UbiqVue™
by LifeSignals™

UX1550

UbiqVue™ 1AX Wireless Patient Monitoring System

User Manual

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Intended purpose

This manual describes the intended use of the UbiqVue™1AX Wireless 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.

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.

Contact address

Manufacturer

LifeSignals, Inc
426 S Hillview Drive, Milpitas, CA 95035, USA
Support Email: lssupport@lifesignals.com
Customer Service (USA): +1 510.770.6412
Website: www.lifesignals.com
SRN: US-MF-000033437

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Glossary

Term	Definition
Alert	Combination of physiological (clinical) and technical alarm conditions that generate alert notifications.
Biosensor	Single-use medical wearable device that acquires and wirelessly transmits patient's physiological signals to the paired UbiqVue™ Patient Relay App or MPR device.
Biosensor ID	A five character alphanumerical code (unique identifier) printed on the Biosensor and Biosensor packaging.
Central Server	Manages the decryption, uploading and storage of Biosensor data from multiple authenticated relay devices. Allows access to derived parameter and Biosensor data using the UbiqVue™ Active Monitoring Portal.
Clinical Facility	Organization that provides healthcare services and utilizes monitoring service e.g. Hospital or Medical Facility.
Clinical Facility Administrator (CFA)	Multiple functions associated with the overall set up and configuration of Active Monitoring Portal for the clinical facility.
Clinician 	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.)
Physician 	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.
Supervisory Clinician 	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 Active Monitoring Portal.
Administrator (CFA) 	Denotes Administrator (CFA) role - Multiple functions associated with the overall set up and configuration of Active Monitoring Portal. For example, create assign roles (Supervisory Clinician (SC) /Clinician/Physician/Additional Clinical Facility Admin) for new users, reset users password, select patient identification method for the facility (MRN or Patient ID), create location/medical groups, configure alert default for the entire clinical facility.
Edit 	Denotes additional edit functionality for SC / Clinician / Physician roles.

Term	Definition
Referral Physician	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 Active Monitoring Portal.
Monitoring Dashboard	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.
Multi-Patient Relay (MPR)	Multi-Patient Relay network transmits data from multiple Biosensors via hardware devices (e.g. wireless access points, computer) to the UbiqVue™ Central Server.
Single Patient Relay (SPR)	Relay device is used for the transmission of a patient's Biosensor data to the UbiqVue™ Central Server.
Service Provider Administrator (SPA)	The highest level user that manages administration of multiple clinical facilities and hospital groups.
Relay Bridge	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.
BLE Gateway	The Bluetooth Gateway communicates with multiple third-party devices and transfers the data to the Multi- Patient Relay without buffering.
UbiqVue™ Active Monitoring Portal	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.

1 Safety information

1.1 Intended use and indications for use

The UbiqVue™ 1AX Wireless Patient Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals for the continuous collection of physiological data at home and in healthcare settings. This shall include Electrocardiography (2-channel ECG), Heart Rate, Respiration Rate, Skin Temperature and Posture. Data is transmitted wirelessly from the UbiqVue™ 1AX Wearable Biosensor and 3rd party device (for Blood Pressure and SpO_2) to the remote central server for display, storage, and analysis.

The UbiqVue™ 1AX Wireless Patient Monitoring System is intended for non-critical, adult population, who are 18 years of age or older.

The UbiqVue™ 1AX Wireless Patient Monitoring System shall include the ability to notify healthcare professionals when physiological parameters fall outside the set limits and to display multiple patient's physiological data for Remote Active monitoring.

Notice

Regulatory cleared 3rd-party devices(BP/SpO_2) may be integrated to the UbiqVue Active monitoring portal.

1.2 Contraindications

- The Biosensor is not intended for use on critical care patients.
- The Biosensor is not intended for use on patients with any active implantable devices, such as defibrillators or pacemakers.

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 theBiosensor 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.

1.4 Precautions

Caution

- Excessive motion or activity may adversely affect the Biosensor performance and adhesion.
- Press down the Biosensor edges and upper area 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 (< 2 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 Biosesnsor LED flashes fast (green) (two flashes for every second), ensure the patient is within 5 meters radius of the Relay device.
- The Biosensor contains a battery. Dispose theBiosensor in accordance with the local laws, care facility laws or hospital laws for non-hazardous electronic waste.
- DO NOT use any skin barrier agents prior to Biosensor application, as it may cause skin irritation/injury due to a reaction between the barrier agent and the hydrogel electrodes.
- DO NOT immerse the Biosensor in water.
- Keep showers short with the back to the flow of water. Gently pat dry with a towel and minimize activity until the Biosensor is fully dry.
- DO NOT use creams or soap near the Biosensor.
- If the Biosensor becomes soiled with blood, and/or bodily fluids/matter, dispose in accordance with the local laws, care facility laws or hospital laws 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 relaydevice (< 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.
- All hardware equipment, for example relay devices,, routers, computer, switches etc. shall comply with the applicable IEC or ISO standards.
- 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 Single Patient Relay for Unintended activities.

2 UbiqVue™ Product description

2.1 UbiqVue™ 1AX Wireless Patient Monitoring System (UX1550)

The system contains the following components:

1AX Wearable Biosensor (UB1550)	Acquires two channels of ECG signals, TTI respiration signals, skin temperature, posture data and transmits to Single Patient Relay (SPR) or Multi Patient Relay (MPR) device.
Single Patient Relay (SPR) Software (UA2550 R)	A compatible relay device which receives and relays signals from the paired Biosensor to the Central Server for processing.
Multi-Patient Relay (MPR) Software (UA2550-MR)	Installed on compatible computer. Receives and relays signals from multiple Biosensors to the Central Server for further processing.
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 Software is hosted in the cloud.
UbiqVue™ BLE Gateway (UA2550-BG)	The Bluetooth Gateway communicates with multiple third-party devices and transfers the data to the Multi-Patient Relay without buffering.
UbiqVue™ Central Server Software (UA2550-S)	Receives data from multiple Biosensors simultaneously. Derives HR, RR, skin temperature, posture information. Stores data securely for access by Active Monitoring Portal.
Active Monitoring Portal (UA2550-C)	Web-based interface used to access and manage patient physiological and alert data.

2.2 UbiqVue™ 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 Single Patient Relay (SPR) or Multi-Patient Relay (MPR) device or other receiver systems. When the SPR or the MPR devices are available within the

wireless range, acquired data is immediately and continuously transmitted to the SPR or MPR devices.

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

1	Right upper electrode.
2	Left upper electrode.
3	Right lower electrode.
4	Left lower electrode.

Figure 1 - UbiqVue™ 1AX Wearable Biosensor

UB1550

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 UbiqVue™ Single Patient Relay (SPR)

The SPR 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 SPR 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 patient to record activities, symptoms and manual entries (SpO_2, 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 SPR and the central server.
- Stores the data securely when there is any disruption in communication with the central server.

2.4 UbiqVue™ Multi-Patient Relay (MPR) Software

A standard Linux-based computing platform meeting the necessary specifications can be transformed into a Multi-Patient Relay (MPR) device by installing the MPR software. 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 3rd 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

The UbiqVue™ Relay Bridge shall provide communication between Biosensors and Multi-Patient Relay instead of a standard access point, when Multi-Patient Relay Software is hosted in the cloud.

A Relay Bridge application acts as a communication bridge between the Biosensor and the Multi-Patient Relay (deployed on cloud). The Application will run on OpenWrt or Linux based devices and it may help to reduce the infrastructure requirements, facilitating easy deployment and increasing its portability. The Relay Bridge application will support communication modes like Cellular, Wi-Fi and Ethernet.

- Relay Bridge replaces hardware like routers and access points in the biosensor setup, providing a complete MPR solution without additional infrastructure.

- The Relay Bridge hardware boasts router functionalities, including a WAN port, cellular network support, battery backup, and access point capabilities. Additionally, it is equipped with BLE technology to facilitate communication with third-party devices.
- The Relay Bridge application, residing within the hardware, is responsible for receiving data from the biosensor and transmitting it to the cloud MPR.
- Relay Bridge Software will allow the Biosensor to roam between multiple Relay Bridge devices within the facility. (Relay bridges connected to a cloud Multi-Patient Relay Software of a specific facility).
- The Relay Bridge Software can communicate with up to 8 biosensors simultaneously.

2.6 UbiqVue™BLE Gateway

Bluetooth Gateway Software in UbiqVue™ 1AX Wireless Patient Monitoring System when installed in a standard OpenWrt based BLE gateway or BLE supported routers, shall provide communication between the third-party BLE devices (e.g. BP device) and Multi-Patient Relay. The Bluetooth Gateway communicates with multiple third-party devices and transfers the data to the Multi-Patient Relaywithout buffering.

2.7 UbiqVue™ Central Server Software

The UbiqVue™ Central Server Software is installed on a compatible Linux based hardware platform of LifeSignals, Inc. and performs the following functions:

- Authenticates the UbiqVue™ SPR and MPR devices, establishes secure connection with 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 UbiqVue™ Active Monitoring Portal.
- 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 UbiqVue™ Active Monitoring Portal

The UbiqVue™ Active Monitoring Portal 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 UbiqVue™ 1AX Wearable Biosensor

3.1 Patient advice

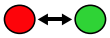
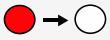
The following guidance should be given to the patient to ensure comfort while wearing the Biosensor and optimal Biosensor performance. The information is also provided in the Patient Information Leaflet found inside individual Biosensor packaging.

- Limit physical activity 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.
- 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 UbiqVue™ Single Patient Relay App.
- 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's - 1AX Wearable Biosensor

Light	Behaviour	Status
	Slow flash	Biosensor connected to the SPR/MPR devices or a monitoring session is in progress.
	Fast flash	Biosensor attempting to connect with SPR / MPR devices.
	Slow flash	Low Battery
	Alternate flashing	Response to SPR - “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.[1]

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 on 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 breast bone.

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

3. Press the Biosensor for 2 minutes.

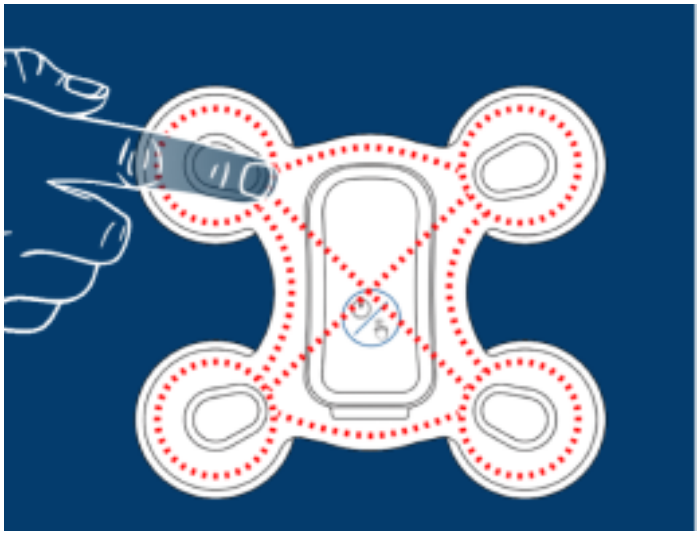


Figure 4 - Red lines indicating to press down on the Biosensor

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.[1]

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 UbiqVue™ Single Patient Relay

The SPR device will have the UbiqVue™ App pre-installed that manages the wireless communication between the Wearable Biosensors and the UbiqVue™ Central Server.

4.1 Authenticating UbiqVue™ 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 SPR devices. Use of incompatible mobile phones may result in degraded performance.

OTP is mandatory to login to the App and also when the App restarts. OTPs are received through email/phone.

1. Open the UbiqVue™ 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 Opening UbiqVue™ App -Relay (mobile) device

1. Open the UbiqVue™ App on the relay (mobile) device.
2. Enter the Clinician login credentials, select **NEXT**.
3. Alternatively, for Patient/Other, enter the patient phone number, select **NEXT**.

Note: Based on login (Patient login or Clinician login) the fields in the UI are displayed.

4.3 Starting a monitoring session - SPR

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 UbiqVue™ Active Monitoring Portal, patient's information will auto-populate in the UbiqVue™ App.

1. Remove the Biosensor from the pouch.
2. Enter the Biosensor ID in the UbiqVue™ 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 SPR.
4. Enter the Patient Info (include mandatory fields) in the UbiqVue™ App, select **ADMIT**.
5. Prepare the patient's skin, select **NEXT**.
6. Follow the UbiqVue™ App instructions to apply the Biosensor, press the entire Biosensor for two minutes, select **NEXT**.
7. Assess 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.

4.4 Transmitting Biosensor data - SPR

1. Select **CONTINUE**.
2. The UbiqVue™ App supports compatible Regulatory cleared SpO_2 / 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 SPR device will make an audible alert.

4.5 Recording symptoms

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

4.6 Recording measurements

1. Press the **RECORD MEASUREMENTS** button on the UbiqVue™ App.
2. Enter the time (24 hr format).
3. Enter the measurements for Blood Pressure and SpO2.
4. Select **CONFIRM**.
5. You can view the measurements in the UbiqVue™Active Monitoring Portal.

4.7 Additional menu features

In the SPR UbiqVue™ 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 **Monitoring Summary** and **BACK** to exit.
Stop Monitoring	The App will attempt to upload data and turn off the Biosensor. This may take a few minutes. When fully stopped, follow *Remove Biosensor* steps.	Select **Stop Monitoring**, then **CONFIRM**. Follow *Remove Biosensor* steps, select **EXIT**.
Add/Change Device(s)	BP and SpO_2 devices can be added/changed to facilitate measurement transmission to the Central Server.	Select **Add / Change Device (s)**. Select *device type*, enter the *Device ID* and select **ADD DEVICE**.
Replace Biosensor	The App will attempt to upload data and turn off the Biosensor.This may take a few minutes. When fully stopped, follow *Remove Biosensor* steps.	Select **Replace Biosensor**. Follow *Remove Biosensor* steps, select **DONE**. A new Biosensor can then be applied.
Identify Biosensor	The monitored Biosensor LED will flash three times.	Select **Identify Biosensor**.

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

5 UbiqVue™ Multi-Patient Relay Software

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

6 UbiqVue™ Relay Bridge

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 UbiqVue™ Active Monitoring Portal

The UbiqVue™ Active Monitoring Portal 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 Active Monitoring Portal 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 Active Monitoring Portal 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.

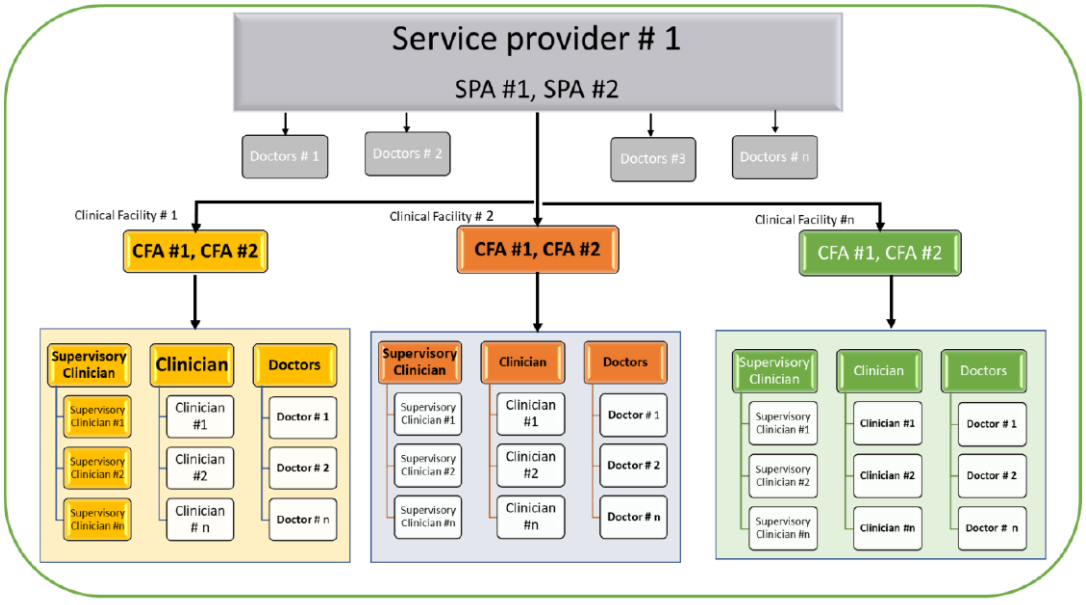


Figure 6 - User Hierarchy

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.

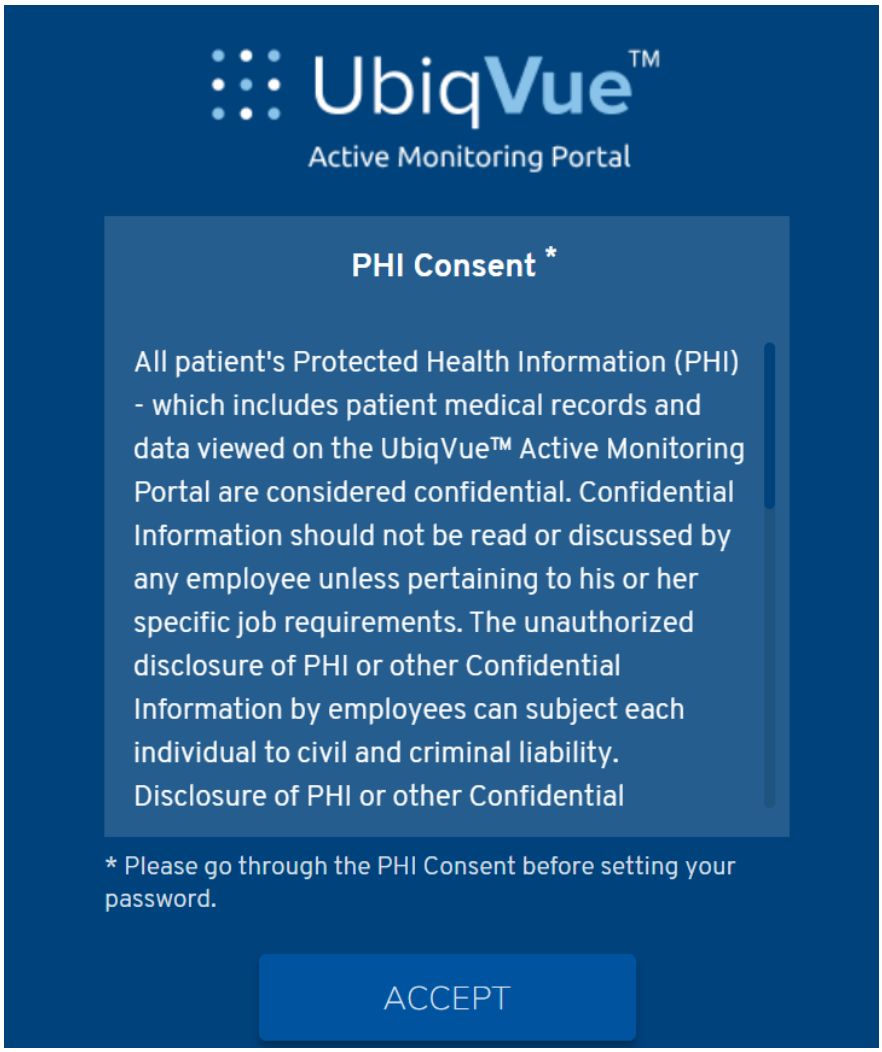


Figure 7 - PHI Consent Screen

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).
- Download Audit logs.

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).
- Download Audit logs.

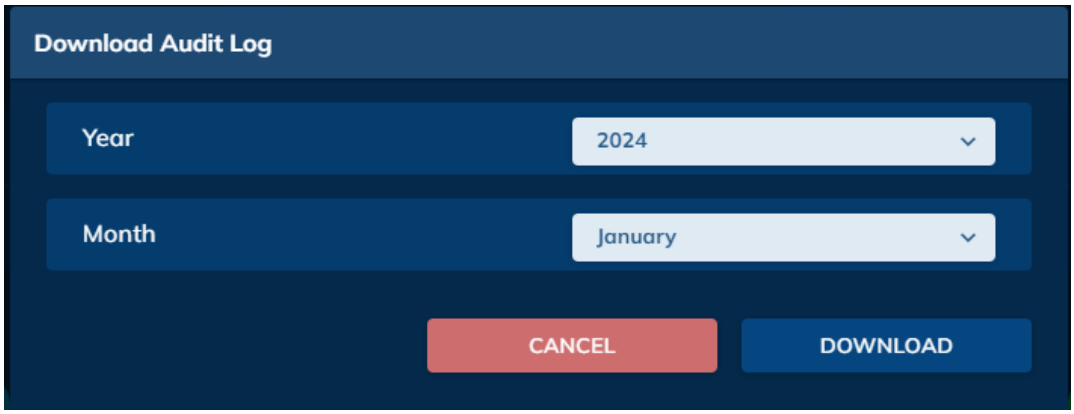


Figure 8 - Download Audit Logs

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 Active Monitoring Portal for the clinical facility. For example, creates assign roles (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 and configures 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 UbiqVue™ Active Monitoring Portal, 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).
- Rename user roles in the Active Monitoring Portal.
- Add/ Delete patient groups based on location or medical group to Clinician or Physician only.
- Enable/disable users (cannot delete)
- 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 SPR device.
- Delete SPR relay IDs.
- Add/Delete MPR Server key.
- Enable/Disable SPR auto deletion date.

Default Alert Configuration (for the facility)

- Enable/Disable/Edit the clinical and technical alerts and alert priority for the clinical facility.
- Set the alert destination for clinical, manual, and technical alerts (SMS, Email, WhatsApp)
- Set the alert Notifications (notification message for Clinician / Supervisory Clinician / Physician).

Miscellaneous

- ECG Settings (Select/Edit ECG filter settings and Select/Edit ECG sampling rate).

- Network Reconfigurations (Enable/Disable/Edit Biosensor wireless network configuration).
- Other Settings: Enable/Disable auto generation of Patient ID/MRN, access to select Service Provider Referral Physician, 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

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 Active Monitoring Portal. 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 and generate reports for discharged patients in the **Home** screen. 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_2, Pulse Rate, 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_2, Pulse Rate, BP values using the Active Monitoring Portal.

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 UbiqVue™ Active Monitoring Portal 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 UbiqVue™ 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.

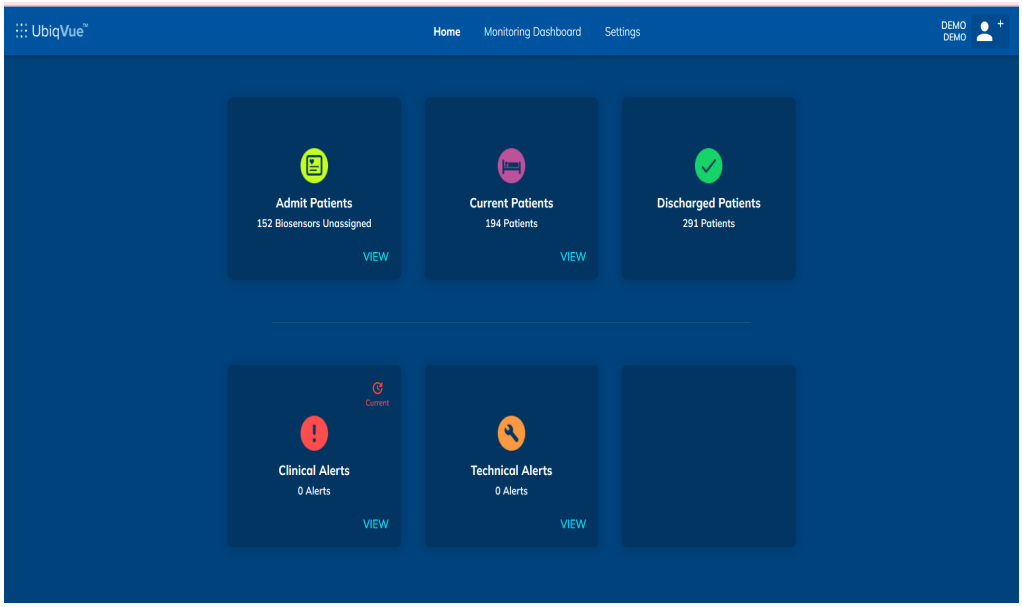


Figure 9 - Home Screen

2. Monitoring Dashboard

The Monitoring Dashboard displays near real-time waves, numerics, 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 Active Monitoring Portal, creating and managing patient groups and associated app settings. Additional rules and Active Monitoring Portal 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

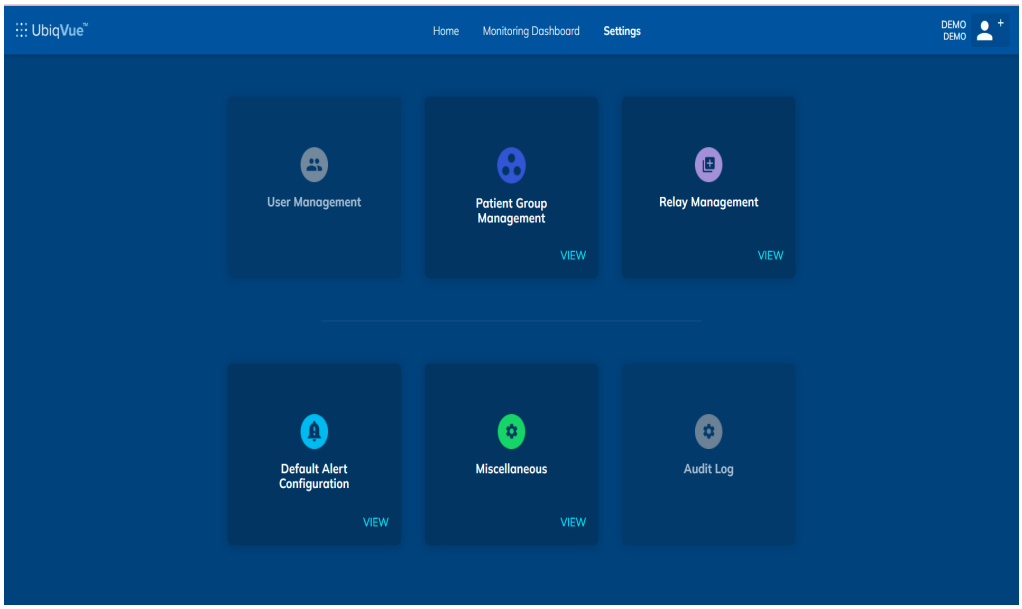


Figure 11 - Settings Screen

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 Active Monitoring Portal. 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 users privileges.

The pencil 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 UbiqVue™. Note that the patient's vital sign data will immediately begin streaming to the Active Monitoring Portal.
4. Return to the Active Monitoring Portal and view the patient vital sign data displayed on the Monitoring Dashboard.

* Mandatory

** Data will be auto-populated if the patient demographics have been previously entered in the Active Monitoring Portal.

Notice

In cases where the Biosensor has been applied to a patient BEFORE admitting a patient, using the relay device or the Active Monitoring Portal, 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	
PATIENT ID / MRN	Enter the Patient ID /MRN. The Patient ID can also be auto-generated by tapping the Autogenerate icon.
FIRST NAME	Enter the First Name of the Patient.
LAST NAME	Enter the Last Name of the Patient.
DATE OF BIRTH	Select the Year, Month and the Day from the Calendar. (Birthdate of the patient).
SEX	Select the sex from the drop-down list.

PHONE NUMBER	Enter the Phone number for the Patient.
ADMITTED ON	Select the Year, Month and the Day from the Calendar. (Admission date of the patient).
BIOSENSOR ID	Enter the Biosensor ID and select ✓.

Figure 12 - Admit Patient Screen

Notice

ADDITIONAL INFORMATION field - Information related to the medical history and admission condition of the patient must be entered.

8.2.2 Transferring to Hospital Network (MPR)

When an admitted patient is relocated from an SPR setting to an MPR setting e.g. from the patient's home or a step-down facility 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 Active Monitoring Portal.

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

8.2.5 Transfer from Hospital Network (SPR)

When an admitted patient is relocated from an MPR setting to an SPR 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 UbiqVue™ Active Monitoring Portal.

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** (dropdown) → **SAVE**.

8.2.10 Assigning/Reassigning devices

During patient admission, a third party device e.g. BP / SpO2 device can be assigned to the patient and data can be streamed to the Active Monitoring Portal 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.

8.2.11 Stop monitoring

When a patient's monitoring session has been completed, the status should be first updated in the Active Monitoring Portal, 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.

8.2.12 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 Active Monitoring Portal 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_2, it may be required to update the parameters manually.

8.3.1 Current patients

The **Current Patient** screen displays a list of actively streaming patients 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**.

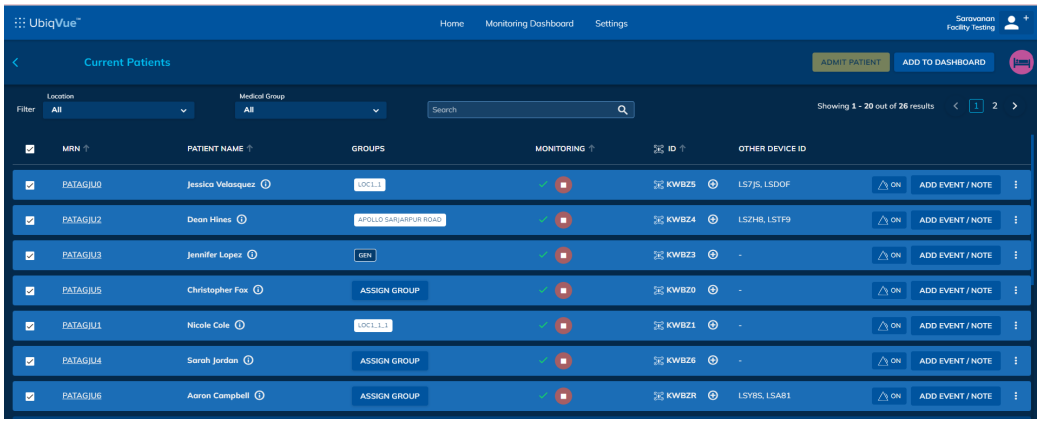


Figure 13 - Current Patient Screen

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).

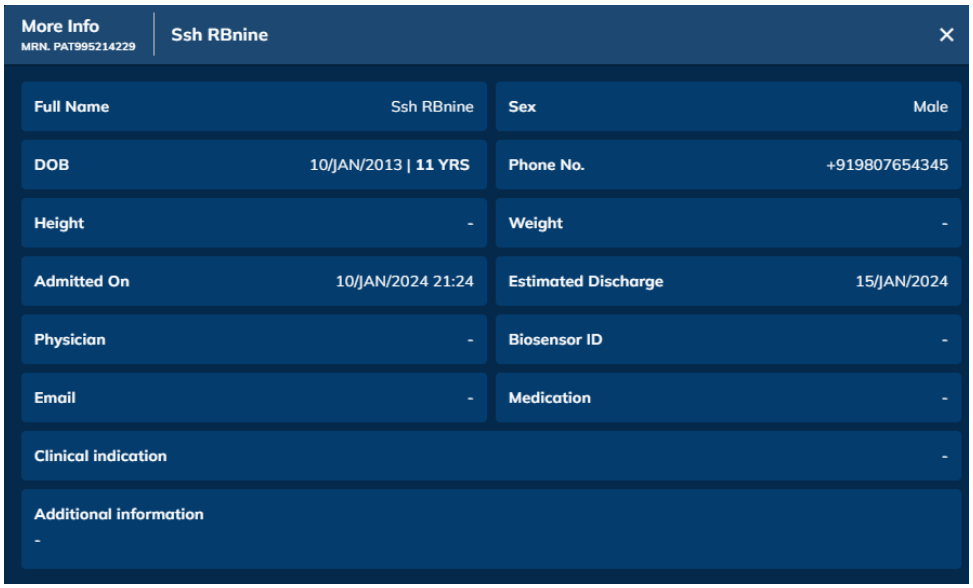


Figure 14 - More Info Screen

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

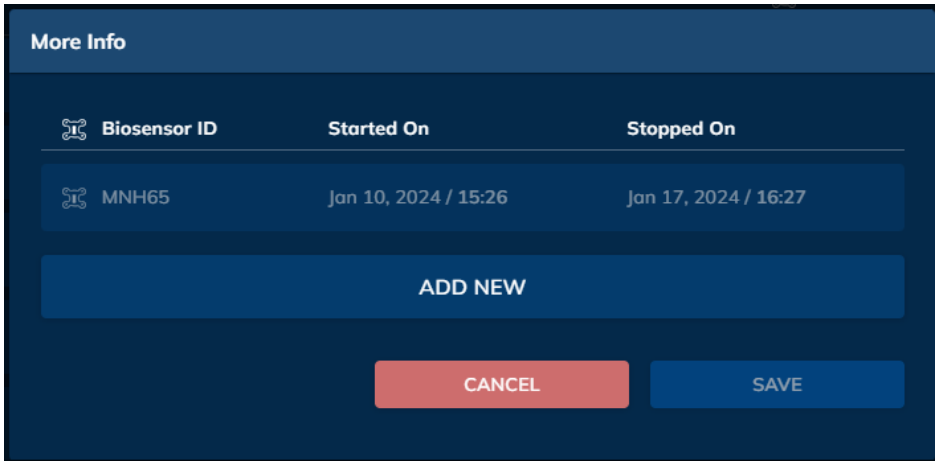


Figure 15 - View Biosensor Info and Add Biosensor Screen

6. 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).

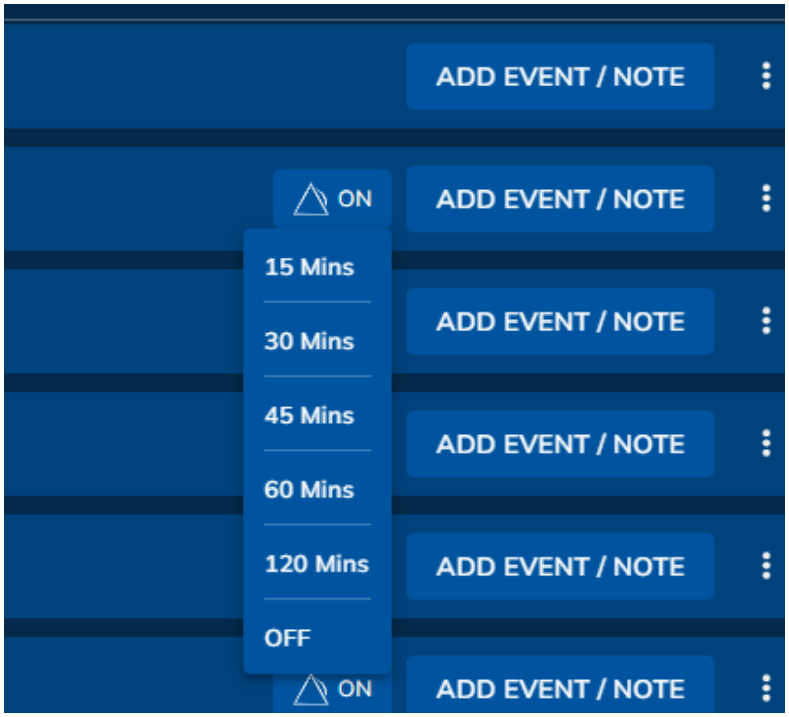


Figure 16 - Pause Alerts

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_2 or RR or Skin Temp or BP**).**

Figure 17 - Patient Trends Screen

Notice

Based on the first channel selection, user shall be able to select the corresponding waveforms in the second channel

Parameter 1 and Parameter 2 represent vital data related to HR, PR, SpO_2, 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,

2. From the **Current Patients** window →  → **VIEW TRENDS** → select **Admission No→ Select recent Time interval → Select Date / Time (From and To) → Select Parameter 1 and 2.**

Figure 18 - Patient Trends - Parameter Alerts

Notice

Parameter alerts are displayed in Red.

Technical alerts are displayed in Blue.

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 user 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

The Clinical alerts are displayed for the selected patient in the Zoom view next to the patient name.

The Technical alerts are displayed in the Zoom view next to the Biosensor.

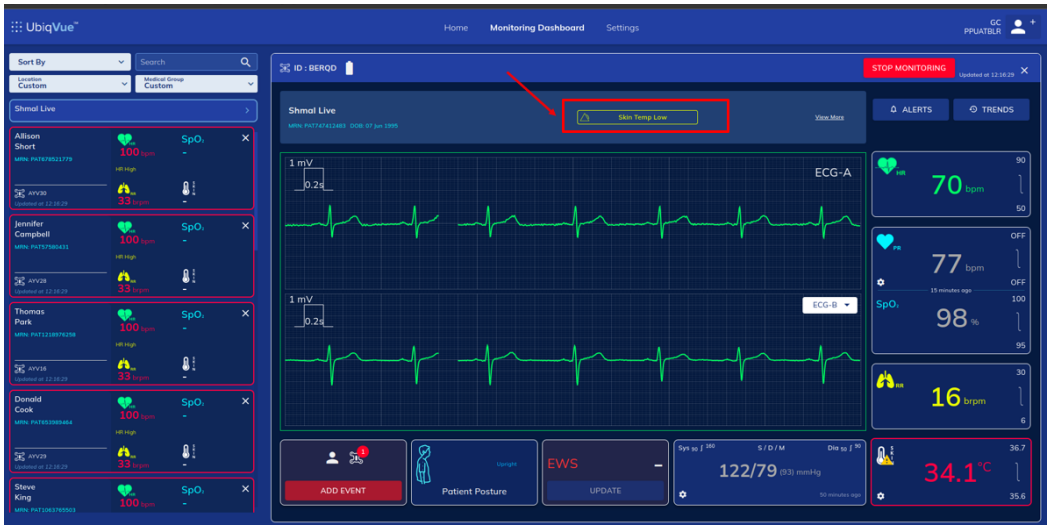


Figure 21 - Zoom View - Clinical Alert Display

8.3.4 Updating blood pressure

If the blood pressure device utilized is not transmitting data to the Active Monitoring Portal, 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 previous three modifications with time stamp.

8.3.5 Updating SpO_2 / Pulse Rate

If an SpO_2 device utilised is not transmitting data to the Active Monitoring Portal, measurements can be entered manually in the patient record.

1. From the **Monitoring Dashboard** → patient zoom view → select the icon in the Spo_2 / Pulse Rate tile → Enter the values → **SAVE.**.

> **Notice**
>
> View Logs provides the log details of the previous three modifications with time stamp.

8.3.6 Requesting patient report

A patient report can be generated during a monitoring session and/or at the end of a monitoring session. Parameters and timelines can be selected for the entire monitoring session. Once the report has been requested, the report will be shown in the View Report section. The time to generate the report will depend on the duration of the monitoring session.

1. From the **Monitoring Dashboard** → patient zoom view → **Trends** → select the **Date/Time (From and To)** → Select **Request Report -> Request Monitoring Report/Request Daily Report.**

8.3.7 Downloading patient report

Patient reports can be downloaded in a PDF format.

1. From the **Monitoring Dashboard** → patient zoom view → **TRENDS** → **View Report** → select  .

   Or

2. From the **Current Patients** window →Individual patient, Select the  icon→ View Trends → Select **GENERATE Report**.

8.3.8 Viewing and Downloading alert log*

Each patient alert is captured and stored within the Active Monitoring Portal. 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 Active Monitoring Portal 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.

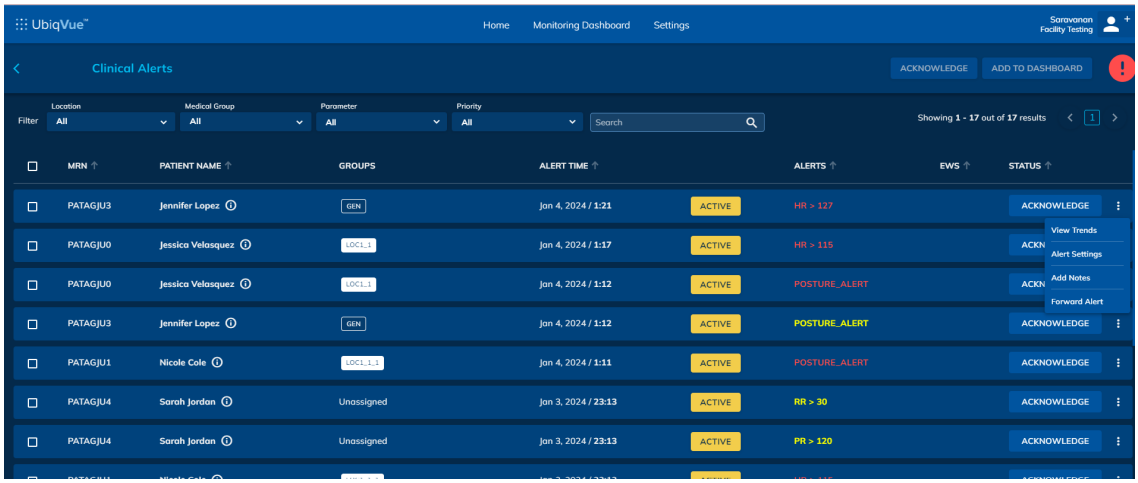


Figure 22 - Clinical Alerts Screen

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 aclnowledge the alerts. (The Acknowledged alerts denote the alerts that have been acknowledged).

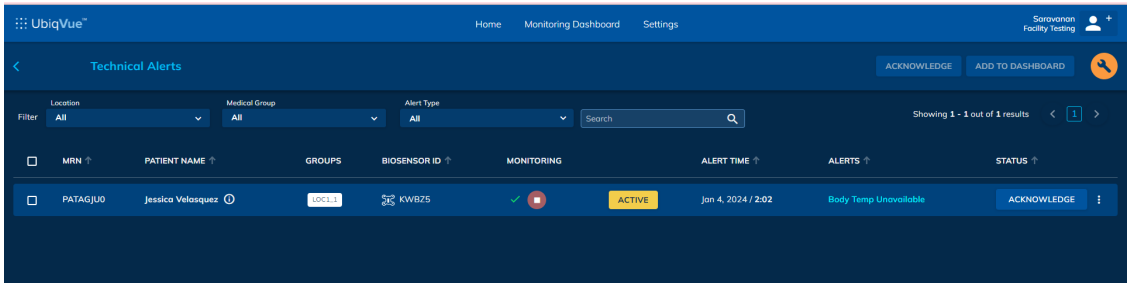


Figure 23 - Technical Alerts Screen

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 47.

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 Active Monitoring Portal. 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 communciation tools (SMS/ WhatsApp/Email) to individual users.

Individual patient

1. From the **Monitoring Dashboard** → patient zoom view → **ALERTS** → **DESTINATIONS**.
2. Enable communication tool→ select user → select → **SAVE**.

Group

1. From **Settings** → **Default Alert Configuration** window → **ALERT DESTINATION**.
2. Enable communication tool → select user → → **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 Active Monitoring Portal 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 on 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**.

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 UbiqVue™ 1AX Wireless Patient 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_2)
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 Compatability	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
Lead off detection	Yes

Common Mode rejection ratio	> 90 dB
Input Impedance	> 10 Mega ohms at 10 Hz
ADC Resolution	16 bits
ECG Electrode	Hydrogel
Heart Rate	
Heart Rate range	30 - 250 bpm
Heart Rate accuracy (Stationary & Ambulatory)	±3 bpm or ±10% whichever is greater
Heart Rate resolution	1 bpm
Heart Rate Averaging Method	Heart rate is computed by averaging the 8 most recent R-R intervals
Time to Alarm for 206 BPM / 1mVpv (Ref : IEC 60601-2-27 : B1 waveform 201.7.9.2.9.101 - b6)	Gain 0.5 (0.5 mV): 34 seconds Gain 1.0 (1.0 mV): 21 seconds Gain 2.0 (2.0 mV): 17 seconds
Time to Alarm for 195 BPM / 1mVpv (Ref : IEC 60601-2-27 : B2 waveform 201.7.9.2.9.101 - b6)	Gain 0.5 (0.5 mV): 17 seconds Gain 1.0 (1.0 mV): 17 seconds Gain 2.0 (2.0 mV): 15 seconds
Response Time of Heart Rate Meter to Change in Heart Rate	HR change from 80 to 120 bpm: Average 15 seconds HR change from 80 to 40 bpm: Average 19 seconds
Heart Rate Meter Accuracy and Response to Irregular Rhythm	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 : A4 waveform : 90 bpm
Update period	Every beat
Heart Rate Method	Modified Pan-Tompkins
Tall T-wave Rejection Capability	1.2 mV
Respiration Rate **	
Measurement Range	5 - 60 breaths per minute
Measurement Accuracy	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
Resolution	1 breath per minute
Respiration rate algorithm	Trans-thoracic Impedance (TTI), Accelerometer and ECG Derived Respiration (EDR).

TTI injection signal frequency	10 kHz
TTI Impedance variation range	1 to 5 Ω
TTI Base Impedance	200 to 2500 Ω
Update period	4 sec
Maximum Latency	20 sec
EDR - ECG derived respiration	R-S amplitude
Skin Temperature	
Measurement Range	29°C to 43 °C
Measurement Accuracy (laboratory)	± 0.2°C
Resolution	0.1°C
Sensor Type	Thermistor
Measurement Site	Skin (chest)
Update Frequency	1 Hz
Accelerometer	
Accelerometer Sensor	3-Axis (digital)
Sampling Frequency	25 Hz
Dynamic Range	± 2 g
Resolution	16 bits
Posture	Lying, Upright, Inclined
Wireless and Security	
Frequency Band (802.11b)	2.400-2.4835 GHz
Bandwidth	20 MHz (WLAN)
Transmit Power	0 dBm
Modulation	Complementary Code Keying (CCK) and Direct Sequence Spread Spectrum (DSSS)
Wireless Security	WPA2-PSK / CCMP
Data Rate	1, 2, 5.5 and 11 Mbps
Wireless Range ****	>5meters (line of sight)**
Environmental	
Operational temperature	+0°C to +45°C (32°F to 113°F) Maximum applied part measured temperature may vary by 0.5°C

Operational relative humidity	10 % to 90 % (non-condensing)
Operational altitude	up to 3000 m (10000 ft)
Storage temperature (< 30 days)	+0°C to +45°C (32 °F to 113°F)
Storage temperature (≥ 30 days)	+10°C to +27°C (50°F to 80°F)
Transportation temperature (≤ 10 days)	-5°C to +50°C (23°F to 122 °F)
Storage relative humidity	10% to 90% (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Shelf life	13 months

Notice

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

Active Monitoring Portal 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, Active Monitoring Portal 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 packet loss and maximize capacity.
- Distance between the biosensor and the relay (WiFi AP for MPR or SPR) to be maintained within 5m for eliminating waveform breaks.
- Keep the BLE relay within 5m from the Biosensor/patient in home use case. 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_2, 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_2, 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 Active Monitoring Portal

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_2	SpO_2 Pulse Rate value has exceeded the high alarm limit.
Pulse Rate Low (Based on 3rd party device data)	SpO_2	SpO_2 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.
SpO2 % High (Based on 3rd party device data)	SpO_2	Arterial oxygen saturation has exceeded the high alarm limit.
SpO2 % Low (Based on 3rd party device data)	SpO_2	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 3rd party device data)	(Priority) Priority Alert; Pulse Rate Low in (ward x) @13:00 Apr 23.
Same Posture (Bed Sore)	(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_2 % High (Based on 3rd party device data)	(Priority) Priority Alert; SpO2% High in (ward x) @13:00 Apr 23.
SpO_2 % Low (Based on 3rd party device data)	(Priority) Priority Alert; SpO2% Low in (ward x) @13:00 Apr 23.
Systolic BP High (Based on 3rd party device data)	(Priority) Priority Alert; Systolic BP High in (ward x) @13:00 Apr 23.
Systolic BP Low (Based on 3rd party device data)	(Priority) Priority Alert; System BP Low in (ward x) @13:00 Apr 23.

Table 6 - Technical Alerts – Alert Message displayed on Active Monitoring Portal

Alert Message	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 Disconnected	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 patients skin, press the Biosensor for 2 min. During ECG Lead off, the HR is displayed as " - -".
Relay Disconnected (SPR)	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 Disconnected	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	When the "Battery Low" alert message occurs, initiate "Stop Monitoring". On completion of the Stop Monitoring procedure, replace with new Biosensor.
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 SPR)	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 (SPR, 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[1] (seconds)	Maximum (seconds)
Heart Rate (Low or High)	5	5	300
Respiration Rate (Low or High)	60	30	300

[1]Excludes the inherent delay in alert generation as per Table 9: Clinical Alert Generation Delay Time - Inherent.

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

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 Bio-sensor	120	15	300
Biosensor communication dis-connection	15	15	300
Relay communication dis-connection	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

Alert Message	Type	Default status	Default	Minimum	Maximum	Steps
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 wireless 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_2	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, Authorisation and Restriction of Chemicals

10.2 EMC compliance and warning statement

IEC 60601-1-2: 2014

UbiqVue™ 1AX 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, 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-UB2550)

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 at 12.8mm 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.

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	Floors should be 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 oftransmitter (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 manufacture.			
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 UbiqVue 1AX Wireless Patient Monitoring System is:

- Data loss between the Biosensor and the Single Patient Relay 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 equipments, the user is recommended to correct the interference by one or more of the following measures:

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

10.6 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.
 NNNNN	GUDID (Level 0) and Serial No.	On the PCBA – Level 0 – GUDID in data matrix format and Serial number in human readable format.
 XXXXX	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.
	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 a 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.

Label	Identification	Description
 >PnD	Temperature range	Operating, storage and transportation temperature, short and long term, in days: • **P**: Duration • **n**: Number • **D**: Calendar days
	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.
	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.

Label	Identification	Description
	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD.
	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.

11 Appendix

11.1 Troubleshooting

11.1.1 Single Patient Relay

Table 18 - Notifications

Notification	Explanation	Resolution
AUTHENTICATION_FAILED	Login with incorrect/non-existent user credentials for 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 I Transferring to Hospital Network I Was reconfiguration successful? I Are you sure the Biosensor has Transferred? I 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 provide.
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.
SPO2 device in use. Unassign from previous patient or enter another device ID.	The SPO2 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_2 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 Active Monitoring Portal

Table 19 - Notifications

Notification	Explanation	Resolution
Auto Generate Patient ID is Disabled. Please enable the Settings to **AutoGenerate the ID**	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 the 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.
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 unsucessful, 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 "Biosensor Disconnected" being displayed in the Active Monitoring Portal?	This could be attributed to a wireless communication failure between the Biosensor and the access point. Reasons: 1) Patient walks out of the network area. 2) Access point gets switched off. Effects: 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. **Contact Technical Team for further assistance.**
Why is the LED blinking fast in green?	This could be attributed to a wireless communication failure between the Biosensor and the Access Point. Reasons: 1) Patient walks out of the network area. 2) Access point gets switched off. Effects: 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. **Contact technical team for further assistance.**

Why is "Relay Disconnected" being displayed?	This could be attributed to a wireless/wired network failure between the Relay device and the Central server. **> Single Patient Relay(SPR)** - 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. **> Multi Patient Relay(MPR)** - The Relay has lost connection with the Central Server. Check for power failure and network/internet connectivity. (Contact Technical Team for assistance). **>Relay Bridge** -The Relay has lost connection with the Central Server. Check for network/ internet connectivity.
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 disonnection will be available in the trend.
What if the Beep sound is heard from the mobile (SPR) ?	It could be due to the wireless communication failure between the Biosensor and the SPR.
What to do when the mobile App (SPR) 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-008 UbiqVue™ SPR Installation & Configuration Manual.
5. DHF09-LBL-010 UbiqVue™ Central Server Installation & Configuration Manual.

11.3 Third Party Devices

Name of the Medical Device	Manufacturer	Model Number
BP Monitor	Omron	HEM7600T-AP3
SpO_2 Watch	Contec	CMS50F

11.4 Cloud Infrastructure

LifeSignals, Inc. uses Amazon Web Services (AWS) for its Central Server and ActiveMonitoring Portal 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 Active Monitoring Portal 24/7 using New Relic and CloudWatch Alarms for anydowntime 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-LevelSLA**
  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”).

Ref: https://aws.amazon.com/compute/sla/

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 another region. The SLA for this operation is 2-3 hours.

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 Active Monitoring Portal 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).