DHF7-LBL-002 | Technical User Manual - LX1250

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WifeSignals

Life Signal ECG Remote Monitoring Patch Platform

(LX1250)

Technical User Manual

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1 Intended Use/Indications for Use:

- The Life Signal ECG Remote Monitoring Patch Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of Electrocardiography (ECG) and Heart Rate monitoring in home and healthcare settings. Data is transmitted wirelessly from Life Signal Biosensor Patch to Remote secure server for storage and analysis.
- The Life Signal ECG Remote Monitoring Patch Platform is intended for non-critical, adult population, who are 18 years of age or older.
- The Life Signal ECG Remote Monitoring Patch Platform includes an ability to notify healthcare professionals when Heart Rate falls outside the set limits.

2 Contraindication:

- The Life Signal ECG Remote Monitoring Patch Platform is contraindicated for use in patients with active implantable medical devices such as pacemakers, implanted cardioverter defibrillators (ICD) and left ventricular assist devices (LVAD); for use in a magnetic resonance (MR) environment;

3 Product Description:

The Life Signal ECG Remote Monitoring Patch Platform contains three components :
(1) Life Signal Biosensor Patch (2) Life Signal Relay Device and (3) Life Signal Remote Secure Server.
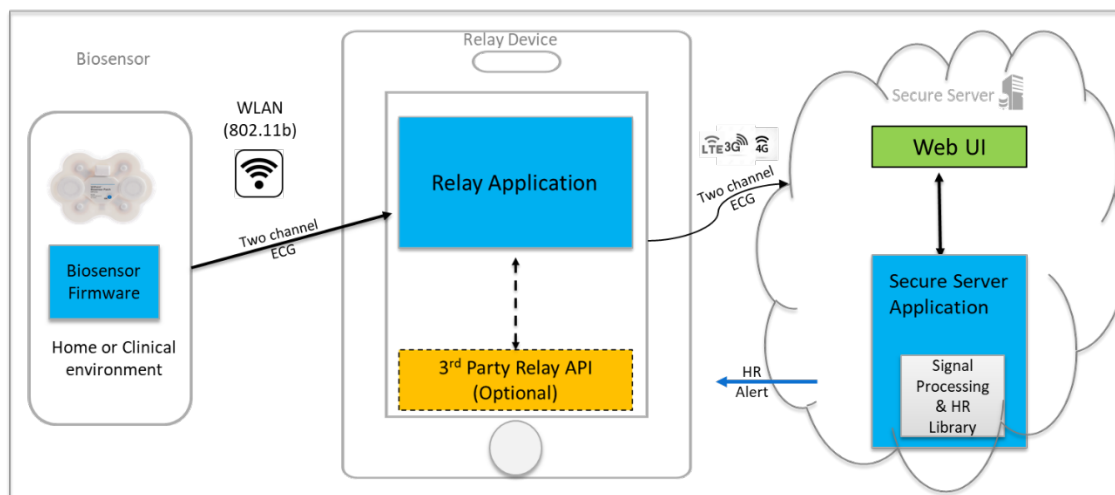

Figure 1 : System components

3.1 Biosensor Patch : (LP1250)
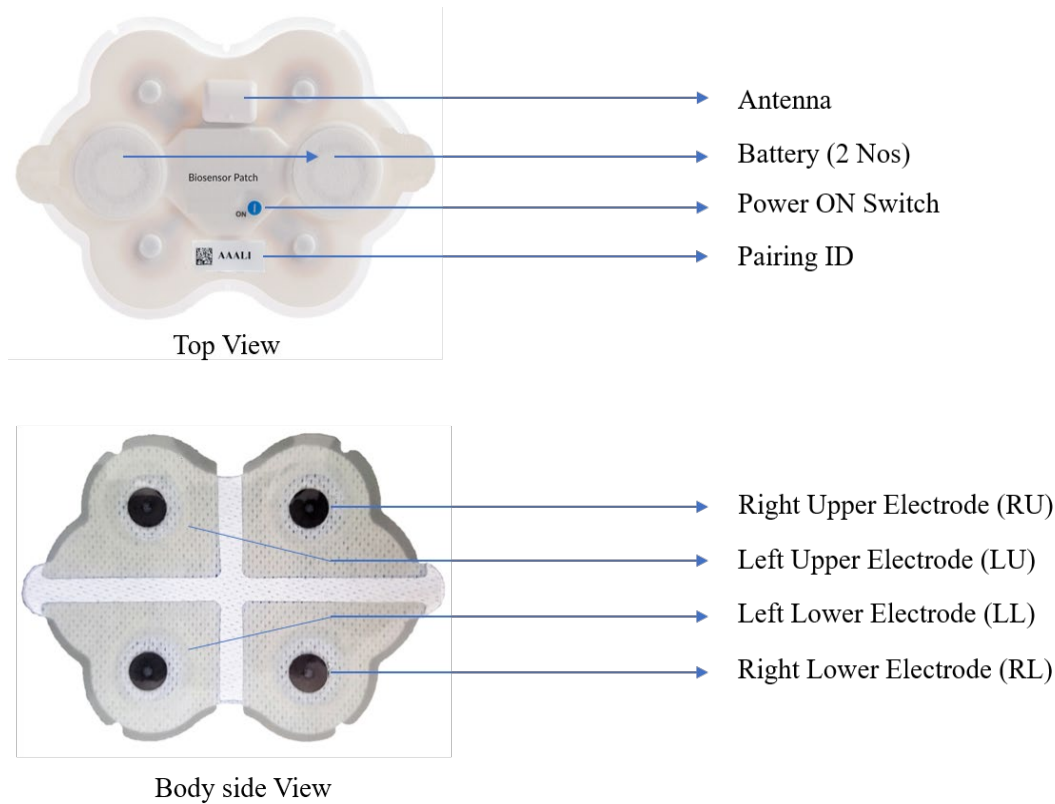

Top View

Body side View

Figure 2 : Biosensor Top & Rear view

Life Signal Biosensor Patch acquires ECG signals from the body, pre-processes as two channels of ECG data and are wirelessly transmitted to the Relay device. Under normal operation, when the Relay Device is available within the wireless range, the acquired data is continuously transmitted to the Relay device immediately. If the Relay device is not available or if there is any interruption in the communication between the Relay device and the Biosensor Patch, data shall be buffered (stored) locally in the Biosensor Patch until the wireless connection is re-established.

Biosensor Patch uses standard WLAN (802.11b) secured (AES) communication protocol for wireless data transmission to the Relay Device.

Biosensor is designed & tested for the wear duration of 72 hours. Wear duration may vary depending on skin condition (e.g. hyperhidrosis, improper skin prep, etc.)

Biosensor is a battery-operated device with two disposable zinc air batteries, and the battery life of the Biosensor may vary depending upon storage temperature and the WLAN environment.

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3.2   Relay Device (Part No : LA1250-R)

Relay Device manages wireless communication between Life Signal Biosensor and Life Signal Remote Secure Server. Relay device is a Life Signal Relay Application Software-installed compatible commercial hardware platform, like a mobile phone or a tablet.

Life Signal Relay Application's functions:

- Manage secured wireless communication (WLAN 802.11b) between Relay device and Biosensor Patch and encrypts communication between the Relay device and the Life Signal Remote Secure Server.

- Receive ECG signals from the Biosensor Patch and transmit them after encryption to Secure Server as quickly as possible. They manage the database in Relay device, for buffering/storing the data securely if there is any disruption in communication with the Secure Server.

- Provide user interface for selecting, pairing and establishing connection with Biosensor Patch.

- Display alert notifications received from the Secure Server when the Heart Rate of its associated Biosensor or of some other Biosensor in its network falls outside the configured range, when it is configured by the Secure Server to receive such notification.

3.3   Secure Server Application (LA1250-S)

Life Signal Secure Server consists of a hardware platform that is a Linux-compatible Secure server, Life Signal Secure Server Application software that is installed in the hardware platform along with a Web UI, a browser-based application that interfaces with Life Signal Secure Server Application.

Life Signal Secure Server Application manages the decryption, uploading and storage of Biosensor data received from multiple authenticated Relay devices. The Signal Processing and Heart Rate Library in the Life Signal Secure Server Application processes and filters the received ECG signals before storing them in a secured location. It also derives the Heart Rate from the ECG data and the Heart Rate value is appended to the filtered ECG Signals.

Life Signal Secure Server Application can include the ability to send alert notifications to any configured Relay Device connected in its network, when Heart Rate value of any Biosensor falls outside the set range of values.

3.4   Web UI Application (Part No : LA1250-C)

Web UI provides user interface for user (login) management, Relay management & Heart Rate Alert setting. It interfaces with Secure Server Application.

4 Typical workflow:

Multiple Biosensor / Relay device at different location (home or healthcare environment) can be remotely connected to single Life Signal Secure Server. The Secure Sever Application does not carry-out any arrhythmia analysis of ECG data by itself. However, the ECG data received / stored by the Life Signal Secure server is intended to be used with an approved third-party ECG analysis software. Based on the type of ECG analysis software, the Life Signal ECG Remote Monitoring Platform can be used for a suitable clinical workflow such as Remote Patient Monitoring, Mobile Cardiac Telemetry, Event Monitoring or Holter Monitoring system.
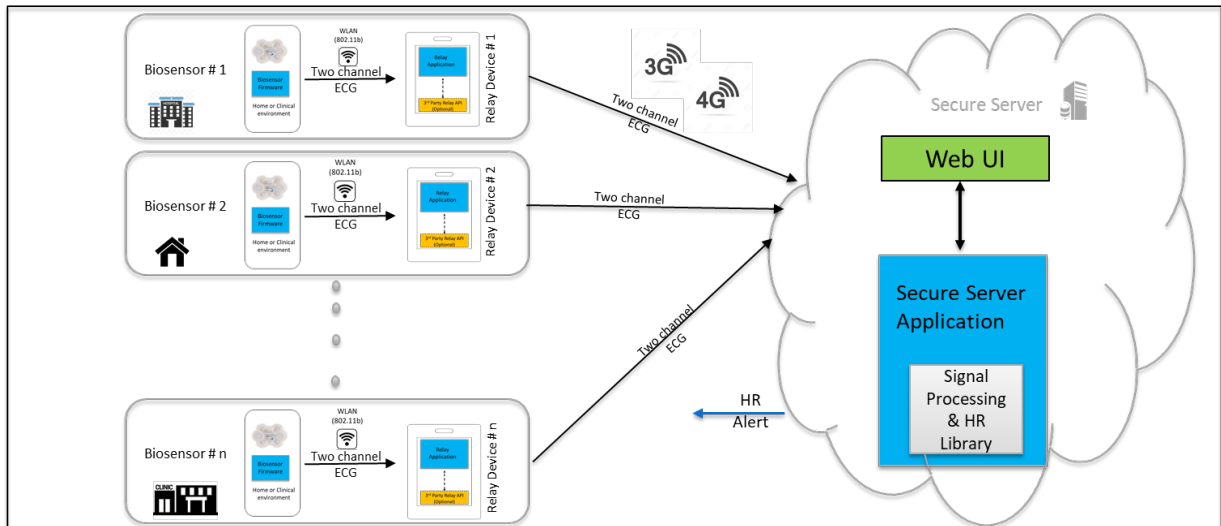

Figure 3 : Life Signal ECG Remote Monitoring Platform Workflow

5 Warnings:

- Do not use Biosensor on patients who are allergic to adhesive, electrode gel or hydrocolloid.
- Do not reuse Biosensor. It is a single-use device.
- Biosensor is rated for ingress protection rating of IP22. It is not designed for being worn in the shower or being submerged in water. Hence, avoid taking direct shower while wearing Biosensor.
- Do not wear Biosensor beyond the recommended maximum wear duration of 72 hours.
- Do not use the Biosensor on damaged (irritated or injured) skin.
- Do not use 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 electrode is dry, discolored or no longer sticky.
- The Biosensor does not have any serviceable parts. Do not modify or repair the Biosensor. Any modification may result in patient harm.

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- 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 Patch & Relay App in Airport due to FAA regulation of wireless network operation during certain period (take-off or landing) and TSA regulation of screening Mobile device (Relay device). Further, Relay device is required to be connected to Internet to continuously transmission of data to Secure server and some airlines do not offer wireless internet connectivity feature on-board.

6   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 services, or against sharp edges and corners. Do not apply weight or pressure or apply excessive stress to 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 IP22 ingress protection rated device. Do not wash or immerse the Biosensor in water or fluids or chemicals.
- Recommended long term storage (more than 1 month) temperature is 5ºC to 27ºC.
- Do not store the Biosensor in direct sunlight.
- Avoid sleeping in the chest down prone position as it will affect the wireless performance.
- 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 zinc air 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 phone

- 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 adopter may be required for charging with during international travel.

7   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 app updates in Relay device for any automatic cybersecurity updates of Relay Application

8   Additional Information:

Biosensor does not contain any natural rubber latex.

9   Indicators & Error Messages:

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

Biosensor Patch 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.

Refer Table 3 & Table 4 for details of various error messages of Relay Application & Web UI

10 Instructions (For Clinical Personnel):

10.1 Configuring the Mobile as a Relay Device

- o 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.

- o Download and Install "Life Signal Relay App" to the mobile phone/tablets from Play Store.

- o Download the Authentication Key received from the Secure Server Administrator (Please refer section 11.1) and place it in 'Downloads' folder of the mobile phone.

- o Open Relay App.

- o Allow permission for the app to access storage.
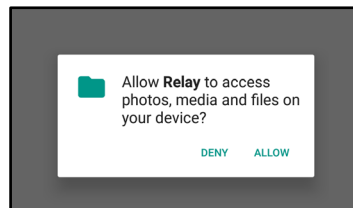
- o The Relay App gets authenticated automatically by connecting to the secure server.
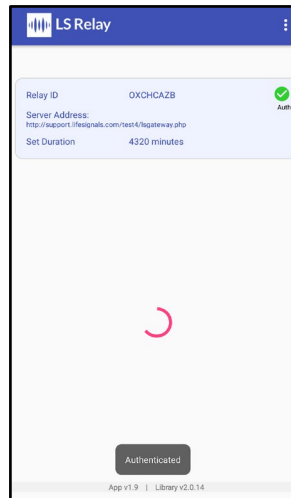
10.2 Configuring Hotspot of the Mobile Device

- o Configure the Wi-Fi Hotspot of the Mobile device as below:
  - Region: United States
  - Wireless Security:
    - Type: WPA/WPA2 - Personal
    - Version: WPA2-PSK
    - Encryption: AES
  - SSID (default): **Reachfd** and Password (default): **copernicus** or any other SSID/password provided by the medical director

- o Recommended Settings:
    - ▪ Recommended Channel Setting: It is preferable to use Channels 1, 6 and 11 as channel map
    - ▪ Recommended Channel Width: It is preferable to use 20MHz

- o Turn ON the Hotspot of the Relay Device
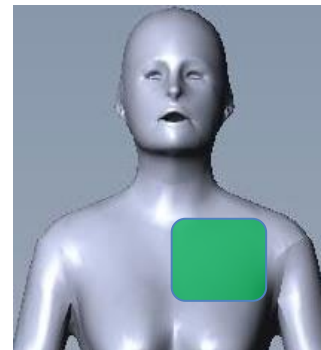
10.3 Patient Body preparation

- o Do a skin preparation on the left upper quadrant of the chest area between clavicle bone & nipple; middle to Left of sternum
- o Remove excess hair by clipping instead of shaving to prevent skin irritation.
- o Remove any oil or lotion by wiping the area with an alcohol pad.
- o 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 alcohol pad and allow it to dry for more than 1 minute. (Do not wipe with alcohol if Nuprep® is used)
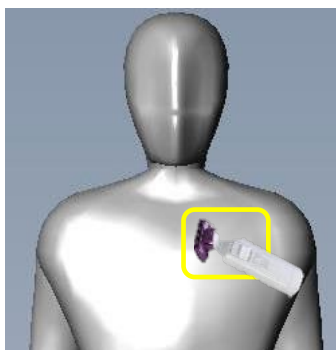
| Hair Clipping site | NuPrep & Gauze Pad | Prep site |

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10.4 Biosensor Affixing

o   Carefully remove Life Signal Biosensor Patch from the Aluminum Pouch.

   ▪   Please check for expiry date information & any damage to the packaging.

o   Remove the release liner in the Biosensor Patch.

o   Hold the Patch with the antenna at the top and letters on the label upright.

o   Align the patch with top right corner (RU electrode), close to the junction of sternum & collar bone. (Prepped site)

o   Place the Biosensor Patch and press firmly across the entire Patch for 2 minutes.
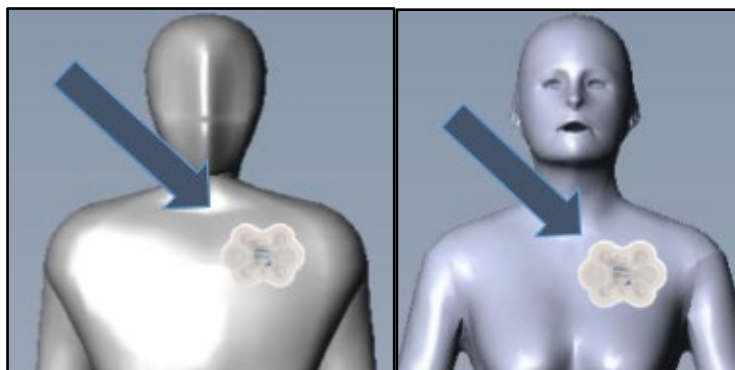
10.5 Switching ON the Patch & Connecting to Mobile device

o   Press ON button to switch on the Patch

o   Momentarily the red LED will turn ON.

o   Green LED will blink at a faster rate (~ 2 blinks per second) indicating that the Patch 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 30 seconds of turning on, the Biosensor will be switched OFF automatically (auto-power off).

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10.6 Pairing the Patch with Relay App & starting the procedure

o Open the Relay App in Mobile device. App will automatically connect to the Secure Server & get authenticated itself.
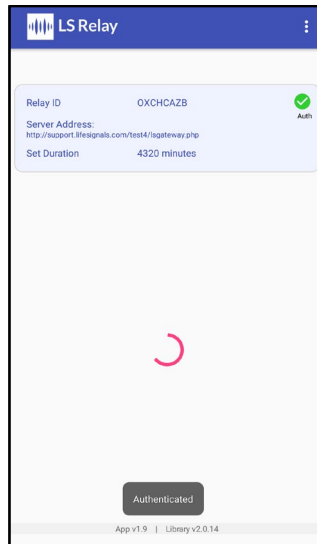
o The ID of Biosensor(s) that is (are) connected to the Mobile Hotspot will be displayed on the screen.
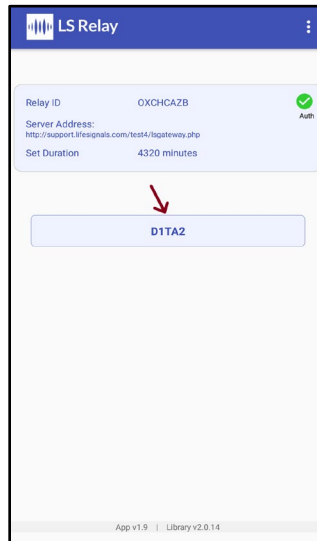
o Select the intended Biosensor for accessing the ECG data, by clicking the Biosensor ID.

o Mobile Device will start acquiring the data from the selected biosensor.
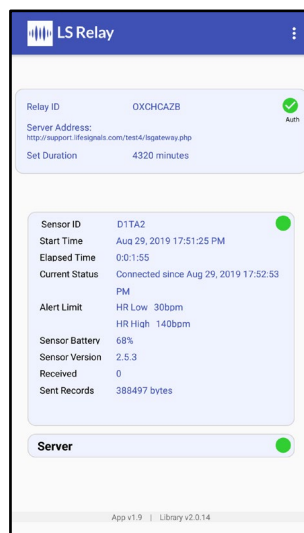
o The acquired data from the Biosensor will automatically transmitted to the Life Signal secure server for evaluation purpose.

o The status of data transfer from Biosensor & to the Secure Server will be displayed on the screen of the mobile phone.

o Instruct Patient to keep the mobile device within 5 meters for continuous ECG data transmission from the Patch to Mobile phone.

10.7 Lead-Off alert

o When any of the electrodes on the Biosensor Patch loses contact with the skin the 'Lead-Off' alert will be displayed as below ;
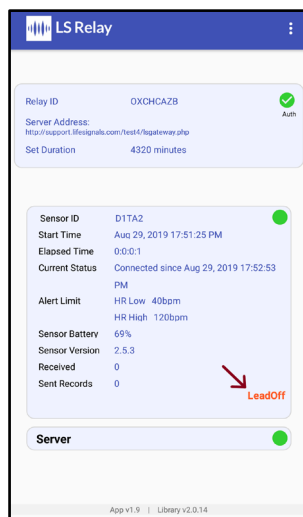
o Press all the electrode location till the "Lead-off" alert disappears.

10.8 End of Monitoring

- After the end of monitoring period (72 hours or as configured by the Secure server), the procedure finalization will happen, as displayed on the screen as below.
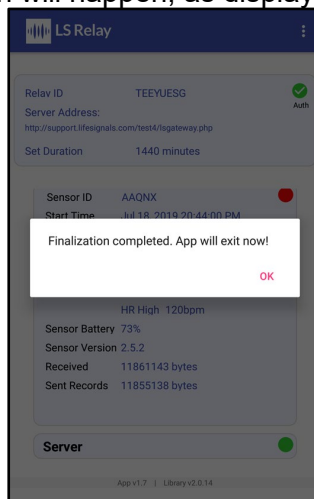
- Once Finalization is complete, Biosensor Patch shall automatically switch off.
- If required, Another Biosensor can be paired to initiate another monitoring procedure.

10.9 Removing the Patch

- Gently pull the bottom right corner of the patch and remove it from the body.
- To aid the removal of patch, 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 Patch while peeling the patch 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 Patch as per the local regulation.

10.10 Relay App as the alert messenger

- Mobile phone with Relay Application downloaded shall also be configured as the alert messenger to receive any low/high Heart Rate Alert message from any of the Biosensor connected to the Life Signal ECG Remote Monitoring Platform.
- The Secure Server Administrator can configure any mobile phone (Relay device) to receive the alert of a specific Biosensor Patch /Patient (Refer Section 11.1)
- Only configuring Mobile Phone as the Relay device as mentioned in Section 10.1 is needed to receive the alert message.
- Alert message would be received irrespective of whether the Mobile device (Relay device) is being used as a Relay device to monitor another patient.

o Below is an example of an Alert message received when the mobile device is not monitoring any other Patient /Biosensor Patch. The alert message belongs to Biosensor Patch ID of RL325.
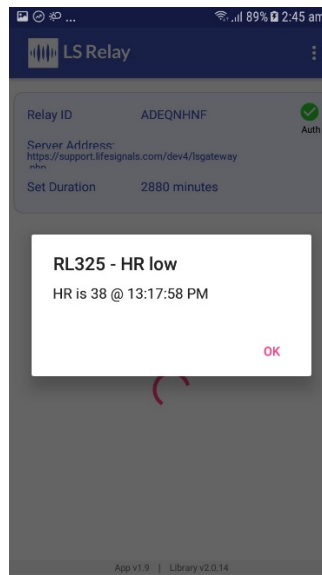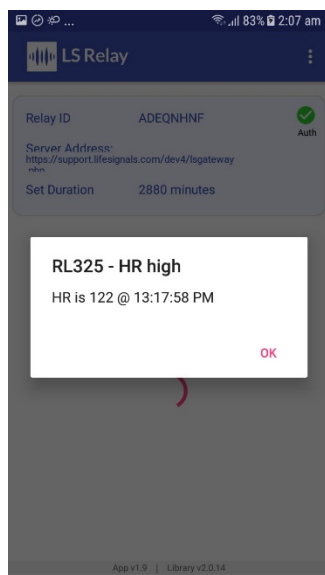
o Below is the example of Alert message pop-up while being monitoring another Patient /Biosensor Patch.
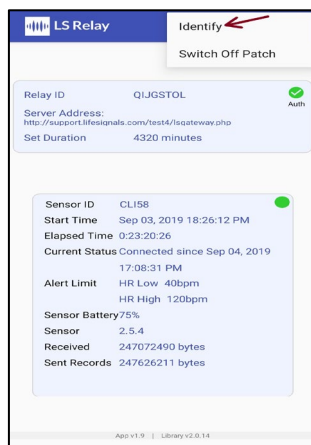
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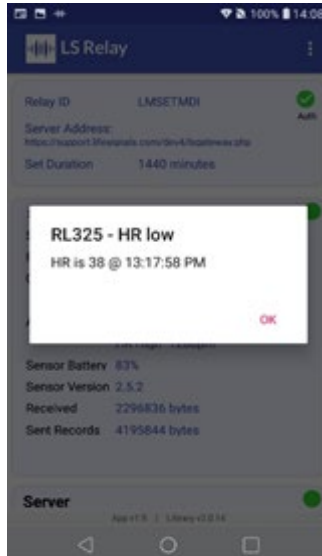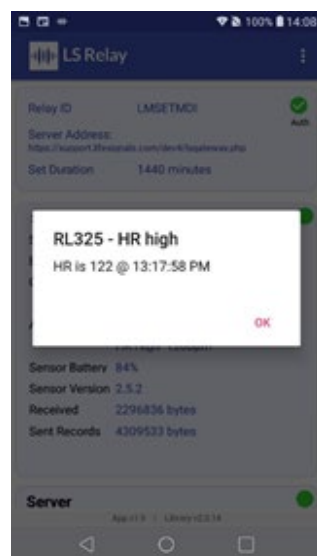
10.11 Identifying the Biosensor Patch that is currently being monitored

o The Biosensor Patch ID will be displayed on the screen. In addition to that, this method can be adopted.

o Click on the three-dot menu on the top right corner of the App.

o Select 'Identify Patch' from the drop-down menu.

o The LED on the patch will blink five times, to identify the Patch that is currently being monitored.

10.12 Switching Off the Biosensor Patch before completion of Monitoring Period

o Biosensor Patch may be switched Off before the end of the monitoring period, if required.

o ECG & Heart Rate data till the switch off time shall continue be available in Secure Server.

o Click on the three-dot menu on the top right corner of the app.

o Select 'Turn off patch' from the drop-down menu.
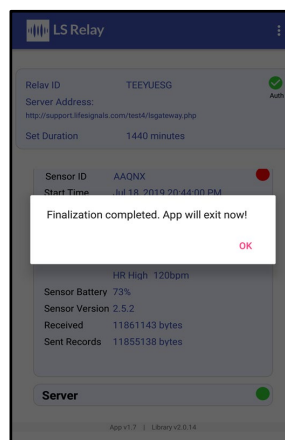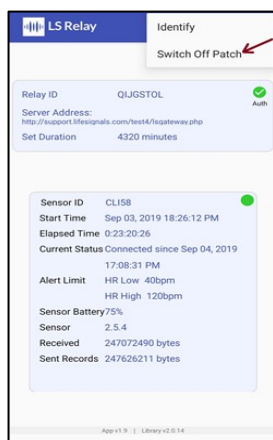
o The App will finalize the procedure and patch will turn off.

11 Instructions (For Secure Server Administrator):

11.1 Adding / Configuring a new Relay device to the Platform through Web UI

o Open Life Signal Web UI and login as 'administrator' (by entering admin Username and Password)

o Once logged in, select on 'RELAY MANAGEMENT' (1) and then click 'Add Relay' button(2)

- Select the ID of the Relay device to which the Heart Rate low/high to be sent.
- Set Low & High limits for Heart Rate Alert.
- Select maximum operating time of the Biosensor (24 hours / 48 hours / 72 hours). Any Biosensor connected to this relay device would be configured to this time.
    - These configuration details can be modified at any time.
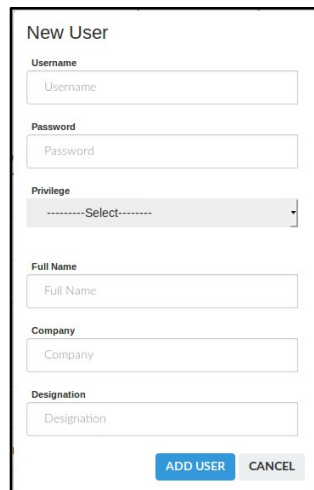
- Then press 'ADD RELAY' button.
- Relay device authentication key (file name: 'xxxxx.key') will get generated & will be downloaded in local drive.
- Forward this key to the clinical personnel who would be configuring his/her Mobile device as a Relay device (Section 10.1)

11.2 Adding New User

- Click on the 'User Management' menu.(1)

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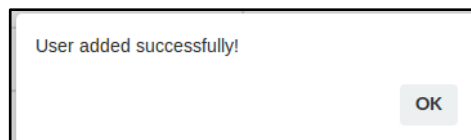
o Click on 'Add User' button.(2)

o Enter a new username and password, select the privilege (Administrator or Normal user) and then enter the name, designation and company of the user.
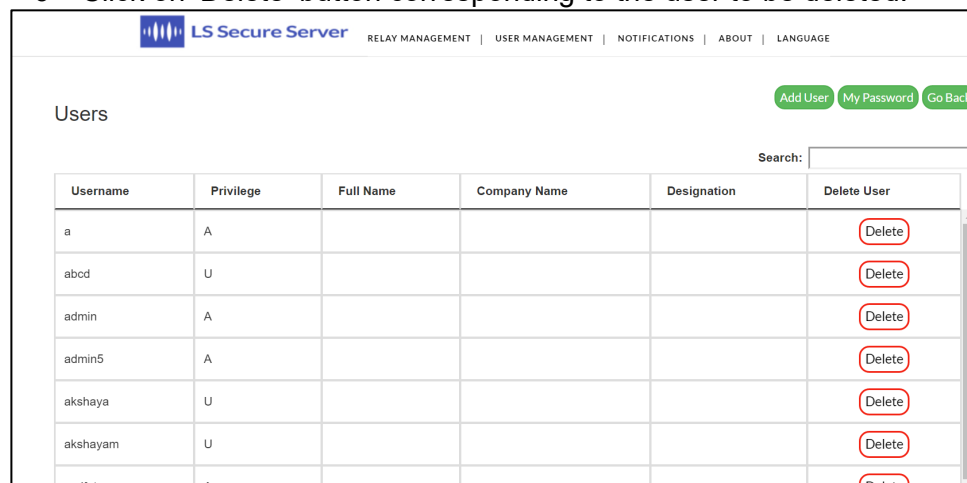
o Click on 'ADD USER' button.

o Once the user is added, 'User added successfully!' is displayed.

o Click OK.

11.3 Deleting Existing User

o Click on the 'User Management' menu.

o Enter the username to be deleted in the 'Search' box.

> o Click on 'Delete' button corresponding to the user to be deleted.

o   Confirm if you want to delete the user.

o   Once the user is removed 'User removed!' will be displayed.
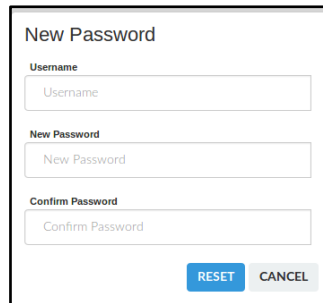
o   Click OK.

11.4   Changing the Password

o   Click on the 'User Management' menu.

o   Click on 'My Password' button.

o   Enter the Username of your account.

o   Enter the new password in the 'New Password' text box.

o   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.

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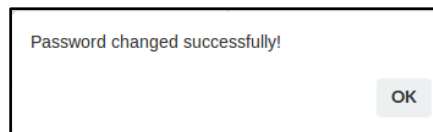Technical User Manual

o   Confirm the password by reentering the password in the 'Confirm Password' text box.

o   Click on 'Reset' button.

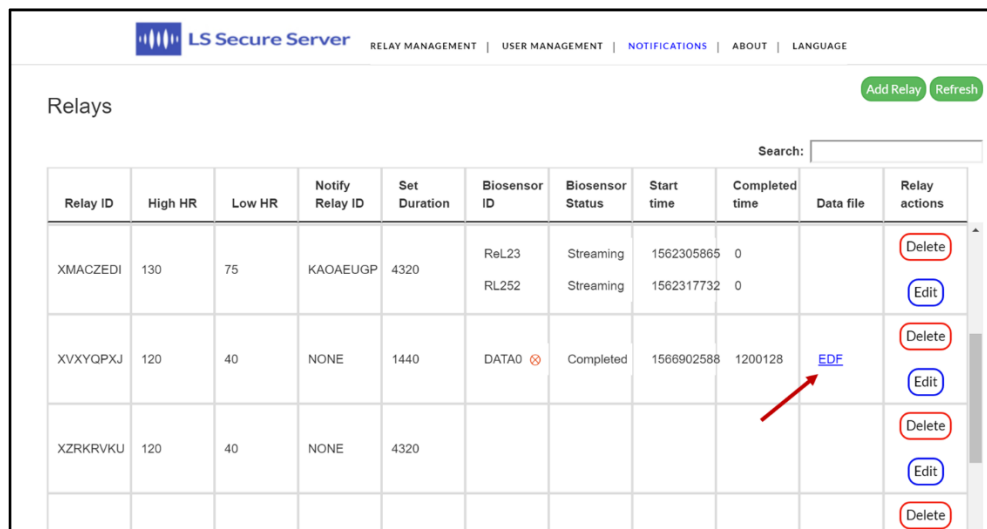o   Once the password is changed 'Password changed successfully!' will be displayed.

o   Click OK.

11.5 Generating EDF file

o   ECG data received from each Relay device is appended with Heart Rate and is securely stored in the server for access by third party analysis software through appropriate API interface.

o   The ECG & HR data can also be downloaded in EDF format by searching through the Relay Device ID & Biosensor ID and clicking "EDF" button as below.

12 Appendix

12.1 Table 1: Biosensor (LP1250) Specifications

Specifications	
ECG channels	Two (2) ECG-A and ECG-B
Classification of Applied parts	Defibrillation proof type CF**
Frequency Response	0.67 Hz to 40 Hz
CMRR	> 90dB
Input impedance	> 2.5 M ohms at 10Hz
ADC sampling rate	250 SPS
ADC resolution	16 bits
Lead off detection	
Injected Current	< 10uA
Injected Frequency	10 KHz
Power Requirements	
Battery Type	Zinc-Air
Battery Life	72 hours maximum or less if stored at a temperature greater than 20º C and/or operated in a congested Wi-Fi network
Battery Capacity	900 mAh
Output Voltage	2.8 V (2 x 1.4V)
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 +40ºC (32ºF to 104ºF)
Storage temperature (> 30 days)	+5ºC to +27ºC (41ºF to 80ºF)
Storage relative humidity	10 % to 90 % (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Ingress protection	IP22
Physical Characteristics	
Dimensions	112 mm x 79 mm x 6 mm
Weight	18 gm
Color	White
Wear life	72 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

12.2 Table 2: Platform (LX1250) Heart Rate 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)

12.3 Table 3: Relay App 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?	Back-press while scanning ongoing
Sensor is streaming. Do you want to exit the app?	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.	On Server Response, patch Status = Completed
Finalization completed. App will exit now!	On Finalize completed
SOCKET ERROR	Socket error on set mode
SOCKET_ERROR. Do you want to reconfigure?	Socket error on reconfigure

12.4 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 10 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	hrLow 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 not6 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.

12.5 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	Life Signal 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	Life Signal 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.

12.6 Table 6: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Life Signal 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

12.7 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.

12.8 Symbols

Label	Identification	Description
⚠	Caution or Warning	This symbol instructs the user to consult the instructions for warnings and safety precautions that could not be presented on the device
	Manufacturer	Legal manufacturer
	Recycle	Disposal of the medical device to be controlled according to local regulations as battery waste

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Symbol	Name	Description
NNNNN	GUDID (Level 0) & Serial No.	On PCBA – Level 0 – GUDID in data matrix format & Serial number in human readable format.
XXXXX	GUDID (Level 0) & Pairing ID	On Patch – Level 0 – GUDID in data matrix format and Pairing ID in human readable format.
	GUDID (Level 1,2 & 3)	Device GUDID (Level 1, 2 & 3) with manufacturing information. – Level 1: Serial No., Level 2 & 3: Lot No.
👤#	Unique Pairing ID	Unique Pairing ID
REF	Catalog Number	Device Catalog number / Labeler Product number
QTY	Quantity	Number of devices in pouch or multi-carton box
℞	Prescription device	To be used under prescription supervision by a medical practitioner
📖i	Consult instructions for use	Refer to instruction manual
🌡	Temperature range	Storage (long term) within the specified temperature range
⧗	Expiry Date (YYYY-MM-DD)	Use device in packaged condition before expiry date
🏭	Manufacturing date	Device manufacturing date
LOT	LOT Code	Manufacturing Batch or LOT code
❤	Applied part	Defibrillation-proof, Type CF Applied Part
②	Do not reuse	Do not reuse; single patient use
IP22	Ingress Protection Rating	Protection against fingers or other objects not greater than 80mm in length and 12mm in diameter and protection from 15-deg vertical dripping water
☂	Keep dry	Keep away from liquids or water or chemicals
5	Max Stack	Do not stack more than 5 boxes tall

FCC ID	Federal Communications Commission	Federal Communications Commission ID
MR (no symbol)	MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
(no pacemaker symbol)	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD

12.9 Contact Information

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Biosensor Patch is assembled in Republic of Korea

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