LifeSignals™

HOLTER CONNECT™

User Manual

This page intentionally left blank

Published on: 24 OCT, 2022
Document ID: 1000001582H

Copyright

Patent protection

LifeSignals®, LifeSignals, LifeSignals Enabled and Holter Connect are trademarks of LifeSignals, Inc.. All product names, brands, logos, and trademarks are the property of their respective owners.

► *For more information, see https://lifesignals.com/patents/*

Intended purpose

This manual describes the intended use of the Holter Connect Platform and observance of the manual is a prerequisite for proper performance, correct operation and ensures patient and user safety.
The intended audience is clinical professionals who are expected to have a working knowledge of medical procedures, practices, and terminology to provide patient care.

Safety notices

The following safety notice formats are used in this manual. Safety notices are used at the start of sections or embedded in operating instructions.
Ensure you fully understand and comply with the notices in this manual.

Warning

Indicates a potential hazardous situation which, if not avoided, could result in serious injury.

Caution

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

Notice

Indicates an important situation which, if not avoided, may seriously impair operations.

Tip

Additional information relating to the current section.

Contact address

LifeSignals, Inc.
426 S Hillview Dr.,
Milpitas
CA 95035, USA

Glossary

Term	Definition
Biosensor ID	A five or seven-character alphabetical code printed on the Biosensor and on the packaging of the Biosensor. This is the unique identifier of the Biosensor.
CFA	Clinical Facility Administrator, provides administration for an individual clinical facility.
Clinician	Clinicians can apply the Biosensor to the patient and commence a Holter test using the In-Clinic initiated Holter test or At-Home initiated Holter Test workflows. Additionally they are nominated to receive, analyze and process patient Holter test data that can be accessed from the Holter Connect Secure Server.
Default Supervisory Technician	The default Supervisory Technician is created by the SPA when adding a new hospital. The Supervisory Technician receives all patient ECG data from a hospital or clinical facility which they can allocate to a technician for review. A Supervisory Technician can be an internal hospital employee or a third party ECG technician service provider.
Doctor	Healthcare Doctor / Physician that receives the report from the technician.
Holter Connect App	Uploads data from a single Biosensor to the Holter Connect Secure Server.
Holter Link App	Uploads data from a batch of Biosensors to the Holter Connect Secure Server.
Hospitals	Term to describe all clinical facilities under the SPA, administered by a CFA. Also known as clinical facility or CF.
Knox License Key	Enables Samsung Knox, a mobile security solution that provides a secure environment for corporate data and apps for all Galaxy devices.
Relay Key	A unique, one time use file. Links the Holter Connect App to the Holter Connect Secure Server.
Revoke User	Remove the user's right to log in. Does not delete the user from the system.
SPA	Service Provider Administrator, provides administration for all clinical facilities.
SPO	Service Provider Operator uploads Biosensor data to the Holter Connect Secure Server for the Service Provider using Holter Link.
Technician	Technicians are nominated to receive, analyze and process patient Holter test data which can be accessed from the Holter Connect Secure Server. On completion of analysis, the Holter Report can be viewed on the Holter Connect Secure Server.

Contents

This page intentionally left blank

1 Safety information

This section provides an overview of all safety aspects for the protection of people as well as safe and uninterrupted operation. Other task related safety instructions are included in the specific sections.

1.1 Intended use and indications for use

The LifeSignals Holter Connect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of electrocardiography (ECG) and heart rate (optional) data in home and healthcare settings.

Patient physiological data is transmitted wirelessly from the LifeSignals Wearable Biosensor to a remote Holter Connect secure server for storage and analysis.

The LifeSignals Holter Connect Platform is intended for non-critical, adult population, who are 18 years of age or older.

1.2 Contraindications

- The Biosensor is not intended for use on critical care patients.
- The Biosensor is not intended for use on patients with any active implantable devices, such as defibrillators or pacemakers.

1.3 Warnings

Warning

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

1.4 Precautions

Caution

- Advise patient to avoid sleeping on their stomach, as this may interfere with the Biosensor performance.
- DO NOT use the Biosensor if the package has been opened, appears damaged or has expired.
- Avoid use of the Biosensor less than 2 meters from any interfering wireless devices such as certain gaming devices, wireless cameras or microwave ovens.
- The Biosensor contains a battery. Dispose of the Biosensor in accordance with local laws, care facility laws or hospital laws for non-hazardous electronic waste.
- If the Biosensor becomes soiled (e.g. coffee spill), wipe clean with a damp cloth and pat dry.
- If the Biosensor becomes soiled with blood, and/or bodily fluids/matter, dispose in accordance with local laws, care facility laws or hospital laws for biohazardous waste.
- DO NOT allow the patient to wear or use the Biosensor during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.
- DO NOT reuse the Biosensor, it is for single use only.
- Keep the Biosensor out of reach of children and pets.
- Advise patient to keep showers short with their back to the flow of water while showering. Gently pat dry with a towel and minimize activity until the Biosensor is fully dry and not to use creams or soap near the Biosensor.
- DO NOT use any skin barrier agents prior to Biosensor application, as it may cause skin irritation/injury due to a reaction between the barrier agent and the hydrogel electrodes.
- DO NOT immerse the Biosensor in water.

1.5 Cybersecurity controls

Notice

- To protect against unauthorized use and cybersecurity threats, enable all access control systems on mobile devices - Password protection and/or Biometric control.
- Enable automatic cybersecurity updates for the Holter Connect App and the mobile device operating system.
- Always use a password protected WiFi connection to access the Holter Connect Server. Do not use an open WiFi network.

2 Product description

This section gives an overview of the Holter Connect Platform.

2.1 LifeSignals Holter Connect Platform

The LifeSignals Holter Connect Platform contains the following components:

Wearable Biosensor	Acquires ECG signals and transmits to the Holter Link App or the Holter Connect App.
Holter Connect App	Installed on compatible mobile device. Assigns Biosensor to a patient. Receives ECG data from an individual Biosensor and transmits it to the Holter Connect Secure Server.
Holter Connect Secure Server	Receives and stores patients ECG data from the Holter Link App or the Holter Connect App, ready for analysis, reporting and viewing.
Holter Connect Web Portal	Web-based interface used to access and manage Biosensors and patient reports.
Holter Link App	Installed on compatible computer. Facilitates data retrieval from a batch of Biosensors and sends to the Holter Connect Secure Server.

Figure 1 - LifeSignals Holter Connect Platform

2.2 LifeSignals Wearable Biosensor

The LifeSignals Wearable Biosensor acquires ECG signals from the body, pre-processes the signals as two channels of ECG data and wirelessly transmits the ECG data to the Holter Connect App.

1	Right upper electrode.
2	Left upper electrode.
3	Right lower electrode.
4	Left lower electrode.

Figure 2 - LifeSignals Wearable Biosensor

LP1251 & LP1251E and private label variants.

- **ECG A**: Right upper electrode → Left lower electrode
- **ECG B**: Right upper electrode → Right lower electrode

To support a Holter Connect workflow, the acquired data is buffered (temporarily stored) in the Biosensor until communication with the Holter Link App or Holter Connect App is unavailable.

The Biosensor uses standard WLAN (802.11b) secured (AES) communication protocol for wireless data transmission to the mobile phone or tablet. The LP1251 and LP1251E are designed and tested for up to 168 hours wear duration(actual wear duration claims may vary between countries based on regulatory clearance).

The Biosensor is a battery-operated device, and the Biosensor battery life may vary depending upon storage temperature and the WLAN environment.

2.3 Holter Connect App

The Holter Connect App is installed on a commercially available compatible mobile phone or tablet. The Holter Connect App receives data from a single Biosensor and transfers it to the Holter Connect Server. The Holter Connect App is designed for uploading data from a Biosensor one at a time.

The Holter Connect App performs the following functions:

Starts the Holter test

- Provides a form to register patient details.
- Verifies if the Biosensor is valid for a new Holter test, on scanning of its QR code.
- Establishes a secure wireless connection to the Biosensor using the mobile phone or tablet WiFi in hotspot mode.
- Receives 2-channel ECG signals from the Biosensor and presents the waveform to the user for verification of Biosensor placement on the patient's body.
- Communicates the patient information to the Holter Connect server.

Transfer of data stored in the Biosensor at the end of the Holter test

- Establishes a secure wireless connection to the Biosensor using the mobile phone or tablet WiFi in hotspot mode.
- Receives the stored ECG data from the Biosensor wirelessly.
- Sends the data securely to the Holter Connect Server.

2.4 Holter Connect Secure Server

Holter Connect Secure Server is a cloud-based server application that operates as the back end of the Holter Connect Platform. Each Service Provider will have an independent instance of the Holter Connect Secure Server.

The Holter Connect Secure Server performs the following functions:

- Maintains credentials for each user category.
- Authenticates the Holter Link App and Holter Connect App and establishes secure connection over the internet.
- Receives and stores ECG data and other patient information sent by the Holter Connect App.
- Manages the server-side workflow of assigning the ECG data to the ECG technician for analysis using a Holter analysis software. Stores Holter reports generated by clinicians/technicians.

2.5 Holter Connect Web Portal

The Holter Connect Web Portal provides the following web based interfaces:

- The Service Provider Administrator (SPA) interface for user management and Biosensor inventory.
- The Clinical Facility Administrator (CFA) interface for user management (doctors, technicians, supervisors) and Biosensor inventory and status.
- The Technician interface provides remote access for Technicians to view ECG waveforms.
- The Doctor interface provides remote access for Doctors to view ECG waveforms and interactive Holter reports.

2.6 Holter Link PC Application

Holter Link is an application installed on a dedicated laptop with a customized Operating System (OS). The OS and support packages are bundled with the Holter Link App distribution, and their installation and customization are performed by Holter Link installer, in addition to installation of the Holter Link App itself.

Holter Link is used for retrieval of data from a batch of Biosensors. The presence of an operator is required only for submitting the batch of Biosensors to the retrieval queue. Operator can then leave the Holter Link system to retrieve data from the Biosensors, one by one, and send it to the Holter Connect Secure Server. The operator may add one or more Biosensorsto the retrieval queue at any point of time.

Additionally,Holter Link can facilitate the capture of Holter Diary images and subsequent uploading of these images to the Holter Connect Secure Server for viewing by the Technician performing the Holter analysis and the ordering Physician. A document camera is required, further details can be obtained from your Service Provider.

Uploading of Biosensor Data and corresponding Holter Diary can be done in any order.

3 Install the Holter Connect App

The following steps describe the installation of the Holter Connect App on a compatible mobile phone or tablet.

Contact LifeSignals for a list of the latest compatible mobile phone or tablets.

1. Download the Holter Connect App installation files and the Relay Key to your PC/Laptop.
2. Connect your mobile phone or tablet to a computer using a USB cable.
3. Navigate to the Holter Connect App install file (***.apk***) and the Relay Key file (***.key***).
4. Copy the Holter Connect App install file and the Relay Key.
5. Paste the copied files into the ***Download*** folder.
6. On the mobile phone or tablet, navigate to ***My Files > Internal Storage > Download***.
   The folder should contain the Holter Connect App install file (***.apk***) and the Relay Key file (***.key***).

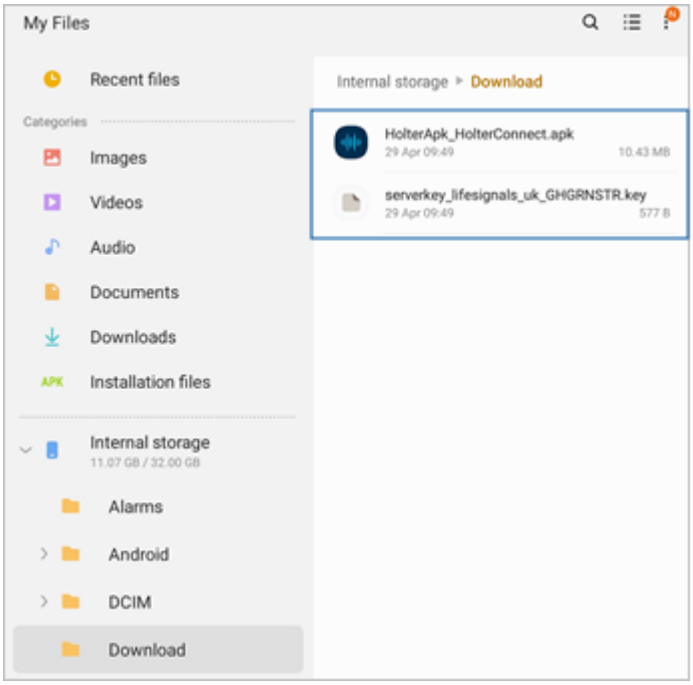


Figure 3 - Holter Connect App install files and Relay Key

7. Select the ***HolterApk_HolterConnect.apk*** file.
8. Select ***Install***.
9. Select ***Open*** after the installation has completed.
10. Select ***Activate***.
11. Select ***Allow*** for the following:

- Allow Holter Connect to take pictures and video.
- Allow Holter Connect to access your device's location.
- Allow Holter Connect to access photos, media and files on your device.

The Holter Connect App opens.

12. Select ***Next*** to continue.
13. Enter your ***Username*** and ***Password***.
14. Select ***LOGIN*** and the app should automatically authenticate the user and the Server key.

    You are presented with the ***Samsung Knox Privacy Policy***.
15. Tick the checkbox to acknowledge the terms and conditions.
16. Select ***Allow*** to continue.

The Holter Connect App is now successfully installed.

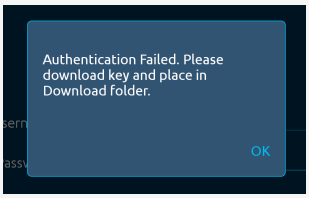
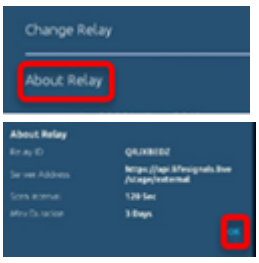
Note: Initial set up of the Holter Connect App on mobile phone

To clear cached usernames in Holter Connect App, double tap the username and select OK to remove. Select Cancel to retain cached usernames.

3.1 Additional menu features in the Holter Connect App

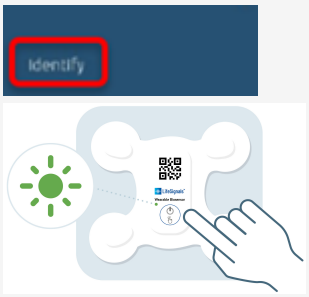
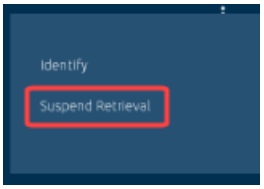
In the Holter Connect App, select  to access the additional menu features shown in Table 1.

Table 1 - Holter Connect App additional menu features

Instructions	Image	Explanation
Select ***Change Relay***. If the new key is not found, the user will see the `'Key not found'` message. Select ***OK*** to return to home screen.		The Relay ID is the unique ID that is used to identify the Relay device (mobile phone or tablet) by the server.
Select ***About Relay***. Select ***OK*** to return to the home screen.		Outlines additional information.

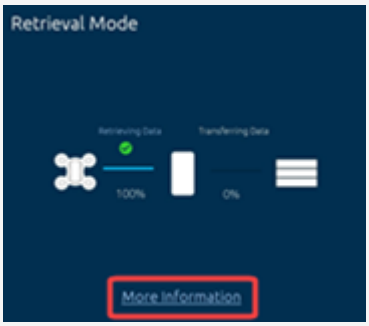
After entering the Biosensor ID, select  to access the additional menu features shown in Table 2.

Table 2 - Holter Connect App additional menu features after entering a Biosensor ID

Instructions	Image	Explanation
Select ***Identify***.		Identifies the Biosensor currently in use. The LED status indicator light of the Biosensor currently in use will flash five times.
Select ***Suspend Retrieval***.		Suspends data retrieval for the Holter test.

During data retieval, select ***More Information*** to access the additional the additional information shown in Table 3.

Table 3 - Additional information available during data retrieval.

Instructions	Image	Explanation
Select ***More Information***.		Displays additional information: • Biosensor ID. • Start Time. • Current Status. • Biosensor Version.

This page intentionally left blank

4 Install Holter Link

Please follow the steps outlined in the Installation Guides (Document ID 1000001943A) to install Holter Link App on a compatible P.C. These instructions along with a list of compatible computers are available from your Service Provider.

4.1 Additional Menu features in the Holter Link App

My profile

Displays user information and Reset Password button.

Settings

Opens the settings popup window

Settings tab

- Max. no. Of Biosensors(1-1000)
- Max. retrieval time (1-1000 hours)
- Units (Metric or Imperial)
- Time zone
- Patient Identification (Patient ID or MRN)
- Screen lock (time in minutes (5-480))
- Button for ***UPLOAD AUDIT LOG***
- Button for ***IMPORT SERVERKEY***
- Button ***SAVE*** (to save the changes made in the settings)
- Button ***CANCEL*** (to discard the changes made)

Advanced tab

- Timeout for Biosensor connection (adding to queue)
- Timeout for Biosensor connection (before retrieval)
- Timeout for Biosensor connection (during retrieval)
- Wi-Fi channel
- Camera source (camera for the Holter Diary.)
- ***UPDATE HOLTER LINK*** - Facilitate remote update of Holter Link App
- ***UPLOAD AUDIT LOG*** - Provides audit trail for specified time period
- ***IMPORT SERVERKEY*** - Created in Holter Connect Web Portal
- ***SAVE***
- ***CANCEL***

About

Provides additional information on Holter Link.

Change user/Screen lock

User is directed to login page.

Logout

Current user can logout.

Shut down

Closes the Holter Link App and shuts down the computer.

5 Holter Connect clinical workflows

The Holter Connect Platform supports two clinical workflows.

1. In-Clinic initiated Holter test:
    - The Holter test is started by a clinician in a hospital or clinical facility using the Holter Connect Web Portal or Holter Connect App. The clinician applies the Biosensor on the patient's chest and explains how to complete the Holter Diary.
    - The patient wears the Biosensor for the prescribed period. At the end of the Holter test, the patient removes and returns the Biosensor.
    - On receipt of the used Biosensor and Holter Diary, the Biosensor data is transferred to the Holter Connect Secure Server via the Holter Link App or Holter Connect App.
2. At-Home initiated Holter Test:
    - The Biosensor is pre-assigned to the patient using the Holter Connect Web Portal and mailed to the patient with a Holter Diary.
    - The patient turns on and self-applies the Biosensor to their chest, making a note of the date and time in the Holter Diary.
    - At the end of the Holter test, the patient removes the Biosensor and returns it, as instructed, with the Holter Diary.
    - On receipt of the Biosensor, the Biosensor data is transferred to the Holter Connect Secure Server via the Holter Link App or Holter Connect App.

5.1 Implement an In-Clinic initiated Holter test

This section describes the correct patient preparation and initiation of a Holter test in a clinical setting with the Biosensor and Holter Link App or Holter Connect App.

Important advice and information is provided for patients to ensure the Biosensor remains functional for the full wear duration and the successful completion of the Holter test.

5.1.1 Advice for patients

The following guidance is also shown in the Patient Information Leaflet found inside the Biosensor packaging:

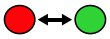
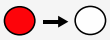
- Limit activity for one hour after the Biosensor has been applied to ensure good skin adherence.
- Carry out normal daily routine but avoid activities that cause excessive sweating.
- Press the ON button when they feel a symptom and record on the Holter Diary.

- Keep showers short with their back to the flow of water while showering.
- If the Biosensor accidentally gets wet, gently pat dry with a towel and minimize activity until the biosensor is fully dry.
- If the Biosensor becomes soiled (e.g. coffee spill), wipe clean with a damp cloth and pat dry.
- If the Biosensor loosens or starts to peel away, press down the edges with their fingers.
- Avoid sleeping on the stomach, as this may interfere with the Biosensor performance.
- Occasional skin itchiness and redness are normal around the Biosensor placement area.

5.1.2 LED status indicators

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

Table 4 - LED status indicators on the LifeSignals Biosensor

Light	Behaviour	Status
	Slow flash	Biosensor is connected to the Holter Link App or Holter Connect App or a Holter test is ongoing.
	Fast flash	Biosensor is attempting to connect with the Holter Link App or Holter Connect App.
	Slow flash	Low Battery indication.
	Alternate flashing	Response to Holter Link App or Holter Connect App - “Identify Biosensor” command .
	Fast flash → Off	Biosensor turned off.

5.1.3 Prepare skin

Before applying the Biosensor, the skin surface must be prepared. Correct skin preparation will ensure the following:

- High patient comfort and compliance
- Reliable and robust ECG waveforms
- Artefact-free ECG reporting
- Good Biosensor adhesion for the wear duration

To prepare the skin for a Biosensor follow this procedure:

1. If required, remove excess hair from upper left chest area, preferably using hair clippers.

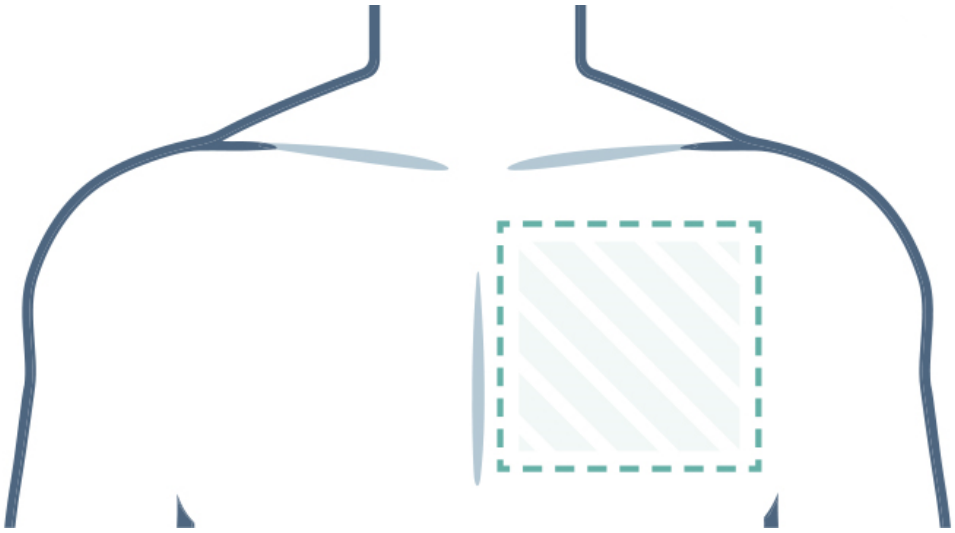


Figure 4 - Area of upper left chest to attach Biosensor

2. Clean the area with non-moisturizing soap and water.
3. Rinse the area making sure you remove all soap residue.
4. Dry the area vigorously.

Notice

Avoid the use of wipes or isopropyl alcohol to clean the skin, as alcohol dries the skin, increases the possibility of skin irritation and can reduce the electrical signal to the Biosensor.

5.1.4 Assign a Biosensor to a Patient

The Biosensorcan be assigned using either the Holter Connect Web Portal or the Holter Connect App.

5.1.4.1 Using the Holter Connect Web Portal

Login to the portal using the credentials provided by your Service Provider

1. Select .
2. From the drop-down list, select ***Hospital***.
3. From the menu, select ***All > Unused Biosensors***
4. From the list of Biosensors, find the Biosensor ID you wish to assign to the patient.
5. In the ***Actions*** tab for that Biosensor ID, select ***Assign Biosensor to Patient.***

6. Enter the Patient details in the popup window.
7. Select the patient timezone amd enter the test start date time.
8. Select ***Did you take patient consent?*** if patient consent has been taken.
9. Select ***Assign***.
   The Biosensor can now be mailed to the patient.
10. Press the BiosensorON button once. A red light will flash followed by a flashing green light.

5.1.4.2 Using the Holter Connect App

Notice

Check the expiry date and the outer package for any damage.

If data is not entered in the mandatory fields (Patient ID, DOB, Doctor), an error message highlighting the fields with missing information will appear.

If an incorrect ***Test Duration*** is selected for the Biosensor, an error message will appear.

1. Open the Holter Connect App on the mobile phone or tablet and enter ***LOGIN*** details.
2. Remove the Biosensor from the pouch.
3. Enter the ***Biosensor ID*** into the Holter Connect App manually or by scanning the QR code on the Biosensor.
4. Select ***Next***.
5. Enter ***Patient Details*** into the Holter Connect App manually or by scanning the patient ID barcode.
6. Select ***Test Duration*** from the drop-down menu. Select ***Next***.
7. Ask the patient to read the Consent Statement and select the ***AGREE*** option.
8. Press the Biosensor***ON*** button once. A red light will flash followed by a flashing green light.
9. In the Holter Connect App, select ***Next***.
10. The Biosensor will automatically connect to the Holter Connect App.
11. Wait for the ***Biosensor connected*** message to be displayed in the Holter Connect App.

5.1.5 Apply the Biosensor to a patient

The Biosensor must be correctly positioned and applied to the patient.

1. Gently peel off the Biosensor protective backing film. Start with the four corners before removing the centre section.
2. Place the Biosensor on the upper left chest of the patient, below the collar bone and left of the sternum.

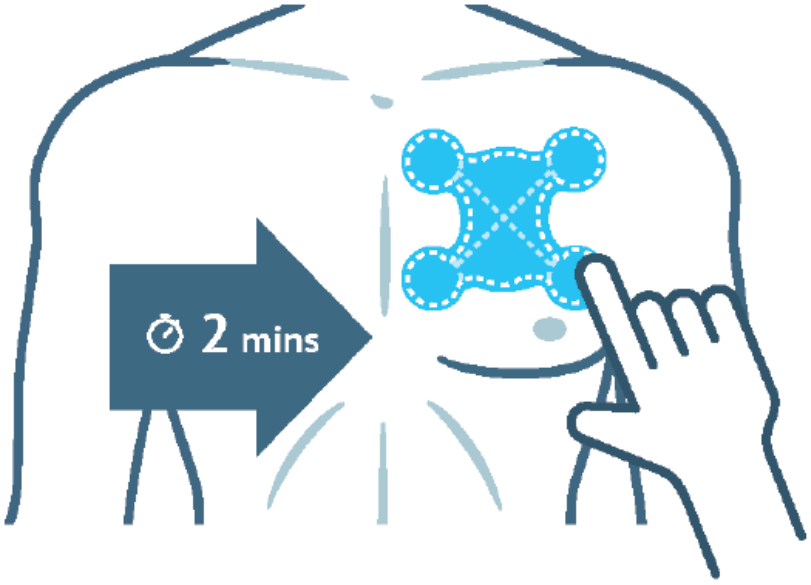


Figure 5 - Biosensor application position

3. Press the entire Biosensor firmly for 2 minutes, especially around the four circular areas.

5.1.6 View waveforms (Holter Connect App only)

1. In the Holter Connect App, select ***Next***.
2. Assess the ECG waveforms being displayed in the Holter Connect App.
3. Select ***Accept*** if good quality ECG waveforms are displayed.
4. A message reading ***Are you sure you want to start the procedure?*** will display. Select ***Yes*** if you wish to start the Holter test.
5. Select ***OK*** when the ***Procedure started successfully*** message appears.

5.1.7 Remove Biosensor

At the end of the Holter test, the green light on the Biosensor will stop flashing and the Biosensor can be removed.

Notice

If patients have fragile or delicate skin, consider using an adhesive remover during Biosensor removal.

Silicone-based adhesive removers are the preferred option for removing adhesive as they leave no adhesive residue on the skin, do not sting the patient and are not associated with drying the skin.

Alcohol-based products may lead to vasoconstriction and drying of the skin. Alcohol may also sting the patient.

To minimise the risk of adhesive-related skin injury, follow these steps*:

1. Slowly peel each of the four Biosensor circular edges towards the centre of the Biosensor, keeping as close to the skin as possible.
2. With the other hand, gently press and support newly exposed skin to reduce skin stretch and avoid patient discomfort.
3. Gently peel off the remaining Biosensor (where relevant, in the direction of hair growth).

Figure 6 - Support newly exposed skin whilst removing the Biosensor

**Fumarola S, Allaway R, Callaghan R, Collier M, Downie F, Geraghty J, Kiernan S, Spratt F.*
Overlooked and underestimated: medical adhesive-related skin injuries. Best practice consensus document on prevention. J Wound Care 2020; 29(Suppl 3c):S1-S24.

5.2 Implement the At-Home initiated Holter Test

In the At-Home initiated Holter Test, the Biosensor can be handed over to the patient to perform the Holter test remotely.

The patient performs their own skin preparation and applies the Biosensor. After the prescribed wear period, the patient returns the Biosensor, by post or hand delivery, for analysis by a health care professional.

Notice

The Holter Diary must accompany the Biosensor, so that the patient has clear guidance for applying, wearing and removing the Biosensor.

The patient must record the date and time when they started the Holter test. This information is essential to permit the upload of Biosensor data to the Holter Connect Secure Server and complete a Holter report.

5.2.1 Start an At-Home initiated Holter Test

► *For more information, see "Start an At-Home initiated Holter Test" on page 30*

5.3 Upload Biosensor data

Biosensor data can be uploaded to the Holter Connect Secure Server using the Holter Link App (batch of Biosensors) or the Holter Connect App (single Biosensor).

5.3.1 Using Holter Link

After logging in, follow these steps:

5.3.1.1 To upload Biosensor data

1. Select ***ADD Biosensor*** button, this opens a popup window.
2. Scan the QR/barcode or manually enter the Biosensor ID, this opens a new popup window with the patient details.
3. For the 'At-home initiated Holter Test', enter the Start date and time from Holter Diary.
4. If there is no Holter Diary, tick the Not Available check box. (Note: Once selected, Holter Diary can NOT be added in the future) OR if you want to add Holter Diary images later, leave the Not Available check box unticked.
    a. Select ***NEXT*** to begin Biosensor data retrieval.
    b. When requested, turn on the Biosensor by pressing the Biosensor ON button once, a red light will flash followed by a flashing green light, then the Biosensor will join the retrieval queue. (Note: It will take a few seconds to connect to the Biosensor).
    c. The popup window to add another Biosensor for data upload will appear.
5. If there is a Holter Diary, select ***ADD IMAGE***, this will open a popup window with camera preview.
    d. Place the Holter Diary underneath the camera and select the camera button (camera preview popup window) to capture an image.
    e. Select ***ADD IMAGE*** to capture another image ***OR*** select ***REPLACE IMAGE*** if the image is unclear (Note: minimum of two images – front & back of Holter Diary– maximum of 10 images)
    f. When image capture is complete, select ***BACK***.
    g. Select ***NEXT*** to begin Biosensor data retrieval.
    h. When requested, turn on the Biosensor by pressing the Biosensor ON button once, a red light will flash followed by a flashing green light, then the Biosensor will join the retrieval queue.
    i. The popup window to add another Biosensor will appear to begin another Biosensor upload.

5.3.1.2 Add Holter Diary images later

1. Select the red Holter Diary icon in the Queue or History tab to open the popup window with the patient details and select ***ADD IMAGE***.
2. Follow the "If there is a Holter Diary" steps to add images.

5.3.1.3 Search for Biosensor or Facility

1. Select the ***History*** tab.

2. Select Biosensor or Facility in the dropdown menu.
3. Enter Biosensor ID or Facility name (partial or complete text) in the search field.
4. Select a ***From date*** and ***To date*** in the calendar dropdown menu.
5. Select ***CONFIRM***.

5.3.1.4 Check status of assigned Biosensor

1. Select the ***Query*** tab.
2. Enter Biosensor ID in the search field.
3. Select ***SEARCH***, this opens the popup window with the patient details.

(**Note**: User can add Holter Diary images (for data transfer ongoing or completed Biosensors) if not previously added.

5.3.2 Using Holter Connect App

1. Open the Holter Connect App on the mobile phone or tablet.
2. Enter your LOGIN details.
3. Turn on the Biosensor.
4. Enter the ***Biosensor ID*** into the Holter Connect App manually or by scanning the QR code on the Biosensor.
5. Select ***Next***.
6. If requested, enter the ***Procedure Start Time*** as documented by the patient in the Holter Diary.
7. The Holter Connect App will automatically connect to the Biosensor.
8. Data is uploaded automatically from the Biosensor to the Holter Connect Secure Server.
9. Select ***OK*** when the ***Procedure completed successfully*** message appears.

During data retrieval, select More Information to view Biosensor details and current status.

6 Holter Connect Web Portal

This chapter describes the function of the Holter Connect Web Portal and the tasks which can be performed by each user group.

6.1 User hierarchy

User accounts are divided into the following user groups in the Holter Connect Web Portal.

- Service Provider Administrator (SPA)
  - Service Provider Operator (SPO)
  - Supervisory Technician
  - Technician
- Clinical Facility Administrator (CFA)
  - Supervisory Clinician
  - Clinician
  - Doctor

Each user group can perform different tasks in the Holter Connect Web Portal. The hierarchy of user groups is shown in Figure 7.

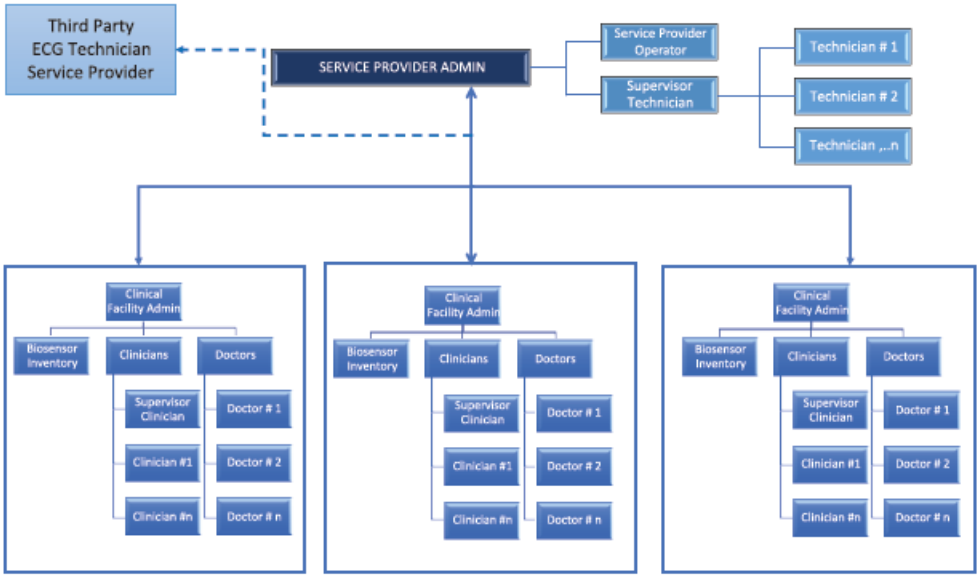


Figure 7 - User hierarchy

6.2 Service Provider Administrator (SPA) tasks

The SPA can perform the following tasks in the Holter Connect Web Portal:

- Register or add new Biosensors to a hospital on the Holter Connect Platform
- View the Biosensors allocated to an individual hospital or clinical facility
- Create and manage a Hospital or clinical facility account
- Create and manage CFA accounts
- Create and manage Technician or Supervisor accounts
- Create and manage SPO accounts
- Manage Relay Keys

In the Holter Connect Web Portal, the SPA home page has the following menu options.

Table 5 - SPA homepage menu options in the Holter Connect Web Portal

Icon	Description	Operation
	***Biosensors***	View the list of Biosensors and passwords. View the status of the Biosensors.
	***Hospitals***	View, Add or Edit the list of hospitals or clinical facilities.
	***CFA***	Create and Edit hospital or clinical administrator logins.
	***Technicians***	Create Supervisor and Technician logins.
	***Relay Apps***	Generate the Relay Keys that manage Holter Connect App access. The Holter Connect App is installed on a mobile phone or tablet with connection to the Holter Connect Secure Server.
	**SPO**	View, Add, Revoke or Edit the Service Provider Operator.

6.2.1 Display a list of Biosensors at a hospital

Select the ***All View*** tab to display a list of Biosensors associated with a hospital along with the following Biosensor information:

- ***Biosensor ID***: a unique five character ID
- ***Password***: the password used by the Holter Connect App to connect to the Biosensor when transferring encrypted data
- **State:** the current status of the Biosensor
  - ***Completed***: Biosensor data has been uploaded
  - ***Unused***: Biosensor has not been used
  - ***Ongoing***: ECG recording has started
  - ***Expired***: The expiry of Biosensor has been met
  - ***Discarded***: Biosensor discarded by a Clinician during the In-Clinic initiated Holter test workflow

6.2.2 Assign Biosensors to a SPA Supervisor

1. Select the ***All View*** tab.
2. Select the ***Completed*** or ***Ongoing*** state of the Biosensor you want to assign.
   The ***Assign Patients*** window opens.
3. From the ***Technician*** drop-down list, select the SPA Supervisor.
4. Select ***Assign***.

6.2.3 Add Biosensors to a hospital

1. Select  to access the ***Add Biosensors*** screen.
2. Select the hospital from the drop-down menu and select ***Upload XLSX***.
3. Select ***Choose File*** and navigate to the required file.
4. Select ***Upload***.
   The ***Successfully uploaded, please check the email after sometime*** message is displayed at the bottom of the screen.
5. An automated email is sent when the file has been processed successfully. The email contains an excel file outlining Biosensor status. Biosensors are shown in the list when the status is shown as ***SUCCESS***.

Notice

After uploading the ***.xlsx*** file, the SPA should check the automated email to ensure the status of every Biosensor is shown as `SUCCESS`.

If the Biosensor status is shown as `FAILED`, contact your supplier.

6.2.4 Filter Biosensors

The list of Biosensors can be filtered using the ***Search Biosensor*** function.

The ***All*** drop-down menu allows Biosensors to be viewed according to their status.

Table 6 - Biosensor status descriptions

Biosensor Status	Description
Unused Biosensors	Biosensors that have not been allocated to a patient yet. Biosensor ID and password will be displayed.
Procedure ongoing	Biosensors currently in use and capturing data. Biosensor ID, Start and Expected End Time of the Holter test will be displayed.
Procedure completed	Biosensors with data that has been uploaded to the Holter Connect App. Biosensor ID, Start and End Time of the Holter test will be displayed.

Biosensor Status	Description
Expired Biosensors	Expired Biosensors that can no longer be used.
Discarded Biosensors	Biosensors discarded during patient assignment via the Holter Connect App.

6.2.5 Move (reallocate) Biosensors

1. Navigate to the ***Unused Biosensors*** view.
2. Select an individual Biosensor or multiple Biosensors using the check boxes.
3. Select ***Move*** in the top right corner.
   The ***Move Biosensors*** dialog box is shown.
4. Select the destination hospital from the ***To*** drop-down menu.
5. Select ***Move***.

Tip

The ***Move*** feature can also be used for inventory management by creating a generic hospital account. This allows Biosensors to be bulk uploaded to the generic clinical facility account.

Biosensors can then be quickly transferred from the generic clinical account to a specific clinical account using the ***Move*** feature.

6.2.6 Display a list of hospitals

Select the ***Hospitals*** tab to display a list of hospitals.

There are three menu options in the ***Hospitals*** tab.

Table 7 - Menu options in the Hospitals tab

Icon	Description	Operation
	***Settings***	Select this option for automatic Invoice Creation.
	***Edit Hospital***	Options for managing email addresses and choosing a default Supervisory Technician.
	***View More Information***	Select this option to view the default Supervisory Technician for the hospital.

6.2.7 Add a hospital

1. Navigate to the ***Hospitals*** tab.
2. Select  to open the ***Add Hospital*** screen.
3. Add the hospital information to the ***Add Hospital*** form.

> **Notice**
>
> You have the option to choose a default Supervisory Technician. This is the person who will receive notifications and access to all uploaded Biosensor data from this hospital.
>
> The default Supervisory Technician can be an internal hospital employee or a third party ECG technician service provider.
>
> A hospital account cannot be deleted or account details edited. For example, the Hospital Name, Phone Number or Address cannot be edited.

4. Select ***ADD***.

6.2.8 Edit a hospital

1. Navigate to the ***Hospitals*** tab.
2. From the ***Actions*** tab, select  .
   The ***Edit Hospital*** window opens.
3. Edit the following information:
   - ***Hospital name and email ID***
   - ***Wristband pattern***
   - ***Default Supervisory Technician***

> **Notice**
>
> If the CFA selects a default Supervisory Clinician, the SPA can no longer select a default Technician for the clinical facility.

4. Select ***Save***.

6.2.9 Display a list of Clinical Facility Administrators

Select the ***CFA*** tab to display a list of Clinical Facility Administrators (CFA) associated with a Hospital.

Select a hospital from the drop-down menu.

There are two menu options in the ***CFA*** tab.

Table 8 - Menu actions in the *CFA* tab.

Icon	Description	Operation
	***Resend Activation Mail***	Resend email to the CFA to enable setting a password. • If enabled, the icon will be highlighted. The administrator can resend activation email to the user. • If disabled, the icon will be shaded. The account has been activated.
	***Revoke User***	To revoke user access. The user will no longer be able to login or access Holter Connect.

6.2.10 Add a Clinical Facility Administrator

1. Navigate to the ***CFA*** tab.
2. Select  to open the ***Add CFA*** screen.
3. Enter the CFA information in to the ***Add CFA*** form.
4. Select ***ADD***.

6.2.11 Display a list of Technicians and Supervisors

Select the ***Technician*** or ***Supervisor*** tabs to view a list of Technician or Supervisors.

Notice

If a hospital wants to outsource ECG analysis to a third party ECG Technician service provider, the SPA can allocate a default Supervisory Technician from the list of Supervisors.

There are two menu options in the ***Technicians*** tab.

Table 9 - Menu options in the Technicians tab

Icon	Description	Operation
	***Resend Activation Mail***	Resend email to the Technician or Supervisor to enable setting a password. • If enabled, the icon will be highlighted. The administrator can resend activation email to the user. • If disabled, the icon will be shaded. The account has been activated.
	***Revoke User***	To revoke user access. The user will no longer be able to login or access Holter Connect.

6.2.12 Add a Supervisor (SPA)

1. Navigate to the Technicians tab and select the ***Supervisor*** tab at the top of the window.
2. Select  to open the ***Add Supervisor*** screen.
3. Enter the Supervisor information to the ***Add Supervisor*** form.
4. Select ***ADD***.

> **Notice**
>
> The Supervisor is also a Technician but has a higher authority to delegate the Biosensor readings to other Technicians if needed.

6.2.13 Add a Technician (SPA)

1. Navigate to the ***Technicians*** tab and select the ***Technician*** tab at the top of the window.
2. Select  to open the ***Add Technician*** screen.
3. Enter the Technician information to the ***Add Technician*** form.
4. Select ***ADD***.

6.2.14 Display a list of Relays

The Holter Link App and the Holter Connect App are used to upload data to the Holter Connect Secure Server. A Relay Key must be generated to configure these Apps and the Relay Key can only be used for a single installation of the Holter Link App or Holter Connect App on compatible devices.

For a Service Provider Operator(SPO), a Relay Key can be generated for a single installation of the Holter Link App to enable batch uploading of Biosensors from ***All Hospitals*** to the Holter Connect Secure Server

The ***Relay apps*** tab displays a list of Relay Apps in the Holter Connect Web Portall.

6.2.15 Create a new Relay Key

1. Navigate to the ***Relay Apps*** tab.
2. Select  to open the ***Add Relay app*** screen.
3. Enter the following information in to the ***Add Relay app*** form.

Table 10 - Information required in the *Add Relay app* form

Name	Purpose/ Explanation
Hospital Name	Required for assigning Relay Key. (* For SPO select ***All Hospitals***)
Knox License Key	A valid Knox License Key is required to authorize the device.
Duration	The Holter test duration. Depending on the Biosensor this can be up to 168 hours.
Duration Unit	The unit of measurement for the duration of the Holter test.

4. Select ***ADD*** to create the Relay Key. The Relay Key will be automatically downloaded within your web browser.
5. The Relay ID and Relay Key should be communicated to the person responsible for installing the Relay App on the mobile phone or tablet.
   ► *For more information, see "Install the Holter Connect App" on page 7*

Notice

This Relay Key must be saved to a secure file location. Check with your hospital IT Administrator for the preferred directory or folder to store this important information.

6.2.16 Download a list of previous Relay Keys

1. Select a Relay App from the list in the ***Relay App*** tab.
2. Select ***Click to download server key*** to download the Relay Key.

Notice

If the Relay Key has already been used for any installation of the Holter Connect App, it will no longer be of use.

6.2.17 Display a list of Service Provider Operators

The Service Provider Operator (SPO) is responsible for uploading batches of Biosensors received from hospitals, using the Holter Link App. The Service Provider Operator tab displays a list of SPO names in the Holter Connect Web Portal.

For each Service Provider Operator, the Service Provider Administrator can do the following:

- Send/Resend activation email.
- Reactivate Service Provider Operator
- Revoke User
- Edit Service Provider Operator details

6.2.18 Add a Service Provider Operator (SPO)

1. Navigate to the ***Service Provider Operator*** tab.
2. Select to open the ***Add Service Operator*** screen.
3. Enter the Service Provider Operator information to the ***Add Service Operator*** form.
4. Select ***ADD***.

6.3 Clinical Facility Administrator (CFA) tasks

The Clinical Facility Administrator (CFA) provides administration for a single clinical facility or hospital.

The CFA login is created by the Service Provider Administrator (SPA). Contact the SPA for access.

The CFA can perform the following tasks in the Holter Connect Web Portal:

- View the Biosensors currently in inventory and the Biosensor status in the hospital
- Add patient details for the At-Home initiated Holter Test
- Add start time for the At-Home initiated Holter Test
- View current Doctors, create new Doctor user accounts and upload Doctor details, including a signature
- Edit Doctor details
- Revoke Doctor access
- Create a new Clinician
- Create a new Supervisory Technician
- Revoke Clinician access
- Revoke Supervisory Technician acces

In the Holter Connect Web Portal, the CFA home page has the following menu options.

Table 11 - CFA homepage menu options in the Holter Connect Web Portal

Icon	Description	Operation
	Biosensors	View the list of Biosensors and passwords. View the status of the Biosensors.
	Doctors	View, Add, Edit, Revoke the list of doctors in the Clinical Facility.
	Clinicians	Create Supervisor and Clinician logins.

6.3.1 Display a list of Biosensors at a hospital

Select the ***All View*** tab to display a list of Biosensors associated with a hospital along with the following Biosensor information:

- ***Biosensor ID***: a unique five character ID

- ***Password***: the password used by the Holter Connect App to connect to the Biosensor when transferring encrypted data
- ***Assigned*** (**Clinician *&* Doctor**: Assign Clinician or reassign Doctor to analyse and review Biosensor data.
  - **Clinician**: Select C to allocate Clinician
  - **Doctor**: Select D to allocate Doctor

6.3.2 Start an At-Home initiated Holter Test

To start an At-Home initiated Holter Test, follow this guidance:

1. Select .
2. From the drop-down list, select ***Hospital***.
3. From the menu, select ***All > Unused Biosensors***
4. From the list of Biosensors, find the Biosensor ID you wish to assign to the patient.
5. In the ***Actions*** tab for that Biosensor ID, select ***Assign Biosensor to Patient.***
6. Enter the Patient details in the popup window.
7. Select the patient timezone amd enter the test start date time.
8. Select ***Did you take patient consent?*** if patient consent has been taken.
9. Select ***Assign***.
   The Biosensor can now be mailed to the patient.

6.3.3 Assign Biosensors to a Supervisor

To assign the Biosensor to a Supervisor:

1. Navigate to the ***Completed (ECG Data uploaded)*** view.
2. Using the check boxes, select an individual Biosensor or multiple Biosensors.
3. Select ***Assign*** in the top right corner.
   A new window will open.
4. Select the ***Supervisor*** radio button.
5. From the drop-down list, select a Supervisor.
6. Select ***Assign***.

> **Tip**
> Alternatively, from the ***All View*** tab, navigate to the ***Assigned Clinician & Doctor*** tab to open a new window.
> Select a ***Supervisor*** or ***Doctor*** from the drop-down list.

6.3.4 Display a list of Doctors

Select the ***Doctors*** tab to display a list of all Doctors who have been nominated to receive Holter Connect ECG reports in a Hospital.

For each Doctor, the Clinical Facility Administrator can do the following.

Table 12 - Menu options in the *Doctors* tab

Icon	Description	Operation
	***Gear***	Opens the Doctor Settings Screen. The CFA can enable or disable the SMS notifications for a Doctor.
	***Resend Activation Mail***	Resend email to the Doctor to enable setting a password. • If enabled, the icon will be highlighted. The administrator can resend activation email to the user. • If disabled, the icon will be shaded. The account has been activated.
	***Revoke User***	To revoke user access. The user will no longer be able to login or access Holter Connect.
	***Pen***	Opens the Edit Doctor Screen. A CFA can add a secondary Doctor, add Doctor Info and upload a Doctor signature.

6.3.5 Add a Doctor

1. Navigate to the ***Doctors*** tab.
2. Select  to open the ***Add Doctor/ Secondary Contact*** screen.
3. Enter the Doctor information in to the ***Add Doctor/ Secondary Contact*** form. The following information can be entered when adding a new Doctor. Fields with an * are required.

Table 13 - Information required in the *Add Doctor* form

Name	Purpose / Explanation
Name *	Full name of Doctor.
Login ID (Email) *	Work email where the login email will be sent. Please ensure that this is a valid email.
Staff ID *	Staff ID used by the hospital.
Additional Info	For example identify the Doctor as a Cardiologist.
Contact Number	Phone number of the Doctor / Secondary Contact
Report Mail ID	Email address of the person to notify when the Patient ECG report is ready for review.

Name	Purpose / Explanation
Email Address for report (optional)	A Patient Report can also be sent to a secondary Doctor. Select the secondary doctor, if required, from the drop-down menu.
Secondary Contact	A Patient Report can also be sent to a Secondary Contact. Select the Secondary Contact, if required, from the drop-down menu.
Upload Sign	The CFA can upload the confidential and pre-prepared signatures (***.png*** or ***.jpeg*** file, max size 100kb)) of the corresponding Doctor into the system. This can be used by the Doctor for e-signature approval.

4. Select ***ADD***.

6.3.6 Display a list of Clinicians and Supervisors

Select the ***Clinicians*** tab to display a list of Clinicians and Supervisors. All Biosensor data is automatically assigned to the Supervisor, who in turn, can assign the Biosensor data to a Clinician.

Select the ***Clinician*** or ***Supervisor*** tab to display a list of Clinicians or Supervisors.

Notice

If a hospital wants to outsource ECG analysis to a third party ECG Technician service provider, the SPA can allocate a default Supervisory Technician from the list of Supervisors.

There are three actions in the ***Supervisor*** tab.

Table 14 - Menu actions in the Supervisor tab

Icon	Description	Operation
	***Resend Activation Mail***	Resend email to the Clinician or Supervisor to enable setting a password. • If enabled, the icon will be highlighted. The administrator can resend activation email to the user. • If disabled, the icon will be shaded. The account has been activated.
	***Mark as default Supervisor***	All patient ECG waveform data will go to this Supervisor for analysis.
	***Revoke Supervisor***	To revoke Supervisor access. The Supervisor will no longer be able to login or access Holter Connect.

6.3.7 Add a Supervisor (CFA)

1. Navigate to the ***Clinicians*** tab and select the ***Supervisor*** tab at the top of the window.
2. Select  to open the ***Add Supervisor*** screen.
3. Enter the Supervisor information to the ***Add Supervisor*** form.
4. Select the ***Set as default Supervisor Technician*** check box to configure the Supervisor as the default Supervisor Clinician for the hospital.
5. Select ***ADD***.

> **Notice**
> The Supervisorcan also be a Clinician. In addition, they have authority to delegate Biosensor readings to other Clinicianswhen required.

6.3.8 Add a Clinician (CFA)

1. Navigate to the ***Clinicians*** tab and select the ***Clinician*** tab at the top of the window.
2. Select  to open the ***Add Clinician*** screen.
3. Enter the Clinician information to the ***Add Clinician*** form.
4. Select ***ADD***.

6.4 Technician/ Clinician and Supervisor tasks

A Technician/ Clinician or Supervisor can perform the following tasks in the Holter Connect Web Portal.

- Reassign a Biosensor exam to others (Supervisor only)
- Reassign Holter diary images review (Supervisoronly)
- Review Holter diary images and add patient symptoms.
- View Biosensor waveform data

The Technician and Clinician login is created by the SPA and CFA respectively. Please contact the SPA or CFA for login details.

6.4.1 Reassign a Biosensor (Supervisor only)

A Biosensor can be reassigned from one Technician / Clinician to another in the Holter Connect Web Portal using the following procedure:

> **Tip**
> This option is only available to a Supervisor.

1. Login to the Holter Connect Web Portal. A list of Biosensors currently assigned to Supervisor will be displayed.
2. Under the ***Assigned Technician*** column, select 
3. In the ***Assign Technician*** window, select a new Technician from the drop-down menu.

   The number of patients currently assigned to the Technician is displayed next to the name of the Technician.
4. Select ***ASSIGN***.

   All reassigned/assigned Biosensors can be viewed in the ***Assigned to other Technicians*** tab.

6.4.2 Reassign Holter Diary review (Supervisor only)

A Holter Diary can be reassigned from one Technician / Clinician to another in the Holter Connect Web Portal using the following procedure:

1. Login to the Holter Connect Web Portal. A list of Biosensors currently assigned to Supervisor will be displayed.
2. Under the ***Assigned Technician*** column, select 
3. In the ***Assign Technician*** window, select a Technician from the drop-down menu.
4. Select ***ASSIGN***.

   All reassigned/assigned Holter Diaries can be viewed in the ***Assigned to other Technicians*** tab.

6.4.3 Review Holter Diary Images (All)

Holter Diary images can be viewed in the Holter Connect Web Portal to check the quality of the uploaded image and add reported symptoms, using the following procedure:

1. Login to the Holter Connect Web Portal. A list of Biosensors currently assigned to Technician/Clinician/Supervisor will be displayed.
2. The Holter Diaries can be filtered according to their status.

i.e., All/Reviewed/Pending.

3. Under the Holter Diary column, select  , this will open a popup window.
4. Scroll through the Holter Diaryimages using the < and > buttons.
5. If the images are clearly visible, select ***CONFIRM AND CONTINUE.***
6. Select ***ADD SYMPTOM*** to enter patient reported symptoms, this will open a popup window.

   a. Enter date, time, activity level and symptoms.

b. Select ***Add***.

c. Repeat steps (a) and (b) to record every symptom.

d. When all the symptoms have been added, select ***Submit***.

e. Select EDIT to review/edit symptoms or select ***CONFIRM AND SUBMIT*** to complete data entry.

f. Select **CONFIRM** to add symptoms or **CANCEL** to go back to previous step.

7. When the Holter Diary images are reviewed, the , is no longer visible.

Note 1: If the images are unclear, tick the box Image not clear and select ***REQUEST REUPLOAD***, this will open a popup window. Select ***CONFIRM*** and a notification email will be sent to the Service Provider Operator.

Note 2: If there are no Holter diary images, select ***CONFIRM AND SUBMIT***, then select ***CONFIRM AND SUBMIT***.

6.4.4 View Biosensor waveform data (All)

Waveform data from all Biosensors assigned to a Doctor, Technician or Clinician can be viewed in the Holter Connect Web Portal.

1. Login to the Holter Connect Web Portal.
   A list of currently assigned Biosensors will be displayed. If no Biosensors are visible, select in the ***Files*** tab and select ***BINARY180***.
2. Select to display the ***View Waveform*** screen.
3. Biosensor waveform data can be viewed in the ***View Waveform*** screen.

Figure 8 - ***View Waveform*** screen

6.4.4.1 Waveform data viewing modes

There are two waveform data viewing modes.

Page Scan View

The ***Page Scan View*** shows more of the waveform at any given time for each channel.

The toggle permits individual viewing between the 2 channels labelled Ch1 or Ch2.

Duration of the page scan can be selected.

10s View

Click on ***10s*** to see 10 seconds of the waveform.

All channels are displayed at the same time, in a continuous waveform.

Duration time can be selected.

6.4.4.2 Waveform data viewing options

Table 15 - Viewing options for Biosensor waveform data

Option name	Option icon	Function
Caliper	Caliper	Displays 2 caliper rulers (displayed as blue lines). Calipers allow you to measure the time distance between the 2 rulers. The measurements are displayed on the top right-hand corner labelled as ***Measured Time***. The ***Caliper*** lines can be moved with the mouse by holding down the left click button and moving the mouse left/right.
Gain	- Gain:1 +	Adjusts the displayed amplitude of the waveform. Affects the Y-axis of the waveform.
Duration	Duration 10 s ▾	Adjusts the displayed frequency of the waveform. Affects the X-axis of the waveform.

6.4.4.3 Waveform data playback options

Table 16 - Playback options for Biosensor waveform data

Option name	Option icon	Function
Print		Opens the print function of the browser.
Go to start		Go to the start of the recording.
Skip X min behind		Go back X min behind, where X is dependent on the duration selected.

Option name	Option icon	Function
Skip X min ahead		Go forward X min ahead, where X is dependent on the duration selected.
Go to end		Go to the end of the recording.
Jump to time		Jump to a certain time. Please select the correct time needed and keep the selection within the Session Range as displayed.
Disable filter		Disables the filter.

6.5 Doctor tasks

A Doctor can perform the following tasks in the Holter Connect Web Portal. A login is required to access the Holter Connect Web Portal. Contact the CFA for login details.

- Display a list of all the patients currently assigned to them.
- Filter the list of patients by hospital
- Review a patients report, ECG waveforms and Holter Diary.
- E-sign a patient report.

6.5.1 Display a list of patients

A Doctor can display a list of all the patients assigned to them in the Holter Connect Web Portal.

1. Login to the Holter Connect Web Portal.
2. The Doctor will see a full view of assigned patients.

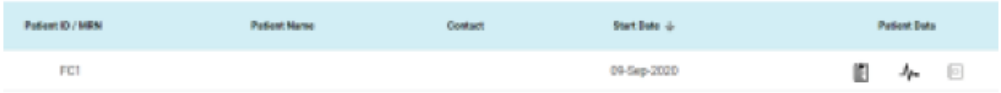


Figure 9 - ***Patient list*** in the Holter Connect Web Portal

3. To filter the list of patients by hospital, use the ***Filter by hospitals*** drop-down list.
4. To view the Biosensor waveform data report, select  .
5. To view Biosensor waveform data, select  .

6. To view the Holter Diary, select  .

6.5.2 View, edit and e-sign patient reports

Patient reports can be viewed in the Holter Connect Web Portal using the following procedure.

1. Select  and the View Report window will open.
2. Select  to view the report edit history.
3. Select  or  to download the report
4. Select  to add/edit comments/findings at the bottom of the first page.

   If text is added, select  and then select  to save changes before downloading the report.
5. if the Doctors e-signature is uploaded*, select  , enter username, select ***Confirm.***

   *If this icon is not displayed, then the Doctors e-signature has not been uploaded by CFA.
6. To return to the patient list, select  .

   Select ***Report*** to return to viewing the patient report.

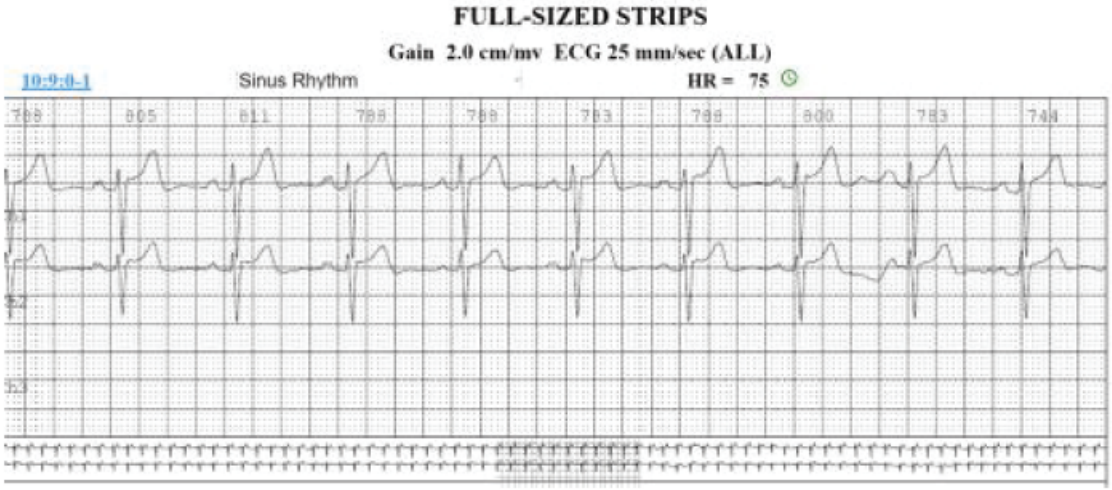


Figure 10 - Typical Biosensor waveform data and time stamp*

*Note: Report layout may vary between geographical locations.

Notice

To revoke an e-signature, select , enter your username and select ***Confirm***.

6.5.3 View Biosensor waveform data

Waveform data from all Biosensors assigned to a Doctor, Technician or Clinician can be viewed in the Holter Connect Web Portal.

► *For more information, see "View Biosensor waveform data (All)" on page 35*

This page intentionally left blank

7 Troubleshoot Holter Connect App notifications

This section provides troubleshooting information for notifications in the Holter Connect App.

Table 17 - Notifications in the Holter Connect App

Notification	Explanation	Resolution
`Are you sure you want to clear all cached usernames?`	User double clicks on username.	Select ***OK*** to remove cached usernames. Select ***Cancel*** to keep cached user names.
`Authentication Failed.`	Holter Server could be down.	Select ***OK*** and try again.
`Authentication failed. Please download key and place in Download folder.`	No server key available in the Download folder.	Select ***OK***, download valid server key and place in Download folder.
`Authentication Failed. Please download valid key and place in Download folder. The Relay ID NDQWXFLT will be retained.`	User selected Change Relay from the menu, but the server key in the Download folder was invalid.	Select ***OK***, download new server key and place it in the Download folder.
`Auto-acceptance of ECG waveforms in 5 minutes.`	If the user views the ECG waveforms for 25 minutes without selecting any options, the Holter test will start in 5 minutes and the dialogue will be updated every minute.	Select ***ACCEPT NOW*** to confirm acceptable ECG waveforms and commence Holter test. Select ***EXTEND TIME*** to continue displaying the ECG waveforms for another 25 mins.
`Biosensor connection lost! Move the phone closer to the Biosensor.`	Biosensor has lost connection with the Holter Connect App.	Select ***OK*** and move the phone/tablet closer to the Biosensor.

Notification	Explanation	Resolution
`Biosensor did not turn off.`	Biosensor failed to turn off after retrieval of Biosensor data.	Ensure Biosensor green LED light is flashing slowly to indicate the Biosensor is connected to the Holter Connect App. If not, move closer to the mobile phone or tablet. Select ***RETRY***.
`Biosensor has auto-started because the Biosensor was turned on and applied before entering patient details. Do you want to discard the Biosensor or proceed with the Holter Test without viewing the ECG waveforms?`	User turned on the Biosensor before entering patient details on the Holter Connect App.	Select ***PROCEED*** to continue with Holter test or ***DISCARD*** to discontinue Holter test.
`Biosensor is not assigned to patient. Go to the Holter Connect Web Portal and Assign Biosensor. Retry Data Retrieval.`	Biosensor has not been assigned to the patient by the administrator.	Select ***OK***.
`Clinician already assigned to device(s).`	Biosensor already assigned to this Clinician.	If required, assign Biosensor to another Clinician.
`Confirm you want to permanently skip the Setup Instructions for the Application.`	After logging in to the Holter Connect App, the user selected “Skip setup instructions” .	Select ***OK*** to permanently remove the “Set Up Instructions” for the application. Select ***CANCEL*** to continue viewing the setup instructions after opening the Holter Connect App.
`Connection to Holter Server failed.` `Ensure WiFi is connected.`	No WiFi connection.	Check if the WiFi is connected and/or move to an area with better WiFi connectivity.
`Current Activity Interrupted. Do you want to continue?`	Low battery may have caused the Holter Connect App to close.	Select ***YES*** to continue previous activity or ***NO*** to begin a new Holter test.

Notification	Explanation	Resolution
`Data has already been uploaded.`	Biosensor data has already been transferred to the Holter Server.	Select ***OK***.
`Do you want to stop data retrieval and retry later?`	***Back*** has been selected during data retrieval.	Select ***YES*** to stop data retreival. Select ***NO*** to continue data retieval.
`Do you want to turn off and discard the Biosensor?`	When the user selects ***DISCARD***, confirmation is required to turn off and discard the Biosensor.	Select ***YES*** if the ECG waveforms are unacceptable. Select ***CANCEL*** if you do not want to discard the Biosensor, the user will return to viewing the ECG waveforms.
`Doctor already assigned to device(s)`	Biosensor already assigned to this Doctor.	If required, assignt o another Doctor.
`Enter Biosensor ID.`	User did not enter Biosensor ID.	Enter Biosensor ID. Select ***Next***.
`Enter valid Biosensor ID.`	User entered Biosensor ID with less than 5 characters.	Enter correct Biosensor ID. Select ***Next***.
`Failed to upload, something went wrong.`	Unable to upload ***.xlsx*** file.	Retry uploading. If unsuccessful, contact Biosensor supplier.
`Holter Test in progress. Do you want to stop the test and retrieve the data?`	Biosensor may have not been worn for the complete test duration.	Select ***Yes*** to stop test and commence data retrieval.
`Incomplete duration of Holter test. Select OK to start retrieval of available Biosensor data.`	The patient may not have worn the Biosensor for the entire test duration.	Select ***OK*** to begin retrieval of Biosensor data.

`Insufficient Memory to store data. Make sure you have enough memory.`
`XXXX MB of storage available.`
`5120 MB of storage required.`
	Occurs during retrieval of Biosensor data. The mobile phone or tablet does not have enough memory to store the data.	Select ***OK*** and either free up memory to allow data retrieval or use another mobile phone/tablet to retrieve Biosensor data.

Notification	Explanation	Resolution
`Invalid/Data Retrieved Biosensor.`	User entered incorrect Biosensor ID or data may have already been retrieved from the Biosensor.	Enter correct Biosensor ID. If Biosensor ID is correct, then check with administrator that Biosensor is available for use on the Holter Connect Web Portal.
`Invalid/Used Biosensor.`	Previously used Biosensor.	Enter new Biosensor ID. Select ***Next***.
`Knox License. Invalid License. Please contact Admin and retry.`	Unable to authenticate Knox Licence key.	Select ***RETRY***, if it fails again, select ***CANCEL*** and contact Admin for new server key.
`Knox License. Please check your WiFi and retry.`	Authentication of Knox License failed due to loss of WiFi connection.	Select ***RETRY*** and ensure WiFi is connected.
`Logout Awaiting transfer of Biosensor data to the server. Ensure WiFi is connected. Warning: if you LOGOUT now, the Biosensor data will remain in this device until new LOGIN.`	Holter Connect App transferring data to server while User manually logging out.	Select ***BACK***, ensure WiFi is connected to transfer Biosensor data to the Holter Server. If you select ***LOGOUT ANYWAY***, the Biosensor data will not be uploaded until a new user logs in.
`Mail could not be sent. Already an active user.`	Existing user with the same email address.	Every user must have a unique email address. The same email address cannot be used for dual roles. For example, for a Clinician and a Technician.
`Please make sure the Biosensor is turned on.`	Biosensor may have timed out (Biosensor turns off after 2 mins if it cannot connect to the hotspot, the Holter Connect App will search for 5 mins.	Select ***OK*** and turn Biosensor on.
`Storage corruption detected on this phone/tablet. This can lead to data loss. Please avoid using this phone/tablet.`	Problem with hardware - Flash may be corrupted on the mobile phone or tablet.	Select ***OK*** and use another phone/tablet to begin Holter test.

Notification	Explanation	Resolution
`This Biosensor has been used. Please scan a new Biosensor.`	The Biosensor has already completed a Holter test, and the user is trying to reuse it.	Select ***OK*** and scan a new Biosensor.
`This Biosensor has no data. Please scan a new Biosensor.`	User attempting to retrieve data from an unused Biosensor.	Select ***OK*** and scan a new Biosensor.
`This Biosensor does not support selected duration. Please scan a new Biosensor.`	The Biosensor cannot be used for the selected test duration. e.g. the user may have selected 7 days but the Biosensor is programmed for 3 days.	Select ***OK*** and scan a new Biosensor.
`Unable to proceed. Please allow App Admin privilege.`	Holter Connect App requires permission to automatically turn the WiFi hotspot on or off.	Select ***RETRY*** and allow App admin permission.
`Unable to proceed. Please enable Location Service and Retry.`	Location service is disabled.	Select ***OK*** and turn on location service.
`Unable to retrieve data.`	If the hotspot is turned off or the Biosensor has moved away from the Holter Connect App.	Select ***RETRY***. Ensure Hotspot is turned on and the Biosensor is in close proximity to the mobile phone or tablet.
`User already exists!`		Enter new user details.
`User Exists.`		Enter new user details.
`User Login failed Incorrect Username / Password. Or Ensure WiFi is connected.`	Login failed due to incorrect username / password, or the WiFI is not connected.	Select ***OK***, ensure WiFi is connected, enter correct login details and select ***LOGIN***.
`Verifying communication with Biosensor. Please wait until ECG waveforms appear.`	The Holter Connect App is verifying communication with the Biosensor.	Select ***OK*** and wait until the ECG waveforms appear.
`Your session has expired. Please LOGIN again.`	Session timed out after 30 minutes of inactivity in the Patient Details screen or 12 hours after initial login.	Re-enter Username and Password, select ***LOGIN***.

This page intentionally left blank

8 Specifications

This chapter details the specifications of the LifeSignals Biosensor.

8.1 Biosensor (LP1251 & LP1251E) Specifications

Table 18 - Biosensor (LP1251 & LP1251E) Specifications

Physical	
Dimensions	105 mm x 94 mm x 12 mm
Weight	28 gm
Status LED Indicators	Amber, Red and Green
Patient Event Logging Button	Yes
Water ingress protection	IP24
Colour	White
Specifications	
Battery type	Primary Lithium Manganese dioxide Li-MnO2
Battery Life	168 hours
Charging Mode	Not rechargeable
Wear Life	Up to 168 hours[1]
Defib Protection	Yes
Applied Part Classification	Defibrillation-proof type CF applied part
Operations	Continuous
Usage	
Intended environment	Home, Clinical and Non-Clinical facilities
Intended Population	18 years or older
MRI safe	No
Single use / Disposable	Yes

[1]Actual wear duration claims may vary between countries based on regulatory clearance.

ECG Performance and Specifications	
ECG number of channels	Two
ECG sampling rate	244.14 and 976.56 samples per second
Frequency response	0.2 Hz to 40 Hz and 0.05 Hz to 150 Hz
Lead off detection	Yes
Common Mode rejection ratio	> 90dB
Input Impedance	> 10 Meg ohms at 10Hz
ADC Resolution	16 bits
ECG Electrode	Hydrogel
Wireless & Security	
Frequency Band (802.11b)	2.400-2.4835 GHz
Bandwidth	20MHz (WLAN)
Transmit Power	0 dBm
Modulation	Complementary Code Keying (CCK) and Direct Sequence Spread Spectrum (DSSS)
Wireless Security	WPA2-PSK / CCMP
Data Rate	1, 2, 5.5 and 11 Mbps
Quality of service–Range	5 meters (typical)
Environmental	
Operational temperature	+0 ºC to +45ºC (32ºF to 113ºF)
Operational relative humidity	10 % to 90 % (non-condensing)
Storage temperature (≤ 30 days)	+0ºC to +45ºC (32ºF to 113ºF)
Storage temperature (> 30 days)	+10ºC to +27ºC (50ºF to 81ºF)
Transportation temperature (≤ 10 days)	-5 ºC to +50 ºC (23 ºF to 122 ºF)
Storage relative humidity	10% to 90% (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Shelf life	12 months

9 Regulatory

The Holter Connect complies with the following regulations.

9.1 Standards used in design, development, labelling, and testing

Table 19 - Standards used in design, development, labelling, and testing

Standards	Rev	Description
ANSI AAMI ES 60601-1	2012	Medical electrical equipment - Part 1: General Requirements for basic Safety & Essential Performance
ANSI AAMI IEC 60601-1-2	2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-1-11	2015	General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
ANSI AAMI IEC 60601-2-47	2012	Particular Requirements For The Basic Safety And Essential Performance of Ambulatory Electrocardiographic Systems
IEC 60601-1-27	2011	Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-1-6	2013	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Usability
ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ANSI C63.27	2017	American National Standard for Evaluation of wireless coexistence
IEC 60086-5	2011	Primary batteries - Part 5: Safety of batteries with aqueous electrolyte

AAMI ANSI EC12	2012	Disposable ECG Electrodes
ASTM D4169	2014	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements.
IEC 62304	2015	Medical device software – Software life cycle processes
IEC 62366-1	2015	Medical devices – Application of usability engineering to medical Devices
ISO 14971	2007	Medical devices – Application of risk management to medical devices
FCC	2015	47 CFR 15

9.2 EMC compliance and warning statement

IEC 60601-1-2: 2014

The LifeSignals Biosensor has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules and with the limits of the standard for medical devices, ANSI/AAMI/IEC 60601-1-2:2014 and ANSI/AAMI/IEC 60601-2-47:2012 202.6.1.1 & 202.6.2.3 suitable for use in all environments including domestic. The unit also complies with the requirements of EN 60601-1-2:2015, providing the presumption of compliance to the European Union's Medical Device Directive 2007/42/EC. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses radio-frequency energy for its functions. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to LifeSignals Biosensor. Otherwise, degradation of the performance of this equipment could result.

9.3 Guidance and manufacturer's declaration – electromagnetic emissions

Table 20 - 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	LifeSignals Biosensor uses 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	LifeSignals 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.
Harmonic emissions EN 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions EN 61000-3-3	Not Applicable	

9.4 Guidance and manufacturer's declaration – electromagnetic immunity

Table 21 - Guidance and manufacturer's declaration – electromagnetic immunity

LifeSignals 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	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative humidity should be at least 30%.

Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical domestic environment.
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM, 1 KHz	10 V/m 80 MHz to 2.7 GHz 80% AM, 1 KHz	Home Healthcare environment.

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.

The Biosensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Biosensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Biosensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	**Separation distance according to the frequency of transmitter (Meters)**		
	150 kHz to 80 MHz $d = 3.5/V1 * \sqrt{P}$	**80 MHz to 800 MHz** $d = 3.5/E1 * \sqrt{P}$	**800 MHz to 2.7 GHz** $d = 7/E1 * \sqrt{P}$
	10V/m	**10V/m**	**10V/m**
0.01	0.04	0.04	0.08
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.22
100	3.50	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: At 80 Hz and 800 MHz the separation distance for the frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflections from structures, objects and people.

9.5 EMC guidance

In accordance with Clause 4.3 of IEC 60601-1, the Essential Performance of LifeSignals Holter Connect Platform is:

- Data loss between Biosensor &Holter Connect App shall be less than 0.035%

- There shall not be noise exceeding 50 uV p-v on ECG signal over any 10 second period continuously

Caution

RF emitting devices such as diathermy, electrocautery, radio frequency identification (RFID), security systems (e.g., electromagnetic anti-theft systems, and metal detectors) may affect essential performance. These sources of electromagnetic energy should be avoided when using Biosensor. In case of potential exposure to this equipment, the user is encouraged to try to correct the interference by one or more of the following measures:

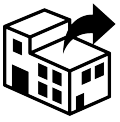
- Reorient Biosensor away from these equipment (behind the patient body)
- Increase the separation between the Biosensor and the equipment.

9.6 Symbols

Table 22 - Symbols

Label	Identification	Description
	Caution or Warning	This symbol instructs the user to consult the instructions for warnings and safety precautions that could not be presented on the device.
	Manufacturer	Legal manufacturer.
	Product Disposal	Dispose of the Biosensor as battery/electronic waste - controlled by local regulations.
 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 Biosensor – 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.

Label	Identification	Description
	Catalogue Number	Device Catalogue number / Labeller Product number.
	Quantity	Number of devices in pouch or multi-carton box.
	Prescription only device	To be used under prescription supervision by a medical practitioner.
	Consult instructions for use	Refer to instruction manual.
 >PnD	Temperature range	Operating, storage and transportation temperature, short and long term, in days: • **P**: Duration • **n**: Number • **D**: Calendar days
	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Humidity limitation	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.
	Expiry Date (YYYY-MM-DD)	Use device in packaged condition before expiry date.
	Manufacturing date and country of manufacture.	Device manufacturing date and country of manufacture.
	LOT Code	Manufacturing Batch or LOT code.
	Applied part	Defibrillation-proof, Type CF Applied Part.
	Do not reuse	Do not reuse; single patient use.
IP24 (LP1251E)	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.

Label	Identification	Description
	Max Stack	Do not stack more than (n) number of boxes tall.
FCC ID	Federal Communications Commission	Federal Communications Commission ID.
	MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.
	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD.
	Authorized representative of European Community	Authorized representative of European Community.
	Authorized representative of Country	Authorized representative of Country XX - Country code as per ISO 3166-1.
	The UKCA (UK Conformity Assessed marking)	Indicates conformance to MHRA guidelines for goods being placed on the market in Great Britain (England, Wales and Scotland).
	CE marking	CE marking indicates product conformance with the applicable European Union Directives.
	Ukraine Symbol of conformity to Technical regulations	Indicates product conformance with applicable Ukrainian Technical Regulations UA.TR.116 - Identifier code of the Conformity assessment body.
	Importer	Indicates entity importing the medical device into the locale.
	Distributor	Entity distributing the medical device into the locale.
	Damaged packaging	Do not use if package is damaged. Device must not be used if the package holding the device is damaged.

This manual is intended for the following catalogue numbers: LP1251A, LX1251, LX1251E, AB1251, AB1257, MA1251, MA1251E, KM1251E.

9.7 Declaration of conformity

CE
2797

(Issued according to EC directive 93/42/EEC relating to Medical Devices)

Manufacturer:	LifeSignals, Inc., 426 S Hillview Dr., Milpitas, CA 95035, USA Tel: +1 510.770.6412 info@lifesignals.com
EC Representative:	Renew Health Limited, IDA Business & Technology Park Garrycastle, Athlone, N37 F786. Ireland Tel : +353 90.646.5460 lssupport@lifesignals.com
Product Category:	Electrocardiography telemetric monitoring system
Product Name:	Holter Connect Platform
Model Number:	Refer Annexure to DOC
Product Description :	The Holter Connect 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
Quantity:	
Lot No .:	
Class:	Class IIa
Annexure No:	Annexure II
Notifying Body:	BSI, Netherlands (notified body No. 2797)
Applied Directive:	Directive 93/42/EEC on medical devices, conformity assessment according to Annexure II, excluding Section 4.

The company, LifeSignals, Inc, herewith declares that the above- mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and specified conditions of storage and use.
The company has instituted a procedure, to continually review the experience gained from devices in post-production phase & to implement appropriate measures for the necessary required improvements.
If the device is modified or used other than the Intended purpose, this declaration becomes invalid.

Date of Issue: 27 July 2022

Saravanan Balasubramanian
Vice President - Medical Systems & Regulatory Affairs

9.7.1 Annex to Declaration of Conformity

No	Name of medical device	Part Numbers	GMDN Codes
1	Holter Connect Platform	LX1251E	**31733**
	Consists of:		
	- Wearable Biosensor	LP1251E, MA1251E, KM1251E	**35162**
	- Holter Connect Relay Application	LA1252-R	**64902**
	- Holter Connect Secure Server Application	LA1252-S	**36870**
	- Holter Connect Business Logic	LA1252-C	**65832**