



LifeSignals Multi Parameter Remote Monitoring  
Platform

**Technical User Manual**

**Revision History:**

| Revision | Date             | Description of change        | Approved by   |
|----------|------------------|------------------------------|---------------|
| Rev A    | See<br>IMSXpress | Initial draft release        | See IMSXpress |
| Rev B    | See<br>IMSXpress | Refer to Redline<br>Document | See IMSXpress |
| Rev C    | See<br>IMSXpress | Refer to Redline<br>Document | See IMSXpress |
| Rev D    | See<br>IMSXpress | Refer to Redline<br>Document | See IMSXpress |
| Rev E    | See<br>IMSXpress | Refer to Redline<br>Document | See IMSXpress |
| Rev F    | See<br>IMSXpress | Refer to Redline<br>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.

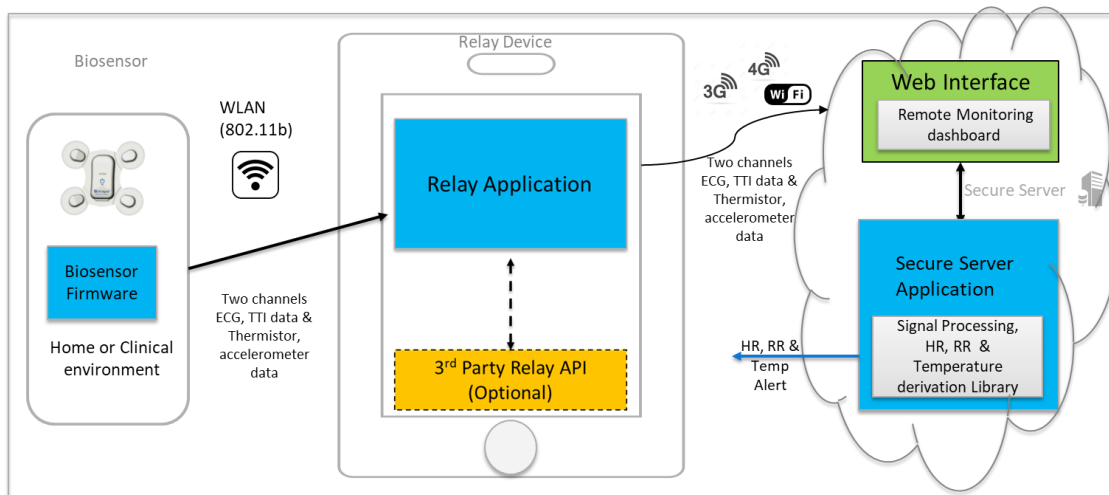
## **2 Contraindication:**

- 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:
  - o Ensure placement of the Biosensor only on clean and thoroughly dried skin
  - o Remove excess hair with hair clippers to avoid skin damage prior to placement
  - o Use Nuprep® or equivalent commercially available ECG skin prep pad per the instructions for use. Do not abrade the skin
  - o Avoid removing the Biosensor frequently and/or applying to the same skin site
  - o When handling the Biosensor, avoid dropping the device on hard surfaces, 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 5°C to 27°C
- 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-MnO<sub>2</sub> 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:

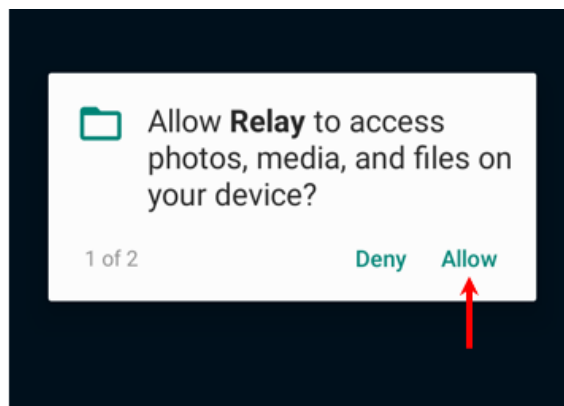
The Biosensor indicator LED provides information related to the functional status of the device

| 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 |

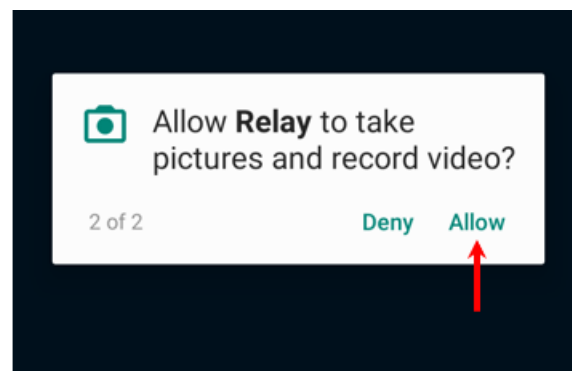
## 9. Instructions (For Clinical Personnel):

### Configuring the Mobile as a Relay Device

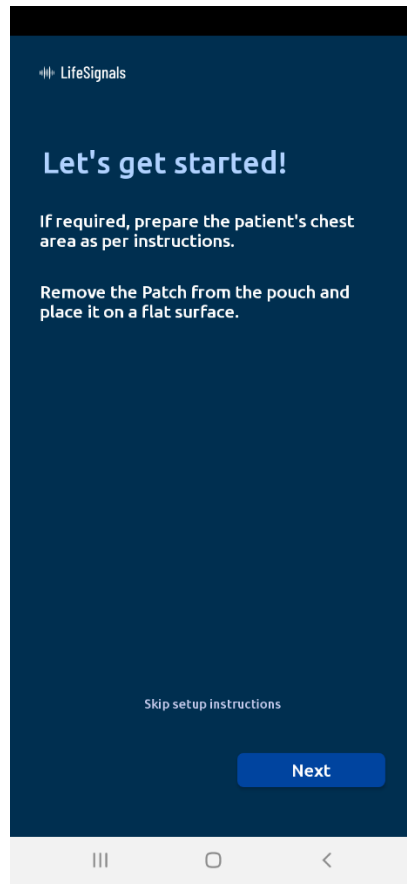
- Use only the compatible mobile phone as a Relay device. Please visit <https://support.lifesignals.com/supportedplatforms> for the details of compatible mobile phone make, model & OS version
- Download and Install LifeSignals Relay Application to the mobile phone
- Download the Authentication Key received 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



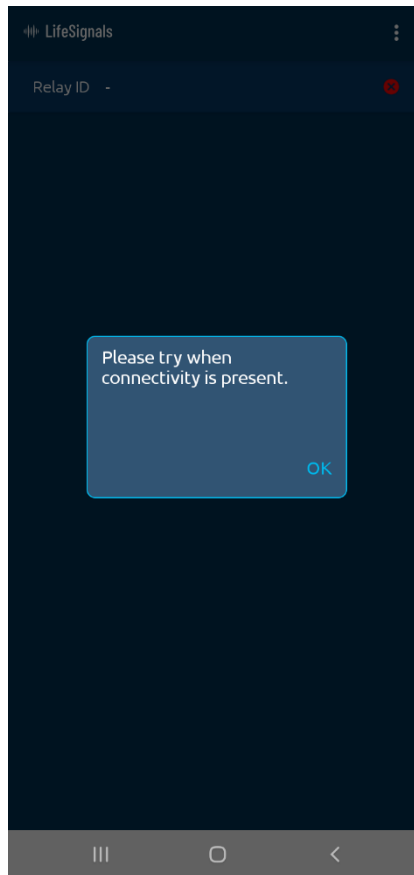
- The Introduction Screen is then displayed. If you select the "Skip setup instructions", you will directly be taken to Section 9.3



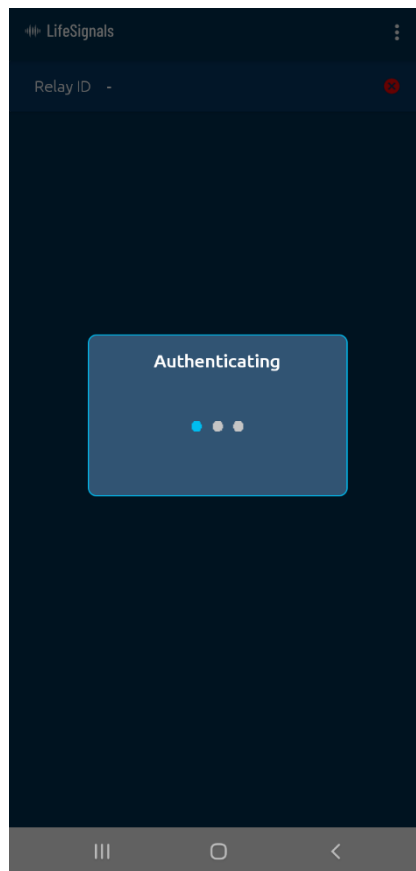
- If for some reason, the Relay Application is not Authenticated, then you will see the below screen

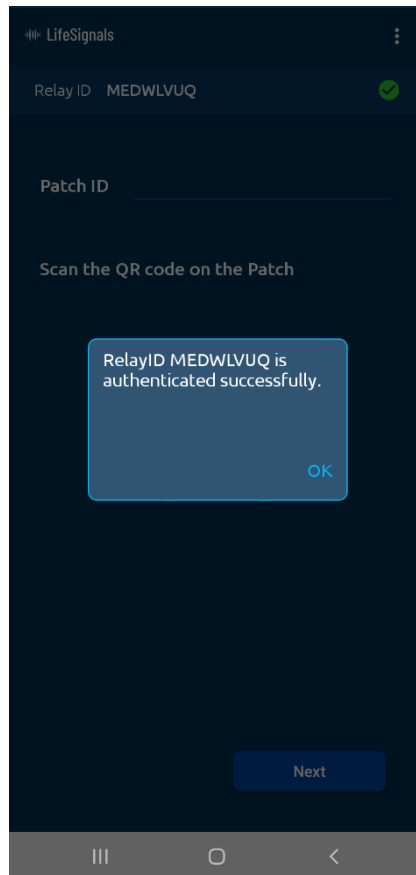


- If there is no connectivity, then the below screen is seen



- 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

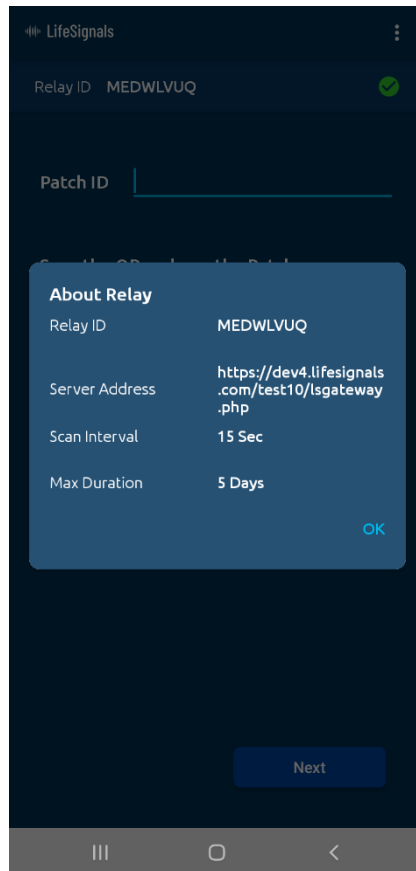




- To know about the Relay, click the Menu (three dots on the top right) (Step 1)
- Select About Relay (Step 2)



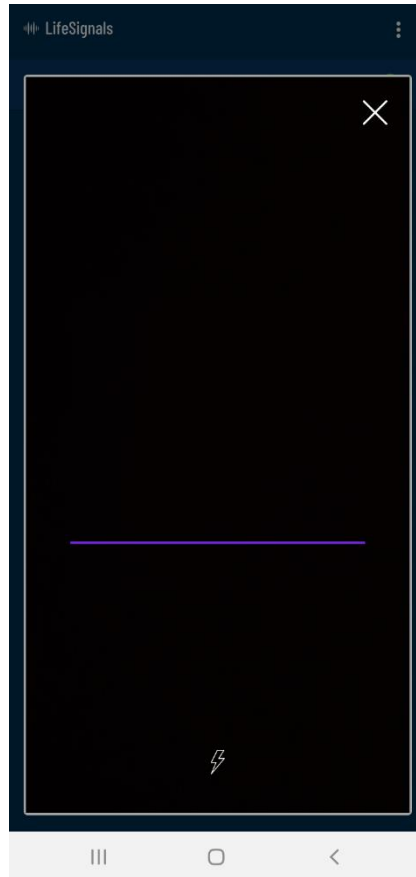
- Details about the device is shown



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



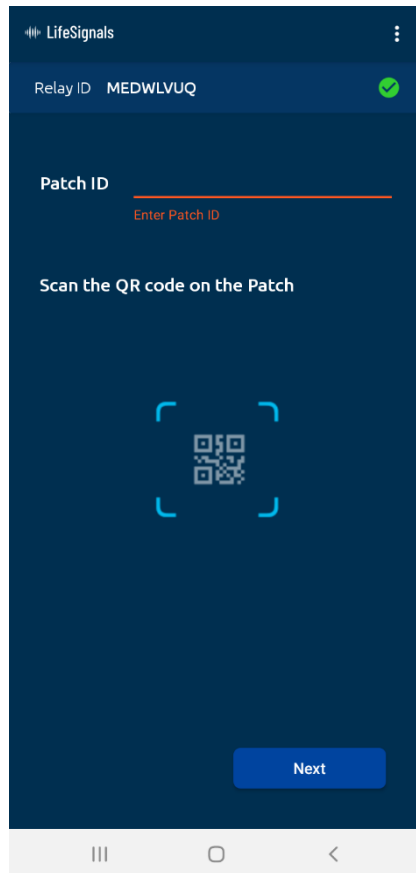
- If QR Code scanning is chosen, then the scanner looks for a QR code to scan



- 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

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Patch ID PATCH

### Patient Details

Patient ID 

First Name

Last Name

Contact

DOB 

Weight kg

Height cm

Doctor

Sex ☐ Male ☐ Female

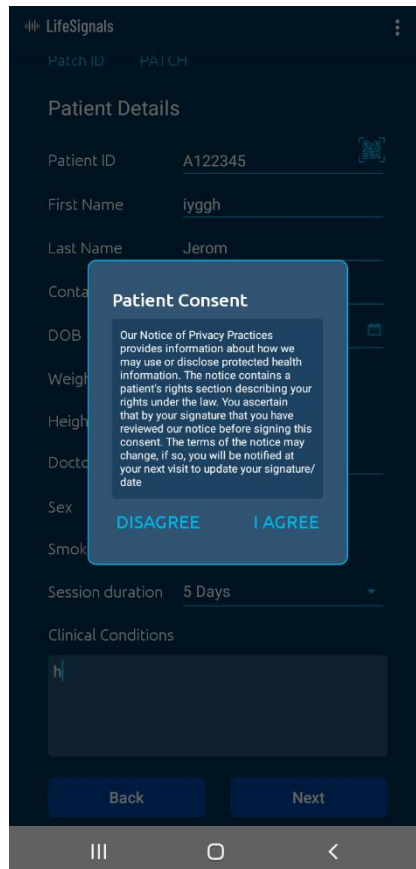
Smoker? ☐ Yes ☐ No

Session duration 5 Days

Clinical Conditions



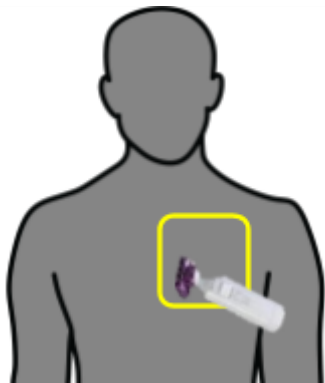
- Once all the information is input, the Patient Consent notice pops-up



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

#### 9.1. **Patient Body preparation**

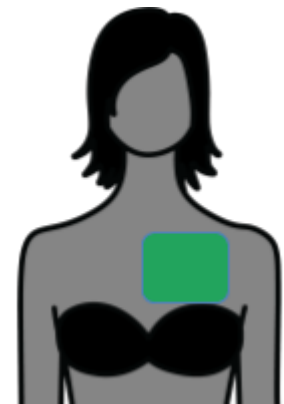
- Do a skin preparation on the left upper quadrant of the chest area between clavicle bone & nipple, middle to Left of sternum
- Remove excess hair by clipping instead of shaving to prevent skin irritation
- Remove any oil or lotion by wiping the area with an alcohol pad
- Prep the skin using Nuprep® Skin Prep Gel (Recommended) or any other non-abrasive skin prep pad
  - Apply enough gel to moisten about 1/4<sup>th</sup> 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)



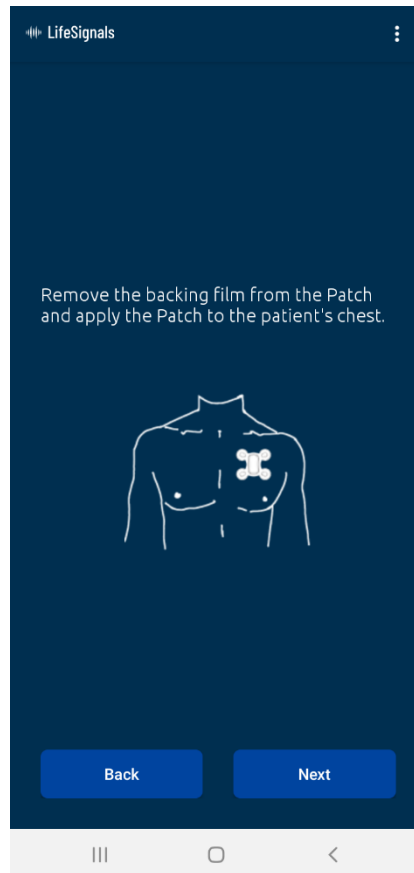
Nuprep® & Gauze Pad



Prep site (Female)

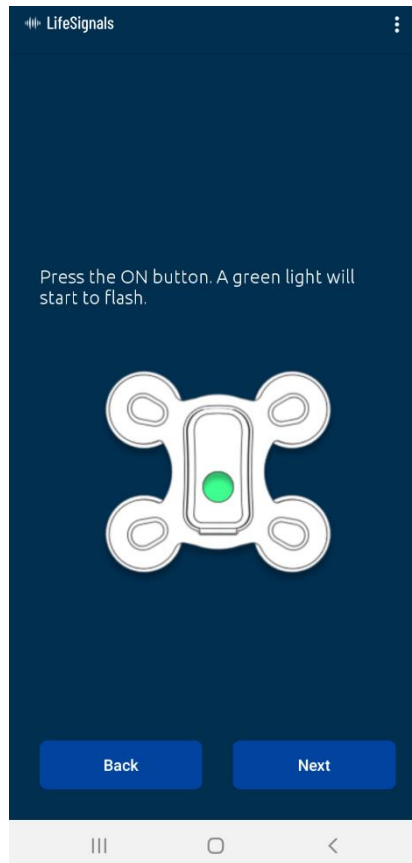
## 9.2. **Biosensor Affixing**

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



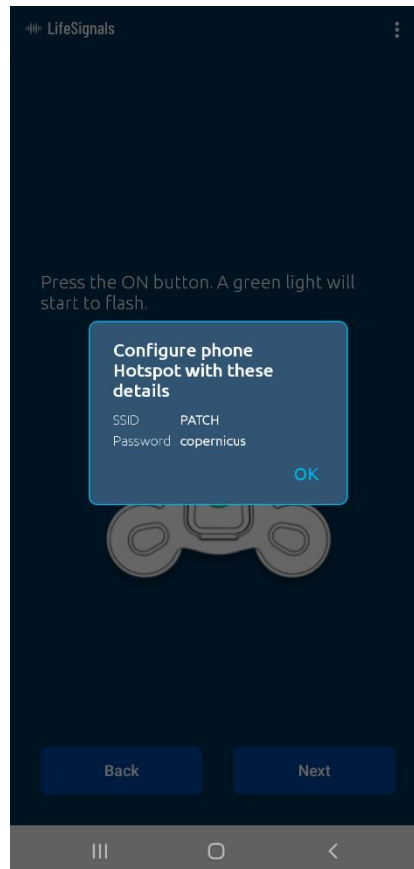
### 9.3. **Switching ON the Biosensor & Connecting to Mobile device**

- o Press ON button to switch on the Biosensor
- o Momentarily the red LED will turn ON
- o 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
- o If the connection is successful, then the green LED blinking rate will be reduced. (~ one blink per 3 sec)
- o 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**

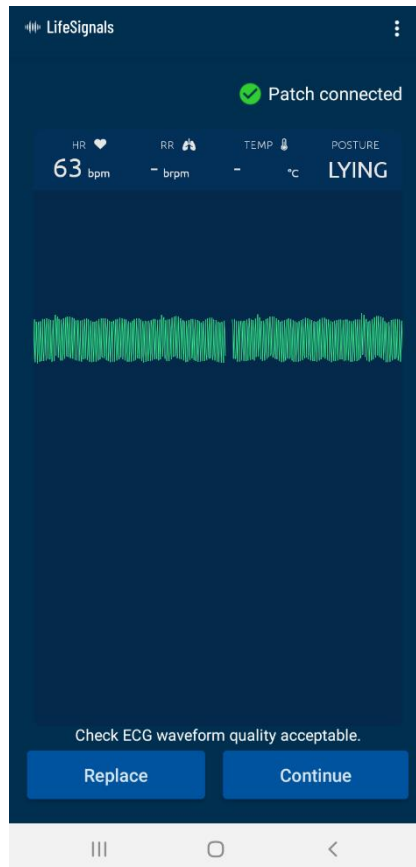
- o Open the Relay Application in Mobile device. Application will automatically connect to the Secure Server & details will be displayed. Select the OK button to start the procedure



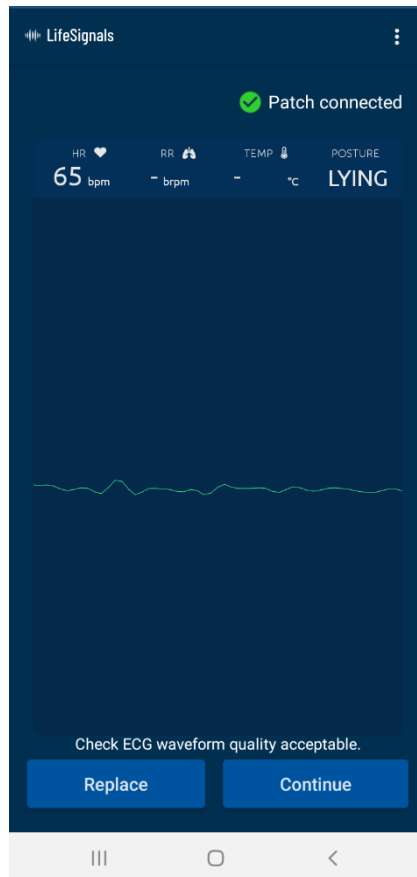
- o Once the App is connected to the biosensor, the plotting screens for the 2 channels of ECG and respiration wave form along with other numerical parameters such as HR, RR, TEMP and Posture will be displayed



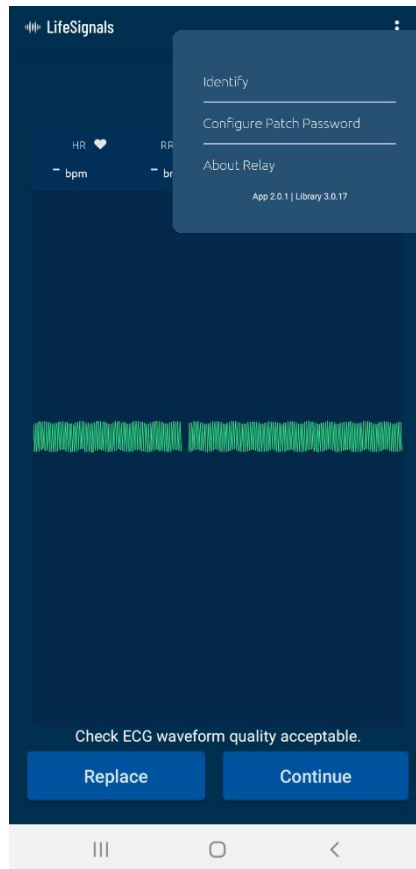
- o Scroll down to view plot from the other ECG channel



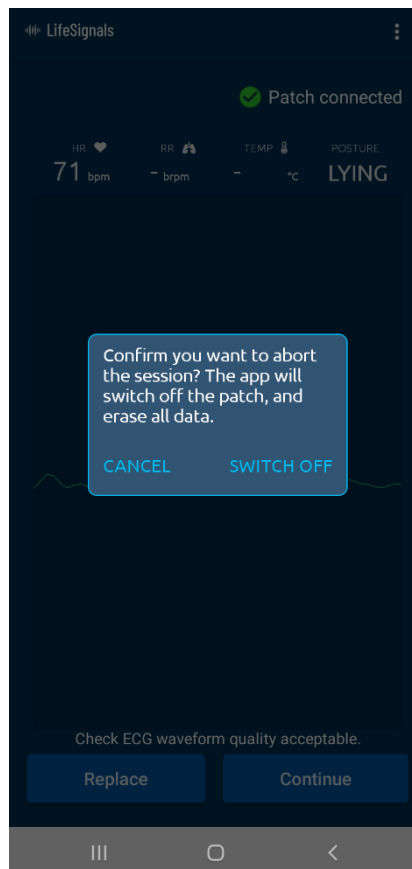
- o Continue to scroll down to view the respiration rate waveform



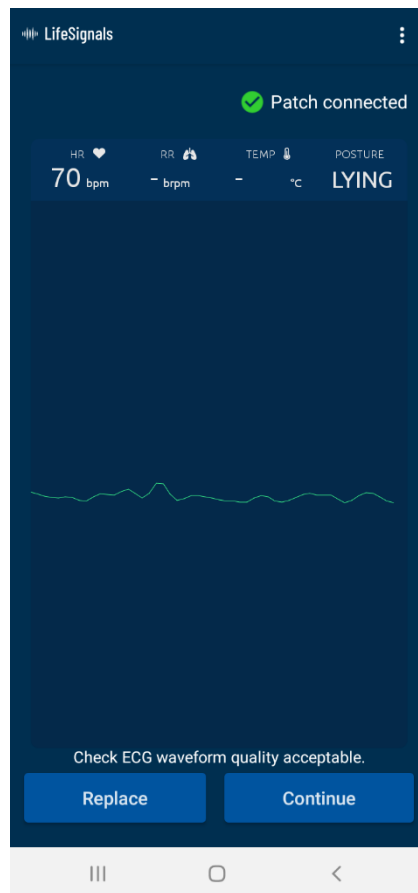
- o By clicking the Menu (top three dots on the right), several options are available



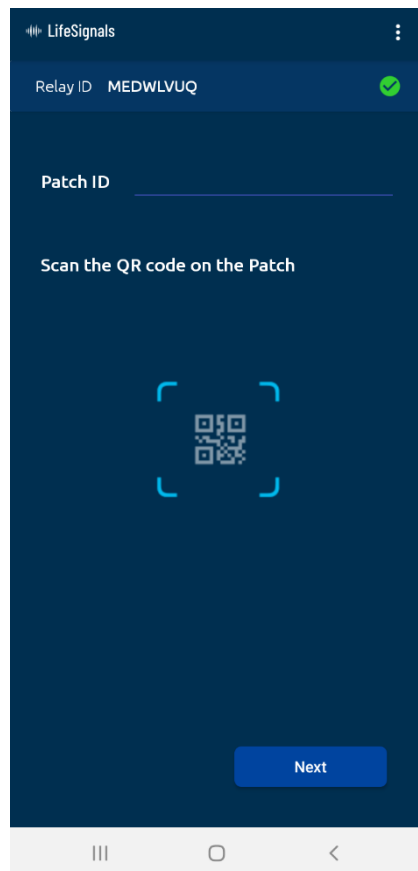
- o If for some reason, you want to remove or replace the patch, you can click the Replace button



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



- o 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



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

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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

Contact

DOB

Weight

Height

Doctor

Sex

Smoker?

Yes

No

Session duration

5 Days

Clinical Conditions

Back

Next

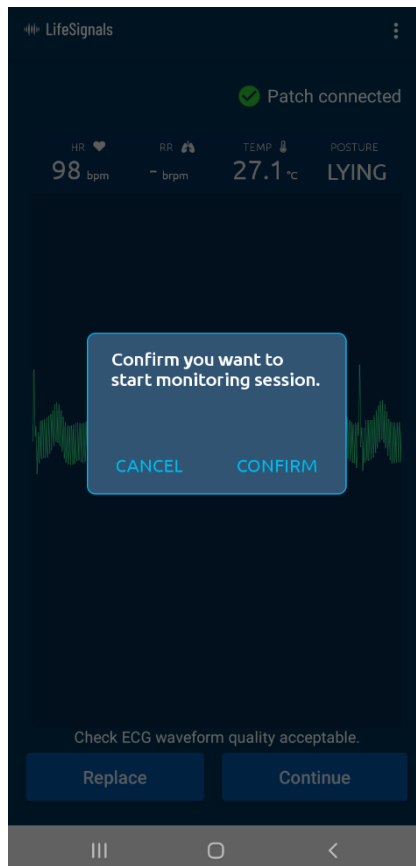
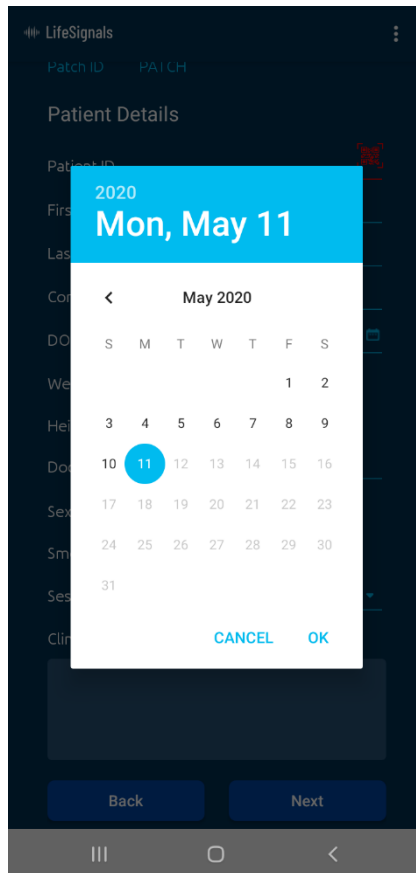
Select

1 Day

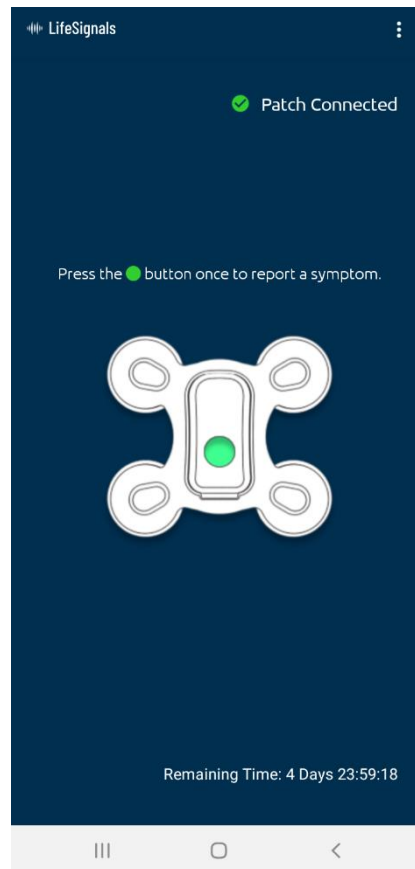
2 Days

3 Days

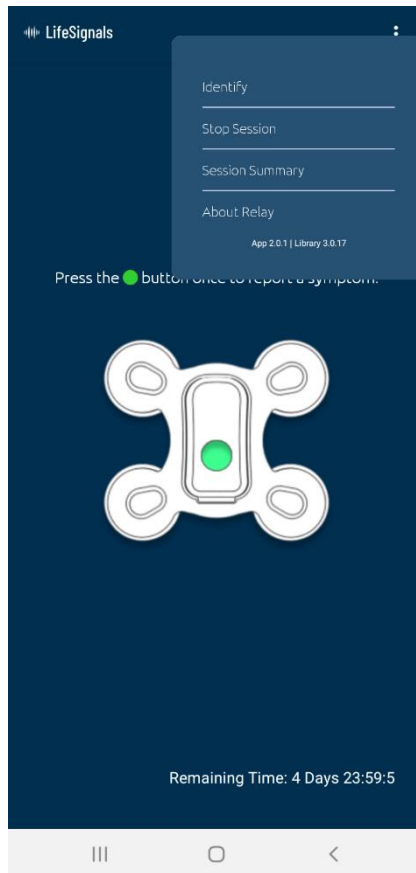
5 Days



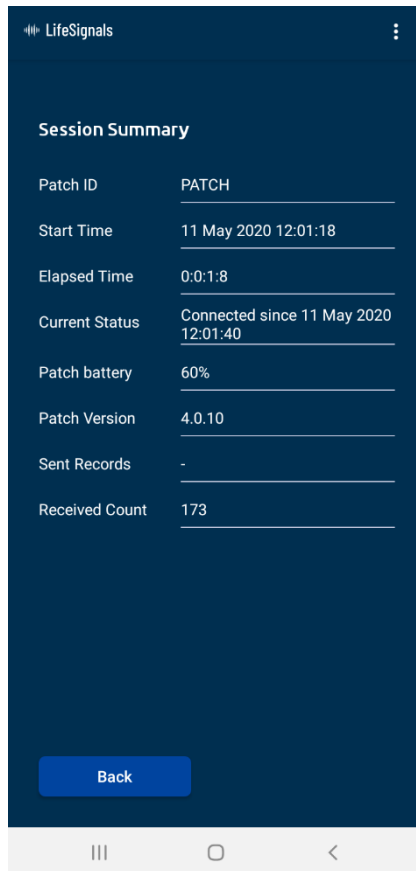
- o Once the CONFIRM button is clicked, the patch is connected and the remaining time for monitoring is displayed



- o 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



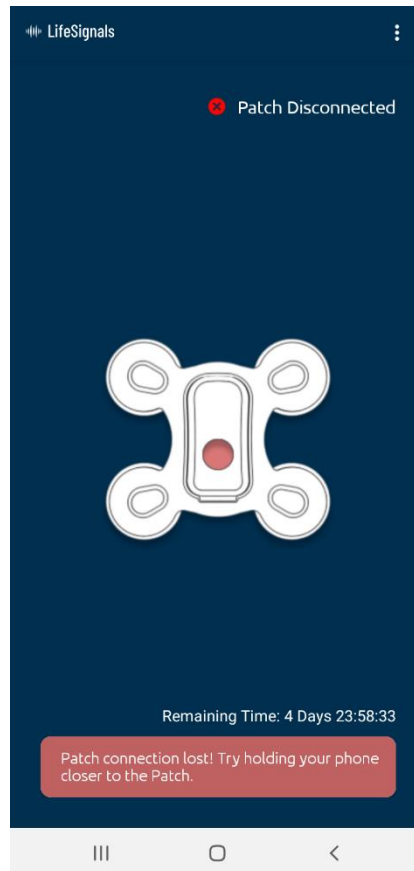
- o The Session Summary is then displayed



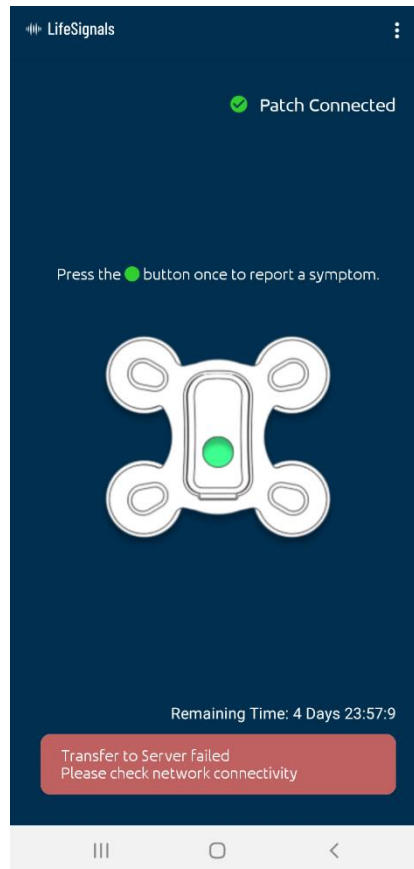
- o Click the Back button to go back to the Main Page

#### 9.5. **Other Alerts and features**

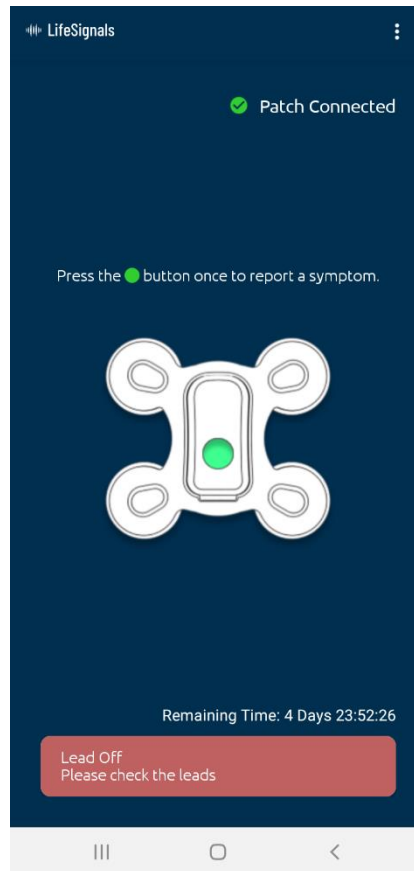
- o When the Patch gets disconnected from the Relay device, the below alert is displayed



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



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



- o 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

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### Add Event

Are you facing any of these symptoms?

☐ Light Headedness
 ☐ Chest tightness

☐ Chest Pain
 ☐ Flutter in the chest

☐ Palpitation
 ☐ Passing out

☐ Dizziness
 ☐ Others

What were you doing when you faced these symptoms?

☐ Normal routine
 ☐ Sitting

☐ Walking
 ☐ Lying down

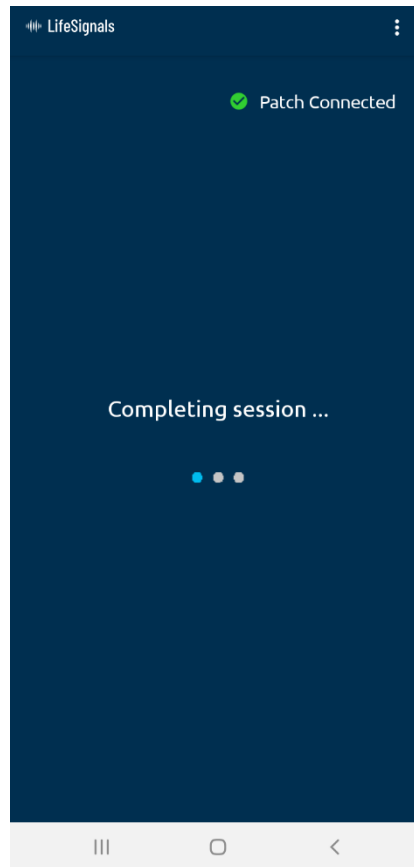
☐ Sleeping
 ☐ Exercising

☐ Others

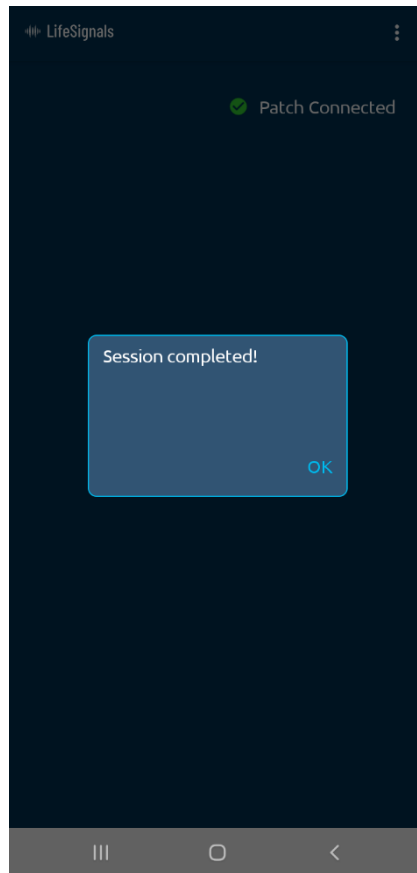
Back Save

#### 9.6. **End of Monitoring**

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



- o 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.



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

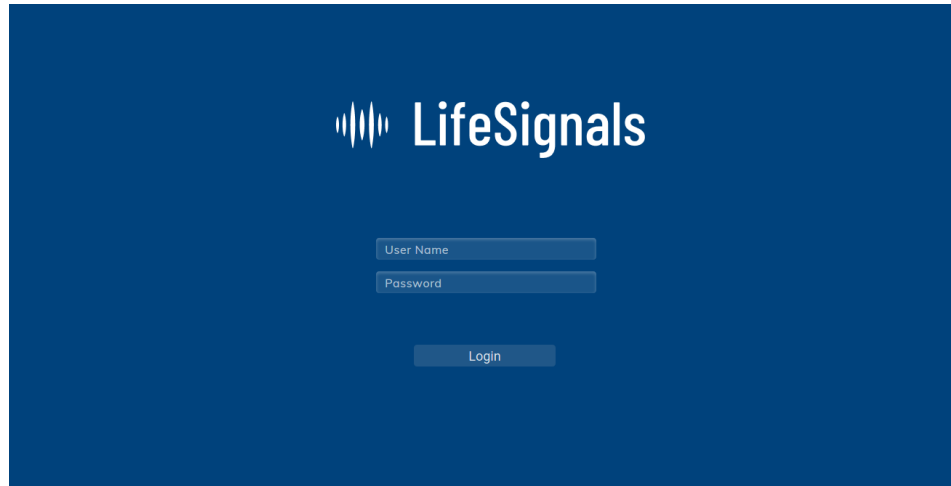
#### 9.7. **Removing the Biosensor**

- o Gently pull the bottom right corner of the Biosensor and remove it from the body
- o 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
- o Wash skin area with mild soap, rinse with water and pat dry
- o Dispose the Biosensor as per the local regulation

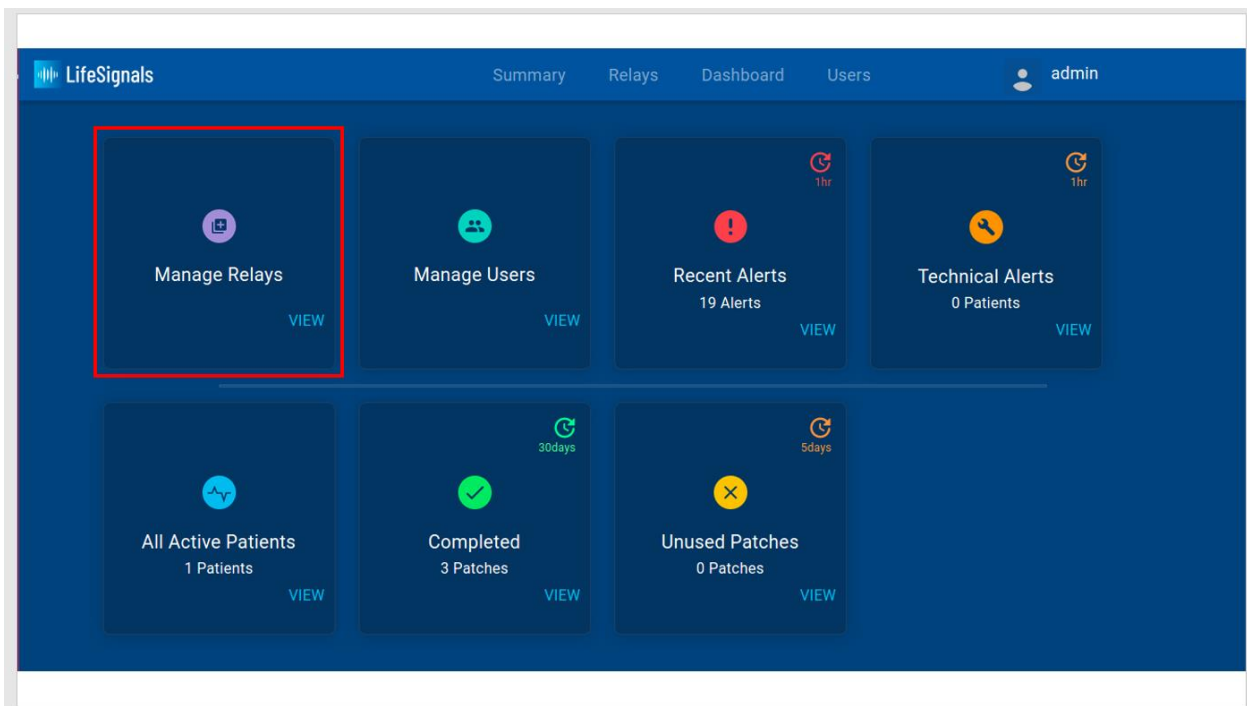
## 10. Instructions (For Secure Server Administrator):

### 10.1. Adding / Configuring a new Relay device to the Platform through Web Application

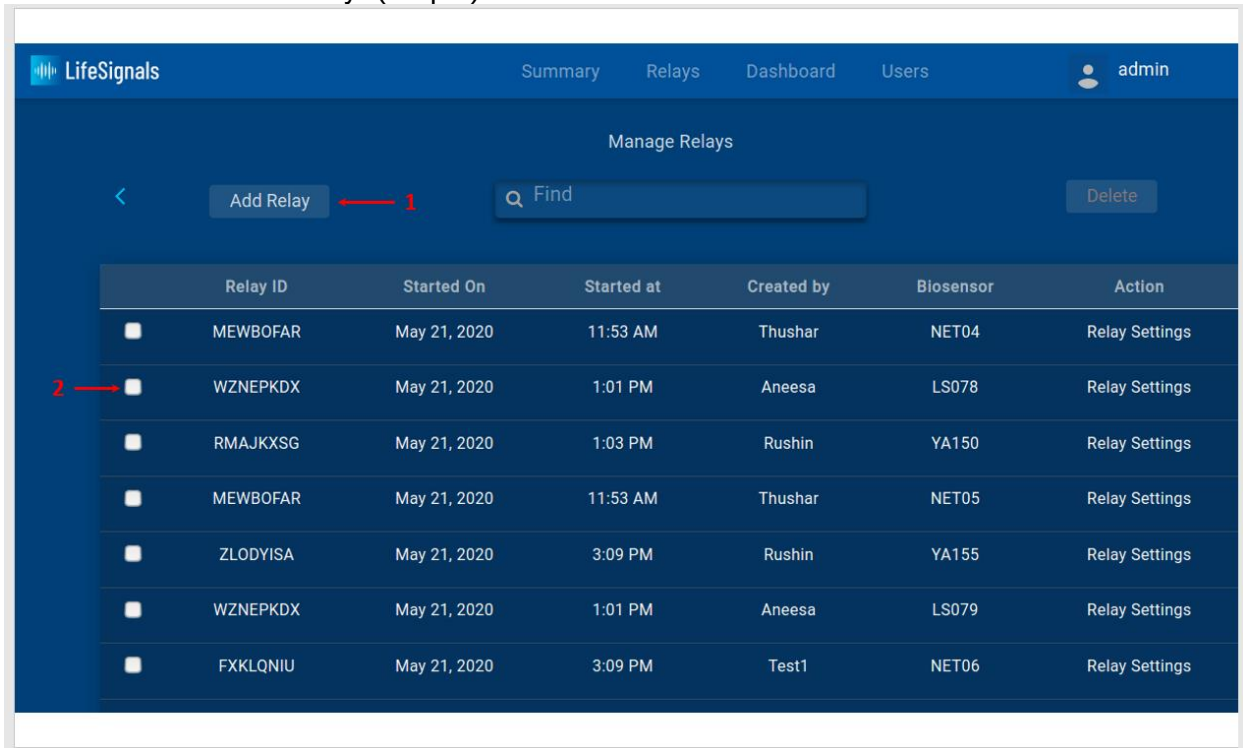
- Open LifeSignals Web Application and login as 'administrator' (by entering admin Username and Password)



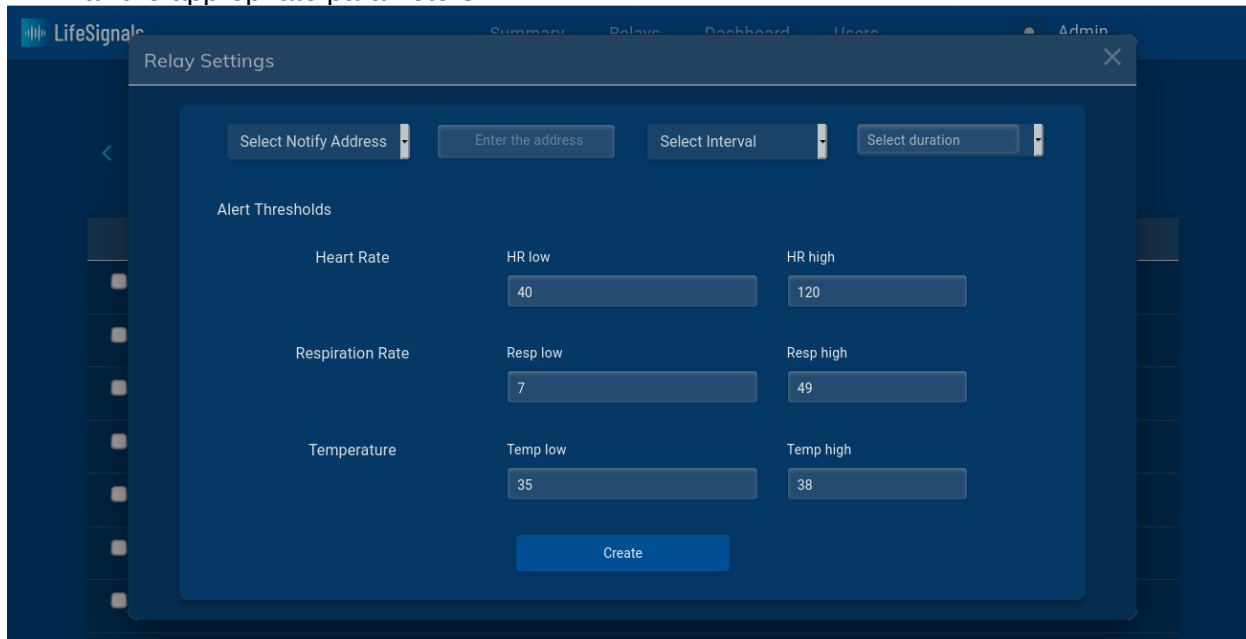
- Once logged in, select 'Manage Relays'



- 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

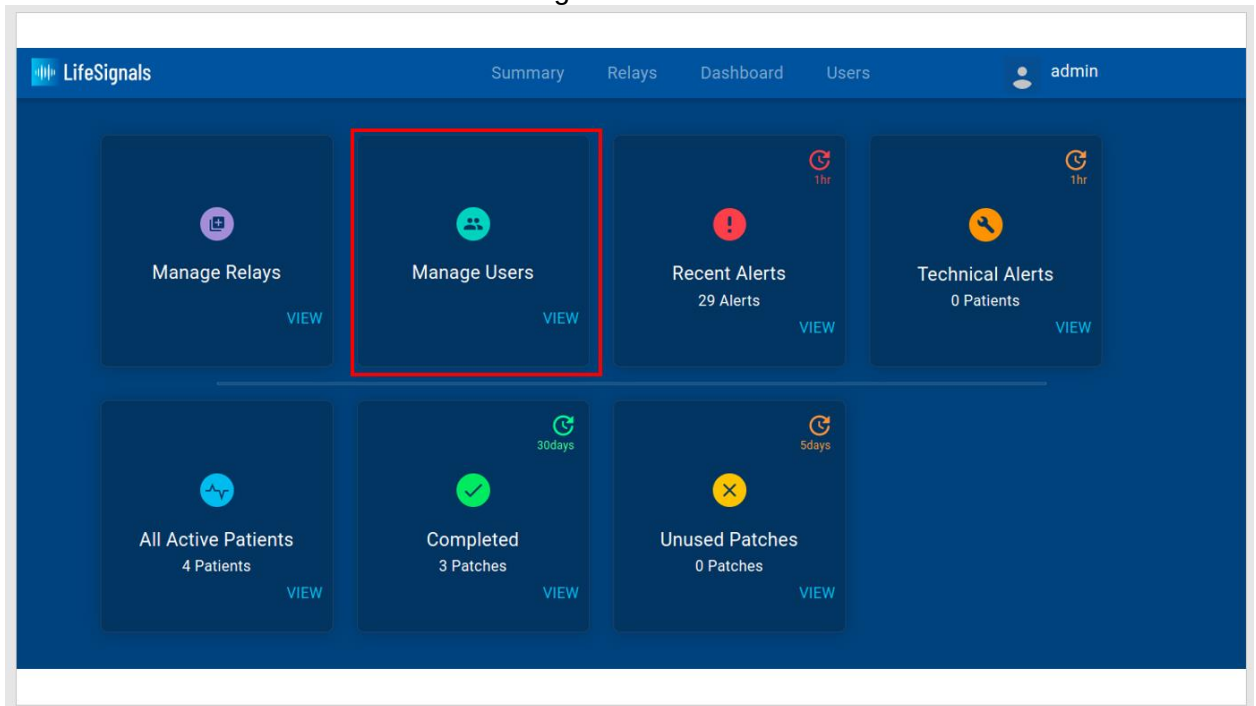


- Select maximum operating time of the Biosensor (120 hours). Any Biosensor connected to this relay device would be configured to this time
  - These configuration details can be modified at any time

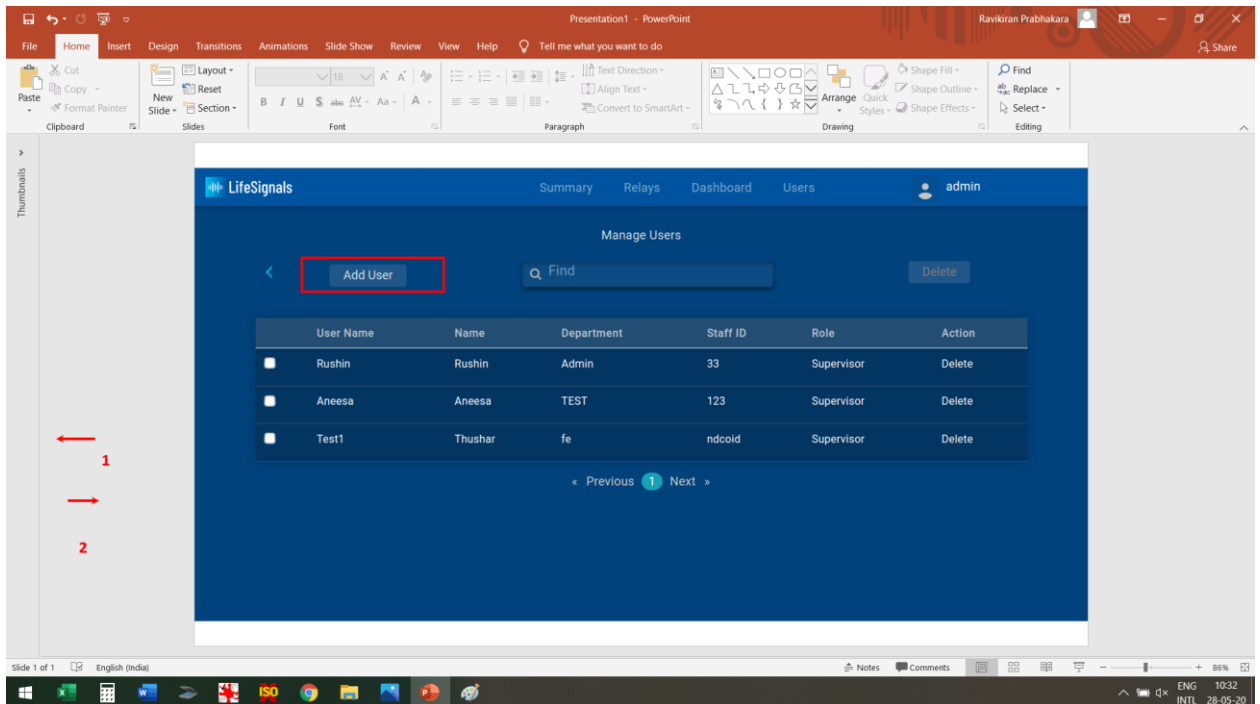
- Then press 'Create' button.
- Relay device authentication key (file name: 'xxxxx. key') will get generated & will be downloaded in local drive.
- Forward this key to the clinical personnel who would be configuring his/her Mobile device as a Relay device

## 10.2. Adding New User

- Click on the 'Manage Users' in the menu



- Click on 'Add User' button



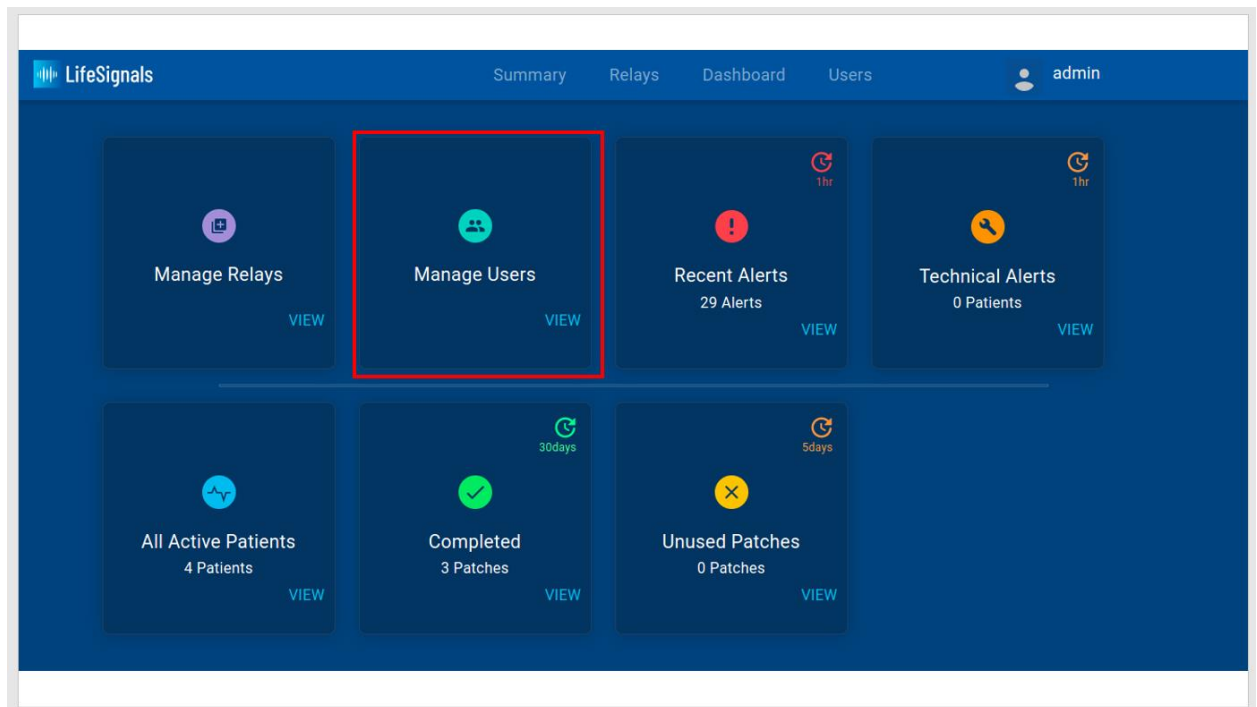
- Select the desired “Role” and fill in all the appropriate information

The 'Add User' form is displayed with the 'Role' dropdown set to 'Supervisor'. The form includes input fields for Name, User Name, Contact No., Email, Department, and Staff ID. An 'ADD USER' button is at the bottom.

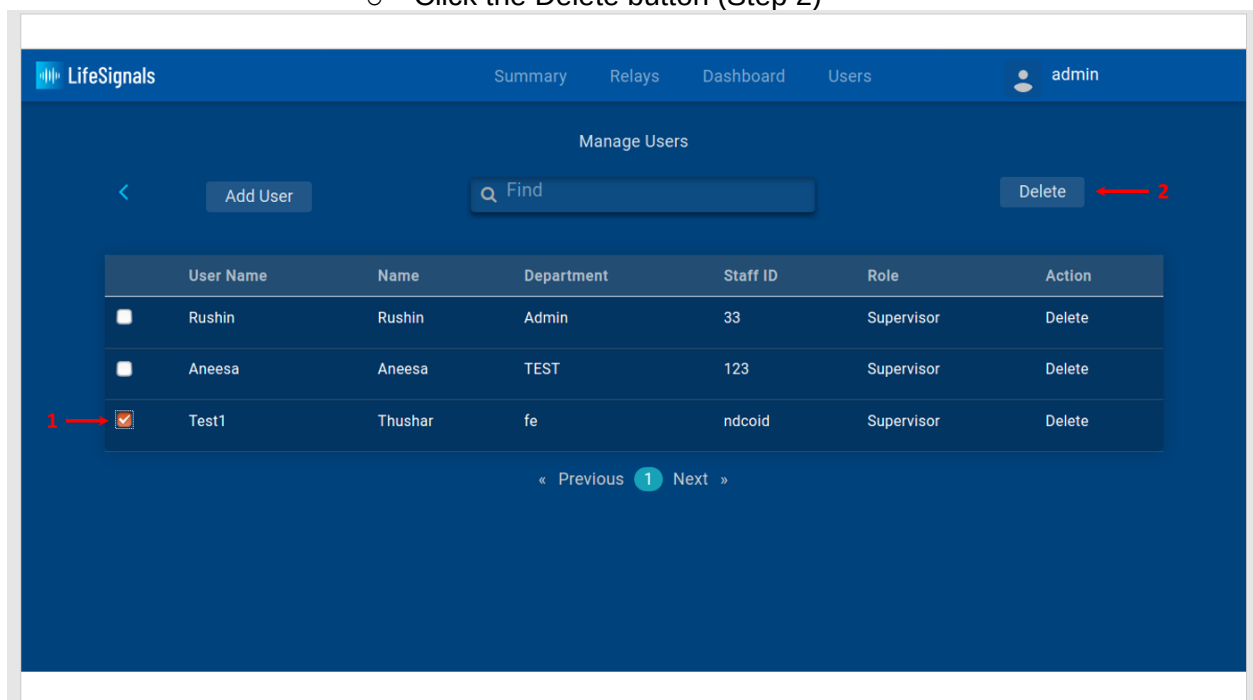
- Click on ‘ADD USER’ button. User will then be added.
- The default password is Life@2020

### 10.3. Deleting Existing User

- Click on the 'Manage Users' in the menu

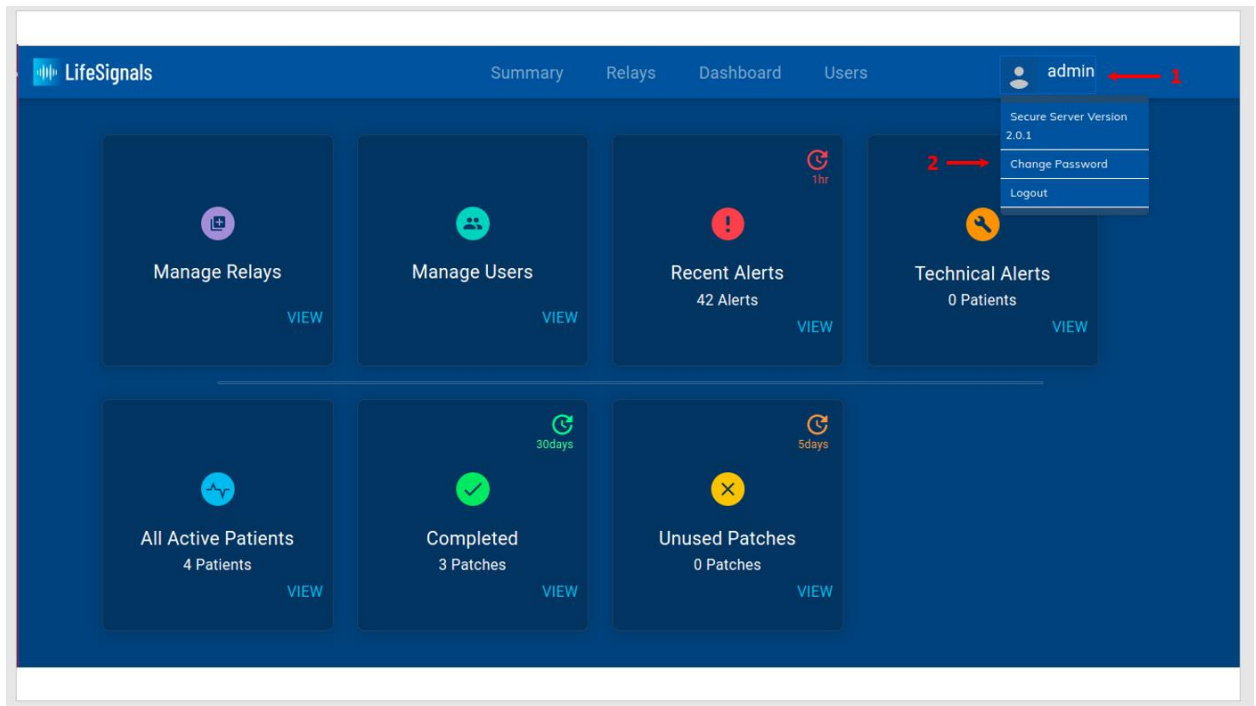


- Search for the User Name that needs to be deleted
  - Check the box next to the User Name that needs to be deleted (Step 1)
  - Click the Delete button (Step 2)



#### 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)



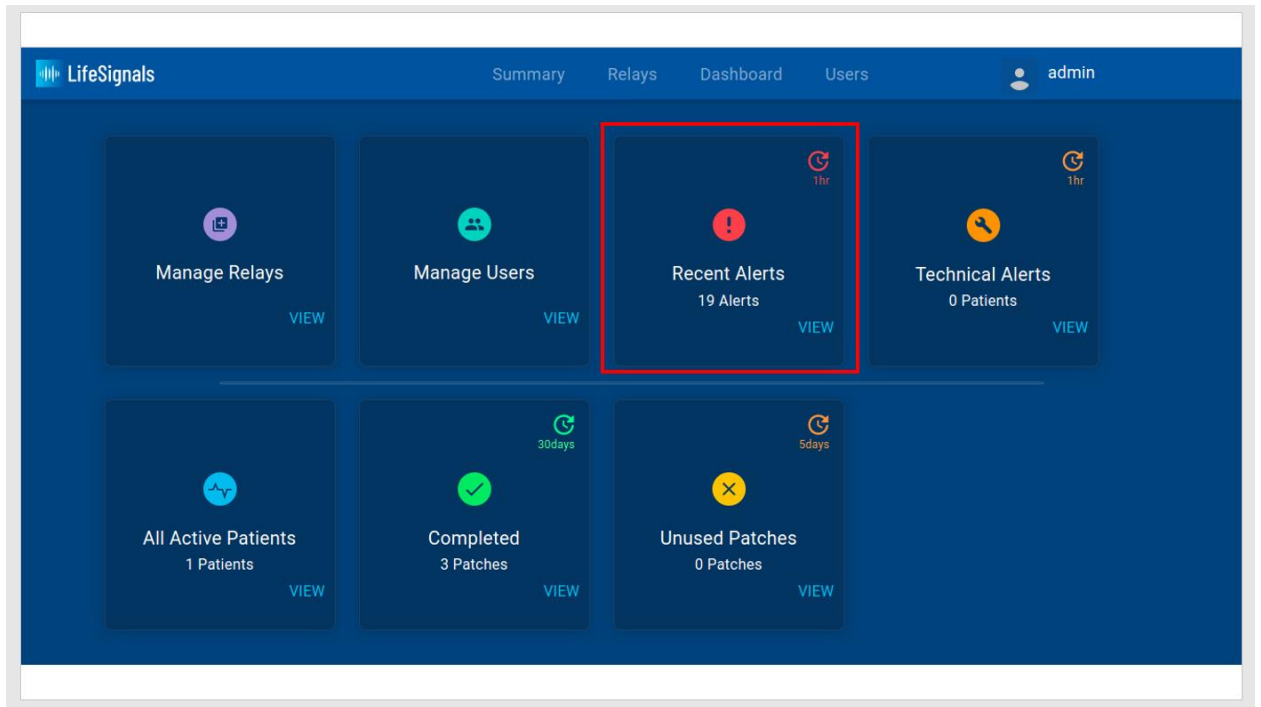
- The default password as stated in Section 10.2 is Life@2020
- Enter the new password in the 'New Password' text box
- Password should be of 8 or more characters in length and should contain at least one numeric digit, one special character, one uppercase and one lowercase letter
- Confirm the password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

 The screenshot shows a 'Change Password' dialog box. It has a title bar with the text 'Change Password' and a close button (X). The form contains two input fields: 'New Password' and 'Confirm Password'. Each field has a placeholder text 'New Password' and 'Confirm Password' respectively. Below the input fields is a blue button labeled 'Change Password'.

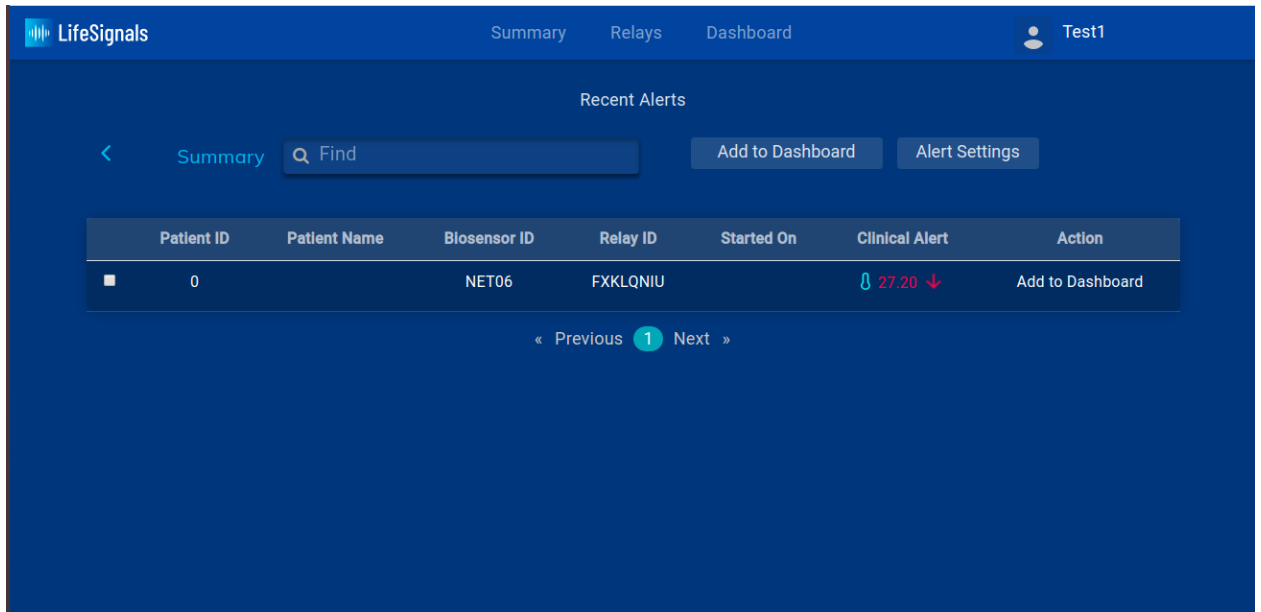
- Click on 'Change Password' button.

## 10.5. Recent Alerts

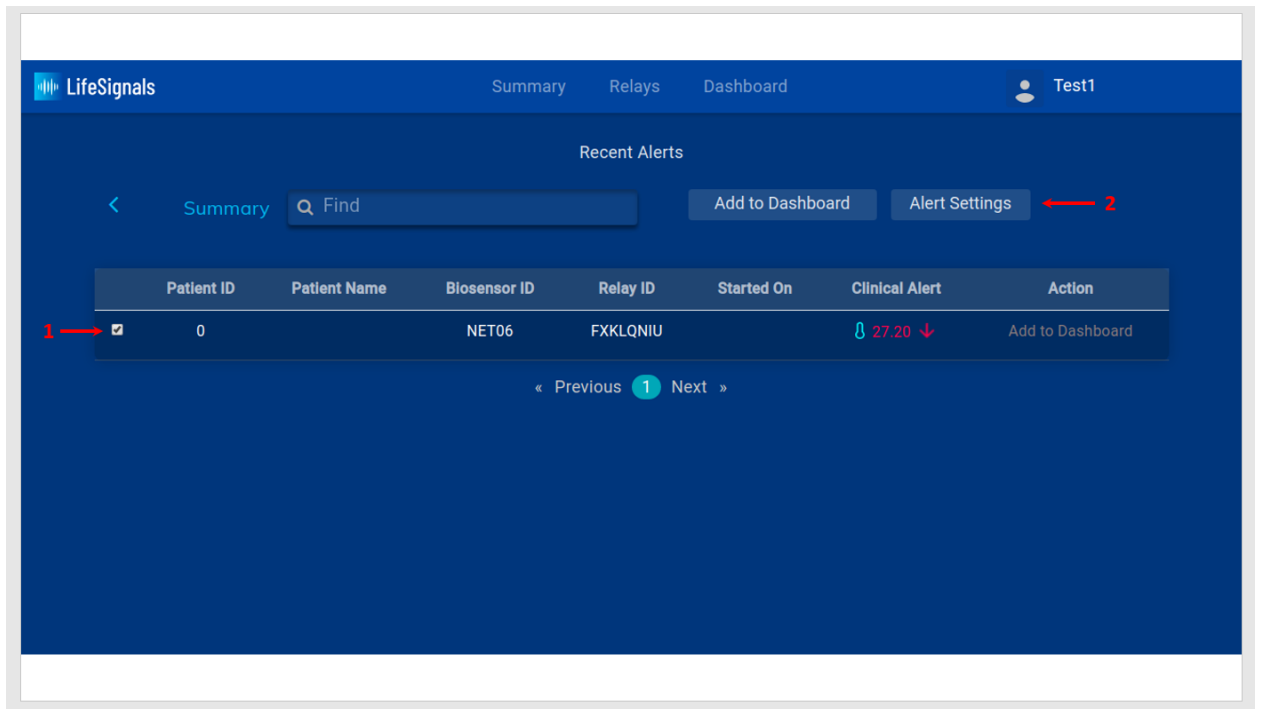
- From the Menu, click on Recent Alerts



- 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)

Alert Settings

Whatsapp 17829229 15 seconds

Alert Thresholds

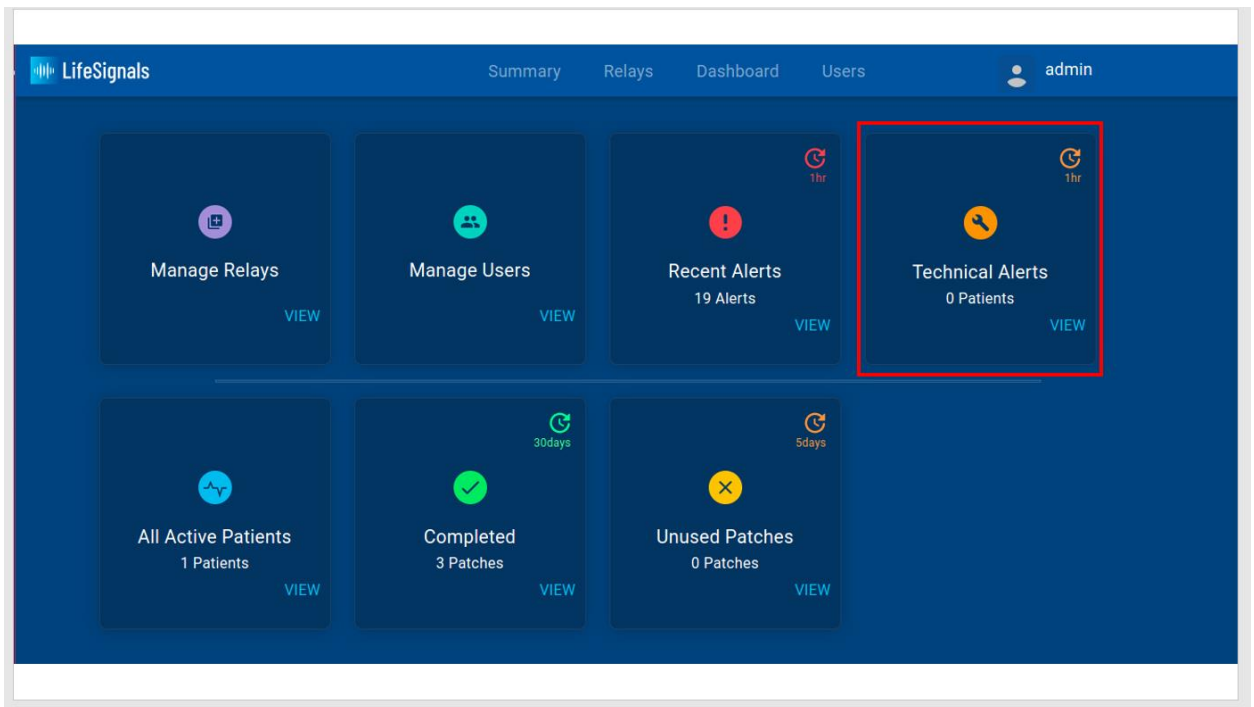
|                  | HR low | HR high |
|------------------|--------|---------|
| Heart Rate       | 40     | 120     |
| Respiration Rate | 49     | 7       |
| Temperature      | 35     | 38      |

Save

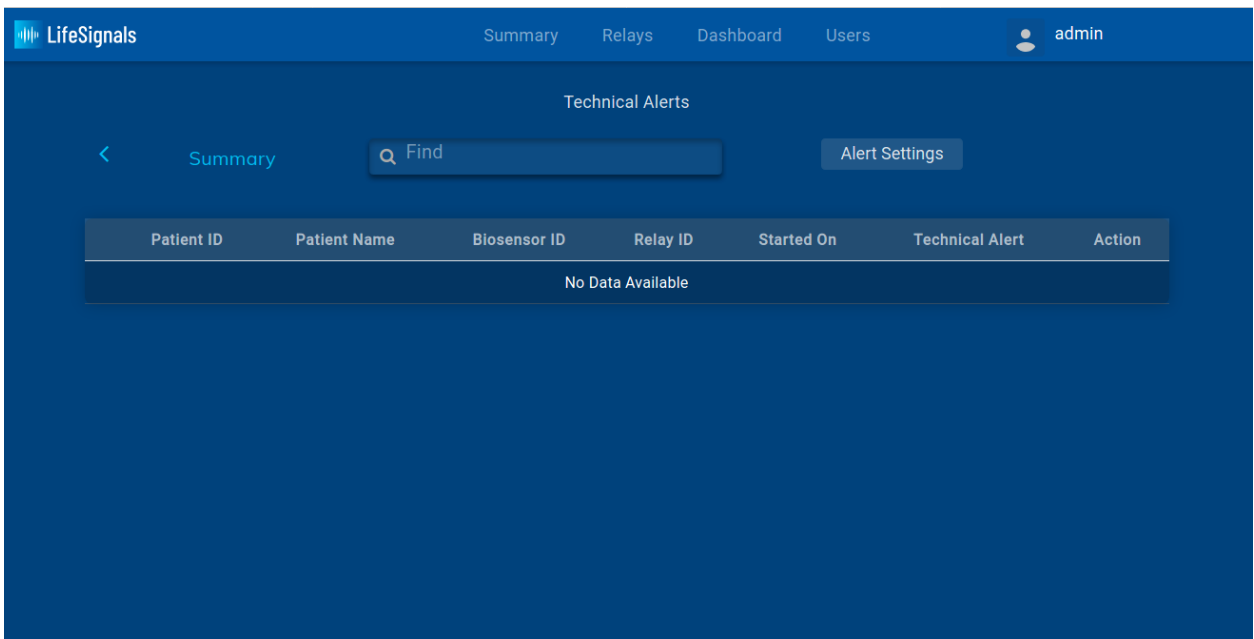
- You can review, edit and Save the different fields as necessary
- If changes are made, click the Save button and all changes will be saved

## 10.6. Technical Alerts

- From the Menu, click on Technical Alerts

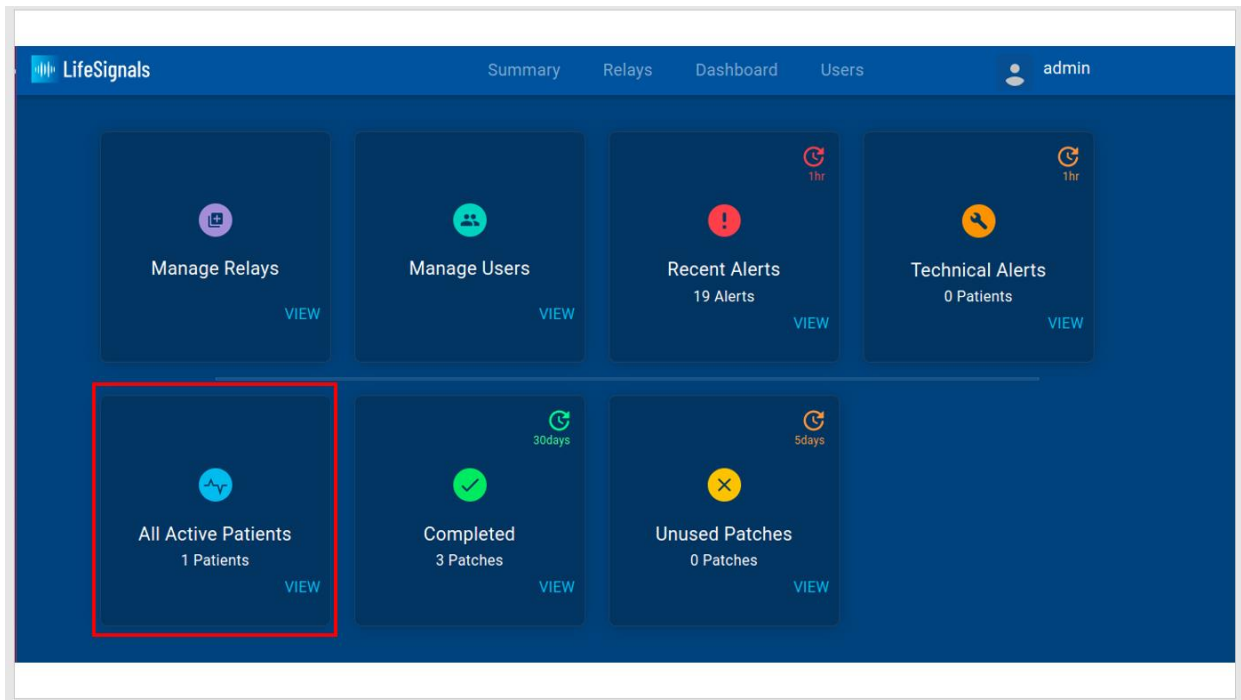


- List of all Technical Alerts will be displayed

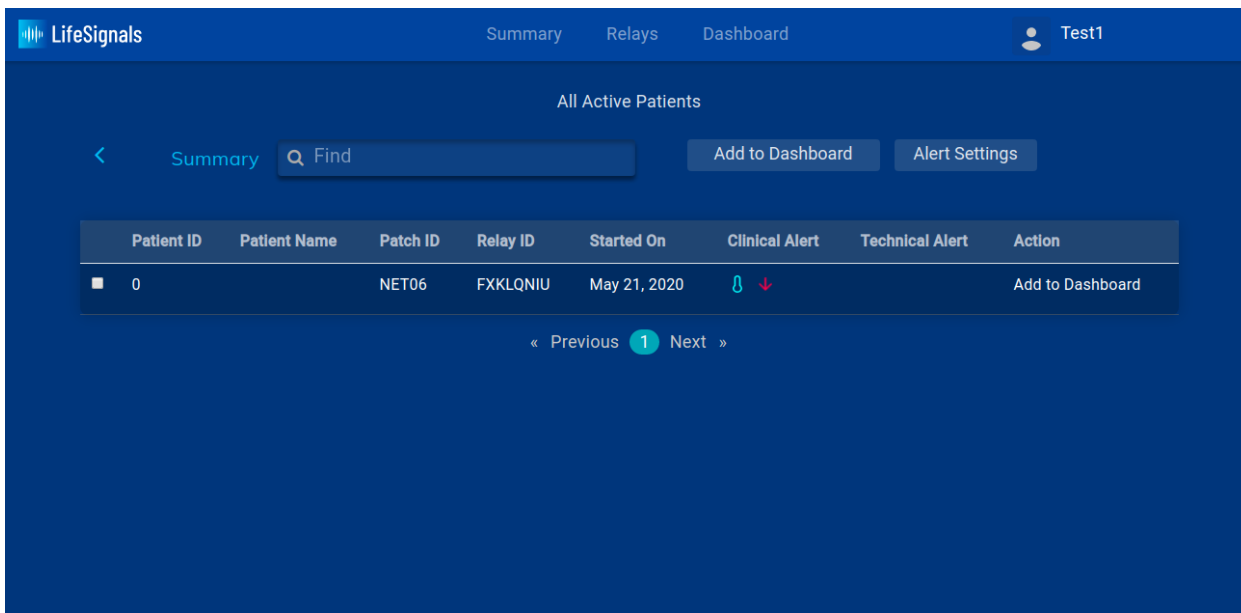


## 10.7. All Active Patients

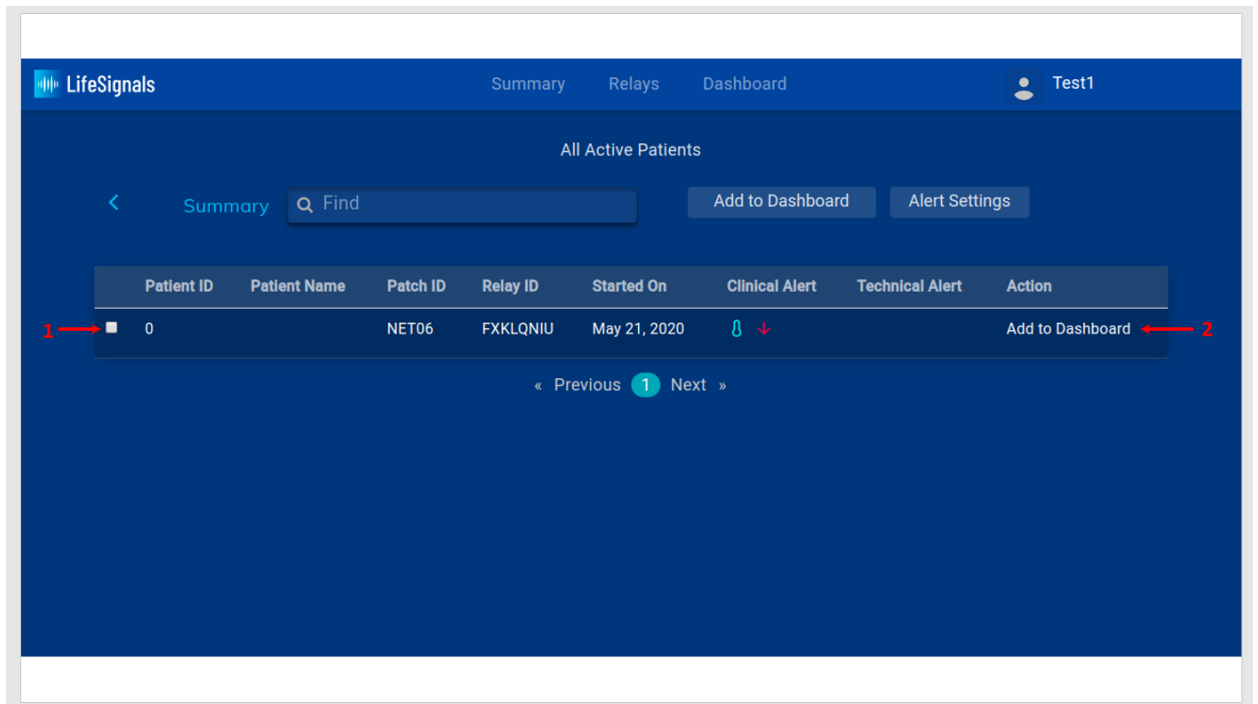
- From the Menu, click on All Active Patients



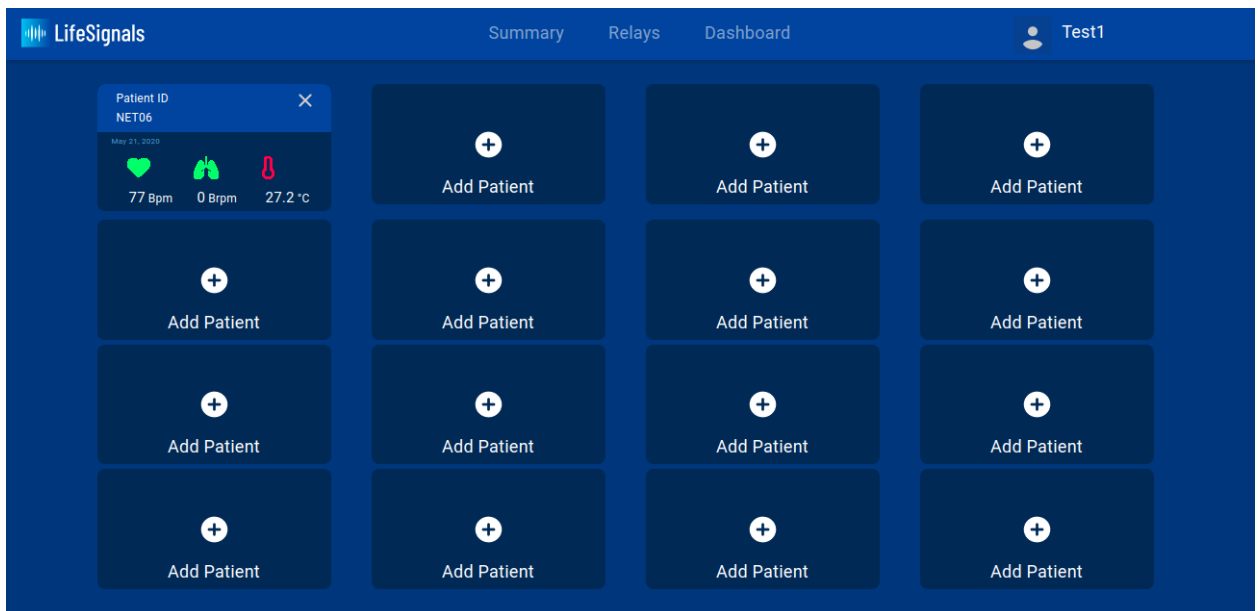
- List of All Active Patients will be displayed



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



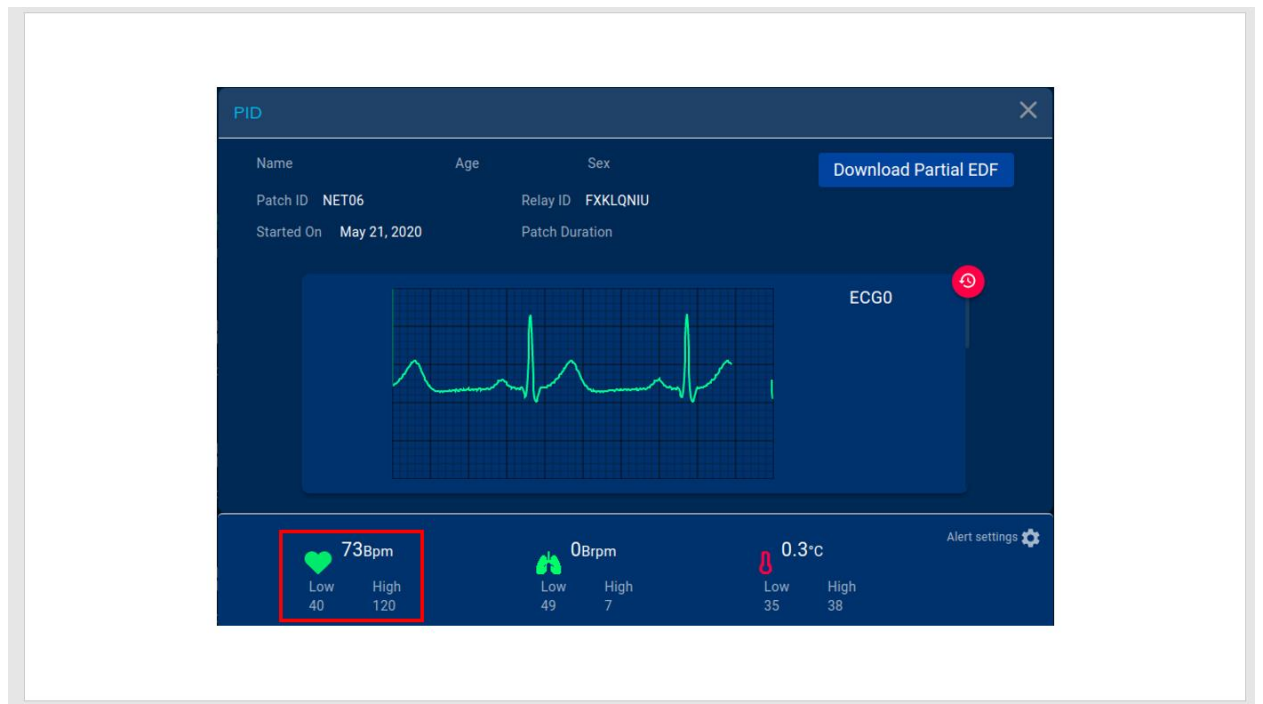
- The selected info will be displayed as shown below



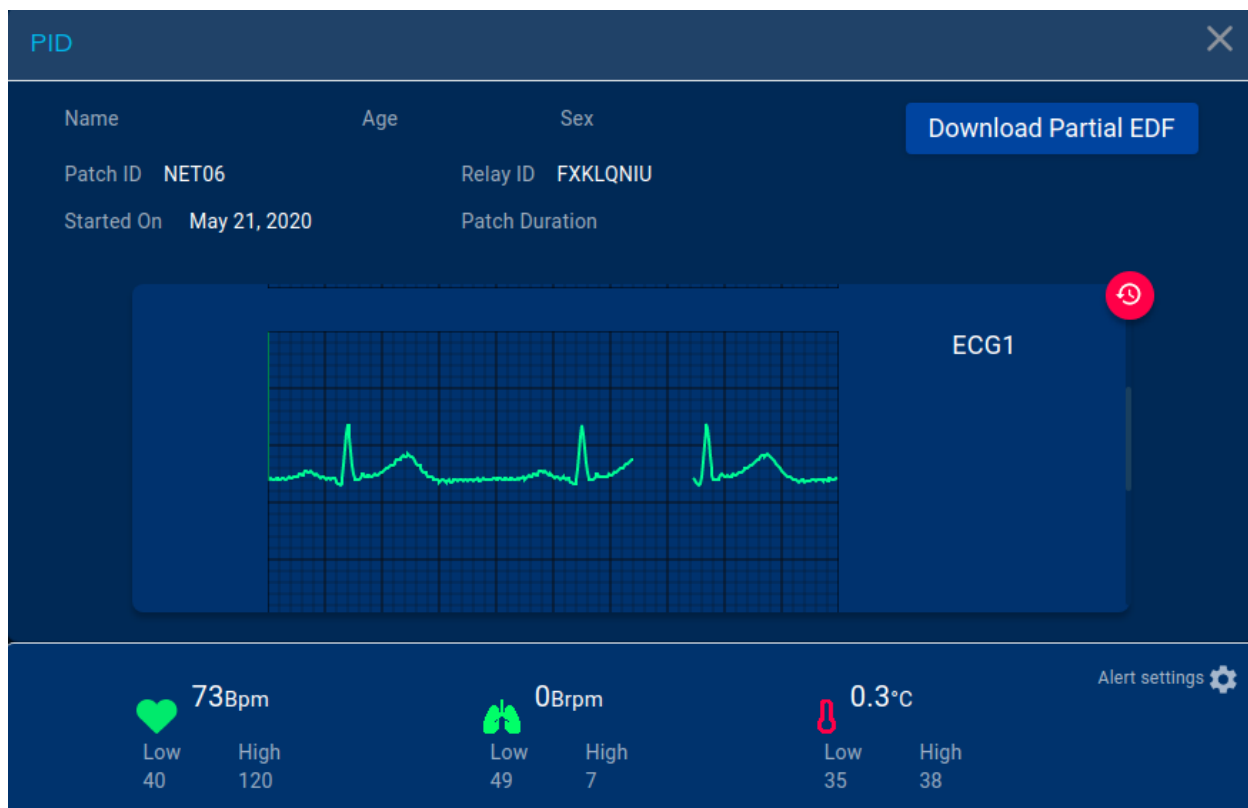
- Click on the info you want to see in more detail
- You will see the ECG waveform from one channel as shown below



- 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

Alert Settings

Enter the address

Alert Thresholds

Heart Rate

HR low

40

HR high

120

Respiration Rate

Resp low

7

Resp high

49

Temperature

Temp low

35

Temp high

38

Save

- 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)

LifeSignals

Summary

Relays

Dashboard

Test1

All Active Patients

<

Summary

Find

Add to Dashboard

Alert Settings

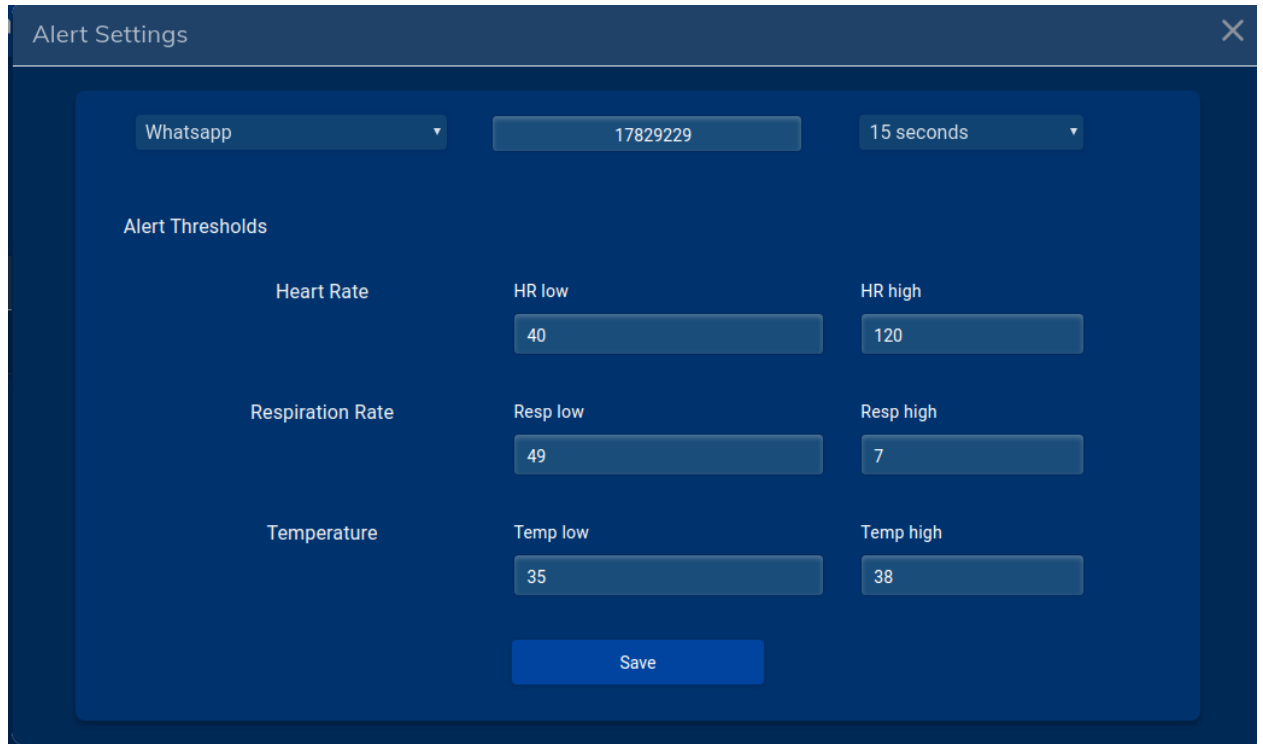
|   | Patient ID                          | Patient Name | Patch ID | Relay ID | Started On   | Clinical Alert         | Technical Alert        | Action           |
|---|-------------------------------------|--------------|----------|----------|--------------|------------------------|------------------------|------------------|
| 1 | <input checked="" type="checkbox"/> | 0            | NET06    | FXKLQNIU | May 21, 2020 | <div><div></div></div> | <div><div></div></div> | Add to Dashboard |

« Previous

1

Next »

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



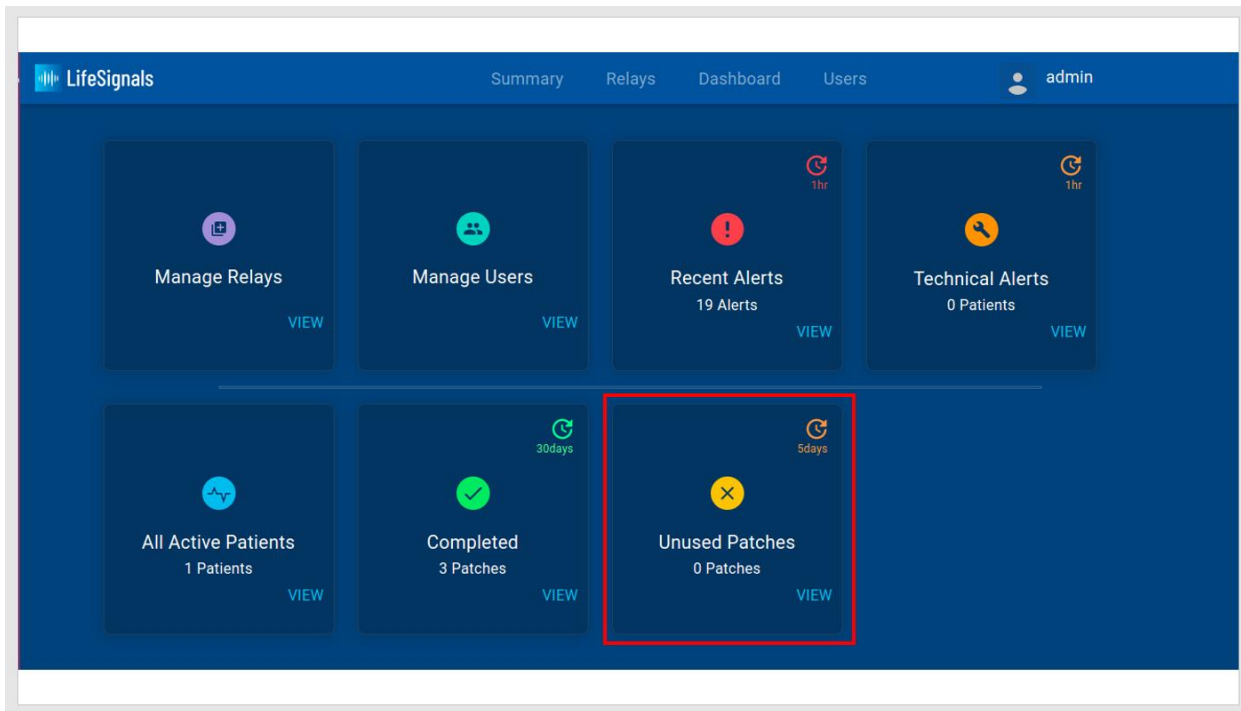
The image shows a software window titled "Alert Settings" with a close button (X) in the top right corner. Inside the window, there are three input fields at the top: a dropdown menu showing "Whatsapp", a text box containing "17829229", and another dropdown menu showing "15 seconds". Below these is a section titled "Alert Thresholds". This section contains three rows of settings:

|                  | HR low | HR high |
|------------------|--------|---------|
| Heart Rate       | 40     | 120     |
| Respiration Rate | 49     | 7       |
| Temperature      | 35     | 38      |

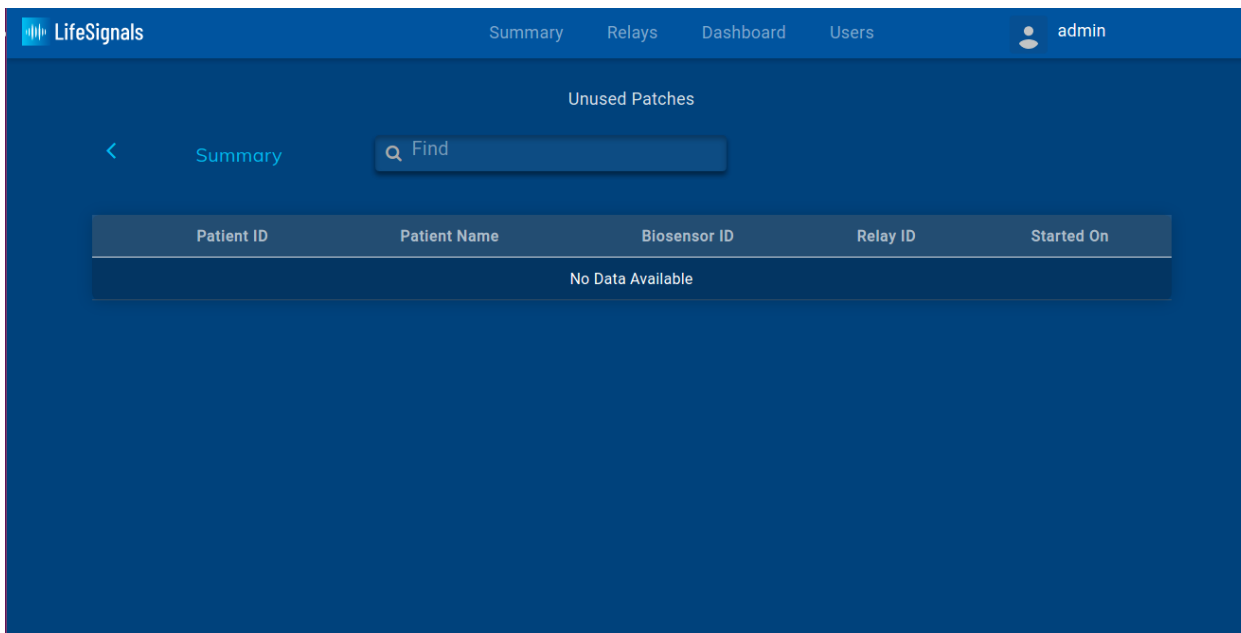
At the bottom of the "Alert Thresholds" section is a blue "Save" button.

#### 10.8. Unused Patches

- From the Menu, click on Unused Patches

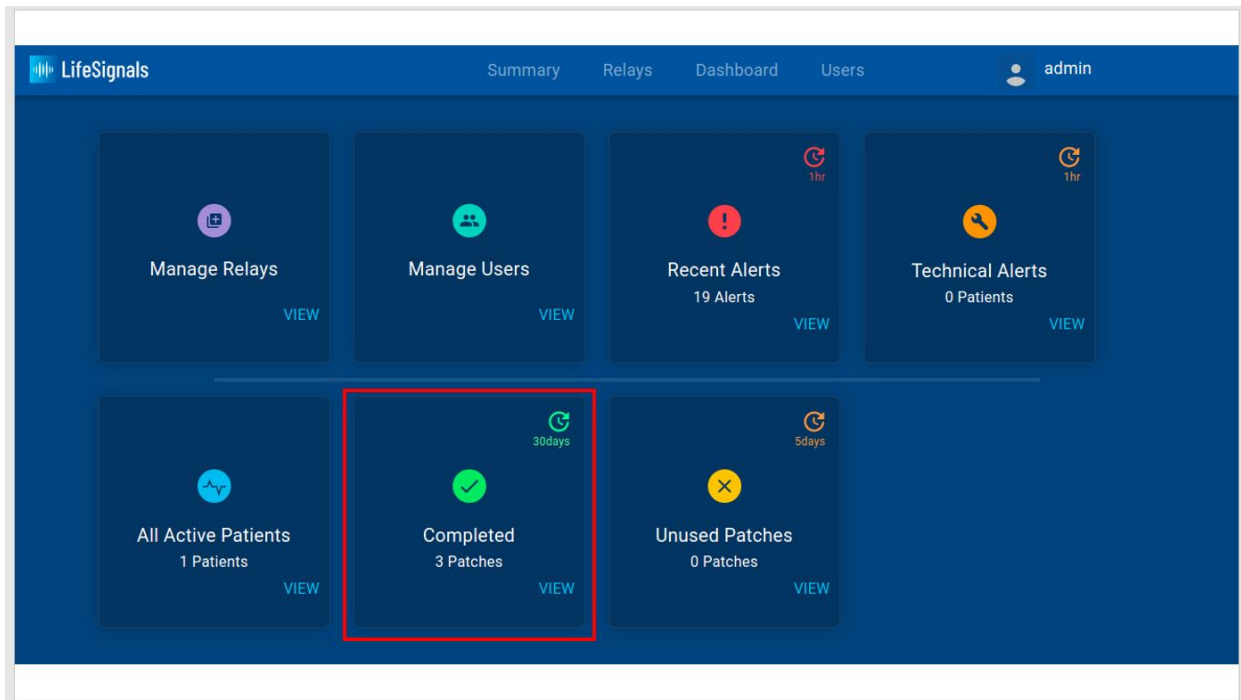


- List of all current Unused Patches are displayed



#### 10.9. **Completed**

- From the Menu, click on Completed



- List of all completed patches are displayed

LifeSignals

SummaryRelaysDashboardUsers

admin

Completed

<Summary

Find

Download

Archive

|                          | Patient ID | Patient Name | Patch ID | Doctor   | Started On   | Ended On     | Status                                        |
|--------------------------|------------|--------------|----------|----------|--------------|--------------|-----------------------------------------------|
| <input type="checkbox"/> | 0          |              | NET04    | MEWBOFAR | May 21, 2020 | May 21, 2020 | <input checked="" type="checkbox"/> Completed |
| <input type="checkbox"/> | 0          |              | LS078    | WZNEPKDX | May 21, 2020 | May 21, 2020 | <input checked="" type="checkbox"/> Completed |
| <input type="checkbox"/> | 0          |              | NET05    | MEWBOFAR | May 21, 2020 | May 21, 2020 | <input checked="" type="checkbox"/> Completed |
| <input type="checkbox"/> | 0          |              | YA155    | ZLODYISA | May 21, 2020 | May 21, 2020 | <input checked="" type="checkbox"/> Completed |

« Previous1Next »

## 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-MnO <sub>2</sub>                                                                                                                      |
| 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) | -5°C to +50°C (23°F to 122°F)                                                                                                            |
| Operational temperature                | +0°C to +45°C (32°F to 113°F)                                                                                                            |

|                                       |                                                                                                                                                                                                         |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operational relative humidity         | 10 % to 90 % (non-condensing)                                                                                                                                                                           |
| Storage temperature ( $\leq 30$ days) | +0°C to +45°C (32°F to 113°F)                                                                                                                                                                           |
| Storage temperature ( $> 30$ days)    | +5°C to +27°C<br>(41°F to 80.6°F)                                                                                                                                                                       |
| Storage relative humidity             | 30 % to 75 % (non-condensing)                                                                                                                                                                           |
| Storage pressure                      | 700 hPa to 1060 hPa                                                                                                                                                                                     |
| Ingress protection                    | IP44                                                                                                                                                                                                    |
| <b>Physical Characteristics</b>       |                                                                                                                                                                                                         |
| Dimensions                            | 115 mm x 110 mm                                                                                                                                                                                         |
| Weight                                | < 30 gm                                                                                                                                                                                                 |
| Color                                 | White or off white                                                                                                                                                                                      |
| Wear life                             | 120 hours                                                                                                                                                                                               |
| <b>Wireless Specifications</b>        |                                                                                                                                                                                                         |
| Frequency band                        | 2.400-2.4835 GHz                                                                                                                                                                                        |
| Bandwidth                             | 20 MHz                                                                                                                                                                                                  |
| Transmitter power                     | 0 dBm                                                                                                                                                                                                   |
| Modulation type                       | Complementary Code Keying (CCK)<br>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                        | $\pm 3$ 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                | $\pm 2$ 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                              | $\pm 0.4^{\circ}\text{C}$                             |
| 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                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| <i>Backend exe Failed</i>                                                                                                                                             | Server broke for some reason       |
| <i>Authenticated</i>                                                                                                                                                  | Authentication success             |
| <i>Authentication Failed</i>                                                                                                                                          | Authentication failure             |
| <i>Duration is not present. Defaulting to 20 min</i>                                                                                                                  | Duration not found in Server key   |
| <i>Authentication key successfully imported !!</i>                                                                                                                    | Successful import of Server key    |
| <i>Failed to parse authentication key</i>                                                                                                                             | Failed to import Server key        |
| <i>Turn off success!!</i>                                                                                                                                             | Success of turning off command     |
| <i>Turn off error!!</i>                                                                                                                                               | Error of turning off command       |
| <i>Please Download authentication key and place it in Downloads folder and import from menu.</i>                                                                      | Server key missing                 |
| <i>No network available. Please try later</i>                                                                                                                         | Internet/Server not available      |
| <i>Program mobile hotspot with SSID and Password same as the SSID and password of Biosensor</i>                                                                       | After sensor is reconfigured       |
| <i>Scanning for Sensors. Do you want to exit the application?</i>                                                                                                     | Back-press while scanning ongoing  |
| <i>Sensor is streaming. Do you want to exit the application?</i>                                                                                                      | Back-press while streaming ongoing |
| <i>Insufficient Memory to store data. \n Please make sure you have enough memory. \n" + freeMB + " MB of storage available. " + reqMB + " MB of storage required.</i> | Insufficient Memory                |
| <i>Manually check if the sensor is turned off. If yes click Finalize to continue.</i>                                                                                 | On socket error on turn-off        |
| <i>Battery Level " + level + "%", "Battery Level is critically low!!!</i>                                                                                             | Battery level lower than 15%       |

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

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

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

|                                                          |                                                                   |
|----------------------------------------------------------|-------------------------------------------------------------------|
| <i>Remove Patch Failed!</i>                              | Server was not able to execute remove patch command               |
| <i>Patch removed!</i>                                    | Server successfully executed remove patch command                 |
| <i>Please provide a valid HR High value</i>              | Invalid HR High value.                                            |
| <i>Please provide a value between 100 BPM to 250 BPM</i> | HR High value is not within the valid range.                      |
| <i>Please provide a valid HR Low value</i>               | Invalid HR Low value.                                             |
| <i>Please provide a value between 30 BPM to 100 BPM</i>  | HR Low value is not within the valid range.                       |
| <i>Please select a valid Scan Interval</i>               | Scan Interval has not been selected from the dropdown menu        |
| <i>Please select a valid Notification Address</i>        | Notification address has not been selected from the dropdown menu |
| <i>Please select a valid Duration</i>                    | Duration has not been selected from the dropdown menu             |
| <i>Key generation failed!</i>                            | Sever key was not generated successfully                          |
| <i>Relay added successfully!</i>                         | Sever key was generated successfully                              |
| <i>EDF download Failed: &lt;WITH SERVER RESPONSE&gt;</i> | Failed to download EDF file                                       |
| <i>Edit Relay Failed!</i>                                | Failed to update relay parameters during editing.                 |
| <i>Relay Updated successfully!</i>                       | Relay parameters were edited successfully                         |
| <i>Only Admin can view the user list!</i>                | User does not have admin privilege to access the user list.       |
| <i>List users Failed!</i>                                | Error while retrieving user information from the database         |
| <i>Remove User Failed!</i>                               | Failed to remove the user.                                        |
| <i>User removed!</i>                                     | The user was successfully removed.                                |
| <i>Please provide a valid User Name.</i>                 | Invalid Username.                                                 |
| <i>Please provide a valid Password.</i>                  | Invalid Password.                                                 |
| <i>Please select a privilege.</i>                        | Select an option either admin or normal while adding a new user.  |

|                                                                                                                                                                            |                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <i>Username already taken! Please try another one.</i>                                                                                                                     | The entered username already exists.                                                                        |
| <i>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.</i> | The password must meet all the specified parameters                                                         |
| <i>Cannot add user</i>                                                                                                                                                     | Failed to create a new user.                                                                                |
| <i>User added successfully!</i>                                                                                                                                            | The user was successfully added to the database.                                                            |
| <i>Please confirm the Password</i>                                                                                                                                         | Re Enter password in 'Confirm Password' text box                                                            |
| <i>Confirm password do not match New Password!</i>                                                                                                                         | The password in the 'New Password' text box does not match the password in the 'Confirm Password' text box. |
| <i>Invalid Username</i>                                                                                                                                                    | The username entered does not exist.                                                                        |
| <i>Cannot change password</i>                                                                                                                                              | The password cannot be changed.                                                                             |
| <i>Password changed successfully!</i>                                                                                                                                      | 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. |                   |                                                                                                                                                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Emissions test</b>                                                                                                                                                             | <b>Compliance</b> | <b>Electromagnetic environment – guidance</b>                                                                                                                                                                           |
| RF emissions<br>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<br>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<br>± 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<br>80 MHz - 2.7 GHz<br>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**

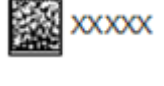
This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

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                                                                                                           |
| <b>IP24</b>                                                                                     | 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                                                                                               |
| <b>5</b><br> | Max Stack                           | Do not stack more than 5 boxes tall                                                                                                        |
| <b>FCC ID</b>                                                                                   | 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**

Manufacturer: LifeSignals, Inc.  
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Biosensor is assembled in Republic of Korea

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