Halo VITAL SIGNS MONITOR

SPO_2 | PULSE RATE | RESPIRATORY RATE | CORE BODY TEMPERATURE | SKIN TEMPERATURE

USER MANUAL

Preface

This Instructions for Use (IFU) manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and procedure to be performed. It is intended as a guide for using the Sempulse Halo only.

Equipment covered in this manual:	Sempulse® Halo™
Sempulse Model Number:	SE0001
Software Revision Number:	v1.00.00
User Manual Revision Number	v1.0
Effective Date:	April 1, 2021
Trademark Acknowledgments:	Halo Device™ and LiveCharts™ are trademarks and/or service marks of Sempulse Corporation in the United States and other countries.
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This device is produced in accordance with one or more of the following US patents: US9883801B2

Conventions Used in this Manual

Warning:

Indicates a potentially hazardous situation, which if not avoided, could result in personal injury or loss of life.

Caution:

Indicates a situation, which if not avoided, may result in equipment or other property damage.

Note:

Highlights additional user instructions.

Table of Contents

I. Safety Information – General

This section describes general safety information about this device. Additional safety information is also provided throughout this manual.

1.1 Prohibitions

PROHIBITION: DO NOT use the Halo while charging the battery.

PROHIBITION: DO NOT use the Halo active medical device or its accessories in a Magnetic Resonance (MR) environment. The Halo is MR Unsafe. The device presents a projectile hazard.

PROHIBITION: DO NOT use the Halo near electrocautery, electrosurgical units, or diathermy equipment.

1.2 Warnings

WARNING: Before using the Halo, read and understand this manual in its entirety.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth/grounding and using manufacturer approved charging devices in accordance with instructions.

WARNING: To avoid the possibility of wearer entanglement or strangulation carefully attach Halo to person, paying special attention to the cable.

WARNING: Be careful not to position the Halo in a manner that would make it difficult to operate or disconnect the device accessories or charging unit.

WARNING: The use of the Halo is restricted to one person at a time.

WARNING: Do not use the Halo or accessories if they are damaged or broken. If damaged, remove immediately from service.

WARNING: Using the Halo outside of specified operating environment may adversely affect its performance.

WARNING: Do not sterilize the Halo or its accessories. Cleaning and disinfection instructions are included in the Maintenance section later in this manual.

WARNING: Penetration of water or other liquids into the Halo may result in damage, and the device may not function properly. If this occurs, immediately remove the device from the wearer and discontinue use.

WARNING: Pulse-Ox function is calibrated to display functional oxygen saturation.

WARNING: Prior to using the Halo to monitor a wearer, all Threshold alarm limit settings should be set and/or reviewed to ensure they are appropriate for the wearer being monitored.

WARNING: Do not use Halo to monitor Pediatrics or Neonates.

WARNING: Potential of Halo being swallowed, keep it and other small parts out of the reach of children and animals as swallowing may cause choking and result in serious injuries.

WARNING: Not charging the Halo before use all the way can cause the device to power off during use.

WARNING: The Halo contains a lithium-polymer battery. Potential for fire or burning. DO NOT disassemble, crush, heat, burn or incinerate.

WARNING: The Halo is not serviceable and do not perform maintenance while the Halo is in use.

WARNING: No modification of the Halo or its accessories is allowed.

WARNING: Do not interconnect Halo with other equipment not described in the instructions for use.

WARNING: The Halo should not be used adjacent to or stacked with other equipment. If this becomes necessary, the Halo should be observed to verify normal operation.

WARNING: Do not use a cardiac defibrillator on a person with a Halo applied. If medically necessary to use a cardiac defibrillator, remove the Halo first.

WARNING: Halo emits infrared radiation from the face of the ear sensor. Do not point the face of the ear sensor towards the eye or skin of any person or animal.

WARNING: Misapplication of the ear sensor with excessive pressure for prolonged periods can induce pressure injury.

WARNING: A functional tester cannot be used to assess the accuracy of a pulse oximeter.

WARNING: Make sure that the Halo is disconnected from a power source before cleaning.

WARNING: Use caution when removing disposable adhesive to avoid damaging wearer's skin.

WARNING: This device is not intended to be used as an apnea monitor. Do not rely on the respiration monitoring for the detection of the cessation of breathing.

WARNING: Check the skin around the wearer's adhesive site and sites where Halo touches the skin for signs of irritation. If irritation occurs, contact your medical provider and Sempulse customer service.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: For continuous monitoring applications that include traumatic injuries, a dedicated or preconfigured LiveCharts app that has been validated for monitoring is required.

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 Halo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: If Halo becomes overheated or hot to the touch, remove from subject and discontinue use immediately. Failure to do so may lead to a skin burn.

WARNING: Dispose of Halo properly. When disposing of or recycling the Halo follow local government ordinances and recycling instructions.

WARNING: Halo does not incorporate means to protect the patient against burns when used with high-frequency (HF) surgical equipment. See HF surgical equipment documentation for advice regarding the location of electrodes, transducers, etc. to reduce the hazards of burns in the event of a defect in the neutral electrode connection of the HF surgical equipment.

WARNING: Continuously-monitored patients must be monitored regularly, even with Alarms active.

1.2.1  Home Healthcare Environment-Specific Warnings

Take all warnings and cautions into consideration at all times, but here are some generally-known conditions pertinent to the home healthcare environment.

- Avoid the effects of lint, dust, light (including sunlight), etc. near Halo whenever possible.
- Do not use Halo near a fireplace or radiant heater.
- Replace Halo immediately if you suspect any degradation of the sensors, electrodes, cable, or enclosure.
- Do not leave Halo in proximity of pets, pests, or children.
- Do not charge Halo while in use.
- Avoid situations where any cable can be wrapped around the neck.

1.2.2  EMS Environment-Specific Warnings

Take all warnings and cautions into consideration at all times, but here are some generally-known conditions pertinent to the EMS environment.

- Avoid the effects of lint, dust, light (including sunlight), salt spray, pollution, conductive particulate matter, etc. near Halo whenever possible.
- Do not place Halo near a direct heat source.
- Do not use Halo near or with EMI-producing devices such as defibrillators, high-frequency surgical equipment, or radio transmitters.
- Replace Halo immediately if you suspect any degradation of the sensors, electrodes, cable, or enclosure.
- Do not charge Halo while in use.
- Avoid situations where any cable can be wrapped around the neck.

1.2.3 Alarms-Specific Warnings

Take all warnings and cautions into consideration at all times, but here are some generally-known conditions pertinent to the Alarms.

- When alarms are paused, there is no notification of a potentially clinically-significant change in the patient's vital signs. Observe the patient by other means when alarms are paused.
- When alarms are turned OFF, there is no notification of a potentially clinically-significant change in the patient's vital signs. Observe the patient by other means when alarm limits are set to OFF.
- When the Halo is not connected or loses wireless connection to LiveCharts, LiveCharts does not receive patient alarms from the Halo device.
- To avoid possible hearing damage, do not place your ear too close to the Halo that is alarming audibly.
- When an Alarm sounds, check the patient first to confirm that there is no immediate danger to the patient.
- Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions.
- A hazard can exist if different alarm presets / limits are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

1.3 Cautions

CAUTION: For best monitoring results minimize wearer motion.

CAUTION: The Pulse-Ox function is intended to determine the percent of arterial oxygen saturation of hemoglobin, which may be affected by any of the following conditions: high levels of dysfunctional hemoglobin (or methemoglobin), excessive ambient light, excessive motion, electrosurgical interference, improperly applied sensor, incorrect sensor type, poor pulse quality, venous pulsations, anemia or low hemoglobin concentrations, cardiogreen, or other intravenous dyes, carboxyhemoglobin, methemoglobin, or dysfunctional hemoglobin.

CAUTION: Even though the Pulse-Ox function attempts to remove motion artifacts, occasionally some motion artifacts may be interpreted as good pulse quality.

CAUTION: Portable or mobile RF communications equipment may affect the function of the Halo.

CAUTION: Even though Halo has been tested for coexistence with RFID readers, wireless power transfer (WPT), 5G cellular, near-field communications (NFC), electromagnetic anti-theft systems (EAS), and metal detectors, these emitters could produce electromagnetic interference when nearby.

CAUTION: Use of the data port / data cable is restricted to use with, and connected to, approved accessories. Unauthorized connection to other equipment via the Micro USB Type-B port could result in malfunction or damage to Halo or connected equipment.

CAUTION: Inspect the Halo and accessories for damage before cleaning.

CAUTION: Use only approved cleaning and disinfecting solutions.

CAUTION: Setting Alarm Limits to extreme values can render the Alarm System useless.

CAUTION: Federal law restricts this device to sale by or on the order of a Physician.

II. Introduction

Sempulse has one goal: *to save lives* by providing accurate and timely vital signs data to medical professionals such as medics, EMTs, and doctors while anywhere in the world. In conjunction with our LiveCharts mobile app and the Command Cloud™ platform, the Halo detects major vital signs wirelessly and noninvasively: Pulse Rate (PR), Pulse Oximetry ($Sp0_2$), Respiratory Rate (RR), Core Body Temperature (BT), and Skin Temperature (ST).

The Halo Platform contains:

Halo	Noninvasive vital signs monitor applied behind the ear and on the neck
LiveCharts	Real-time and continuous (multi-patient) measurement app
Command Cloud	Cloud-based web application which provides reporting and monitoring tools

Indications for Use

The Halo vital signs monitor is a prescription device intended to be used as an adult patient monitor. It is indicated as a single- or multi-parameter vital signs monitor for SpO_2 – pulse oximetry, pulse rate, respiratory rate, core body temperature, and skin temperature for spot-check measurements and continuous monitoring from the back of the cavum concha and the neck.

The Halo monitor may be used in hospitals, healthcare facilities, emergency medical applications, medical transport, home healthcare settings, and other healthcare applications to include medical military settings in the field. The monitor is intended to be used in trauma scenarios, triage, motion, low perfusion, general monitoring, remote monitoring, and telemedicine settings. It is reusable, transportable, and for use in all types of ambulances.

The Halo monitor uses wired or wireless communications to transmit vital signs data to a handheld or personal computer. The monitor is intended to be used by trained healthcare providers who are trained to interpret the vital signs readings and make appropriate medical interventions or patients who are under the direct care and guidance of a medical professional or doctor. Alarms can be set with user-defined thresholds.

Contraindications

Halo should be avoided or applied with extreme caution in patients with the following conditions or circumstances:

- Patient must have intact ears without major injury to them, to include but not limited to burns, lacerations, abrasions, or gross deformity due to injury or mutilation.
- Not intended for use with those younger than 22 years of age.

About the User Documentation

The documentation for the Halo includes the following:

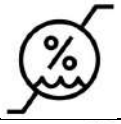
- Halo User Manual (IFU)
  - Description: A comprehensive document containing all materials and instructions available to those who will apply the device clinically or operate its functions.
  - Where to Find It: Available online at https://ifu.sempulse.com/.

Using this Manual

This Halo User Manual is designed to be an instructional guide for new users and a reference for experienced users. It assumes that you have formal training in medicine and a working knowledge of technology and medical devices.

Explanation of Symbols

The following symbols are used in the Halo labeling.

Symbol	Description
	The indicates the manufacturer's catalogue number so that the medical device can be identified.
	This symbol indicates the manufacturer's serial number so that a specific medical device can be identified.
 YYYY-MM	This symbol indicates the medical device manufacturer, and the date the medical device was manufactured.
	Refer to instruction manual / booklet. The user manual must be read.
 ifu.sempulse.com	Electronic Instruction for Use. The user manual is available online at https://ifu.sempulse.com/.
	This symbol indicates a floating circuit provides added protection against electric shock.
	This symbol indicates the maximum (right) and minimum (left) temperature limits at which the item shall be stored and transported.
	This symbol indicates the maximum (right) and minimum (left) relative humidity limits at which the item shall be stored and transported.
	This symbol indicates the maximum (right) and minimum (left) atmospheric pressure limits at which the item shall be stored and transported.
IP67	This symbol indicates the Ingress Protection (IP) Rating. • Protected against internal access and solids. • Protected against the effects of temporary submersion in water – up to 1 meter for 30 minutes.
	Warning symbol with supplementary text.
	Prohibition symbol with supplementary text.
	MR Unsafe symbol.
℞ only	For use by a physician's prescription only.

III. Theory of Operation

The Halo device is a multiparameter patient monitor for both spot-checking and continuous monitoring while in-motion or at rest. It has an applied part sensor that is placed on the back of the cavum concha on the ear (ear sensor) with a wired connection to a small device (base unit) attached to the neck directly below the ear with a snap electrode patch. No pulse oximetry accessories are used. The base unit processes the data received from the sensors into reportable vital signs information and then stores that data. This data is then communicated via wireless Bluetooth communication to a hand-held smart device or personal computer app called LiveCharts and then the data is transferred via Wi-Fi or cellular connectivity into the Cloud.

The Halo device calculates the functional oxygen saturation of arterial hemoglobin (% SpO_2) by measuring the absorption of red and infrared light passing through perfused tissue from the ear sensor. Light is reflected onto a photo detector and results are stored as a photoplethysmography (PPG) waveform, even in low perfusion conditions. These waveforms are processed at the start of each sample to determine the subject's skin pigmentation and adjust the sensor's LED light levels to produce the most accurate results. Pulse rate is calculated by the number of systolic peaks per minute in the PPG waveform and Respiratory Rate is calculated from the respiration-induced variations in the PPG. Skin Temperature is taken from the back of the ear and Core Body Temperature is calculated from Skin Temperature and Ambient Temperature.

The Sempulse Platform provides a comprehensive alarm system that annunciates alarms based upon changes to a patient's physiologic status or technical details. Users can manually change the Thresholds for each patient or use alarm defaults to provide individualized care or they can monitor multiple patients with the same Thresholds. Technical alarms are provided to notify the user of situations that may impede their ability to continue monitoring their patients.

IV. Description of Halo

Figure 1

On/Off Power Button

- The Power button is located on the front of the Halo.
- Press firmly for 1 second and release the On/Off Power Button to activate the Device.
- Press firmly for 5 seconds and release the On/Off Power Button to deactivate the Device.
- Do not hold the On/Off Power Button for longer than 5 seconds. If you do and a blue LED appears, allow the Halo to sit unapplied for 30 seconds to reset itself.

Display Screen

- The LiveCharts app is controlled by using the color touch panel screen located on the front of the smart device you are using.
- All system management and user input will be managed through the options presented on the display screen within the LiveCharts app.

Other Components

- Electrode Adhesive is used to attach the Halo base unit to the neck. Snap the back of the Halo base unit to the electrode adhesive and attach it to the neck as per the guidance provided in §VIII – *Application and Operation* of this User Manual.
- Adhesive is used to affix the ear sensor to the back of the ear as per the guidance provided in §VIII – *Application and Operation* of this User Manual.

Material List

- Polycarbonate / Acrylonitrile Butadiene Styrene (PC/ABS)
- Medical-grade stainless steel
- High Density Polyethylene (HDPE)
- Polyester Film
- Polytetrafluoroethylene (PTFE)
- Nickel-plated brass
- Silicone

V. Unpacking, Assembling, Storing, Transporting, and Disposing of the Device

Unpacking the Device

- Retain the original shipping container for use when transporting to keep the device clean and ensure it is not affected. Perform a function test when receiving the device; remove from the packaging and power cycle the device. Refer to the steps in the Quick Start Guide. Check that the device pairs with the LiveCharts app, please refer to the Troubleshooting section for guidance if issues are encountered. Plug the device into the charger to check the battery; if the LED blinks green (not at 100% charge), leave the device on the charger until the LED is solid green (indicates 100% charge). Halo devices are provided in a non-sterile condition and can be reused.

Caution:

Do not bend or twist the cable unnecessarily as this may damage the connection points and cause the device to fail.

Assembling the Device

- No assembly is required.

Caution:

Take care in handling the Device during unpacking to avoid damage to the device.

Storage and Transportation of the Device

- The device must be stored upright in a well-ventilated room without severe variations in temperature and humidity.
- For transporting outside the treatment facility:
  - The ambient temperature must be maintained between -40°F to 158°F (-40°C to 70°C) when the module is stored and not in use. See §XV.D for more information.
  - The Module must be stored within an ambient relative humidity between 15% to 90%, non-condensing.
  - Atmospheric pressure during storage and transport should be greater than or equal to atmospheric pressure at or below 15,000 ft (4,572m).

Disposing of the Device After Use

- Use the appropriate disposal process for Lithium batteries and potential hazards when disposing of the Halo.

VI. Requirements for the Facility, Accessories, Consumables, and Disposables

Warning:

All conditions specific in this section must be met prior to the usage of the Halo Device.

Facility

General Requirements:

- The ambient temperature should be between 32°F to 104°F (0°C to 40°C)
- The ambient temperature must be maintained between -40°F to 158°F (-40°C and 70°C) when the module is stored and not in use.
- The ambient relative humidity must be between 5% to 98%, non-condensing.
- The Device will operate normally as long as ambient barometric pressure is greater than or equal to atmospheric pressure at or below 15,000 ft (4,572m).

Caution:

This device may be susceptible to Electromagnetic Interference (EMI). The use of equipment known to cause EMI, such as defibrillators, high-frequency surgical equipment, and radio transmitters (cell phones), in close proximity to the module while it is operating should be avoided when possible. EMI may cause the device to not connect to the app or it may cause the device to not record vital signs.

Accessories

- Smart device or computer capable of running an iOS or Android-compatible app.

Electrical:

- While charging the battery, the device must be plugged into an isolated electrical outlet having the correct voltage, current, and frequency for your medical-grade power supply. The electrical service must meet all national and local requirements for electrical supply to a medical device.
- While charging the battery, the device should use a medical-grade power supply for electrical isolation that supplies 5V DC.

Warning:

- To avoid the risk of electric shock, the Halo should never be worn while charging the battery.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth/grounding and using manufacturer-approved charging devices in accordance with these instructions.
- WARNING: Use only 60601-1-approved isolating power adapters to charge Halo Devices.

Consumables

- Cleaning:
    - Clean the Halo and associated surfaces following each treatment with one of the following:
        - Soapy water
        - Disinfecting wipes (e.g., Clorox, Lysol, etc.)
        - Chlorhexidine wipes
        - Bleach solution
        - Isopropyl alcohol

Disposables

These single-use, disposable accessories are to be used with the Halo. These disposables are single-use, paired accessories. Other similar-type disposable accessories can be used at the User's discretion. Note that Halo may touch the skin around the Electrode Adhesive Patch. Sempulse identifies the following accessories as recommended for use:

3M 2560 - Electrode Adhesive Patch

- No special handling or storage requirements.
- An applied part.

3M 1527 - Transpore Surgical Tape

- No special handling or storage requirements.

3M 4076 – Spunlace PET Tape with Extended Wear Adhesive

- When stored at temperatures of 50-80 °F (10-27 °C) and a relative humidity between 40-60 percent.

VII. Preparation Prior to Use

Warning:
All conditions specified in this section of the manual must be met before the Halo is used.

Application Installation Activity Procedure

- Download the LiveCharts app onto your smart device and/or personal computer using an app store. Confirm your ability to run the app prior to use.

Charging the Halo Prior to Use

- The Halo should be fully charged prior to first use. Using an approved medical device charging Micro USB Type-B cable, fully charge the Halo. This equipment must only be connected to a supply main with protective earth/grounding and using manufacturer approved charging devices in accordance with instructions.
- Confirm device battery charge percentage prior to using first by plugging device into charger, solid green light indicates fully charged, blinking green light indicates not fully charged.

Connecting Halo to the LiveCharts App

- Refer to §VIII – *Application and Operation* in this User Manual.

Cleaning and Disinfecting the Halo Device

- Use one of the following for cleaning and disinfecting in between uses; lightly wipe exterior surfaces while paying special attention to cleaning the back of the ear sensor and the attachment point of cable as gross manipulation may damage connection points:
    - Soapy water
    - Disinfecting wipes (e.g., Clorox, Lysol, etc.)
    - Chlorhexidine wipes
    - Bleach solution
    - Isopropyl alcohol
- Do not submerge the Halo in any liquid. If grossly contaminated set aside and use a new device for each new patient.

Conducting a Halo Self-Test

- Each time the Halo is powered on, a Self-Test is conducted to ensure all critical components and functionalities of the Halo are performing properly. Normal operation confirms Self-Test success.

VIII. Application and Operation

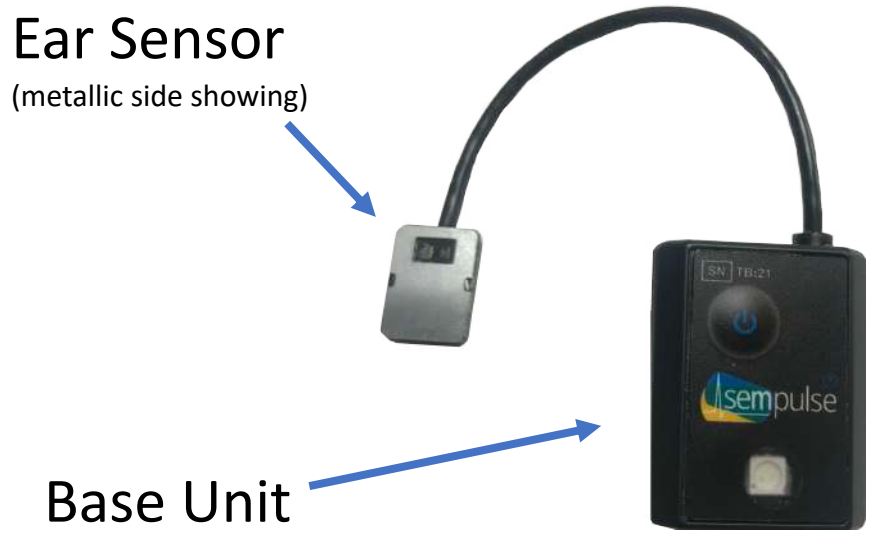


Figure 2

Applying the Halo

1. Gather and prepare the Halo and adhesives (Base Unit ECG electrode with adhesive and Ear Sensor adhesive shown in Figure 3). Peel back the adhesive for the ear sensor (Figure 4), and place ear sensor metallic side down in center of adhesive (Figure 5) and press down adhesive onto the back of the ear sensor, being careful to minimize folds or kinks of the adhesive surrounding the ear sensor and make sure to fully adhere to the sides of the ear sensor. If using medical tape (Figure 6), cut appropriately and place on back of the ear sensor in preparation for application.

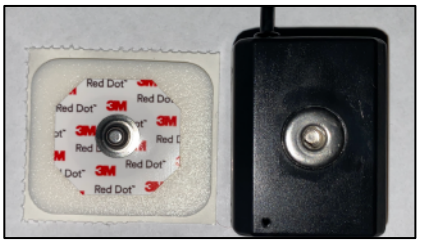


Figure 3

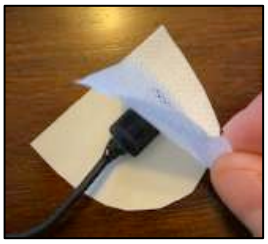


Figure 4

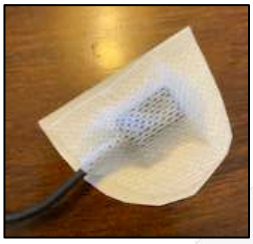


Figure 5

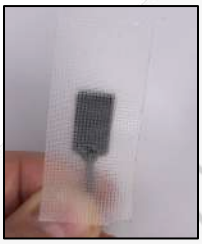


Figure 6

2. The application sites (Figure 7 and Figure 8) should be as clean as possible. Prepare the ear and neck by cleaning the skin with an alcohol square, or a damp cloth, and then drying to the touch.

Remove the backing from the ECG electrode adhesive and place on the soft tissue at the bottom of the left side of the neck (Figure 7) and directly below the ear canal. This is the "Sempulse Point" directly below the ear canal in most people. It is a point of soft tissue with a very spongy feel near the base of the neck. Around this point you will feel bones or muscle, but there is a distinct 1-2" wide pocket in-between the Middle and Anterior Scalene muscles and above the Trapezius muscle. Leave enough cable length to comfortably reach the ear.

Halo can be used on either side of the head and neck, but the left side is recommended due to its proximity to the heart unless the user determines that the left side is unfit based on the contraindications listed in §II – *Introduction*.

Place the base unit ECG electrode adhesive on the green-highlighted area in the picture. (Figure 7). The ideal location is such that the base unit is furthest from the ear but still allows enough cable for the ear sensor to reach the back of the ear. See Figure 9 for the base unit correctly placed with its ECG electrode adhesive for reference.

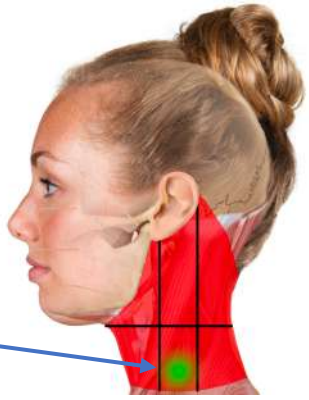


Figure 7

3. Locate the cavum concha (Figure 8) – Place left index finger in left ear canal at a 90-degree angle and then bring the thumb to meet the index finger on the back of the ear. The application site is the posterior cavum concha, where the thumb is touching the back of the ear. Adhere the ear sensor using a Sempulse ear adhesive or medical tape to secure the ear sensor on all sides by pressing it firmly to the skin. Proper application without excessive pressure is important.

Cavum Concha – Posterior View Placement for Ear Sensor

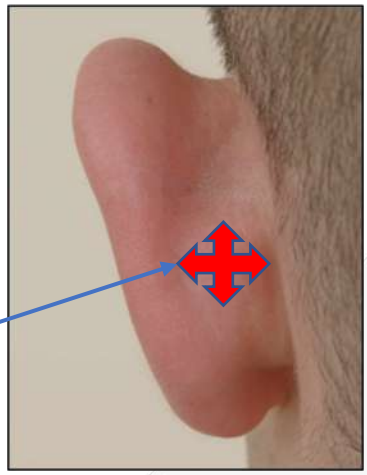


Figure 8

4. Snap the Halo onto the neck base unit ECG electrode adhesive (Figure 9). Turn on the Halo by holding the power button for 1 second and releasing. The Halo will beep once. Note: Sempulse encourages local training programs designed to familiarize users with the features of the Halo device and how to use it in a safe and effective manner.

Figure 9

Tips for a successful application:

- The ear should be as clean and dry as possible with minimal dirt, sweat, or other substances covering the application site. Clean the back of the ear with an alcohol pad or a damp cloth to remove dirt and other debris and then ensure that the area is dry to touch.
- The Ear sensor adhesive is designed with the ability to remove and reapply the ear sensor to the application site multiple times, but environmental conditions and overall cleanliness of the site can affect this number. In the event that you cannot get the ear sensor to adhere firmly to the back of the ear, discontinue use of that ear sensor adhesive and either apply a fresh ear sensor adhesive or use a new Halo. Reapply the sensor and inspect the application sites for skin integrity at least every 24 hours.
- Halo is able to be applied by the patient, but in some cases it may need to be applied by another person. When applied by the patient who then becomes the operator, a mirror can aid in identifying the correct placement.

Removing the Halo

- Press and hold the Halo's power button for 5 seconds to power it off.
- Carefully peel off the ear sensor adhesive from the application site, ensuring to grab the ear sensor and peel back the adhesive, NOT pulling the wire to remove, as this could cause unnecessary strain on the ear sensor and wire connection point, potentially leading to damage and/or failure to work properly. Continue in this manner to remove the adhesive from the ear sensor after removal from the skin.
- Remove the base unit from the ECG electrode on the neck by unbuttoning the snap connection point and then securing the Halo. Remove the base unit adhesive on the neck slowly to avoid irritating the skin. If adhesives leave residue, remove by applying rubbing alcohol gently scrub it off in a circular motion, discontinue if irritation occurs and use warm water and soap.
- Clean the ear sensor and base unit with a single-use alcohol swab to remove any excess residue. If further cleaning is required, refer to the Halo maintenance instructions in this manual.

Sync Halo with LiveCharts App

Once the Halo is applied it must be paired to a smart device so that vital signs can be monitored:

1. Make sure your smart device has Bluetooth enabled (turned "ON") in Settings, and the Halo is within 5 feet of the smart device with the LiveCharts app.
2. Open the LiveCharts app and turn on the Halo if not already on by pressing and holding the power button for 1 second and then releasing. The LED indicator light will flash white and green until the ear sensor determines good contact with the skin on the back of the ear. The LED indicator light will turn solid green, yellow, or red when good skin contact is determined. LiveCharts may receive the messages "SUGGEST REAPPLY" or "REAPPLY DEVICE" when slight device repositioning will be required. Repeat as necessary until you no longer receive these messages.
3. Inside the LiveCharts app, the Dashboard will show the new Halo if a successful unattended pairing has occurred. It will take anywhere from 5-30 seconds for the first vital signs readings to show on the Dashboard. Any previously-cached data will be transmitted first.
4. Once the Halo is paired to the LiveCharts app you will need to enter the patient's information so they can be monitored. See §X – *LiveCharts App*.

Operating in an Environment with Multiple Halo Devices and/or Multiple LiveCharts Apps

The Halo Platform is designed to share connections evenly across running LiveCharts applications, such that if 2 patients with Halo Devices applied had 2 available caregivers each with smart devices running the LiveCharts app, then each LiveCharts app would connect to a single patient. Additionally, the strength of the Bluetooth signal and the availability of the LiveCharts apps when the Halo Devices were first powered on are also considered algorithmically.

Sync with Command Cloud

The smart device running the LiveCharts app will sync with Command Cloud automatically when connected to Wi-Fi or a cellular data plan and then transfer its data. If no connection exists, the LiveCharts app will store the data locally (cache) until an Internet connection is established and the app will then automatically transfer its data to the Command Cloud.

Monitor Vital Signs

Once Halo is applied and the patient is added to the app, additional Halo Devices can be synced to a single smart device for multi-patient continuous monitoring. The number of Halo Devices that can be added depends on how many active Bluetooth connections the smart device can support. All modern iOS and Android versions can support at least 8 concurrent clients. The latest versions can support up to 15 concurrent clients. These are limiting decisions made by the smart device manufacturers. It is always best to have enough LiveCharts app instances to cover the maximum number of concurrent patients at 8 Halo devices per smart device.

IX. Halo Monitor

Introduction

The Halo is the core of the Sempulse Platform. The Halo connects wirelessly using Bluetooth to a smart device or personal computer running the LiveCharts app, which you and your team can use to monitor vital signs in real-time. In the event the Halo is temporarily disconnected from the smart device, the base unit allows for vital signs data to be stored locally to ensure continuous monitoring once a connection has been reestablished, then the cache of vital signs data will upload to the LiveCharts app and then the Command Cloud.

Figure 10

In order to utilize a Halo, the following requirements must be met:

- The patient has at least one (1) ear intact with the cavum concha accessible.
- The patient's cavum concha must have the skin intact with no open wounds .
- A smart device with LiveCharts installed must be available to view real-time data.

Restrictions for use:

- Halo cannot be used in any other locations except the back of the Cavum Concha (Figure 8) for the ear sensor and the same side of the neck at the "Sempulse Point" (Figure 7) for the base unit or the readings and values cannot be relied upon and do not meet any of the accuracy or specifications provided.

Power On Self-Test

Each time the Halo is powered on, a Self-Test is conducted to ensure all critical components and functionalities of the Halo are performing properly, including verification of its pulse oximetry operation.

LED Indicator Light

Each Halo comes equipped with an LED light which indicates the Halo's status and that it is powered on:

- *Green*: Indicates vital signs readings are within the normal Threshold parameters set in LiveCharts app. The Halo has good ear sensor contact with the skin and is functioning normally.
- *Yellow*: The subject and/or the app should be evaluated. Yellow indicates that vital signs readings are outside the upper and lower yellow Thresholds set in the app. The Halo has good ear sensor contact with the skin and is functioning normally.

- *Red*: The subject and the app should be evaluated immediately. Red indicates that vital signs readings are outside the upper and lower red Thresholds set in the app. The Halo has good ear sensor contact with the skin and is functioning normally.
- *Cyan:* A Low-Priority Alarm has been triggered. The patient and/or the Halo should be evaluated.
- *Blinking Yellow:* A Medium-Priority Alarm has been triggered. The patient should be evaluated soon.
- *Blinking Red:* A High-Priority Alarm has been triggered. The patient should be evaluated immediately.
- *Alternating White and Green*: Halo is in proximity mode ready to be applied to a person and is discoverable with Bluetooth and able to be connected to a smart device running the LiveCharts app. When proper skin contact from the ear sensor is lost, Halo will revert back to proximity mode and alternate flashing green and white until it is properly reapplied. “SUGGEST REAPPLY” or “REAPPLY DEVICE” will display on the LiveCharts app.
- *Blue*: In *Bootloader Mode*. If not desired, allow the device to sit un-applied for 30 seconds.
- *Flashing Green When Charging*: When plugged in to a charging cable and outlet to charge, this indicates a not fully-charged battery; leave the Halo to charge longer.
- *Solid Green When Charging*: When plugged in to a charging cable and outlet to charge, this indicates a fully-charged battery.
- *Orange*: Solid orange light indicates that startup tests have failed; discontinue use. Blinking orange lights indicate that there is an error; discontinue use.
- *No Light*: Halo is powered off or has exhausted its battery charge.

Troubleshooting the Halo

If the Halo’s LED indicator light turns flashing or solid orange or the Halo’s performance becomes impaired, discontinue use of the Halo and apply a new one. This means a serious error which prevents accurate monitoring has occurred. The LiveCharts app will also display a prompt alerting the Command Cloud to the error with the Halo if it is connected to the app. When an error is detected, the app will promptly send the error details back to Sempulse for further analysis.

Refer to §XIII – *Application and Operation* for additional troubleshooting and FAQ.

X. LiveCharts App

Introduction

The LiveCharts app is compatible with iOS and Android smart devices. Within the Dashboard multiple patients can be monitored simultaneously. Vital signs are displayed clearly across the screen in a format similar to that of a hospital bedside monitor. LiveCharts communicates with the Command Cloud platform through Wi-Fi, ethernet, cellular data, or satellite networks, allowing remote medical professionals to monitor patients' vital signs data.

Pairing the Halo to LiveCharts

Once the Halo is applied it must be paired to a smart device so that vital signs can be monitored. This is an unattended and automatic process. Refer to the instructions in §VIII – *Application and Operation*.

LiveCharts Login

LiveCharts requires an authentic login and password combination to begin. Contact your system administrator for details. LiveCharts will not monitor patients or connect to Halo Devices prior to login.

Dashboard View and Controls

The Dashboard presents patient data in a format like that of a hospital bedside monitor, called Patient Cards. Patients are prioritized by severity calculated from the value difference to each enabled Threshold and graphs are shown in configurable time periods with a 60-second default. Each Patient Card displays:

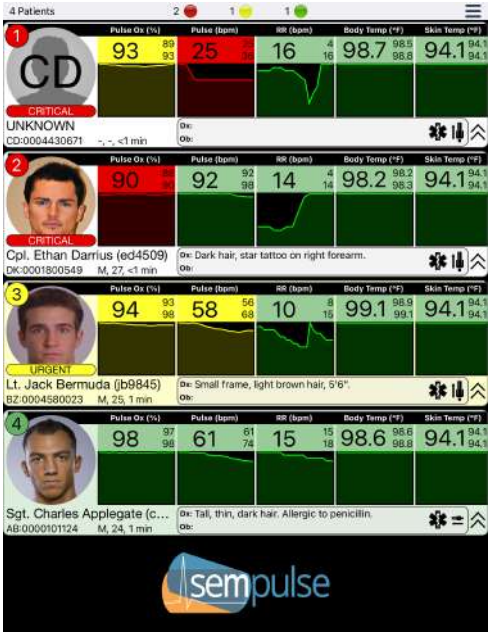


Figure 11

- **A* - Patient Photograph:**
  - Patient Severity Ranking
  - Status Information
  - Trending Data
- **B* - Patient Information:**
  - Name
  - Age
  - Gender
  - Identification Number
  - Halo ID
  - Connection Timer
- **C* - Patient's Vital Signs:**
  - Pulse Oximetry – SpO_2
  - Pulse Rate
  - Respiratory Rate
  - Core Body Temperature
  - Skin Temperature
  - Minimum Value for Time Period
  - Maximum Value for Time Period
- **D* - Descriptions and Observations:**
  - Body Orientation
  - Patient Minimizer Tool

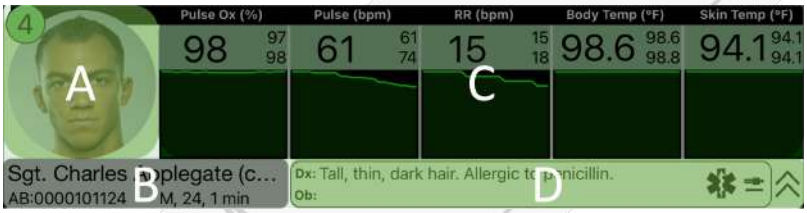


Figure 12

* Section Letters reference the labeled Patient Card regions in Figure 12.

Patients can be clicked on to reach the Patient Details page (Figure 14) or a Patient Card can be swiped left (Figure 13) to view the Patient Menu (Figure 15), to be added to the Ignore List, or to reach the Patient Details page. Patient Cards can be minimized to allow for more Patient Cards on the screen at once. Minimized Patient Cards will be expanded on Alarm conditions.

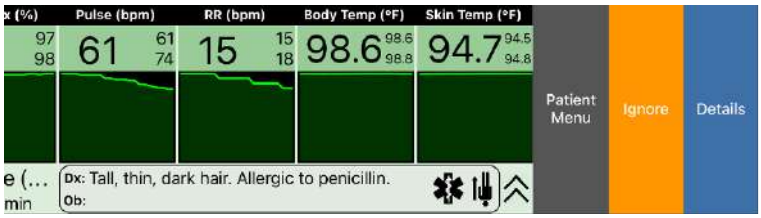


Figure 13

Ignore List

The Ignore List is a blacklist used to remove and disconnect particular Halo Devices and prevent them from re-connecting to a running LiveCharts app instance. Use cases include a patient who has been determined to no longer require monitoring or a patient who connects to a user's LiveCharts app instance who is not assigned to treating them. In this example the user who has the incorrect Halo on their app would add this Halo to their Ignore List and it would disconnect from their smart device. It would then only connect to a different LiveCharts app instance from then on. Halo Devices can be removed from the Ignore List on the Configuration page by swiping left and selecting Remove.

Patient Details

The Patient Details page is another Patient Card and it allows for patient data to be added or edited and it shows larger versions of the patient's vital signs graphs that can display the value of the graph location selected. Additionally, more screens are available for selection across tabs at the bottom of the page:

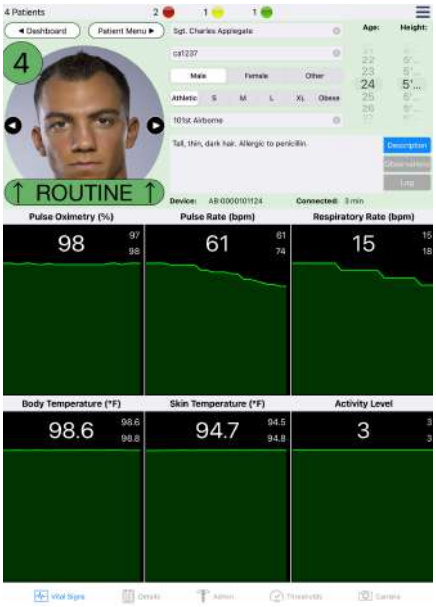


Figure 14

- **Vital Signs**
  - Larger versions of the patient's vital signs graphs, as described above. Only current session data is available.
- **Details**
  - Additional information related to the patient's Halo, including remaining battery percentage, signal strength, version data, connection details, approximate distance to the Halo device, etc.
- **Admin**
  - Optional medical interventions, updates, and MIST fields.
- **Thresholds**
  - Patient-specific vital signs Alarm Limit Thresholds for determining this patient's status and severity.
  - Must be enabled and set by the User.
- **Camera**
  - Take live and add existing photos of the patient or their surroundings for the patient's electronic record.

Vital Signs Monitoring + Alarms

Each patient's Patient Card on the Dashboard will display their vital signs from the currently-configured time period: SpO_2 (Pulse Ox), Pulse Rate (PR), Respiratory Rate (RR), Core Body Temperature (BT), and Skin Temperature (ST). The vital signs are presented in a manner similar to that of a hospital bedside monitor. The data collected by the LiveCharts app is then relayed to the Command Cloud which gives offsite medical personnel the ability to monitor the patients' vital signs remotely.

Based on the Alarm Limits Thresholds that the user may have set, LiveCharts has audible and visual alarms to alert the user that their set Thresholds have been reached. Colors, flashing, and text changes indicate alarm status; see Figure 11. Halo has visual indicator alarms via LED colors to indicate Threshold status; see §IX – *LED Indicator Light*. Red and Yellow Thresholds, corresponding with high- and medium-priority alarm limits respectively, can be set for all patients on the Configuration page or they can be set individually for a specific patient. If the user sets the Thresholds and the patient's current vital signs value meets or exceeds its associated Yellow Threshold, then the Medium-Priority alarm is triggered. Similarly, the High-Priority alarm is triggered if its Red Thresholds are met. See §IX – Alarms for more.

Patient Severity Ranking

Patient Cards are ranked by their severity, which is defined as the difference between a vital signs value and its associated Threshold that has been met. A patient with an SpO_2 that is 3% below their Threshold has a higher severity than another patient with an SpO_2 that is 1% below their Threshold. Also, 2 patients with differing SpO_2 values that are both above their Yellow Threshold have an equal severity. These severities are then numerically ranked, from highest to lowest. This is the order shown on the Dashboard.

Patient Menu

The Patient Menu can be accessed by swiping from left to right over the patient or by choosing "Patient Menu" from above patient's picture on the Patient Details page, where these functions become available:

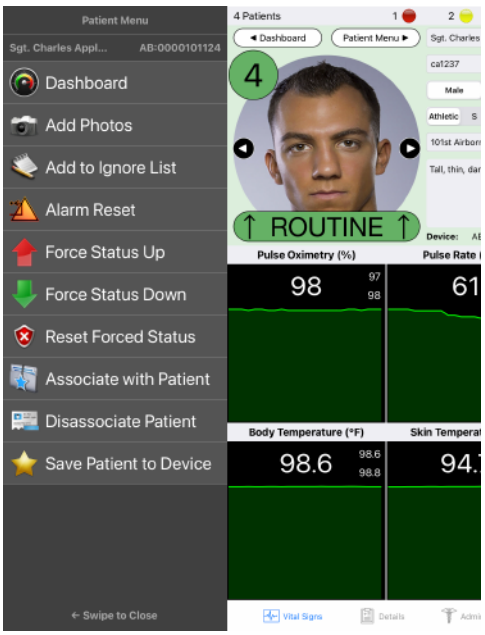


Figure 15

- Return to Dashboard
- Add Photos
- Add to Ignore List
- Alarm Reset
- Force Status Up
- Force Status Down
- Reset Forced Status
- Associate with Patient
- Disassociate Patient
- Save Patient to Device

Associating and Disassociating a Patient

Once a Halo is paired to the LiveCharts app, the patient's information should be entered so they can be properly monitored. This can be accomplished on the Patient Details page or by Associating a pre-registered patient. To do this open the Patient Menu and choose "Associate with Patient" and select the correct pre-registered patient. This pre-registered patient's data is then linked to this Halo.

If a Halo is Associated with the wrong patient's records, you can remedy this by opening the Patient Menu and choosing "Disassociate Patient" to remove the old association. Then, choose "Associate with Patient" to sync the sensor to the correct pre-registered patient's records.

Pre-Registering a Patient

Pre-registering a patient allows for patient information to be pre-loaded and it allows for specific Halo Devices to be associated with pre-registered patients for more timely monitoring. To pre-register a patient:

- Click the Menu button (three horizontal bars) in the upper-right corner.
- Choose "Registration" from the Main Menu. This will bring you to Patient Registration (Figure 16).
- Select "Registration" in the upper-left corner (Figure 16). From there you will be able to add the following patient information:
    - First and Last Name (Figure 17)
    - Identifying Number (Figure 17)
    - Gender (Figure 17)
    - Body Description (Figure 17)
    - Age or Age Range if unknown (Figure 18)
    - Patient Details, such as notes on appearance (tattoos, etc.)
    - Patient-Specific Vital Signs Thresholds
    - Patient Photos

Figure 16

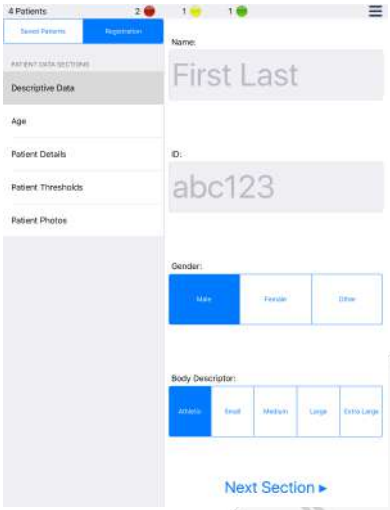


Figure 17

Figure 18

Associating Halo Devices to a Pre-Registered Patient

Pre-registered patients can be associated with specific Halo Devices so that when these particular Halo Devices sync to this LiveCharts app instance, they are automatically associated with their pre-registered patient records. To accomplish this:

- Click the Menu button (three horizontal bars) in the upper-right corner.
- Choose “Registration” from the Main Menu. This will bring you to Patient Registration (Figure 16) with “Saved Patients” highlighted in the upper-left corner.
- Select the pre-registered patient to associate a Halo with.
- Either enter the Halo ID in the input screen on the right or once you have authorized the LiveCharts app for camera use on your smart device, you may scan the QR code of the Halo.

Onscreen Symbols

If a connected Halo is in Proximity Mode, meaning that it has been successfully synced to the LiveCharts app but has not yet been successfully applied to a patient, a black box with a spinning icon will cover all of the patient’s vital signs charts. If each chart has a box with a spinning icon, then the Halo has exited Proximity Mode and is calculating its first vital signs measurement, which can take up to 90 seconds.

If a connected Halo has cached vital signs data stored on it, then this data will be transmitted to the LiveCharts app before live data is transmitted. You can determine if this is happening if all spinning icons have disappeared and a single, unchanging vital signs value is displayed for all patient vital signs, but the graphs are quickly changing to show the newly-transmitted vital signs. SpO_2 or Pulse Rate data aged >30 sec will be overlayed with a spinning icon and the corresponding SpO_2 or Pulse Rate Low-Priority alarms will be triggered if they have been enabled by the User.

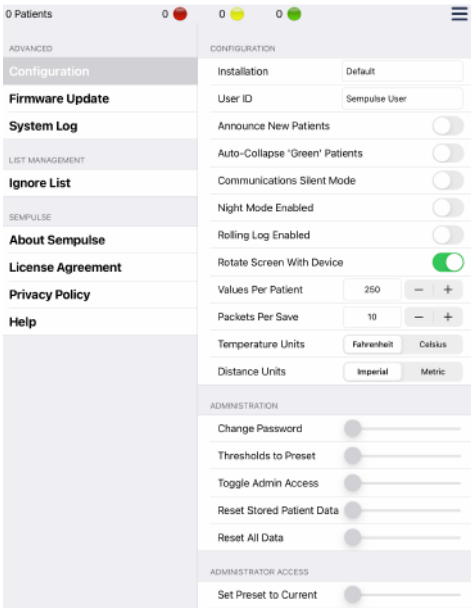
A displayed *Critical* status indicates that High-Priority alarms have been triggered. Similarly, an *Urgent* status indicates Medium-Priority alarms and *Routine* indicates Low-Priority or no alarms have been triggered. Trend arrows on either side of a patient’s status indicate that the patient’s status has shown a consistent trend of 7 or more calculated Patient Severity Ranking values in the indicated direction, either up or down.

Figure 19

A patient’s body orientation is shown on the right-hand side of the Descriptions and Observations box (Figure 12) with icons from Figure 19.

Configuring the LiveCharts App

To configure the LiveCharts App, first click the Menu button (three horizontal bars) in the upper right corner of the screen and choose “Configuration” from the Main Menu. From here you can:



- Change Installation Parameters
  - Installation Environment Names
  - Organizational User IDs
  - App Options
- Reset / Delete Data on the Device for Troubleshooting
- Set / Change Global Alarm Limit Threshold Values
  - Each vital sign has global Threshold values that must be set by the User.
  - Individual Thresholds can still be added for each patient.
- View Bluetooth Log for Troubleshooting
- View and Edit the Ignore List
- Learn more about Sempulse
- View the License Agreement
- View the Privacy Policy
- View Help Information

Figure 20

LiveCharts Tutorial

LiveCharts provides a tutorial, but it should only be used when the user is not monitoring patients. To start the tutorial, restart the LiveCharts app and click the Menu button (three horizontal bars) in the upper right corner of the screen and choose “Tutorial” from the Main Menu.

The tutorial will take you back to the Dashboard with 4 simulated patients. Follow the onscreen prompts to continue each step of the tutorial. Once completed, close the app by double pressing the home button and/or swiping up from the bottom of the screen, depending on OS type and version.

LiveCharts Logout

To logout of the LiveCharts app and end your LiveCharts session, click the Menu button (three horizontal bars) in the upper right corner of the screen and choose “Logout” from the Main Menu. The app will return to the Login screen and you may now safely close the LiveCharts app.

Applying Updates

All LiveCharts updates will be processed from your smart device’s app store. All Halo updates will be handled by LiveCharts. When a Halo is ready for an update, you will be notified on the Patient Details’ *Admin* tab. You can either install the update immediately or choose to update it at a later time. If you choose to update the Halo immediately, LiveCharts will enter the Halo into *Bootloader Mode* for updating. If you choose to update the Halo later, you can enter *Bootloader Mode* by holding the Halo button for 15 seconds when you are ready. You will then select “Firmware Update” on the Configuration page and swipe left on an available Halo. Halos are non-operational while a firmware update is being performed. You should not perform this task while monitoring patients.

Signal Inadequacy

The Halo device can determine when either or both the ear sensor and the base unit are not positioned correctly. In the event that this state of pulse oximetry signal inadequacy is detected, the Halo will prompt the LiveCharts app to display that the SpO_2 or pulse rate value is potentially incorrect. LiveCharts uses the visual information signals “SUGGEST REAPPLY” to indicate partial signal inadequacy and “REAPPLY DEVICE” to indicate a more urgent signal inadequacy. The Halo device will indicate whether perfusion index (Pi), pulse amplitude index, or signal strength levels indicate insufficient pulse strength to the LiveCharts app. Extraneous light entering the ear sensor or insufficient contact with the skin are the two main causes of signal inadequacy, but there are other physiological and environmental reasons. If either visual information signal is presented, first attempt to reposition the ear sensor on the back of ear to the correct placement. Remove the adhesive tape and ear sensor, then remove the adhesive from the ear sensor if needed and reapply new adhesive on the back of ear sensor; see §VIII– Application and Operation. Then, reapply the ear sensor on the back of ear in the correct location and allow the LiveCharts app and the Halo to normalize its readings. If the visual information signals continue, reposition the base unit.

Troubleshooting and Errors with the LiveCharts App

If the Halo’s LED indicator light displays flashing orange or a solid orange color, discontinue use of the Halo and apply a new one. This means a serious error which prevents accurate monitoring has occurred. The LiveCharts app will also display a prompt alerting the Command Cloud to the error with the Halo if it is connected to the app. When an error is detected, the app will promptly send the error details back to Sempulse for further analysis.

Occasionally app errors may occur. In the event an error occurs with the LiveCharts app the patient or medical professional should completely close (double press the home button and/or swipe up from the bottom oof the screen depending on OS type and version) and relaunch the LiveCharts app. This may result in the Halo needing to be reconnected to the smart device and app. Users should check the connection status of the Halo Devices after restarting the app and periodically throughout the course of using the device.

Halo and LiveCharts’ range of use is highly-dependent upon the environment and items within it. Distances between Halo devices and a LiveCharts app should be evaluated prior to use. LiveCharts’ smart device should be configured to not go into any standby, sleep, or power-conservation mode that limits availability to the app. The smart device’s remaining battery levels should be regularly monitored.

XI. Command Cloud

Introduction

The Command Cloud platform communicates directly with multiple LiveCharts app instance users, called *medics* in Command Cloud, to give offsite personnel the ability to coordinate and assist with treatment and administrative tasks.

Command Cloud mimics the visuals and functionality of the LiveCharts app but includes the concept of viewing patients and data from multiple LiveCharts app instances (medics) from your organization or department. These multiple medics are displayed as an abstraction, meaning that the Dashboard shows all patients from all medics while also allowing Command Cloud to drill down to view the patients from a single medic, multiple medics, or even to view a single patient. This allows remote personnel to view and monitor all patients or to partner with a particular medic for the care of one or many of their patients.

Otherwise, Command Cloud's functionality is the same as the LiveCharts app and more information on this functionality can be found in §X – *LiveCharts App*. In this User Manual section we will highlight the differences between LiveCharts and Command Cloud.

Command Cloud Login

Command Cloud requires an authentic login and password combination that is different from your LiveCharts app login and password. Contact your system administrator for details and your login URL.

Command Cloud Dashboard View and Controls

The Command Cloud Dashboard presents patient data in a format like that of a hospital bedside monitor, just like the LiveCharts app, but data can now be reviewed retroactively. Patients are prioritized by severity and vital signs graphs are shown in configurable time periods with a 60-second default. However, Command Cloud allows the user to select one, many, or all medics to view their patients.

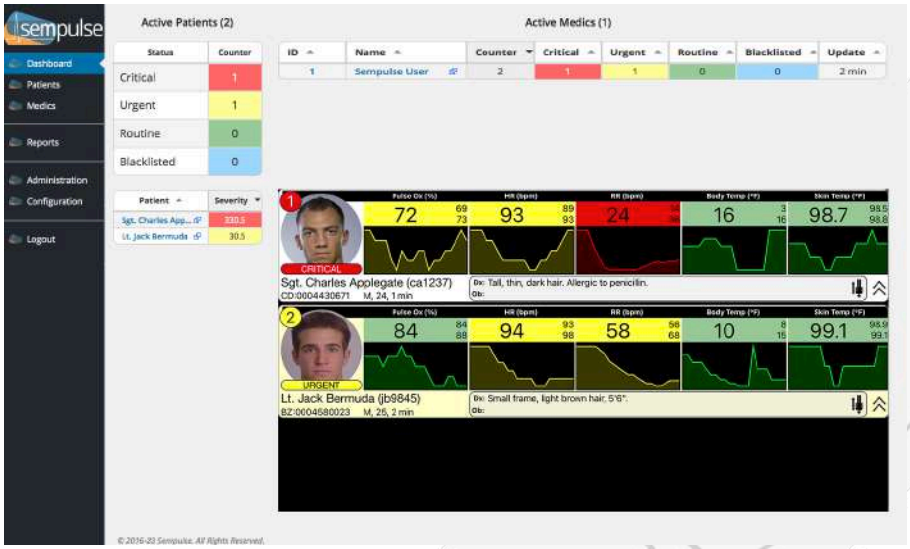


Figure 21

The Command Cloud's Main Menu is on the left side of the screen (Figure 21). A counter of all active patients currently being monitored on the system (within the last hour) is at the top-middle of the screen (Figure 21). A selectable list of all active medics is on the top-right of the screen. Below the counter is a simplified priority list of all active patients presently on the system and to its right is the Dashboard view from the LiveCharts app with all of the Patient Cards from all of the above-selected medics (Figure 21).

Clicking on a patient will bring you to the Patient Details page, just like in LiveCharts (Figure 22), but now there are Administration utilities that allow a Command Cloud user to communicate with a LiveCharts user, append data, annotate, or modify the patient's record, and override a patient's priority (Figure 23).

Figure 22

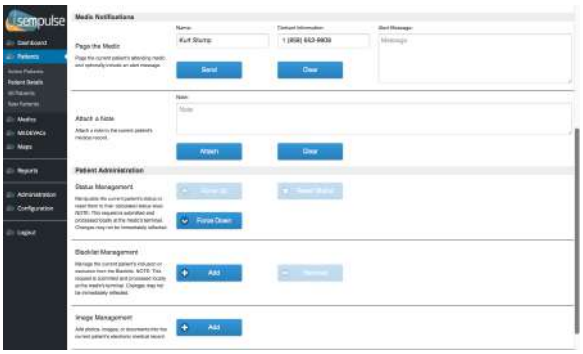


Figure 23

The Command Cloud Main Menu has the following links:

- **Dashboard**
- **Patients**
  - **Active Patients** – View a selectable list of all patients active within the last hour.
  - **Patient Details** – Patient Details page for a single patient.
  - **All Patients** – View a selectable list of all patients in the system with the most common data fields.
  - **Raw Patients** – View a selectable list of all patients in the system with all available data fields.
- **Reports**
  - **24-Hour Report** – View an interactive report of all patient activity within the last 24 hours.
  - **After Action Report** – Aid to develop and write a custom After Action Report.
  - **Direct SQL Reporting** – Provides the ability to input read-only SQL queries against live system data.
- **Medics**
  - **Active Medics** – View a selectable list of all medics active within the last hour.
  - **Medic Details** – Details page for a single medic and all of their monitored patients.
  - **All Medics** – View a selectable list of all medics in the system with the most common data fields.
  - **Raw Medics** – View a selectable list of all medics in the system with all available data fields.
- **Administration**
  - **LiveCharts Apps** – Interactive report of all LiveCharts apps and their smart devices.
  - **Error Log** – Interactive error report.
  - **Halo Log** – Interactive sensor data report.
  - **Raw Transactions** – Interactive list of all Halo transactions in the system.
- **Configuration**
  - **System** – Command Cloud configuration values and setup.

Medic Details

Command Cloud users can access a complete overview of the patients of all connected, active medics or they can view the details of individual medics, including:

Figure 24

- Patients Prioritized by Severity
- Drilldown Data for Each Patient
- LiveCharts app and Smart Device Details
- Administration Tools to Work with the User
  - Live Paging, Messaging, and Annotation Capabilities with the Medic
  - Live Editing of Patient Data
  - Remote Override of Status Level
  - Attach Notes to a Patient's Online Data
  - Add Photos or Files to a Patient's Online Data

Interactive Reporting and Data Access

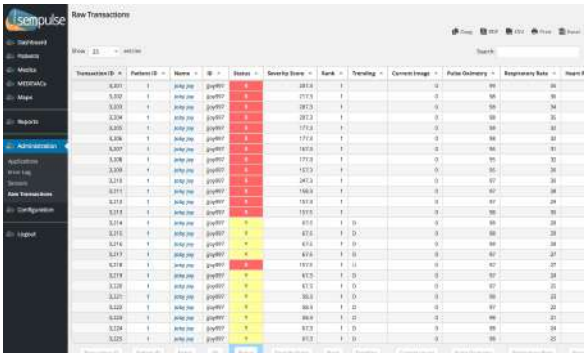


Figure 25

Canned reports exist for patients and medics broken down by currently-active (within the last hour), active within the past 24 hours, and inactive / all-known data in the system database for your organization. Reports can include search terms for each field and all fields can be sorted. These reports can be run live at any time or custom reports can be created via embedded report generation features or via direct SQL querying.

Further Command Cloud user instructions / training resources are available to licensed users and are accessible on the Command Cloud platform.

Command Cloud Logout

To logout of Command Cloud and end your online session, click the bottom item on the Main Menu called "Logout." Command Cloud will then return to the Login screen and you may now safely close your browser.

XII. Alarms

Overview

The Sempulse Platform provides a comprehensive alarm system that annunciates alarms based upon changes to a patient's physiologic status or technical details. Alarms on both the Halo device and LiveCharts app provide for a distributed alarm system. The system provides default alarm limit thresholds (Thresholds) for physiological alarms, but all alarms are disabled by default from the manufacturer. Organizations can choose to enable or set default alarm limits. Users can manually change the Thresholds for each patient to provide individualized care or they can monitor multiple patients with the same Thresholds. Technical alarms are provided to notify the user of situations that may impede their ability to continue monitoring their patient(s). Alarm conditions are grouped into physiological alarm conditions and technical alarm conditions. This section goes into detail on each alarm system area.

System Alarm Management

During the installation or operation of the Sempulse Platform, alarm configurations may be modified to conform to the alarm policies set by an organization.

The following general alarm management rules pertain to the Sempulse Platform:

- All Sempulse Platform alarms conform to IEC 60601-1-8.
- Alarms originate from the Halo (worn by the patient).
- Acknowledging an alarm suspends its auditory alarms and some visual alarm. If a new alarm occurs after the acknowledgement, the new alarm will be immediately annunciated.
- When the user acknowledges an alarm, all active alarms in progress will also be acknowledged. The user does not need to acknowledge each alarm individually.
- Auditory alarm annunciation may be turned off for an indefinite period of time called Silent Mode. This disables the annunciation of auditory alarms on both Halo and the LiveCharts app until they are re-enabled.
- All alarm annunciations may be turned off for an indefinite period of time. This disables the annunciation of all alarms on both Halo and the LiveCharts app until they are re-enabled. Disabling the alarm system must be done from the LiveCharts app.

Alarm Functionality

The Sempulse Platform has 2 types of alarms: physiological alarm condition alarms and technical alarm condition alarms. Physiological alarm conditions arise from a monitored patient-related variable. Thresholds, set by the user, are simple operator-adjustable setpoints that trigger or cause the generation of auditory and/or visual alarms whenever a monitored vital sign reaches this prescribed Threshold. Each vital signs grouping has Yellow and Red Thresholds. Yellow Thresholds are the first Thresholds to be reached and they annunciate Medium Priority Alarm signals, while Red Thresholds are the second Thresholds to be reached and they annunciate High Priority Alarm signals. All Thresholds except for Pulse Oximetry (SpO_2) have corresponding high- and lower-bounded Thresholds. SpO_2 only has a single set of Thresholds since this value is based on percentages. Alarms start once all vital signs have been received.

Based on the Thresholds that the user may have set, Halo and LiveCharts have auditory and visual alarms to alert the user that their set Thresholds have been reached. Halo uses visual alerts via LED indicator lights and chirps from its buzzer to indicate alarm conditions, see §IX – *LED Indicator Light*. LiveCharts use colors, flashing, and text to indicate its alarm conditions; see §X – *LiveCharts App*. Thresholds can be set for all patients on the Configuration page or they can be set individually for a patient on the Patient Details page or the Patient Registration page. If the user sets Thresholds and a Halo's current vital signs value matches its associated Yellow Threshold, then the Yellow (Medium Priority) alarm is triggered. Similarly, the Red (High Priority) alert is triggered if its associated Thresholds are matched. If multiple alarms have been annunciated, all will show on the patient's Patient Card or Patient Details page.

Technical alarm conditions arise from equipment failures and alerts. The Sempulse Platform provides a Low Battery Alarm as a technical alarm condition. If the battery reaches 5% charge (≥ 15 minutes), then the Low Battery Alarm (Low Priority) is annunciated. Low Priority alarms do not feature auditory alerts since the user is expected to check the Halo and the patient at intervals. In the event that the user does not acknowledge a Low Battery Alarm within 30 minutes, the Low Battery Alarm will escalate from a low priority alarm to medium priority alarm.

Alarms are acknowledged from Halo with a single press of the Halo's button. Alarms are acknowledged from LiveCharts by clicking on the alarm symbol. A window will be presented and then this alarm can be acknowledged. All Sempulse Platform alarms are non-latching, meaning they automatically stop when their associated triggering event condition no longer exists. In the case of an alarm condition of short duration, all alarm signals will complete at least one full burst, unless acknowledged by the user.

Users should verify alarm functionality periodically by setting a Yellow or Red Threshold to an easily-obtainable vital signs value while the Halo is monitoring a subject or themselves. The user can confirm the alarm's functionality when the alarm condition annunciates once the newly-set Threshold is reached. Users must be sure to reset the Thresholds after performing this test.

Managing Thresholds

Thresholds are set in 3 areas of the LiveCharts app, but all 3 look and function identically. The Thresholds are grouped by vital sign and each group can be enabled or disabled. Each group's alarm conditions can be enabled or disabled and each Yellow and Red Threshold can be set by typing in a new value or using the up and down arrow keys to increment or decrement the current value by 1 per click. The Alarm System continues to operate normally during any Thresholds adjustments.

When Thresholds are set in the Configuration page, these Thresholds are used by default for all Halo devices connected to this LiveCharts app instance (Figure 26). If Thresholds are set in the Patient Details or Patient Registration pages, then these Thresholds are only used by this specific Halo and this Halo Threshold configuration will be used on all LiveCharts app instances that this Halo connects to, e.g. the Patient Registration and the Thresholds will follow the Halo device. However,

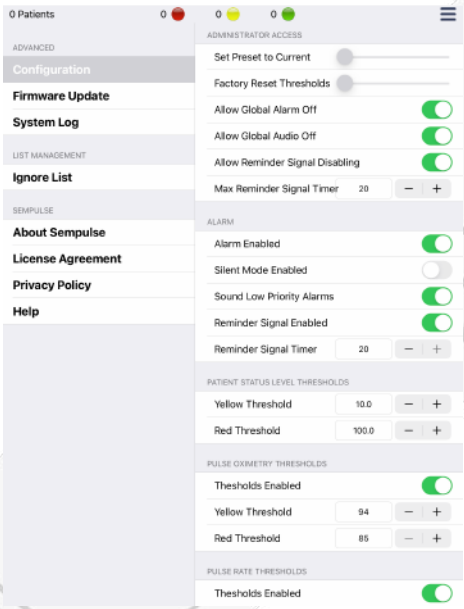


Figure 26

whenever an unregistered Halo is powered on after 30 minutes of inactivity, the Alarm System is newly-enabled, or the user elects to “Disassociate Patient” on a registered Halo, the Alarm System will default to the LiveCharts app’s current Preset Thresholds.

The LiveCharts app retains Thresholds data and no power loss duration will cause a connected Halo to lose its alarm settings. Similarly, the LiveCharts app retains all alarm settings and unless the app is deleted or becomes corrupted, no duration or power interruption will render the Halo unable to restore its connected Halo devices’ alarm settings.

Alarm Presets

Halo’s Thresholds are completely user-configurable, but they do come with a built-in preset, suitable for unattended monitoring, that can be customized or reset by organizational administrators. The default values in these preset Thresholds are simple operator-adjustable setpoints based on industry-standard setpoints for the Halo’s set of vital signs.

The user can enable the built-in alarm presets by sliding the “Reset Thresholds” slider to the right and confirming their choice to reset all Thresholds to the preset values.

Alarm Summary

Here is a summary of all Sempulse Platform alarms:

Acknowledging Alarms					
Priority	**Alarm Symbol**	**Acknowledgement**	**Where to Respond to Alarm**		**Audio Tones**
			Halo	**LiveCharts**	
High		 Acknowledge	Acknowledge at Halo or LiveCharts app		10 chirps
Medium		 Acknowledge	Acknowledge at Halo or LiveCharts app		3 chirps
Low		 Acknowledge	Acknowledge at Halo or LiveCharts app		N/A

Here are the Sempulse Platform's indicator lights and colors:

Alarm Priority	Indicator Color	Flashing Frequency	Duty Cycle
High Priority	Red	1.5Hz	50% on
Medium Priority	Yellow	0.5Hz	50% on
Low Priority	Cyan	Constant (on)	100% on

The Halo uses auditory chirps from a buzzer for its tones. Here are the Sempulse Platform's auditory tones:

Auditory Tones							
Device	**Severity**	**Melody**	**Frequency**	**Duration**	**Spacing**	**5th-6th**	**Inter-Burst**
Halo	High	C8.C8.C8..C8.C8	4250Hz	150ms	100ms	350ms	750ms
	Medium	C8.C8.C8	4250Hz	150ms	200ms	N/A	N/A

Here are the Threshold adjustment ranges and their resolutions.

Vital Sign	Lower Limit	Higher Limit	Resolution
Pulse Oximetry (SpO_2)	85%	100%	1%
Pulse Rate	0 bpm	250 bpm	1 bpm
Respiratory Rate	0 bpm	250 bpm	1 bpm
Core Body Temperature	80.0 °F	130.0 °F	0.1 °F
Skin Temperature	0.0 °F	250.0 °F	0.1 °F

The built-in Thresholds preset is based on industry-standard vital signs thresholds data and is disabled by default. Organizational administrators must review and set these values.

Vital Sign	Red High	Yellow High	Yellow Low	Red Low	Annunciation Delay
Pulse Oximetry (SpO_2)	N/A	N/A	94%	85%	< 1.1 sec
Pulse Rate	110 bpm	100 bpm	60 bpm	50 bpm	< 1.1 sec
Respiratory Rate	26 bpm	20 bpm	5 bpm	4 bpm	< 1.1 sec
Core Body Temperature	101.0 °F	99.6 °F	97.3 °F	95.8 °F	< 1.1 sec
Skin Temperature	101.8 °F	98.4 °F	85.3 °F	80.5 °F	< 1.1 sec

Here is a Patient Card showing Low-Priority SpO_2 and Pulse Rate Staleness Alarms:

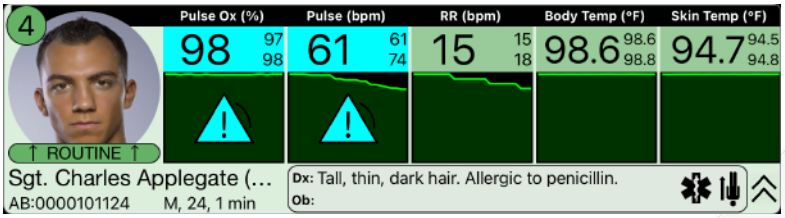


Figure 27

Alarm Condition Listing

This is a complete list of all Sempulse Platform alarms.

#	Alarm	Priority	Description
1	Pulse Oximetry Yellow Alarm	Medium	SpO_2 Medium Priority Alarm Threshold
2	Pulse Oximetry Red Alarm	High	SpO_2 High Priority Alarm Threshold
3	Pulse Rate Red High Alarm	High	Pulse Rate Upper Bounds High Priority Threshold
4	Pulse Rate Yellow High Alarm	Medium	Pulse Rate Upper Bounds Medium Priority Threshold
5	Pulse Rate Yellow Low Alarm	Medium	Pulse Rate Lower Bounds Medium Priority Threshold
6	Pulse Rate Red Low Alarm	High	Pulse Rate Lower Bounds High Priority Threshold
7	Respiratory Rate Red High Alarm	High	Respiratory Rate Upper Bounds High Priority Threshold
8	Respiratory Rate Yellow High Alarm	Medium	Respiratory Rate Upper Bounds Medium Priority Threshold
9	Respiratory Rate Yellow Low Alarm	Medium	Respiratory Rate Lower Bounds Medium Priority Threshold
10	Respiratory Rate Red Low Alarm	High	Respiratory Rate Lower Bounds High Priority Threshold
11	Body Temperature Red High Alarm	High	Body Temperature Upper Bounds High Priority Threshold
12	Body Temperature Yellow High Alarm	Medium	Body Temperature Upper Bounds Medium Priority Threshold
13	Body Temperature Yellow Low Alarm	Medium	Body Temperature Lower Bounds Medium Priority Threshold
14	Body Temperature Red Low Alarm	High	Body Temperature Lower Bounds High Priority Threshold
15	Skin Temperature Red High Alarm	High	Skin Temperature Upper Bounds High Priority Threshold
16	Skin Temperature Yellow High Alarm	Medium	Skin Temperature Upper Bounds Medium Priority Threshold
17	Skin Temperature Yellow Low Alarm	Medium	Skin Temperature Lower Bounds Medium Priority Threshold
18	Skin Temperature Red Low Alarm	High	Skin Temperature Lower Bounds High Priority Threshold
19	Data Corruption	High	Halo device experienced a data corruption technical error
20	SpO_2 / Pulse Rate Staleness Alarm	Low	SpO_2 / Pulse Rate data aged ≥ 30 seconds
21	Low Battery Alarm	Low	Battery Percentage Remaining is at 5% or lower (Prompt)
22	Halo Disconnected	Low	Communications Lost Technical Alarm

Delays

The maximum delay time from the onset of an alarm condition to the point that the representation of the alarm condition leaves the Halo's signal output part is < 1.0 seconds. The maximum remote alarm signal generation delay or the time to determine the generation of a technical alarm condition is < 0.1 seconds. So, the maximum alarm condition delay is < 1.1 seconds. The Sempulse Platform's distributed alarm system measures and reports alarm signal generation delay from the point that the presentation of the alarm condition leaves the signal output part of the Halo to the point that the presentation of the alarm condition arrives at the smart device's signal input part.

Alarm Modes

The Sempulse Platform's Alarm System Operates in selections of these paired global modes:

- **Enabled / Disabled**

  The Sempulse Platform Alarm System can be either enabled (activated) or disabled (inactivated). When the alarm system is enabled, all enabled alarms will be annunciated both audibly and visually, based on configuration. Alarm Disabled can be disabled by organizational administrators.

- **Normal Mode / Silent Mode**

  The Sempulse Platform Alarm System can be either in Normal Mode (AUDIO ON) or Silent Mode (AUDIO OFF). When the alarm system is in Normal Mode, all enabled alarms will be annunciated audibly and visually. When the alarm system is in Silent Mode, all enabled alarms will only annunciate visually. Silent mode does not inactivate any visual alarm signals and does lower the priority of any alarm conditions. Silent Mode can be disabled by organizational administrators.

Here are the mode symbols:

Mode	Alarm Icon	Function	Description
Alarm Disabled		ALARM OFF	The alarm system is disabled. The Alarm Reset function can be accomplished on the Patient Menu or by causing the alarm system to be enabled and/or re-enabled.
Silent Mode		AUDIO OFF	The alarm system's auditory tones are disabled. Shown on Patient Card in a blue circle.

If there is a communications failure between Halo and the LiveCharts app while in Silent Mode, the affected Halo will terminate its Silent Mode, if active. If the user subsequently activates Silent Mode again, further communications failures will not disable Silent Mode.

Global alarm modes are set and can be confirmed on the Configuration page, which also contains the Threshold groupings, which can also be enabled or disabled.

In addition to these global modes, individual Halo devices can be set to the same modes (Enabled / Disabled and Normal Mode / Silent Mode). Users can determine which alarm mode is active on a particular Halo by the symbols shown on the Patient Card.

Inactivation States

Alarms can be temporarily disabled for a specific Halo device by using the Alarm Paused command on the Patient Menu. Alarm Pauses are 120 seconds in duration by default and cannot be changed.

Alarms can also be inactivated (Acknowledged / Acknowledgements). Acknowledgments are provided to inactivate the auditory alarm signals of all currently-active alarm conditions but they do not affect the alarm signals of disabled alarm conditions. Acknowledgements are indefinite, e.g. they do not time out and must be explicitly re-enabled with an Alarm Reset. Users can determine which, if any, inactivation states are active by the symbols shown on the Patient Card. However, Acknowledged states do terminate automatically, alarm condition by alarm condition, when the affected alarm condition(s) no longer exists (non-latching). Acknowledgements do not inactivate IEC 60601-1-8: 6.3.2.2.2 visual alarm signals and do not cause the de-escalation of any alarm condition priority.

See Figure 11 for the Dashboard with alarms disabled and thresholds enabled, see Figure 28 for the Dashboard with alarms and thresholds enabled and alarms signaling without inactivation, and see Figure 29 for the Dashboard with alarms and thresholds enabled and all alarms inactivated.

Alarm system states are re-evaluated every second, so when an alarm signal inactivation state is terminated, the alarm system will re-evaluate the need for alarm conditions and generate alarm signals, if appropriate.

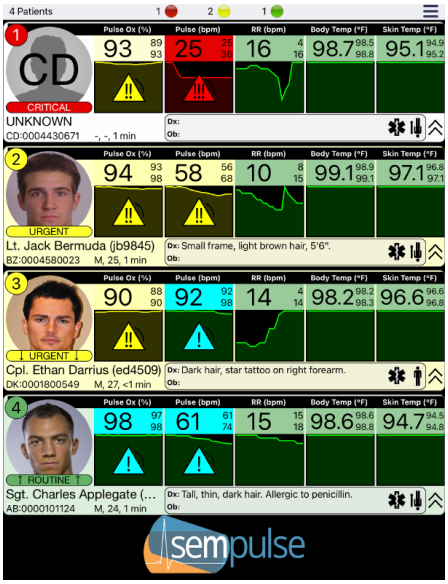


Figure 28

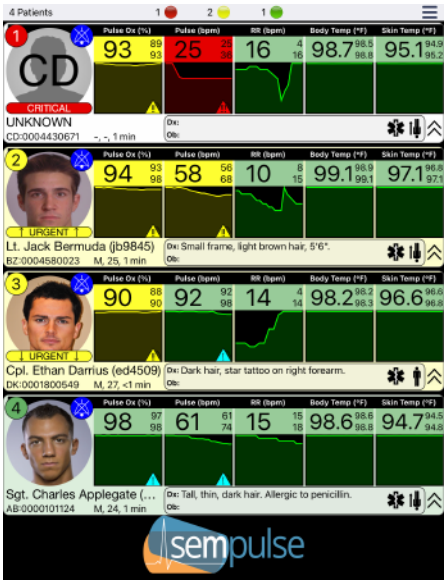


Figure 29

Reminder Signals

The Sempulse Platform Alarm System provides default 20-minute reminder signals for all high- and medium-priority alarms that have been Acknowledged, as well as Alarm Off and Silent Mode conditions. Organizational administrators can modify the length of this reminder signal, they can disable it, or they can configure the system to allow users to modify the reminder signal with a maximum value.

Alarm Reset

Alarm Reset is available on the Patient Menu and it is a virtual function that can be accomplished by re-enabling either a specific Halo or the alarm system as a whole. Since all Sempulse Platform alarms are non-latching, there is no need for them to be reset. Rather, Alarm Resets in the Sempulse Platform serve to only reset all Acknowledgements, Alarm Off, Audio Off, Alarm Pauses, and Reminder Signals.

Operation	Alarm Icon	Function	Description
Alarm Reset Operation		Alarm Reset	An alarm reset function can be accomplished by causing the alarm system to be enabled and/or re-enabled. Since all alarms are non-latching, this operation only serves to reset any existing inactivation states active on the alarm system or any alarm limit group.

Distributed Alarm System

The Sempulse Alarm System is a distributed alarm system comprising a LiveCharts app and one or more Halo devices. The alarm system sends and receives data, including the indication of alarm conditions, to or from other parts of the alarm system. Each Halo is uniquely identified and the various components generate alarm signals that indicate the urgency of the response required, the categorization of the cause of the alarm condition, and the identification of the Halo that generated the alarm.

The Sempulse Platform's distributed alarm system is intended for the confirmed delivery of alarm conditions and is designed such that a communications failure in any remote part of the distributed alarm system does not adversely affect any other part of the distributed alarm system other than the loss of the distributed functionality. Parts of the alarm system may be located outside of the patient environment and connected remotely, but it is recommended that one or both of Halo and LiveCharts are within auditory or visual range of the user at all times so they can be notified.

The safe use of the Sempulse Platform's distributed alarm system requires the use of relevant and non-extreme Thresholds, which could lead to a hazardous situation. See §1.2.3 – *Alarms-Specific Warnings*.

The Sempulse Platform also generates technical alarm conditions, including a technical alarm generated in the event of a networking failure or caching failure where data could be lost on a Halo device. This also initiates a technical alarm condition for any affected remote parts (LiveCharts apps) of the distributed alarm system that can generate alarm signals. Care was taken in the design of the Sempulse Platform to ensure that it reverts to a safe mode of operation in the case of technical issues.

Users should continuously monitor their patients; if that is not possible the preferred alarm settings are to have the Alarm enabled, Silent Mode disabled, and all Inactivation States are to be avoided. These settings should also be used for the elderly and those with special healthcare needs.

Remote Alarm System Controls

The Sempulse Platform's distributed alarm system provides secure, remote access to all user-specific alarm system controls for validated users. The alarm system provides means for the organizational administrators to restrict remote access to the available remote controls and only these organizational administrators can enable / disable these remote alarm system controls.

Alarm Security

Validated users are intended to set the Thresholds for individuals and for those connecting to their particular LiveCharts app instance, and these Thresholds will persist power cycles, but users cannot save changes to the built-in Thresholds. This is restricted to organizational administrators who are exclusively allowed to save changes or reset the Thresholds to their default values by following the instructions in Bulletin 1, a series of instructions not intended for the user community but rather for technicians and organizational administrators. Bulletin 1 contains instructions and an administrator password algorithm. Contact your Sempulse Representative if you need a copy of Bulletin 1.

Alarm System Logging

All alarm conditions are logged to the Patient Card when the alarm system is enabled so that the user can view, print, or record their details. This log contains the identity of high priority alarm conditions, all Thresholds (met and set), and the dates and times of their beginnings and endings. The log also contains dates and times for all technical alarm conditions and alarm mode changes, including logging enabled and disabled events.

All logs are written to storage and will persist if the alarm system experiences a power loss of any duration. The log has no defined capacity, but if an unforeseen capacity were reached, the oldest data would be deleted. The log is not resettable or editable by the user.

XIII. Maintenance and Repair

Responsibility of the Manufacturer

Sempulse is responsible for the safety, reliability, and performance of the Halo only under the following circumstances:

- Installation and setup procedures in this manual are followed.
- The equipment is used in accordance with operating instructions.

Routine Maintenance

The following maintenance should occur for the Halo Device:

- The device battery should be charged once per day following extended use.
- The base unit, cable, and ear sensor should be inspected for wear and damage between treatments and new wearer applications.
- The device should be thoroughly cleaned after usage and prior to new wearer application.

Cleaning the Halo

1. Clean the Halo and associated surfaces following each treatment with one of the following:
    - Soapy water
    - Disinfecting wipes (e.g., Clorox, Lysol, etc.)
    - Chlorhexidine wipes
    - Bleach solution
    - Isopropyl alcohol
2. Follow your facility's protocol for cleaning the external surfaces of medical equipment using cleansers from the list above.
3. The Halo should be cleaned thoroughly before being stored or returned to use.

Contacting Customer Support

If you still have questions about the Halo after consulting this User Manual or you have unexpected operations to report, please contact Sempulse:

Sempulse Corporation 3055 Hunter Road, Suite 175A San Marcos, TX 78666	
Website:	sempulse.com
Telephone:	(512) 790-HALO

XIV. Troubleshooting and Frequently Asked Questions

How do I find the cavum concha?

The cavum concha is the deepest recess of the earlobe, just behind the ear canal. Place your index finger in front of your ear canal at a 90-degree angle and then bring your thumb to meet your index finger. The application site is the posterior cavum concha, where the thumb is touching the back of the ear. See Figures F1a- F1d. below or refer to §VIII – *Application and Operation* for more information.

Figure F1a

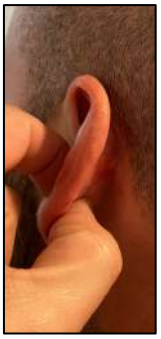


Figure F1b

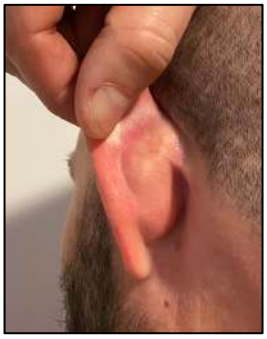


Figure F1c

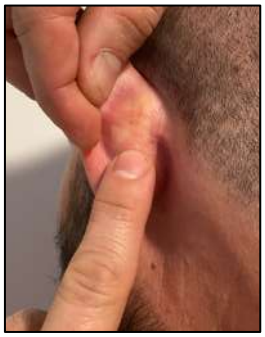


Figure F1d

How do I apply the adhesive on the ear sensor and keep it from coming off?

Check to ensure the base unit is placed in the correct location with an adequate length of cable to reach the back of the ear without unnecessarily pulling on the ear sensor.

Check the application of the adhesive on the ear sensor to ensure it is properly centered, up and down, and left to right, with enough tape on the top and bottom to attach and adhere to the skin. Reference §VIII – *Application and Operation*, Figures 7, 8, and 9 for more information.

Where do I place the ear sensor on the back of the ear?

After locating the back of the cavum concha with the instructions above, place the ear sensor on the target area in Figure F2, taking time to ensure that the ear sensor has good skin contact and is maintaining good skin contact continuously.

If you imagine your ear as a circular clock, you want to place the ear sensor between 4:00 and 5:00 on the clock face so that the ear sensor is on the bottom-side of the ear with the cable is placed in the direction of your feet. It is very important that the end of the ear sensor closest to the cable is flush against the skin, as in Figure F3.

Refer to §VIII – *Application and Operation* for more information.

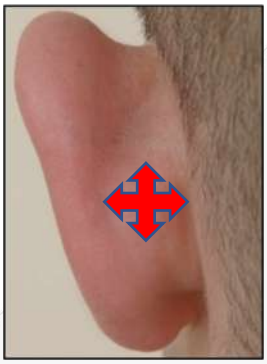


Figure F2

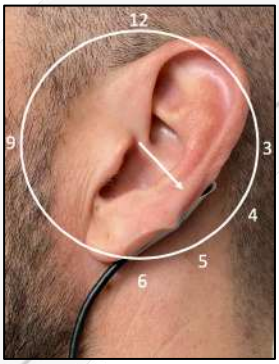


Figure F3

Why is my Halo not powering on?

Make sure the Halo has been fully charged prior to use (overnight). Hold the power button down for 1 second and release. The device should power on and the LED should blink white and red, indicating that it is ready to sync with the LiveCharts app. If the Halo does not power on, plug Halo into an approved charger and attempt to charge. If after charging Halo for a minimum of 1 hour, the Halo still does not power on, set aside and use another Halo. Contact Sempulse for guidance.

You can check the battery charge status of Halo Devices in the LiveCharts app, under the Details tab. See Figure F4 to the right and refer to §VII – *Preparation Prior to Use* for more information.

Figure F4

What if Halo LED is solid Orange after powering on?

If the Halo's LED is a solid orange color, discontinue use as this color is indicative of a malfunction with the Halo POST startup test. Use another Halo and contact Sempulse for guidance.

Refer to §IX – *Halo Monitor* for more information.

What if I'm not getting consistent vital signs readings?

Start by checking to ensure that you have properly placed the base unit and ear sensor in the indicated locations and that the Halo is properly charged; see §VII – *Preparation Prior to Use* for more information. Next, check the ear sensor to ensure that flush skin contact is being maintained while wearing. It is important to limit quick head movements as it may cause strain on the ear sensor cable and pull the ear sensor off the skin.

There may be a 5-10 minute period of time where the Halo ear sensor is normalizing with skin salts on the wearer's neck, this is normal and is usually limited to new Halo's first use. Allow this time for normalization.

Ensure that the LiveCharts app has been updated. If the steps fail to normalize the vital signs readings, set Halo aside and use a new one. Contact Sempulse for further guidance.

Why is the Halo shutting down on its own?

Check to make sure the Halo is fully-charged. Check placement of both ear sensor and base unit. Power Halo back on and continue monitoring. If the problem continues, contact Sempulse for guidance.

What do I do if the Halo is not syncing to the LiveCharts app?

1. Make sure your smart device has Bluetooth enabled (turned “ON”) in settings.
2. Make sure smart device is within 5 feet of Halo and there is no obstruction to line of sight.
3. Check the Halo’s LED light for malfunction colors (solid orange or blinking orange). If so, set aside and use another Halo.
4. Close LiveCharts on your smart device and any other open apps completely and then reopen the LiveCharts app.
5. Power off your smart device and the Halo. Then, restart your smart device and open the LiveCharts app. Next, power on the Halo and attempt to sync.
6. Check to ensure you have the latest Software updates on your smart device.
7. Use another Halo and attempt to sync with the LiveCharts app.

If the patient does not require further monitoring the patient should be added to the Ignore List. To add a patient to the Ignore List, open the Patient Menu by swiping from left to right across their row on the Dashboard and select “Add to Ignore List”. Once disconnected remove the Halo, turn off the power, and properly stow or discard.

For cybersecurity reasons Halo Devices do not connect as traditional Bluetooth devices via the Bluetooth pairing method. Instead, they connect programmatically and unattended via the Bluetooth LE pairing method on the LiveCharts app after confirming each other’s parameters and identities. You will not be able to connect to the Halo via the traditional Bluetooth pairing method.

What do I do if the patient I’m treating is showing up on someone else’s LiveCharts app?

If a patient is showing up on the wrong LiveCharts app instance, it should be added to that app’s Ignore List. To add a patient to the Ignore List, open the Patient Menu by swiping from left to right across their row on the Dashboard and select “Add to Ignore List”. The Halo will be removed from this LiveCharts app and will connect to the nearest LiveCharts app with the strongest signal. If this is also not the desired LiveCharts app instance, repeat this process.

If you inadvertently added a Halo to the Ignore List or would like to otherwise remove a Halo from a LiveCharts app instance, you can remove its entry from the Configuration menu by sliding the Halo’s ID that you would like to remove to the left and selecting “Remove.”

What do I do if the LiveCharts app freezes or is not working?

If the LiveCharts app freezes, quit the app via the method appropriate to your smart device or OS version. For older iOS implementations, double press the home button and quit LiveCharts app and any other open apps by swiping up on their app windows. Most other implementations require you to swipe up on the screen and select the apps to close. After this is completed, re-open LiveCharts and reattempt.

If issues persist ensure that the app software is up to date. Then, confirm that the device is or has recently been connected to the Internet so that cached data can be transferred to the Command Cloud. If that still does not solve the issue, contact Sempulse for guidance.

What if I've lost the Bluetooth connection?

Halo Devices can cache vital signs data so that no data is lost in the event that Bluetooth connections are lost. You should continue to monitor the patient and other wearers as normal and wait for the lost Bluetooth connection to be restored. When reconnected, the Halo will then transfer all cached vital signs data to the LiveCharts app.

Some instances where Bluetooth connections could be lost include, but are not limited to, exceeding distance maximums, physical or electrical barriers between Halo and the smart device such as concrete walls or EMI, buildings or objects that disrupt the line of sight between the two, and out-of-date software or firmware on devices.

Halo Devices utilize Bluetooth LE 5.0 Long Range, which extends the range of Bluetooth LE connectivity, but not all smart devices implement this standard. Your smart device may be limiting your range.

What if I've lost my network connection?

The LiveCharts app can cache vital signs data locally so that no data is lost. You should continue to monitor patients as normal and either wait for network connectivity to be restored or locate alternate networks to use, and once reconnected the LiveCharts app will then transfer all cached vital signs data to the Command Cloud. Some instances where network connectivity is lost include but not limited to network outages, inclement weather, and outdated software or firmware on devices.

Be aware that each smart device imposes restrictions on the amount of data that can be cached. For instance, older iOS versions limit app storage based on the amount of available storage on the device, so 5 hours of a single Halo could overfill the app's capacity and the app could shut down. Newer implementations can theoretically hold hundreds of thousands of hours of Halo data. Please take this into account and connect to the Internet regularly.

How do I disconnect a Halo from the LiveCharts app?

Simply power off the Halo by pressing down on the power button for 5 seconds and the close the LiveCharts app. Take care to ensure you are fully depressing the power button.

What does it mean if the LiveCharts app is displaying "SUGGEST REAPPLY" or "REAPPLY DEVICE?"

This prompt is an indicator of signal inadequacy given when the Halo device determines that either sensor is not in the correct position or is not maintaining good skin contact with the back of the ear (Figure F5). "REAPPLY DEVICE" is more urgent than "SUGGEST REAPPLY," but both indicate that extraneous light is

entering the ear sensor or insufficient electrical contact has been made with the skin. If either displays, attempt to reposition the ear sensor on the back of ear to the correct placement. Remove the adhesive tape and ear sensor, then remove the adhesive from the ear sensor if needed and reapply new adhesive on the back of ear sensor; see §VIII– *Application and Operation*. Then, reapply the ear sensor on the back of ear in the correct location and allow the LiveCharts app and the Halo to normalize its readings.

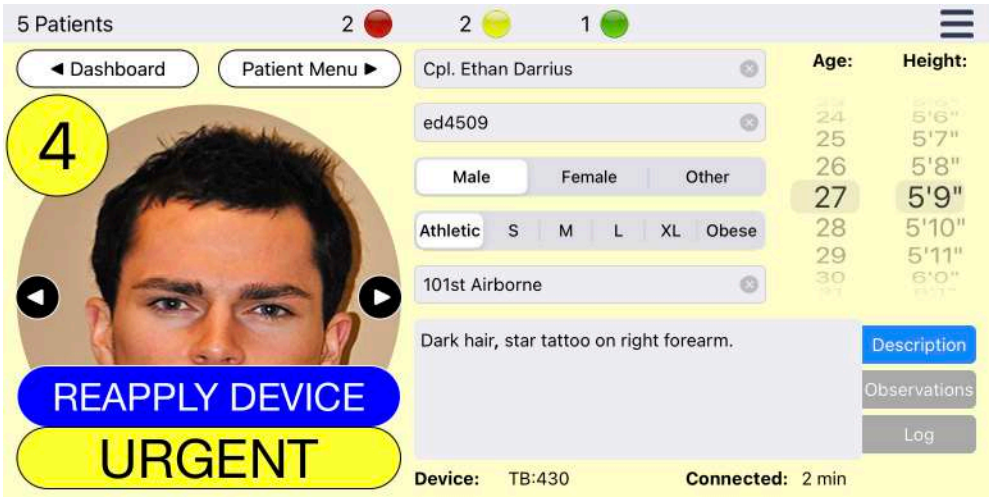


Figure F5

If the visual information signals continue, reposition the base unit. If the prompt is still given or received again, follow the steps above with the addition of first powering off the Halo and closing the LiveCharts app. Then reapply the Halo and sync with the LiveCharts app as you would from the start.

If both attempts listed above have failed, check the LED light on the Halo to ensure that it is not a solid orange or blinking orange color. These LED colors on the Halo are indicative of an error and/or malfunction and you should discontinue use of Halo. See §IX – *Halo Monitor* for more information. Use a new Halo and contact Sempulse for guidance.

What do I do if the LiveCharts app is crashing and closing?

Check to make sure you have the latest software version (refer to app store for latest app version). Close out the app completely, reopen and sync with the Halo and continue monitoring the wearer. If the problem continues, close the app and power off the smart device and the Halo completely, power both back on and sync to continue monitoring.

Then, confirm that the device is or has recently been connected to the Internet so that cached data can be transferred to the Command Cloud. If that still does not solve the issue, contact Sempulse for guidance.

XV. Specifications

Introduction

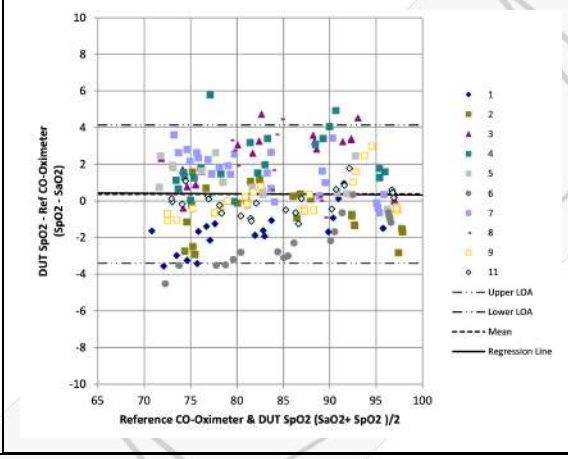
This section provides specifications regarding measurement ranges, accuracy levels, and environmental operating conditions for the Sempulse Halo.

Vital Sign Measurements + Accuracy

1. Respiratory Rate

Respiratory Rate	
Method	PPG-based
Display Range	4 to 70 BR/MIN
Accuracy Range	4 to 70 BR/MIN
Accuracy	± 3 A_{RMS}, ±1 BR/MIN mean error
Resolution	1 BR/MIN
Validation Study	Conducted – Study ID # TR 2020 - 402

2. Pulse Oximetry

<table>
<tr><th colspan="4">Pulse Oximetry (SpO_2 and Pulse Rate)</th></tr>
<tr><td>Normative Reference</td><td colspan="3">ISO 80601-2-61</td></tr>
<tr><td rowspan="4">SpO_2 Functional Oxygen Saturation</td><td>Display Range</td><td colspan="2">70% to 100%</td></tr>
<tr><td>Accuracy Range</td><td colspan="2">70% to 100%</td></tr>
<tr><td>Resolution</td><td colspan="2">1%</td></tr>
<tr><td>Accuracy</td><td colspan="2">≤1.9% A_{RMS}
<table>
<tr><td colspan="2">Discrete SpO_2 Ranges</td></tr>
<tr><td>100% - 90%</td><td>1.4 A_{RMS}</td></tr>
<tr><td>90% - 80%</td><td>2.1 A_{RMS}</td></tr>
<tr><td>80% - 70%</td><td>2.0 A_{RMS}</td></tr>
</table>

</td></tr>
</table>

	Accuracy (Motion)	≤3.0% $A_{RMS.}$ A reference comparison was completed against a pulse oximeter cleared for use while in motion. Comparisons were done during mild, medium, and strenuous exercise. The average percentage modulation during quiescent periods was 8.7% and it was 14.0% during motion.
	Accuracy (Low Perfusion)	≤1.9% $A_{RMS.}$ Halo was validated for low perfusion accuracy in bench-top testing against a WhaleTeq AECG100 simulator with percentage modulation of the infrared signal greater than 0.02% for saturations ranging from 70%-100%.
Pulse Rate	Display Range	25 BPM to 240 BPM
	Accuracy Range	25 BPM to 240 BPM
	Resolution	1 BPM
	Accuracy	±3 BPM
	Accuracy (Motion)	±5 BPM – A reference comparison was completed against a pulse oximeter cleared for use while in motion. Comparisons were done during mild, medium, and strenuous exercise. The average percentage modulation during quiescent periods was 8.7% and it was 14.0% during motion.
	Accuracy (Low Perfusion)	±3 BPM – Halo was validated for low perfusion accuracy in bench-top testing against a WhaleTeq AECG100 simulator with percentage modulation of the infrared signal greater than 0.02% for saturations ranging from 70%-100%.
LED Details	Peak wavelength range	RED λ= 660nm ± 3 and IR λ= 880nm ± 5
	Maximum optical output power	66 mW
	Recommended maximum application time at a single site	24 hours; less if especially susceptible to UV light or if continuously monitoring; consult your prescribing physician.
	Wavelength range can be especially useful to clinicians.	
Equipment Response	Data Averaging	≤ 4 seconds
	Data Update Period	1 second
	Alert Condition Delay	≤ 4 seconds
	Alert Signal Generation Delay	< 0.1 seconds

Notes	Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ± A_{RMS} of the value measured by a co-oximeter. Contact Sempulse to request Halo's Bland and Altman plot. Incorrect positioning of the sensor, extraneous environmental light, excessive physical movement, low perfusion, electrosurgical devices, dysfunctional hemoglobin, the presence of certain dyes, or electromagnetic interference could all affect SpO_2 accuracy.
Validation Study	Conducted - Study ID # PR 2021 – 445. The purpose of this clinical study was to validate the SpO_2 accuracy of the Sempulse Halo Pulse Oximetry during non-motion conditions over the range of 70-100% SaO_2 as compared to arterial blood samples assessed by Co-Oximetry. Pulse rate accuracy was compared to reference ECG. Motion conditions were compared to reference oximeters. Test subjects were healthy, 50% male/female, ages 23-40, and ≥15% darkly-pigmented skin tone according to the Fitzpatrick Scale.

3. Temperature

Temperature (Skin and Body)		
Normative Reference	IEC 80601-2-56	
Skin Temperature	Method	Direct Measurement
	Range	15.0°C to 50.0°C / 59.0°F to 122.0°F
	Accuracy	±0.3°C / ±0.5°F
	Resolution	0.1°C / 0.1°F
Core Body Temperature	Method	Adjusted Mode from skin and ambient temperature
	Measuring Site	Back of the cavum concha
	Reference Site	Gut
	Range	33.5°C to 42.0°C / 92.3°F to 107.6°F
	Accuracy	±0.3°C / ±0.5°F
	Resolution	0.1°C / 0.1°F
Validation Studies	Conducted Study ID #s TR 2020-403 and SEMP_2024-1 to validate core body temperatures from 33.7°C to 40.7°C / 92.6°F to 105.3°F for accuracy. Conducted Study ID # SEMP_2022-4 to validate simulated core body temperatures from 33.5°C to 42.0°C / 92.3°F to 107.6°F.	

4. Accelerometer Features

Accelerometer (Activity Level, Step Counter, Body Posture, Fall Detection)		
Method	Dual 3D accelerometers	
Activity Level	Range	0 (at rest) – 9 (high motion)
	Accuracy	< 5% Absolute Error Compared to Manual Count
Step Counter	Range	Step or No Step
	Accuracy	< 5% Absolute Error Compared to Manual Count
Body Posture	Range	Lying Face Down, Lying face up, Lying on Left Side, Lying on Right Side, Reclining, Upright, Walking, Running, or High-Speed Transit
	Accuracy	>70% Accuracy Compared to Visual
Fall Detection	Range	Fall or No Fall
	Accuracy	> 90% Sensitivity and > 98% Specificity
Validation Study	Conducted - Study ID # SEMP_2022-1 Accelerometer Validation	

5. Physical Components

Halo Device		
Physical Characteristics	Dimensions (base unit)	Width:30mm, Length: 39mm, Height:16mm
	Dimensions (ear sensor)	Width:8mm, Length 11mm, Height:4mm
	Total Weight	17 g
Battery	Operating Time	> 40 hours
	Charge Time	< 4 hours
	Battery Type	Li-Ion, 3.7 V, 400 mAh, single cell
	Maximum Temperature	45°C / 113°F *Refer to IEC 60601-1:2005 (Section 11)*
	Typical Battery Service Life	300-500 charge cycles before its capacity degrades (to approximately 80% of its original capacity)
Charging	Cable	Micro USB Type-B
	Power Supply	60601-1-approved, medical-grade isolating power adapter supplying 5V
Cleaning / Disinfecting	Liquid Ingress Rating	IP67 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Soapy water • Disinfecting wipes (i.e., Clorox, Lysol) • Chlorhexidine wipes • Bleach solution • Isopropyl alcohol (IPA)
Expected Service Life	Halo and Accessories	1 year

Wireless Communications	
Frequency	2402 MHz to 2480 MHz
Protocol	IEEE 802.15.4 Bluetooth Low Energy (BLE) 5.0
FCC ID	X8WBT840F
Modulation	4x4-channel pulse width modulator (PWM)
Security	ECDHE, 128-bit AES with ECB, CBC, CMAC/CBC-MAC, CTR, CCM/CCM
Power Output + Distance (max)	+8dBm to -20dBm (8dBm) with operating distances tested to 2.3km with direct line of sight; distances limited by smart device power levels
Data Throughput	< 125 kbps; Quality of Service (QoS): 11kbps with priority every 30 sec.

Warning:

If you have any concerns regarding a cybersecurity breach or vulnerability, contact Sempulse.

Display Unit	
Operating Systems	iOS v13.0 to Current, Android 11 (Level 30) to Current
Storage	200MB
Bluetooth Requirements	Optimized for IEEE 802.15.4 Bluetooth LE 5.0, but downward compatible to IEEE 802.15.4 Bluetooth 4.0
Database	SQLite v3.33.0
Network Requirements	IPv4 via IEEE 802.11b Wi-Fi or IEEE 802.3 Ethernet with a QoS of 20 kbps throughput with priority every 30 seconds, bidirectional HTTPS via SSL on port 443 between LiveCharts and Command Cloud

6. Environmental Conditions

Environmental Conditions		
Condition	**Storage / Transport (Packaged / Unpacked)**	**Operating (Unpackaged)**
Temperature	• -40°C to 5°C / -40°F to 41°F without relative humidity control. • 5°C to 35°C / 41°F to 95°F at a relative humidity up to 90%, non-condensing. • 35°C to 70°C / 95°F to 158°F at a water vapor pressure up to 50hPa.	-40°C to 70°C / -40°F to 158°F, as tested for extreme EMS environments
Humidity	15% to 90%, non-condensing	5% to 98% non-condensing, but not requiring a water vapor partial pressure greater than 50hPa
Atmospheric Pressure Range	620hpa to 1060hpa	620hpa to 1060hpa

Caution:

The Sempulse Halo may not perform to specification if stored or shipped outside the specified temperature range or other environmental conditions.

At least 30 minutes is required for Sempulse Halo to warm from the minimum storage temperature between uses until it is ready for intended use. Similarly, at least 30 minutes is required for Sempulse Halo to cool from the maximum storage temperature between uses until it is ready for intended use.

Compliances

1. Federal Communication Commission (FCC)

Halo complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

Changes or modifications not expressly approved by Sempulse shall void the warranty for this equipment and could void the user's authority to operate the equipment. Manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Consult the dealer or an experienced radio/TV technician for help

2. Electromagnetic Emissions

Halo is suitable for use in the electromagnetic environment specified in the table below. Ensure that the Monitor is used in such an environment. This device has not been evaluated for use in all aircraft.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declarations - Electromagnetic Emissions</th></tr>
<tr><td>Emission Test</td><td>Compliance</td><td>Electromagnetic Environment - Guidance</td></tr>
<tr><td>Radio Frequency (RF) Emissions</td><td>Group 1</td><td>Halo 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.</td></tr>
<tr><td>RF Emissions CISPR 11</td><td>Class B</td><td rowspan="3">Halo is suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage Fluctuations IEC 61000-3-3</td><td>N/A</td></tr>
</table>

3. Electromagnetic Immunity

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

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declarations - Electromagnetic Immunity @ 5Vdc, Battery Powered</th></tr>
<tr><td rowspan="2">Immunity Test</td><td colspan="2">IEC 60601-1-2</td><td rowspan="2">Electromagnetic Environment - Guidance</td></tr>
<tr><td>Test Level</td><td>Compliance Level</td></tr>
<tr><td>Electrostatic Discharge (ESD)
IEC 61000-4-2</td><td>± 8 kV Contact

± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air</td><td>± 8 kV Contact

± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air</td><td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Radiated RF Electromagnetic (EM) Fields
IEC 61000-4-3</td><td>10 V/m
80 MHz to 2.7 GHz
80% AM at 1kHz</td><td>10 V/m
80 MHz to 2.7 GHz
80% AM at 1kHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance from §E.4.</td></tr>
<tr><td>Proximity Fields from RF Wireless Communications Equipment

Clause 8.10</td><td colspan="3">
<table>
<tr><th>Test Frequency (MHz)</th><th>Band (MHz)</th><th>Immunity Test Level (V/m)</th></tr>
<tr><td>385</td><td>380-390</td><td>27</td></tr>
<tr><td>450</td><td>430-470</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">704-787</td><td rowspan="3">9</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">800-960</td><td rowspan="3">28</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1720</td><td rowspan="3">1700-1990</td><td rowspan="3">28</td></tr>
<tr><td>1845</td></tr>
<tr><td>1970</td></tr>
<tr><td>2450</td><td>2400-2570</td><td>28</td></tr>
<tr><td>5240</td><td rowspan="3">5100-5800</td><td rowspan="3">9</td></tr>
<tr><td>5500</td></tr>
<tr><td>5785</td></tr>
</table>
</td></tr>
<tr><td>Power Frequency (50/60Hz) Magnetic Field
IEC 61000-4-8</td><td>30 A/m
60 Hz</td><td>30 A/m
60 Hz</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td></tr>
</table>

4. Recommended Separation Distance

Portable and mobile RF communications equipment should be used no closer to any part of the Halo, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Recommend Separation Distance Calculations

d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular, cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Halo is used exceeds the applicable RF compliance level above, the Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Halo Device.

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

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

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d=1,2 √P	800 MHz to 2,5 GHz d=1,2 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a different maximum rated output power than specified above, the recommended guarding distance *d* in meters (m) can be estimated using the equation for the relevant transmission frequency, where *P* is the maximum rated output power of this transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

5. Standards

Agency Compliances	
General Standards	
IEC 62304:2006 Ed.1 +A1	Medical Device Software - Software Life Cycle Processes (2012) required by IEC 60601-1 (2005) + A1 (2012) Including Cybersecurity
ISO 13485: 2016	Medical Devices – Quality Management Systems
IEC 62366:2007Ed.1+A1	Medical Devices - Application Of Usability Engineering To Medical Devices
ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. Including: cytotoxicity(10993-5), sensitization and irritation (10993-10)
AAMI TIR 69:2017/(R)2020	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
AIM Standard 7351731	Med Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers Version 3.0

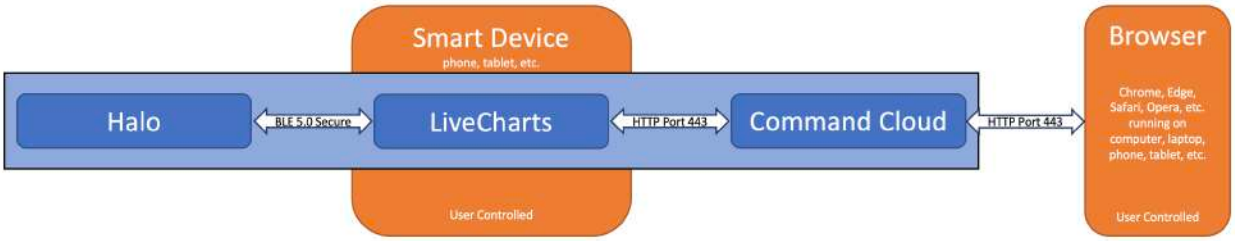
ANSI IEEE C63.27-2017	American National Standard for Evaluation of Wireless Coexistence
General Safety Standard	
IEC 60601-1:2005Ed.3+A1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety & Essential Performance Including FCC Part 15 Subpart B Unintentional Radiator Report, AIM Standard 7351731, medical electrical equipment, and system electromagnetic immunity test for exposure to radio frequency identification readers - an AIM standard, completion of EMC tables, Crosstalk per FDA, and Coexistence testing
Collateral Safety Standard	
IEC 60601-1-2 - 4th Edition	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-6:2010Ed.3+A1	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
IEC 60601-1-8:2006/AMD2:2020	Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems
IEC 60601-1-12: 2014/06/01 Ed: 1	Medical Electrical Equipment - Part 1-12: Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended For Use in the Emergency Medical Services Environment
IEC 60601-1-11: 2015/01/20 Ed. 2	Medical Elec. Equip.- Part 1-11: Gen. Req. for Basic Safety & Essential Perf.- Collateral Standard - Req. for Medical Elec. Equip. & Medical Elec. Systems Used in the Home Healthcare Environment
Particular Safety Standard	
IEC 80601-2-49:2018Ed.1.0	Medical Electrical Equipment - Part 2-49: Particular Requirements For The Basic Safety And Essential Performance Of Multifunction Patient Monitors
ISO 80601-2-56:2017Ed.2	Medical Electrical Equipment -- Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement
ISO 80601-2-61:2017Ed.2.0	Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment
IEC 80601-2-30:2018	Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-2 Third edition 2018-11	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
IEEE 1073 Series Health Informatics	10404 Pulse Oximeter, 10408 Thermometer, 10102 Point of Care

6. Network Risk Mitigation

Halo communicates vital signs data with LiveCharts via Bluetooth LE 5.0 and the LiveCharts app utilizes the local IT network infrastructure (Wi-Fi or Ethernet) to communicate between individual LiveCharts installations and the Command Cloud. This includes home healthcare use with IT network infrastructures either run by the homeowner, a wireless telecom provider, or an Internet Service Provider (ISP). The

reliability of this IT network is essential in ensuring that the remote monitoring and reporting capabilities maintain functionality.

To achieve this users and organizations must have appropriate guidelines and protocols in place regarding timely updates to network security (firewalls, antivirus software, software updates, password updates, etc.) in order to maintain appropriate cybersecurity. Wi-Fi networks should always utilize Wi-Fi Protected Access (WPA / WPA2 / WPA3), including network passwords. Modern wireless networking protocols should be used and older protocols such as Wired Equivalent Privacy (WEP) should be avoided. Users should always be aware of what they plug their smart devices in to charge, but Halo Devices must only be plugged into appropriate charging devices, as described in §VI – *Requirements for the Facility, Accessories, Consumables, and Disposables*. Here is a diagram depicting the recommended cybersecurity controls:



Perform a risk assessment and verification before implementing a change or modification to your existing IT infrastructure. Changes to IT network configurations (connection of additional items, disconnection of items, updates of equipment, upgrades of equipment) can compromise your continuous vital signs monitoring and report delivery and could introduce new risks that require additional analyses. Connecting Halo, LiveCharts, or Command Cloud to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. Organizations should identify, analyze, evaluate, and control these risks.

Other RF radiating devices (such as high-powered RFID readers, Wi-Fi-enabled phones, Bluetooth devices, electrocautery, electrosurgical units, or diathermy equipment) that are in close proximity to the Halo may interfere with its wireless communications. During such interference, the Halo continues to monitor vital signs and will cache them until the interference has dissipated and communication can resume. Similarly, LiveCharts caches all data and sends it when network connectivity has been restored. If wireless communication is affected when using Halo or LiveCharts in close proximity with another RF radiating device, move the other device away from the Halo one meter at a time, discontinue the use of the other device, or restart the Halo and LiveCharts-enabled smart device. Sempulse recommends having no other coexisting wireless devices within 1m of the line of sight between a Halo device and its connected LiveCharts app.

7. Risk Analysis Summary

In the event that network connectivity is lost, all remote monitoring is disabled until connectivity can be restored. However, all vital signs monitoring and status updates will continue between the Halo Devices and LiveCharts apps.

8. MRI Safety Information

The Halo device is MR Unsafe. The device presents a projectile hazard.