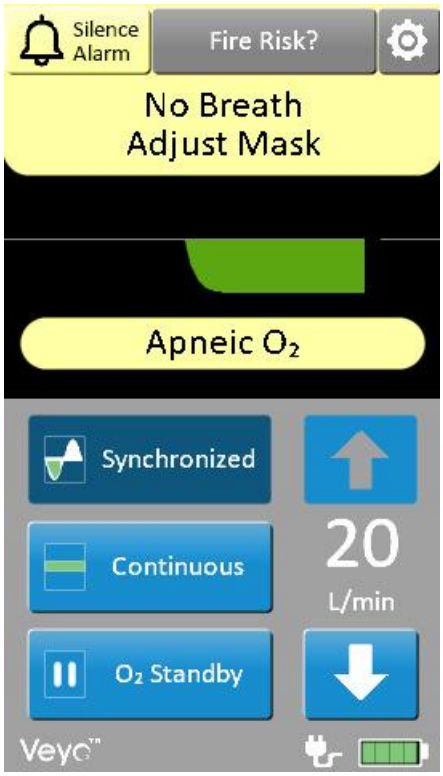
NOTE: This alarm is only available in Synchronized Flow mode.

NOTE: If the Automatic Apneic O2 Flow is adjusted up or down, the new flow rate will remain active while Automatic Apneic O_2 flow is given until the accessory has been replaced.

No Breath, Check Cannula/Mask Placement (Low Priority)

This warning appears if the Smart Oxygen accessory is not properly positioned on the patient. When this condition is detected, the screen will indicate that no breath is detected and suggest that the user check cannula or mask placement as shown below.





While this alarm is active, the Sovant will deliver Automatic Apneic O_2 Flow at the currently selected flow rate until a breath is detected, at which point it will return to Synchronized Flow mode.

This alarm is triggered when no breaths are detected and the measured pressure change in response to a pulse of oxygen is low. When using the Smart Prongs cannula, this usually occurs then the cannula is dislodged from the nostrils. Repositioning the cannula within the nostrils will usually correct this problem. This alarm may be triggered if the nostrils are large relative to the cannula prongs. In this situation, if repositioning the cannula prongs does not resolve the problem, it may be necessary to use the Veyo mask accessory rather than the Smart Prongs cannula. The audio alarm sequence for this alarm is the low priority (two tone) alarm sound.

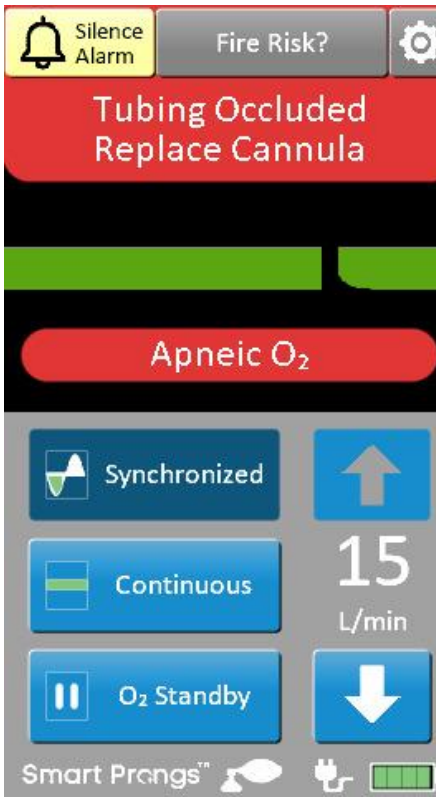
When this alarm is triggered while the Veyo mask is in use, it may be necessary to adjust the mask placement on the patient by tightening the head strap and/or the metal nose bar on the mask.

The Silence Alarm button in the upper left corner of the screen can be used to silence the audio alarm sequence for two minutes while this warning is active. The audio alarm sequence for this alarm is the low priority (two tone) alarm sound.

	NOTE: This alarm is only available in Synchronized Flow mode.

Tubing Occluded

This warning appears if the port or tube in the SmartProngs Cannula accessory is has become occluded with water or mucus. When this condition is detected, the screen will indicate that no breath is detected and suggest that the user replace the cannula.



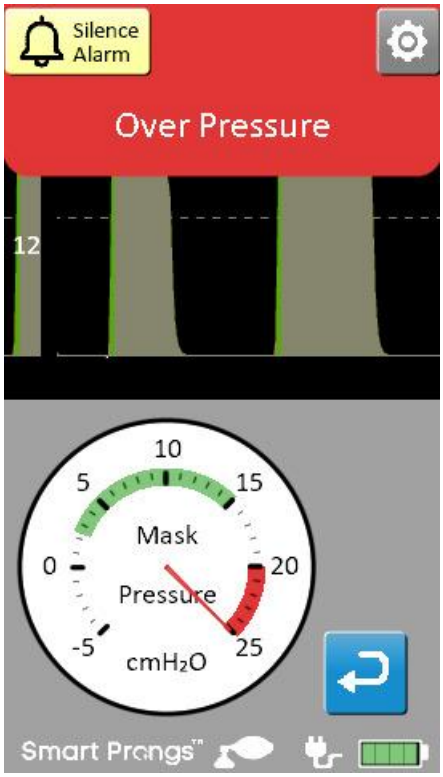
While this alarm is active, the Sovant will deliver Automatic Apneic O_2 Flow at the currently selected flow rate until the occlusion has been cleared and breath is detected, at which point it will return to Synchronized Flow mode.

This alarm is triggered when liquid or mucus in the patient's nares enters the pressure measurement port on the nasal prongs. When this occurs, the best course of action is to replace the SmartProngs with a new dry nasal or to use the VeyO_2 mask in place of a cannula. The audio alarm sequence for this alarm is the high priority (five tone) alarm sound.

	NOTE: This alarm is only possible when using Synchronized Flow mode.

Over Pressure (High Priority)

This alarm appears if detected mask pressure is above recommended levels (exceeding 20 cmH2O).



To resolve this alarm the user can choose to decrease the positive pressure of their masked breaths. The audio alarm sequence for this alarm is the high priority (five tone) alarm sound.

NOTE: This alarm is only available while Mask Assist mode is active.

Alarm Silencing

The “Silence Alarm” button located in the top left corner of the screen allows the user to disable the audio alarm while a problem is resolved. Each press of the “Silence Alarm” button adds two minutes to the time that alarms will be silenced up to a maximum of 10 minutes. When audio alarms are silenced and the time countdown is active, a red X is drawn over the alarm symbol, and the countdown time until alarms will be re-activated is shown on the Silence Alarm button.



Pressing and holding the Silence Alarm button for one second will permanently silence the alarm until the Sovant is powered off and back on. When permanently silenced, a red X is placed over the alarm symbol on the button and no count down time is shown.

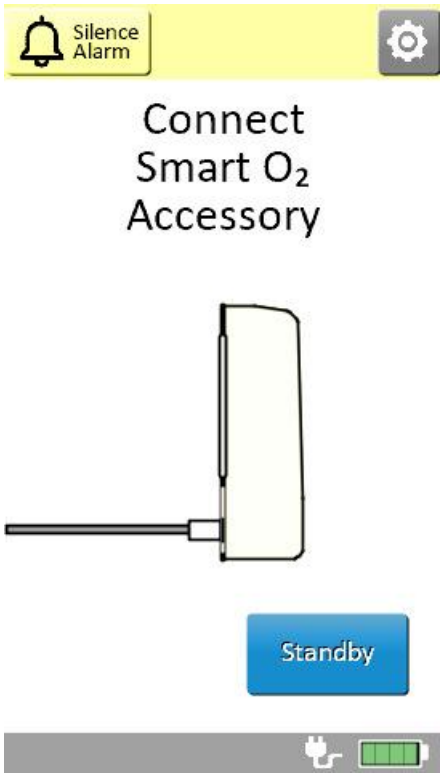


Pressing and holding the button again when alarms are permanently silenced will reactivate alarm sounds.

Prompts, Buttons and Indicators

Connect Smart Oxygen Accessory

If no Smart Oxygen accessory is detected, or the connector is improperly seated, the Sovant screen will display this an animation showing how to connect the accessory.



No oxygen delivery modes may be accessed until this issue is resolved. To access the main screen the operator should connect a Smart Oxygen accessory (i.e., Smart Prongs cannula, Veyo oxygen mask, etc.). After two minutes of displaying this screen the Sovant will automatically enter Standby mode (more information on Standby mode is found later in this chapter).

Fire Risk

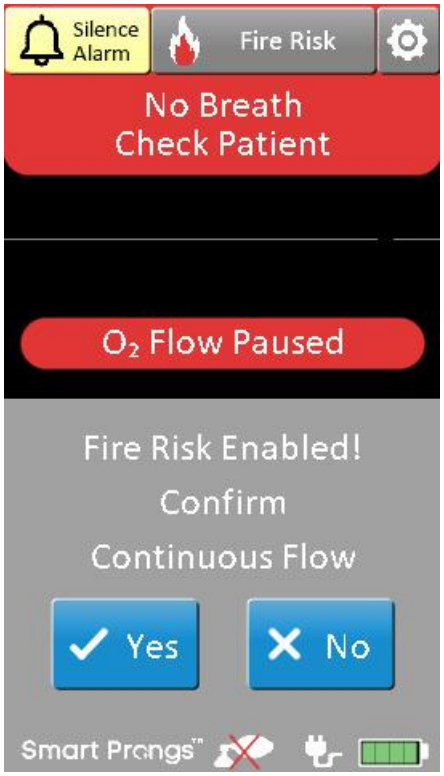
Oxygen flow can contribute to operating room fire. Additionally, continuous flow oxygen contributes to excessively high concentrations of oxygen beneath surgical drapes, further increasing the risk of fire. Because the Sovant automatically switches to continuous flow oxygen when no breaths are detected in Synchronized Flow mode, the risk of fire may be higher. The Fire Risk button is used to disable Automatic Apneic O_2 Flow when no breaths are detected, and also require secondary confirmation from the user before administering flows greater than 1 L/min. Pressing the Fire Risk button activates the screen shown below asking the user if they would like to require secondary confirmation to administer flows greater than 1 L/min.



Pressing the Confirm Limited Oxygen Flow button changes how the Sovant responds when no breaths are detected and adds the red flame symbol to the Fire Risk button as shown below.

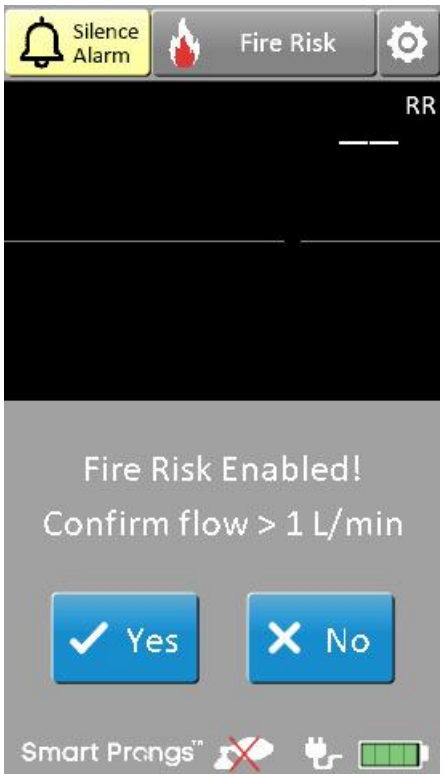


When Fire Risk is active and no breaths are detected, the No Breath Alarm is shown and the display indicates that no oxygen is flowing. If you wish to give continuous flow oxygen at this point, you must select and confirm Continuous Flow mode.



When this screen is shown, the user can press “Yes” to confirm and give continuous flow oxygen or press “No” and go back to the previous screen.

If the flow rate is increased, the following screen is shown.



When this screen is shown, the user can press “Yes” to confirm and give higher oxygen flow or press “No” and go back to the previous screen. After confirming, the user has 5 seconds to adjust the flow without secondary confirmation. After five seconds, secondary confirmation will once again be required to increase the flow rate.

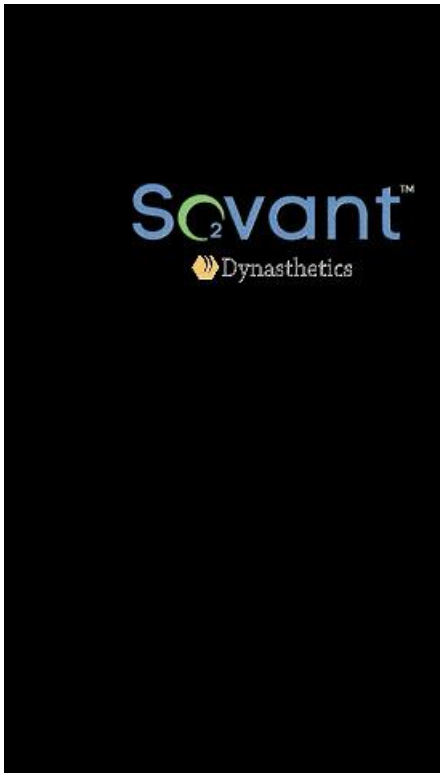
Pressing the Fire Risk button while fire risk is active displays the screen below asking the user if they would like to confirm that there is no fire risk present. Selecting the Confirm No Fire Risk button will cause the device to exit Fire Risk mode. Continuous flow oxygen or oxygen flow greater than 1 L/min will then be possible without confirmation and will be given automatically when no breaths are detected in Synchronized Flow mode. The flame symbol is removed from the Fire Risk button for visual indication.



NOTE: Because Synchronized Flow mode only uses 40% of the set oxygen flow, use of oxygen flow rates up to 1 L/min are possible without requiring confirmation while fire risk is active.

System Standby Mode

Sovant enters Standby mode when the Standby button is pressed while no accessory is installed. Alternatively, if two minutes pass while no accessory is installed, the Sovant will automatically enter Standby mode. In Standby mode the animated screen saver is shown.



Touching the Sovant screen, inserting an accessory, or pressing the power button causes the Sovant to exit Standby mode.

Shut Down

To power off the Sovant, press the power button on the front of the device. The user will then be prompted to confirm or cancel the action on the screen shown below.



Pressing the “Shut Down” button will cause the Sovant to power down. Pressing the “Go Back” button will return the Sovant to the screen that was active when the power button was pressed.



At any time, the user can force the device to shut down by pressing and holding the power button for three seconds. The above screen will appear when the button has been pressed long enough.

NOTE: if the Sovant is connected to the power adapter, its battery continues to be charged even though the Sovant has been powered down.

Battery and Power Indicators

The lower right section of the screen shows the Sovant power and battery status. If the power plug  symbol is shown, then the Sovant is connected to the external power supply. The battery symbol adjacent to the power plug indicates the status of the Sovant backup battery. If the battery symbol is green  , then the battery is fully charged. If the battery signal is red  , then the battery charge is critically low. If the battery color is white  and the power adapter is connected, then the battery is charging. If the battery color is white  and the power adapter is not connected, then the battery is discharging.

When the battery is low, it will trigger the Low Battery alarm as described earlier in this chapter.

LED Light Indicators



There are three LED light indicators located above the power button on the lower right side of the Sovant. The green indicator on the right is illuminated when DC power is connected. This indicator is illuminated any time DC power is applied even if the Sovant is turned off. The green indicator in the center is illuminated when the Sovant is powered on. The alarm indicator on the left is yellow when a low priority alarm is active and it is red and flashing when a high priority alarm is active.

Chapter 7: Connections

Power

The Sovant is powered by an external power adapter which provides direct current at 9 volts. The power connection is a barrel connector located on back of the Sovant device.



NOTE: The Sovant must be powered using the power adapter which was supplied with the instrument. Use of a power adapter other than the one provided with the Sovant may lead to incorrect operation, risk to patient or users and permanent damage to the device.

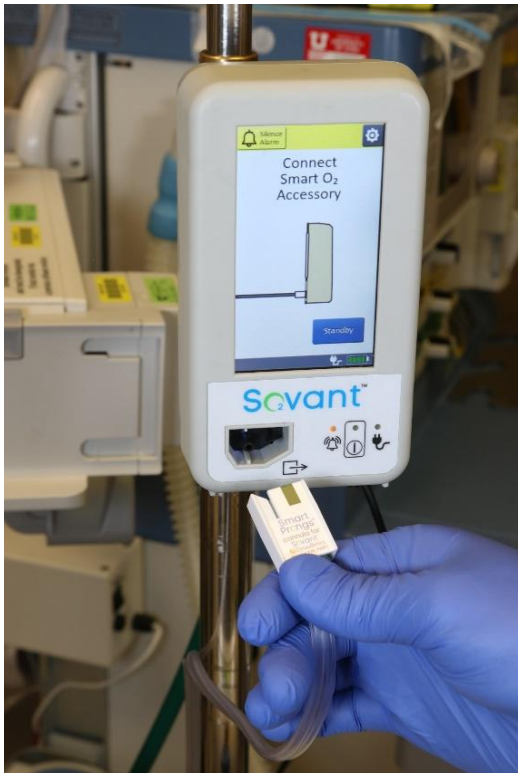
Oxygen

The Sovant requires a compressed oxygen source. Correct operation requires the oxygen pressure to be 50-55 psi (345-380 kPa). The Sovant automatically tests the ability of the oxygen source to provide adequate oxygen flow and an on-screen warning message will be shown if oxygen pressure is inadequate. The photo below shows an oxygen hose connected to the Sovant using a standard DISS 1240 threaded oxygen hose fitting.



Accessory

The Sovant connector includes ports for oxygen delivery and pressure measurement. A single plug makes both of these connections between the accessory and the Sovant. The connector plug is encoded so that the Sovant automatically detects which type of Smart Oxygen accessory has been connected.



Capnometry

Sovant Smart Oxygen accessories include a lumen that facilitates expired CO_2 gas monitoring, or capnometry. The gas monitoring tube is attached to the oxygen and pressure tubes. To separate the gas monitoring tube from the other tubes, simply pull on the gas monitoring tube to separate them so that the tube can be connected to the patient monitor as shown in the photo below.



If needed, Sovant Smart Oxygen accessories can be connected to standard oxygen barbs so that the accessory can be used in patient care locations where the Sovant instrument is not available as shown in the photo below.



To make this connection, simply press the larger oxygen lumen within the Sovant accessory plug onto the oxygen barb as shown.



Chapter 8: Settings

Press the gear button  in the upper right of the screen to access the Settings Adjustment screen. The Settings screen is used to adjust the volume of the alarms and the brightness of the display screen as shown below. Pressing the buttons to the right increase the volume or brightness and the buttons to the left decrease the volume or brightness as labeled. Press the Go Back button to return to the previous screen.



Appendix

A1. Specifications

Inlet oxygen pressure range	50-55 psi
Liter flow equivalency	40 percent of set flow rate delivered during inhalation using dynamic pulse volume adjusted according to breath rate (see table of nominal pulse volumes below)
Oxygen flow rate range	1-15 L/min when using a cannula or 2-20 L/min when using an oxygen mask. Oxygen flow rate is settable by the user. Note that momentary peak flow during oxygen pulse can momentarily exceed 30 L/min when needed.
Oxygen pulse volume range	10 to 1000 ml depending on set oxygen flow rate, breath rate and tidal volume
Oxygen pulse volume accuracy	±2ml or 10% of nominal volume
Maximum breath rate	40 breaths per minute
Continuous flow rate range	Cannula: 1 to 15 L/min Mask: 2-20 L/min
Continuous flow rate accuracy	Greater of 0.25 L/min or 10% of set flow rate
Oxygen saving ratio:	2.5:1
Trigger method:	Negative inspiratory pressure
Trigger threshold:	0.05 cm H_2O
Cannula:	Use only with Smart Prongs multi-lumen cannula
Oxygen mask:	Use only with Veyo oxygen mask
Maximum outlet pressure	Equals inlet pressure (50-55 psi) during continuous flow
Maximum operating altitude	Up to 10,000 ft. (3048 meters) above sea level
Operating temperature range	Between 39.2 and 100.4 ˚F (4 and 38 ˚C)
Operating humidity range	20%-80% non-condensing
Operating atmospheric pressure	68-101 kPa
Power supply	9 Volts DC, 36 Watts max, Class II, Continuous Duty
Battery	2 cell Li-Ion, certified per IEC 62133
Classification according EN 60601-1 Degree of protection against electric shock	IEC Class II Internally Powered Equipment
Applied parts	Nasal cannula, Type BF[1]
Degree of protection against harmful ingress of water	IPX1 as per IEC 60529
Mode of operation	Continuous operation
Alarm signal sound pressure level	69 dB
[1]Applied part identified according to IEC 60601-1 4.6 per IEC 60601-2-67	

A2. Table of nominal oxygen bolus volumes by breath rate during Synchronized Flow mode

Nominal Bolus Volumes in ml for Set Flow Rates and Breath Rates							
Set Flow Rate	**1 LPM**	**2 LPM**	**4 LPM**	**6 LPM**	**10 LPM**	**15 LPM**	**20 LPM**
8 Breaths /min	50 ml	100 ml	200 ml	300 ml	425 ml*	>750 ml*	>1000 ml*
10 Breaths /min	40 ml	80 ml	160 ml	240 ml	400 ml*	>600 ml*	>800 ml*
15 Breaths /min	27 ml	53 ml	107 ml	160 ml	267 ml	>400 ml*	>533 ml*
20 Breaths /min	20 ml	40 ml	80 ml	120 ml	200 ml	>300 ml	>400 ml*
30 Breaths /min	13 ml	27 ml	53 ml	80 ml	133 ml	>200 ml	>267 ml

* Large oxygen bolus volumes are only possible when inspiratory duration is sufficiently long and tidal volume exceeds the nominal oxygen bolus volume.

A3. Sovant Smart Oxygen Accessories and Other Parts

Please visit www.dynasthetics.com for a list of Smart Oxygen accessories and other parts compatible with the Sovant.

A4. Electromagnetic Compatibility

The Sovant is suitable for the electromagnetic environment of typical hospital settings.

During the immunity testing described below the Sovant continued to deliver continuous flow oxygen.

WARNINGS:

- 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 Sovant, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The Sovant should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Sovant should be observed to verify normal operation. If operation is not normal, the Sovant or the other equipment should be moved.
- Use of accessories, transducers, and/or cables other than those specified and 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.
- 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 or 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 distance.
- Unplugging the power supply from the device isolates the device electrically from the supply mains.

Emissions

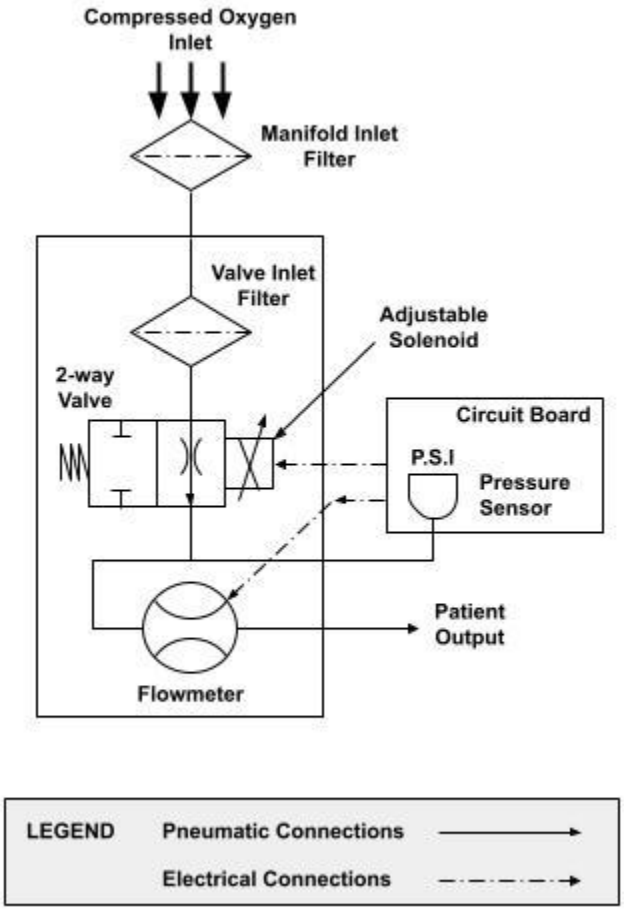
Electromagnetic Emissions		
The Sovant is intended for use in the electromagnetic environment of hospital environments.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Sovant uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Sovant is suitable for use in all establishments other than domestic network that supplies buildings used for domestic purposes. Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Immunity

Electromagnetic Immunity		
The Sovant is intended for use in the electromagnetic environment of hospital environments.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2, 4, 8, 15kV air	The relative humidity should be at least 5 %
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	Mains power quality should be that of a typical hospital environment. If the user requires continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the Sovant be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields should be at levels characteristic in a typical hospital environment. Keep the Sovant away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 6 V rms in ISM and amateur radio bands	The Sovant is suitable for the electromagnetic environment of typical hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

A5. Pneumatic Diagram of the Sovant Device



A6. Inspiratory Trigger Sensitivity Test Methods

Trigger sensitivity level stated in the specification section were tested using a ramped negative pressure and comparing the trigger pressure applied by the Sovant against a calibrated reference pressure signal.

A7. Cleaning, Disinfecting, and Disposal

Cleaning and Disinfection

The Sovant is a non-sterile and reusable device. The exterior of the Sovant should be cleaned when the device is visibly dirty, before and after each procedure, and/or according to hospital practice. To surface clean, wipe down the outer surface of the Sovant using 70% isopropyl alcohol solution. Do not allow liquids to enter the interior of the Sovant. Using the recommended cleaning solution on the touch screen will not affect the performance of the Sovant.

Smart Oxygen accessories are for single-patient use only and should not be reused.

Disposal

The Sovant Smart Oxygen accessories are single-patient use disposables and should be discarded.

For support with the Sovant, assistance with ordering Smart Oxygen accessories or parts, or answers to questions, please contact us.

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