



# LX1550

**LifeSignals<sup>TM</sup> 1AX Multiparameter Remote Monitoring Platform**  
**User Manual**



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## Intended purpose

This manual describes the intended use of the LifeSignals 1AX Multi-Parameter Patient Monitoring System and observance of the manual is a prerequisite for proper performance, correct operation and ensures patient and user safety. The intended audience are clinical professionals who are expected to have a working knowledge of medical procedures, practices, and terminology to provide patient care.



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## Safety notices

The following safety notice formats are used in this manual. Safety notices are used at the start of sections or embedded in the operating instructions.

Ensure you fully understand and comply with the notices in this manual.



### Warning

Indicates a potential hazardous situation which, if not avoided, could result in serious injury.



### Caution

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.



### Notice

Indicates an important situation which, if not avoided, may seriously impair operations.



### Tip

Additional information relating to the current section.

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## Glossary

Term	Definition
<b>Alert</b>	Combination of physiological (clinical) and technical alarm conditions that generate alert notifications.
<b>Biosensor</b>	Single-use medical wearable device that acquires and wirelessly transmits patient's physiological signals to the paired LifeSignals Patient Relay App or MPR device.
<b>Biosensor ID</b>	A five-character alphanumerical code (unique identifier) printed on the Biosensor and Biosensor packaging.
<b>Central Server</b>	Manages the decryption, uploading and storage of Biosensor data from multiple authenticated relay devices. Allows access to derived parameter and Biosensor data using the LifeSignals Web UI Application.
<b>Clinical Facility</b>	Organization that provides healthcare services and utilizes monitoring service e.g. Hospital or Medical Facility.
<b>Clinical Facility Administrator (CFA)</b>	Multiple functions associated with the overall set up and configuration of Web UI Application for the clinical facility.
<b>General Clinician / Clinician</b> 	Denotes Clinician role - can assign new patients to any location or medical group (A clinician can assign patients only to those groups that are assigned to the Clinician).
<b>Physician</b> 	Denotes Physician role - can set/edit default alert limits for any assigned patients, view data and acknowledge alerts of multiple assigned patients or patient groups.
<b>Supervisory Clinician</b> 	Denotes Supervisory Clinician (SC) role - SC can set/edit default alarms for specific groups of patients, assign patients or patient groups to the user with Clinician or Physician role, and generate reports and view trends for discharged patients. View all patients or patient groups in the clinical facility, acknowledge alerts for all patients in the clinical facility using the Web UI Application.
<b>Administrator (CFA)</b> 	Denotes Administrator (CFA) role - Multiple functions associated with the overall set up and configuration of Web UI Application. For example, creates assign roles (Supervisory Clinician (SC) /Clinician/Physician/Additional Clinical Facility Admin) for new users, reset user's password, selects patient identification method for the facility (MRN or Patient ID), creates location/medical groups, configures alert default for the entire clinical facility.
<b>Edit</b> 	Denotes additional edit functionality for SC / Clinician / Physician roles.



Term	Definition
<b>Referral Physician</b>	External or referral healthcare Physician who is not a user within the clinical facility and is provided with access to view specific patient data in the Web UI Application.
<b>Monitoring Dashboard</b>	Multi-Patient monitoring window displays continuous physiological parameters, waveforms and alert status of assigned patients to authorized clinical personnel for near-real time active monitoring.
<b>Multi-Patient Relay (MPR)</b>	Multi-Patient Relay network transmits data from multiple Biosensors via hardware devices (e.g. wireless access points, computer) to the LifeSignals Central Server.
<b>Relay Application</b>	Relay device is used for the transmission of a patient's Biosensor data to the LifeSignals Central Server.
<b>Relay Bridge</b>	The Relay Bridge provides communication between the Biosensor(s) and the Multi-Patient Relay (MPR) instead of a standard access point, when the Multi-Patient Relay Software is hosted in the cloud. It helps in reducing the infrastructure requirements, thereby facilitating easy deployment and increased portability.
<b>BLE Gateway</b>	The Bluetooth Gateway communicates with multiple third-party devices and transfers the data to the Multi- Patient Relay without buffering.
<b>Service Provider Administrator (SPA)</b>	The highest-level user that manages administration of multiple clinical facilities and hospital groups.
<b>LifeSignals™ Web UI Application</b>	Web-based application provides clinical staff remote access, via the in-built Monitoring Dashboard, to the patient's near real-time physiological data (Biosensor and derived), demographics, trends and alert status.

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# 1 Safety Information

## 1.1 Intended use and indications for use

The LifeSignals 1AX Multiparameter Remote Monitoring Platform is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography (2-Channel ECG), heart rate, SpO2%, respiration rate, pulse rate, photoplethysmography waveform, skin temperature, body posture, body motion, R-R interval, heart rate variability (HRV) and blood pressure. Data is transmitted wirelessly near real-time from the LifeSignals 1AX Wearable Biosensor, and 3rd party device (for SpO2%, PPG, pulse rate and blood pressure) to remote central server for display, storage, and analysis.

The LifeSignals 1AX Multiparameter Remote Monitoring Platform is intended for non-critical, adult population.

The LifeSignals 1AX Multiparameter Remote Monitoring Platform shall include the ability to notify healthcare professionals through alerts when physiological parameters fall outside the set limits, manual trigger by the patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring at hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.



### Notice

Blood pressure shall be available only with 3rd party BP device. SpO<sub>2</sub>%, PPG and pulse rate are available only with 3rd party SpO<sub>2</sub> device.

## 1.2 Contraindications

None



## 1.3 Warnings



### Warning

- DO NOT use the Biosensor if the patient has known allergic reaction to adhesives or electrode hydrogels.
- DO NOT use the Biosensor if the patient has inflamed, irritated or broken skin in the Biosensor placement area.
- Remove the Biosensor if skin irritation such as severe redness, itching or allergic symptoms develop; and seek medical attention if an allergic reaction persists.
- DO NOT allow the patient to wear the Biosensor for more than the prescribed hours.
- Remove the Biosensor immediately if the patient reports of uncomfortably warm skin or experiences a burning sensation.
- The Biosensor should not be used as an apnea monitor as it has not been validated for use in pediatric population.
- Verify all the applicable alarm presets when admitting a patient. By default, the alarm presets are assigned based on group association (location and medical group) and this may not be applicable to some patients.
- DO NOT use on patients with active implantable medical devices including pacemakers, Implantable Cardioverter Defibrillators (ICDs) and Left Ventricular Assist Device (LVAD).

## 1.4 Precautions



### Caution

- Excessive motion or activity may adversely affect the Biosensor performance and adhesion.
- Press down the Biosensor edges with fingers at least twice a day, to maintain adhesion.
- Avoid sleeping on stomach, as this may interfere with the Biosensor performance.
- DO NOT use the Biosensor if the package has been opened, appears damaged or has expired.
- Avoid use of Biosensor near (< 0.3 meters) from any interfering wireless devices such as gaming devices, wireless cameras or microwave ovens.
- Avoid use of Biosensor near any RF emitting devices such as RFID, electro-magnetic anti-theft devices and metal detectors as this could affect communication between the Biosensor and the relay device.
- If the Biosensor LED flashes fast (green) (two flashes for every second), ensure the patient is within 5 meters radius of the Relay device.

**Caution**

- The Biosensor contains a battery. Dispose the Biosensor in accordance with the local laws and guidelines for routine non-hazardous electronic waste.
- Using certain skin barrier agents before applying the Biosensor may cause skin irritation or injury due to interaction with the hydrogel electrodes.
- DO NOT immerse the Biosensor in water.
- Keep showers short with your back to the flow of water. Gently pat dry with a towel and minimize activity until the Biosensor is fully dry.
- DO NOT use cream or soap near Biosensor.
- If the Biosensor becomes soiled with blood or bodily fluids, dispose in accordance with the local laws and guidelines for bio-hazardous waste.
- DO NOT wear or use the Biosensor during a magnetic resonance imaging (MRI) procedure or in a location where it can be exposed to strong electromagnetic forces.
- DO NOT run any other application on the device when the procedure is ongoing.
- DO NOT reuse the Biosensor, it is for single use only.
- Keep the Biosensor out of reach of children and pets.
- The Biosensor should remain within the operating distance of the relay device (< 5 meters) for uninterrupted viewing.
- The relay device utilizes a mobile data network (3G or higher) to operate. Before travel, it may be required to enable data roaming and obtain an international adapter for charging the relay device.
- To ensure continuous streaming of data, the relay device should be charged every 12 hours or whenever there is a low battery indication.
- Setting alert thresholds to extreme values may reduce the alert system efficiency.
- Maintain a minimum distance of 5 meters radius between the relay device and the Biosensor.



## 1.5 Cybersecurity controls



### Notice

- To protect against unauthorized use and cybersecurity threats, enable all access control systems on mobile devices, password protection and/or Biometric control.
- Ensure the relay device has firewall protection to avoid virus/malware attack.
- Keep the Android software version up-to-date as updates enhance existing features, patch security flaws, add new security features, fix bug issues and improve performance for devices.
- Limit access to essential personnel tasked with maintaining and operating the Relay device.
- Refrain from using the Relay Application for Unintended activities.



## 2 LifeSignals Product Description

### 2.1 LifeSignals 1AX Multi-Parameter Patient Monitoring System (LX1550)

The system contains the following components:

LifeSignals 1AX Wearable Biosensor (LP1550)	Acquires two channels of ECG signals, TTI respiration signals, skin temperature, posture data and transmits to Relay Application or Multi Patient Relay (MPR) device.
LifeSignals Relay Application (LA1550 R)	A compatible relay device which receives and relays signals from the paired Biosensor to the Central Server for processing.
LifeSignals Multi-Patient Relay (MPR) Application (LA1550-MR)	Installed on compatible computer. Receives and relays signals from multiple Biosensors to the Central Server for further processing.
UbiqVue Relay Bridge (UA2550-RB)	The Relay Bridge provides communication between the Biosensor(s) and the Multi-Patient Relay (MPR) instead of a standard access point, when the Multi-Patient Relay application is hosted in the cloud.
UbiqVue Bluetooth Gateway (UA2550 -BG)	The Bluetooth Gateway communicates with multiple third-party devices and transfers the data to the Multi- Patient Relay without buffering.
LifeSignals Secure Server Application (LA1550-S)	Receives data from multiple Biosensors simultaneously. Derives HR, RR, skin temperature, posture information. Stores data securely for access by LifeSignals Web UI Application.
LifeSignals Web UI Application (LA1550-C)	Web-based interface used to access and manage patient physiological and alert data.



## 2.2 LifeSignals 1AX Wearable Biosensor

The Biosensor incorporates the LifeSignals proprietary semiconductor chip (IC), LC1100, a fully integrated sensor and wireless system supporting WLAN (802.11b) wireless communications.

The Biosensor acquires two channels of ECG signals, TTI respiration signals (one of the inputs for deriving respiration rate), skin temperature (measured using thermistor), posture data (detected by accelerometer), pre-processes and wirelessly transmits the signals to a paired Relay Application or Multi-Patient Relay (MPR) device or other receiver systems. When the Relay Application or the MPR devices are available within the wireless range, acquired data is immediately and continuously transmitted to the Relay Application or MPR devices.

If the Relay Application or MPR devices are not available or if there is any interruption in the communication between the Relay Application or the MPR devices and the Biosensor, data will be temporarily buffered locally in the Biosensor until the wireless connection is re-established.

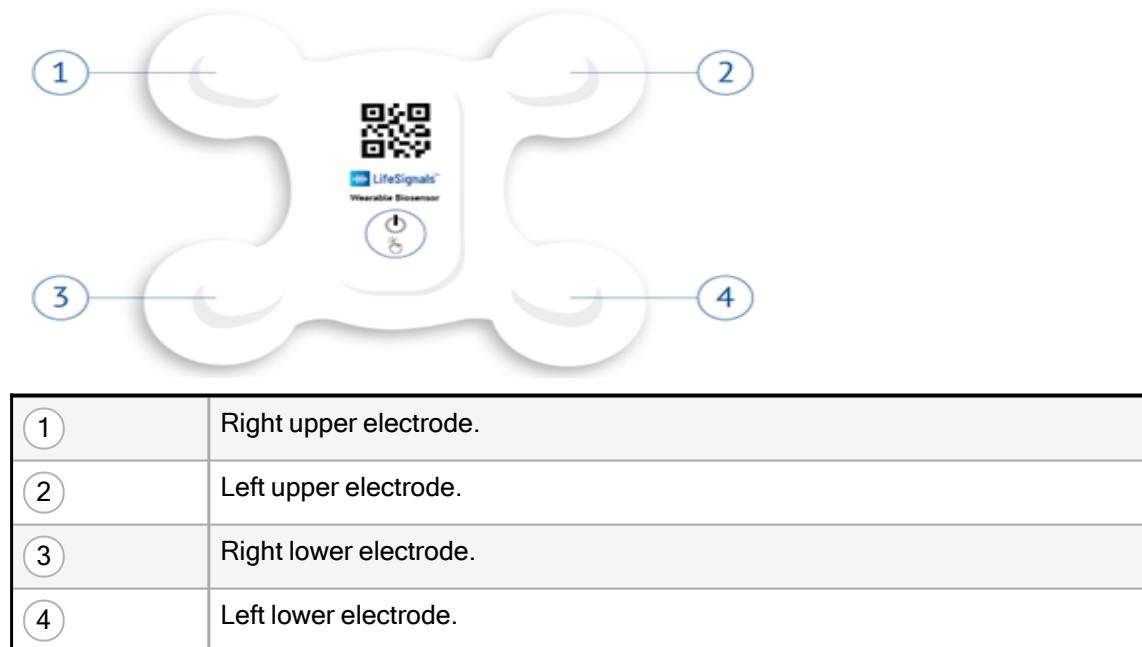


Figure 1 - LifeSignals1AX Wearable Biosensor

### LP1550

**Channel 1:** Right Upper electrode - Left Lower electrode

**Channel 2:** Right Upper electrode - Right Lower electrode

The Biosensor uses standard WLAN (802.11b) secured (AES) communication protocol for wireless data transmission to the mobile phone or tablet.

The Biosensor is a battery-operated device, and the Biosensor battery life may vary depending upon the storage temperature, WLAN environment and the parameter settings selected.



## 2.3 LifeSignals Relay Application

The Relay Application is a relay device that receives data from a single Biosensor and transfers it to the Central Server for display, storage and analysis. and performs the following functions:

- Manages secured wireless communication (WLAN 802.11b) between the Relay Application and the Biosensor.
- Facilitates Biosensor placement if required.
- Provides user interface for entering the Biosensor and patient information and for pairing and establishing the connection with the Biosensor.
- Provides user interface for patients to record activities, symptoms and manual entries (SpO<sub>2</sub>, Blood Pressure readings).
- Provides user interface to stop patient monitoring session, replace the Biosensor and view monitoring summary.
- Receives and encrypts physiological signals from the Biosensor and transmits the data to the central server as quickly as possible.
- Manages encrypted communication between the Relay Application and the central server.
- Stores the data securely if there is any disruption in communication with the central server.

## 2.4 LifeSignals Multi-Patient Relay (MPR) Application

A standard Linux-based computing platform meeting the necessary specifications can be transformed into a Multi-Patient Relay (MPR) device by installing the MPR application.

Following authentication, the MPR's functions can be configured remotely via the Central server. The MPR facilitates communication with multiple Biosensors through a Wi-Fi network (standard Access point) and with various third-party devices through a BLE gateway.

The MPR device performs the following functions:

- The MPR Device establishes communication to a preconfigured LifeSignals Central server or 3<sup>rd</sup> party server, after appropriately authenticating itself.
- The MPR transmits any data received from Biosensors to the connected Central Server as early as possible, subject to the availability of network connectivity.
- The MPR sends the data to the Central Server only in encrypted form, preventing eavesdropping of the data while in transit.
- The MPR securely buffers all received data in its memory temporarily (for at least 2 hours) with necessary encryption during communication breaks between the MPR and Central Server.



## 2.5 UbiqVue Relay Bridge Software

The UbiqVue Relay Bridge is a software application that serves as a communication bridge between the Biosensor and the Multi-Patient Relay Application (deployed on the cloud). The application runs on select models of OpenWrt or Linux-based devices.

The Relay Bridge functions:

- Simplifies infrastructure for environment with less Biosensor density
- Acts as a relay by receiving data from the Biosensor and transmitting it to the cloud-based MPR
- Secures data communication between the relay device and cloud server using TLS (Transport Layer Security) encryption
- Enhances patient mobility
- Supports backhaul communication modes such as Cellular, Wi-Fi, and Ethernet.

## 2.6 UbiqVue BLE Gateway

The Bluetooth Gateway Software Application is installed on an OpenWrt-based Bluetooth Gateway. It functions as a communication bridge between the 3<sup>rd</sup> party devices and the Multi-patient Relay application.

The Bluetooth Gateway device performs the following functions:

- Communicates with a minimum of 4 BLE devices simultaneously.
- Pairs and connects with the specified 3<sup>rd</sup> party Bluetooth device.
- Does not buffer any 3<sup>rd</sup> party device data in the event of a communication disconnection with the Multi-Patient Relay application.
- Allows 3<sup>rd</sup> party devices to roam between multiple Bluetooth Gateway devices within the facility.

## 2.7 LifeSignals Secure Server Application

The LifeSignals Secure Server application is installed on a compatible Linux based hardware platform of LifeSignals, Inc. and performs the following functions:

- Authenticates the LifeSignals Relay Application and MPR devices, establishes secure connection with the relay devices over the internet.
- Manages the decryption, uploading and storage of Biosensor data received from multiple authenticated relay devices.
- Contains the sensor processing library which processes and filters the received physiological signals, then derives heart rate, respiration rate, skin temperature, posture data for storage with the received Biosensor data.
- Allows access to derived parameter and Biosensor data using the LifeSignals Web UI Application.



- Optional ability to send alert notifications to a configured destination e.g. email, SMS, WhatsApp when the parameters (heart rate, etc.) of a specific Biosensor (patient) exceeds the configured limits.

## 2.8 LifeSignals Web UI Application

The LifeSignals Web UI Application is a web-browser application and provides the following:

- The Clinical Facility Administrator (CFA)\* interface for management of roles (Supervisory Clinician, Clinician, Physician, Additional Clinical Facility Admin, patient groups and default alert configuration).
- Enables clinical personnel to login to central server remotely and access patient physiological data and view alert status.
- Depending on the role of clinical personnel (normal or supervisory), they can access data from multiple patients assigned to them and search for patients based on recent alert status. This includes active patients (wearing Biosensor) and patients who have completed the monitoring procedures.
- Monitoring Dashboard continuously displays physiological parameters, waveforms and alert status of all assigned patients to authenticated clinical personnel for near real-time active monitoring. Various options to view patient data can be selected, including multiple patient tile view or single patient zoom view.

\* The Clinical Facility Administrator is set up by the Service Provider Administrator.



## 3 LifeSignals 1AX Wearable Biosensor

### 3.1 Patient advice

The following guidance should be given to the patient to ensure comfort while wearing the Biosensor and optimal Biosensor performance. The information is also provided in the Patient Information Leaflet found inside individual Biosensor packaging.

- Limit physical activity for one hour after the Biosensor has been applied to ensure good adherence.
- Keep showers short with your back to the flow of water.
- If the Biosensor accidentally gets wet, gently pat dry with a towel and minimize activity until fully dry.
- Press down Biosensor edges with your fingers at least twice a day, to maintain good adhesion.
- Avoid sleeping on the stomach, as this may interfere with the Biosensor performance.
- Occasional skin itchiness and redness are normal around the Biosensor placement area.
- Ensure the relay (mobile) device has sufficient battery charge during monitoring.
- Report symptoms such as dizziness, palpitations or breathlessness, press the Biosensor Event button once. You may also be asked to record symptoms using the LifeSignals Relay Application.
- Travel is permitted when wearing the Biosensor. If questioned during security screening, show the Patient Information Leaflet.

### 3.2 LED status indicators

The Biosensor light (LED) provides information related to the functional status of the Biosensor.

**Table 1 - LED Light Behavior and Status 1AX Wearable Biosensor**

Light	Behavior	Status
●	Slow flash	Biosensor connected to the Relay Application /MPR devices, or a monitoring session is in progress.
●	Fast flash	Biosensor attempting to connect with Relay Application / MPR devices
●	Slow flash	Low Battery



### 3 LifeSignals 1AX Wearable Biosensor

Light	Behavior	Status
	Alternate flashing	Response to Relay Application - "Identify Biosensor" command
	Fast flash → Off	Biosensor turned off



### 3.3 Skin preparation

**Tip**

Correct skin preparation will ensure the following:

- High patient comfort
- Reliable and robust ECG waveforms
- Artefact-free ECG reporting
- Good Biosensor adhesion for the wear duration

**Tip**

Avoid the use of wipes or isopropyl alcohol to clean the skin, as alcohol dries the skin, increases the possibility of skin irritation and can reduce the electrical signal to the Biosensor, thereby diminishing ECG waveforms.<sup>1</sup>

1. Sendelbach S et al, 2015/ Crit Care Nurse. 2015 Aug;35(4):15-22

1. If required, remove hair from the chest, preferably using clippers. Shaving should be avoided as it is more likely to damage the skin and increase patient discomfort while wearing the Biosensor.

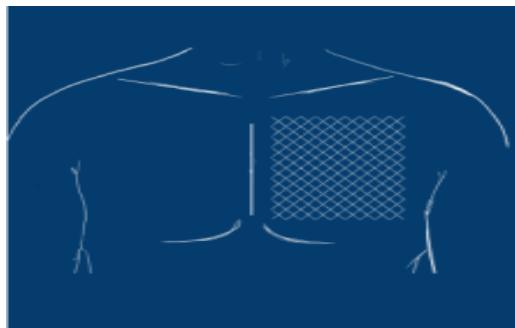


Figure 2 - Biosensor placement area

2. Clean the area with non-moisturizing soap and water using a paper towel or gauze swab. Using soap will remove grime or sweat from the skin and dissolves skin oils. This will help reduce skin-to-Biosensor impedance, which is required to achieve consistent, good quality ECG waveforms.
3. Rinse the area thoroughly with a wet paper towel or gauze swab, making sure to remove all soap residue.
4. Dry the area vigorously with a towel. The gentle abrasion will remove any dead skin cells, further reducing impedance between the skin and the Biosensor. Drying with a towel will also increase skin blood flow, warming the skin for optimal Biosensor adhesion.



## 3.4 Applying the Biosensor

1. Peel off the backing film.
2. Place the Biosensor on the chest, below the collar bone and the left of the breastbone.

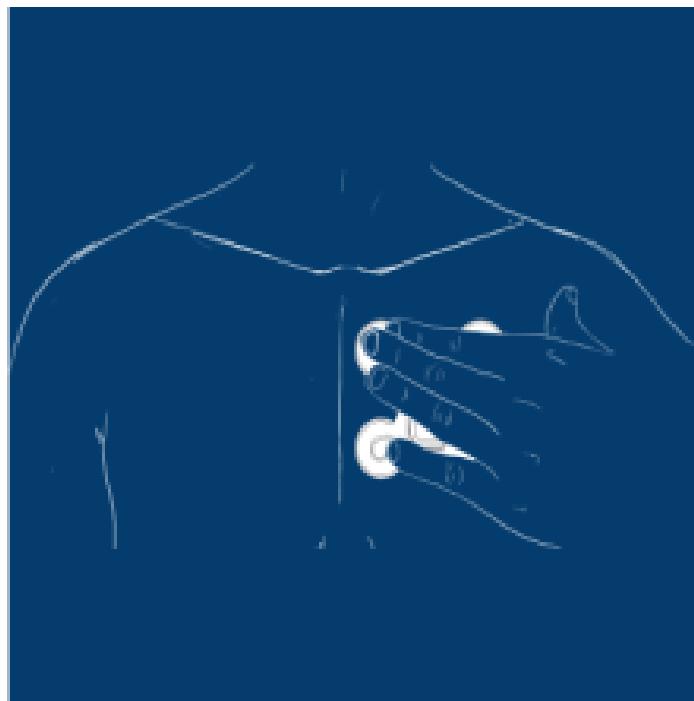


Figure 3 - Lifting the left side of the Biosensor without moving the Biosensor out of place

3. Press the Biosensor for 2 minutes.

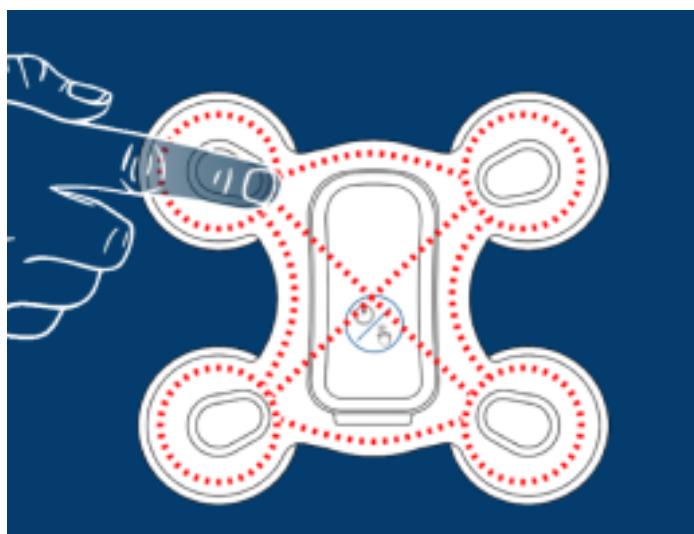


Figure 4 - Red lines indicating to press down on the Biosensor



## 3.5 Removing the Biosensor



### Tip

For patients with fragile or delicate skin, consider using an adhesive remover when removing the Biosensor. Silicone-based adhesive removers are preferred (instead of alcohol-based removers) as they fully remove adhesive residue from the skin, do not cause skin dehydration or an uncomfortable stinging sensation.

Follow these steps to prevent skin injury.<sup>1</sup>

1. Remove the Biosensor close to (parallel with) the skin surface while pulling it back over itself.



Figure 5 - Biosensor removal

2. With the other hand, press the newly exposed skin to reduce skin stretch and discomfort.
3. Gently, peel off the remaining Biosensor in the direction of hair growth.

1. Fumarola S et al, 2020/ J Wound Care 2020; 29(Suppl 3c): S1-S24.



## 4 LifeSignals Relay Application

The Relay Application device will have the LifeSignals App pre-installed that manages the wireless communication between the Wearable Biosensors and the LifeSignals Central Server.

### 4.1 Authenticating LifeSignals App - Relay (mobile) device

#### Notice

 One Time Password (OTP) required for Clinician's first time use of the App or whenever a new device is used. Contact LifeSignals customer support for a list of compatible mobile phones to act as Relay Application devices. Use of incompatible mobile phones may result in degraded performance. OTP (received through email) is needed when the User logs in and when the App restarts.

1. Open LifeSignals App on the relay (mobile) device.
2. Enter the Server ID i.e. server URL or scan the QR/barcode (sent via email/text message), select **NEXT**.
3. Enter the Clinician login credentials, select **NEXT** to receive the OTP (if requested).
4. Enter the OTP, the App automatically authenticates the user.
5. Alternatively, for Patient/Other, enter the patient phone number and patient ID, select **NEXT** to receive the OTP.
6. Enter the OTP, the App takes you automatically to the next screen.



## 4.2 Starting a monitoring session - Relay Application



### Notice

Check the expiry date and the outer package for any damage. If data is not entered in the mandatory fields, an error message highlighting the fields with missing information will appear. If the patient has been admitted using the LifeSignals Web UI Application, patient's information will auto-populate in the LifeSignals App.

1. Remove the Biosensor from the pouch.
2. Enter the Biosensor ID in the LifeSignals App manually or by scanning the QR code on the Biosensor packaging. It takes you to the next screen automatically.
3. Press the Biosensor ON  button once. A red light will flash followed by a flashing green light and the Biosensor will automatically connect to the Relay Application.
4. Enter the Patient Info (including mandatory fields) in the LifeSignals App, select **ADMIT**.
5. Prepare the patient's skin, select **NEXT**.
6. Follow the LifeSignals App instructions to apply the Biosensor, press the entire Biosensor for two minutes, select **NEXT**.
7. Assess the quality of ECG, if acceptable, select **TRANSFER** to use the hospital network for Biosensor data transmission to the Central Server and **CONFIRM** to start the monitoring session. If unacceptable, go to the menu , select **Replace Biosensor** and enter the new Biosensor ID.

## 4.3 Transmitting Biosensor data - Relay Application

1. Select **CONTINUE**.
2. The LifeSignals App supports compatible Regulatory cleared SpO<sub>2</sub> / BP devices.
3. Select the device type, enter the device ID manually or scan the QR code on the device.
4. Alternatively, select **SKIP** to add the device later.

Now the Biosensor is connected, if the connectivity is lost, the Relay Application device will make an audible alert.

## 4.4 Recording symptoms

1. Press the **Event** button on the Biosensor or select **Events** in the LifeSignals App.
2. Select the appropriate symptoms and activity.
3. Select **Done**.
4. Patient activated events can be viewed in the LifeSignals Web UI Application. The Clinician can input additional comments about the event if required.



## 4.5 Recording measurements

1. Press the **RECORD MEASUREMENTS** button on the LifeSignals App.
2. Enter the time (24 hr. format).
3. Enter the measurements for Blood Pressure and SpO<sub>2</sub>.
4. Select **CONFIRM**.
5. You can view the measurements in the LifeSignals Web UI Application.

## 4.6 Additional menu features

In the Relay Application LifeSignals App, select  to access the additional menu features.

Table 2 - Additional Menu Features

Feature	Explanation	Action
Monitoring Summary	Provides current details of the monitoring session.	Select <b>Monitoring Summary</b> and <b>BACK</b> to <b>EXIT</b> .
Stop Monitoring	The App will attempt to upload data and turn off the Biosensor. This may take a few minutes. When fully stopped, follow <i>Remove Biosensor</i> steps.	Select <b>Stop Monitoring</b> , then <b>CONFIRM</b> . Follow <i>Remove Biosensor</i> steps, select <b>EXIT</b> .
Add/Change Device(s)	BP and SpO <sub>2</sub> devices can be added/changed to facilitate measurement transmission to the Central Server.	Select <b>Add / Change Device(s)</b> . Select <i>device type</i> , enter the <i>Device ID</i> and select <b>ADD DEVICE</b> .
Replace Biosensor	The App will attempt to upload data and turn off the Biosensor. This may take a few minutes. When fully stopped, follow <i>Remove Biosensor</i> steps.	Select <b>Replace Biosensor</b> . Follow <i>Remove Biosensor</i> steps, select <b>DONE</b> . A new Biosensor can then be applied.
Identify Biosensor	The monitored Biosensor LED will flash three times.	Select <b>Identify Biosensor</b> .



<b>Transfer (Hospital Network)</b>	Biosensor data transmission will be transferred from the Relay Application to the hospital network (MPR).	Select <b>Transfer (Hospital Network)</b> . The App will contact the Central Server for details. Select <b>CONFIRM</b> . Ensure reconfiguration is successful, select <b>YES</b> . If the Biosensor is transferred, select <b>YES</b> . If not, select <b>NO</b> .
<b>Help</b>	Website link to user manuals.	The link is directed to the website with user manuals.
<b>About</b>	Outlines additional App information	Select <b>About</b> to view information and <b>BACK</b> to <b>EXIT</b> .



## 5 LifeSignals Multi-Patient Relay Application

Follow the steps outlined in the **DHF09-LBL-004 UbiqVue MPR Installation & Configuration Manual**.



## 6 UbiqVue Relay Bridge Software

For more information, refer the **DHF09-LBL-007 UbiqVue Relay Bridge Software Installation & Configuration Manual**.



## 7 UbiqVue BLE Gateway

Refer the DHF09-LBL-004 UbiqVue MPR Installation & Configuration Manual and the DHF09-LBL-007 UbiqVue Relay Bridge Software Installation & Configuration Manual.



## 8 LifeSignals Web UI Application

The LifeSignals Web UI Application is the central gateway for facility administrators and clinical teams to access patient data and user settings according to the following user permissions:

- Set up and manage user access and permissions to patient data and system function settings for a single facility or group facility.
- Manage and initiate patient monitoring sessions, and their individual alert settings.
- Access displays of near real-time and stored continuous monitoring of patient vital signs data from admission to discharge, whether the patient is in, or transitions to/from a home or clinical environment.
- Manage default settings and alerts.
- View session, daily or end of monitoring patient reports generated from the consolidated vital sign data collated from the Biosensors, third-party devices and Clinician notes.

### 8.1 Users and roles

The user hierarchy for the Web UI Application helps to maintain the privacy and security of patient information and permits system functions to be set on a facility-wide basis. By assigning user roles and permissions, the system ensures that only authorized users have access to patient data and the ability to configure the Web UI Application settings. Each user will have specified roles (functions) and permissions to access the Portal settings and patient data. Users can be assigned one or more roles (functions) with pre-configured set of privileges. The User Hierarchy is shown below.

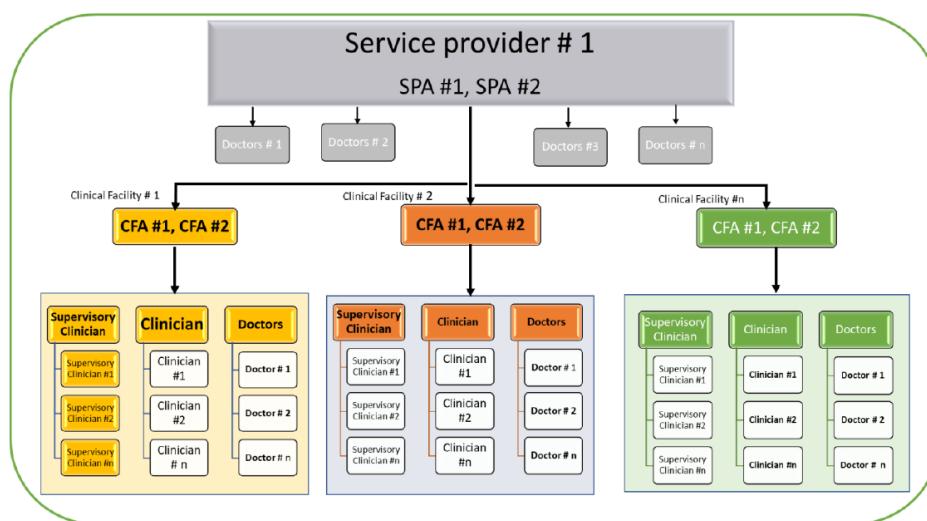


Figure 6 - User Hierarchy



### 8.1.1 Protected Health Information (PHI) Consent

It is mandatory for all users to accept the PHI Consent when logging in for the first time before setting the Password.

#### Notice

The Protected Health information (PHI) is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.

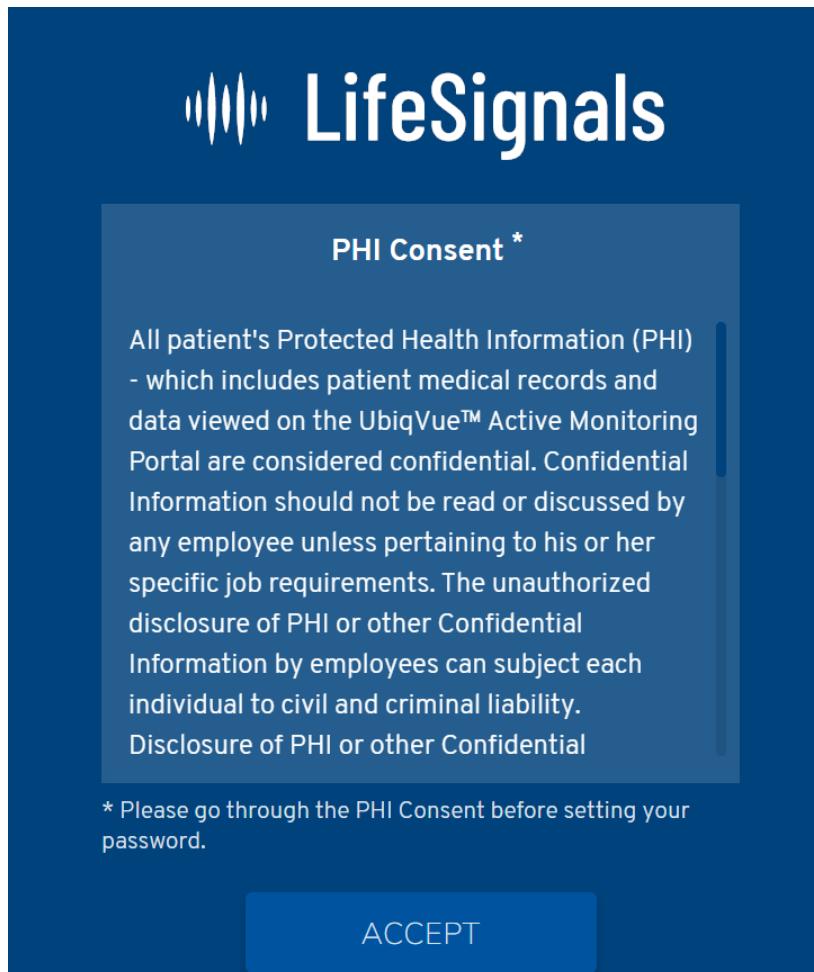


Figure 7 - PHI Consent Screen



## 8.1.2 Service Provider Administrator (SPA)

The SPA manages the administration of clinical facilities and can perform the following functions:

### SPA User Management

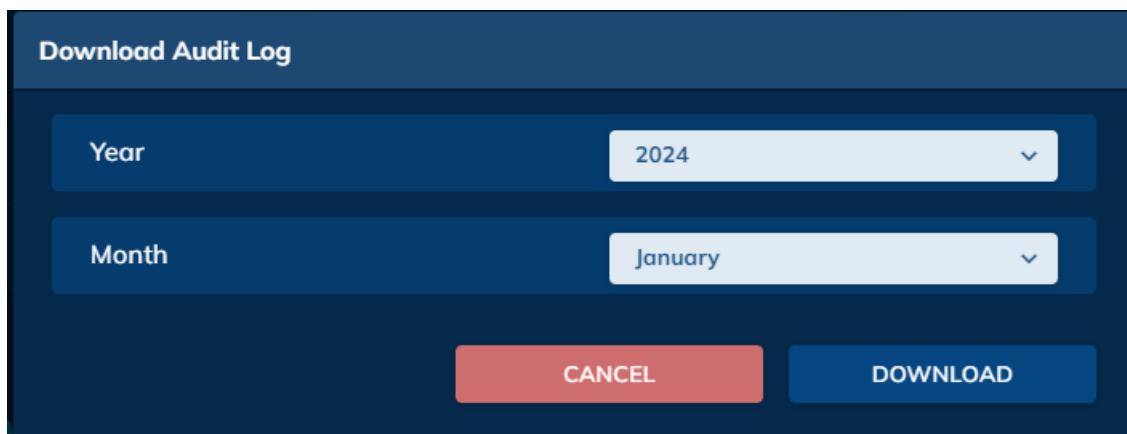
- Create another SPA.
- Enable/disable users (cannot delete) and edit their contact details.
- Reset password for users (a temporary password is sent to the registered email address).
- Add Referral Physician (permission for access must be granted by CFA).

### Clinical Facility Management

- Add new clinical facility (unique ID automatically assigned).
- Edit contact details of clinical facilities.
- Enable/disable multi-factor authentication.
- Configure the data storage period for each clinical facility.
- Manage admin for each clinical facility (add/enable/disable CFA).

### Audit Logs

- Download Audit Logs for the required year and month



Download Audit Log

Year: 2024

Month: January

CANCEL DOWNLOAD

Figure 8 - Download Audit Logs



#### Tip

Only SPA (default SPA) created by the Super Administrator can assign/remove SPA role to/from one or more users.

If the default SPA is disabled by Super Administrator, all the SPA's created by default SPA will automatically be disabled.



### 8.1.3 Clinical Facility User with Admin Privilege. Clinical Facility Administrator (CFA)

The Clinical Facility Administrator (CFA) has multiple functions associated with overall set up and configuration of Web UI Application for the clinical facility. For example, create and assign roles (SC / Clinician (General Clinician) / Physician / Additional Clinical Facility Admin) for new users, reset user's password, select patient identification method for the facility (MRN or Patient ID), create location/medical groups and configure alert defaults for the entire clinical facility.

The CFA login is created by the Service Provider Administrator (SPA). Contact the SPA for access.



#### Tip

CFA cannot view or access individual patient data or **Monitoring Dashboard**.

After logging in to the LifeSignals Web UI Application, the CFA can perform the following functions:

#### User Management

- Add/edit roles for users (Supervisory Clinician, Clinician, Physician, Additional Clinical Facility Admin).
- Edit contact details of users (Supervisory Clinician, Clinician, Physician Additional Clinical Facility Admin). When you update or change user contact information, an email will be sent to the previous email address.
- Rename user roles in the Web UI Application.
- Add/ Delete patient groups based on location or medical group to Clinician or Physician.
- Reset password for users (temporary password sent to user email address and mobile number).

#### Patient Group Management

- Create/Add/Edit/Delete levels in locations and medical group.

#### Relay Management

- Send SERVER ID/QR code to the registered Relay Application device.
- Delete Relay Application IDs.
- Add/Delete Relay for Multi-patient relay.
- Delete/ Resend /Resend (Legacy mode) / Disable already created Relays.
- CFA can verify the version and status of MPR

#### Default Alert Configuration (for the facility)

- Enable/Disable or Edit the clinical and technical alerts and set the alert frequency and delay time for the clinical facility.



- Configure alert thresholds and set alert priorities, including frequency and breakthrough, for clinical alerts
- Set the alert destinations for clinical, manual, and technical alerts via SMS, Email, or WhatsApp
- Set the Alert notifications including messages for Clinicians, Supervisory Clinicians, and Physicians.

#### Miscellaneous

- **ECG Settings:** Select/Edit ECG filter settings and Select/Edit ECG sampling rate.
- **Network Reconfigurations - Biosensor:** Enable/Disable/Edit Biosensor wireless network configuration.
- **Network Reconfiguration-Relay Bridge:** Configure/edit Primary Biosensor Wi-Fi SSID/Password, Secondary Biosensor Wi-Fi SSID/Password, and Hospital/Home Wi-Fi SSID and Password.
- **Other Settings:** Enable/Disable auto generation of **Patient ID/MRN**, access to select Service Provider Referral Physician, **Access of General Clinician to EWS Module**, Mandatory note for parameter acknowledgment, Mandatory note on discharge, Display Pulse Rate in Patient Zoom View, select Patient Identification (local terminology i.e. MRN or PID), Enter facility name, Upload a file for co-branding logo and Patient barcode parsing.

#### Audit Log

- Download the Audit logs for the required year and month. (Information related to every user action can be downloaded).

### 8.1.4 Clinical Facility User with Supervisory Clinician Privilege

The Supervisory Clinician (SC) can view all patients or patient groups in the clinical facility, acknowledge alerts for all patients in clinical facility using the Web UI Application. SC can set/edit default alarms for specific groups of patients, assign patients or patient groups to the user with Clinician or Physician role and view discharged patients.

The SC login is created by the CFA. Contact CFA for access.



#### Tip

Only the SC can access the list of discharged patients, view trends, generate reports for discharged patients, and filter patients by admission dates in the **Discharged Patients** screen.

The SC cannot admit patients or add events/notes.

### 8.1.5 Clinical Facility User with Clinician Privilege

The Clinician can admit patients, assign new patients to any location or medical group, set/edit default alert limits for any assigned patients, view data and acknowledge alerts



of multiple assigned patients, enter manual Events/Notes, SpO<sub>2</sub>, BP value using the Monitoring Portal. The Clinician login is created by the CFA. Contact the CFA for access.



**Tip**

Only the Clinician can admit patients. The Clinician cannot access the list of discharged patients or view trends and generate reports for discharged patients in the **Home** screen.

### 8.1.6 Clinical Facility User with Physician Privilege

The Physician can set/edit default alert limits for any assigned patients, view data and acknowledge alerts of multiple assigned patients or patient groups, enter manual Events/Notes, SpO<sub>2</sub>, Pulse Rate, BP values using the Web UI Application.

The Physician login is created by the SPA or CFA. Contact the SPA or CFA for access.



**Tip**

If the SPA creates Physician login, then the Physician may have access to patients in multiple clinical facilities when the Physician is selected during patient admission.

Whereas, if the CFA creates the login, then the Physician will have access to patients in the single clinical facility only.

The Physician cannot admit patients or access discharged patients in the **Home** screen.

### 8.1.7 Main display screens

The LifeSignals Web UI Application displays three screens: Home, Monitoring Dashboard and Settings, supporting clinical workflows and functions.

#### 1. Home screen

The Home screen is the primary navigation screen for all core functions of LifeSignals including Patient Management, Clinical and Technical Alerts. The Home screen also provides quick access to the Monitoring Dashboard, Settings and User information. User permissions provide access to various functions.

[Admit Patients](#) | [Current Patients](#) | [Discharged Patients](#) | [Clinical Alerts](#) | [Technical Alerts](#).

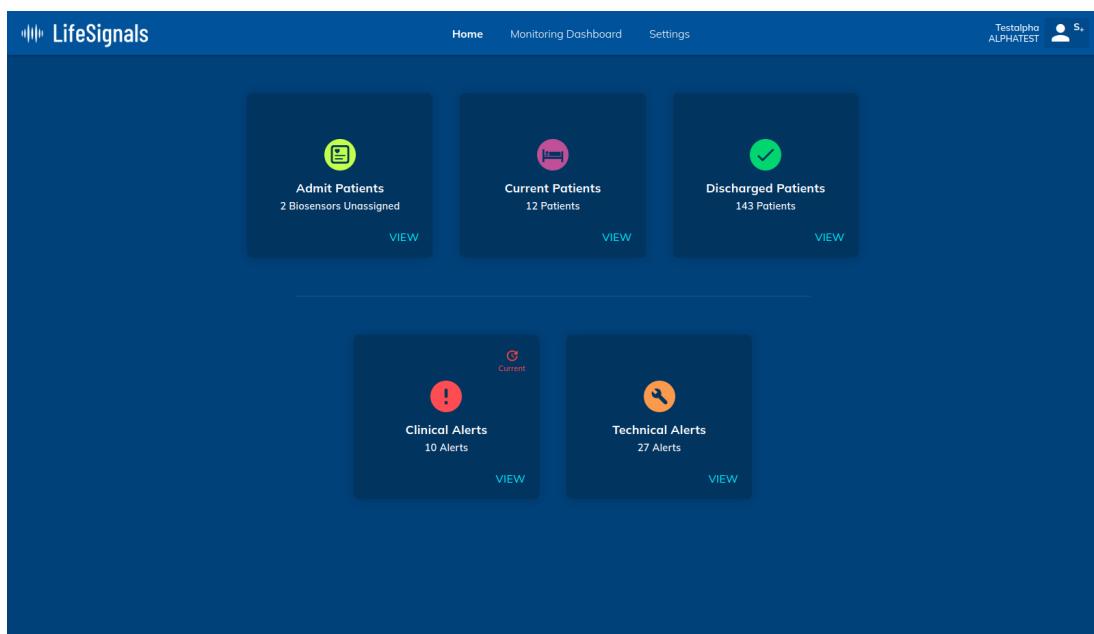


Figure 9 - Home Screen



## 2. Monitoring Dashboard

The Monitoring Dashboard displays near real-time waves, numeric, and alarms from multiple patients. Patient tiles can be selected to view individual patient data, trends and alert settings (Zoom View). Supervisory Clinicians, Physicians, and Clinicians can remotely access the Monitoring Dashboard.

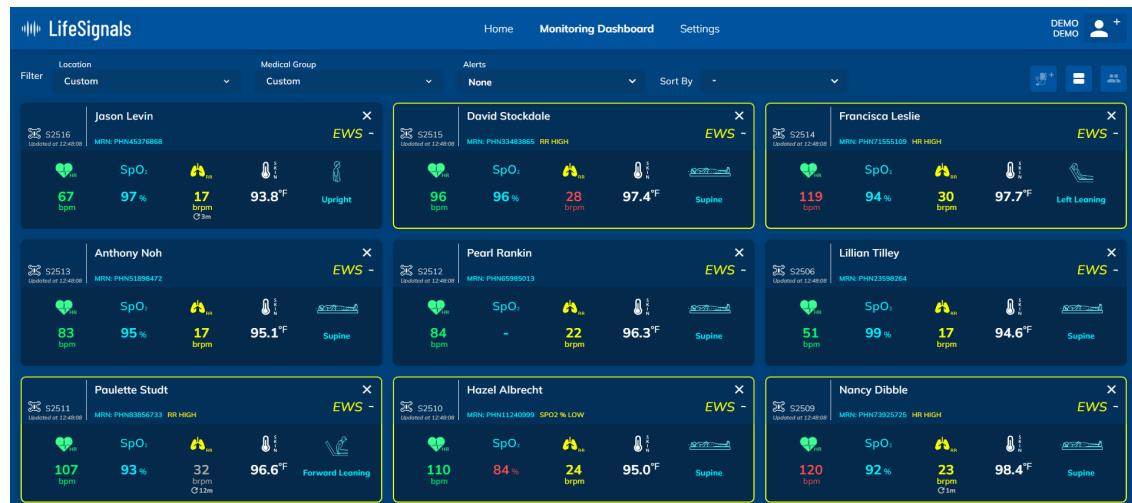


Figure 10 - Monitoring Dashboard

## 3. Settings screen

The Settings screen provides access to functions enabling management of authorized users permitted to access the Web UI Application, creating and managing patient groups and associated app settings. Additional rules and Web UI Application functions can also be set through the settings screen. Only the CFA is authorized to configure default settings.

**User Management | Patient Group Management | Relay Management | Default Alert Configuration | Miscellaneous | Audit Log**

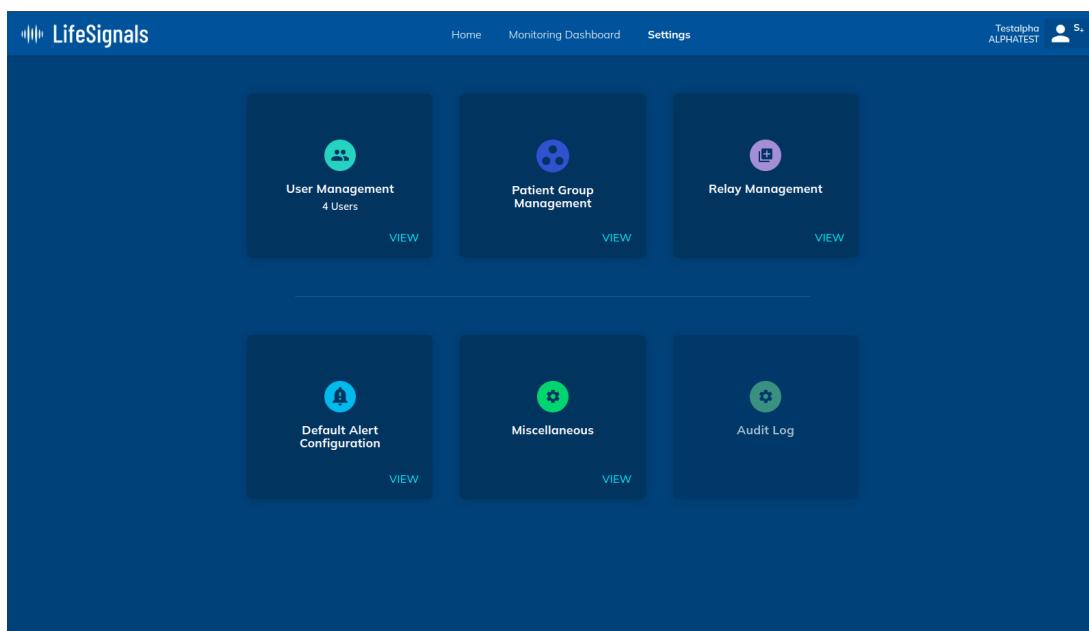


Figure 11 - Settings Screen

## 8.2 Patient management

**Patient management** provides functions to enable users to:

- Manage patient transitions from admission to discharge, whether the patient is located at home or in a clinical environment.
- Enter and update patient information.
- Enter and update Physicians or Caregivers to receive notifications for the patient.
- Manage the Biosensors and third-party device assigned to a patient.
- Enter Events and notes into the patient record.

Users with the roles of Supervisory Clinician, Clinician and Physician manage the patients in the clinical facility and perform the clinical workflows outlined below using the Web UI Application. A user can have multiple roles.



### Tip

Permission to admit/discharge patients, view patient vital signs and configure clinical/technical alerts is dependent on the user's privileges.

The  beside the user icon denotes access to the respective clinical workflow.



## 8.2.1 Admitting patient



To start monitoring a patient, follow the steps below to admit the patient to the Facility.

1. From the **Admit Patients** viewer → Select **ADMIT PATIENT** → Enter the patient details\* and the Biosensor ID → **SAVE**.
2. Follow the step-by-step instructions shown in For more information, see "Skin preparation" on page 12 and For more information, see "Applying the Biosensor" on page 13.
3. Complete the patient admission to LifeSignals. Note that the patient's vital sign data will immediately begin streaming to the Web UI Application.
4. Return to the Web UI Application and view the patient vital sign data displayed on the Monitoring Dashboard.

\* Mandatory

\*\* Data will be autopopulated, if the patient demographics have been previously entered in the Web UI Application.

### Notice

In cases where the Biosensor has been applied to a patient BEFORE admitting a patient, using the relay device or the Web UI Application, the patient is NOT being actively monitored, no alarms will be generated and the Biosensor data will not be displayed on the Monitoring Dashboard. It is advised to always follow the **Admitting patient** procedure detailed above to ensure a patient can be monitored as soon as the Biosensor is applied.

Mandatory Fields	
<b>PATIENT ID / MRN</b>	Enter the Patient ID /MRN. The Patient ID can also be autogenerated by tapping the Auto-generate icon
<b>FIRST NAME</b>	Enter the First Name of the Patient.
<b>LAST NAME</b>	Enter the Last Name of the Patient.
<b>DATE OF BIRTH</b>	Select the Year, Month and Day from the Calendar. (Birthdate of the patient).
<b>SEX</b>	Select the sex from the drop-down list.
<b>PHONE NUMBER</b>	Enter the Phone number for the Patient.
<b>ADMITTED ON</b>	Select the Year, Month and the Day from the Calendar. (Admission date of the patient)
<b>BIOSENSOR ID</b>	Enter the Biosensor ID and select <input checked="" type="checkbox"/> .



**Admit Patient**

PATIENT ID / MRN \*

ADMISSION ID

Autogenerate New ID

FIRST NAME \*

LAST NAME \*

DATE OF BIRTH \*

AGE

SEX \*

WEIGHT  kg

HEIGHT  cm

EMAIL

PHONE NUMBER \*

DOCTOR'S NAME

GROUP

ADMITTED ON \*

ESTIMATED DISCHARGE

BIOSENSOR ID \*

THIRD PARTY DEVICE TYPE

THIRD PARTY DEVICE ID

CLINICAL INDICATION (Select All That Applies)

Yellow Fever

Typhoid Fever

Beta Blockers (e.g. Atenolol, Bisoprolol, Esmolol)

Pacemaker

Brain Abscess

MEDICATION

ADDITIONAL INFORMATION

Figure 12 - Admit Patient Screen

**Notice**

ADDITIONAL INFORMATION field - Information related to the medical history, admission condition, allergies related to the patient can be entered.



## 8.2.2 Transferring to Hospital Network (MPR)

When an admitted patient is relocated from a Relay Application to an MPR e.g. from the patient's home to a hospital ward, the **Transfer to Hospital Network** function enables the seamless transfer of continuous vital sign monitoring without the requirement to remove the assigned Biosensor.

1. From the **Current Patients** window → → **Transfer to Hospital Network** → **CONFIRM** → **Transfer Initiated**.

## 8.2.3 Editing patient

Choosing the Edit option enables the user to modify all information for an individual patient, except for the Patient ID, Admission ID, First Name, Last Name, Age, Date of Birth, and Sex.

1. From the **Current Patients** window → individual patient → **Edit** → **Edit** information → **SAVE**.

## 8.2.4 Discharging patient

When a patient monitoring session has been completed, the patient can be discharged from the Web UI Application.

1. From the **Current Patients** window → individual patient → **Discharge** → **CONFIRM** → **OK**

## 8.2.5 Transfer from Hospital Network (Relay Application)

When an admitted patient is relocated from an MPR setting to a Relay setting e.g. from a hospital ward to the patient's home or a step-down facility, the **Transfer from Hospital Network** function enables the seamless transfer of continuous vital sign monitoring without the requirement to remove the assigned Biosensor.

1. From the **Current Patients** window → → **Transfer from Hospital Network** → **CONFIRM** → **Transfer Initiated**.

## 8.2.6 Adding Biosensor

If a patient requires a new Biosensor to be applied i.e. previous Biosensor wear-life completed, removed for MRI, this function permits continuation of patient monitoring session. There are two ways to add Biosensor. They are:



1. From the **Current Patients** window → (beside the Biosensor ID) → **ADD NEW** → Enter the Biosensor ID → → **SAVE**.  
Or
2. From the **Current Patients** window → Click the icon → **Edit** → (beside the Biosensor ID) → **ADD NEW** → Enter the Biosensor ID → → **SAVE**.

## 8.2.7 Extending discharge

Every patient has an estimated discharge date\* scheduled on their patient file. i.e. when monitoring is no longer required or when the patient leaves the hospital. If a new Biosensor is applied, the discharge date will be automatically updated. If a patient's Biosensor is not streaming data on the discharge date, the patient's details automatically transfer from the current patients to the discharged patients.

1. From the **Current Patients** window → individual patient → **Edit** → choose new **ESTIMATED DISCHARGE** date → **SAVE**.

\* Discharge date refers to entry in the LifeSignals™ Web UI Application.

## 8.2.8 Assigning/Reassigning patient to location/medical group

During patient admission, a physical location or medical group e.g. Cardiology, Oncology can be assigned. This enables multiple patients to be managed according to their location or medical group in near real time. If a patient has changed location or medical group, details can be updated accordingly.

1. From the **Current Patients** window → **ASSIGN GROUP** → **Location/Medical Group** → **ASSIGN**.
2. To reassign, select **Location/Medical Group** → choose new **Location/Medical Group** → **ASSIGN**.

## 8.2.9 Assigning/Reassigning Physician

During patient admission, a Physician can be assigned. If the patient has been transferred from the care of one Physician to another, details can be updated accordingly.

1. From the **Current Patients** window → Individual patient → **Edit** → **PHYSICIAN NAME** (drop-down) → **SAVE**.



## 8.2.10 Stop monitoring

When the patient's monitoring session has been completed, the status should be first updated in the Web UI Application, before removing the Biosensor to ensure all the data is captured.

1. From the **Monitoring Dashboard** → Patient zoom view → **STOP MONITORING** → **CONFIRM** → **OK**.

Or

2. From the **Current Patients** window → Select the icon → **CONFIRM** → **OK**.



### Notice

Ensure the Biosensor is switched off (LED no longer flashing).

3. Follow the steps for removing the Biosensor. For more information, see "Removing the Biosensor" on page 14.

## 8.2.11 Assigning/Reassigning devices

During patient admission, a third-party device e.g. BP / SpO<sub>2</sub> device can be assigned to the patient, and data can be streamed to the Web UI Application together with the other Biosensor data. When a patient's monitoring session has been completed, the device can be reassigned.

1. Open the **Current Patients** window → Individual patient → **Edit** → **THIRD PARTY DEVICE TYPE** → Enter the **DEVICE ID** → **SAVE**.
2. To assign more devices, select → Enter the details → **SAVE**.
3. To reassign devices, select → Enter the details → **SAVE**.
4. To pair Third-party devices:
  - Keep the third-party device close to the Bluetooth gateway (Access Point).
  - 5. Long press the pairing button on the third-party device.
  - 6. When the devices are paired, you can start taking the readings.

## 8.2.12 Adding events/notes

If a Patient pushes the Biosensor event button, a record will show in the patient tile. Supplementary notes can be added by the Clinician with further information to assist with patient monitoring records.





1. From the **Monitoring Dashboard** → patient zoom view → **ADD EVENT** → select **Symptoms/Activities or Record Note** → **SAVE**.



2. From the **Current Patients** window → **ADD EVENT/NOTE** → select **Symptoms/Activities or Record Note** → **SAVE**.

## 8.3 Patient monitoring

The Web UI Application provides access to multiple patient physiological measurements, posture status and alarm events, continuously streamed from the Biosensor and third-party device. This information is displayed in various formats to assist in reviewing a patient's status. Continuous physiological data can be streamed in near-real time from the patients located in a clinical or home environment. When intermittent data is captured using third party devices e.g. Pulse Rate, BP / SpO<sub>2</sub>, it may be required to update the parameters manually.

### 8.3.1 Current patients

The **Current Patient** screen displays a list of actively streaming and non-streaming patients (Stop Monitored Patients) and their vital sign measurements.

1. From the **Current Patients** window, view the patient details e.g. **MRN, PATIENT NAME, MONITORING STATUS**.

The screenshot shows the 'Current Patients' screen of the LifeSignals Web UI Application. The interface includes a header with the 'LifeSignals' logo, a user profile, and navigation links for 'Home', 'Monitoring Dashboard', and 'Settings'. Below the header is a search bar and a table displaying patient data. The table columns are: MRN, PATIENT NAME, GROUPS, MONITORING, ID, and OTHER DEVICE ID. Each row represents a patient with their details and monitoring status. For example, the first patient listed is 'PATAGJU0' with 'Jessica Velasquez' as the name, 'LOC1\_1' as the group, and 'KWBZ5' as the ID. The 'MONITORING' column shows a green checkmark and a red square, indicating active monitoring. The 'OTHER DEVICE ID' column shows 'LS7J5, LSDDOF'. Action buttons for 'ADMIT PATIENT', 'ADD TO DASHBOARD', and 'EDIT' are located at the top right of the table. The bottom right of the table shows page navigation with 'Showing 1 - 20 out of 26 results' and page numbers 1, 2, and 3.

Figure 13 - Current Patients Screen

2. Filter the patients based on **Location** or **Medical Group**.
3. Sort the patient list shown in the window based on **MRN/ PATIENT NAME/ MONITORING/ ID**.



**Notice**

**MRN -** Clicking on the MRN of a particular patient will direct you to the Hybrid view of the Patient.

4. To view the patient information → select the icon (Medication, Clinical indication and Additional information details of the patient can also be viewed).

**More Info** MRN. PAT995214229 **Ssh RBnine** X

Full Name	Ssh RBnine	Sex	Male
DOB	10/JAN/2013   11 YRS	Phone No.	+919807654345
Height	-	Weight	-
Admitted On	10/JAN/2024 21:24	Estimated Discharge	15/JAN/2024
Physician	-	Biosensor ID	-
Email	-	Medication	-
Clinical indication			
Additional information			
-			

Figure 14 - More Info Screen

5. To view the Biosensor information or Add Biosensor to the Patient → Select the icon.



**More Info**

Biosensor ID	Started On	Stopped On
MNH65	Jan 10, 2024 / 15:26	Jan 17, 2024 / 16:27

**ADD NEW**

**CANCEL** **SAVE**

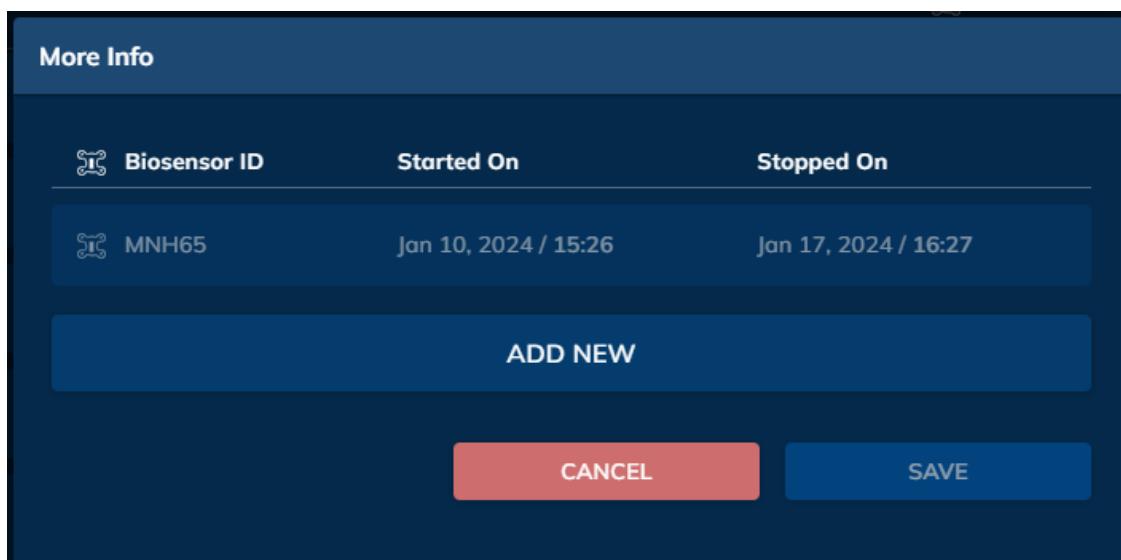


Figure 15 - View Biosensor Info and Add Biosensor

6. The user can start / stop (ON /OFF) Alerts for specific time intervals (15 Mins, 30 Mins, 45 Mins, 60 Mins, and 120 Mins). Paused alerts DO NOT reach the Destinations (SMS, WhatsApp, Email).

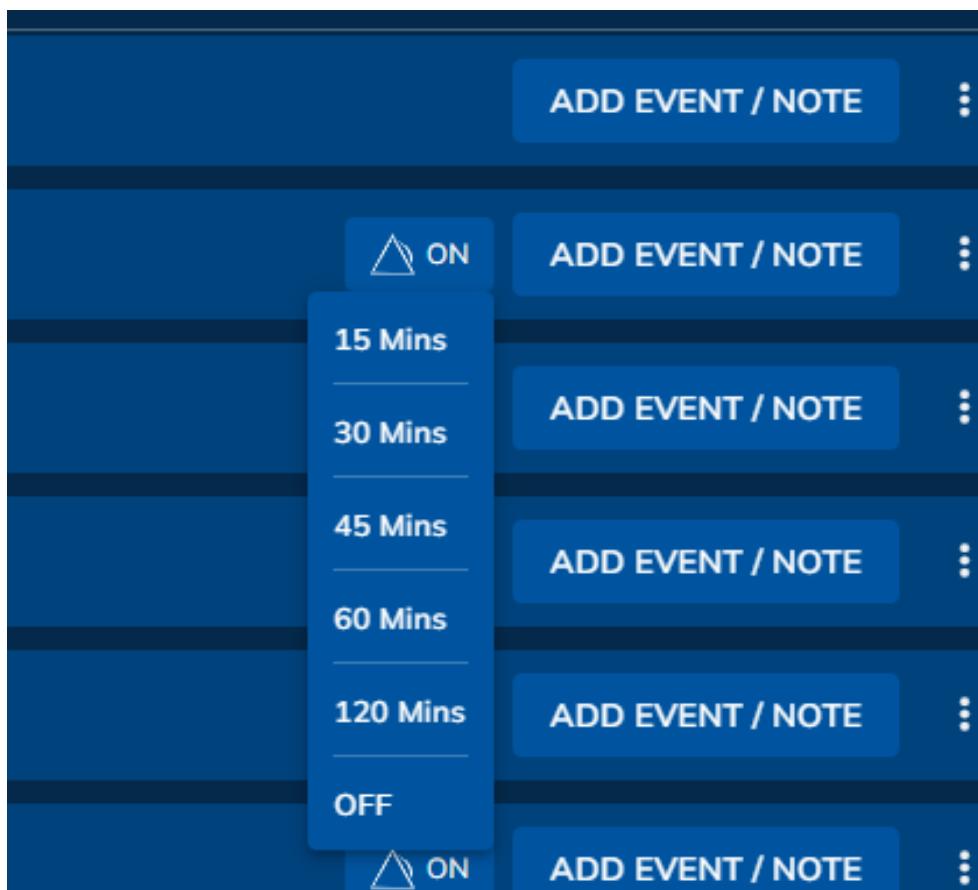


Figure 16 - Pause Alerts



### 8.3.2 Patient trends



The Trends window displays a patient's physiological measurements over a selected timeline.

1.

From the **Monitoring Dashboard** → **patient zoom view** → **TRENDS** → Select Admission No. → Select recent Time interval → Select Date/Time (From and To) **Parameter 1 and Parameter 2 (select HR or PR or SpO<sub>2</sub> or RR or Skin Temp or BP)**.



Figure 17 - Patient Trends



#### Notice

Based on the first channel selection, User will be able to select the corresponding waveforms in the second channel.

Parameter 1 and Parameter 2 represent vital data related to **HR, PR, SpO<sub>2</sub>, RR, Skin Temp, and BP**.

When the **HR** is selected in Parameter 1; Parameter 2 can also display the **ECG A** or **ECG B** of the patient.

Alternatively,

From the **Current Patients** window → → **VIEW TRENDS** → select **Admission**



No → Select recent Time Interval → Select Date / Time (From and To) → Select Parameter 1 and Parameter 2 (select HR or PR or SpO2 or RR or Skin Temp or BP).

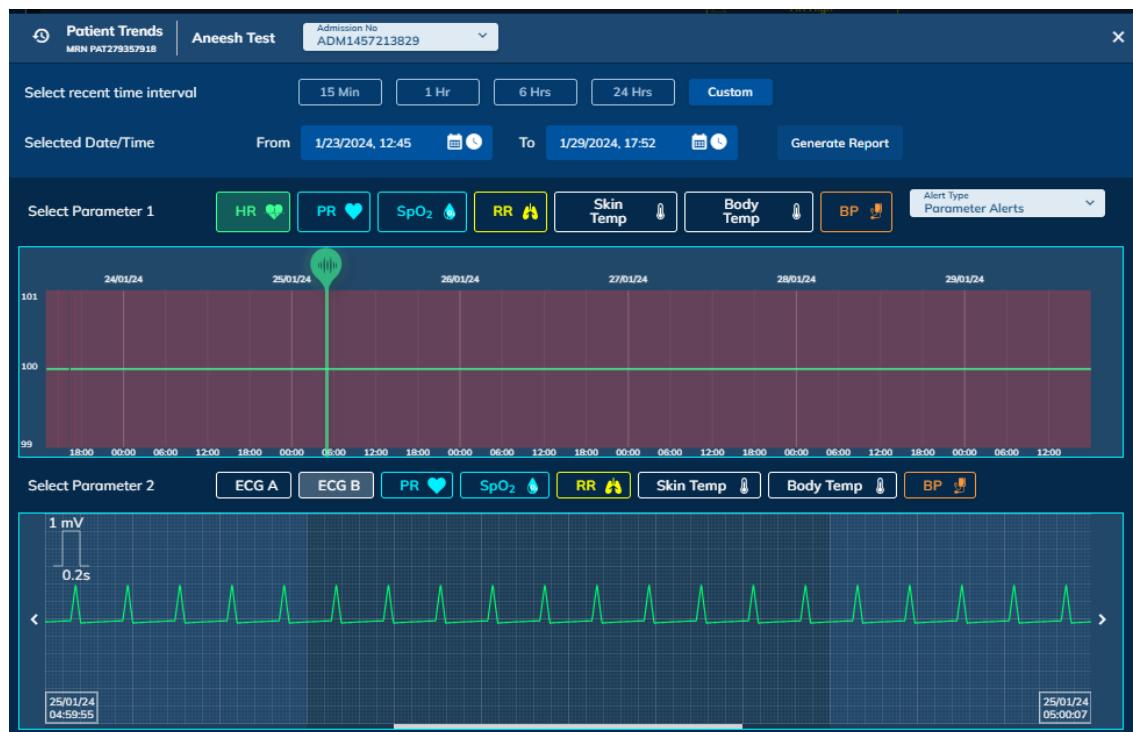


Figure 18 - Patient Trends - Parameter Alerts

#### Notice

Parameter alerts are displayed in Red.

Technical alerts are displayed in Blue.

Manual events are displayed in Green.

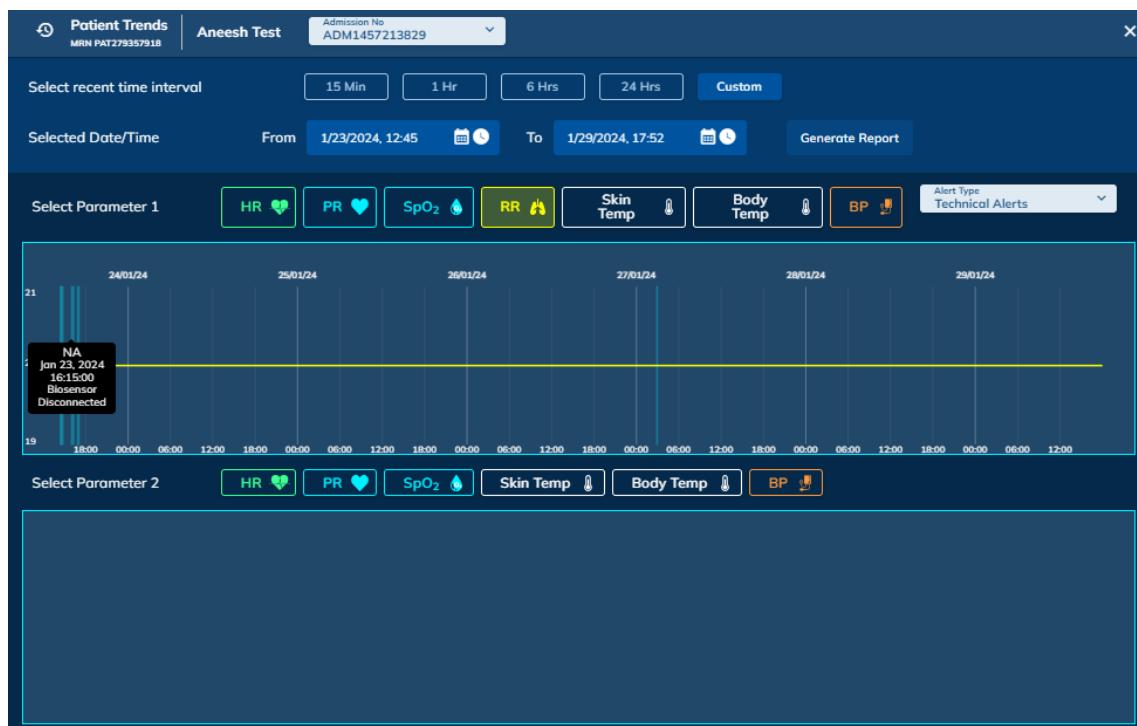


Figure 19 - Patient Trends - Technical Alerts

### 8.3.3 Monitoring Dashboard

The Multi-Patient monitoring window displays continuous physiological parameters, waveforms and alert status of assigned patients to authenticated clinical personnel for near-real time active monitoring. It has the option for users to select multiple patient tile view or single patient zoom view for any patient using the available filter settings.

1. Filter the patients based on **Location**, **Medical condition** and **Parameter alerts**.
2. Sort the dashboard based on **MRN**, **Patient First name**, **Biosensor ID**.
3. To view BP in patient tile, select →
4. To view ECG in patient tile, select →
5. To view BP and ECG in patient tile, select →
6. To view Group Grid View, select →
  - a. Overview about the patient active alerts- Active Parameter/Technical/Manual alerts.
  - b. To view detailed alert window, select →
7. Add Patient to the Monitoring Dashboard.
8. Select individual patient tile to go to zoom view.



Figure 20 - Zoom View Screen

### Notice

- Clinical alerts and technical alerts are displayed both in the zoom view and Tile view.
- Clinical alerts are displayed for the selected patient in the zoom view next to the patient's name.
- Technical alerts are displayed in the zoom view next to the Biosensor.
- The Respiration Rate (RR) waveform is available in the ECG B (channel 2 drop-down menu).

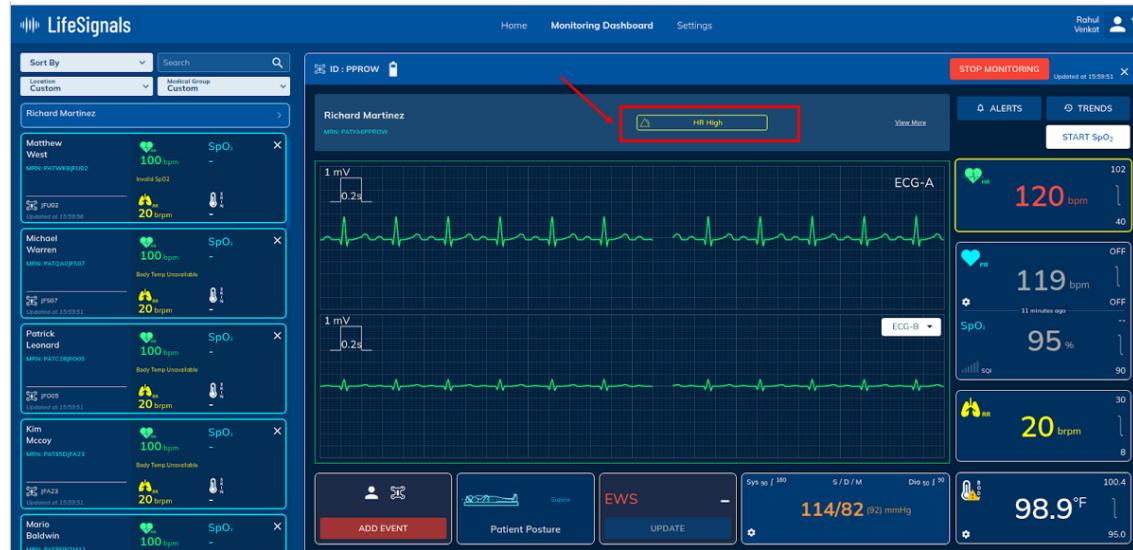


Figure 21 - Zoom View - Clinical Alert Display



### 8.3.4 Updating blood pressure

If the blood pressure device utilized is not transmitting data to the Web UI Application measurements can be entered manually in the patient record.

1. From the **Monitoring Dashboard** → patient zoom view → Select the  icon in the Blood Pressure tile → Enter the BP Values → **SAVE**.



#### Notice

View Logs provides the log details of the previously entered values with time stamp.

### 8.3.5 Updating SPO<sub>2</sub> / Pulse Rate

If a SpO<sub>2</sub> device utilized is not transmitting data to the Web UI Application measurements can be entered manually in the patient record.

1. From the **Monitoring Dashboard** → patient zoom view → Select the  icon in the SpO<sub>2</sub> /Pulse Rate tile → Enter the values → **SAVE**.



#### Notice

View Logs provides the log details of the previously entered values with time stamp.

### 8.3.6 Requesting patient report

Patient reports can be generated either during or after a monitoring session. There are three types of reports:

- Monitoring Report
- Daily Report and
- Alert Report.

To request monitoring report:

1. From the **Monitoring Dashboard** → Patient zoom view → **TRENDS** → Select the **Date/Time (From and To)** → Select  → **Request Monitoring Report/Request Daily Report**

or



2. From the **Current Patient** window → Individual patient → Select the  icon → **View Trends** → Select the **Date /Time (From and To)** → Select  → **Request Monitoring Report / Request Daily Report**.

The requested monitoring report will automatically download to the system with a password by default.

The Monitoring report can also be viewed in the "Report History" section on the dashboard without a password.

You can find all the requested reports in the "View available report" section.

1. From the **Monitoring Dashboard** → Patient zoom view → **TRENDS** → Select the **Date/Time (From and To)** → Select  → Select **View Available Report**.

#### Notice

1. The password for the monitoring report is the first 4 letters of your registered email, followed by the last 4 digits of your registered mobile number. (If you do not have a registered number / email, use 0000 instead).
2. Alert report will also be generated while requesting monitoring reports.

### 8.3.7 Downloading daily report and alert report

Reports can be downloaded in a PDF format.

1. From the **Monitoring Dashboard** → patient zoom view → **TRENDS** → Click  → **Select Monitoring/Daily Report** → select .

Or

2. From the **Current Patients** window → Individual patient, select the  icon → **View Trends** → Click  → **Select Monitoring/Daily Report** → Select .

### 8.3.8 Viewing and Downloading alert log\*

Each patient alert is captured and stored within the Web UI Application. Users can view and download the list of alerts for further review.

1. From the **Monitoring Dashboard** → patient zoom view → **ALERTS** → select .

\* Alert logs are stored in the AWS cloud. If memory storage is full, the alert logs will be stored in the backup.



### 8.3.9 Viewing and Downloading Event Log\*

When a patient experiences any kind of discomfort symptoms, the event button on the Biosensor can be activated. This facilitates the event to be recorded on the Dashboard. Users can view and download the list of alerts for further review.

From the **Monitoring Dashboard** → patient zoom view → **ALERTS** → **EVENT LIST** → Select 

## 8.4 Alert management

The Web UI Application generates alerts notifications that can be viewed on the Monitoring Dashboard. When an alert notification is raised, clinical staff can view details of the alert, acknowledge receipt, take necessary action and forward the alert details to another clinical team member, if necessary.

**Clinical Alerts** - indicates the patient's physiological measurements collated from the Biosensor and third-party devices that have fallen outside the pre-set alert parameters.

**Technical Alerts** - indicates the Biosensor cannot measure or detect alerts reliably e.g. The Biosensor has slipped off or is out of battery.

Clinical and Technical Alerts can be pre-configured in the **Settings** screen. Details of Alert messages can be found here [Alerts.htm](#).



#### Caution

Always check the default alarm settings are appropriate prior to monitoring individual patients as extreme parameters may make the alert system ineffective.

### 8.4.1 Viewing and acknowledging clinical alerts

A list of all generated clinical alerts by location, medical group or vital sign parameters can be reviewed and acknowledged in the Clinical Alerts tab. Along with the current Clinical Alerts, the alerts that were generated in the last 30 minutes, 1 hour, 3 hours, and 6 hours can also be viewed.

To view and acknowledge the required clinical alerts:

1. From the **Home** screen, navigate to **Clinical Alerts** window → Select **View** → Select the search criteria for alerts based on **Location/Medical Group/Parameter/Priority** → Select **Search**.
2. The various details pertaining to the **MRN**, **Patient Name**, **Groups**, **Alert Time**, **Alerts**, and **Status** are displayed.
3. Select **Acknowledge** to acknowledge the alerts.
4. Click the  icon and select the desired options.



MRN	PATIENT NAME	GROUPS	ALERT TIME	ALERTS	EWS	STATUS
PATAGJU3	Jennifer Lopez	GEN	Jan 4, 2024 / 1:21	ACTIVE	HR > 127	ACKNOWLEDGE
PATAGJU0	Jessica Velasquez	LOC1	Jan 4, 2024 / 1:17	ACTIVE	HR > 115	ACKNOWLEDGE
PATAGJU0	Jessica Velasquez	LOC1	Jan 4, 2024 / 1:12	ACTIVE	POSTURE_ALERT	ACKNOWLEDGE
PATAGJU3	Jennifer Lopez	GEN	Jan 4, 2024 / 1:12	ACTIVE	POSTURE_ALERT	ACKNOWLEDGE
PATAGJU1	Nicole Cole	LOC1	Jan 4, 2024 / 1:11	ACTIVE	POSTURE_ALERT	ACKNOWLEDGE
PATAGJU4	Sarah Jordan	Unassigned	Jan 3, 2024 / 23:13	ACTIVE	RR > 30	ACKNOWLEDGE
PATAGJU4	Sarah Jordan	Unassigned	Jan 3, 2024 / 23:13	ACTIVE	PR > 120	ACKNOWLEDGE

Figure 22 - Clinical Alerts Screen

## 8.4.2 Viewing and acknowledging technical alerts

A list of all generated technical alerts by location, medical group or vital sign parameter can be reviewed and acknowledged. To view and acknowledge the required technical alerts.

1. From the **Home** screen, navigate to **Technical Alerts** window → Select **View** → Select the search criteria for alerts based on **Location/Medical Group/Alert Type**→ Select **Search**.
2. The various details pertaining to the **MRN**, **Patient Name**, **Groups**, **Biosensor ID**, **Monitoring**, **Alert Time**, **Alerts** and **Status** are displayed.
3. Click **Acknowledge** to acknowledge the alerts. (The Acknowledged alerts denote the Alerts that have been acknowledged.)

MRN	PATIENT NAME	GROUPS	BIOSENSOR ID	MONITORING	ALERT TIME	ALERTS	STATUS
PATAGJU0	Jessica Velasquez	LOC1	525 KW825	✓	Jan 4, 2024 / 2:02	Body Temp Unavailable	ACKNOWLEDGE

Figure 23 - Technical Alerts Screen

## 8.4.3 Viewing and acknowledging manual alerts

1. From the individual patient zoom view → **ALERTS** → **EVENT LIST** → Enter the **SYMPTOMS/ACTIVITY/NOTE**.



## 8.4.4 Forwarding alerts

Details of a patient alert can be forwarded to members of the clinical team for review.

1. From the **Clinical Alerts** window → Select  → **Forward Alert** → **Select Role (Supervisory Clinician/Clinician/ Physician)** → **Select User** → **Select Alert Type** → **SEND**.

## 8.4.5 Configuring clinical alerts

Default settings for clinical alerts are pre-set for each vital sign measurement. If required, clinical alert settings can be configured for an individual patient, patient group or for all patients in a clinical facility. Alert configurations include setting vital sign thresholds, selecting the duration of the vital signs falling outside the given parameter before raising an alert and prioritizing the alerts listed.

### Individual patient

1. From the **Monitoring Dashboard** → patient zoom view → **ALERTS** → **CLINICAL**.
2. To configure threshold and delay time, select  → enter the values →  → **SAVE**.
3. To configure priority, select  → choose the priority →  → **SAVE**.
4. To enable/disable alerts →  . For more information, see "Configuring technical alerts " on page 48.

### Group

1. Select **Settings**, open **Default Alert Configuration** window.
2. To configure threshold and delay time, select  → Enter the values →  → **SAVE**.
3. To configure priority, select  → choose the priority →  → **SAVE**.



#### Tip

Only the SC can configure clinical alerts for patient groups.

### Clinical facility

1. Select **Settings**, open **Default Alert Configuration** window.
2. To configure threshold and delay time, select  → Enter the values →  → **SAVE**.
3. To configure priority, select  → choose the priority →  → **SAVE**.

**Tip**

Only the CFA can configure clinical alerts for clinical facility.

#### 8.4.6 Configuring technical alerts

Technical alerts relate to the Biosensor being unable to capture signals from the patient or transmit vital sign data to the Web UI Application. Technical alert settings can be configured for an individual patient, patient group or for all patients in a clinical facility. For group and clinical facility settings, technical alert configurations include setting the alert frequency and selecting the delay time or duration before an alert is raised.

Refer to [Alerts.htm](#) for further information.

**Individual patient**

1. From the **Monitoring Dashboard** → patient zoom view → **ALERTS** → **TECHNICAL**.
2. View technical alerts.
3. To enable/disable alerts →

**Group**

1. From **Settings** → **Default Alert Configuration** window → **TECHNICAL ALERTS**.
2. To configure **ALERT FREQUENCY/DELAY TIME** → → Enter values → → **SAVE**.

**Tip**

Only the SC can configure technical alerts for patient groups.

**Clinical facility**

1. From **Settings** → **Default Alert Configuration** window → **TECHNICAL ALERTS**.
2. To configure **ALERT FREQUENCY/DELAY TIME** → → enter the values → → **SAVE**.

**Tip**

Only the CFA can configure technical alerts for clinical facility.

#### 8.4.7 Configuring alert destination

Clinical and technical alerts can be sent via various communication tools (SMS/WhatsApp/Email) to individual users.



### Individual patient

1. From the Monitoring Dashboard → patient zoom view → **ALERTS** → **DESTINATIONS**.

### Group

1. From **Settings** → **Default Alert Configuration** window → **ALERT DESTINATION**.
2. Enable communication tool → select user → select → **SAVE**.



#### Tip

Only the SC can configure alert destination for patient groups.

### Clinical facility

1. From **Settings** → **Default Alert Configuration** window → **ALERT DESTINATION**.
2. Enable communication tool → select user → → **SAVE**.



#### Tip

Only the CFA can configure alert destination for clinical facility.

## 8.5 Network and facility settings (CFA only)



#### Tip

CFA can select **RESET TO FACTORY DEFAULT** in the **Default Alert Configuration** and **Miscellaneous** windows.

### 8.5.1 Network Reconfiguration

The CFA can reconfigure network settings for clinical facility.

1. Select **Settings**, open **Miscellaneous** window, select **NETWORK RECONFIGURATION**.
2. Enable/Disable Biosensor wireless network configuration → **SAVE**.
3. To change **RELAY PASSWORD/HOSPITAL SSID/HOSPITAL PASSWORD** → → Enter the text → → **SAVE**.



## 8.5.2 Facility settings

The CFA can configure various other settings in the Web UI Application which include Enabling/Disabling auto generation of Patient ID/MRN, allowing SC/Clinician access to select Service Provider Referral Physician during patient admission, mandatory note for parameter acknowledgment, mandatory note on discharge, Display Pulse Rate in Patient Zoom View, select Patient Identification (local terminology i.e. MRN or PID), enter facility name, upload a file for co-branding logo and patient barcode parsing.

1. Select **Settings**, open the **Miscellaneous** window, select **OTHER SETTINGS**.
2. To enable/disable **Auto generation of Patient ID / MRN**, select from the dropdown → **SAVE**.
3. To enable/disable **Access to Service Provider Physician**, select from the dropdown → **SAVE**.
4. To enter **Facility Name**, select  → Enter the text →  → **SAVE**.
5. To choose **Co-branding Logo**, select  → choose the image file → **SAVE**.
6. To choose **Patient Barcode Parsing**, select  → choose the image file → **SAVE**.
7. To select **Patient Identification**, select from the dropdown menu → **SAVE**.
8. To select **Mandatory Note for parameter acknowledgement**, select from the dropdown menu → **SAVE**.
9. To select **Mandatory Note for Discharge**, select from the drop-down menu → **SAVE**.
10. To select **Display Pulse Rate in Patient Zoom View**, select from the drop-down menu → **SAVE**.
11. To enable/disable **Access of General Clinician to EWS Module**, select from the dropdown → **SAVE**.

## 8.5.3 Configuring ECG Settings

1. From the **Settings** → **Miscellaneous** window → **ECG SETTINGS** → Select/ Edit diagnostic/ monitoring → select/ edit sampling rate → **SAVE**.



## 9 Specifications

### 9.1 LifeSignals 1AX Multiparameter Remote Monitoring System

Table 3 - Technical Specification

Physical (Biosensor)	
Dimensions	105 mm x 94 mm x 12 mm
Weight	28 g
Status LED Indicators	Amber, Red and Green
Patient Event Logging Button	Yes
Water ingress protection	IP24
Color	White
Specifications (Biosensor)	
Battery type	Primary Lithium Manganese dioxide (Li-MnO <sub>2</sub> )
Battery Life	120 hours (under continuous transmission under normal wireless environment)
Wear Life	120 hours (5 days)
Defib Protection	Yes
Applied Part Classification	Defibrillation-proof type CF applied part
Operations	Continuous
HF Surgical Equipment Compatibility	Yes
Intended environment	Home, Clinical and Non-Clinical facilities
Intended Population	18 years or older
MRI safe	No
Single Use / Disposable	Yes
ECG Performance and Specifications	
ECG number of channels	Two
ECG sampling rate	244.14 and 976.56 samples per second (sps)
Frequency response	0.2 Hz to 40 Hz and 0.05 Hz to 150 Hz



<b>Lead off detection</b>	Yes
<b>Common Mode rejection ratio</b>	> 90 dB
<b>Input Impedance</b>	> 10 Mega ohms at 10 Hz
<b>ADC Resolution</b>	16 bits
<b>ECG Electrode</b>	Hydrogel
<b>Heart Rate</b>	
<b>Heart Rate range</b>	30 - 250 bpm
<b>Heart Rate accuracy (Stationary &amp; Ambulatory)</b>	±3 bpm or ±10% whichever is greater
<b>Heart Rate resolution</b>	1 bpm
<b>Heart Rate Averaging Method</b>	Heart rate is computed by averaging the 8 most recent R-R intervals
<b>Time to Alarm for 206 BPM / 1mVpv (Ref: IEC 60601-2-27 : B1 waveform 201.7.9.2.9.101 - b6)</b>	Gain 0.5 (0.5 mV): 34 seconds Gain 1.0 (1.0 mV): 21 seconds Gain 2.0 (2.0 mV): 17 seconds
<b>Time to Alarm for 195 BPM / 1mVpv (Ref: IEC 60601-2-27 : B2 waveform 201.7.9.2.9.101 - b6)</b>	Gain 0.5 (0.5 mV): 17 seconds Gain 1.0 (1.0 mV): 17 seconds Gain 2.0 (2.0 mV): 15 seconds
<b>Response Time of Heart Rate Meter to Change in Heart Rate</b>	HR change from 80 to 120 bpm: Average 15 seconds HR change from 80 to 40 bpm: Average 19 seconds
<b>Heart Rate Meter Accuracy and Response to Irregular Rhythm</b>	Ref: IEC 60601-2-27 : A1 waveform : 80 bpm Ref: IEC 60601-2-27 : A2 waveform : 60 bpm Ref: IEC 60601-2-27 : A3 waveform : 120 bpm Ref: IEC 60601-2-27 : A2 waveform : 90 bpm
<b>Update period</b>	Every beat
<b>Heart Rate Method</b>	Modified Pan-Tompkins
<b>Tall T-wave Rejection Capability</b>	1.2 mV
<b>Respiration Rate **</b>	
<b>Measurement Range</b>	5 - 60 breaths per minute
<b>Measurement Accuracy</b>	9-30 Breaths per Minute with a mean absolute error of less than 3 Breaths per Minute, validated by clinical studies
	6-60 Breaths per Minute with a mean absolute error of less than 1 Breaths per Minute, validated by simulation studies
<b>Resolution</b>	1 breath per minute



<b>Respiration rate algorithm</b>	Trans-thoracic Impedance (TTI), Accelerometer and ECG Derived Respiration (EDR).
<b>TTI injection signal frequency</b>	10 kHz
<b>TTI Impedance variation range</b>	1 to 5 Ω
<b>TTI Base Impedance</b>	200 to 2500 Ω
<b>Update period</b>	4 sec
<b>Maximum Latency</b>	20 sec
<b>EDR - ECG derived respiration</b>	R-S amplitude
<b>Skin Temperature</b>	
<b>Measurement Range</b>	29°C to 43 °C
<b>Measurement Accuracy (laboratory)</b>	± 0.2°C
<b>Resolution</b>	0.1°C
<b>Sensor Type</b>	Thermistor
<b>Measurement Site</b>	Skin (chest)
<b>Update Frequency</b>	1 Hz
<b>Accelerometer</b>	
<b>Accelerometer Sensor</b>	3-Axis (digital)
<b>Sampling Frequency</b>	25 Hz
<b>Dynamic Range</b>	± 2 g
<b>Resolution</b>	16 bits
<b>Posture</b>	Lying, Upright, Inclined
<b>Wireless and Security</b>	
<b>Frequency Band (802.11b)</b>	2.400-2.4835 GHz
<b>Bandwidth</b>	20 MHz (WLAN)
<b>Transmit Power</b>	0 dBm
<b>Modulation</b>	Complementary Code Keying (CCK) and Direct Sequence Spread Spectrum (DSSS)
<b>Wireless Security</b>	WPA2-PSK / CCMP
<b>Data Rate</b>	1, 2, 5.5 and 11 Mbps
<b>Wireless Range ****</b>	>5meters (line of sight)**
<b>Environmental</b>	



<b>Operational temperature</b>	+0°C to +45°C (32°F to 113°F)
<b>Operational relative humidity</b>	10 % to 90 % (non-condensing)
<b>Operational altitude</b>	up to 3000 m (10000 ft)
<b>Storage temperature (&lt; 30 days)</b>	+0°C to +45°C (32 °F to 113°F)
<b>Storage temperature (≥ 30 days)</b>	+10°C to +27°C (50°F to 81°F)
<b>Transportation temperature (≤ 10 days)</b>	-5°C to +50°C (23°F to 122 °F)
<b>Storage relative humidity</b>	5% to 95% (non-condensing)
<b>Storage pressure</b>	700 hPa to 1060 hPa
<b>Shelf life</b>	13 months

**Notice**

\*\*\*\* QoS verified for 5 meters range in bench setup.

Web UI Application software user interface (zoom view) designed for the ECG display of fixed gain of 10 mm/mV and sweep speed of 25 mm/s. However, Web UI Application is a browser-based application, the height in mm could vary based on the resolution and size of the display used. Hence, the horizontal gridlines (thinner line with 0.1 mV and thicker line with 0.5 mV resolutions) are provided for measuring the amplitude. Similarly, the width in mm could vary based on the resolution and size of the display used. Hence, the vertical gridlines (thinner line with 0.04 ms and thicker line with 0.2 ms resolutions) are provided for reference.

**Notice**

- Biosensor has an automatic scan feature when the wireless link fails for a channel. This feature finds best channel from the available 11 channels in 2.4GHz band and reconnects to it
- 11b technology with higher adjacent channel rejection and spread spectrum technique is being used for connectivity in hospital use cases with higher deployment density. The throughput required per patch is just 30kbps which is much lower than 5 Mbps throughput of 11b(0,6%). Therefore, the waveform breakage is the least encountered.
- Tx power, DTIM and Beacon interval are set optimally for concurrent monitoring of 100s of patients in a hospital. Smart rate control algorithms in biosensor can find optimum link rate to minimize packetloss and maximize capacity.
- Distance between the biosensor and the relay (Wi-Fi AP for MPR or Relay Application ) to be maintained within 5m for eliminating waveform breaks.
- Keep the BLE relay within 5m from the Biosensor/patient in home usecase. In case of breaks reported by monitoring health care professional, keep the relay close to the body but not right above the biosensor.
- Technical alerts are sent over SMS, WhatsApp and email when the biosensor is disconnected to alert the monitoring healthcare professional. It is also displayed on the dashboard against each biosensor.

**Notice**

When 5 minutes has elapsed from the latest respiration rate, SpO<sub>2</sub>, pulse rate or BP measurements, the respective numeric value digits turn gray (tile and zoom views).

When 15 minutes has elapsed from the latest Respiration Rate (RR) measurement, the gray numeric value digits are replaced by a dashed line.

When 60 minutes has elapsed from the latest Blood Pressure (BP), the gray numeric value digits are replaced by a dashed line.

When 30 minutes has elapsed from the latest SpO<sub>2</sub>, the gray numeric value digits are replaced by a dashed line.



## 9.2 Alerts

**Notice**

The Alert messages outlined in the table below will be displayed in the tile and zoom (hybrid) views. When a parameter alert is triggered, the numeric measurement in alert will always change to red (irrespective of priority).

**Table 4 - Parameter Alerts - Alarm Messages displayed on the Web UI Application**

Alert Message	From	Condition
Diastolic BP High (Based on 3rd party device data)	BP	Diastolic BP value has exceeded the high alarm limit.
Diastolic BP Low (Based on 3rd party device data)	BP	Diastolic BP value has fallen below the low alarm limit.
HR High	ECG	Heart Rate value has exceeded the high alarm limit.
HR Low	ECG	Heart Rate value has fallen below the low alarm limit.
Mean BP High (Based on 3rd party device data)	BP	Mean BP value has exceeded the high alarm limit.
Mean BP Low (Based on 3rd party device data)	BP	Mean BP value has fallen below the low alarm limit.
Pulse Rate High (Based on 3rd party device data)	SpO <sub>2</sub>	SpO <sub>2</sub> Pulse Rate value has exceeded the high alarm limit.
Pulse Rate Low (Based on 3rd party device data)	SpO <sub>2</sub>	SpO <sub>2</sub> Pulse Rate value has fallen below the low alarm limit.
RR High	Resp.	Respiration Rate value has exceeded the high alarm limit.
RR Low	Resp.	Respiration Rate value has fallen below the low alarm limit.
Same lying Posture (Bed Sore)	Posture	Lying Left/Right/Supine Posture value has exceeded the alarm limit.
Skin Temp High	Skin Temp.	Skin Temperature value has exceeded the high alarm limit.
Skin Temp Low	Skin Temp.	Skin Temperature value has fallen below the low alarm limit.
SpO <sub>2</sub> % High (Based on 3rd party device data)	SpO <sub>2</sub>	Arterial oxygen saturation has exceeded the high alarm limit.



SpO <sub>2</sub> % Low (Based on 3rd party device data)	SpO <sub>2</sub>	Arterial oxygen saturation has fallen below the low alarm limit.
Systolic BP High (Based on 3rd party device data)	BP	Systolic BP value has exceeded the high alarm limit.
Systolic BP Low (Based on 3rd party device data)	BP	The Systolic BP value has fallen below the low alarm limit.

**Notice**

The Alert messages outlined in the table below will be sent via SMS/WhatsApp/Email to the configured users. Clinical personnel or caregiver shall make sure their mobile phone or computer is configured for appropriate notification (audible) upon receipt of the alert message.

**Table 5 - Parameter Alerts - via SMS/WhatsApp/Email**

Parameter Alert	Alert Message (SMS/WhatsApp/Email)
Diastolic BP High (Based on 3rd party device data)	(Priority) Priority Alert; Diastolic BP high in (ward x) @13:00 Apr 23.
Diastolic BP Low (Based on 3rd party device data)	(Priority) Priority Alert; Diastolic BP Low in (ward x) @13:00 Apr 23.
HR High	(Priority) Priority Alert; Heart Rate High in (ward x) @13:00 Apr 23.
HR Low	(Priority) Priority Alert; Heart Rate Low in (ward x) @13:00 Apr 23.
Mean BP High (Based on 3rd party device data)	(Priority) Priority Alert; Diastolic BP high in (ward x) @13:00 Apr 23.
Mean BP Low (Based on 3rd party device data)	(Priority) Priority Alert; Diastolic BP Low in (ward x) @13:00 Apr 23.
Pulse Rate High (Based on 3rd party device data)	(Priority) Priority Alert; Pulse Rate High in (ward x) @13:00 Apr 23.
Pulse Rate Low (Based on 3 <sup>rd</sup> party device data)	(Priority) Priority Alert; Pulse Rate Low in (ward x) @13:00 Apr 23.
Same Posture	(Priority) Priority Alert; Same Posture (Bed Sore) in (ward x) @13:00 Apr 23
Skin Temp High	(Priority) Priority Alert; Skin Temperature High in (ward x) @13:00 Apr 23.
Skin Temp Low	(Priority) Priority Alert; Skin Temperature Low in (ward x) @13:00 Apr 23.



SpO <sub>2</sub> % High (Based on 3 <sup>rd</sup> party device data)	(Priority) Priority Alert; SpO <sub>2</sub> % High in (ward x) @13:00 Apr 23.
SpO <sub>2</sub> % Low (Based on 3 <sup>rd</sup> party device data)	(Priority) Priority Alert; SpO <sub>2</sub> % Low in (ward x) @13:00 Apr 23.
Systolic BP High (Based on 3 <sup>rd</sup> party device data)	(Priority) Priority Alert; Systolic BP High in (ward x) @13:00 Apr 23.
Systolic BP Low (Based on 3 <sup>rd</sup> party device data)	(Priority) Priority Alert; System BP Low in (ward x) @13:00 Apr 23.

Table 6 - Technical Alerts - Alert Message displayed on the Web UI Application

Alert Mes- sage	From	Resolution
Battery Low	Battery	When the "Battery Low" alert message occurs, initiate "Stop Monitoring". On completion of the Stop Monitoring procedure, replace with new Biosensor.
Biosensor Dis- connected	Biosensor	Biosensor has lost connection with the Patient Relay device or Wireless Access Point. Request patient stays within 5 meters of Patient Relay device or Wireless Access Point
Invalid HR	Heart Rate	System is unable to calculate Heart Rate. This may be due to motion artefact or outside the measurement limits. The HR is displayed as " - - ". Make sure the Biosensor is fully adherent to the patient's skin.
Invalid RR	Respiration	System is unable to calculate Respiration Rate. This may be due to motion artefact.
ECG Lead Off	ECG	Biosensor is not fully adherent to the patient's skin, press the Biosensor for 2 min. During ECG Lead off, the HR is displayed as " - - "
Relay Disconnected (Relay Application)	Relay	Relay has lost connection with Central Server. Check your mobile phone battery charge or network connectivity.
Relay Disconnected (MPR)	Relay	Relay has lost connection with Central Server. Check for power failure and network connectivity.
Relay Dis- connected	Relay	The relay bridge has lost connection with the Cloud MPR. Check the device status and network connectivity for troubleshooting.

**Table 7 - Technical Alerts - Alert Messages via SMS/WhatsApp/Email**

Parameter Alert	Alert Message (SMS/WhatsApp/Email)
Battery Low	Low Battery Alert for Biosensor (Biosensor ID) @13:00 Apr 23. Replace the Biosensor within XX hours.
Biosensor Disconnected (to MPR)	The Biosensor has lost connection with the Wireless Access Point in (ward x/bed x) @13:00 Apr 23. Hours.
Biosensor Disconnected (to Relay Application)	The Biosensor has lost connection with the Patient Relay device (Relay ID) @13:00 Apr 23.
Biosensor Disconnected (to Relay Bridge)	The Biosensor has lost connection with the Wireless Access Point @13:00 Apr 23. Hours.
ECG Lead Off	ECG Lead Off detected for the Biosensor (Biosensor ID) @13:00 Apr 23.
Relay Disconnected (Relay Application, or MPR, or Relay Bridge)	Relay (Relay ID) has lost connection with the Central Server @13:00 Apr 23.

**Notice**

Alert condition delay refers to the total time from the occurrence of triggering event (physiological value exceeding the set limits or cardiac standstill) detected in the Biosensor to the generation of the alert signal in the central server. User configurable independent alert condition delay for each parameter and frequency of alert is based on acknowledgment and priority of the alert. The delivery time of alert to the Clinician/Caregiver mobile or computer is dependent on the internet/mobile network connectivity.

**Table 8 - Clinical Alert Generation Delay Time - Inherent**

Parameters	Minimum* (seconds)	Maximum (seconds)
Heart Rate (Low or High)	5	11
Respiration Rate (Low or High)	30	60
Pulse Rate (Low or High)	12	24
Skin Temperature (Low or High)	300	480

**Table 9 - Clinical Alert Condition Delay Time - User Selectable**

Parameters	Default (seconds)	Minimum <sup>1</sup> (seconds)	Maximum (seconds)
Heart Rate (Low or High)	5	5	300
Respiration Rate (Low or High)	60	30	300
Skin Temperature (Low or High)	120	20	300
Cardiac Standstill	5	5	300
Posture	2 hours	1 hour	168 hours
Systolic	NA	NA	NA
Diastolic	NA	NA	NA

<sup>1</sup>Excludes the inherent delay in alert generation as per Table 9: Clinical Alert Generation Delay Time - Inherent.

**Table 10 - Technical Alert Condition Delay Time - User Selectable**

Parameters	Default (seconds)	Minimum* (seconds)	Maximum (seconds)
ECG Lead-off	5	5	300
Low Battery / Replace Biosensor	120	15	300
Biosensor communication disconnection	15	15	300
Relay communication disconnection	15	15	300
Invalid Heart Rate	5	5	300
Invalid Respiration Rate	15	15	300

**Table 11 - Parameter Alert Frequency - User Selectable**

Priority	Type	Default	Minimum	Maximum	Steps
High (Time)	Un-Ack	5 min	5 mins	12 hours	5 min (till 60 min) & after that 30 min
	Ack	15 min			
Medium (Time)	Un-Ack	10 min			
	Ack	30 min			
Low (Time)	Un-Ack	15 min			
	Ack	60 min			
High (%)	Un-Ack	5%	3%	100%	1%
	Ack	10%			
Medium (%)	Un-Ack	10%			
	Ack	15%			
Low (%)	Un-Ack	15%			
	Ack	20%			

**Table 12 - Technical Alert Frequency - User Selectable**

<b>Alert Message</b>	<b>Type</b>	<b>Default status</b>	<b>Default</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Steps</b>
ECG Lead-off	Un-Ack	ON	5 min	5 mins	12 hours	5 min (till 60 min) & after that 30 min
	Ack		15 min			
Biosensor wire-less disconnection	Un-Ack	ON	5 min			
	Ack		30 min			
Relay communication disconnection	Un-Ack	ON	5 min			
	Ack		30 min			
Low Battery / Replace Biosensor	Un-Ack	ON	30 min			
	Ack		12 hours			
Invalid HR / RR	Un-Ack	OFF	5 min			
	Ack		15 min			

**Notice**

Alert limits must be set based on the clinical condition of the patient. Setting the alert threshold limits to extreme values can render the alert system useless.

There is no automatic alert threshold limit setting available. The alert generation is based on the operator selected value or the factory configured pre-set (default) values.

**Table 13 - Alert Threshold allowed limits**

Parameters		Default Priority	Default	Minimum	Maximum
Heart Rate	High (BPM)	MEDIUM	120	60	250
	Low (BPM)		40	30	160
Respiration Rate	High (BrPM)	LOW	30	10	60
	Low (BrPM)		8	6	55
SpO <sub>2</sub>	High (%)	MEDIUM	OFF	95	100
	Low (%)		90	70	95
Pulse Rate	High (/min)	LOW	120	60	250
	Low (/min)		40	30	120
Skin Temperature	High (°C)	LOW	38.0	20.0	43.0
	Low (°C)		31.0	15.0	33.0
Systolic Pressure	High (mmHg)	LOW	160	75	240
	Low (mmHg)		90	35	150
Diastolic Pressure	High (mmHg)	LOW	90	50	180
	Low (mmHg)		50	15	50
Posture		LOW	Lying down		



# 10 Regulatory

## 10.1 Standards used in design, development, labelling, and testing

Table 14 - Standards used in design, development, labelling, and testing

Description
ANSI AAMI ES 60601-1:2005 (R) (Cons. Text) [Incl. AMD2:2021] /2012, EN 60601-1 2006 /A1:2013, IEC 60601-1 :2005 /A1 2012 +AMD2:2020, IS 13450: Part 1: 2018
ANSI AAMI IEC 60601-1-2: 2014, EN 60601-1-2: 2015, IEC 60601-1-2: 2014+AMD1:2020, IS 13450: Part 1: SEC 2:2018
ANSI AAMI HA 60601-1-11:2015, EN 60601-1- 11:2010, IEC 6061-1-11:2015+AMD1:2020, IS 13450: Part 1: SEC 11 :2020
IEC 60601-1-6:2013 (ed 3.1) +AMD2:2020, EN 60601-1-6: 2010 or ANSI AAMI IEC 62366-1:2015+AMD1:2020, IEC 62366:2008, IEC 62366- 1:2015+AMD1:2020, IS 13450: Part 1: Sec 6: 2020
IEC 60601-1-8:2006+AMD2020; BS EN 60601-1- 8:2007+ A2:2021
IEC 60601-1-9:2020; BS EN 60601-1- 9:2008+A2:2020
IEC 60601-2-49; IS 13450-2-49
ANSI AAMI IEC 60601-2-47:2012 (R2016), EN 60601-2-47:2001, IEC 60601-2-47 :2012, IS 13450: Part 2: Sec 47: 2018
ANSI AAMI ISO 60601-2-25:2011(R2016), IEC 60601-2-25: 2011, EN 60601-2-25:1995/A1:1999, IS 13450: Part 2: Sec 25: 2018
ANSI/AAMI/IEC 60601-2-27:2011/(R)2016, IEC 60601-2-27: 2011, IS 13450: Part 2: Sec 27: 2018
ISO 80601-2-61:2017; EN ISO 80601-2-61:2019; IS/ISO 80601: Part 2: Sec 61: 2011
ISO 80601-2-56:2017; IS/ISO 80601-2-56: 2017
IEEE ISO 11073-10404, 10406, 10408, 10441, 40101, 40102
ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2021
AAMI ANSI EC12 2000 (R) / 2012
FCC CFR47 Part 15 subpart C
ETSI EN 300 328 V2.2.2
ETSI EN 301 489-17 V2.2.3
IEC 62304:2015



ANSI AAMI ISO 14971:2019 / EN ISO 14971:2019/A11:2021
ANSI C63.27: 2017 American National standard for Evaluation of wireless coexistence
IEC 60086-4:2019 Primary batteries - Part 4: Safety of lithium batteries
ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 15223-1: 2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ASTM E1112-00: Electronic Thermometer - Intermittent - Patient temperature
IEC 82304-1 :2016 Health Software - Product requirements for Safety
MIL-STD-810H-CHG-1 (Temperature & Humidity Cycling, Thermal Shock & Vibration)
ASTM F2761-09 Essential Safety Requirements For Equipment Comprising The Patient-Centric Integrated Clinical Environment (ICE) - Part 1: General Requirements And Conceptual Model
ANSI/CAN/UL 2900-1:2020
ANSI/CAN/UL 2900-2-1:2020
IEC 80001-1:2021; BS EN IEC 80001-1:2021; ANSI/AAMI/IEC 80001-1:2010
IEC TR 80001-2-2:2012; ANSI/AAMI/IEC TIR80001-2-2:2012
IEC TR 80001-2-5:2014; ANSI/AAMI/IEC TIR80001-2-5:2014
ISO 20417:2021; EN ISO 20417:2021
Restriction of Hazardous Substances Directive 2011/65/EU AMD 2015/863
Registration, Evaluation, Authorization and Restriction of Chemicals

## 10.2 EMC compliance and warning statement

IEC 60601-1-2: 2014

LifeSignals1AX Wearable Biosensor has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules and with the limits of the standard for medical devices, ANSI/AAMI/IEC 60601-1-2:2014 and ANSI/AAMI/IEC 60601-2-47:2012 202.6.1.1 & 202.6.2.3 suitable for use in all environment including domestic. The unit also complies with the requirements of EN 60601-1-2:2015, providing the presumption of compliance to the European Union's Medical Device Directive 2007/42/EC. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates and uses radio-frequency energy for its functions. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to LifeSignals 1AX Wearable Biosensor. Otherwise, it could result in degradation in the performance of the equipment.



### FCC Statement (FCC ID: 2AHV9-LP1550)

This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

- This device may not cause harmful interference.
- This device must accept any interference received including interference that may cause undesired operation of this device.

Any changes or modifications not expressly approved by the party responsible for Compliance could void the user's authority to operate the equipment. Biosensor radiator (Antenna) is 12.8 mm away from the body and hence, exempted from SAR measurement. Affix the Biosensor on the body as instructed in this manual for maintaining the separation distance.

#### Notice

 All recommended 3<sup>rd</sup> party hardware equipment (e.g. for LifeSignals Relay Application) in the system complies with applicable CAN, IEC or ISO standard.

#### Caution

 Any 3<sup>rd</sup> party hardware equipment in the system (e.g. routers, access points, network switches, Multi-Patient Relays) must comply with applicable CAN, IEC or ISO standard.

## 10.3 Guidance and manufacturer's declaration - electromagnetic emissions

Table 15 - Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11 / EN5501	Group 1	LifeSignals Biosensor uses RF energy only for its internal functions. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.



RF emissions CISPR 11 /EN5501	Class B	LifeSignals Biosensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions EN 61000-3-3	Not Applicable	

## 10.4 Guidance and manufacturer's declaration - electromagnetic immunity

Table 16 - Guidance and manufacturer's declaration - electromagnetic immunity

LifeSignals Biosensor is tested for conformance to meet the following intended for use in the electromagnetic environment specified below. The customer or the user of the Biosensor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The floor should be made of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative humidity should be at least 30%.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical domestic environment.
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM, 1 KHz	10 V/m 80 MHz to 2.7 GHz 80% AM, 1 KHz	Home Healthcare environment.

The Biosensor is also tested for immunity to proximity to wireless communication equipment as per Table 9 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-3.



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

Rated maximum output power of transmitter (Watts)	Separation distance according to the frequency of transmitter (Meters)		
	150 kHz to 80 MHz $d = 3.5/V1 * \sqrt{P}$	80 MHz to 800 MHz $d = 3.5/E1 * \sqrt{P}$	800 MHz to 2.7 GHz $d = 7/E1 * \sqrt{P}$
	10V/m	10V/m	10V/m
0.01	0.04	0.04	0.08
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.22
100	3.50	3.50	7.00

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

NOTE 1: At 80 Hz and 800 MHz the separation distance for the frequency range applies.  
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflections from structures, objects and people.

## 10.5 EMC guidance

In accordance with Clause 4.3 of IEC 60601-1, the Essential Performance of LifeSignals 1AX Wireless Patient Monitoring System is:

- Data loss between the Biosensor and the Relay Application shall be less than 0.035%.
- There shall not be noise exceeding 50 uV p-v on ECG signal over any 10 second period continuously

**Caution**

RF emitting devices such as diathermy, electrocautery, radio frequency identification (RFID), security systems (e.g., electromagnetic anti-theft systems, and metal detectors) may affect essential performance. These sources of electromagnetic energy should be avoided when using the Biosensor. In case of potential exposure to such equipment, the user is recommended to correct the interference by one or more of the following measures:

- Reorient the Biosensor away from the equipment (behind the patient body).
- Increase the separation between the Biosensor and the equipment.

## 10.6 Manufacturer's Notes to the User

In the event of a serious incident involving this device, please notify LifeSignals at [lsupport@lifesignals.com](mailto:lsupport@lifesignals.com). In addition, such incidents must also be reported to the competent authority in your EU member state or country.

## 10.7 Symbols

Table 17 - Symbols

Label	Identification	Description
	Caution or Warning	This symbol instructs the user to consult the instructions for warnings and safety precautions that could not be presented on the device.
	Manufacturer	Legal manufacturer.
	Product Disposal	Dispose the Biosensor as a battery/electronic waste - controlled by the local regulations.
	GUDID (Level 0) and Serial No.	On the PCBA - Level 0 - GUDID in data matrix format and Serial number in human readable format.
	GUDID (Level 0) and Pairing ID	On the Biosensor - Level 0 - GUDID in data matrix format and Pairing ID in human readable format.
	GUDID (Level 1,2 and 3)	Device GUDID (Level 1, 2 & 3) with manufacturing information. - Level 1: Serial No., Level 2 & 3: Lot No.



Label	Identification	Description
	Unique Pairing ID	Unique Pairing ID.
	Catalogue Number	Device Catalogue number / Labeler Product number.
	Quantity	Number of devices in a pouch or in a multi-carton box.
	Prescription only device	To be used under prescription supervision by a medical practitioner.
	Electronic instructions for use	Indicated on the product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed form.
	Consult instructions for use	Refer to the instruction manual.
	Temperature range	Operating, storage and transportation temperature, short and long term, in days: <ul style="list-style-type: none"><li>• P: Duration</li><li>• n: Number</li><li>• D: Calendar days</li></ul>
	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Humidity limitation	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.
	Expiry Date (YYYY-MM-DD)	Use the device in packaged condition before the expiry date.
	Manufacturing date and country of manufacture.	Device manufacturing date and country of manufacture.
	LOT Code	Manufacturing Batch or LOT code.
	Applied part	Defibrillation-proof, Type CF Applied Part.



Label	Identification	Description
	Do not reuse	Do not reuse; single patient use.
IP24	Ingress Protection Rating	Protection against solid objects that are over 12.5 mm (e.g. large tools and hands) and protection against water splashing from any angle.
	Keep dry	Keep away from liquids or water or chemicals.
	Max Stack	Do not stack more than (n) number of boxes. "n" indicates the number of boxes.
FCC ID	Federal Communications Commission	Federal Communications Commission ID.
	MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.
	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD.
	Authorized representative of European Community	Authorized representative of European Community
	Authorized representative of Country	Authorized representative of Country XX - Country code as per ISO 3166-1.
	Importer	Indicates the entity importing the medical device into the locale.
	Distributor	Entity distributing the medical device into the locale.
	Damaged packaging	Do not use, if the package is damaged. The Device must also not be used if the package holding the device is damaged.



## 10.8 Declaration of Conformity

(Issued according to Regulation (EU) 2017/745 (EU MDR) relating to Medical Devices)

<b>Manufacturer</b>	<b>LifeSignals, Inc.</b> 426 S Hillview Drive Milpitas, California 95035 United States of America Tel: +1 510.770.6412 info@lifesignals.com
<b>SRN</b>	US-MF-000033437
<b>EC Representative</b>	<b>Renew Health Limited</b> IDA Business & Technology Park Garrycastle Athlone, N37 F786. Ireland Tel : +353 90.646.5460 lssupport@lifesignals.com
<b>SRN</b>	IE-AR-000013707
<b>Product Name</b>	LifeSignals 1AX Multiparameter Remote Monitoring Platform
<b>Registered Trade Name</b>	LifeSignals, UbiqVue
<b>Model Number &amp; UDI</b>	Refer Annexure to DOC
<b>Product Description</b>	<p>The LifeSignals 1AX Multiparameter Remote Monitoring Platform is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography (2-Channel ECG), heart rate, SpO<sub>2</sub>%, respiration rate, pulse rate, photoplethysmography waveform, skin temperature, body posture, body motion, R-R interval, heart rate variability (HRV) and blood pressure. Data is transmitted wirelessly near real-time from the LifeSignals 1AX Wearable Biosensor, and 3rd party device (for SpO<sub>2</sub>%, PPG, pulse rate and blood pressure) to remote central server for display, storage, and analysis.</p> <p>The LifeSignals 1AX Multiparameter Remote Monitoring Platform is intended for non-critical, adult population.</p> <p>The LifeSignals 1AX Multiparameter Remote Monitoring Platform shall include the ability to notify healthcare professionals through alerts when physiological parameters fall outside the set limits, manual trigger by the patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring at hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which</p>



care is administered by healthcare professionals.

**Note:** Blood Pressure shall be available only with 3rd party BP device. SpO<sub>2</sub>%, PPG and pulse rate are available only with 3rd party SpO<sub>2</sub> device.

<b>Class</b>	Class IIb under EU MDR Annex VIII Rue 10 and Rule 11
<b>Annexure No</b>	Annexure IX, Chapter I and Chapter III
<b>Notifying Body</b>	BSI, Netherlands (notified body No.2797)
<b>MDR Certificate Number</b>	MDR 802405
<b>Applied Regulation/Directive</b>	<ol style="list-style-type: none"><li>1. Regulation (EU) 2017/745 (EU MDR) on medical devices, conformity assessment according to Annexure IX, Chapter I and Chapter III.</li><li>2. RoHS Directive 2011/65/E</li><li>3. Radio Equipment Directive (RED) 2014/53/EU</li></ol>

The company, LifeSignals, Inc., herewith declares that the above- mentioned product meets all applicable provisions of the Regulation (EU) 2017/745 (EU MDR). The product is safe under prescribed and specified conditions of storage and use.

The company has instituted a procedure to continually review the experience gained from devices in the post-production phase and to implement appropriate measures required for improvement as necessary.

If the device is modified or used other than the Intended purpose, this declaration becomes invalid. This EU declaration of conformity is issued under the sole responsibility of the manufacturer..

**Date of Issue:** 23/Jan/2025

**Place of Issue:** Milpitas, CA, US

Saravanan Balasubramanian  
VP - Global Medical Technology and Regulatory Operations and Regulatory Operations



## ANNEX to DOC

No	Name of Medical Device	Part Number	EMDN Code	UDI
1	The LifeSignals 1AX Multiparameter Remote Monitoring Platform consists of the following components:	LX1550	Z12030202	
	LifeSignals 1AX Wearable Biosensor	LP1550	Z1203020280	+B353LP15501/\$\$7BIV0ASLLTTTTBBBBB/16DYYYYMMDD/14DZZZZMMDD
	LifeSignals Single Patient Relay	LA1550-R	Z1203020292	+B353LA1550R1/\$\$7BIV
	LifeSignals Multi-Patient Relay	LA1550-MR	Z1203020292	+B353LA1550MR1/\$\$7BIV
	UbiqVue Relay Bridge	UA2550-RB	Z1203020292	+B353UA2550RB1/\$\$7BIV
	LifeSignals Secure Server Application	LA1550-S	Z1203020292	+B353LA1550S1/\$\$7BIV
	LifeSignals Web UI Application	LA1550-C	Z1203020292	+B353LA1550C1/\$\$7BIV
	UbiqVue Bluetooth Gateway Application	UA2550-BG	Z1203020292	+B353UA2550BG1/\$\$7BIV



# 11 Appendix

## 11.1 Troubleshooting

### 11.1.1 Relay Application

Table 18 - Notifications

Notification	Explanation	Resolution
AUTHENTICATION_FAILED.	Login with incorrect/non-existent user credentials clinical facility.	Enter correct login details.
PATIENT_NOT_FOUND.	Login with incorrect/non-existent user credentials for patient login.	Login with correct user credentials.
OTP_invalid.	Entered OTP is invalid.	Enter the correct OTP.
Connection Unsuccessful.	Biosensor not found.	Ensure Biosensor is turned ON.
PATIENT_ALREADY_DISCHARGED.	Entered MRN/PID of a discharged patient.	Enter or generate new MRN/PID.
ADMISSION_ID_ALREADY_EXISTS.	Entered existing Admission ID.	Enter correct Admission ID.
No internet. Please check your connection.	Internet unavailable on the relay device.	Check with your local internet provider.
Connection lost, check Biosensor LED is ON and move relay(mobile) device closer to Biosensor.	Biosensor is out of 5 meters radius of relay device.	Move the Biosensor closer to the relay device.
Biosensor battery level is low.	Battery <15%.	Consider replacing the Biosensor.
Retrieving Biosensor Information   Transferring to Hospital Network   Was reconfiguration successful?   Are you sure the Biosensor has Transferred?   Transfer in progress.	Sequence of messages which appear following Transfer to Hospital request.	Check whether the Biosensor has transferred.



Lead OFF. Check Biosensor adherence to skin and retry.	Biosensor has detached from the skin.	Press the entire Biosensor for two minutes.
Server connection failed.	Server unavailable.	Please contact your service provider.
Unable to transfer Biosensor to hospital network.	Failed the transfer process.	Try to transfer to the hospital network again.
BP device in use. Unassign from previous patient or enter another device ID.	The BP device that is attempting to connect is already linked to another patient.	Remove it from the previous patient profile or use another device.
SPO <sub>2</sub> device in use. Unassign from previous patient or enter another device ID.	The SPO <sub>2</sub> device that is attempting to connect is already linked to another patient.	Remove it from the previous patient profile or use another device.
Finger Out!	The finger is removed from the SPO <sub>2</sub> probes.	When recording the measurements, ensure the finger is properly positioned.
Device not found.	Third-Party device not found or device is turned off.	Turn on the device or move closer to the mobile.
Invalid server ID	When the user tries to login with invalid server id or enters incorrect spelling in the server id. It does not connect to the server.	Enter the correct Server ID.

### 11.1.2 Web UI Application

Table 19 - Notifications

Notification	Explanation	Resolution
Auto Generate Patient ID is Disabled. Please enable the Settings to <b>AutoGenerate the ID</b> .	Autogeneration of new MRN/ID has been disabled by administrator.	Contact CFA.
Biosensor already in use.	The Biosensor is already assigned to some other patient.	Enter the new Biosensor ID.



Device is already in use.	Attempting to assign Third party device which is currently in use by another patient.	Select different device.
Error! Group Name Already Exists.	This group name has been added.	Add new group name.
**Error! Logo height exceeds the width.	Height exceeds the width for co-branding logo.	Select image with correct height and width ratio.
**Error! Logo should be at least 48x48 px.	Image too small for co-branding logo.	Select image with minimum 48 x 48 pixels.
**Error! Logo should be within 800x512 px.	Image too large for co-branding logo.	Select image with maximum 800 x 512 pixels.
Error! More than one Biosensor streaming.	Attempting to assign two streaming Biosensors to a single patient.	Assign patient to the correct Biosensor.
Error! Previous Admission is not Discharged.	Attempting to admit existing patient with new admission ID.	Discharge patient, then admit the patient.
**File size exceeds maximum size limit of 2 MB.	File size too large for co-branding logo.	Select file size <2 MB.
**Invalid File Format. Please select an image file.	Selected invalid file format for co-branding logo	Select image file with correct format e.g. gif, jpeg, png, svg, webp.
Operation Failed.	Attempt to reset/save password from profile page unsuccessful.	Try to reset/save password again. If unsuccessful, contact the administrator.
Patient Already Discharged. Replace Patient ID.	Attempting to readmit a patient using previous Patient ID	Enter the new Patient ID for the patient.
Password Reset Failed.	Attempt to reset password unsuccessful	Request password reset again. If unsuccessful, contact the CFA.



## 11 Appendix

Something went wrong. Please try again !	Attempt to relay the Biosensor data via hospital network/mobile relay unsuccessful. (not connecting to access point).	Try to relay the Biosensor data via hospital network/mobile again. If unsuccessful, contact the administrator.
Something went wrong. Please try again !	Attempt to save Event/Note unsuccessful.	Try to save Event/Note again. If unsuccessful, contact the administrator.
USER ALREADY EXISTS WITH THIS EMAIL/PHONE NUMBER!!	This user's email/phone number is already in the system	Enter new email/phone number for the user.



### 11.1.3 Frequently Asked Questions

Wireless Communication Failure Queries	
Why is “ <b>Biosensor Disconnected</b> ” being displayed in the Web UI Application?	<p>This could be attributed to a wireless communication failure between the Biosensor and the access point.</p> <p><b>Reasons:</b></p> <ul style="list-style-type: none"><li>1) Patient walks out of the network area.</li><li>2) Access point gets switched off.</li></ul> <p><b>Effects:</b> Access to real time/streaming data will be discontinued. The data will resume streaming upon reconnection to the network. Ensure that the patient is within 5-meter radius of the Access point. Verify the functionality of the access point.</p> <p><b>Contact Technical Team for further assistance.</b></p>
Why is the LED blinking fast in green?	<p>This could be attributed to a wireless communication failure between the Biosensor and the Access Point.</p> <p><b>Reasons:</b></p> <ul style="list-style-type: none"><li>1) Patient walks out of the network area.</li><li>2) Access point gets switched off.</li></ul> <p><b>Effects:</b> Access to real time/streaming data will be discontinued. The data will resume streaming upon reconnection to the network. Ensure that the patient is within a 5-meter radius of the Access point and the Biosensor - LED is blinking slow (green) (once in every 3 secs). Verify the functionality of the access point.</p> <p><b>Contact technical team for further assistance.</b></p>



Why is "Relay Disconnected" being displayed?	<p>This could be attributed to a wireless/wired network failure between the Relay device and the Central server.</p> <p>&gt; <b>Relay Application</b> - Relay has lost connection with the Central Server. Make sure the mobile phone has enough battery charge and the network/internet connectivity is good. Make sure the Flight mode is OFF. Make sure the App is not stopped forcefully.</p> <p>&gt; <b>Multi Patient Relay(MPR)</b> - The Relay has lost connection with the Central Server. Check for power failure and network/internet connectivity. (Contact Technical Team for assistance).</p> <p>&gt; <b>Relay Bridge</b> -The Relay has lost connection with the Central Server. Check for network/internet connectivity.</p>
If the "Biosensor is disconnected" due to wireless communication error, can we still view the data?	Live data will not be available. However, the missing data will be stored in the central server. The data recorded prior to Biosensor disconnection will be accessible.
If the "Relay is disconnected" due to wireless communication error, can we still view the data in the trend?	The data recorded prior to the relay disconnection will be available in the trend.
What if the Beep sound is heard from the mobile (Relay Application)?	It could be due to the wireless communication failure between the Biosensor and the Relay Application.
What to do when the mobile App (Relay Application) shows "No internet, please check your connection"?	It could be due to mobile coverage issue or wrong setting like Airplane mode ON or inadequate bandwidth.

## 11.2 Document References

1. DHF09-LBL-005 UbiqVue™ HDO Network Configuration Manual.
2. DHF09-LBL-004 UbiqVue™ MPR Installation & Configuration Manual.
3. DHF09-LBL-007 UbiqVue™ Relay Bridge Installation & Configuration Manual.
4. DHF09-LBL-010 UbiqVue™ Central Server Installation & Configuration Manual.
5. DHF09-LBL-008 UbiqVue™ SPR Installation & Configuration Manual.

## 11.3 Third Party Devices

Manufacturer	Name of the Medical Device	Model Number
Omron	BP Monitor	HEM7600T-AP3
Contec	SpO <sub>2</sub> Watch	CMS50F



## 11.4 Cloud Infrastructure

LifeSignals, Inc. uses Amazon Web Services (AWS) for its Central Server and Web UI Application and Infrastructure. LifeSignals AWS Infrastructure primarily uses two EC2 Servers which are in the same availability zone. The LifeSignals' Monitoring team monitors the performance of the Central Server and the Web UI Application 24/7 using New Relic and CloudWatch Alarms for any downtime or service disruptions. In case of any alerts, the team will try to solve the issue as per the Runbook and create Root Cause Analysis.

### Amazon Web Services - Service Level Agreement (SLA)

- **Region-Level SLA**  
For Amazon EC2 with all running instances deployed concurrently across two or more availability zones in the same region (or at least two regions if there is only one availability zone in a given region), AWS will use commercially reasonable efforts to make Amazon EC2 available for each AWS region with a Monthly Uptime Percentage of at least 99.99%.
- **Instance -Level SLA**  
For each individual Amazon EC2 instance (“Single EC2 Instance”), AWS will use commercially reasonable efforts to make the Single EC2 Instance available with an Instance-Level Uptime Percentage of at least 99.5% in each case during any monthly billing cycle (“Instance-Level SLA”).
- **Reference:** <https://aws.amazon.com/compute/sla/>

### Data Retention for Biosensor Data and Clinical Reports

The following standard and customized data retention policies can be implemented provided there is a service agreement in place with the clinical facility for these services.

- **Standard Policy**  
Up to 12 months instant access using a combination of AWS S3 and Glacier services. Up to 6 years six (6) hour delayed retrieval access using AWS Glacier service.
- **Customized Policy**  
Different data retention periods can be provided to meet clinical facility and local regulatory requirements. These extended retention options ensure compliance with jurisdiction-specific mandates and can be customized upon request, leveraging AWS storage solutions.

### Disaster Recovery Plans

- Hourly Backups are taken in the form of AWS AMI.
- In case of AWS availability zone failure, LifeSignals shall launch the EC2 server from the latest AMI in another availability zone and attach Elastic IP to continue the operations. The SLA for this operation is 1-2 hours.
- In case of a regional failure for AWS, LifeSignals shall use an hourly AMI taken from the last region of failure and to be restored on the new EC2 server launched in an another region. The SLA for this operation is 2-3 hours.



## 11 Appendix

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- Note: Availability Zones are distinct locations within an AWS Region that are engineered to be isolated from failures in other availability Zones.

### Impact on AWS Outage

- Central Server and Web UI Application shall be inaccessible during the AWS outage.
- If Regional/Availability zone outage occurs, the users may lose up to one hour of data (i.e. AMI Snapshots are taken on an hourly basis).

For printed copies, contact by mail or phone. (Refer Page ii).