LifeSignals Multi Parameter Remote Monitoring Platform

Technical User Manual

Revision History:

Revision	Date	Description of change	Approved by
Rev A	See IMSXpress	Initial draft release	See IMSXpress
Rev B	See IMSXpress	Refer to Redline Document	See IMSXpress
Rev C	See IMSXpress	Refer to Redline Document	See IMSXpress
Rev D	See IMSXpress	Refer to Redline Document	See IMSXPress
Rev E	See IMSXpress	Refer to Redline Document	See IMSXpress
Rev F	See IMSXpress	Refer to Redline Document	See IMSXpress

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1 Intended 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 in home and healthcare settings. This can include Electrocardiography, Heart Rate, Respiration Rate, skin temperature & body posture in home and healthcare settings. Data is transmitted wirelessly from LifeSignals Biosensor to Remote secure server for display, storage and analysis.
- The LifeSignals Multi-Parameter Remote Monitoring Platform is intended for non-critical, adult population (>18 years).
- The LifeSignals Multi-Parameter Remote Monitoring Platform can include the ability to notify healthcare professionals when Physiological parameters falls outside the set limits.

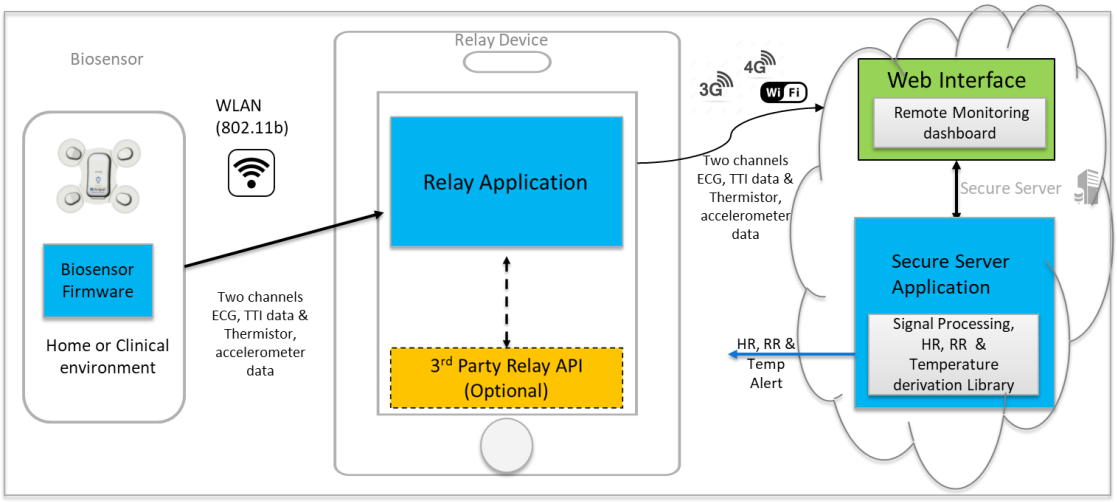
2 Contraindication:

- The Life Signal Multi Parameter Remote Monitoring Platform is contraindicated for use in patients with active implantable medical devices such as pacemakers or implanted cardioverter defibrillators (ICD).

3 Product Description and Workflow:

The Multi-Parameter Remote Monitoring Platform consists of four major components:

- LifeSignals Biosensor Patch - LP1550 (referred as “Biosensor”)
- LifeSignals Relay Device - LP1550-RA (Application Part number)
- LifeSignals Secure Server - LP1550-S (Application Part number)
- Web Interface / Remote Monitoring Dashboard – LP1550-C



Remote Monitoring Workflow

The Multi Parameter Remote Monitoring platform will be able to measure parameters such as 2 channel ECG, Heart Rate, Respiration Rate & skin Temperature. It shall also include accelerometer to detect activities, in addition to providing input to the Respiration algorithm. Respiration algorithm is based on TTI (Trans-thoracic Impedance), EDR (ECG Derived Respiration) and accelerometer data.

4. Warnings:

- Do not use Biosensor on patients who are allergic to adhesive, electrode gel or non-woven materials
- Do not reuse Biosensor. It is a single-use device
- Biosensor is rated for ingress protection rating of IP24. It is not designed for being submerged in water. Hence, avoid swimming while wearing a Biosensor
  Note: Avoid taking direct shower while wearing a Biosensor
- Do not wear Biosensor beyond the recommended maximum wear duration of 120 hours
- Do not use the Biosensor on damaged (irritated or injured) or breached skin
- Do not use the Biosensor beyond the expiration date
- Do not use the Biosensor if the package or the device is damaged, leaking or tampered with
- Do not use the Biosensor if the gel in any of the electrodes is dry, discolored or no longer sticky
- The Biosensor does not have any serviceable parts. Do not try to modify or repair the Biosensor. Any modification may result in patient harm
- Avoid use of the Biosensor near (< 2 meter) other 2.4GHz continuous emission devices such as certain gaming devices, wireless cameras, older cordless phones, or a microwave oven
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Biosensor. Otherwise, degradation of the performance of this equipment could result

- There may be some restriction in using Biosensor & Relay Application in Airport due to FAA regulation of wireless network operation during a certain period (take-off or landing) and TSA regulation of screening Mobile device (Relay device). Further, Relay device is required to be connected to the Internet continuously for transmission of data to Secure Server and some airlines do not offer wireless internet connectivity feature on-board

5. Precautions:

- A new skin site should be used with each new Biosensor to prevent trauma to the skin
- For proper skin management and to minimize skin irritation, skin sites must be properly prepared prior to placement of the Biosensor. Use your facility's electrode application protocol to prepare the site. Alternatively:
    - Ensure placement of the Biosensor only on clean and thoroughly dried skin
    - Remove excess hair with hair clippers to avoid skin damage prior to placement
    - Use Nuprep® or equivalent commercially available ECG skin prep pad per the instructions for use. Do not abrade the skin
    - Avoid removing the Biosensor frequently and/or applying to the same skin site
    - When handling the Biosensor, avoid dropping the device on hard services, or against sharp edges and corners. Do not apply weight or pressure or apply excessive stress on the Biosensor
- Assess the Biosensor site periodically. In the event of skin irritation, itching or discomfort, remove the Biosensor immediately and bring to the attention of clinical care personnel
- Keep the Biosensor dry during use. The Biosensor is IP24 ingress protection rated. Do not immerse the Biosensor in fluids or chemicals
- Recommended long term storage (more than 1 month) temperature is 5ºC to 27ºC
- Do not store the Biosensor package in direct sunlight
- Avoid sleeping in the chest down (prone) position as it will affect the wireless performance
- Avoid wearing Jewellery (like chains) or any accessories that may come in physical contact and potentially catch on, lift or dislodge the biosensor
- Avoid any direct pressure (Example: sleeping in prone position, take care while using aids like safety harnesses, exercise and using exercise equipment etc.) on the biosensor when worn on the body
- Carefully remove the Biosensor at the end of monitoring to avoid skin injury. Use adhesive removal pads to loosen the adhesive
- Recycle the Biosensor in accordance with local, state and federal requirements as Li-MnO2 battery waste
- Keep the Biosensor away from small children
- Biosensor should be within the operating distance of the Relay device (< 5 meters) for uninterrupted monitoring
- Use recommended hardware platform as Relay device. Please visit https://support.lifesignals.com/supportedplatforms for the details for the compatible mobile phones

- Use only the recommended OS version (Android version) for compatibility of Relay Application Please visit https://support.lifesignals.com/supportedplatforms for the details for the compatible operating system
- Relay (Mobile) device uses mobile data network for its function. Hence, necessary precaution (e.g. enabling data while roaming) may be required before international travel
- Relay (mobile) device battery requires necessary charge for this function. Hence international adapter may be required for charging during international travel

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)
- To protect against unauthorized use and cybersecurity threat, configure Biosensor / Mobile device with a Unique SSID & Password and not default SSID & password
- Enable automatic application updates in Relay device for any automatic cybersecurity updates of Relay Application

7. Additional Information:

- Biosensor does not contain any natural rubber latex

8. Indicators & Error Messages:

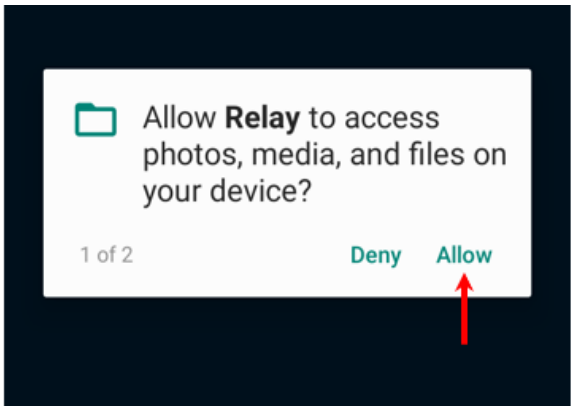
The Biosensor indicator LED provides information related to the functional status of the device

Biosensor LED indicator	Description
Slowly blinking Green LED	Device is connected to a relay device
Rapidly blinking Green LED	Device is attempting to connect to a Relay Device
Slow Blinking Red LED	Low Battery indication
Blinking red and Green light in sequence	Response to receiver's "Identify Biosensor" command
Rapidly Blinking Red LED followed by LED off	Device "Turned off" through a command by the receiver device

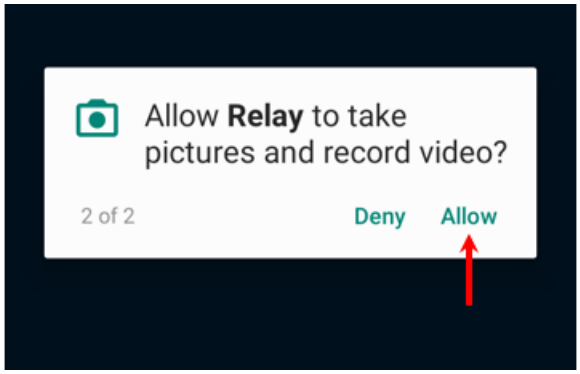
9. Instructions (For Clinical Personnel):

Configuring the Mobile as a Relay Device

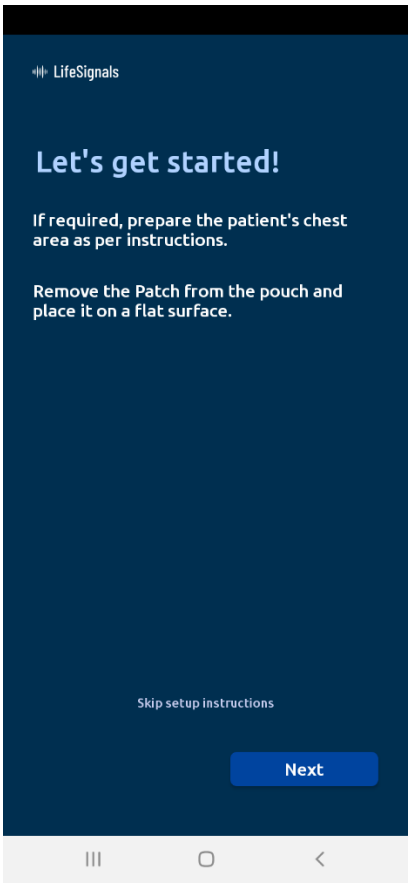
- Use only the compatible mobile phone as a Relay device. Please visit https://support.lifesignals.com/supportedplatforms for the details of compatible mobile phone make, model & OS version
- Download and Install LifeSignals Relay Application to the mobile phone
- Download the Authentication Key received from the Secure Server Administrator and place it in 'Download' folder of the mobile phone (internal storage)
- Open Relay App
- Select "Allow" permission for the app to access storage



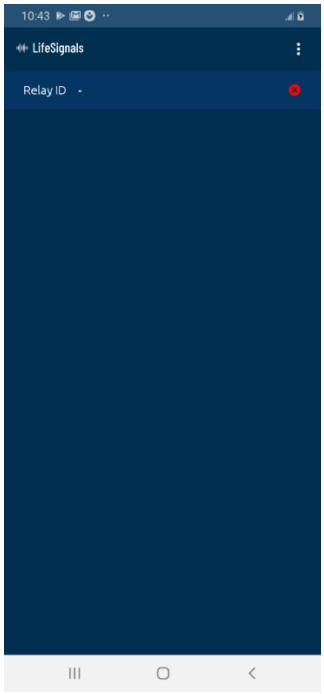
- Select "Allow" permission for the app to take pictures and record video



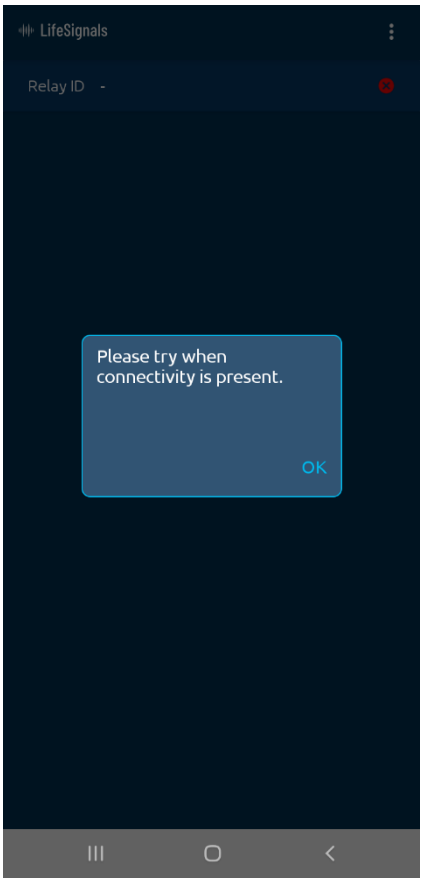
- The Introduction Screen is then displayed. If you select the "Skip setup instructions", you will directly be taken to Section 9.3



- If for some reason, the Relay Application is not Authenticated, then you will see the below screen

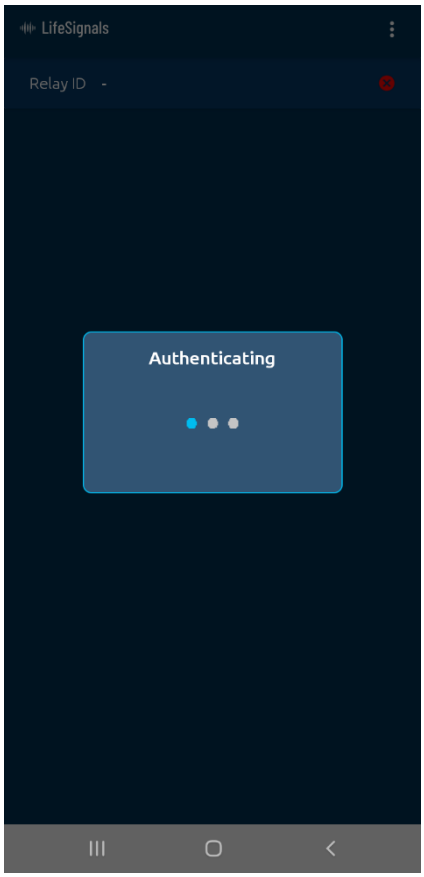


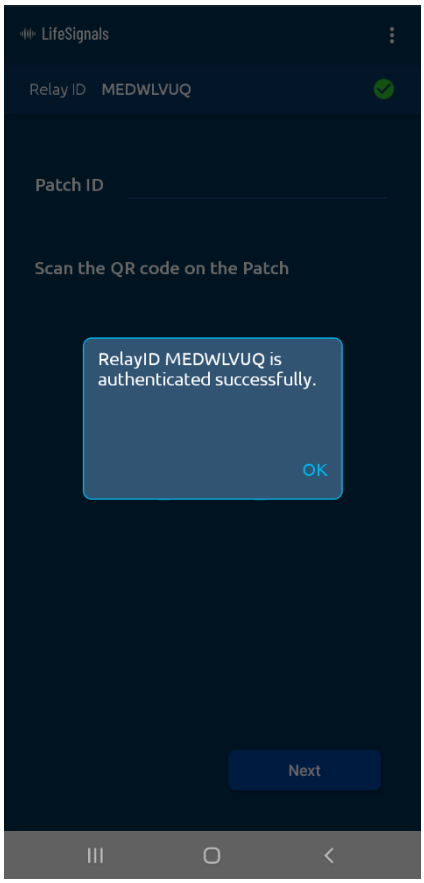
- If there is no connectivity, then the below screen is seen



- Go to Device settings and check for Internet connectivity and ensure that the device is connected to the internet. Once the device is connected, follow the next steps

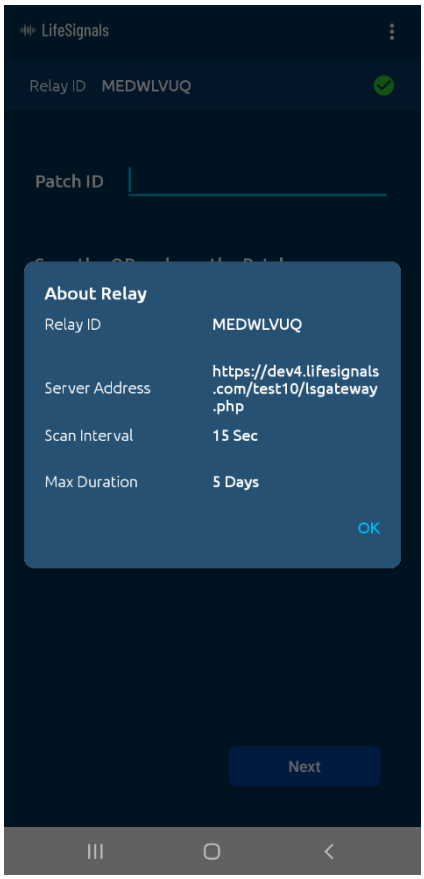
- When the Relay Application gets authenticated automatically by connecting to the secure server, you will see the biosensor QR Code scanning page. The device then gets authenticated


LifeSignals
Relay ID -
Authenticating



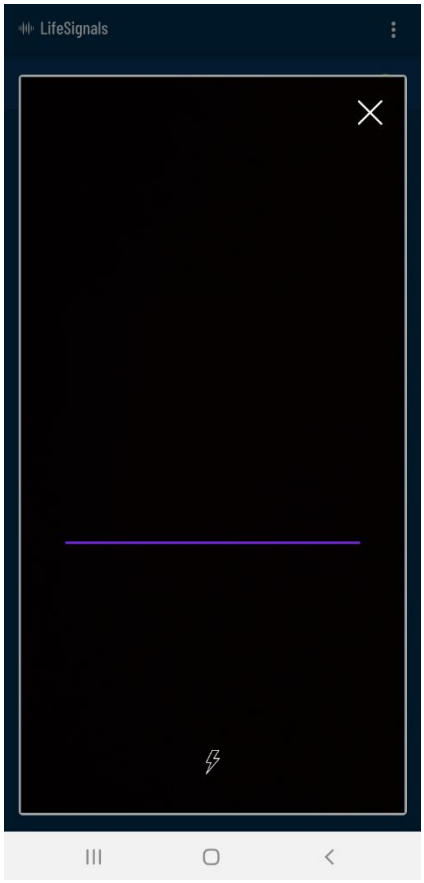
- To know about the Relay, click the Menu (three dots on the top right) (Step 1)
- Select About Relay (Step 2)

- Details about the device is shown

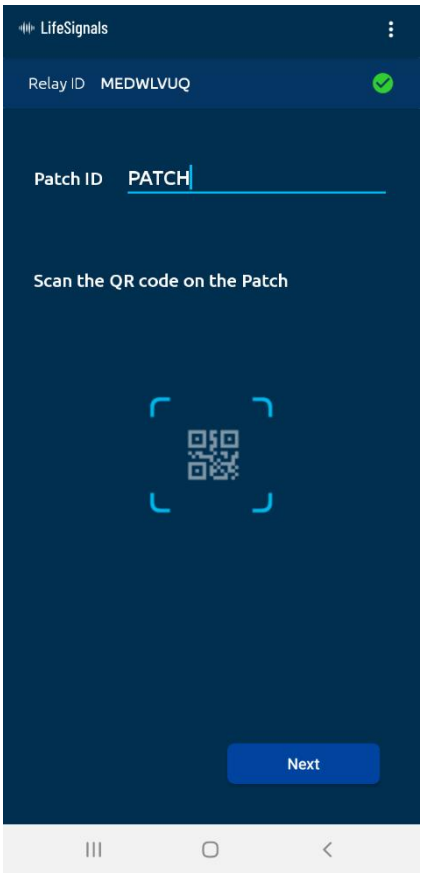


- The Discovery page can add new biosensors in two ways, with QR code scanning (Option 1) or manual entry (Option 2).

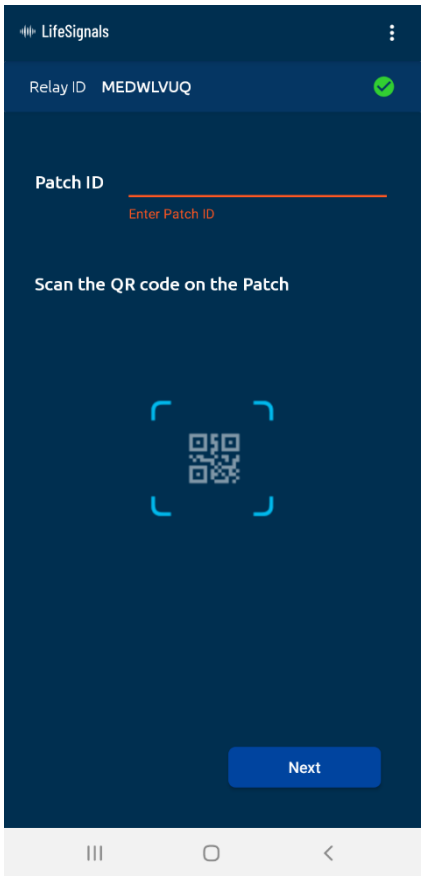
- If QR Code scanning is chosen, then the scanner looks for a QR code to scan



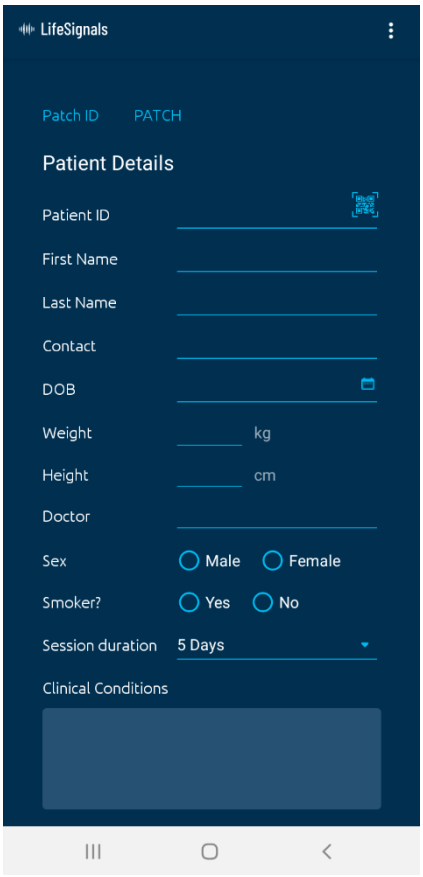
- If Relay is added through manual entry, then the information must be typed in the Patch ID section



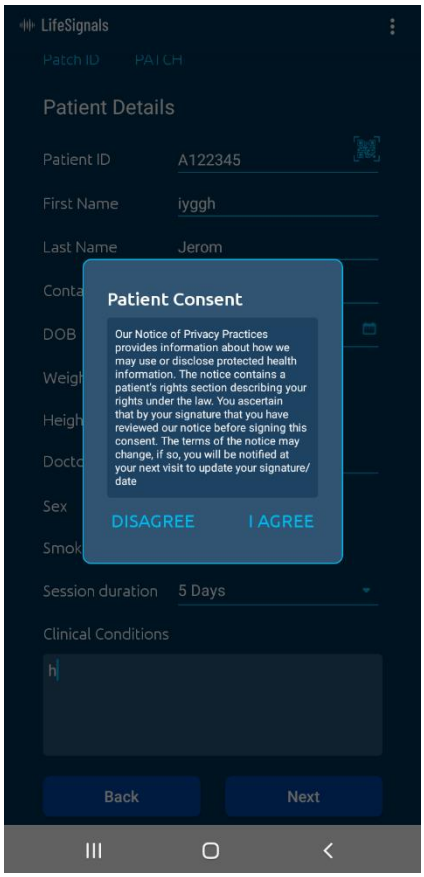
- If information is not typed and Next button is clicked, error is displayed



- For manual entry, once the information is provided and the Next button clicked, the screen requesting more information comes up. If all the mandatory fields are not entered, there will be an error highlighting the fields that are missing information



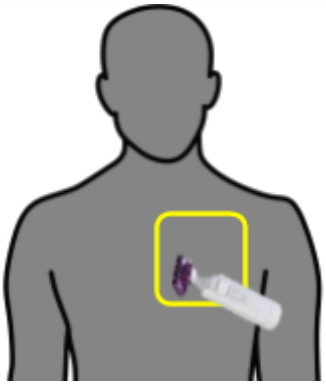
- Once all the information is input, the Patient Consent notice pops-up



- On choosing the I AGREE option, the initial setup is complete.

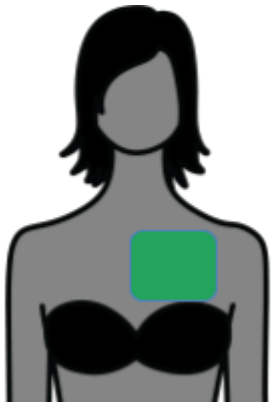
9.1. **Patient Body preparation**

- Do a skin preparation on the left upper quadrant of the chest area between clavicle bone & nipple, middle to Left of sternum
- Remove excess hair by clipping instead of shaving to prevent skin irritation
- Remove any oil or lotion by wiping the area with an alcohol pad
- Prep the skin using Nuprep® Skin Prep Gel (Recommended) or any other non-abrasive skin prep pad
  - Apply enough gel to moisten about 1/4th of a gauze pad
  - Apply gel sparingly to the skin by rubbing in a circular motion with 6 to 7 strokes
  - Remove any excess gel with a dry part of the gauze pad
  - If non-abrasive skin prep is used instead of Nuprep®, clean the area with an alcohol pad and allow it to dry for more than 1 minute. (Do not wipe with alcohol if Nuprep® is used)



Prep site (Male)

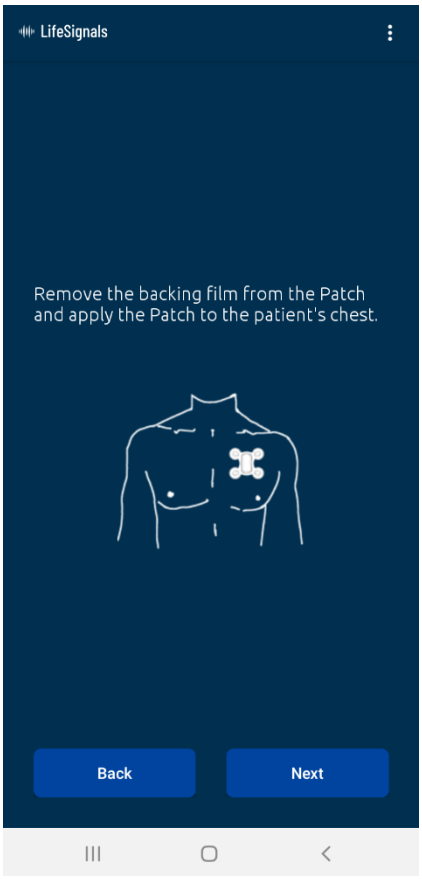
Nuprep® & Gauze Pad



Prep site (Female)

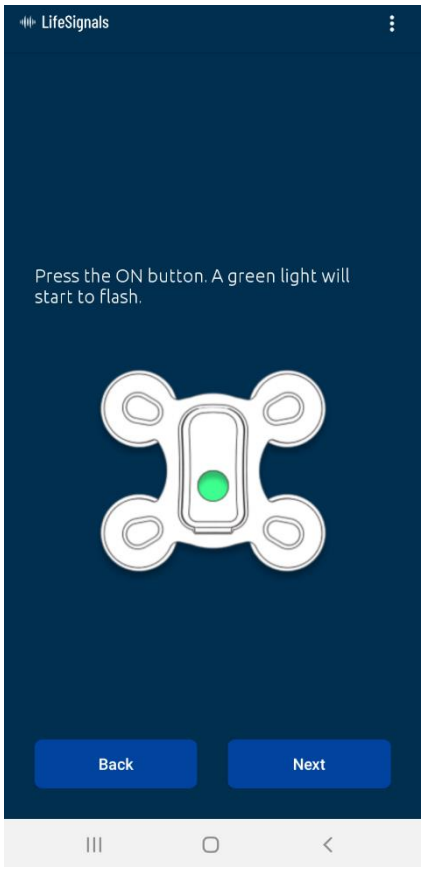
9.2. **Biosensor Affixing**

- Carefully remove Biosensor from the Aluminum Pouch
  - Please check for expiry date information & any damage to the packaging
- Remove the release liner in the Biosensor
- Hold the Biosensor with the antenna at the top and letters on the label upright
- Align the Biosensor with top right corner (RU electrode), close to the junction of sternum & collar bone. (Prepped site)
- Place the Biosensor and press firmly across the entire Biosensor for 2 minutes



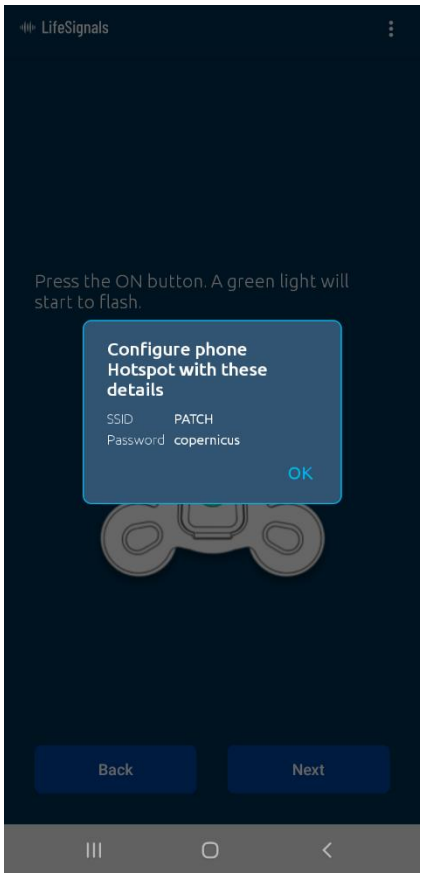
9.3. Switching ON the Biosensor & Connecting to Mobile device

- Press ON button to switch on the Biosensor
- Momentarily the red LED will turn ON
- Green LED will blink at a faster rate (~ 2 blinks per second) indicating that the Biosensor is trying to establish a connection with the Mobile device Hotspot
- If the connection is successful, then the green LED blinking rate will be reduced. (~ one blink per 3 sec)
- If the connection is not successful within 120 seconds of turning on, the Biosensor will be switched OFF automatically (auto-power off)

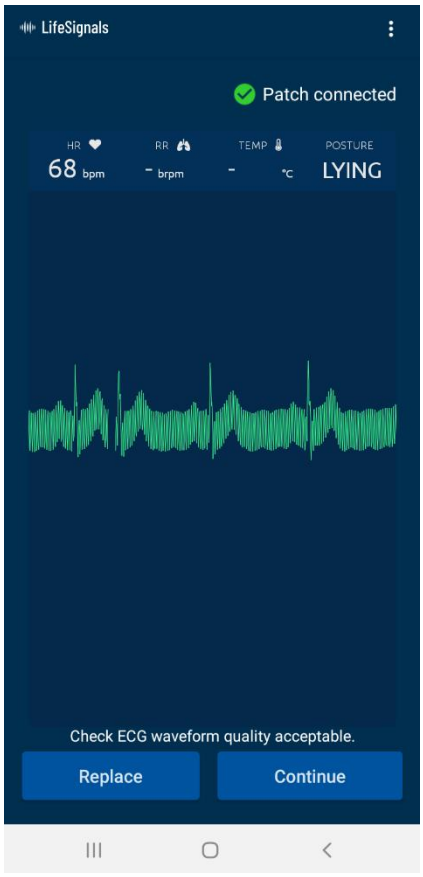


9.4. **Pairing the Biosensor with Relay Application & starting the procedure**

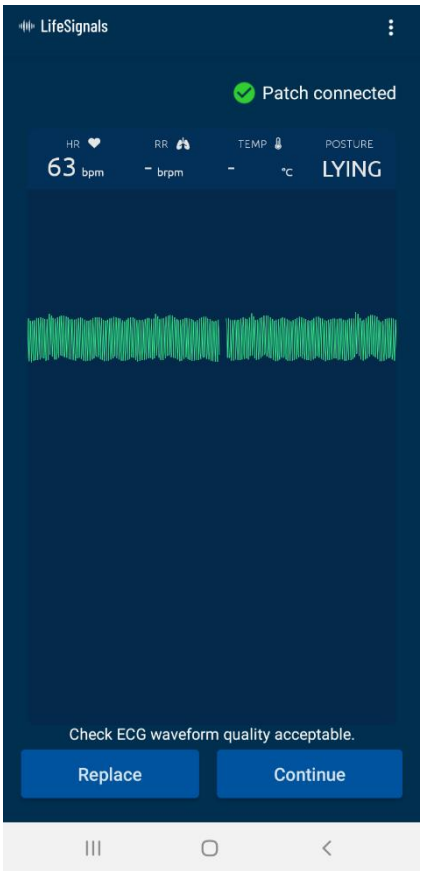
- Open the Relay Application in Mobile device. Application will automatically connect to the Secure Server & details will be displayed. Select the OK button to start the procedure



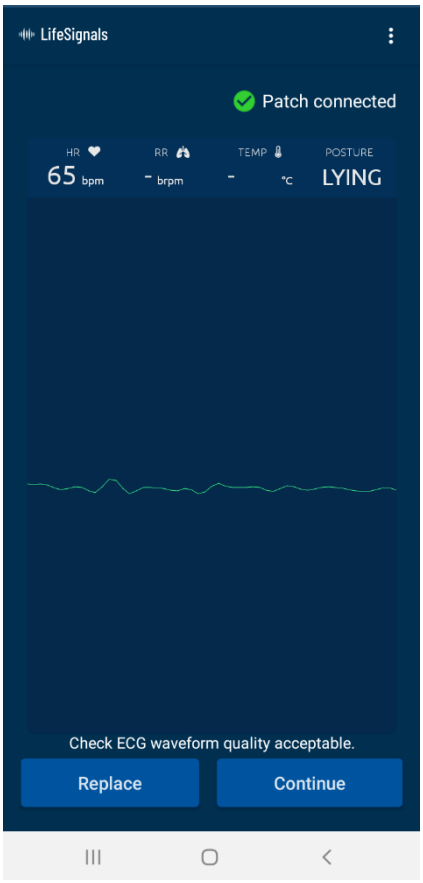
- Once the App is connected to the biosensor, the plotting screens for the 2 channels of ECG and respiration wave form along with other numerical parameters such as HR, RR, TEMP and Posture will be displayed



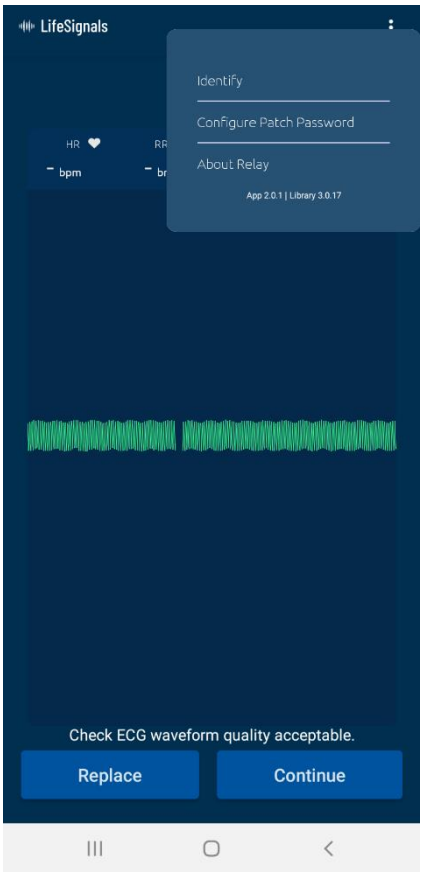
- Scroll down to view plot from the other ECG channel



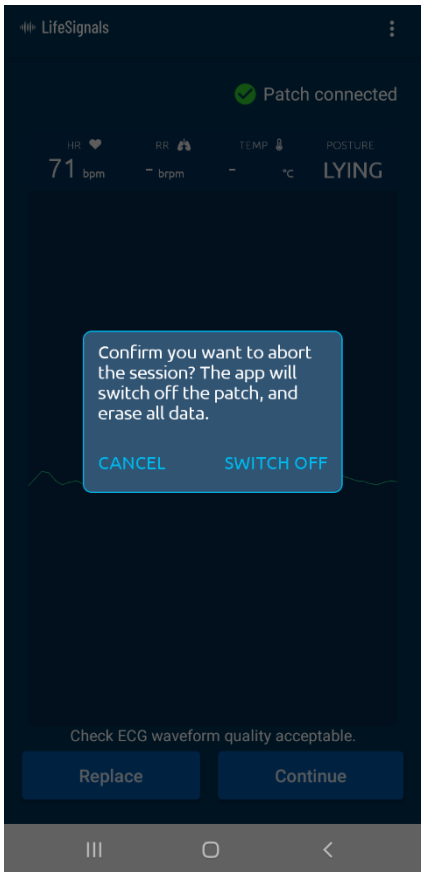
- Continue to scroll down to view the respiration rate waveform



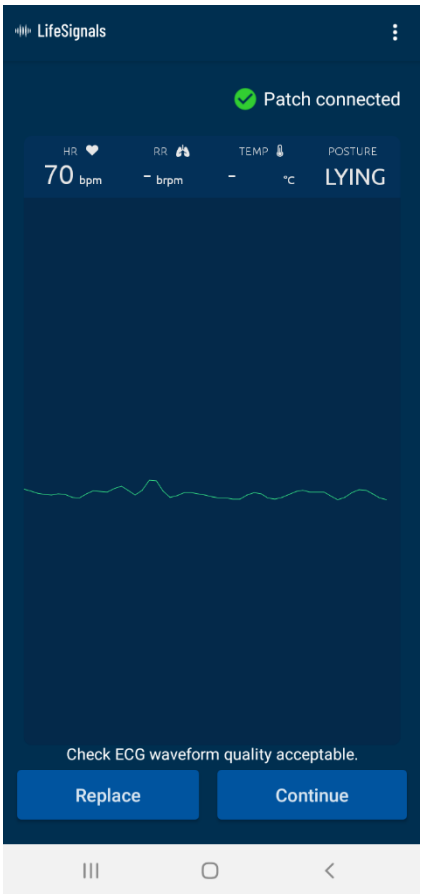
- By clicking the Menu (top three dots on the right), several options are available



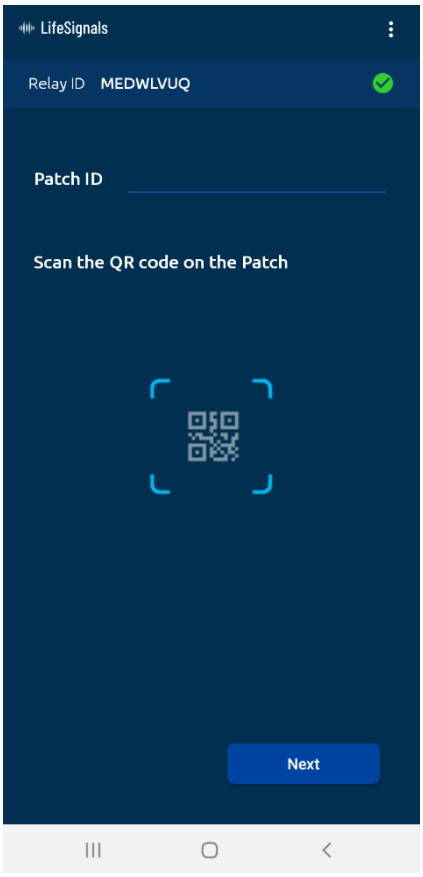
- If for some reason, you want to remove or replace the patch, you can click the Replace button



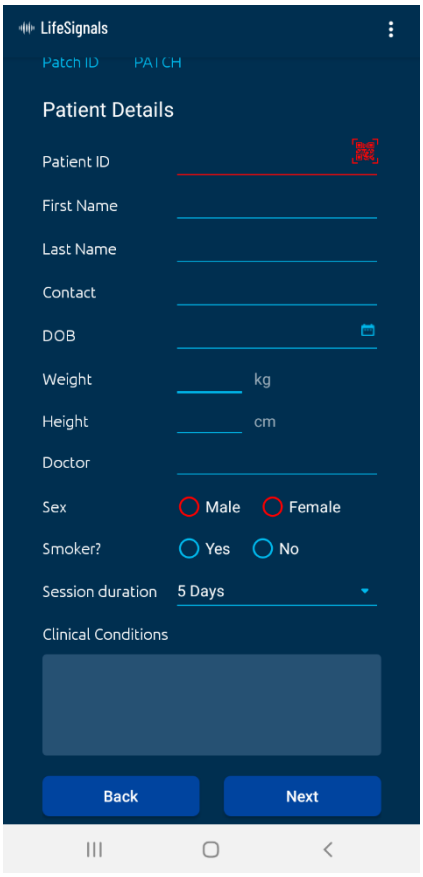
- By selecting the CANCEL button, it goes back to the previous screen

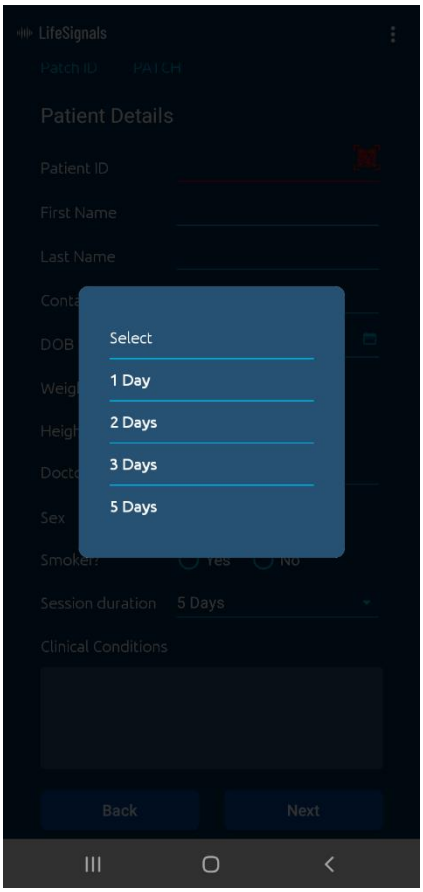


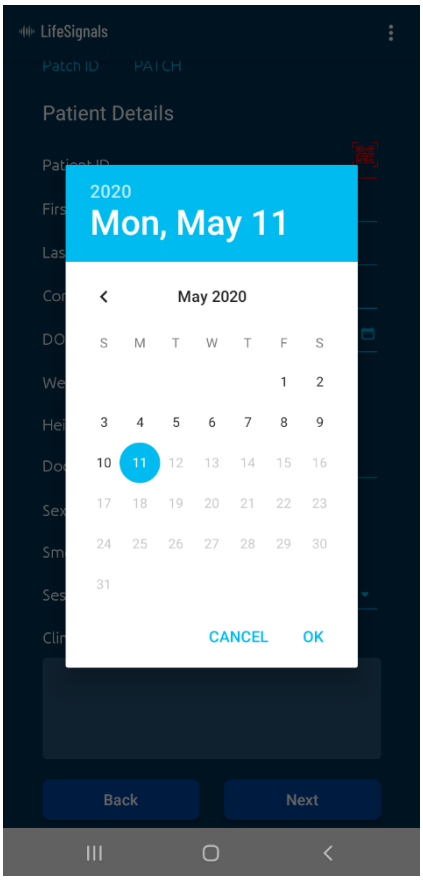
- If SWITCH OFF option is selected, then the screen goes back to the initial setting where Patch ID can be entered by scanning with QR Code or manual entry

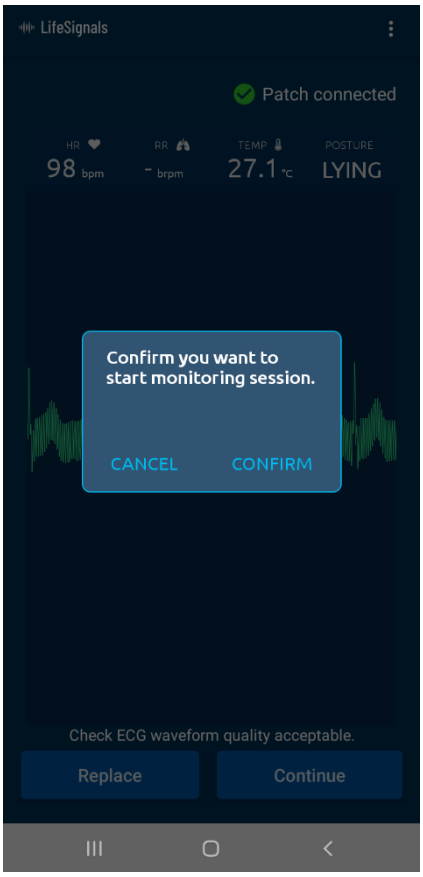


- Once all the relevant information is input and verified, there is an option to CANCEL OR CONFIRM

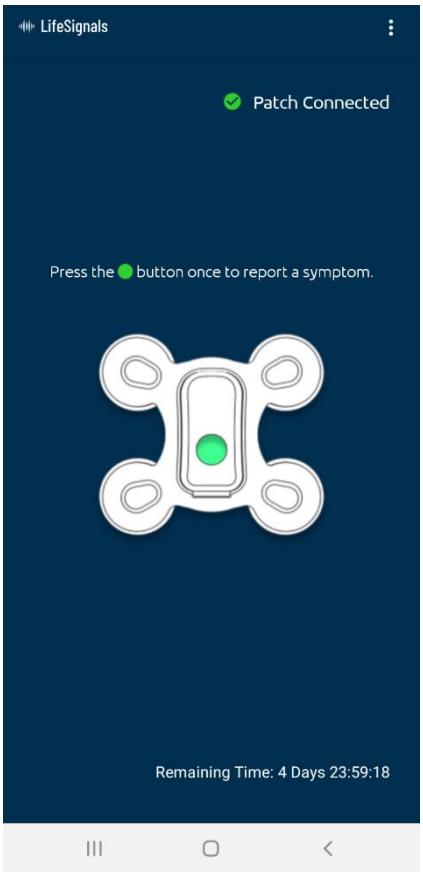

LifeSignals
Patch ID
PATCH
Patient Details
Patient ID
First Name
Last Name
Contact
DOB
Weight
kg
Height
cm
Doctor
Sex
Male
Female
Smoker?
Yes
No
Session duration
5 Days
Clinical Conditions
Back
Next


LifeSignals
Patch ID
PATCH
Patient Details
Patient ID
First Name
Last Name
DOB
Sex
Smoker:
Yes
No
Session duration
5 Days
Clinical Conditions
Back
Next
Select
1 Day
2 Days
3 Days
5 Days

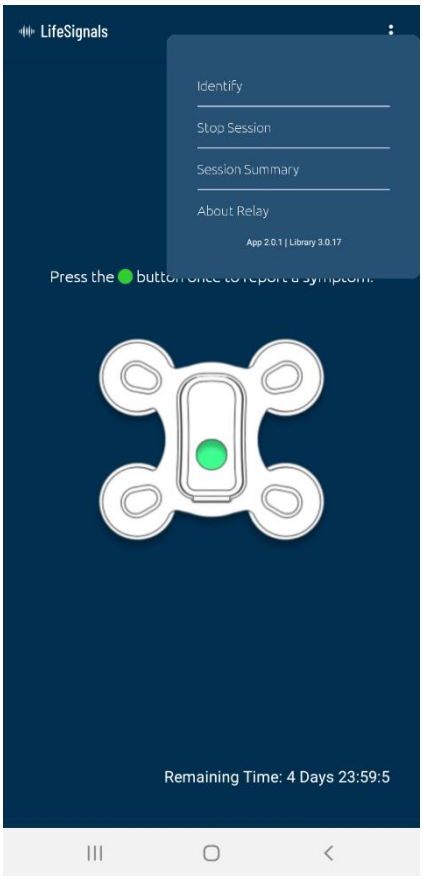

LifeSignals
Patient Details
2020
Mon, May 11
May 2020
S M T W T F S
1 2
3 4 5 6 7 8 9
10 11 12 13 14 15 16
17 18 19 20 21 22 23
24 25 26 27 28 29 30
31
CANCEL
OK
Back
Next


LifeSignals
Patch connected
HR
98 bpm
RR
- brpm
TEMP
27.1 °C
POSTURE
LYING
Confirm you want to start monitoring session.
CANCEL
CONFIRM
Check ECG waveform quality acceptable.
Replace
Continue

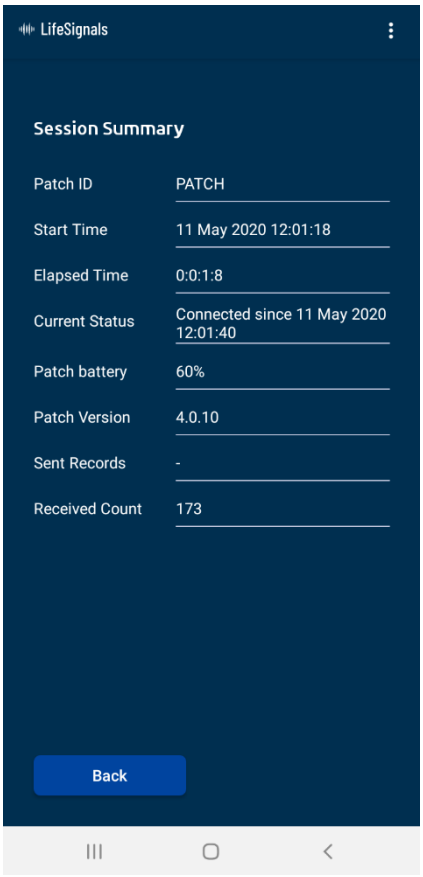
- Once the CONFIRM button is clicked, the patch is connected and the remaining time for monitoring is displayed



- If at any time, the details of the session are needed, the Menu (3 dots on the top) can be chosen and Session Summary selected



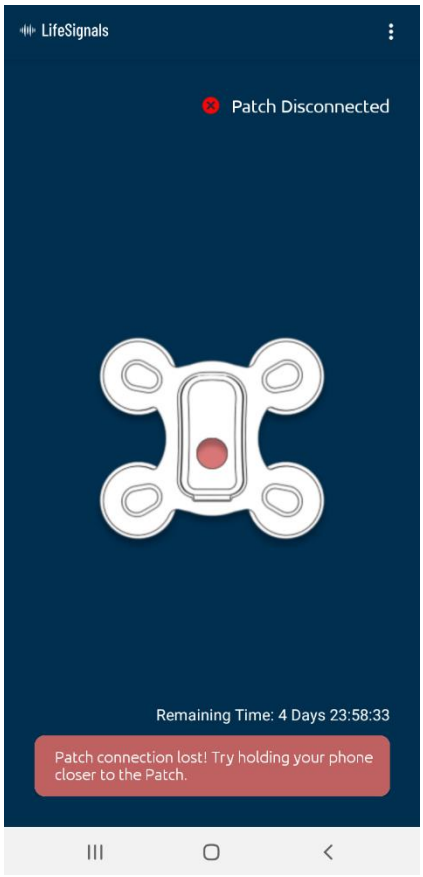
- The Session Summary is then displayed



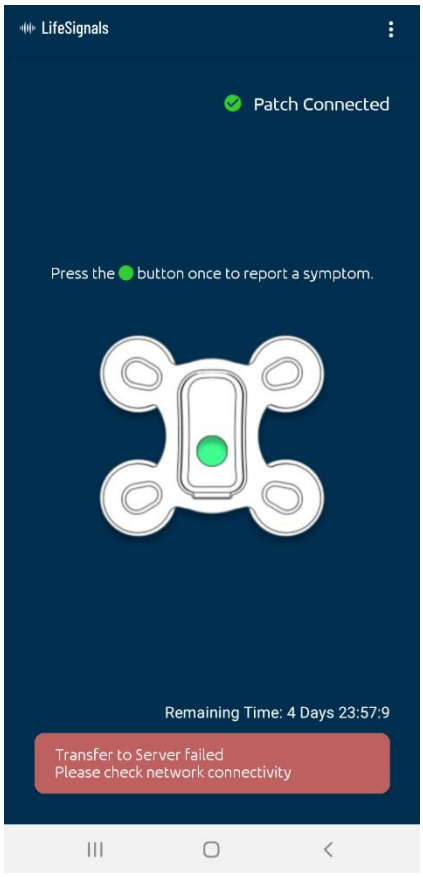
- Click the Back button to go back to the Main Page

9.5. **Other Alerts and features**

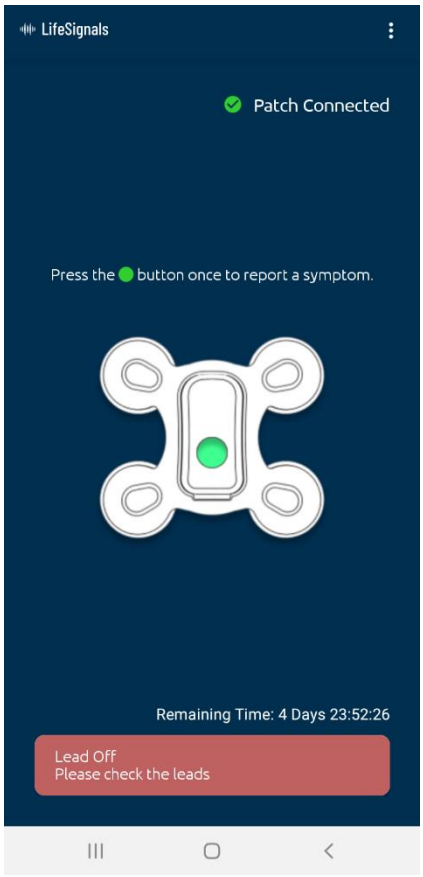
- When the Patch gets disconnected from the Relay device, the below alert is displayed



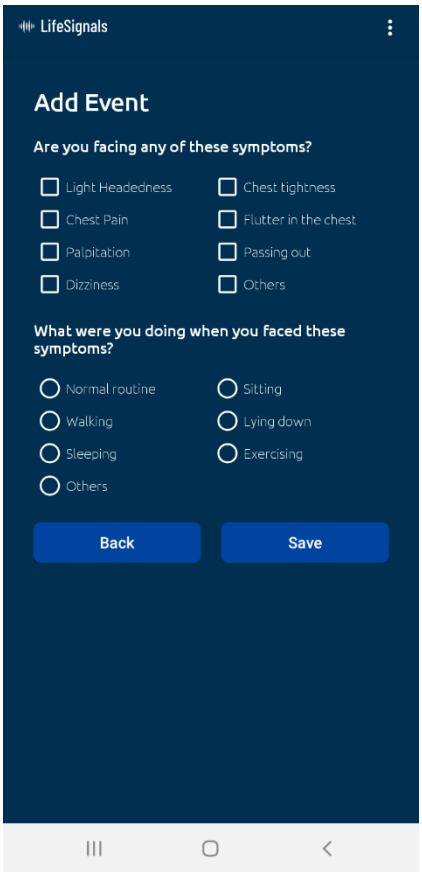
- When connection between Relay Device and Server is broken, below alert is displayed



- When any leads of the biosensor are lifted from the body, then the Lead Off alert is displayed

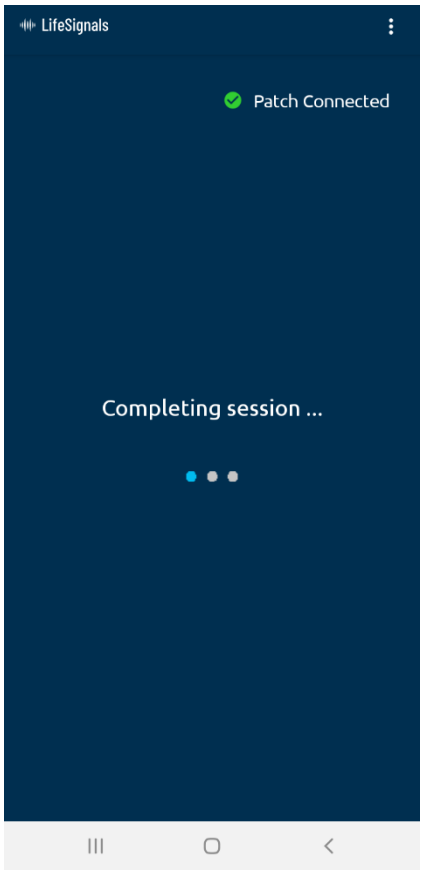


- Add Event feature: At any time during the procedure, if the Patient feels the need to record an event, he or she can do so by appropriately pressing the ON button on the biosensor or the Green button in the Relay Application (above screen) and Add Event page comes up on the Relay Device. Appropriate details can be entered about that specific event

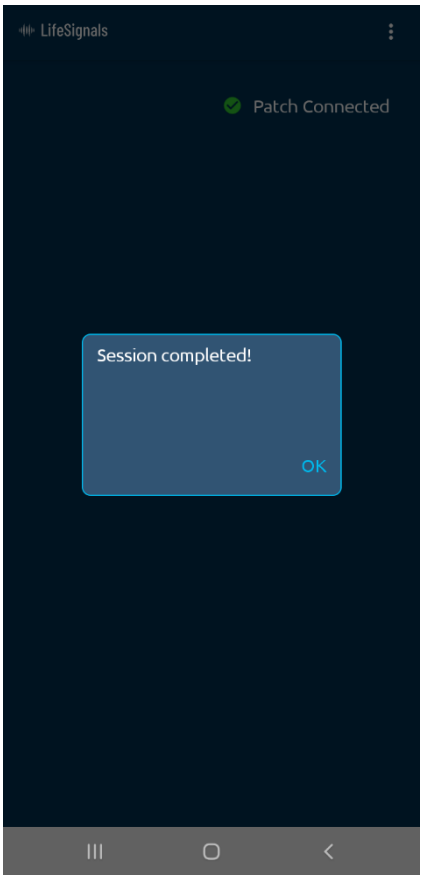


9.6. **End of Monitoring**

- After the end of monitoring period (120 hours or as configured), the procedure finalization will happen



- Once Finalization is complete, the Relay Application will try to switch off the Biosensor and erase all the data present in the biosensor and on the Relay Device.



- If required, another Biosensor can be paired to initiate another monitoring procedure

9.7. **Removing the Biosensor**

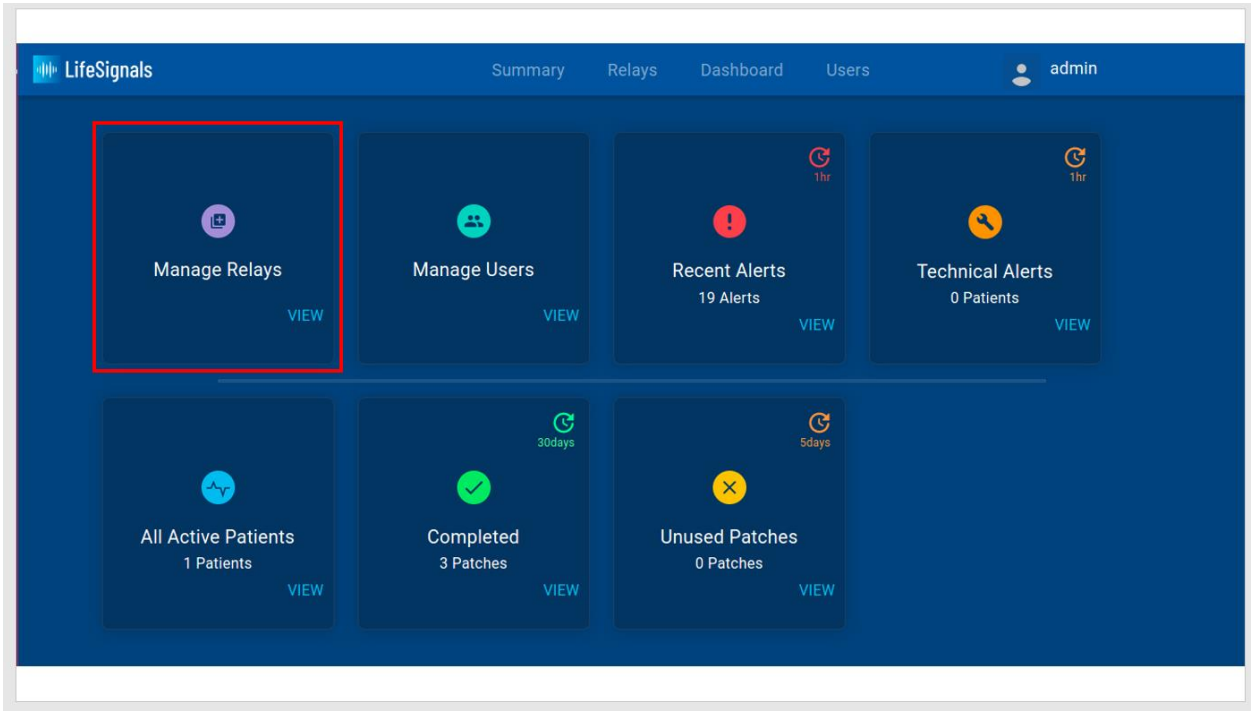
- Gently pull the bottom right corner of the Biosensor and remove it from the body
- To aid the removal of Biosensor, it may be helpful to use an over-the-counter medical adhesive remover. Sweep the adhesive remover between the skin of the Patient and the Biosensor while peeling the Biosensor from the bottom right corner to the left top corner
- Wash skin area with mild soap, rinse with water and pat dry
- Dispose the Biosensor as per the local regulation

10. Instructions (For Secure Server Administrator):

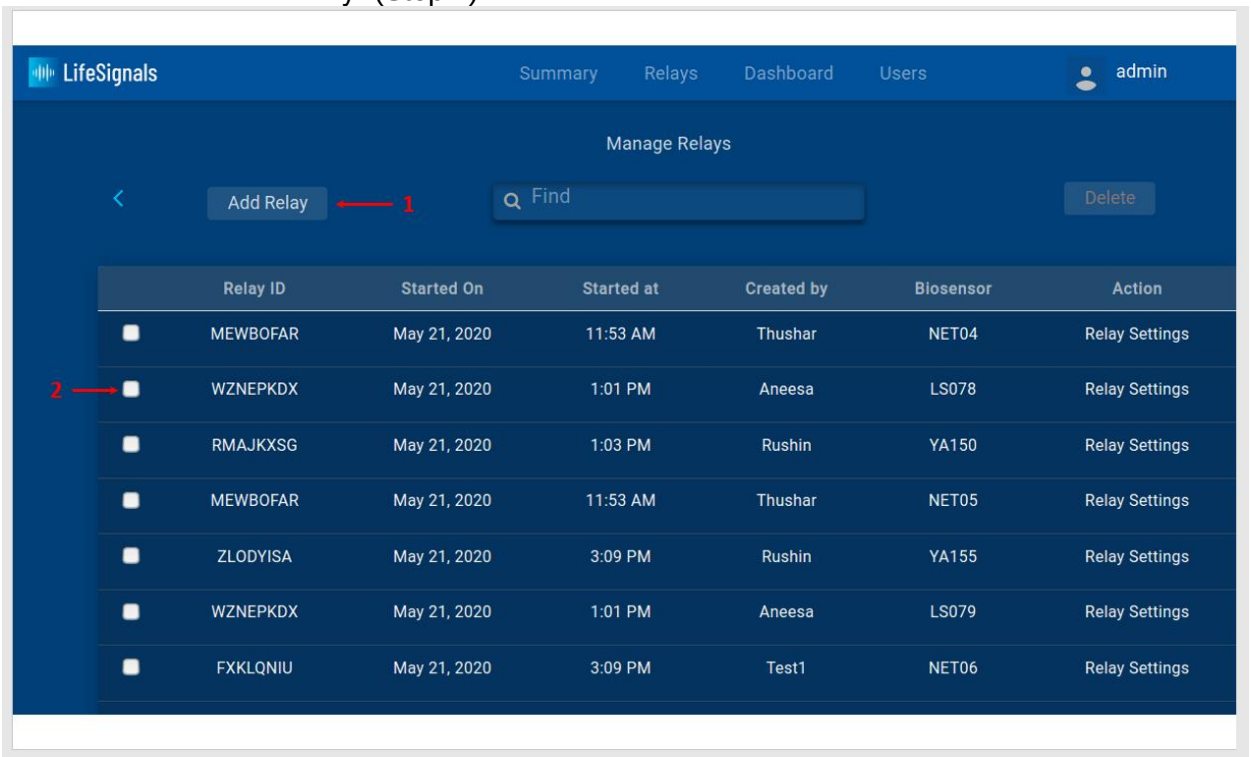
10.1. <u>Adding / Configuring a new Relay device to the Platform through Web Application</u>

- Open LifeSignals Web Application and login as ‘administrator’ (by entering admin Username and Password)

- Once logged in, select ‘Manage Relays

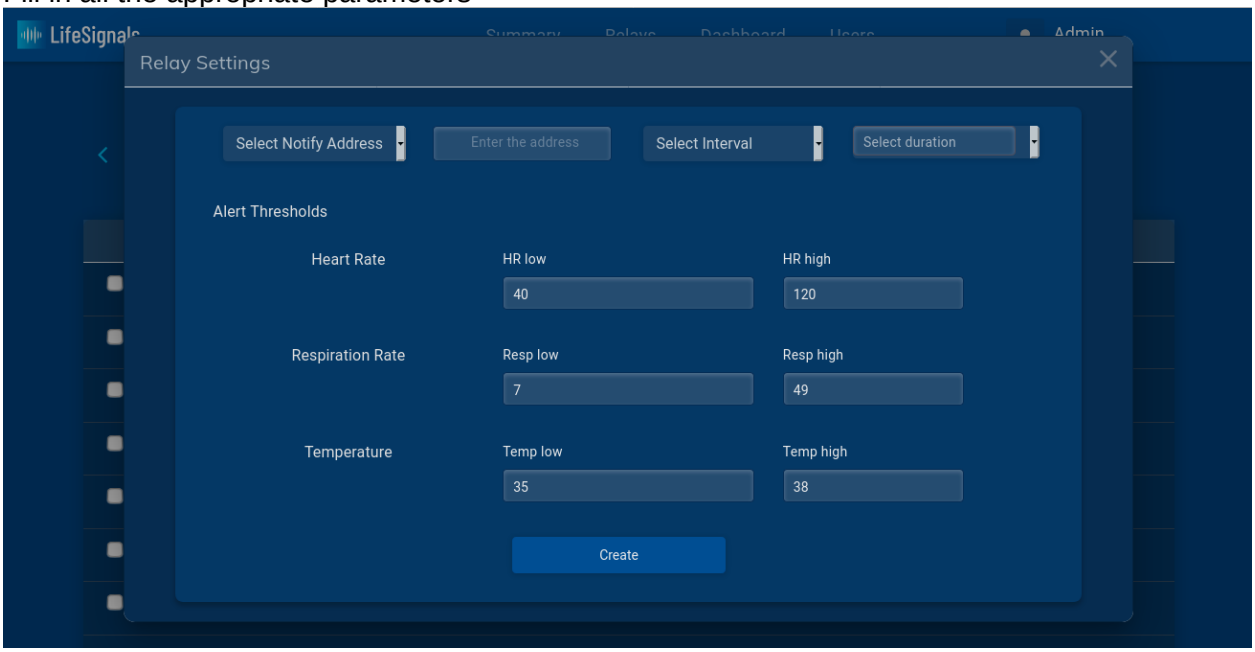


- Then select the “Add Relay” (Step 1)



- Select the ID of the Relay device for which Alert Thresholds need to be updated (Step 2)

- Fill in all the appropriate parameters

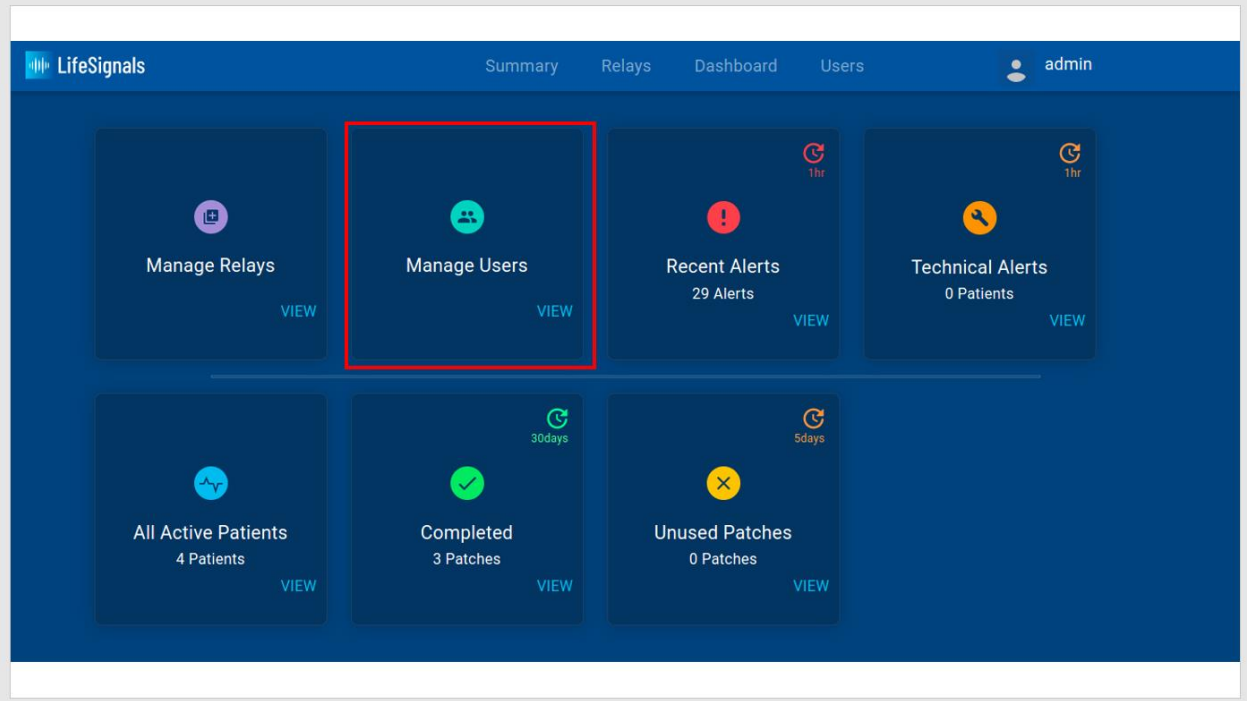


- Select maximum operating time of the Biosensor (120 hours). Any Biosensor connected to this relay device would be configured to this time
    - These configuration details can be modified at any time

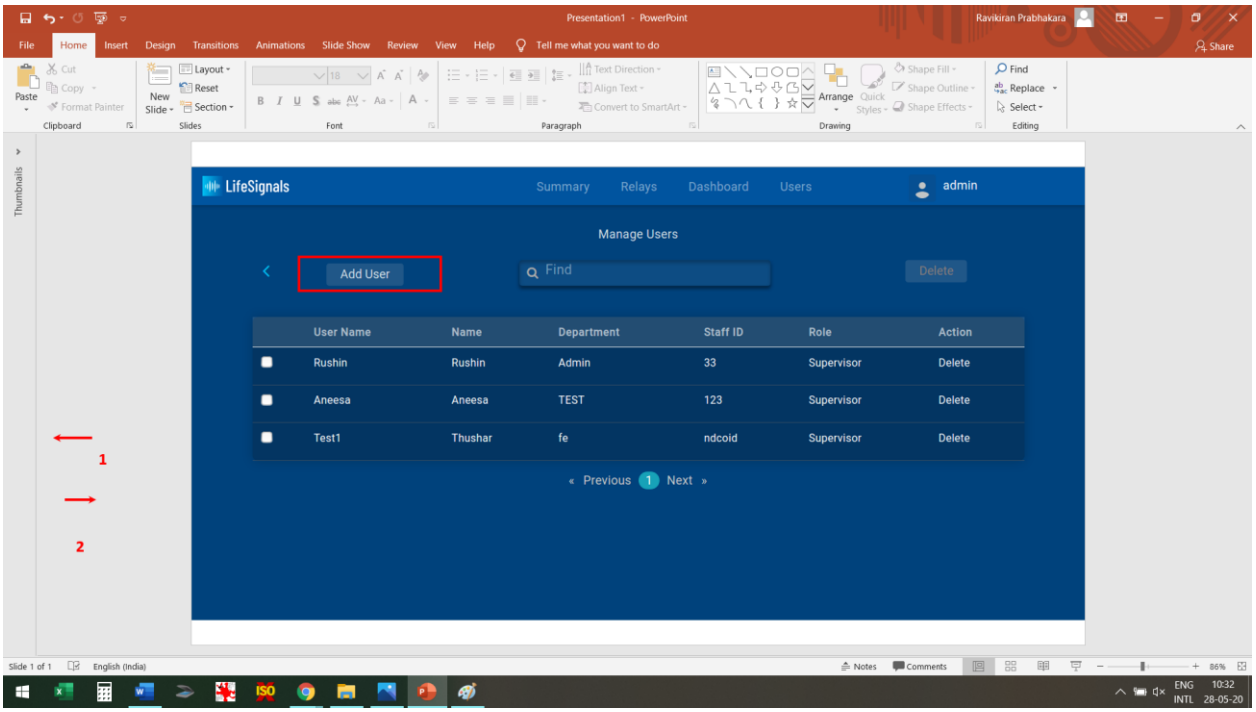
- Then press ‘Create’ button.
- Relay device authentication key (file name: ‘xxxxx. key’) will get generated & will be downloaded in local drive.
- Forward this key to the clinical personnel who would be configuring his/her Mobile device as a Relay device

10.2. Adding New User

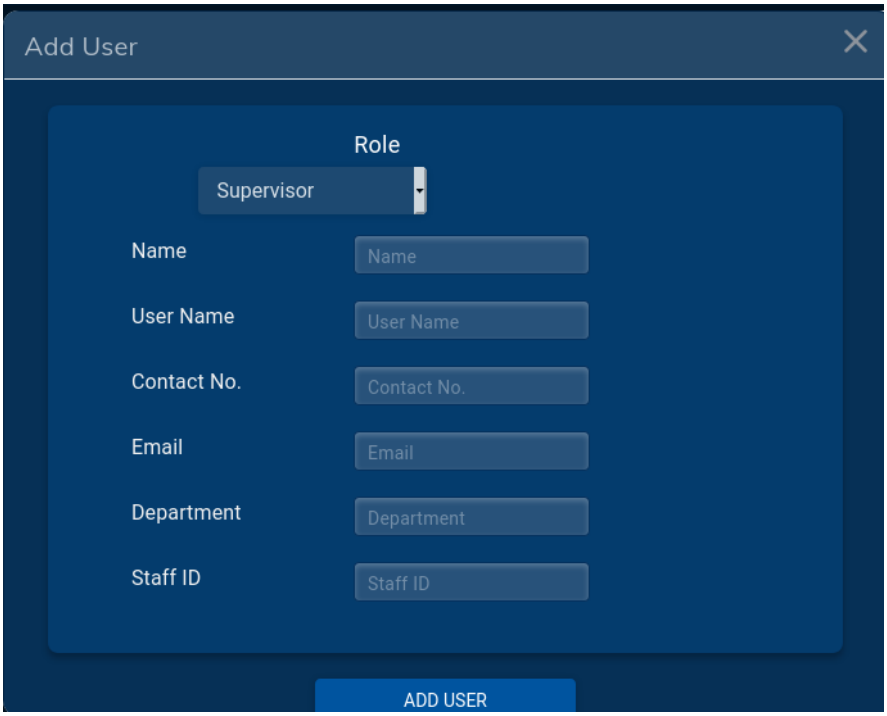
- Click on the ‘Manage Users’ in the menu



- Click on ‘Add User’ button



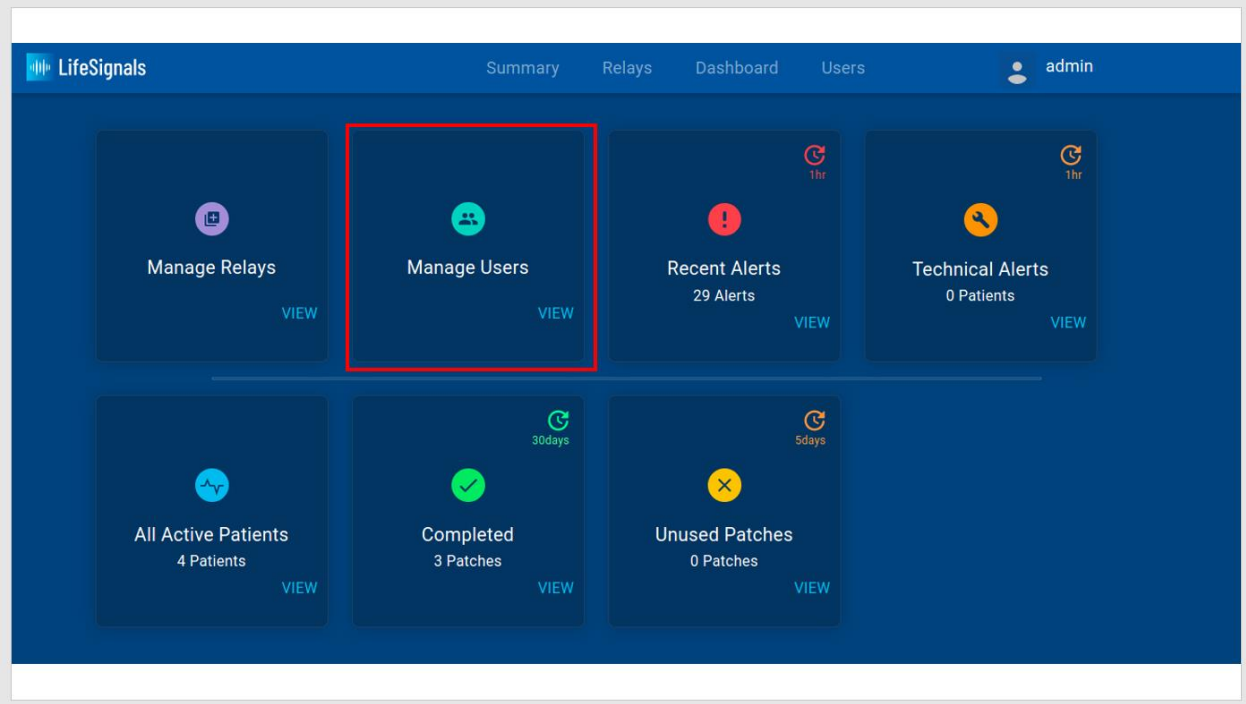
- Select the desired “Role” and fill in all the appropriate information



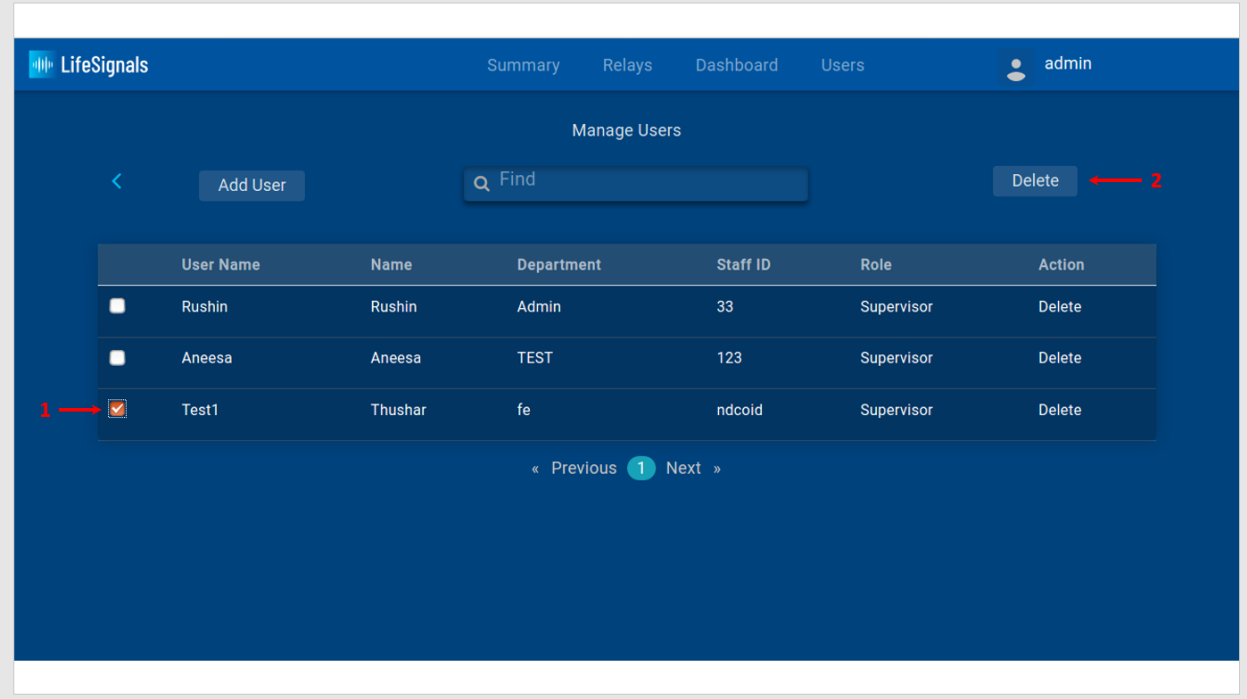
- Click on ‘ADD USER’ button. User will then be added.
- The default password is Life@2020

10.3. **Deleting Existing User**

- Click on the ‘Manage Users’ in the menu

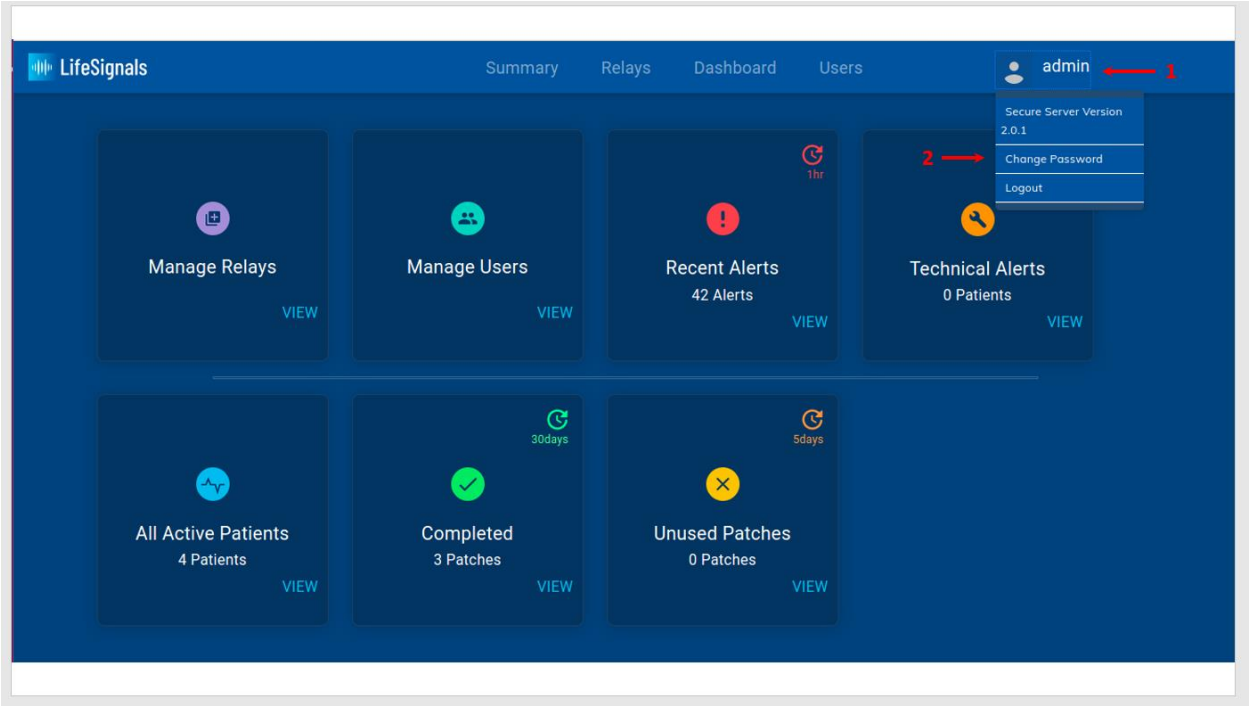


- Search for the User Name that needs to be deleted
    - Check the box next to the User Name that needs to be deleted (Step 1)
        - Click the Delete button (Step 2)

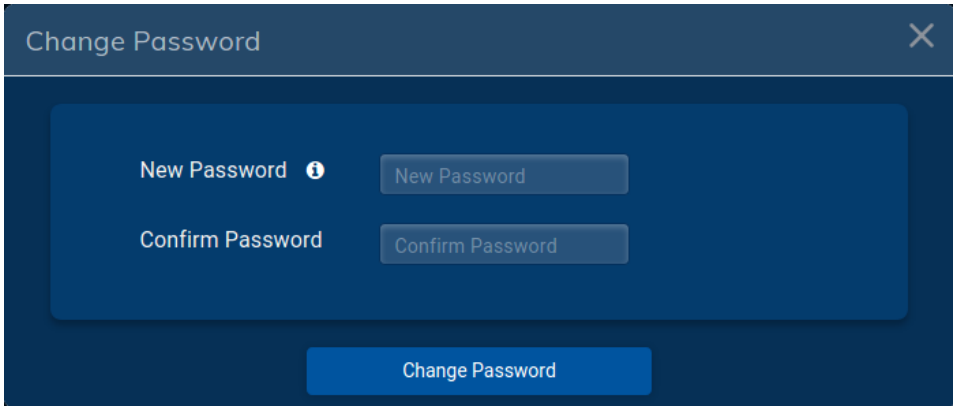


10.4. **Changing the Password**

- Click on the Profile in the menu (Step 1)
- From the drop-down menu, click on ‘Change Password’ button. (Step 2)



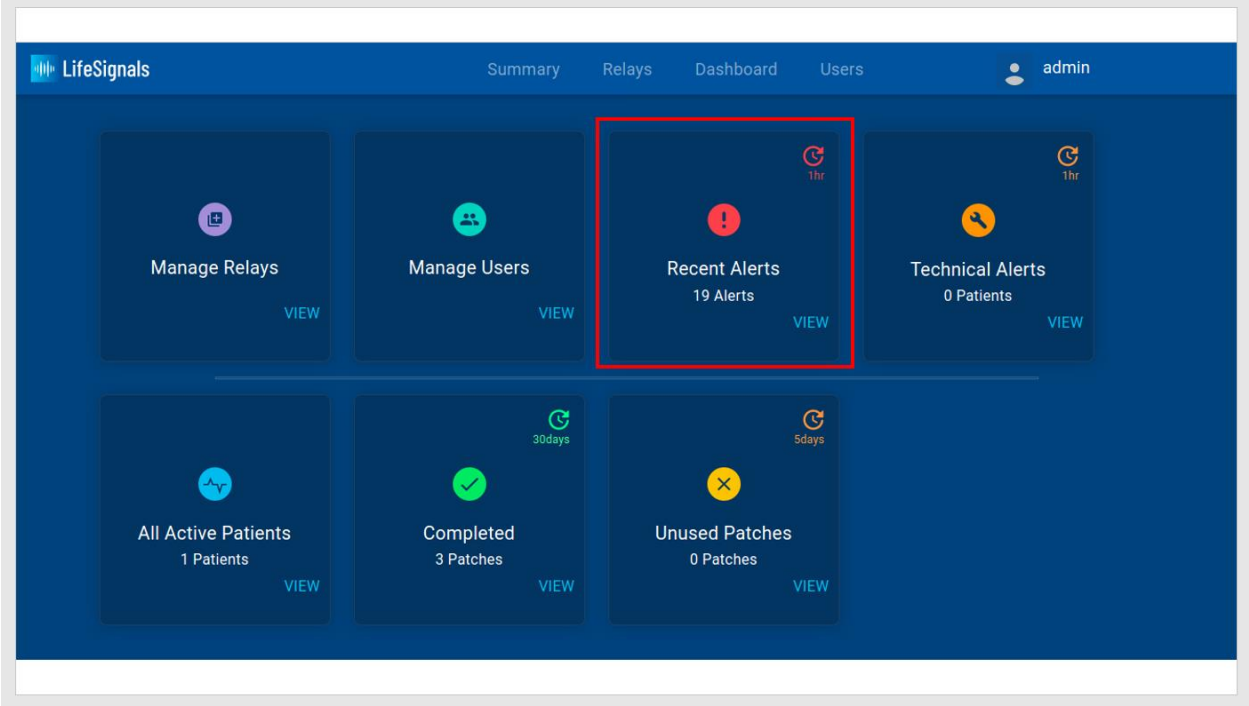
- The default password as stated in Section 10.2 is Life@2020
- Enter the new password in the ‘New Password’ text box
- Password should be of 8 or more characters in length and should contain at least one numeric digit, one special character, one uppercase and one lowercase letter
- Confirm the password by re-entering the password in the ‘Confirm Password’ text box



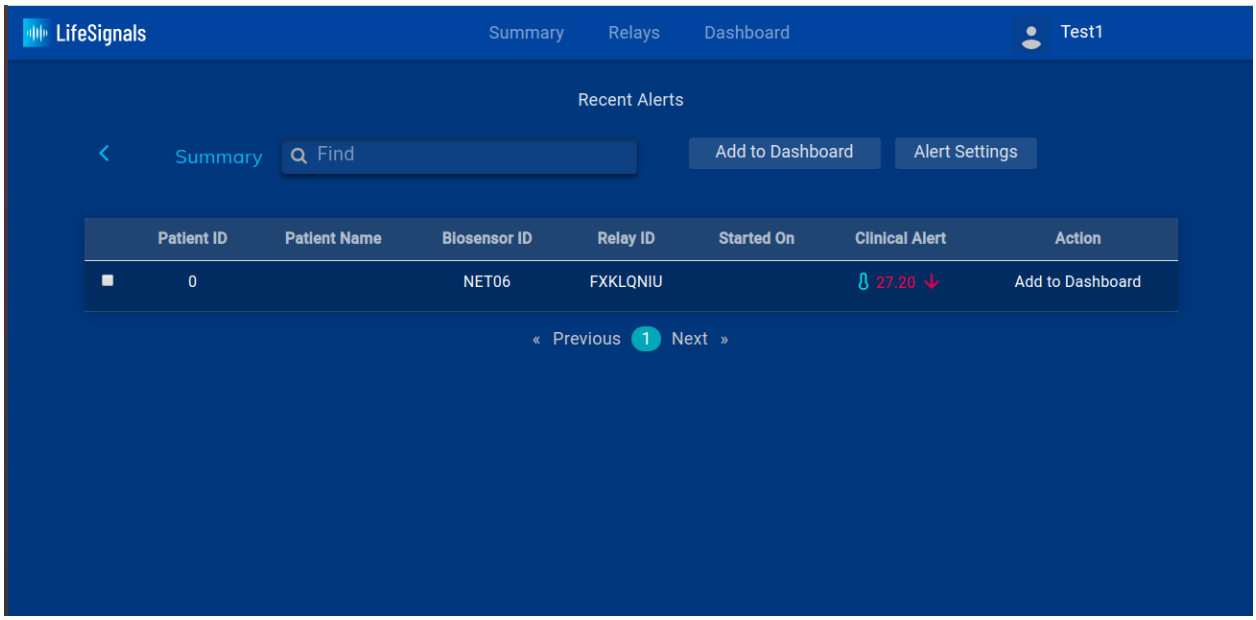
- Click on ‘Change Password’ button.

10.5. **Recent Alerts**

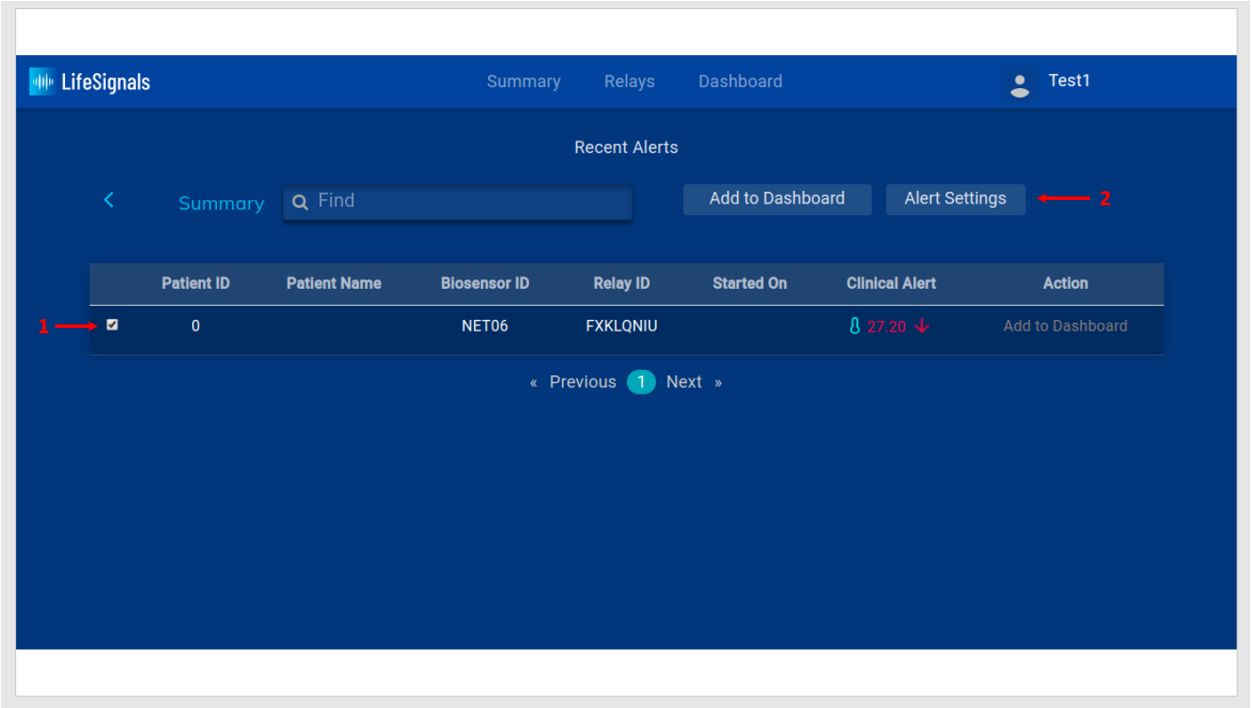
- From the Menu, click on Recent Alerts



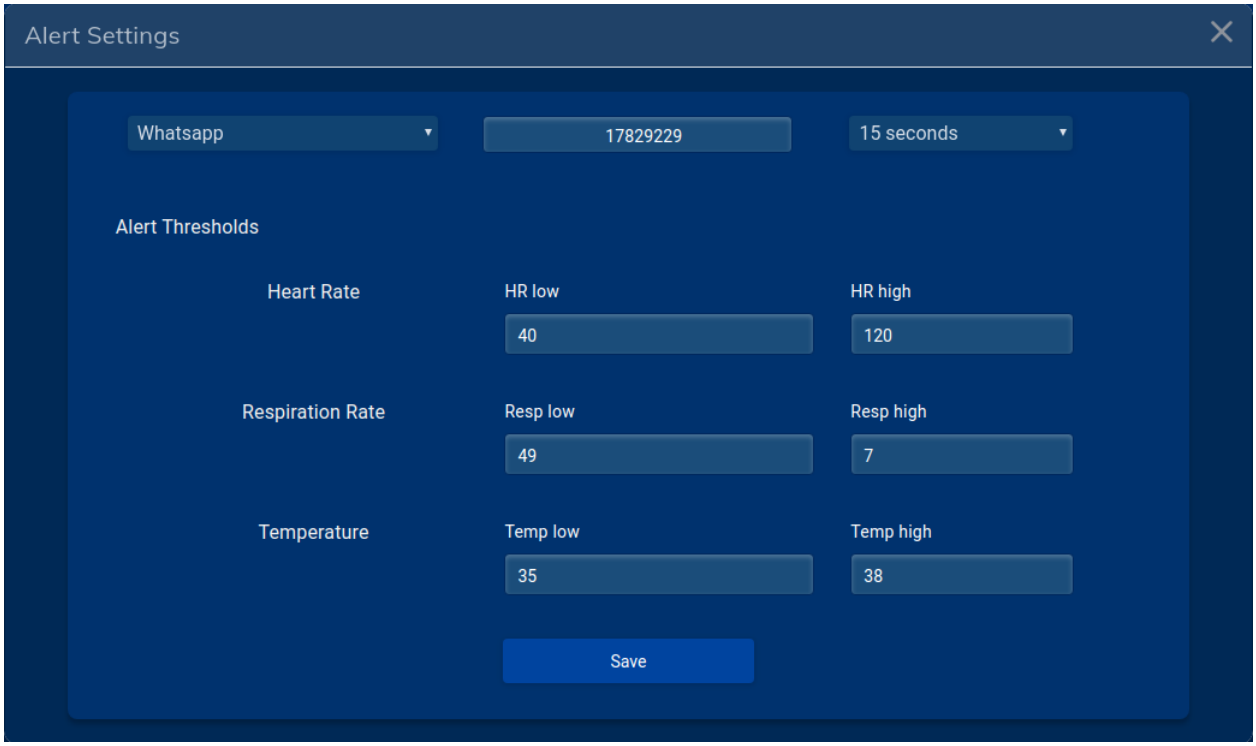
- A list of all the recent alerts are displayed



- A list of all the recent alerts are displayed



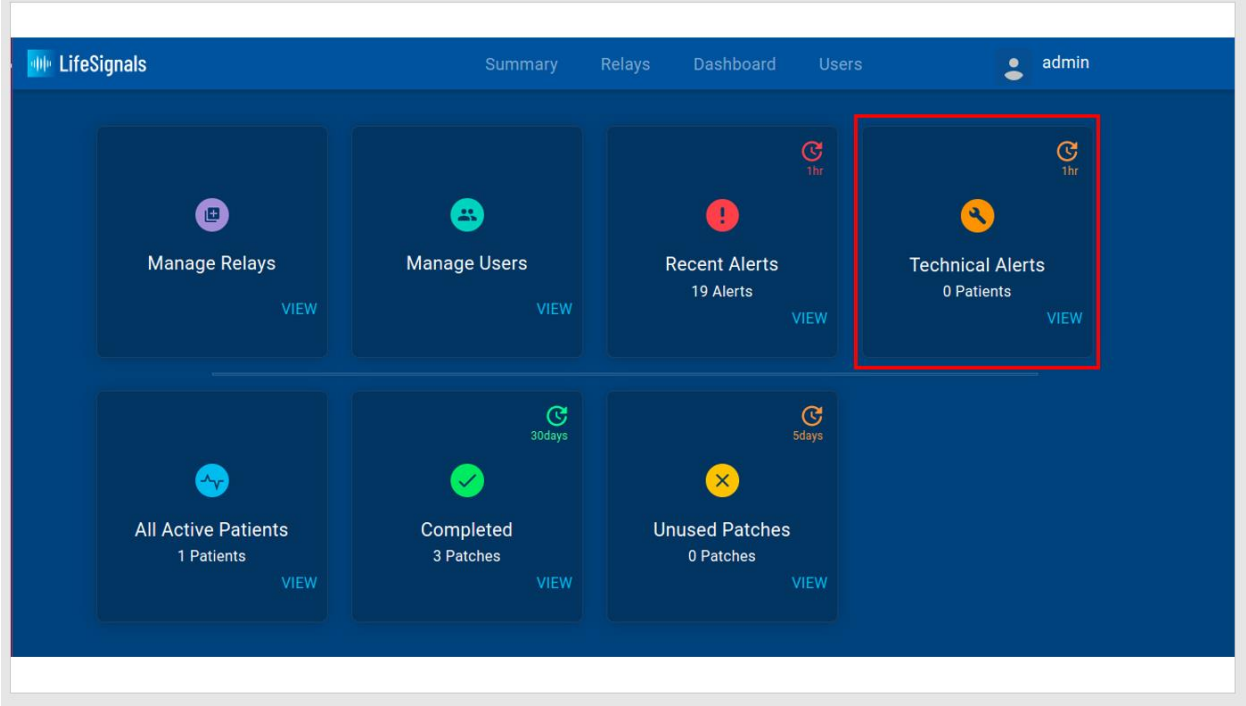
- Select the Alert you want to review (Step 1)
- Click on Alert Settings (Step 2)



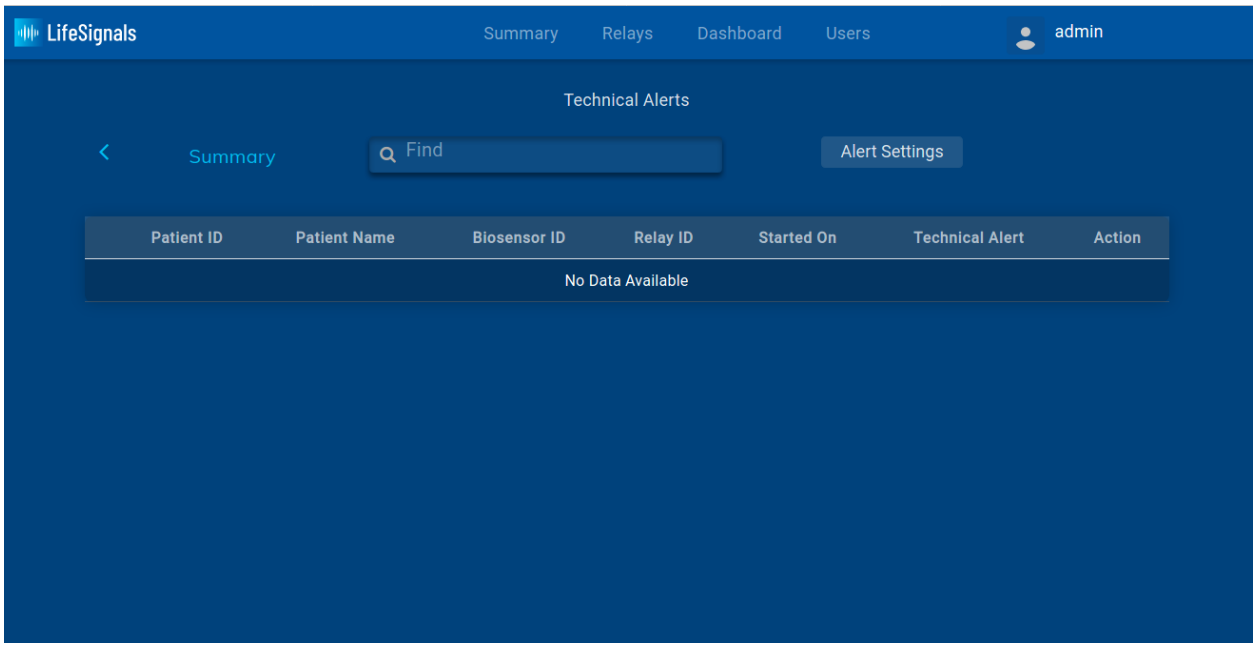
- You can review, edit and Save the different fields as necessary
- If changes are made, click the Save button and all changes will be saved

10.6. **Technical Alerts**

- From the Menu, click on Technical Alerts

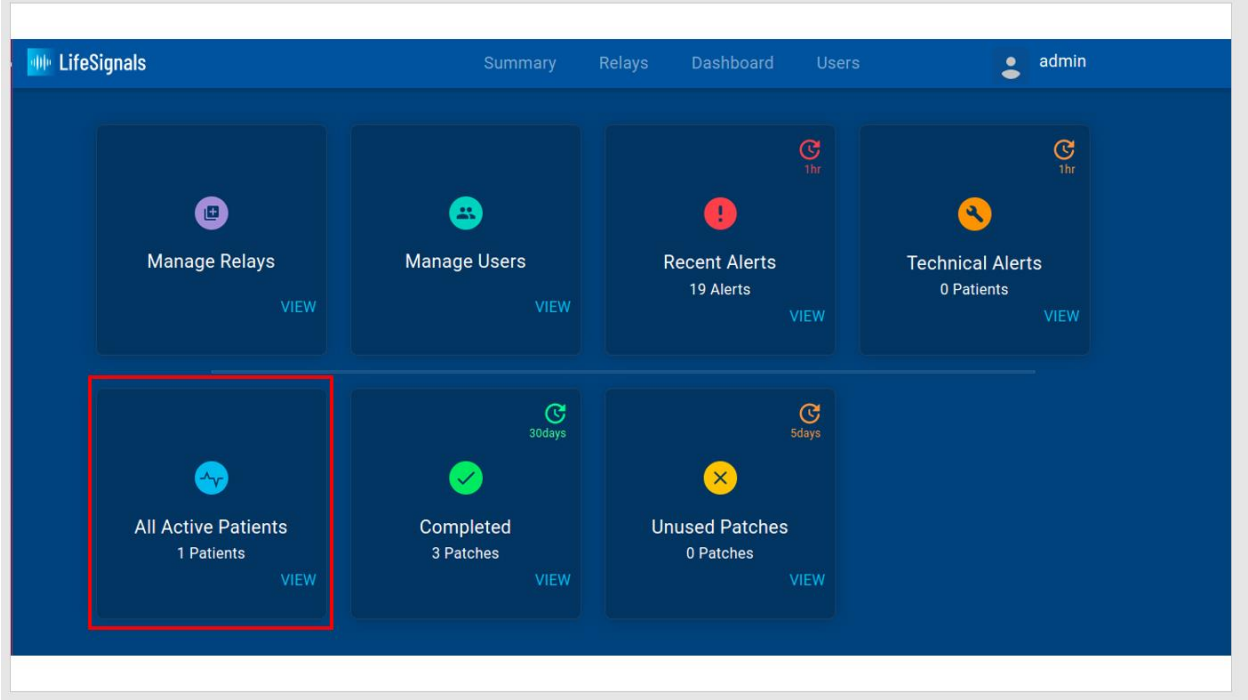


- List of all Technical Alerts will be displayed

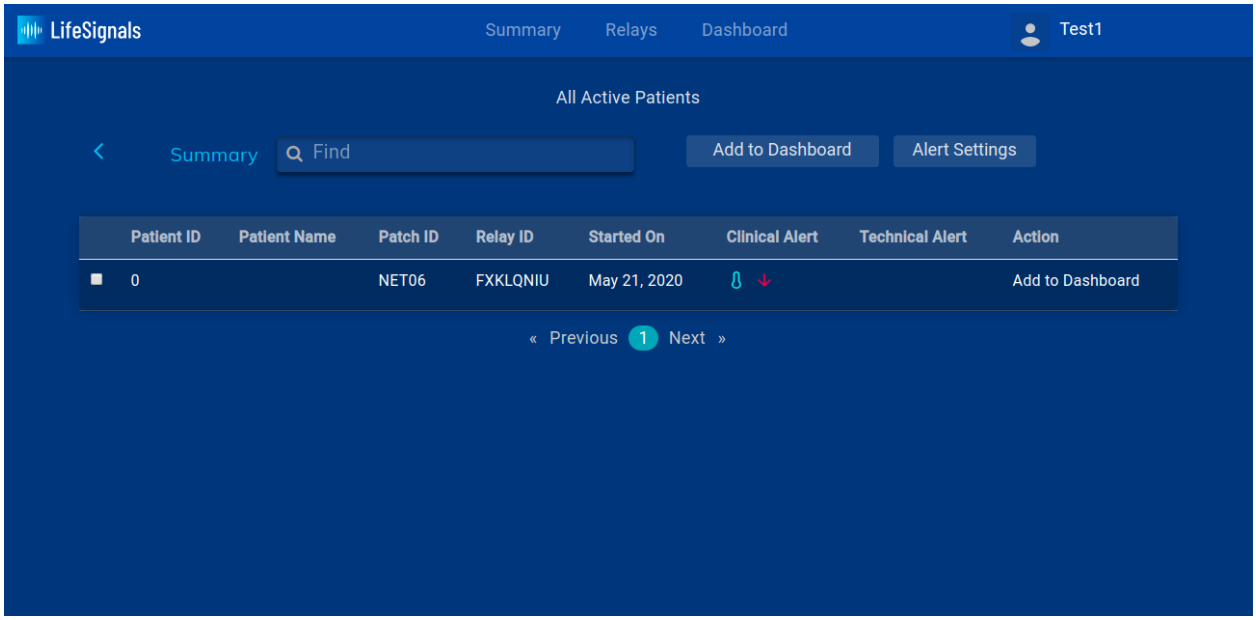


10.7. **All Active Patients**

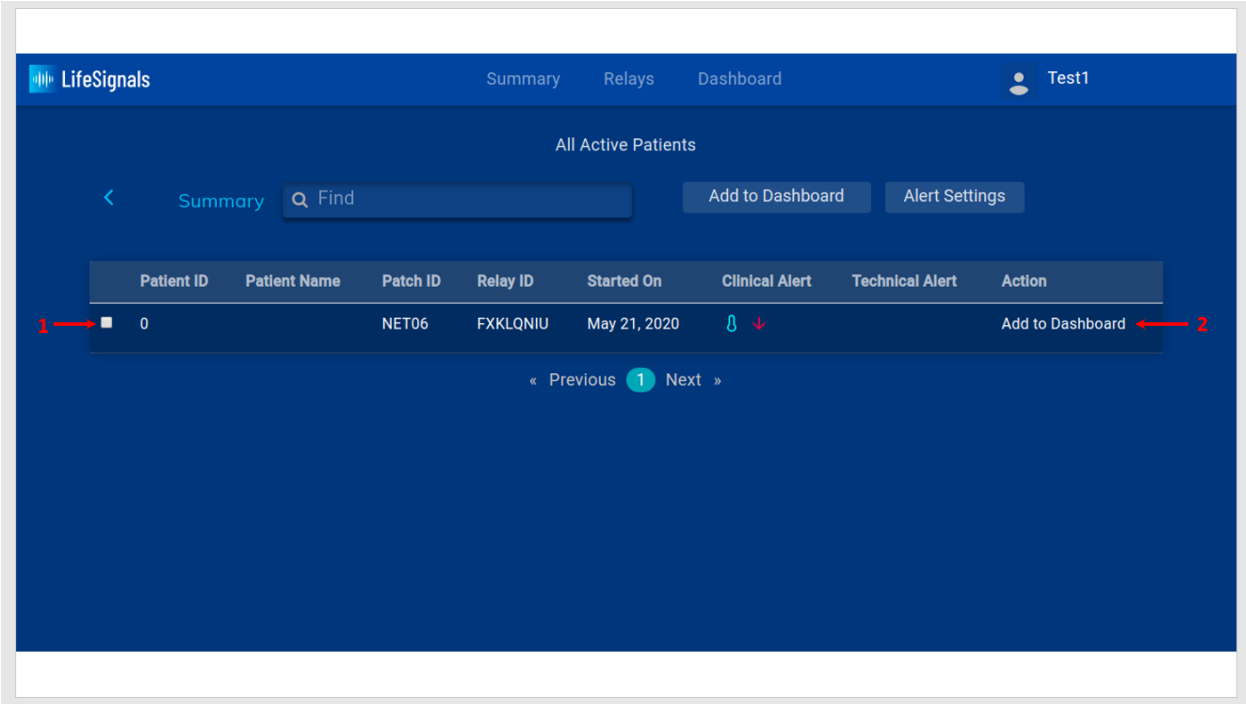
- From the Menu, click on All Active Patients



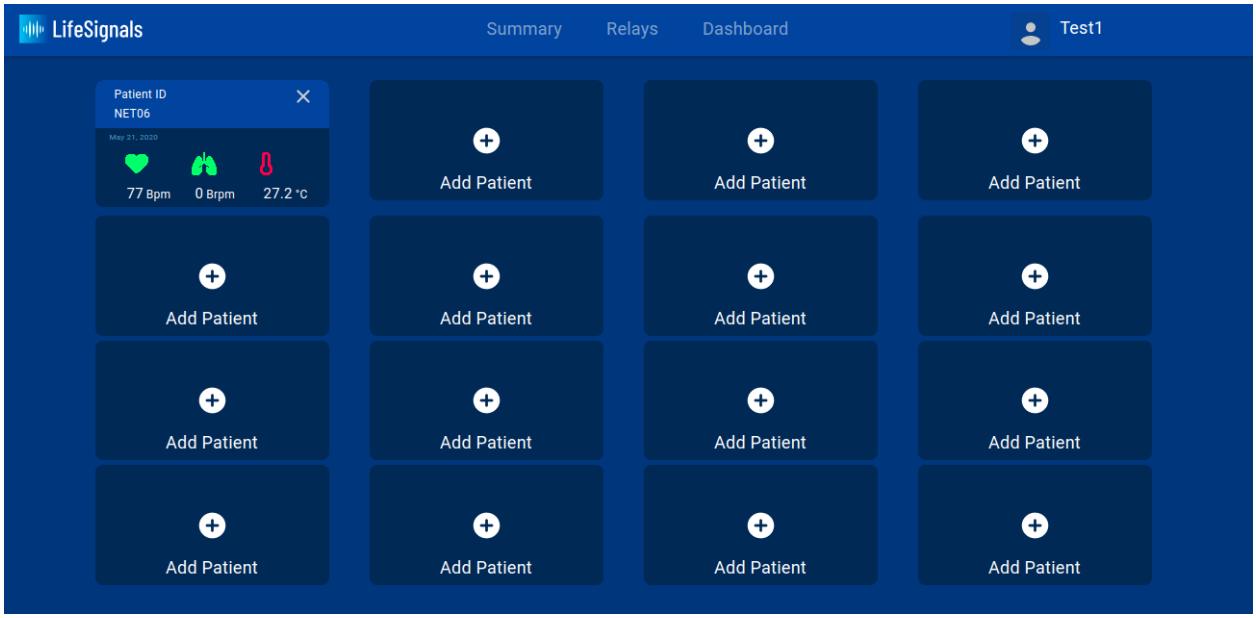
- List of All Active Patients will be displayed



- Select the info you want to further review in detail (Step 1)
- Click the Add to Dashboard button (Step 2)

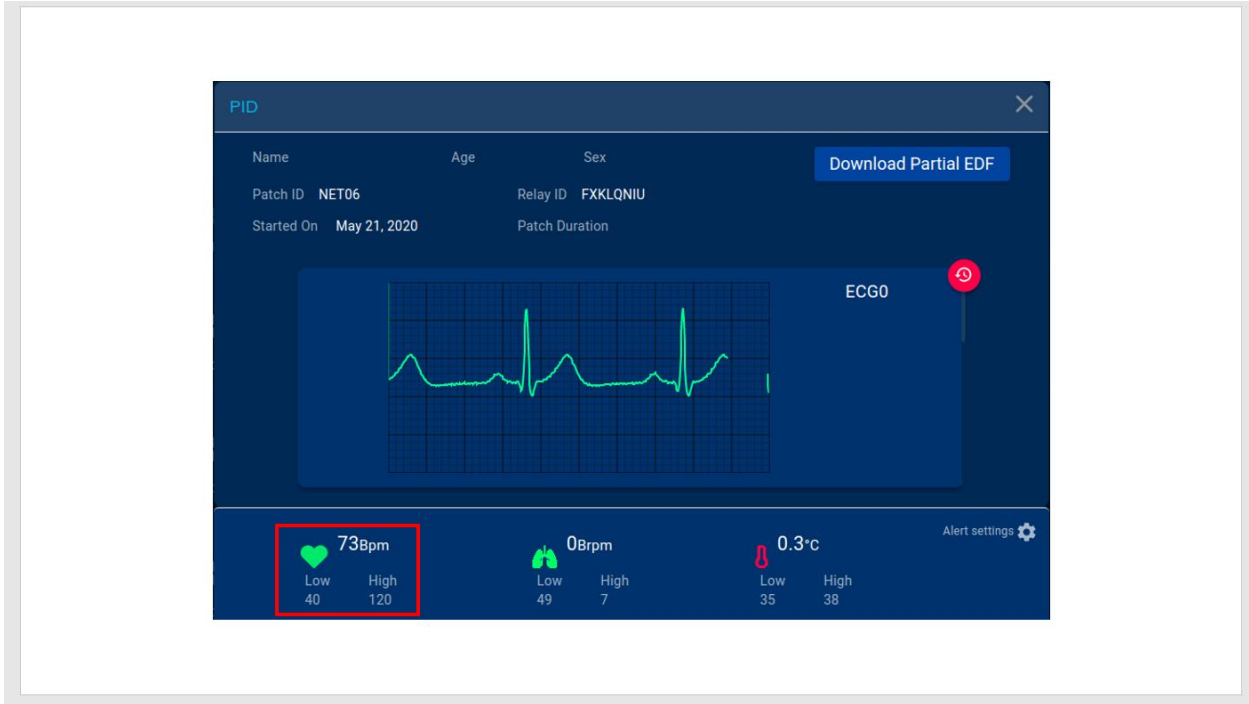


- The selected info will be displayed as shown below



- Click on the info you want to see in more detail
- You will see the ECG waveform from one channel as shown below

- To see the ECG from the other channel, click on the Heart Rate display as shown below

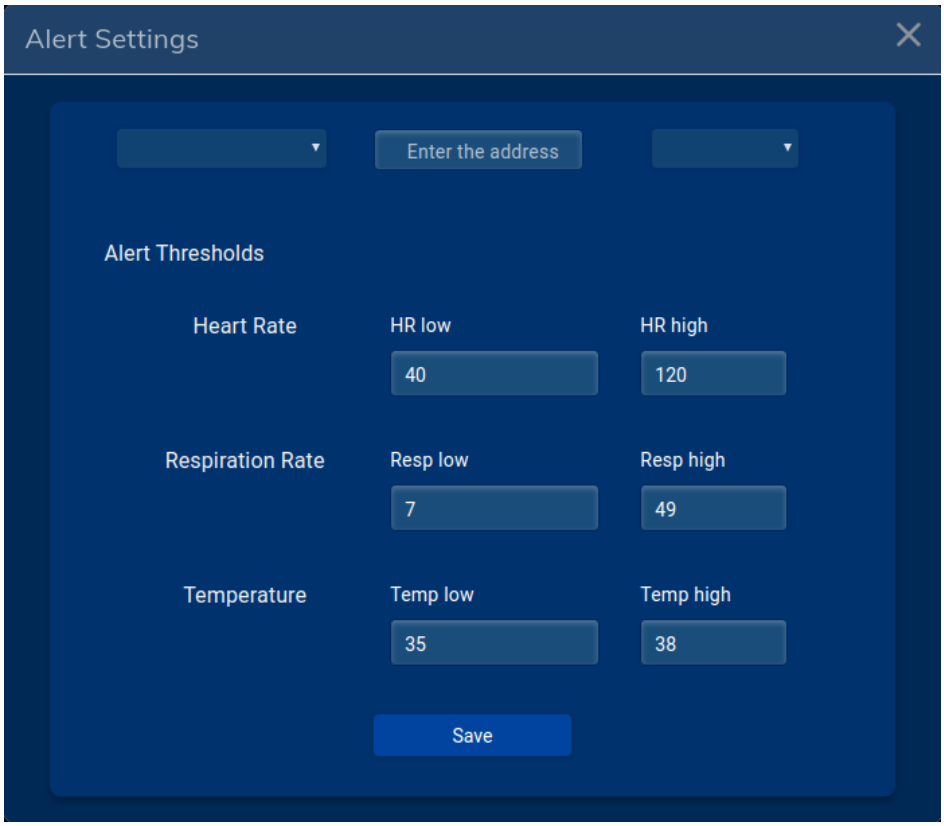


- You will now see the ECG from the other channel as shown below

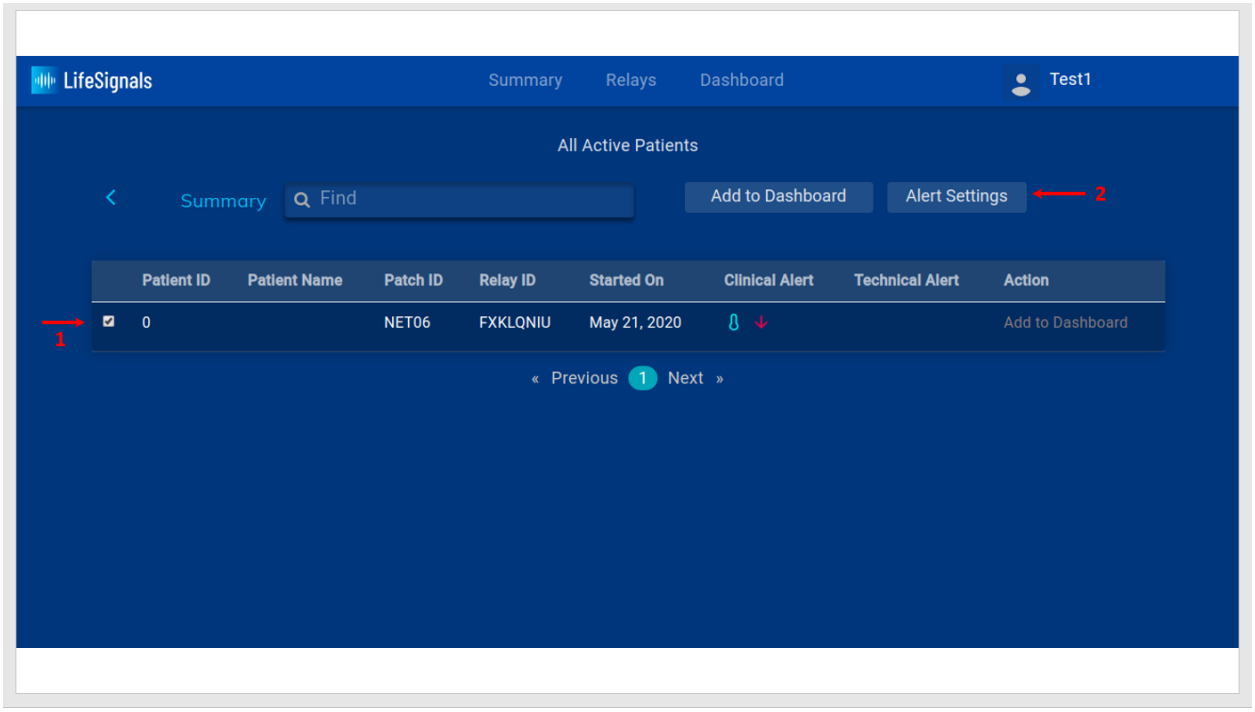
- Click on the Respiration Rate information and the graph for Respiration rate is shown as below

- Click on Alert settings

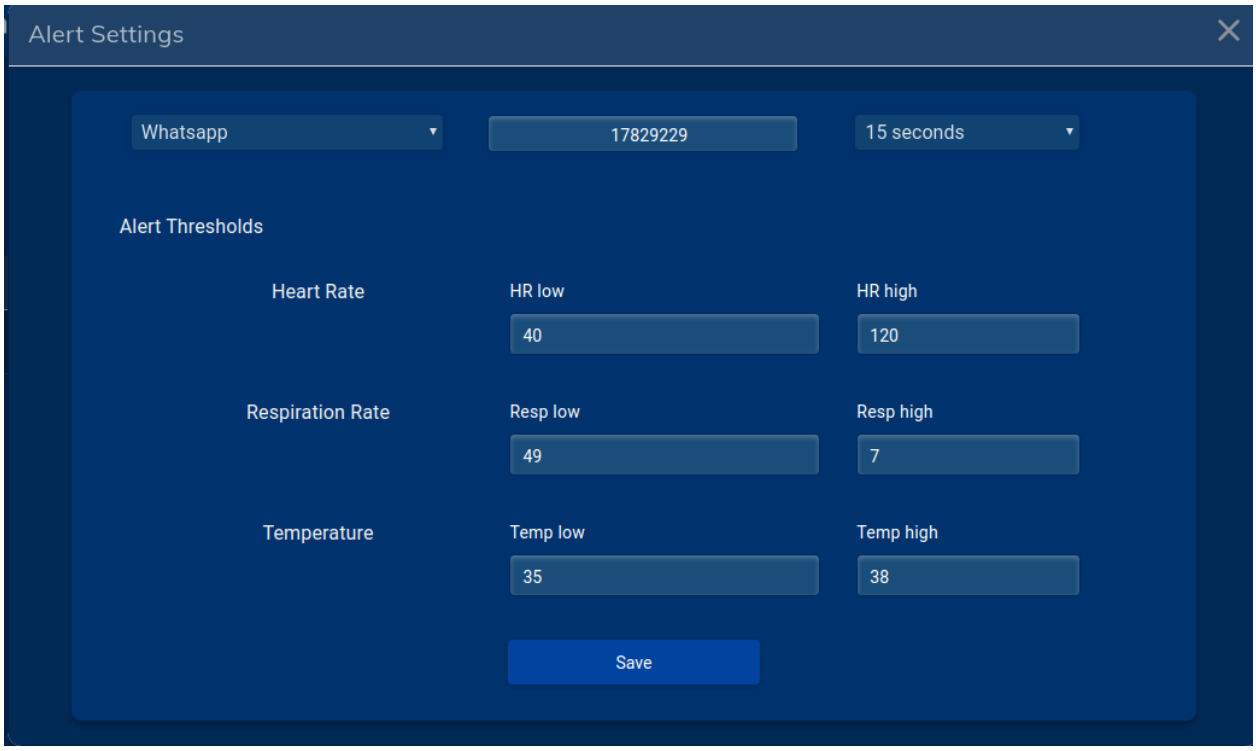
- You can review and edit the Alert Thresholds as required
- Once done, click on the Save button



- Another way of directly updating the Alert Settings from the All Active Patients menu is to select the Patient (Step 1)
- Click on the Alert Settings button (Step 2)

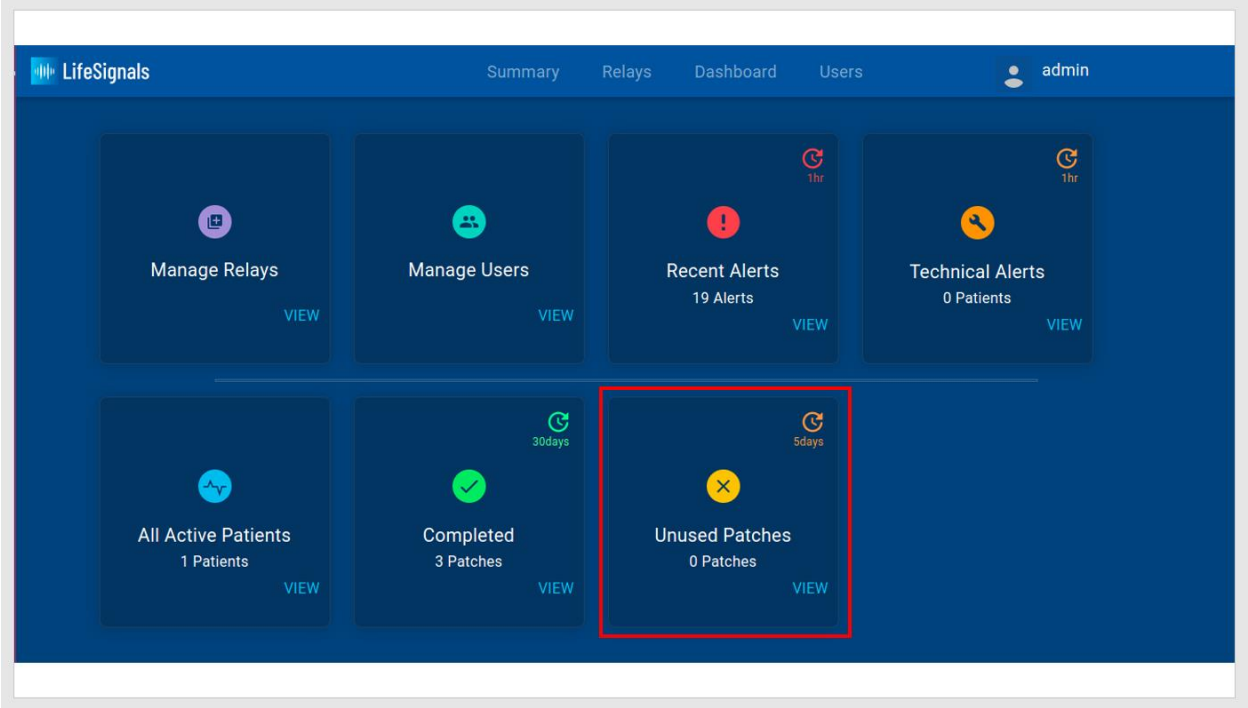


- You will get the Alert Settings options where you can edit information as required and Save the changes

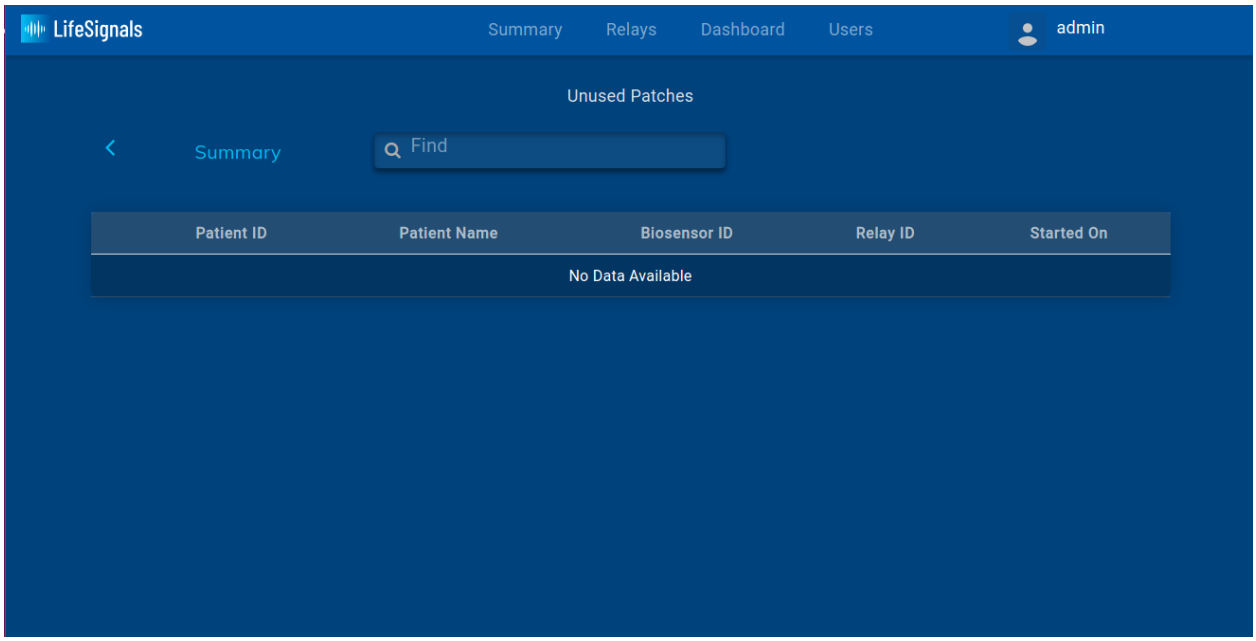


10.8. **Unused Patches**

- From the Menu, click on Unused Patches

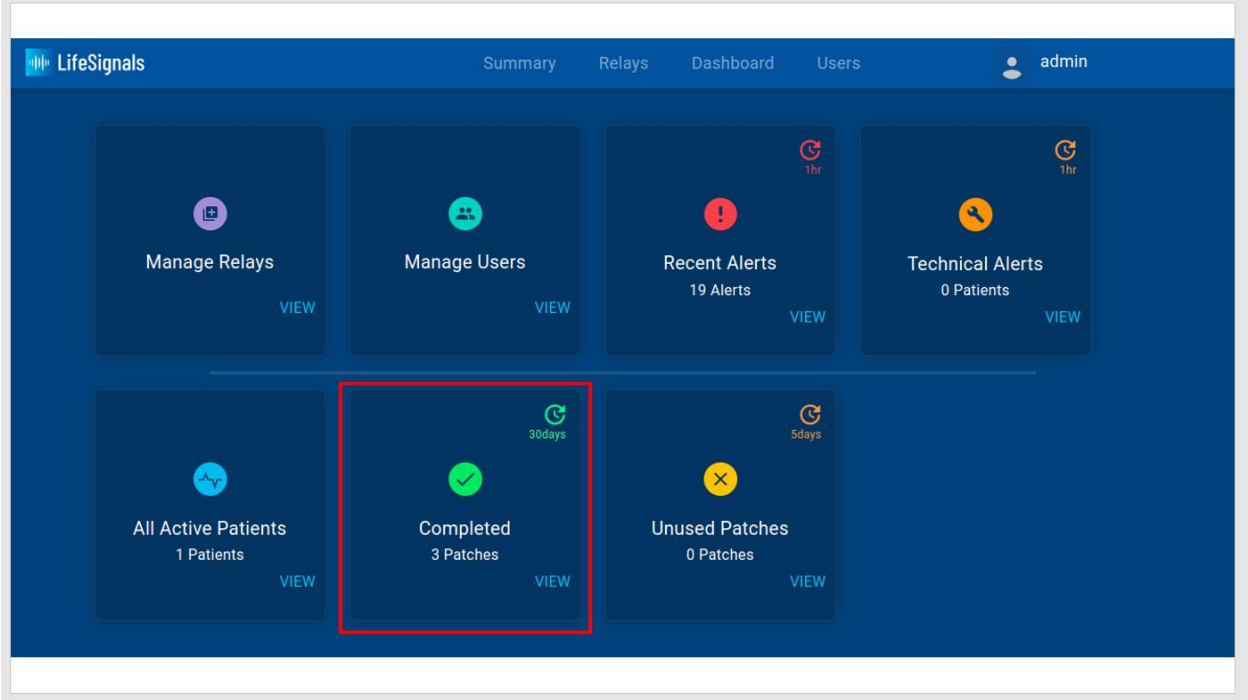


- List of all current Unused Patches are displayed

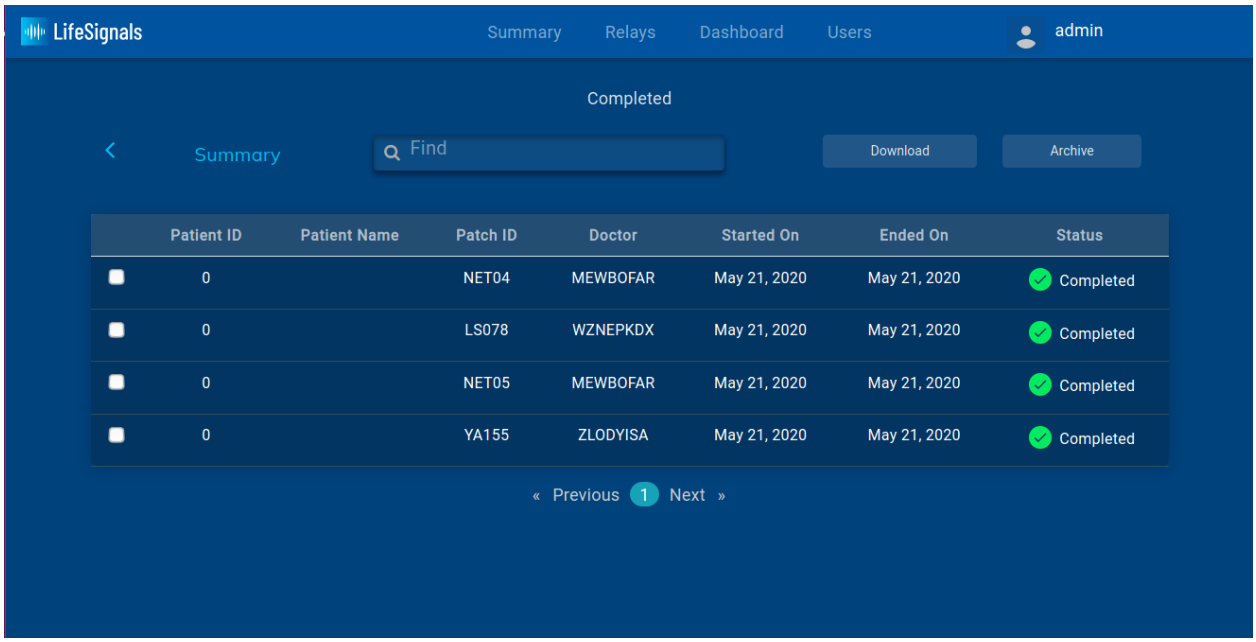


10.9. **Completed**

- From the Menu, click on Completed



- List of all completed patches are displayed


LifeSignals
Summary
Relays
Dashboard
Users
admin
Completed
Summary
Find
Download
Archive
Patient ID
Patient Name
Patch ID
Doctor
Started On
Ended On
Status
0
NET04
MEWBOFAR
May 21, 2020
May 21, 2020
Completed
0
LS078
WZNEPKDX
May 21, 2020
May 21, 2020
Completed
0
NET05
MEWBOFAR
May 21, 2020
May 21, 2020
Completed
0
YA155
ZLODYISA
May 21, 2020
May 21, 2020
Completed
« Previous
1
Next »

11. Appendix

11.1. Table 1: Biosensor (LP1550) Specifications

Specifications	
ECG channels	Two (2) ECG-A and ECG-D
Classification of Applied parts	Defibrillation proof type CF**
Frequency Response	0.2 Hz to 40 Hz
CMRR	> 90dB
Input impedance	> 10 Meg ohms at 10Hz
ADC sampling rate	244.14 SPS
ADC resolution	16 bits
Noise	<30uVpp
Dynamic Range	±300mV
Lead off detection	
Injected Current	< 10uA
Injected Frequency	10 KHz
Power Requirements	
Battery Type	Li-MnO2
Battery Life	Biosensor shall have a battery life of minimum 120 hours of normal operation (continuous transmission) under normal wireless environment
Battery Capacity	1200 mAh
Output Voltage	3 V
Charging Mode	Not rechargeable
Environmental Specifications	
Transportation temperature (≤ 10 days)	-5ºC to +50ºC (23ºF to 122ºF)
Operational temperature	+0ºC to +45ºC (32ºF to 113ºF)

Operational relative humidity	10 % to 90 % (non-condensing)
Storage temperature (≤ 30 days)	+0ºC to +45ºC (32ºF to 113ºF)
Storage temperature (> 30 days)	+5ºC to +27ºC (41ºF to 80.6ºF)
Storage relative humidity	30 % to 75 % (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Ingress protection	IP44
Physical Characteristics	
Dimensions	115 mm x 110 mm
Weight	< 30 gm
Color	White or off white
Wear life	120 hours
Wireless Specifications	
Frequency band	2.400-2.4835 GHz
Bandwidth	20 MHz
Transmitter power	0 dBm
Modulation type	Complementary Code Keying (CCK) and Barker Coding
Data Rate	1, 2, 5.5 and 11 Mbps
Quality of service—Range	5 meters (Note*)
Wireless security	WPA2-PSK
Declaration and Disclaimers	Other equipment may interfere with the operation of the Biosensor, even if it complies with CISPR EMISSION requirements. Portable and mobile RF Communication equipment can affect Biosensor operation.

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

**: ECG Signals shall recover within 6 seconds after removal of defibrillation voltage

11.2. **Table 2: Platform (LX1550) Heart Rate, RR, Skin temperature and Accelerometer Specifications**

Measurement Range	30 BPM to 250 BPM
Measurement algorithm	Four consecutive R-R intervals averaging
Accuracy	± 3 BPM or 10% whichever is higher
Heart Rate Alert setting - High	100 to 250 BPM (Default: 120 BPM)
-Low	30 to 100 BPM (Default: 40 BPM)

Measurement Range	5 to 60 BrPM
Measurement algorithm	Respiration algorithm based on both TTI (Trans-thoracic Impedance) and EDR (ECG Derived Respiration).
Accuracy	±2 BrPM
RR Alert setting - High	Above 50 BrPM
-Low	Below 6 BrPM

Measurement Range	32°C to 43 °C (minimum)
Measurement algorithm	Steinhart-Hart Equation using second order polynomial
Accuracy	±0.4°C
Skin temperature Alert setting - High	Above 39°C
-Low	Below 34°C

Number of channels	3 (x, y and z)

Sampling rate	25 SPS
Dynamic range	± 2g

11.3. **Table 3: Relay Application Error Messages**

Message	Description
Backend exe Failed	Server broke for some reason
Authenticated	Authentication success
Authentication Failed	Authentication failure
Duration is not present. Defaulting to 20 min	Duration not found in Server key
Authentication key successfully imported !!	Successful import of Server key
Failed to parse authentication key	Failed to import Server key
Turn off success!!	Success of turning off command
Turn off error!!	Error of turning off command
Please Download authentication key and place it in Downloads folder and import from menu.	Server key missing
No network available. Please try later	Internet/Server not available
Program mobile hotspot with SSID and Password same as the SSID and password of Biosensor	After sensor is reconfigured
*Scanning for Sensors. Do you want to exit the app*lication*?*	Back-press while scanning ongoing
*Sensor is streaming. Do you want to exit the app*lication*?*	Back-press while streaming ongoing
Insufficient Memory to store data. \n Please make sure you have enough memory. \n" + freeMB + " MB of storage available. " + reqMB + " MB of storage required.	Insufficient Memory
Manually check if the sensor is turned off. If yes click Finalize to continue.	On socket error on turn-off
Battery Level " + level + "%", "Battery Level is critically low!!!	Battery level lower than 15%

Do you want to re-configure sensor to a different SSID?	On patch selected, to change SSID
A session with the sensor was found incomplete. Do you want to continue the current session?	Restore session
Device configuration updated successfully.	Reconfigure patch success
Unable to reconfigure patch.	Reconfigure patch failure
FINALIZING...	Finalizing started
*The sensor has completed streaming. Please exit the app*lication.	On Server Response, patch Status = Completed
*Finalization completed. App*lication *will exit now!*	On Finalize completed
SOCKET ERROR	Socket error on set mode
SOCKET_ERROR. Do you want to reconfigure?	Socket error on reconfigure

11.4. **Table 4: Web UI Error Messages**

Messages	Description
Session Expired! You have been inactive for 5 minutes. Login to continue.	Session timeout.
Invalid Login!	Login credentials are invalid
Internal Failure!	API call failed.
You can select only 500 patches at a time.	Relay select limit exceeded.
List Patches Failed!	Server failed to load patch list
List Relay Failed!	Error while retrieving relay information from database
Admin only!	User does not have admin privilege.
Remove relay Failed!	Server was not able to execute remove relay command
Relay removed!	Server successfully executed remove relay command

Remove Patch Failed!	Server was not able to execute remove patch command
Patch removed!	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
Please select a valid Duration	Duration has not been selected from the dropdown menu
Key generation failed!	Sever key was not generated successfully
Relay added successfully!	Sever key was generated successfully
EDF download Failed: <WITH SERVER RESPONSE>	Failed to download EDF file
Edit Relay Failed!	Failed to update relay parameters during editing.
Relay Updated successfully!	Relay parameters were edited successfully
Only Admin can view the user list!	User does not have admin privilege to access the user list.
List users Failed!	Error while retrieving user information from the database
Remove User Failed!	Failed to remove the user.
User removed!	The user was successfully removed.
Please provide a valid User Name.	Invalid Username.
Please provide a valid Password.	Invalid Password.
Please select a privilege.	Select an option either admin or normal while adding a new user.

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
Cannot add user	Failed to create a new user.
User added successfully!	The user was successfully added to the database.
Please confirm the 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 Username	The username entered does not exist.
Cannot change password	The password cannot be changed.
Password changed successfully!	The password was successfully updated.

11.5. **Table 5: 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	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.

11.6. **Table 6: Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The 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	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

11.7. **Table 7: FCC Statement**

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

11.8. **Symbols**

Label	Identification	Description
	Stand-By	This symbol indicates that the switch or switch position by means of which part of the equipment is switched on
	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
	Recycle	Disposal of the medical device to be controlled according to local regulations as battery waste
	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 device	To be used under prescription supervision by a medical practitioner

	Refer to Instruction Manual/booklet	Refer to instruction manual/booklet
	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
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 5 boxes tall
FCC ID	Federal Communications Commission	Federal Communications Commission ID
	MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD

	Damaged package Indication	Do not use if package is damaged

Contact Information

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Biosensor is assembled in Republic of Korea

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