UbiqVue™ 2A Wireless Patient Monitoring System

(UX2550) User Manual

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Intended purpose

This manual describes the intended use of the UbiqVue™ 2A 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 operating instructions.
Ensure you fully understand and comply with the notices in this manual.

Warning

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

Caution

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

Notice

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

Tip

Additional information relating to the current section.

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Glossary

Term	Definition
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 paired UbiqVue™ Patient Relay App or MPR device.
Biosensor ID	A five or seven-character alphabetical 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. Can send alert notifications to configured users through E-mail, SMS, or WhatsApp from any clinical (physiological), technical, or manual alert conditions.
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 overall set up and configuration of Active Monitoring Portal for the clinical facility. For example, creates assign roles (SC/Clinician/Physician) for new users, reset users password, selects patient identification method for the facility (MRN or Patient ID), creates location/medical groups and configures alert defaults for entire clinical facility.
	Denotes Clinician role - 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, BP values and perform EWS using the Active Monitoring Portal.
	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, enter manual events, BP values and perform EWS using the Active Monitoring Portal.
	Denotes Supervisory Clinician (SC) role - view all patients or patient groups in the clinical facility, acknowledge alerts and perform EWS 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 user with Clinician or Physician role and view discharged patients.

Term	Definition
	Denotes Administrator (CFA) role - Multiple functions associated with overall set up and configuration of Active Monitoring Portal. For example, creates assign roles (SC/Clinician/Physician) for new users, reset users password, selects patient identification method for the facility (MRN or Patient ID), creates location/medical groups, configures alert default for entire clinical facility.
	Denotes additional edit functionality for SC / Clinician / Physician roles.
Early Warning Score	Early Warning Score (EWS) based on the National Early Warning System (NEWS) is a tool used to support the recognition and response to a deteriorating patient. It is a composite score of six bedside vital parameters: pulse rate, blood pressure (BP), oxygen saturation (SpO_2), body temperature, respiratory rate, and level of consciousness.
Guest Physician	External or referral healthcare professional 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. Users can select multiple patient tile view or single patient zoom view/hybrid view using available filter settings.
Multi-Patient Relay (MPR)	Multi-Patient Relay network transmits data from multiple Biosensors via hardware devices (e.g. wireless access points, computer) to UbiqVue™ Central Server.
Single Patient Relay (SPR)	Relay (mobile) device for transmission of a patient's Biosensor data to UbiqVue™ Central Server.
Service Provider Administrator (SPA)	The highest level user that manages administration of multiple clinical facilities and hospital groups.
UbiqVue™ Active Monitoring Portal	Web-based application provides clinical staff remote access, via the in-built Monitoring Dashboard, to patient near real-time physiological data (Biosensor and derived), demographics, EWS score, trends and alert status.

Contents

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1 Safety information

1.1 Intended use and indications for use

The UbiqVue™ 2A Wireless Patient Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include electrocardiography (ECG), heart rate (HR), SpO2 (%), respiration rate (RR), pulse rate (PR), photoplethysmography (PPG) waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart rate variability (HRV) and Blood Pressure (BP) (optional) in home and healthcare settings. Data is transmitted wirelessly from UbiqVue™ 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to the remote central server for display, storage, and analysis.

The UbiqVue™ 2A Wireless Patient Monitoring System is intended for non-critical, adult population, who are 18 years of age or older.

The UbiqVue™ 2A Wireless Patient Monitoring System includes the ability to notify healthcare professionals when physiological parameters fall outside the set limits and displays multiple patient's physiological data for remote active monitoring.

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 Biosensor if patient has known allergic reaction to adhesives or electrode hydrogels.
- DO NOT use Biosensor if patient has inflamed, irritated or broken skin in Biosensor placement area.
- Remove 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 patient to wear Biosensor for more than the prescribed hours.
- Remove Biosensor immediately if patient reports their skin feels uncomfortably warm or experiences a burning sensation.
- Biosensor should not be used as an apnea monitor and has not been validated for use in pediatric population.
- Prolonged usage of Biosensor may induce a temporary pressure impression on the skin.

1.4 Precautions

Caution

- Press down Biosensor edges and upper area with fingers at least twice a day, to maintain adhesion.
- Excessive motion or activity may adversely affect Biosensor performance and adhesion.
- Avoid sleeping on stomach, as this may interfere with Biosensor performance.
- DO NOT use 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 communciation between Biosensor and the relay (mobile) device.
- If Biosensor LED flashes quickly (one flash every second), move relay (mobile) device closer to Biosensor.
- Biosensor contains a battery. Dispose of Biosensor in accordance with 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 Biosensor in water.
- Keep showers short with back to the flow of water. Gently pat dry with a towel and minimize activity until Biosensor is fully dry. DO NOT use creams or soap near Biosensor.
- If Biosensor becomes soiled with blood, and/or bodily fluids/matter, dispose in accordance with local laws, care facility laws or hospital laws for bio-hazardous waste.
- DO NOT wear or use Biosensor during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.

- DO NOT reuse Biosensor, it is for single use only.
- Keep Biosensor out of reach of children and pets.
- Biosensor should remain within operating distance of relay (mobile) device (< 5 meters) for uninterrupted viewing.
- The relay (mobile) device utilizes a mobile data network (3G/4G) to operate. Before travel, it may be required to enable data roaming and obtain an international adapter for charging the relay (mobile) device.
- To ensure continuous streaming of data, relay (mobile) 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 (mobile) devices (phones), routers, computer, switches etc. shall comply with applicable IEC or ISO standards.
- Maintain minimum distance of 5 mm between relay (mobile) device and 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 (mobile) device has firewall protection to avoid virus/malware attack.

2 UbiqVue™ Product description

2.1 UbiqVue™ 2A Wireless Patient Monitoring System (UX2550)

The system contains the following components:

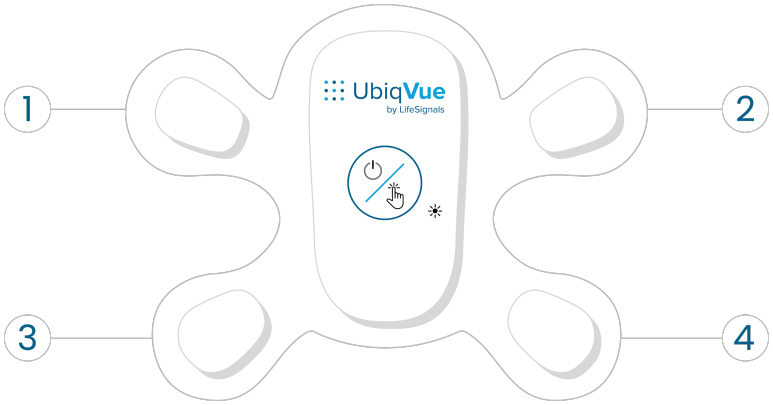
2A Wearable Biosensor (UB2550)	Acquires two channels of ECG signals, TTI respiration signals, PPG waveform, skin temperature, ambient temperature, posture, motion, SpO_2 and pulse rate data and transmits to Single Patient Relay (SPR) or Multi Patient Relay (MPR) device.
Single Patient Relay (SPR) Software (UA2550-R)	A compatible relay (mobile) device which receives and relays signals from paired Biosensor to Central Server for processing.
Multi-Patient Relay (MPR) Software (UA2550-MR)	Installed on compatible computer. Receives and relays signals from multiple Biosensors to Central Server for further processing.
Central Server Software (UA2550-S)	Receives data from multiple Biosensors simultaneously. Derives HR, RR, skin temperature, body temperature, posture information, HRV and R-R interval. 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™ 2A 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), photoplethysmography waveform (PPG), skin temperature (measured using thermistor), ambient temperature, posture data (detected by accelerometer), SpO_2 and pulse rate from the patient, pre-processes and wirelessly transmits the signals to a paired Single Patient Relay (SPR) or Multi-Patient Relay (MPR) device or other receiver system. 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™ 2A Wearable Biosensor

UB2550

- **ECG A**:Right upper electrode → Left lower electrode
- **ECG B**: Right lower electrode → Left 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 storage temperature, WLAN environment and parameter settings selected.

2.3 UbiqVue™ Single Patient Relay (SPR)

The SPR is a relay (mobile) 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 SPR and Biosensor
- Manages encrypted communication between the SPR and the central server.

- Receives and encrypts physiological signals from the Biosensor and transmits the data to the central server as quickly as possible.
- Manages the database in SPR for buffering or storing the data securely if there is any disruption in communication with the central server.
- Provides user interface for entering Biosensor and patient information and for pairing and establishing connection with the Biosensor.
- Provides user interface for patient to record symptoms or manual alerts.
- Provides user interface to stop patient monitoring session, replace Biosensor and view monitoring summary.

2.4 UbiqVue™ Multi-Patient Relay (MPR) Software

MPR Software can be installed on to a compatible Linux based hardware platform to facilitate an in-hospital central monitoring station. Alternatively, MPR can be installed in the remote central server hardware and performs the following functions:

- Manages secured wireless communication (WLAN 802.11b) between the MPR and Biosensor
- Manages encrypted communication between the MPR and the central server.
- Receives physiological signals from the Biosensor and transmits them after encryption to the central server as quickly as possible.
- Manages MPR database for buffering or storing the data securely if there is any disruption in communication with the central server.

2.5 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 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, HRV, R-R interval, respiration rate, skin and body temperature, posture and body motion 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, when the parameters (heart rate etc) of a specific Biosensor (patient) exceed the configured limits.

2.6 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, 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 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™ 2A Wearable Biosensor

3.1 Patient advice

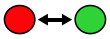
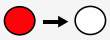
The following guidance should be given to the patient to ensure comfort while wearing the Biosensor and optimal Biosensor performance. The information is also provided in the Patient Information Leaflet found inside individual Biosensor packaging.

- Limit physical activity after Biosensor has been applied to ensure good adherence.
- Keep showers short with your back to the flow of water.
- If Biosensor accidentally gets wet, gently pat dry with a towel and minimize activity until fully dry.
- Press down Biosensor edges and Upper Area with your fingers at least twice a day, to maintain adhesion.
- Avoid sleeping on the stomach, as this may interfere with Biosensor performance.
- Occasional skin itchiness and redness are normal around Biosensor placement area.
- If a continuous red LED is displayed, press and hold Biosensor Upper area for 30 seconds.
- 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™ App.
- Travel is permitted when wearing 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 - 2A Wearable Biosensor

Light	Behaviour	Status
Confirming location		
	Slow flash	Assessing quality of SpO_2 signal
	Solid - no flashing	Good SpO_2 signal
	Solid - no flashing	Poor SpO_2 signal
Following application		
	Slow flash	Biosensor connected to SPR/MPR devices or a monitoring session is in progress.
	Fast flash	Biosensor attempting to connect with SPR / MPR devices
	Slow flash	Low Battery
	Solid - no flashing	Upper part of Biosensor has become detached from skin
	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 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.

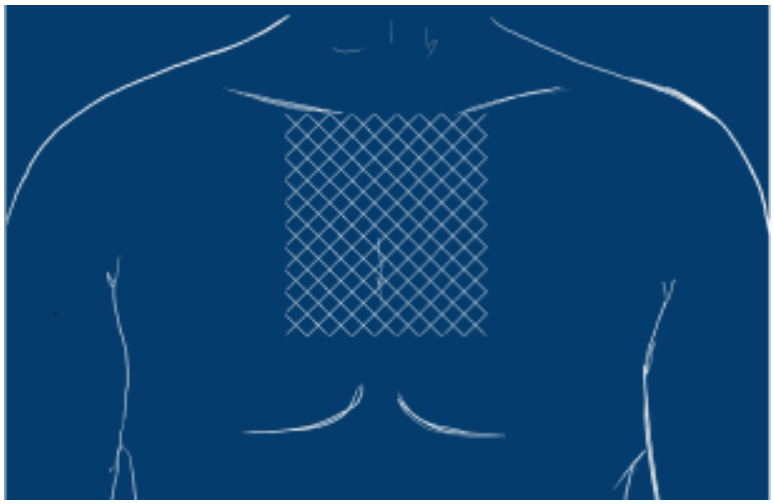


Figure 2 - Biosensor placement area

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 Biosensor. Towel drying will also increase skin blood flow, warming the skin for optimal Biosensor adhesion.

3.4 Identifying placement location

Tip

Follow step-by-step instructions in the relay (mobile) device for Biosensor placement.

1. Locate hollow at base of neck.
2. Move fingers downwards to locate the first bump.

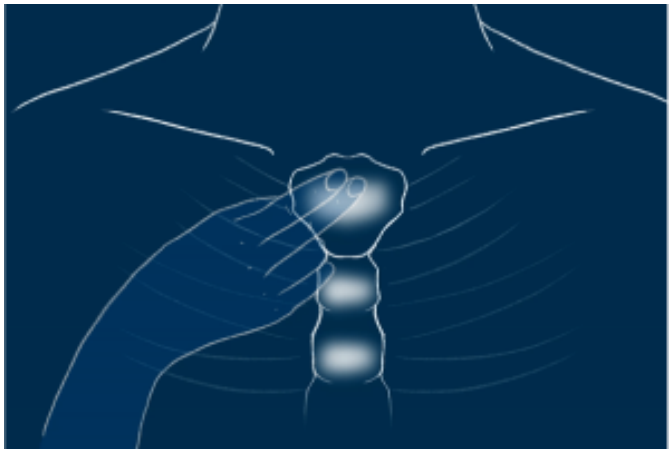


Figure 3 - Placement location

If patient has bulky, well built chest muscles, check the box in the App.

Figure 4 - Example of muscular chest

3.5 Confirming placement location

1. Do not remove Biosensor backing film.
2. Turn on Biosensor, a red light will start flashing.

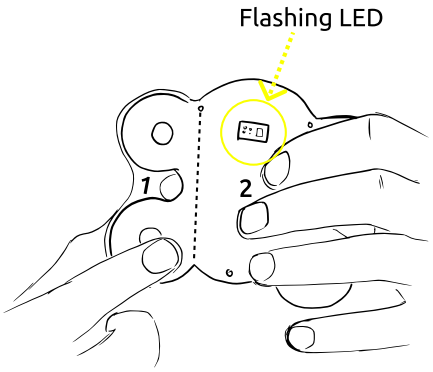


Figure 5 - SpO_2 flashing LED

3. Place flashing LED on top of the first bump, hold in place until 🟠 changes to 🟢 or 🔴.

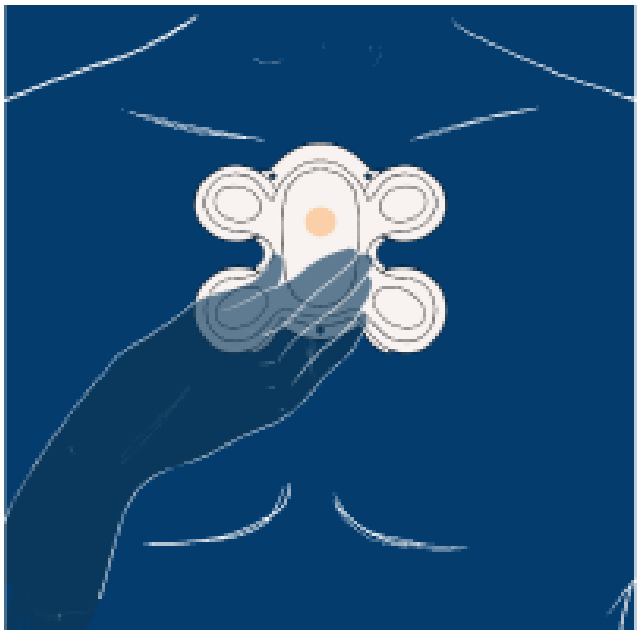


Figure 6 - Holding Biosensor in position until orange LED changes colour

4. If 🔴 appears, move Biosensor down to next bump, hold in place until 🟠 changes to 🟢.
5. Repeat previous step until 🟢 appears.

3.6 Applying Biosensor

Tip
Remove the backing film using the round holes.

1. Press center of Biosensor to keep in position.
2. Lift left side of Biosensor without moving the Biosensor out of place.

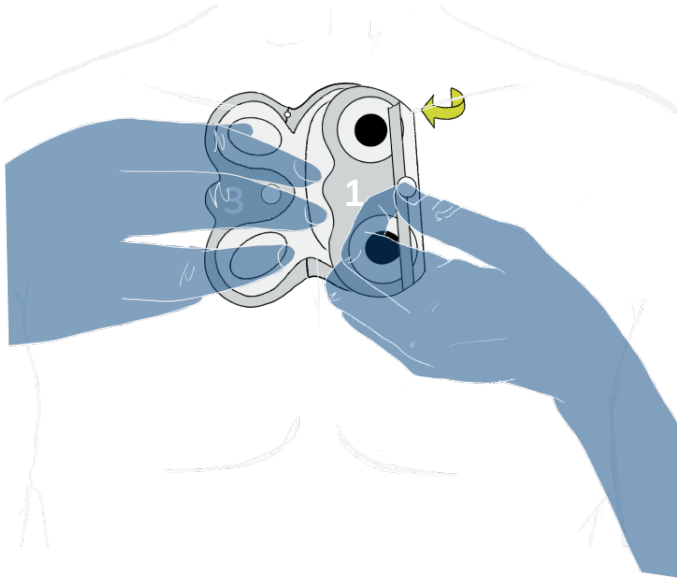


Figure 7 - Lifting left side of Biosensor without moving Biosensor out of place

3. Remove backing film labelled ① . Press upper and lower circular electrodes firmly on skin.
4. Keep fingers on upper and lower electrodes, remove backing film labelled ② .
5. Press down Biosensor.
6. Press center of Biosensor and remove backing film labelled ③ .
7. Press entire Biosensor for 2 minutes, especially around the upper and outer edges, circular areas and across the center.

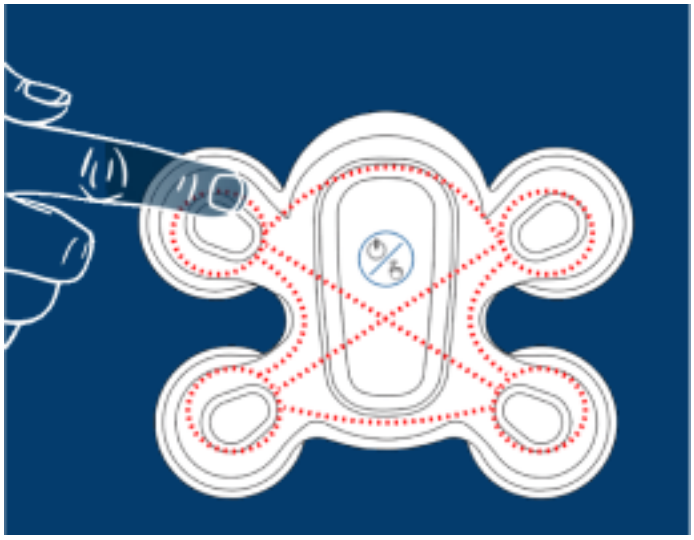


Figure 8 - Red lines indicating where to press down on Biosensor

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

Figure 9 - Biosensor removal

2. With the other hand, press 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 (mobile) device will have the UbiqVue™ App pre-installed which manages the wireless communication between the Wearable Biosensors and UbiqVue™ Central Server.

4.1 Authenticating UbiqVue™ App - relay (mobile) device

Notice

One time password (OTP) required for Clinicians first time use of the App or whenever a new device is used. Contact LifeSignals customer support for list of compatible mobile phones to act as SPR devices. Use of incompatible mobile phones may result in degraded performance.

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

4.2 Opening UbiqVue™ App - relay (mobile) device

1. Open UbiqVue™ App on the relay (mobile) device.

2. Enter Clinician login credentials, select **NEXT**.

3. Alternatively, for Patient/Other, enter patient phone number and patient ID, select **NEXT**.

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 mandatory fields, an error message highlighting the fields with missing information will appear. If patient has been admitted using the UbiqVue™ Active Monitoring Portal, patient's information will auto-populate in UbiqVue™ App.

1. Remove Biosensor from the pouch.
2. Enter Biosensor ID in UbiqVue™ App manually or by scanning the QR code on the Biosensor packaging, select **NEXT**.
3. Press 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 Patient Info (include mandatory fields) in UbiqVue™ App, select **ADMIT**.
5. Prepare the patient's skin, select **NEXT**.
6. Follow UbiqVue™ App instructions to identify and confirm location for Biosensor's placement, select **NEXT**.
7. Follow UbiqVue™ App instructions to apply Biosensor, press the entire Biosensor for two minutes, select **NEXT**.
8. Assess quality of ECG, SpO_2 and respiration waveforms, if acceptable select **TRANSFER** to use the hospital network for Biosensor data transmission to the Central Server and **CONFIRM** to start monitoring session. If unacceptable, go to menu , select **Replace Biosensor** and enter new Biosensor ID.

4.4 Transmitting Biosensor data - SPR

1. Select **CONTINUE**.
2. The UbiqVue™ App supports compatible Blood Pressure (BP) devices.
3. Select device type, enter device ID manually or scan QR code on the device.
4. Alternatively, select **SKIP** to add 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 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 time (24 hr format).
3. Enter measurements for Oral Temperature / Blood Pressure.
4. Select **CONFIRM**.
5. Measurements can be viewed in the UbiqVue™Active Monitoring Portal.

4.7 Additional menu features

In the SPR UbiqVue™ App, select  to access additional menu features.

Table 2 - Additional menu features

Feature	Explanation	Action
Monitoring Summary	Provides current details of monitoring session.	Select **Monitoring Summary** and **BACK** to exit.
Stop Monitoring	App will attempt to upload data and turn off 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**.
SpO_2 Settings	Set continuous or intermittent ON/OFF SpO_2 measurements.	Select **SpO_2 Settings**, tick box for *Continuous* or enter ON/OFF values, select **CONFIRM**.
BP Settings (if supported)	Set BP mode/interval measurements.	Select **BP Settings**, choose *Mode* from dropdown menu, enter interval measurement values, select **CONFIRM**.
Add/Change Device(s)	BP devices can be added/changed to facilitate measurements transmission to Central Server.	Select **Add / Change Device (s)**. Select *device type*, enter *Device ID* and select **ADD DEVICE**.
Replace Biosensor	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**. New Biosensor can then be applied.
Identify Biosensor	Biosensor LED being monitored will flash three times.	Select **Identify Biosensor**.

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

4.8 Optimal relay (mobile) device settings

Action*	**Rationale**	**Instructions**
Change Turn Off when no device connected to **Never timeout**	Prevents device hotspot from turning off automatically if Biosensor disconnects for more than the configured timeout.	Mobile Hotspot--> Configure --> Advanced --> Turn Off when no device connected for--> **Never timeout**
Change **Phone MAC** to **Randomised MAC**	Prevents changing of the MAC address whenever hotspot turned on/off.	**Mobile Hotspot** setting --> select Configure --> Select Advanced --> Tap on Mac Address Type --> Change from Phone MAC to Randomised MAC
Disable **Auto delete unnecessary data**	Some devices will Auto delete unnecessary data if the UbiqVue™ App is unavailable for >1 day. Disabling the storage booster helps to avoid deleting the relay log which can help with technical troubleshooting	Battery and device care --> More option --> storage booster --> disable the **Auto delete unnecessary data**
		Battery and device care --> More option --> Automation --> disable the **Auto optimize daily**
Disable the **Do Not Disturb** option	Prevents interference with the UbiqVue™ App	Do Not Disturb --> Off

Action*	Rationale	Instructions
Disable the Nearby device scanning, **Wi-Fi & BLE Scanning**	Reduces possibility of data loss.	Connections --> More connection settings --> disable **Nearby device scanning**
		Location --> Improve accuracy --> disable the **Wi-Fi scanning & Bluetooth scanning**
Enable the **Always ON Display**	Prevents potential issues reopening the UbiqVue™ App.	Lock Screen --> enable the **Always ON Display**

*Some actions may not apply

5 UbiqVue™ Multi-Patient Relay Software

Please follow the steps outlined in the UbiqVue™ Multi-Patient Relay (MPR) software - Installation Manual (Document ID 1000001979A) to install Multi-Patient Relay Software on a compatible laptop or computer. The instructions and a list of compatible devices are available from LifeSignals Customer Support. Use of incompatible mobile phones may result in degraded performance.

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6 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.
- View EWS derived from consolidated vital sign data collated from Biosensors and third party devices.
- Manage default settings and alerts.
- View session, daily or end of monitoring patient reports generated from consolidated vital sign data collated from Biosensors, third-party devices and Clinician notes.

6.1 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 functions and permissions to access Portal settings and patient data. Users can be assigned one or more roles (functions) with pre-configured set of privileges. The hierarchy of user groups is shown below.

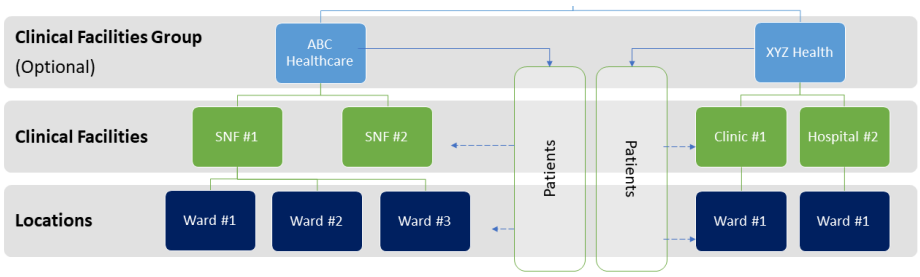

Figure 10 - User hierarchy

6.1.1 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 their email address).
- Add Guest Physician (permission for access must be granted by CFA).

Clinical Facility Management

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

Tip

Only SPA (default SPA) created by 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.

6.1.2 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) for new users, reset users password, selects patient identification method for the facility (MRN or Patient ID), creates location/medical groups and configures alert defaults for 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:

CFA User Management

- Add/edit roles for users (Supervisory Clinician, Clinician, Physician)
- Rename user roles, set time zone and select units for all users in the Active Monitoring Portal.
- Create 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)
- Enable/disable access to Guest Physician during patient admission

Patient Group Management

- Add/edit/delete levels in locations and medical group

Patient App Management

- Send OTP/QR code to register SPR device
- Delete SPR relay ID's
- Add/delete MPR device for clinical facility
- Enable/disable SPR auto deletion date and Relay Configurations

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 and technical alerts (SMS, Email, WhatsApp)

Miscellaneous

- Enable/disable/edit BP and SpO_2 device settings
- Enable/disable/edit ECG filter settings
- Enable/disable/edit Biosensor wireless network configuration
- Enable/disable auto generation of Patient ID/MRN, access to SPA Guest Physician, mandatory note for parameter acknowledgment, mandatory note on discharge, enter facility name, upload a file for co-branding logo and patient barcode parsing in Other Settings.

6.1.3 Supervisory Clinician

The Supervisory Clinician (SC) can view all patients or patient groups in the clinical facility, acknowledge alerts and perform EWS 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 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.

6.1.4 Physician

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, BP values and perform EWS using the Active Monitoring Portal.

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

Tip

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

Whereas, if CFA creates the login, then 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.

6.1.5 Clinician

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, BP values and perform EWS using 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.

6.1.6 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 | Arrhythmia Alerts* | Technical Alerts

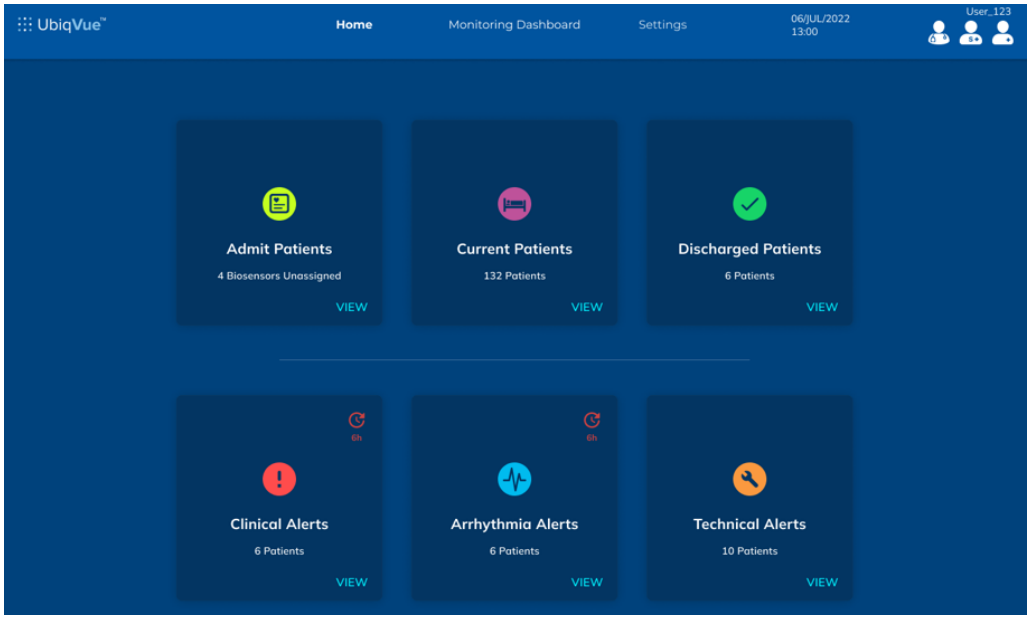

Figure 11 - Home screen

* Availability dependent on regulatory clearance

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 12 - 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 permitted to access the setting functions.

User Management | Patient Group Management | Patient App Management | Default Alert Configuration | Miscellaneous

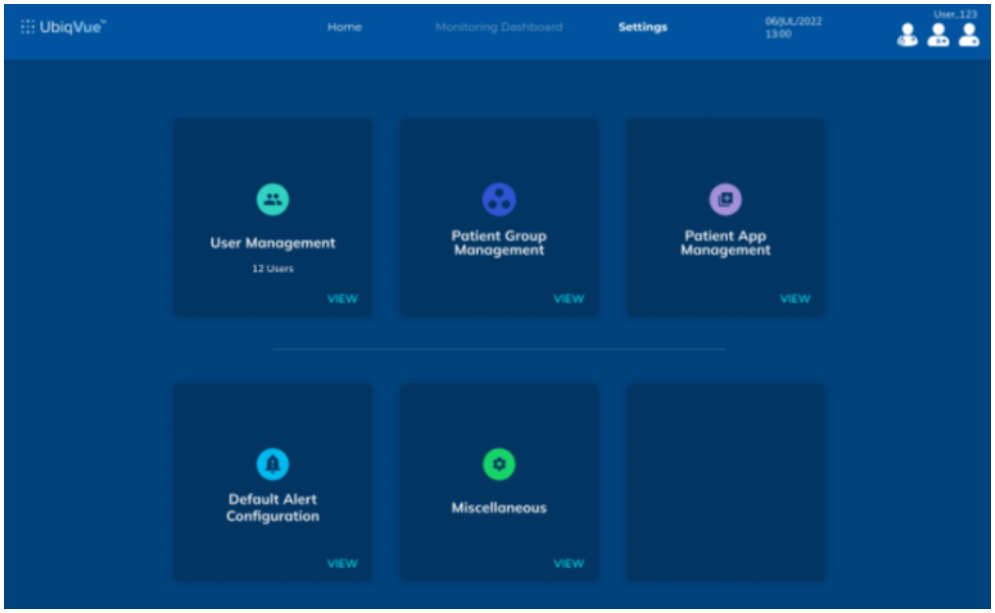

Figure 13 - Settings screen

6.2 Patient management

Patient management provides functions to enable users to:

- Manage patient transitions from admission to discharge, whether that patient is located in a home or 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 in to 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.

6.2.1 Admitting patient

To start a monitoring session, the following steps are required.

1. From **Admit Patients** viewer → **ADMIT PATIENT** → enter patient details* and Biosensor ID → **SAVE**.
2. Take relay (mobile) device and Biosensor to patient bedside.
3. Follow step-by-step instructions shown on the relay (mobile) device to apply Biosensor and complete patient admission** to UbiqVue™. Note patient vital sign data will immediately begin streaming to the Active Monitoring Portal.
4. Return to Active Monitoring Portal and view patient vital sign data displayed on the Monitoring Dashboard.
5. Adjust patient alarm limits if necessary.

* Mandatory

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

Notice

In cases where a Biosensor has been applied to a patient BEFORE admitting a patient using the relay (mobile) device or Active Monitoring Portal, the patient is NOT being actively monitored, no alarms will be generated and 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.

6.2.2 Transferring to hospital network

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

6.2.3 Editing patient

Selecting Edit patient allows user to change individual patient demographic or alert setting information.

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

6.2.4 Discharging patient

When a patient monitoring session has been completed, the patient can be discharged from the Active Monitoring Portal.

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

6.2.5 Transferring to 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 to SPR** function enables the seamless transfer of continuous vital sign monitoring without the requirement to remove the assigned Biosensor.

1. From **Current Patients** window →  → **Transfer to SPR** → **CONFIRM** → **Transfer Initiated**.

6.2.6 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.

1. From **Current Patients** window →  (beside Biosensor ID)→ **ADD NEW** → enter Biosensor ID →  → **SAVE**.

6.2.7 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 hospital. If a new Biosensor is applied, the discharge date will automatically adjust. If a patient's Biosensor is not streaming data on the discharge date, the patient's details automatically transfer from current patients to discharged patients.

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

* Discharge date refers to entry in UbiqVue™ Active Monitoring Portal.

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

6.2.9 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 **Current Patients** window → individual patient → **Edit** → **PHYSICIAN NAME** (dropdown) → **SAVE**.

6.2.10 Assigning/Reassigning devices

During patient admission, a third party device e.g. BP 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 patients monitoring session has been completed, the device can be reassigned.

1. Open **Current Patients** window → individual patient  → **Edit** → **THIRD PARTY DEVICE TYPE** → enter **DEVICE ID**→ **SAVE**.
2. To assign more devices, select  → enter details → **SAVE**.
3. To reassign devices, select  → enter details → **SAVE**.

6.2.11 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 of the data is captured.

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

Or

2. From **Current Patients** window →  → **CONFIRM** → **OK**.
3. Ensure Biosensor has switched off (LED no longer flashing).
4. Follow steps for Biosensor removal.

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

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

6.3 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 a various formats and displays to assist with reviewing a patient's status. Continuous physiological data can be streamed in near-real time from patients located in a clinical or home environment. When intermittent data is captured using third party devices e.g. oral temperature or BP, it may be required to update parameters manually.

6.3.1 Current patients

The **Current Patient** screen displays a list of patients, actively being monitored and their vital sign measurements.

1. From **Current Patients** window.
2. View patient details e.g. **MRN**, **NAME**, **MONITORING STATUS**.
3. Filter patients based on **Location** or **Medical Group**.
4. Sort the patient list shown in the window based on **MRN/ PATIENT NAME/ MONITORING/ ID/ OTHER DEVICES ID**.
5. To view patient information →  .
6. To view Biosensor information →  .

6.3.2 Patient trends

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

1. From **Monitoring Dashboard** → patient zoom view → **TRENDS** → select **Admission No** → **Real Time Trend/Post Processed Trend** → **recent time interval** → **date/time** → **Parameter 1** and **2.**

Alternatively,

2. From **Current Patients** window →  → **VIEW TRENDS** → select **Admission No**→ **Real Time Trend/Post Processed Trend** → **recent time interval** → **date/time** → **Parameter 1** and **2.**

6.3.3 Monitoring Dashboard

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 available filter settings.

1. Filter patients based on **Location, Medical condition** and **Parameter alerts**.

2. Sort the dashboard based on **MRN, Patient First name, Biosensor ID**and **EWS score**.
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. Select individual patient tile to go to zoom view.

Figure 14 - Zoom view

8. When there is a clinical alert, the numeric value will always change to red regardless of priority. Additionally, the patients tile border will display the following:

Alert Priority	Patient tile border
High	Red - flashing
Medium	Yellow - flashing
Low	Yellow - solid

9. When there is a technical alert, visual alert message will be displayed in yellow color and the individual patient tile border will display blue colour (solid).

6.3.4 Updating Early Warning Score (EWS)

If measurements from external devices are being manually entered into a patient record e.g. oral temperature, an updated EWS can be generated.

1. From **Monitoring Dashboard** → patient zoom view → **UPDATE** → **GENERATE NEW SCORE**.

6.3.5 Updating oral temperature

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

1. From **Monitoring Dashboard** → patient zoom view → select → **Enter Body Temperature** → **SAVE**.

6.3.6 Updating blood pressure

If a blood pressure device is being utilised and not transmitting data to the Active Monitoring Portal, measurements can be entered manually in the patient record.

1. From **Monitoring Dashboard** → patient zoom view → select → **START BP**/ enter the details → **SAVE**.

6.3.7 Configuring BP

1. From **Settings** → **Miscellaneous** viewer → → enter interval settings for BP device → → **SAVE**.

6.3.8 Updating SpO_2

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

1. From **Monitoring Dashboard** → patient zoom view → select → **START SpO_2**/ enter the details → **SAVE**.

6.3.9 Configuring SpO2

1. From **Settings** → **Miscellaneous** window → → select INTERVAL or CONTINUOUS from dropdown, enter ON/OFF TIME for SpO_2 device → → **SAVE**.

6.3.10 Configuring ECG filter

1. From **Settings** → **Miscellaneous** window → **ECG FILTER** → enable/disable → select 244 or 976 from dropdown → **SAVE**.

6.3.11 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 **Monitoring Dashboard** → patient zoom view → **TRENDS** → select required time → **REQUEST REPORT** → **Monitoring/Arrhythmia/Daily report** or **EDF+File.**

6.3.12 Downloading patient report

Patient reports can be downloaded in a PDF format.Patient reports can be downloaded in a PDF format.

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

6.3.13 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 **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.

6.4 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 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 have fallen outside the pre-set alert parameters.

Arrhythmia* Alerts - indicates the patient's ECG waveform data collated from the Biosensor has fallen outside the pre-set alert parameters.

Technical Alerts - indicates the Biosensor cannot measure or detect alerts reliably e.g. Biosensor has slipped off or 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.

* Availability dependent on regulatory clearance

6.4.1 Viewing and acknowledging clinical alerts

A list of all generated clinical alerts by location, medical group or vital sign parameter can be reviewed and acknowledged.

1. From **Clinical Alerts** window → Filter alerts based on **Location/Medical Group/Parameter** → **ACKNOWLEDGE**.

6.4.2 Viewing and acknowledging arrhythmia alerts*

1. From **Arrhythmia Alerts** window → Filter alerts based on **Location/Medical Group/Parameter→ ACKNOWLEDGE**.
2. To view →  .

* Availability dependent on regulatory clearance

6.4.3 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.

1. From **Technical Alerts** window → Filter alerts based on **Location/Medical Group/Parameter** → **ACKNOWLEDGE**

6.4.4 Viewing and acknowledging manual alerts

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

6.4.5 Forwarding alerts

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

1. From **Clinical/Arrhythmia/Technical Alerts** window → → **Forward Alert** → **Select Role/User/ALERT TYPE** → **SEND**.

6.4.6 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 sign falling outside the given parameter before raising an alert and prioritizing the alerts listed.

Individual patient

1. From **Monitoring Dashboard** → patient zoom view → **ALERTS** → **CLINICAL**.
2. To configure threshold and delay time, select → enter values → → **SAVE**.
3. To configure priority, select → choose priority → → **SAVE**.

Group

1. Select **Settings**, open **Default Alert Configuration** window.
2. To configure threshold and delay time, select → enter values → → **SAVE**.

3. To configure priority, select → choose 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 values → → **SAVE**.
3. To configure priority, select → choose priority → → **SAVE**.

> **Tip**
> Only the CFA can configure clinical alerts for clinical facility.

6.4.7 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 **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 values → → **SAVE**.

> **Tip**
> Only the CFA can configure technical alerts for clinical facility.

6.4.8 Configuring alert destination

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

Individual patient

1. From **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.

6.5 Network and facility settings (CFA only)

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

6.5.1 Network configuration

The CFA can configure network settings for clinical facility.

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

6.5.2 Facility settings

The CFA can configure various other settings in the Active Monitoring Portal which include addition of facility name and co-branding logo, enabling/disabling auto generation of Patient ID, allowing SC/Clinician access to select Service Provider Guest Physician during patient admission, select Patient Barcode Parsing method, Patient Identification (local terminology i.e. MRN or PID), ensure mandatory note is entered for parameter acknowledgement and selection of Electronic Medical Record (EMR) system.

1. Select **Settings**, open **Miscellaneous** window, select **OTHER SETTINGS**.
2. To enable/disable **Auto generation of Patient ID / MRN**, select from dropdown → **SAVE**.
3. To enable/disable **Access to Service Provider Physician**, select from dropdown → **SAVE**.

4. To enter **Facility Name**, select  → enter text →  → **SAVE**.
5. To choose **Co-branding Logo**, select **+** → choose image file → **SAVE**.
6. To choose **Patient Barcode Parsing**, select **+** → choose image file → **SAVE**.
7. To select **Patient Identification**, select from dropdown menu → **SAVE**.
8. To select **Mandatory Note for parameter acknowledgement**, select from dropdown menu → **SAVE**.
9. To select **EMR**, select from dropdown menu → **SAVE**.

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7 Troubleshooting

7.1 Single Patient Relay

Table 3 - Notifications

Notification	Explanation	Resolution
Access denied	Login credentials may have been revoked.	Contact your service provider or CFA.
Attempting to stop session Completing procedure Retrieving data Finalizing procedure	Sequence of messages which appear following Replace Biosensor request	Informational, no action required.
Biosensor password updated	After successful Biosensor reconfiguration, password is updated.	Informational, no action required.
Biosensor battery level is low	Battery <15%.	Consider replacing Biosensor.
Connection lost! Hold your phone close to Biosensor.	Biosensor is out of 5 meter range of relay device.	Move Biosensor closer to the relay device.
Failed to reconfigure the Biosensor	Failed to reconfigure the Biosensor when Biosensor is diconnected.	Go to menu and reselect *ReconfigureBiosensor*.
Finalizing procedure Retrieving Data Session completed!	Sequence of messages which appear following Stop Monitoring request.	
SpO2 Sensor Off	The Biosensor Upper Area (SpO2 sensor) has become detached from skin.	Press and hold the BiosensorUpper Area for 30 seconds.
Lead status is OFF. Check the lead and try again	Biosensor has become detached from skin.	Press the entire Biosensor for two minutes.
No internet. Please check your connection.	Internet unavailable on relay device.	Check with your local internet provider.
Server connection failed.	Server unavailable.	Please contact your service provider.

Transferring to Hospital Network Was reconfigure successful? Are you sure? Biosensor Transferred!	Sequence of messages which appear following Transfer to Hospital request.	Check Biosensor has transferred to MPR.
Turning off the Biosensor	Biosensor turning off following Stop Monitoring request.	Informational, no action required.
Unavailable	Server unavailable	Please contact your service provider.
Unauthorized	Login with incorrect/non-existent user credentials for clinical facility	Please contact your CFA.

7.2 Active Monitoring Portal

Table 4 - Notifications

Notification	Explanation	Resolution
Admission ID already Exists!	Attempting to admit new patient using existing admission ID	Enter new admission ID for this patient.
Admitted On time is invalid	Attempting to assign Biosensor prior to patient's admitted time	Update patient's admitted time, then assign Biosensor.
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 administrator.
Biosensor already in use	The Biosensor is already assigned to some other patient	Enter new Biosensor ID.
Devices already in use	Attempting to assign Third party device 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 patch streaming	Attempting to assign two streaming Biosensors to single patient	Assign patient to correct Biosensor.
Error! Previous Admission is not Discharged	Attempting to admit existing patient with new admission ID	Discharge patient, then admit patient.
EWS request failed	Attempt to generate new EWS unsuccessful	Try to generate new EWS. If unsuccessful, contact the administrator.
**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 administrator.
Patient Already Discharged. Replace admission Id	Attempting to readmit a patient using previous admission ID	Enter new admission ID for this 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 Biosensor data via hospital network/mobile relay unsuccessful	Try to relay Biosensor data via hospital network/mobile again. If unsuccessful, contact 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	If required, enter new email/phone number for user.

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8 Specifications

8.1 UbiqVue™ 2A Wireless Patient Monitoring System

Table 5 - Technical Specification

Physical (Biosensor)	
Dimensions	116 mm x 91 mm x 17 mm
Weight	35 g
Patient Event Logging Button	Yes
Water ingress protection	IP24 (IEC 60529:2013)
Color	White
Specifications (Biosensor)	
Battery type	Primary Lithium Manganese dioxide (Li-MnO_2)
Battery Life	120 hours of normal operation under normal wireless environment with SpO_2 update 3 minutes every 30 minutes
	40 hours of normal operation under normal wireless environment with continuous SpO_2
Wear Life	120 hours (5 days)
Applied Part Classification	CF
Applied Part	Biosensor
Defib Proof	Yes
HF Surgical Equipment Compatibility	Yes
Single Use / Disposable	Yes
MRI safe	No
Intended environment	Home, Clinical and Non-Clinical facilities
Intended Population	18 years or older
ECG Performance and Specifications	
Number of channels	Two

Channel to Channel Skew	<5ms
Sampling rate	244.140625 and 976.5625 samples per second (sps)
Frequency response	Monitoring mode : 0.2 Hz to 40 Hz (with 244.14 sps)
	Diagnostic Mode : 0.05 Hz to 150 Hz (with 976.56 sps)
Lead off detection	Yes
Common Mode rejection ratio	> 90 dB
Input Impedance	> 10 Mega ohms at 10 Hz
ADC Resolution	16 bits, 5uV/LSB
ECG Electrode	Hydrogel
Heart Rate	
Range	30 – 250 bpm
Accuracy (Stationary & Ambulatory)	±3 bpm or ±5% whichever is higher
Resolution	1 bpm
Heart Rate Averaging Method	Heart rate is computed by averaging the 8 most recent R-R intervals
Time to Alarm for Tachycardia - Vent Tachycardia 1 mVpp 206 bpm	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 Tachycardia - Vent Tachycardia 1 mVpp 195 bpm	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	Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 60 bpm Rapid alternating bigeminy: 120 bpm Bidirectional systoles: 90 bpm
Method	Modified Pan-Tompkins
Tall T-wave Rejection Capability	1.2 mV
SpO_2*	
Range	0 - 100%
Accuracy	± 3 % (100 to 70%); Less than 70% is unspecified
Resolution	1%

Method	Spectral Sensor
Averaging	8 pulse average
Update frequency	1 Hz
Minimum Signal Amplitude	0.01% modulation
Signal Strength Indication	Yes (1 sps)
Plethysmograph	Yes (120 sps).
Pulse Rate	
Range	30 – 250 bpm
Accuracy	± 2% or 2 bpm, whichever is greater
Resolution	1 bpm
Averaging	8 pulses average
Update frequency	1 Hz
Respiration Rate **	
Measurement Range	6 – 60 breaths per minute
Accuracy	⩽ 1 breath per minute (Mean Absolute Error based on Simulation study)
	⩽ 3 breaths per minute (Mean Absolute Error based on Clinical study)
Resolution	1 breath per minute
Method	TTI (Trans-thoracic Impedance), Accelerometer and EDR (ECG Derived Respiration).
EDR - ECG derived respiration	R-S amplitude Respiratory Sinus Arrhythmia
TTI injection signal frequency	10 kHz
TTI Impedance variation range	0.5 to 5 Ω
TTI Base Impedance	200 to 2500 Ω
Update period	4 sec
Skin Temperature	
Range	15°C to 43°C

Accuracy (laboratory)	< 35.8°C (96.4°F) ± 0.3°C (± 0.5°F) 35.8°C (96.4°F) to less than 37°C (98°F) ± 0.2°C (± 0.3°F) 37°C (98°F) to 39°C (102°F) ± 0.1°C (± 0.2°F) >39°C (102°F) to 41°C (106°F) ± 0.2 °C (± 0.3 °F) >41°C (106°F) ± 0.3°C (± 0.5°F)
Resolution	0.1°C
Method	Thermistor
Measurement Site	Skin (chest)
Update Frequency	1 sps
Response time	5-8 minutes
Body Temperature	
Range	32°C to 43°C (minimum)
Accuracy	⩽ 1°C (Mean absolute error)
Resolution	0.1°C
Method	Adjusted mode (with Skin Temperature, Ambient Temperature, Heart Rate and Activity)
Update Frequency	1 sps
Posture/ Ambulation	
Accelerometer Sensor	3-Axis (digital)
Sampling Frequency	25 sps
Dynamic Range	± 2 g
Resolution	16 bits
Posture	Supine, Prone, Lying – Left/Right, Reclining, Recline Left/Right, Leaning Forward, Upright, Upside down
Body Motion	No Body Motion, Mild Body Motion, Moderate Body Motion, Severe Body Motion
Wireless & Security (WLAN)	
Frequency Band (802.11b)	2.400-2.4835 GHz
Bandwidth	20 MHz
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 ***	5 meters (typical)
Wireless & Security (BLE 5.2)	
Frequency Band	2.400-2.4835 GHz
Bandwidth	1/2 MHz, 80/40 channels, frequency hopping
Transmit Power	< -1 dBm
Modulation	Frequency Shift Key (FSK)
Wireless Security	Advanced Encryption Standard – CCM Mode (AES-CCM 128-bit Encryption)
BLE Range	5 meters (typical)
Environmental	
Operational temperature	+0°C to +45°C (32°F to 113°F) Maximum applied part measured temperature may vary by ±1°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

* Maximum age of SpO_2 data is 20 seconds. After 30 seconds, the SpO_2 numeric values will be grayed out.

**Respiration Rate and SpO_2 values may not be available (shall not be displayed), when patient undergoes significant motion or severe activity.

*** QoS verified for 10 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 & 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 & 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 & 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 the reference.

Table 6 - Heart Rate Variability Specifications

HRV Metric	Duration of data	Remarks
SDNN	1 min to <5 min	Ultra short term
	5 min to <24 hr	Standard short term
	≥24 hr	Accurate - Gold standard to predict morbidity & mortality
SDANN	≥5 min	Standard deviation of 5 minutes means
SDNNI (ASDNN)	≥5 min	Mean of 5 minute standard deviation
RMSSD	1 min to <5 min	Ultra short term
	≥5 min	Standard short term
VLF band	5 min to <24 hr*	Standard short term
	≥24 hr*	Preferred
LF band	≥2 min*	
HF band	≥1 min*	

Notice

* Minimum of 4 valid HR data must be available.

8.2 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) and flash in both the tile and zoom (hybrid) views.

Also, individual tile borders will change colour and flash depending on the following priority settings; **Low (solid yellow), Medium (flashing yellow) and High (flashing red).**

If there are multiple alerts of different priority, the tile borders will change colour and flash the highest priority. Additionally, if there are simultaneous technical and clinical alerts, the tile border will flash based on the clinical alert priority. Visual display or alert in the Active Monitoring Portal is dependent on the internet connectivity.

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 measurement, the gray numeric value digits are replaced by a dashed line.

When 30 minutes has elapsed from the latest BP , the gray numeric value digits are replaced by a dashed line.

If SpO_2 acquisition mode is 'OFF' for more than 30 minutes, then the gray numeric values for SpO_2 and pulse rate are replaced by a dashed line.

If the SpO_2 acquisition mode is 'ON' and interval set to less than 30 minutes, if a valid SpO_2 measurement cannot be displayed within 30 minutes, then the numeric value digits turn gray after 3 minutes and the gray numeric value digits are replaced by a dashed line after 5 minutes.

Table 7 - Parameter Alerts – Alarm Messages displayed on Active Monitoring Portal

Alert Message	From	Condition
Body Temp High	Body Temp.	Body Temperature value has exceeded the high alarm limit.
Body Temp Low	Body Temp.	Body Temperature value has fallen below the low alarm limit.
Diastolic BP High	BP	Diastolic BP value has exceeded the high alarm limit.
Diastolic BP Low	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	BP	Mean BP value has exceeded the high alarm limit.
Mean BP Low	BP	Mean BP value has fallen below the low alarm limit.
Pulse Rate High	SpO2	SpO_2 Pulse Rate value has exceeded the high alarm limit.
Pulse Rate Low	SpO2	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	SpO2	Arterial oxygen saturation has exceeded the high alarm limit.
SpO2 % Low	SpO2	Arterial oxygen saturation has fallen below the low alarm limit.
Systolic BP High	BP	Systolic BP value has exceeded the high alarm limit.
Systolic BP Low	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 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 8 - Parameter Alerts – via SMS/WhatsApp/Email

Parameter Alert	Alert Message (SMS/WhatsApp/Email)
Body Temp High	(Priority) Priority Alert; Body Temp High; in (ward x) @13:00 Apr 23.
Body Temp Low	(Priority) Priority Alert; Body Temp Low; in (ward x) @13:00 Apr 23.
Diastolic BP High	(Priority) Priority Alert; Diastolic BP high in (ward x) @13:00 Apr 23.
Diastolic BP Low	(Priority) Priority Alert; Diastolic BP Low in (ward x) @13:00 Apr 23.
EWS Low-Medium Risk	Alert; EWS Low-Medium Clinical Risk in (ward x) @13:00 Apr 23.
EWS Medium Risk	Alert; EWS Medium Clinical Risk in (ward x) @13:00 Apr 23.
EWS High Risk	Alert; EWS High Clinical Risk 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	(Priority) Priority Alert; Diastolic BP high in (ward x) @13:00 Apr 23.
Mean BP Low	(Priority) Priority Alert; Diastolic BP Low in (ward x) @13:00 Apr 23.
Pulse Rate High	(Priority) Priority Alert; Pulse Rate High in (ward x) @13:00 Apr 23.
Pulse Rate Low	(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.
SpO2 % High	(Priority) Priority Alert; SpO2% High in (ward x) @13:00 Apr 23.
SpO2 % Low	(Priority) Priority Alert; SpO2% Low in (ward x) @13:00 Apr 23.
Systolic BP High	(Priority) Priority Alert; Systolic BP High in (ward x) @13:00 Apr 23.
Systolic BP Low	(Priority) Priority Alert; System BP Low in (ward x) @13:00 Apr 23.

Table 9 - Technical Alerts – Alert Message displayed on Active Monitoring Portal

Alert Message	From	Resolution
Battery Low	Battery	Estimated remaining battery-powered operating time is less than xx. Replace the Biosensor immediately.
Biosensor Dis-connected	Biosensor	Biosensor has lost connection with the Patient Relay device or Wireless Access Point. Request patient stays within 5 meters of Patient Relay device or Wireless Access Point
Body Temp Unavailable	Body Temp	Body Temperature is unavailable as calibration is expired.
Invalid HR	Heart Rate	System is unable to calculate Heart Rate. This may be due to motion artefact. 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.
Invalid SpO_2	SpO_2	System is unable to calculate SpO_2 value. This could be due to poor signal quality or low perfusion or motion artifact.
ECG Lead Off	ECG	Biosensor is not fully adherent to the patients skin, press the Biosensor for 2 min.
Relay Dis-connected (SPR)	Relay	Relay has lost connection with Central Server. Check mobile phone battery charge or network connectivity.
Relay Dis-connected (MPR)	Relay	Relay has lost connection with Central Server. Check for power failure & network connectivity.
SpO2 Sensor Off	SpO2	Biosensor is not fully adherent to patients skin, press Bio-sensor for 30 seconds.

Table 10 - Technical Alerts – Alert Messages via SMS/WhatsApp/Email

Parameter Alert	Alert Message (SMS/WhatsApp/Email)
Battery Low	Low Battery Alert for Biosensor (Biosensor ID) @13:00 Apr 23. Replace Biosensor within XX hours.
Biosensor Disconnected (to MPR)	Biosensor has lost connection with Wireless Access Point in (ward x/bed x) @13:00 Apr 23. Hours.
Biosensor Disconnected (to SPR)	Biosensor has lost connection with Patient Relay device (Relay ID) @13:00 Apr 23.
ECG Lead Off	ECG Lead Off detected for Biosensor(Biosensor ID) @13:00 Apr 23.
Relay Disconnected (SPR or MPR)	Relay (Relay ID) has lost connection with the Central Server @13:00 Apr 23.
SpO_2 sensor off from body (2A Biosensor)	SpO_2 Sensor Off from body detected for Biosensor (Biosensor ID) @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 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 to the Clinician/Caregiver mobile or computer is dependent on the internet/mobile network connectivity.

Table 11 - Clinical Alert Condition Delay Time – User Selectable

Parameters	Default (seconds)	Minimum* (seconds)	Maximum (seconds)
Heart Rate (Low or High)	5	5	300
Respiration Rate (Low or High)	60	30	300
SpO_2 (Low or High)	60	20	300
Pulse Rate (Low or High)	60	20	300
Skin Temperature (Low or High)	120	20	300

Body 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 12 - Technical Alert Condition Delay Time – User Selectable

Parameters	**Default (seconds)**	**Minimum* (seconds)**	**Maximum (seconds)**
ECG Lead-off / SpO_2 sensor off from body	5	5	300
Low Battery / Replace Biosensor	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
Invalid SpO_2 (error code xxx)	15	15	300
Body temperature unavailable	15	15	300

Table 13 - 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 14 - 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 / SpO_2 / Body temp	Un-Ack	OFF	5 min			
	Ack		15 min			
Body temperature unavailable	Un-Ack	OFF	15 min			
	Ack		1 hour			

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 15 - 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
Body Temperature	High (°C)	LOW	38.0	37.0	43.0
	Low (°C)		35.0	32.0	36.0
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		

8.3 Monitoring SpO2

Notice

Traditionally, SpO_2 pulse rate was compared with ECG calculated heart rate to confirm validity of the SpO_2 reading. With newer algorithms, such as UbiqVue this is no longer a valid criteria because the correct calculation of SpO_2 is not directly linked to the correct detection of each pulse.

When a very low pulse rate or strong arrhythmias are present, the SpO_2 or Pleth pulse rate may differ from the ECG calculated heart rate and does not indicate an inaccurate SpO_2 reading. Use the signal quality index (SQI) or the PPG waveform instead to assess accuracy of the SpO_2 measurement.

With pulse oximetry, heavy respiration, activity or electromagnetic interference can give unexpected intermittent readings when the Biosensor is not properly attached to a patient.

UbiqVue Wireless Patient Monitoring System provides three pulse oximetry measurements:

• Oxygen saturation of arterial blood (SpO_2) - percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).

• Pleth or PPG waveform - visual indication of patient's pulse

• Pulse rate (derived from Pleth or PPG waveform) - detected pulsations per minute

Additionally, a Signal Quality Indicator (SQI) is displayed with the SpO_2 numeric values.

Table 16 - Signal Quality Indicator (SQI)

Number of Bars	Signal Quality Indicator
	Poor signal quality - SpO_2 numeric values are not displayed
	Very low signal quality - Check Biosensor adhesion on the skin
	Low signal quality - Check Biosensor adhesion on the skin
	Moderate signal with artifacts - If this continues, check Biosensor adhesion on the skin
	Good signal
	Excellent signal

Notice

Measurement validation: The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. Functional tester shall not be used to assess the accuracy of SpO_2 performance.

Accuracy of pulse rate is root-main-square (RMS) difference of paired pulse rate data recorded with an electronic pulse simulator.

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9 Regulatory

9.1 Standards used in design, development, labelling, and testing

Table 17 - 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

9.2 EMC compliance and warning statement

IEC 60601-1-2: 2014

The LifeSignals 2A 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 environments 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 Biosensor. Otherwise, degradation of the performance of this equipment could result.

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. Please affix Biosensor on body as instructed in this manual for maintaining the separation distance.

9.3 Guidance and manufacturer's declaration – electromagnetic emissions

Table 18 - Guidance and manufacturer's declaration – electromagnetic emissions

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	

9.4 Guidance and manufacturer's declaration – electromagnetic immunity

Table 19 - 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 portable and 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.			

9.5 EMC guidance

In accordance with Clause 4.3 of IEC 60601-1, the Essential Performance of UbiqVue 2A Wireless Patient Monitoring System is:

- Data loss between Biosensor & 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 Biosensor. In case of potential exposure to this equipment, the user is encouraged to try to correct the interference by one or more of the following measures:

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

9.6 Symbols

Table 20 - 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 of the Biosensor as battery/electronic waste - controlled by local regulations.
 NNNNN	GUDID (Level 0) & Serial No.	On PCBA – Level 0 – GUDID in data matrix format & Serial number in human readable format.
 XXXXX	GUDID (Level 0) & Pairing ID	On Biosensor – Level 0 – GUDID in data matrix format and Pairing ID in human readable format.
	GUDID (Level 1,2 & 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 / Labeller Product number.
	Quantity	Number of devices in pouch or multi-carton box.
	Prescription only device	To be used under prescription supervision by a medical practitioner.
	Electronic instructions for use	To indicate on 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 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 device in packaged condition before 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 tall.
FCC ID	Federal Communications Commission	Federal Communications Commission ID.

Label	Identification	Description
	MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.
	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD.
	Authorized representative of Country	Authorized representative of Country XX - Country code as per ISO 3166-1.
	Importer	Indicates entity importing the medical device into the locale.
	Distributor	Entity distributing the medical device into the locale.
	Damaged packaging	Do not use if package is damaged. Device must not be used if the package holding the device is damaged.

For printed copies, contact your Provider (details available on packaging and product labels).