LifeSignals LX1550 Multi Parameter Remote Monitoring Platform Instruction Manual

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LifeSignals LX1550 Multi Parameter Remote Monitoring Platform

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 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.

Contraindication

- 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.

Product Description

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

- LifeSignals Multi-parameter Biosensor – LP1550 (Referred as “Biosensor”)
- LifeSignals Relay Device – LA1550-RA (Application Software Part number)
- LifeSignals Secure Server – LA1550-S (Application Software Part number)
- Web Interface / Remote Monitoring Dashboard – LA1550-C**

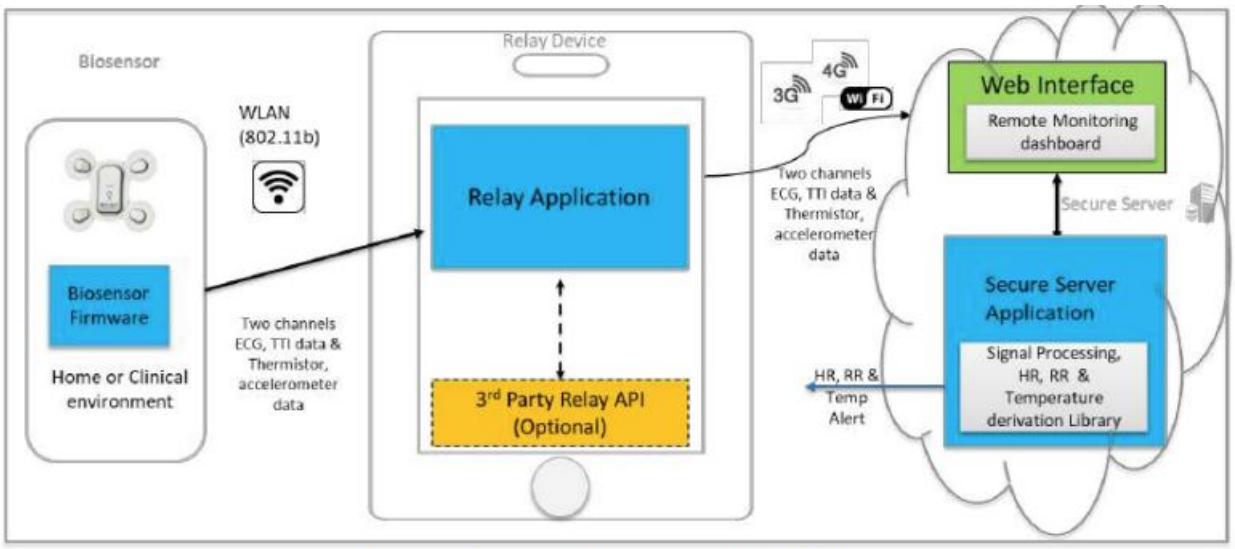


Figure 1. Remote Monitoring Workflow

LifeSignals Multi-parameter Biosensor

The Biosensor is based on the LifeSignal's proprietary semiconductor chip (IC), LC1100, that has a fully integrated sensor & wireless systems. The LX1550 Biosensor supports WLAN (802.11b) wireless communications.

Figure 2. Wearable Biosensor

The Biosensor acquires physiological signals, pre-processes and transmits as two channels of ECG signals, ECG-A and ECG-B (Fig. 2 ECG-A: Right Upper electrode → Left Lower electrode and ECG-B: 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.

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.

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 not immerse the Biosensor in water.
- 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 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.

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.
- Avoid use of the Biosensor near (less than 2 meters) any interfering wireless devices such as certain gaming devices, wireless cameras or microwave ovens.
- 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, advise patient 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.
- 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.

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

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 our 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.

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"

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.

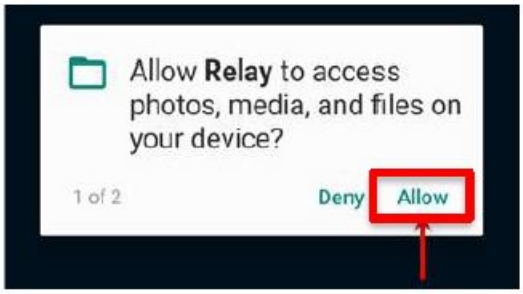
a) Download and install LifeSignals Relay App on the mobile phone/tablet.	

b) Download the Authentication Key received from the Secure Server Administrator and place it in ‘Download’ f older of the mobile phone/tablet (internal

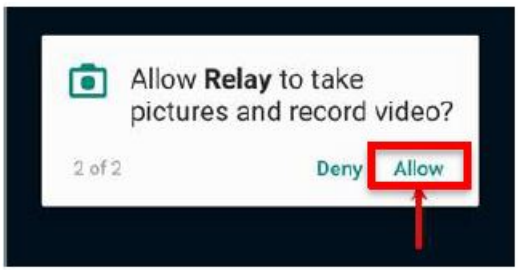
storage). Refer to User manual for authentication key generation instructions.

c) Select OPEN (Relay App).

d) Select Allow.

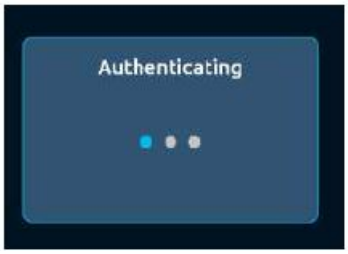


e) Select Allow.



f) The Introductory Screen will be displayed, Select Next.

g) The Relay App will automatically begin the authentication process.



Start Monitoring

Perform Skin Preparation

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

Note: 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.

Assign Biosensor to the Patient

- Open the LifeSignals Relay App on your mobile phone/tablet.
- Remove the Biosensor from the pouch.
- Select Next.

d) Manually input the unique Patch ID. ***Or*** **e)** Scan the QR code / barcode. **f)** Select Next.	 

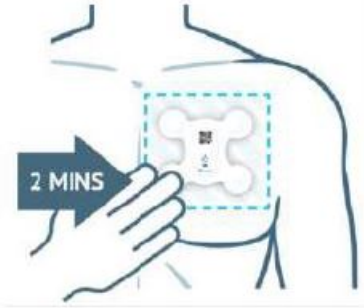
g) Enter Patient Details (Patient ID, DOB, Doctor, Sex). ***Or*** **h)** Scan the barcode in the patient ID bracelet. Select Next.	
i) Ask the Patient to read the Consent statement and press the AGREE option.	

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.

Connect Biosensor

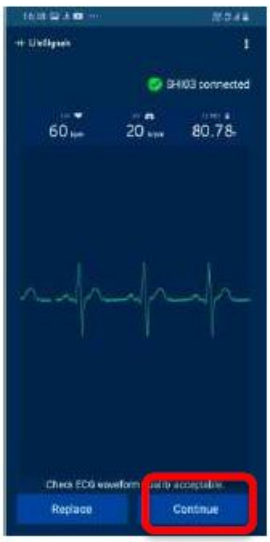
a) If requested, turn on Mobile Hotspot in your pho ne/tablet settings. **b)** Configure phone hotspot with these details – SSID (Biosensor ID). **c)** Enter Password "*copernicus*".	
d) Return to Relay App, select OK.	
e) Press the Biosensor ON button once. (A red light wi ll flash followed by a flashing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

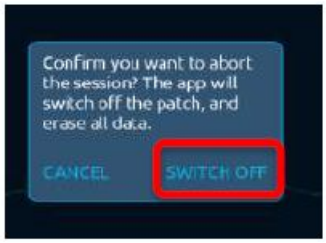
Apply Biosensor

a) Gently peel off the protective backing fil m. **b)** Place the Biosensor on the upper left c hest, below the collar bone and left of the ster num. **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).

Confirm and Start Monitoring Session

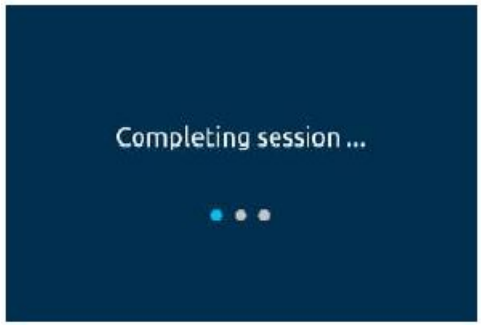
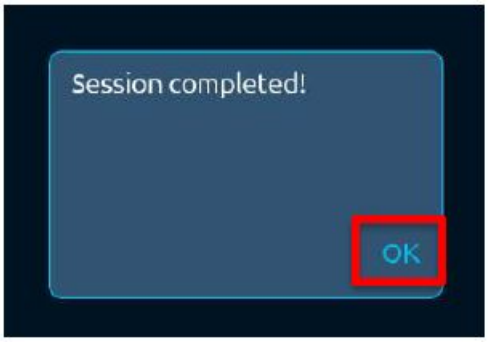
a) Scroll down to ensure good quality ECG and res piration waveforms are present. **b)** If acceptable, select Continue.	

c) If unacceptable, select Replace. **d)** Select SWITCH OFF. The user will be brought b ack to ‘Assign Biosensor to the Patient’.	 
e) Select CONFIRM to start monitoring session.	
f) The Biosensor is connected and the remaining ti me for the monitoring session is displayed.	

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.	

End of Monitoring

a) When the monitoring is completed, the session will stop automatically.	
b) Select OK.	
c) If required, another Biosensor can be assigned to in itiate another monitoring session. Follow the instructio ns on ‘Start Monitoring’.	

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.

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.

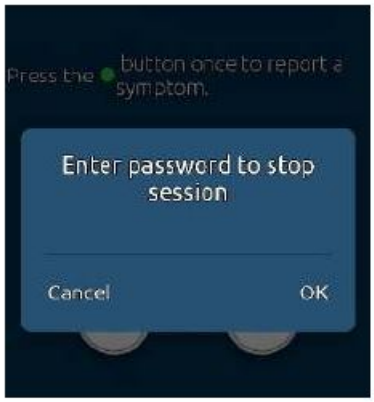
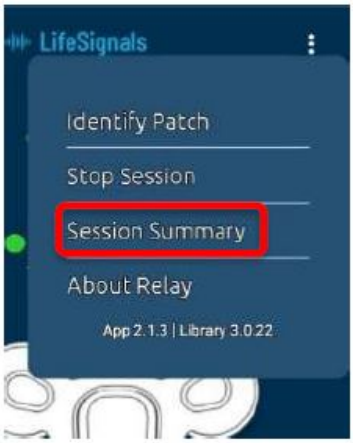
Troubleshooting Alerts – Relay App

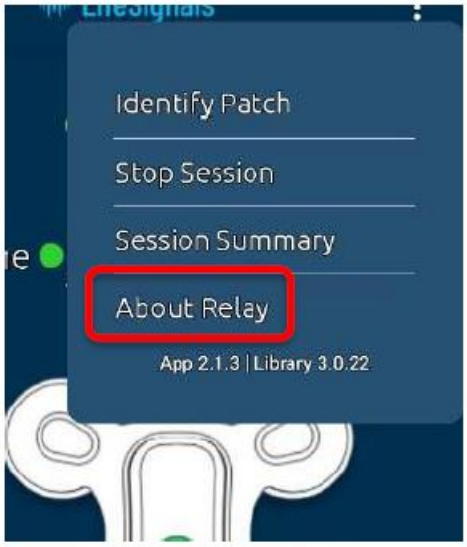
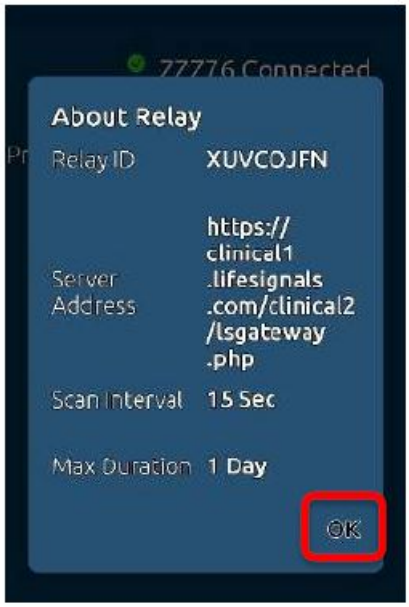
ALERT	SOLUTION
a) Enter Patch ID If you forget to enter the Patch ID and select Next, this aler t will be displayed. 	Enter Patch ID, then Select Next.
b) Lead Off If any of the Biosensor electrodes begin to lift off and lose contact with the skin, this alert will be displayed. 	Press all the electrodes firmly on the chest. Ensur e alert disappears.
c) Patch connection lost! Try holding your phone closer to the Patch. If the Biosensor is too far away from the mobile phone/tabl et, or if there is electromagnetic interference (e.g. metal de tectors), this alert will be displayed. 	Avoid use of the Biosensor near any electromagnetic anti-theft devices and metal detectors. If not sure, bring the mobile phone/tablet closer to the Biosensor when this message appears. .Keep the mobile phone/tablet within 5 meters of t he Biosensor at all times.

d) Transfer to Server failed. Please check network con nectivity If the mobile phone/tablet is not connected to the network, this alert will be displayed.  	Avoid use of the Mobile phone near any electroma gnetic anti-theft devices and metal detectors. Check the cellular network connection on your mo bile phone/tablet.

Additional Features – Relay App

INSTRUCTIONS	IMAGE	EXPLANATION
a) Select Menu icon.	 	User can view Additi onal Information.
b) Select Identify Patch.	 	
Note: – The LED on the Biosensor will blink five times, to identify the Bio sensor that is currently being monitored.	 	Identifies the Biosens or that is currently in use.

c) Select Stop Session. **Note**: – Contact your te chnical support for pass word.	 	Correct password will stop the monitoring s ession.
d) Select Session S ummary. **e)** Select Back to ret urn to 'report symptom' screen.	 	Provides current deta ils about the monitori ng session.

f) Select About Relay. **g)** Select OK to return to ‘Home screen.	  	Extra details are shown about the Relay

Appendix

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
T wave amplitude rejection	1.0 mV
Respiration Rate**	
Measurement Range	5-60 breaths per minute
Measurement Accuracy	Ø 9-30 Breaths per Minute with a mean absolute error of less than 3 B reaths per Minute, validated by clinical studies. Ø 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	32°C to 43 °C
Measurement Accuracy (Lab)	Ø Less than 35.8°C ± 0.3°C Ø 35.8°C to less than 37°C ± 0.2°C

	Ø 37°C to 39°C ± 0.1°C Ø Greater than 39.0°C to 41°C ± 0.2°C Ø Greater than 41°C ± 0.3°C
Resolution	0.1°C
Sensor Type	Thermistor

Measurement site	Skin (chest)
Measurement Mode	Continuous
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 ^{0}C to +45^{0}C (32^{0}F to 113^{0}F) Maximum applied part measured temperature may vary by 0.5 ^{0}C
Operational relative humidity	10 % to 90 % (non-condensing)
Storage temperature (< 30 days)	+0^{0}C to +45^{0}C (32^{0}F to 113^{0}F)
Storage temperature (> 30 days)	+5^{0}C to +27^{0}C (41^{0}F to 80^{0}F)
Transportation temperature (≤ 5 days)	-5^{0}C to +50^{0}C (23^{0}F to 122^{0}F)
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.

** : Respiration Rate value may not be available (shall not be displayed) when patient undergoes significant motion or severe activity

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…	Biosensor turning off
Failed to switch off the Patch	Bisoensor 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 chan ge 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 Biosensor 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

Electromagnetic Compatibility (EMC)

- Biosensor is tested for electromagnetic compatibility in accordance with IEC 60601-1-2:2014 (Refer Section 17.4 & 17.5)
- Biosensor should be used according to the EMC related information provided in the “Warning” and “Caution” sections of this document.
- Electromagnetic disturbances beyond the specification (Ref 17.5) on Biosensor may results in:
    - Loss of communication between Biosensor & Relay device.
    - ECG noise exceeding 50 uV.
    - ECG (full disclosure) data loss more than 0.035%

Table 3: 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 i n nearby electronic equipment.
RF emissions CISPR 11 /EN5501	Class B	Biosensor is suitable for use in all establishments, including domesti c establishments and those directly connected to the public low-volt age power supply network which supplies buildings used for domestic purposes.

Table 4: 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.

FCC Statement (FCC ID : 2AHV9-LP1550)
This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference.
2. 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.

Table 4. Symbols

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
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
Catalog Number	Device Catalog number / Labeler 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
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 Code	Manufacturing Batch or LOT code
Applied part	Defibrillation-proof, Type CF Applied Part
Do not reuse	Do not reuse; single patient use

Ingress Protection Rating	Protection against solid objects that are over 12.5 mm (e.g. large t ools 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 5 boxes tall
Federal Communications Commission	Federal Communications Commission ID
MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
No pacemaker	Contraindicated for use on patients with active implantable medica l devices including pacemakers, ICD and LVAD

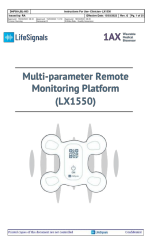
Contact Information

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**

Biosensor is assembled in Republic of Korea

1000001387 | Instructions for Use – Clinician – LX1550 | Rev. G | Printed copies of this document are not controlled |

Documents / Resources

	**LifeSignals LX1550 Multi Parameter Remote Monitoring Platform** [pdf] Instruction Manual LX1550, Multi Parameter Remote Monitoring Platform, LX1550 Multi Parameter Remote Monitoring Platform, Remote Monitoring Platform, Platform

References

- **Homepage | LifeSignals®**