LifeSignals

Multi-parameter Remote Monitoring Platform (LX1550E)

User Manual

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1. Intended Use/Indications for Use

- The LifeSignals Multi-parameter Remote Monitoring Platform is a wireless remote monitoring system intended for use by healthcare professionals for the continuous collection physiological data at home and in healthcare settings. This shall include Electrocardiography (2-channel ECG), Heart Rate, Respiration rate, Skin Temperature & Posture. Data is transmitted wirelessly from LifeSignals Biosensor to Remote secure server for display, storage & analysis.
- The LifeSignals Multi-parameter Remote Monitoring Platform is intended for non-critical, adult population.
- The LifeSignals Multi-parameter Remote Monitoring Platform can include the ability to notify healthcare professionals when physiological parameters fall outside the set limits and to display multiple patient physiological data for remote monitoring.

Note: The terms Biosensor and Patch are used interchangeably throughout this document.

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.

3. Product Description

The LifeSignals Multi-parameter Remote Monitoring Platform contains four components:

- LifeSignals Multi-parameter Biosensor - LP1550E (referred as "Biosensor")
- LifeSignals Relay Device - LA1550-RA (Application Part number)
- LifeSignals Secure Server - LA1550-S (Application Part number
- Web Interface / Remote Monitoring Dashboard – LA1550-C

3.1 LifeSignals Multi-parameter Biosensor

The Biosensor is based on the LifeSignals' proprietary semiconductor chip (IC), LC1100, that has a fully integrated sensor & wireless systems. The LX1550E Biosensor supports WLAN (802.11b) wireless communications.

(1. Right Upper electrode 2. Left Upper electrode 3. Right Lower electrode 4. Left Lower electrode)

Figure 2. Wearable Biosensor

The Biosensor acquires physiological signals, pre-processes and transmits as two channels of ECG signals (Fig. 2 – Channel 1: Right Upper electrode – Left Lower electrode & Channel 2: Right Upper electrode - Right Lower electrode), TTI respiration signals (one of the input for deriving Respiration Rate), resistance variation of Thermistor attached to the body (used for deriving skin temperature) & accelerometer data (input for deriving Respiration Rate & Posture). The Biosensor does not contain any natural rubber latex.

3.2 Relay Application

The Relay Application (App) can be downloaded onto a compatible mobile phone or tablet and manages the wireless communication between the Biosensor and the LifeSignals Secure Server.

The Relay App performs the following functions.

- Manages secured wireless communication (WLAN 802.11b) between Relay device & Lifesignals Biosensor and encrypted communication between the Relay device and the LifeSignals Remote Secure Server.
- Receives physiological signals from the Biosensor and transmit them after encryption to Secure Server as quickly as possible. It manages the database in Relay device for buffering/storing the data securely, if there is any disruption in communication with the Secure Server.
- Provides user interface for entering the Biosensor & Patient information and pairing & establishing connection with the Biosensor.
- Provides User Interface to record any manual alert events by the patient.

3.3 LifeSignals Secure Server

Secure Server is a LifeSignals Secure Server Application software installed in a compatible Linux based hardware platform of LifeSignals Inc. or any 3rd Party.

LifeSignals Secure Server Application manages the decryption, uploading and storage of Biosensor data received from multiple authenticated Relay devices. The "*Sensor Processing Library*" installed in Secure Server then process, filters the received physiological signals and derives Heart Rate, Respiration Rate, Skin Temperature & Posture before storing them in a secured location along with the received Biosensor data. These derived parameters and received data of various Biosensor shall be accessed by LifeSignals Remote Monitoring Dashboard or any 3rd party software for display or analysis purpose.

LifeSignals Secure Server Application shall have optional ability to send alert notifications to any configured destination (email, SMS, WhatsApp), when the parameters (Heart Rate, Respiration Rate or Skin temperature) of a specific Biosensor (patient) exceeds the configured limits.

3.4 Remote Monitoring Dashboard/Web UI

LifeSignals Web UI / Remote Monitoring dashboard is a web-browser User Interface Application that enable Care Provider (Clinical personnel) to login to the Secure server remotely and access the patient physiological data (Biosensor & derived data) & Alert status. The Care Provider (Clinical personnel) depending on the roles (normal or supervisory) can access multiple patient data and search them based on the recent alert status. This includes patients that are active (wearing Biosensor) and procedures completed.

Remote Monitoring Dashboard/Web UI shall also have an ability to continuously display physiological parameters (Heart Rate, Respiration Rate, Skin Temperature, Posture) & waveforms (ECG & Respiration) of multiple patients (up to 16 patients in single screen) or single patient quasi-real time remotely on the screen for monitoring by a Care Provider (Clinical personnel).

4. Warnings

- DO NOT USE if the patient has a known allergic reaction to adhesives or electrode hydrogels.
- DO NOT use if the patient has inflamed, irritated or broken skin in the Biosensor placement area.
- The patient should remove the Biosensor if skin irritation such as severe redness, itching or allergic symptoms develop and seek medical attention if an allergic reaction persists beyond 2 to 3 days.
- The patient should not wear the Biosensor for more than the prescribed hours.
- The patient should remove the Biosensor immediately if their skin feels uncomfortably warm or experience a burning sensation.
- The Biosensor should not be used as an apnea monitor and it has not been validated for use in the pediatric population.

5. Precautions

- Advise patient to avoid sleeping on their stomach, as this may interfere with the Biosensor performance.
- DO NOT use the Biosensor if the package has been opened, appears damaged or has expired.
- Advise patients to avoid use of the Biosensor near (less than 2 meters) any interfering wireless devices such as certain gaming devices, wireless cameras, or microwave ovens.
- Advise patients to avoid use of the Biosensor near any RF emitting devices such as RFID, electromagnetic anti-theft devices & metal detectors as this could affect communication between Biosensor, Relay device & Server resulting in interruption of monitoring.
- The Biosensor contains a battery. Dispose of the Biosensor in accordance with local laws, care facility laws or hospital laws for routine/non-hazardous electronic waste.
- If the Biosensor becomes soiled (e.g. coffee spill), advise patients to wipe clean with a damp cloth and pat dry.
- If the Biosensor becomes soiled with blood, and/or bodily fluids/matter, dispose in accordance with local laws, care facility laws or hospital laws for biohazardous waste.
- DO NOT allow the patient to wear or use the Biosensor during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.
- DO NOT reuse the Biosensor, it is for single use only.
- Advise patients to keep the Biosensor out of reach of children and pets.
- Advise patient to keep showers short with their back to the flow of water while showering. Gently pat dry with a towel and minimize activity until the Biosensor is fully dry and not to use creams or soap near the Biosensor.
- The patient should not immerse the Biosensor in water.
- The Biosensor should remain within the operating distance of the Relay (mobile) device (< 5 meters) for uninterrupted monitoring.
- The Relay (mobile) device uses a mobile data network (3G/4G) for its function. Before international travel, it may be required to enable data roaming.
- To ensure continuous streaming of data, the Relay (mobile) device should be charged once every 12 hours or whenever there is a low battery indication.
- Setting the alert threshold limits to extreme value can render the alert system useless.

6. Cybersecurity controls:

- To protect against unauthorized use and cybersecurity threat, enable all access control systems on Mobile device (Password protection and/or Biometric control)
- Enable automatic application updates in Relay device for any automatic cybersecurity updates of Relay Application

7. For Optimal Results

- Perform skin preparation according to the instructions. If required, remove excess hair.
- Advise patients to limit activity for one hour after the Biosensor has been applied to ensure good skin adherence.

- Advise patients to carry out normal daily routine but avoid activities that cause excessive sweating.
- Advise patients to avoid sleeping on their stomach, as this may interfere with the Biosensor performance.
- Choose a new skin placement area with each additional Biosensor to prevent skin trauma.
- Advise patients to remove Jewelry such as necklaces during the monitoring session.

8. LED Status Indicators

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

Light	Status
Slow flash	Biosensor is connected to Relay App
Fast flash	Biosensor is connecting to Relay App
Slow flash	Low Battery indication
Alternative flashing	Response to receiver's "Identify Biosensor" command.
Fast flash *Off*	Biosensor "Turned off"

Table 1. LED status

9. Configuring the Mobile Phone/Tablet as a Relay Device

- **Note:** This section can be ignored if the Mobile Phone is already configured as Relay device by the IT Administrator.
- You can only use a compatible mobile phone/tablet as a Relay device. Please visit https://support.lifesignals.com/supportedplatforms for a detailed list.

a) Download and install LifeSignals Relay App on the mobile phone/tablet.

b) Download the Authentication Key received from the Secure Server Administrator (step 17.3 i) and place it in 'Download' folder of the mobile phone/tablet (internal storage). Refer to steps in section 17.3 on authentication key generation	
c) Select '**OPEN**' (Relay App).	
d) Select '**Allow**'.	
e) Select '**Allow**'.	
f) The Introduction Screen is then displayed, select '**Next**'.	
g) The Relay App automatically begin authenticating.	
h) When complete, click '**OK**'.	

10. Start Monitoring

10.1 Perform Skin Preparation

a) If required, remove excess hair from upper left chest area. **b)** Clean the area with non-moisturizing soap and water. **c)** Rinse the area making sure you remove all soap residues. **d)** Dry the area vigorously.	

Note: Do not use wipes or isopropyl alcohol to clean the skin prior to applying the Biosensor. Alcohol dries the skin, increases the possibility of skin irritation and can reduce the electrical signal to the Biosensor.

10.2 Assign Biosensor to the Patient

a) Open the LifeSignals Relay App on your device. **b)** Remove the Biosensor from the pouch. **c)** Select '**Next'**.
d) Manually input the unique Patch ID. ***Or*** **e)** Scan the QR code / barcode. **f)** Select '**Next**'.
g) Enter Patient Details (Patient ID, DOB, Doctor, Sex). ***Or*** **h)** Scan the barcode in the patient ID bracelet. Select '**Next'**.
i) Select '**I AGREE**'.

Note: Check the expiry date and the outer package for any damage. If data is not entered in the mandatory fields (Patient ID, DOB, Doctor), an error message highlighting the fields with missing information will appear.

10.3 Connect Biosensor

a) If requested, turn on Mobile Hotspot in your phone/tablet settings. **b)** Configure phone hotspot with these details - SSID (**Biosensor ID**). **c)** Enter Password '**copernicus**'.
d) Return to Relay App - Select '**OK**'.
e) Press the Biosensor '**ON**' button once. (A red light will flash followed by a flashing green light).
f) The mobile phone/tablet will automatically connect to the Biosensor.

10.4 Apply Biosensor

a) Gently peel off the protective backing film. **b)** Place the Biosensor on the upper left chest, below the collar bone and left of the sternum. **c)** Press the Biosensor firmly around the edges and center for 2 mins.
d) Select '**Next**'.

Note: If the connection is not successful within 2 minutes of turning on, the Biosensor will switch OFF automatically (auto-power off).

10.5 Confirm and Start Monitoring Session

a) Scroll down to check quality of ECG & respiration waveforms. **b)** If acceptable, Select '**Continue'**.
c) If unacceptable, Select '**Replace**'. **d)** Select '**SWITCH OFF**'. The user will be brought back to 'Assign Biosensor to the patient'.
e) Click '**CONFIRM**' to start monitoring session.
f) The Biosensor is connected and the remaining time for the monitoring session is displayed.

11. Report Symptoms during Monitoring

a) Press the 'Green' button on the Relay App. once. ***Or*** **b)** Press the Biosensor '**ON**' button once.
c) Select appropriate symptom(s). **d)** Select activity level. **e)** Select '**Save**'.

12. End of Monitoring

a)	When session duration has been reached, the session completes automatically.
b)	Click '**OK**'.
c)	If required, another Biosensor can be assigned to initiate another monitoring session. Follow the instructions of Clinical Personnel on how to replace another Biosensor & continue session.

13. Advice for Patients

Inform the patient to:

- Limit activity for one hour after the Biosensor has been applied to ensure good skin adherence.
- Carry out normal daily routine but avoid activities that cause excessive sweating.
- Press the ***Biosensor ON*** button or the ***Relay App Green button ONCE*** to report a symptom.
- Keep showers short with their back to the flow of water while showering.
- If the Biosensor accidentally gets wet, gently pat dry with a towel and minimize activity until the biosensor is fully dry.
- If the Biosensor loosens or starts to peel away, press down the edges with their fingers.
- Avoid sleeping on their stomach, as this may interfere with the Biosensor performance.
- Occasional skin itchiness and redness are normal around the Biosensor placement area.
- Charge the Relay (mobile) device once every 12 hrs or whenever there is low battery indication.
- There may be some restriction in using the Biosensor and Relay App whilst flying, for example during take-off and landing, so you might have to turn off your mobile phone/tablet.

14. Inform your Patient

- The Flashing green light is normal. When the monitoring session is complete, the green light will stop flashing.
- To remove the Biosensor, gently peel off the four corners of the Biosensor, then slowly peel off the remainder of the Biosensor.
- The Biosensor contains a battery. Dispose of the Biosensor in accordance with local laws, care facility laws or hospital laws for routine /non-hazardous electronic waste.

15. Troubleshooting Alerts – Relay App

ALERT	SOLUTION
a) Enter Patch ID If you forget to enter the Patch ID and select '**Next'**, this alert will be displayed.	Enter Patch ID, then select '**Next**'.
b) Lead Off If any of the Biosensor electrodes become loose and lose contact with the skin, this alert will be displayed.	Press all the electrodes firmly on the chest. Ensure alert disappears.
c) Patch connection lost! Try holding your phone closer to the Patch. If the Patch is too far away from the mobile phone/tablet, this alert will be displayed.	Keep the mobile phone/tablet within 5 meters of the Patch at all times.
d) Transfer to Server failed. Please check network connectivity If the mobile phone/tablet is not connected to the network, this alert will be displayed.	Check the cellular network connection on your mobile phone/tablet

16. Additional Features – Relay App

INSTRUCTIONS	EXPLANATION
a) Select Menu icon.	User can view Additional information
b) Select "**Identify Patch**". Note: - The LED on the patch will blink five times, to identify the Patch that is currently being monitored.	Identifies the Biosensor that is currently in use.

c) Select '**Stop Session'**. **Note**: - Contact your technical support for password.	Correct password will stop monitoring session.
d) Select '**Session Summary'**. **e)** Select '**Back'** to return to 'report symptom' screen.	Provides current details about the monitoring session.
f) Select '**About Relay'**. **g)** Select '**OK'** to return to 'Home screen.	Extra details are shown about the Relay

17. Monitoring Patients – Web Application

17.1 Add New User (Applicable only for the user with Administrative Privilege)

a) Login to LifeSignals Web Application, select '**Manage Users**'.
b) Select **Add User**'.
c) Select the desired "Role" and fill in all the appropriate information. **d)** Select '**ADD USER**'.

17.2 Delete Existing User (Applicable only for the user with Administrative Privilege)

a) Select '**Manage Users'.**
b) Select Username. **c)** Select 'DELETE'

17.3 Adding & Configuring a new Relay device / Default Biosensor alerts

a) Select '**Manage Relays**'.
b) Select '**Add Relay**' **c)** This enables the user to create an authentication key that will be saved in the "Download" folder in your system.
d) Enter the chosen contact method- WhatsApp/Email- for alert notifications and the default Biosensor Alert Thresholds. **e)** Select maximum operating time of the Biosensor **f)** Enter the relay ID and select create as highlighted
g) Relay device authentication key (file name: 'server key') will be generated and downloaded to the local drive **h)** Select the desired folder and select save.
i) Forward this key to the IT administrator who will configure the Mobile phone as a Relay device.
j) Select the created Relay ID.
k) Set the default Alert Thresholds to the Biosensor connected to this selected relay (Note. This alert thresholds can be modified for each Biosensor - Ref 17.6)

17.4 Recent Alerts & Adjusting Individual Alert Settings

a) Select '**Recent Alerts**'.
b) A list of recent alerts is displayed.
c) Select Patient ID & Select '**Alert Settings**'.

d) Review and edit alerts – Select '**Save**' to update Alert Thresholds.

17.5 Technical Alerts of Active Patients

a) Select '**Technical Alerts**'. **b)** A list of technical alerts is displayed.

17.6 Monitoring Active Patients using Dashboard

a) Select '**All Active Patients**'.
b) A list of Active Patients is displayed.
c) To display a patient on the Dashboard - Select Patient ID & Select '**Add to Dashboard**'.
d) The selected Patient's data will be displayed on the Dashboard.
e) From the Dashboard - Select the individual Patient ID to review data in more detail.
f) Select on trend icon to Display the trend visualisation for the patient
g) Detailed patient trend visualisation shows up on screen for the patient.
h) Select '**Alert Settings**' to review and edit Alarm Thresholds.
i) Once completed – Select '**Save**' to update Alert Thresholds.
j) Alert Settings can also be accessed from the All Active Patients.

17.7 Downloading the data from the completed session.

a) Select '**Completed Biosensors**'.
b) A list of Completed biosensors is displayed

17.8 Unused Biosensors

a) Select **'Unused Biosensors'**.
b) A list of Unused Patches is displayed.

Note: This feature shall be supported only if Secure server is integrated with Inventory management system.

17.9 Change Password

a) Select on the Profile (Admin as shown in picture). b) Select '**Change Password**'.
c) Enter New password in the 'New Password' text box. d) Re-enter Password in 'Confirm Password'. e) Select '**Change password**' to complete the process.
f) The password requirements would pop-up when cursor is taken to the "**i**" next to New password

Note: Password should be minimum of 8 characters (include one number, one special character, one uppercase & one lowercase letter).

18. Appendix

18.1 Table 1 : Technical Specifications

Physical (Biosensor)	
Dimensions	105 mm x 94 mm x 12 mm
Weight	28 gm
Status LED Indicators	Amber, Red and Green
Patient Event Logging Button	Yes
Water ingress protection	IP24
Specifications (Biosensor)	
Battery type	Primary Lithium Manganese dioxide Li-MnO2
Battery Life	120 hours (under continuous transmission under normal wireless environment)
Wear Life	120 hours (5 days)
Defib Protection	Yes
Applied Part Classification	Defibrillation-proof type CF applied part
Operations	Continuous
Usage (Platform)	
Intended environment	Home, Clinical and Non-Clinical facilities
Intended Population	18 years or older
MRI safe	No
Single use / Disposable	Yes
ECG Performance and Specifications	
ECG number of channels	Two
ECG sampling rate	244.14 and 976.56 samples per second
Frequency response	0.2 Hz to 40 Hz and 0.05 Hz to 150 Hz
Lead off detection	Yes
Common Mode rejection ratio	> 90dB
Input Impedance	> 10 Meg ohms at 10Hz
ADC Resolution	18 bits
ECG Electrode	Hydrogel

Heart Rate	
Heart rate range	30 – 250 bpm
Heart rate accuracy (Stationary & Ambulatory)	± 3 bpm or 10% whichever is greater
Heart rate resolution	1 bpm
Update period	every beat
Heart rate method	Modified Pan-Tompkins
Respiration Rate	
Measurement Range	5-60 breaths per minute
Measurement Accuracy	➢ 9-30 Breaths per Minute with a mean absolute error of less than 3 Breaths per Minute, validated by clinical studies ➢ 6-60 Breaths per Minute with a mean absolute error of less than 1 Breaths per Minute, validated by simulation studies
Resolution	1 breath per minute
Respiration rate algorithm	TTI (Trans-thoracic Impedance), Accelerometer and EDR (ECG Derived Respiration).
TTI injection signal frequency	10 KHz
TTI Impedance variation range	1 to 5 Ω
TTI Base Impedance	200 to 2500 Ω
Update period	4 sec
Maximum Latency	20 sec
EDR - ECG derived respiration	R-S amplitude
Skin Temperature	
Measurement Range	29°C to 43 °C
Measurement Accuracy (Lab)	± 0.2°C
Resolution	0.1°C
Sensor Type	Thermistor
Measurement site	Skin (chest)
Update Frequency	1 Hz
Accelerometer	
Accelerometer Sensor	3-Axis (digital)
Sampling Frequency	25 Hz
Dynamic Range	+/-2g
Resolution	16 bits
Posture	Lying, Upright, Inclined
Wireless & Security	
Frequency Band (802.11b)	2.400-2.4835 GHz
Bandwidth	20MHz (WLAN)
Transmit Power	0 dBm
Modulation	Complementary Code Keying (CCK) and Direct Sequence Spread Spectrum (DSSS)
Wireless Security	WPA2-PSK / CCMP
Data Rate	1, 2, 5.5 and 11 Mbps
Wireless Range	5 meters (typical)

Environmental	
Operational temperature	+0 ºC to +45ºC (32ºF to 113ºF) Maximum applied part measured temperature may vary by 0.5 ºC
Operational relative humidity	10 % to 90 % (non-condensing)
Storage temperature (< 30 days)	+0ºC to +45ºC (32ºF to 113ºF)
Storage temperature (> 30 days)	+10ºC to +27ºC (41ºF to 80ºF)
Transportation temperature (⩽ 5 days)	-5ºC to +50ºC (23ºF to 122ºF)
Storage relative humidity	10% to 90% (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Shelf life	12 months

Note*: QoS verified for 10 meters range in bench setup.

18.2 Table 2. Relay Application Messages

Message	Description
Unable to connect to server, Try again	Server unavailable
RelayID [relay_id] is authenticated successfully.	Authentication success
Authentication failed. Try again with correct key	Authentication failure
Key Error, Authentication failed. Try again with correct key	Failed to import Server key
Turning off the Patch...	Patch turning off
Failed to switch off the Patch	Patch failed to switch off
Copy Server key to the Download folder	Server key missing from download folder
Try when network connectivity is present	Internet/Server not available
Reconfigure Patch with a different password?	After Biosensor is configured, you can change the password
"Insufficient space to store data (" + (int) reqMB + "MB required). Delete any unwanted files or photos."	Insufficient Memory on the mobile device
Failed to switch off the Patch.	On socket error on turn-off
Patch battery level is low	Battery level lower than 15%
"Patch password updated" Reconfigure the hotspot SSID [value] password[value]	Patch password successfully reconfigured
Failed to reconfigure the Patch	Unable to reconfigure Patch password
Ending session...	Monitoring session ending
Session completed!	Monitoring session completed
Session completed!	On Finalize completed
Patch connection failure. Select OK to retry.	Socket error on set mode
Failed to reconfigure the Patch	Socket error on reconfigure

18.3 Table 3: Web Application Messages

Messages	Description
Invalid Login!	Login credentials are invalid
Remove relay Failed!	Server was not able to execute remove relay command
Relay removed!	Server successfully executed remove relay command
Patch Archived!	Server successfully executed remove patch command
Please provide a valid HR High value	Invalid HR High value.
Please provide a value between 100 BPM to 250 BPM	HR High value is not within the valid range.
Please provide a valid HR Low value	Invalid HR Low value.
Please provide a value between 30 BPM to 100 BPM	HR Low value is not within the valid range.
Please select a valid Scan Interval	Scan Interval has not been selected from the dropdown menu
Please select a valid Notification Address	Notification address has not been selected from the dropdown menu
Relay added successfully!	Sever key was generated successfully
Relay Updated successfully!	Relay parameters were edited successfully
User removed!	The user was successfully removed.
Please provide a valid Username	Invalid Username.
Please provide a valid Password.	Invalid Password.
Username already taken! Please try another one.	The entered username already exists.
Password should be of 8 or more characters in length and should contain at least one numeric digit, one special character, one uppercase and one lowercase letters.	The password must meet all the specified parameters
User added successfully!	The user was successfully added to the database.
Confirm password	Re Enter password in 'Confirm Password' text box
Confirm password do not match New Password!	The password in the 'New Password' text box does not match the password in the 'Confirm Password' text box.
Invalid Login!	The username entered does not exist.
Password changed successfully!	The password was successfully updated.
Patient Updated Successfully!	Patient Details Updated from Patient Management Module

Event Added Successfully	Add event from Patient Management, Zoom view
Please provide a value less than 102.2 °F	Maximum allowed value is 102.2 °F
Temp High should be at least 2 point greater than temp Low value	Temp Min/Max difference should be minimum of 2°F
Please provide a value greater than 85 °F	Temp Low value must be greater than 85 °F
Please provide a value less than 50 BrPM	RR Low value must be lower than 50 BrPM
Resp High should be at least 2 point greater than resp low value	RR Min/Max difference should be minimum of BrPM
Please provide a value greater than 6 BrPM	RR low value must be higher than 6 BrPM
Please provide a valid relay id	Relay Id from User in create Relay
Invalid Contact No.	Add/Edit User Phone
enter a valid email address	Add/Edit User Email
Biosensor Disconnected	Biosensor to server communication is absent
Relay Disconnected	Relay App to server connection absent
Request for Stop Procedure has Initiated	Request for Stop Procedure is Success
Earlier request Pending	No of active Requests for Stop Procedure is >1
Request successful, you will get the EDF link sent to the given email	Request for EDF is Success
Earlier request Pending for the Patient	No of active Requests for EDF is >1
<BIOSENSOR_ID> are already streaming. Please remove	Biosensor already added to dashboard

18.4 Table 4. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Biosensor is intended for use in the electromagnetic environment specified below.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11 / EN5501	Group 1	Biosensor use 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	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.

18.5 Table 5. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Biosensor is intended for use in the electromagnetic environment specified below.	
Immunity test	**Compliance Level test level**
Electrostatic discharge (ESD) as per IEC 61000-4-2	± 8 kV contact ± 15 kV air

Power frequency magnetic field as per IEC 61000-4-8	30 A/m
Radiated RF as per IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz, 80% AM at 1 KHz

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.

18.6 FCC Statement

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 8.6mm 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.

18.7 Table 6. 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 shall be separated when disposed of	Dispose of the Biosensor as battery waste - controlled by local regulations
	GUDID (Level 0) & Serial No.	On PCBA – Level 0 – GUDID in data matrix format & Serial number in human readable format.
	GUDID (Level 0) & Pairing ID	On Patch – 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

REF	Catalog Number	Device Catalog number / Labeler Product number
QTY	Quantity	Number of devices in pouch or multi-carton box
Rx Only	Prescription only device	To be used under prescription supervision by a medical practitioner
	Consult instructions for use	Refer to instruction manual
	Temperature range	Storage (long term) within the specified temperature range
	Expiry Date (YYYY-MM-DD)	Use device in packaged condition before expiry date
	Manufacturing date	Device manufacturing date
LOT	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
5	Max Stack	Do not stack more than 5 boxes tall
FCC ID	Federal Communications Commission	Federal Communications Commission ID
MR	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
EC REP	Authorized representative of European Community	Authorized representative of European Community
CE	CE marking	CE marking indicates product conformance with the applicable European Union Directives

18.8 Contact Information

Manufacturer:

LifeSignals, Inc.
426 S Hillview Drive,
Milpitas, CA 95035, USA
Customer service (USA): +1 510.770.6412
www.lifesignals.com
email: info@lifesignals.com

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European Representative:

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IDA Business Park, Garrycastle,
Dublin Rd, Athlone, N37 F786, Ireland
email: info@lifesignals.com

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