



HOLTER CONNECTTM

Instructions for Use - Clinician

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Intended purpose

This manual describes the intended use of the Holter Connect Platform and observance of the manual is a prerequisite for proper performance and 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

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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	Relays information from the Biosensor to the Holter Connect Secure Servers.
Hospital	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.



Term	Definition
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
Technician	Technicians are nominated to receive, analyze and process patient Holter test data that can be accessed from the Holter Connect Secure Server.



Contents

1 Safety information	1
1.1 Intended use and indications for use	1
1.2 Contraindications	1
1.3 Warnings	2
1.4 Precautions	3
1.5 Cybersecurity controls	4
2 Product description	5
2.1 LifeSignals Holter Connect Platform	5
2.2 LifeSignals Wearable Biosensor	6
2.3 Holter Connect App	7
2.4 Holter Connect Secure Server	8
2.5 Holter Connect Web Portal	8
3 Install the Holter Connect App	9
3.1 Additional menu features in the Holter Connect App	11
4 Holter Connect clinical workflows	15
4.1 Implement an In-Clinic initiated Holter test	15
4.1.1 Advice for patients	16
4.1.2 Remove the Biosensor from a patient	16
4.1.3 LED status indicators	17
4.1.4 Prepare the skin	18
4.1.5 Assign a Biosensor to a patient	20
4.1.6 Connect the Biosensor to the Holter Connect App	20
4.1.7 Apply the Biosensor to a patient	21

4.1.8 View waveforms and confirm start of an In-Clinic initiated Holter test.....	22
4.1.9 Upload Biosensor data to the Holter Connect Secure Server	22
4.2 Implement the At-Home initiated Holter Test	22
4.2.1 Start an At-Home initiated Holter Test	23
4.2.2 Upload Biosensor data to the Holter Connect Secure Server	23
5 Holter Connect Web Portal	25
5.1 User hierarchy	25
5.2 Clinical Facility Administrator (CFA) tasks	26
5.2.1 Display a list of Biosensors at a hospital	27
5.2.2 Start an At-Home initiated Holter Test	27
5.2.3 Add start time for At-Home initiated Holter Test	28
5.2.4 Assign Biosensors to a Supervisor.....	28
5.2.5 Display a list of Doctors	29
5.2.6 Add a Doctor.....	30
5.2.7 Display a list of Clinicians and Supervisors.....	31
5.2.8 Add a Supervisor (CFA).....	32
5.2.9 Add a Clinician (CFA)	32
5.3 Technician/ Clinician and Supervisor tasks	32
5.3.1 Reassign a Biosensor (Supervisor only).....	33
5.3.2 Reassign Holter Diary review (Supervisor only).....	32
5.3.3 Review Holter Diary images (All).....	33
5.3.4 View Biosensor waveform data (All).....	34
5.3.4.1 Waveform data viewing modes.....	35
5.3.4.2 Waveform data viewing options.....	35
5.3.4.3 Waveform data playback options.....	36
5.4 Doctor tasks	37
5.4.1 Display a list of patients	37
5.4.2 View, edit and e-sign patient reports.....	38
5.4.3 View Biosensor waveform data	39

6 Troubleshoot Holter Connect App notifications	40
7 Specifications	48
7.1 Biosensor (LP1251 & LP1251E) Specifications	48
8 Regulatory	51
8.1 Standards used in design, development, labelling, and testing	51
8.2 EMC compliance and warning statement	53
8.3 Guidance and manufacturer’s declaration – electromagnetic emissions	54
8.4 Guidance and manufacturer’s declaration – electromagnetic immunity	55
8.5 EMC guidance	57
8.6 Symbols	58
8.7 Declaration of conformity	62
8.7.1 Annex to Declaration of Conformity	63

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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:

- LifeSignals Wearable Biosensor
- Holter Connect App (installed on compatible mobile phone or tablet)
- Holter Connect Secure Server
- Holter Connect Web Portal (Business Logic)

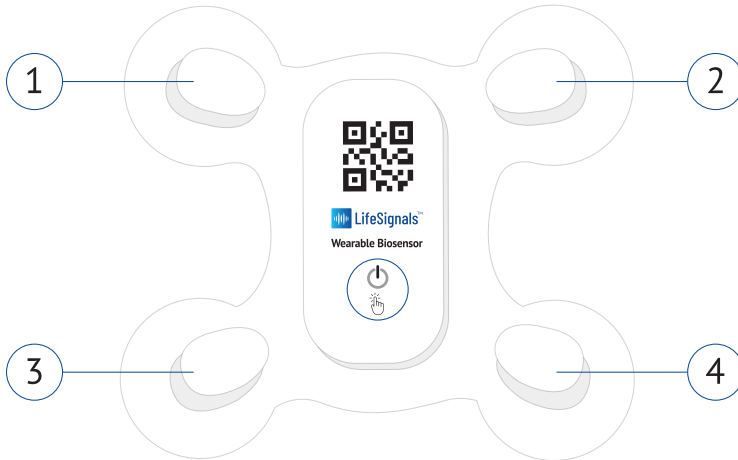


1	Wearable Biosensor	Acquires ECG signals and transmits to the Holter Connect App.
2	Holter Connect App	Assigns Biosensor to a patient. Receives ECG data from Biosensor and transmits to the Holter Connect Secure Server.
3	Holter Connect Secure Server	Receives and stores patient and ECG data from the Holter Connect App, ready for analysis, reporting and viewing.
4	Holter Connect Web Portal	Web-based interface used to access and manage Biosensors and patient reports.

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 clinical workflow, the acquired data is transmitted wirelessly from the Biosensor to the Holter Connect App. The Biosensor data will be buffered (temporarily stored) in the Biosensor if communication with the 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 the Biosensor and transfers it to the Holter Connect Server.

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 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.



3 Install the Holter Connect App

The following steps describe the installation of the Holter Connect App on a compatible mobile phone or tablet, for example, a Samsung SM- T515 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**).

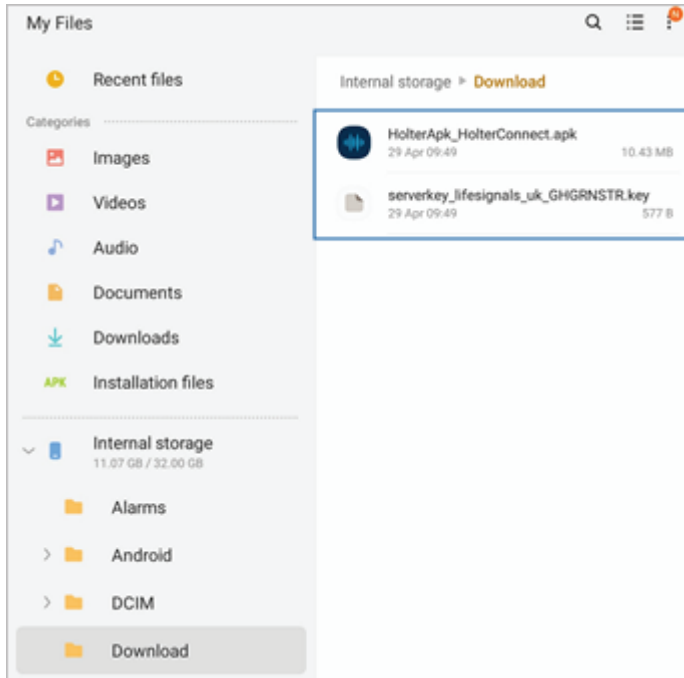


Figure 3 - Holter Connect App install files and Relay Key

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 **Agree** to continue.

The Holter Connect App is now successfully installed.

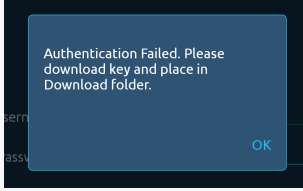
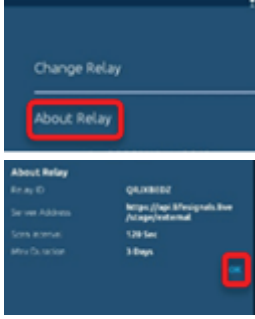
Note: Initial set up of Holter Connect App on mobile phone

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

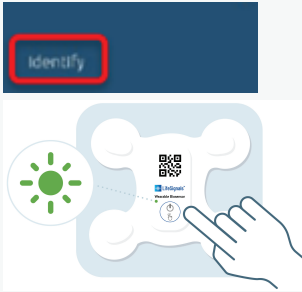
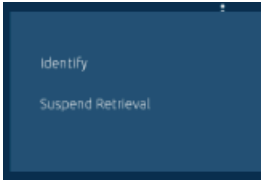
Instructions	Image	Explanation
<p>Select Change Relay.</p> <p>If the new key is not found, the user will see the 'Key not found' message.</p> <p>Select OK to return to home screen.</p>		<p>The Relay ID is the unique ID that is used to identify the Relay device (mobile phone or tablet) by the server.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

After entering the Biosensor ID, select



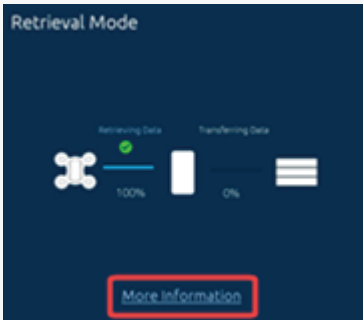
to access the additional menu features shown in Table 2.

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

	Image	Explanation
<p>Select Identify.</p>		<p>Identifies if the Biosensor currently in use. The LED status indicator light of the Biosensor currently in use will flash five times.</p>
<p>Select Suspend Retrieval to suspend data retrieval process.</p>		<p>Suspends data retrieval for the Holter Test.</p>

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

Table 3 - Additional information available during data retrieval.

Instructions	Image	Explanation
Select <i>More Information.</i>		Displays additional information: <ul style="list-style-type: none">• Biosensor ID• Start Time• Current Status• Biosensor Version



4 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 App. The clinician applies the Biosensor on the patient's chest.
 - 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, the Biosensor data is transferred to the Holter Connect Secure Server via the 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 Connect at Home Patient Information Leaflet.
 - The patient turns on and self-applies the Biosensor to their chest, making a note of the date and time in the Holter Connect at Home Patient Information Leaflet
 - At the end of the Holter test, the patient removes the Biosensor and returns it, by mail or in person, with the Holter Connect at Home Patient Information Leaflet.
 - On receipt of the Biosensor, the Biosensor data is transferred to the Holter Connect Secure Server via the Holter Connect App.

4.1 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 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.

4.1.1 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 symptom 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.

4.1.2 Remove the Biosensor from a patient

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.

Silicone-based adhesive removers are the best option for removing adhesive as they evaporate, leave no adhesive residue on the skin, do not sting the patient (contain no alcohol) and are not associated with drying the skin.

Alcohol-based products can be used to dissolve the adhesive and make it easier to detach. However, evaporation of the alcohol can lead to vasoconstriction and drying of the skin. Alcohol will also sting the patient.




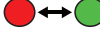
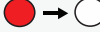
To minimise the risk of adhesive-related skin injury, follow these steps:

1. Slowly peel each of the four circles towards the centre of the Biosensor.
Ensure you are peeling the edges at a low horizontal angle, close to the skin surface. At the same time, use your other hand to gently press near the newly exposed skin to reduce skin stretch and trauma.
2. When the four corners have been removed, peel off the remaining Biosensor in the direction of hair growth.

4.1.3 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 Connect App or a Holter test is ongoing.
	Fast flash	Biosensor is attempting to connect with the Holter Connect App.
	Slow flash	Low Battery indication.
	Alternative flashing	Response to Holter Connect App - "Identify Biosensor" command.
	Fast flash Off	Biosensor turned Off.

4.1.4 Preparing the skin

Before attaching the Biosensor, the skin surface must be prepared. Preparing the skin correctly 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.

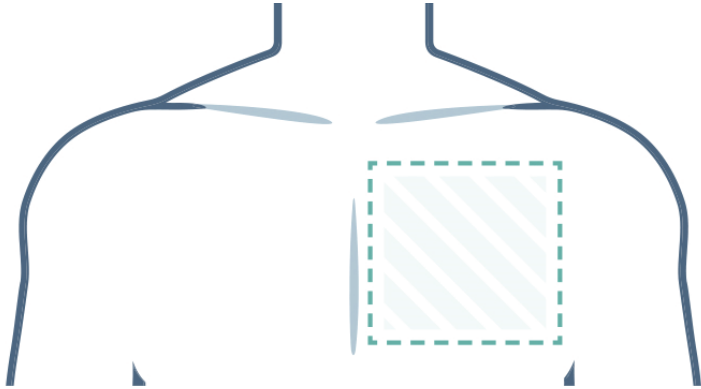


Figure 4 - Area of upper left chest to attach Biosensor

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.

4.1.5 Assign a Biosensor to a patient

**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.

4.1.6 Connect the Biosensor to the Holter Connect App

1. Press the Biosensor **ON** button once. A red light will flash followed by a flashing green light.
2. In the Holter Connect App, select **Next**.
3. The Biosensor will automatically connect to the Holter Connect App.
4. Wait for the **Biosensor connected** message to be displayed in the Holter Connect App.

4.1.7 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.



Figure 5 - Removal of protective backing film from Biosensor

2. Place the Biosensor on the upper left chest of the patient, below the collar bone and left of the sternum.

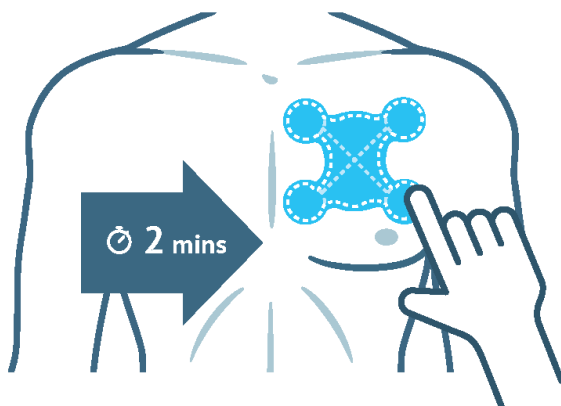


Figure 6 - Biosensor application position

3. Press the entire Biosensor firmly for 2 minutes, especially around the four circular areas.
4. In the Holter Connect App, select **Next**.

4.1.8 View waveforms and confirm start of an In-Clinic initiated Holter test

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

4.1.9 Upload Biosensor data to the Holter Connect Secure Server

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. The Holter Connect App will automatically connect to the Biosensor.
7. Data is uploaded automatically from the Biosensor to the Holter Connect Secure Server.
8. Select **OK** when the **Procedure completed successfully** message appears.
During data retrieval, select More Information to view Biosensor details and current status.

4.2 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.



Notice

Prior to mailing the Biosensor to a patient, the Biosensor must be pre-assigned using the Holter Connect Web Portal.

▶ *For more information, see "Starting a Zero-Contact Holter test" on page 27.*

If you do not have a Holter Connect Web Portal account, please contact your Service Provider Administrator.

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

Patient instructions must accompany the Biosensor, so that the patient has clear guidance for applying and wearing 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.

4.2.1 Start an At-Home initiated Holter Test

For more information, see "Start an At-Home initiated Holter Test" on page 27

4.2.2 Upload Biosensor data to the Holter Connect Secure Server

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 Patient Instruction Leaflet.
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.



5 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.

5.1 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.

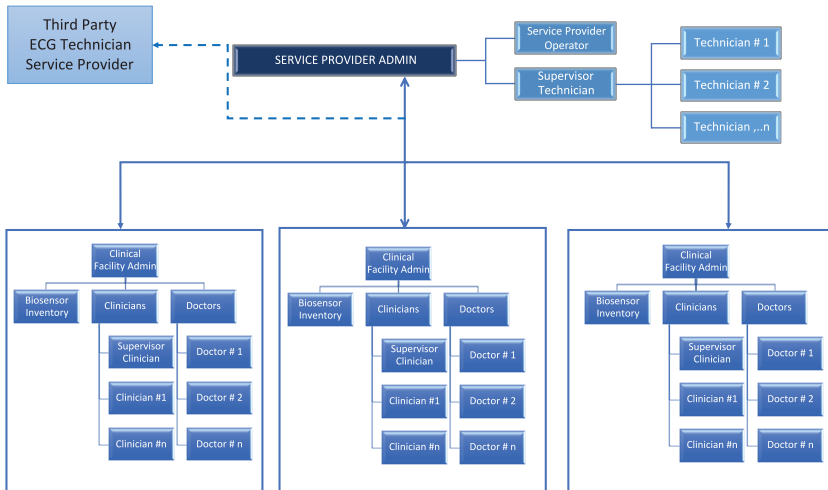


Figure 7 - User hierarchy

5.2 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 access



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

Table 5 - 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.


5.2.1 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.
- **Assigned (Clinician & Doctor):** Assign Clinician or reassign Doctor to analyse and review Biosensor data
 - **Clinician:** Select  to allocate Clinician
 - **Doctor:** Select  to allocate Doctor


5.2.2 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 .
6. Enter the Patient details in the pop-up window.
7. Select the patient timezone.
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.

5.2.3 Add start time for At-Home initiated Holter Test

1. Select .
2. From the menu, select **All > Contactless - assigned to patient (Provisioned)**.
3. From the list of Biosensors, find the Biosensor ID you wish to add a start time to.
4. From the Biosensor ID **Actions tab**, select **Add Start Time**.
5. In the **Add Start Time** box, enter the Time zone, start date and time for the Holter Test.
6. Select **ADD**.
The Biosensor data can now be uploaded and sent for analysis.

5.2.4 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.

5.2.5 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.

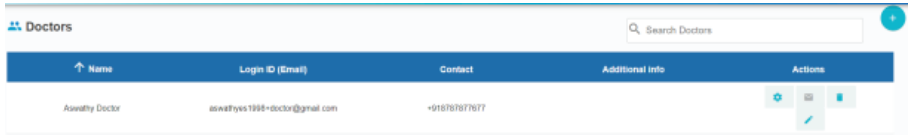






Figure 8 - **Doctors** tab

For each doctor, the Clinical Facility Administrator can do the following:

Table 6 - 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	Resends 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	Revokes 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.

5.2.6 Add a Doctor


1. Navigate to the **Doctors** tab.
2. Select  icon 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 a * are required.

Table 7 - 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.
Email address for report (optional)	Email address of the person to notify when the Holter report is ready for review
Secondary Contacts	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**.

5.2.7 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 8 - Menu actions in the Supervisor tab

Icon	Description	Operation
	Resend Activation Mail	Resends email to the Clinician or Supervisor to enable setting a password. <ul style="list-style-type: none"> • 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.

5.2.8 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 supervisor is also a Clinician but has a higher authority to delegate the Biosensor readings to other Clinicians if needed.

5.2.9 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**.

5.3 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 (Supervisor only)
- 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 login details.


5.3.1 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 the 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.

5.3.2 Reassign Holter Diary review (Supervisor only)



A Holter diary review can be reassigned to another Technician/Clinician using the following procedure:

1. Login to the Holter Connect Web Portal. A list of Biosensors currently assigned to the 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.

5.3.3 Review Holter Diary images (All)

The Holter Diary images can be reviewed 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 the 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 viewer.
4. Scroll through the holter diary images using the < and > buttons.
5. If the images are clearly visible, select **CONFIRM AND CONTINUE**.
6. Select **ADD SYMPTOM** to enter patient 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**.

5.3.4 View Biosensor waveform data (All)

Waveform data from all Biosensors assigned to a Doctor, Supervisor, 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 9 **View Waveform** screen.

5.3.4.1 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. You can toggle between the 2 channels labelled Ch1 or Ch2.

You can select the duration of the page scan.

10s View




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

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

You can select the duration time.







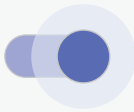
5.3.4.2 Waveform data viewing options

Table 9 - Viewing options for Biosensor waveform data

Option name	Option icon	Function
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 . Caliper lines can be moved with the mouse by holding down the left click button and moving the mouse left / right.
Gain		Adjusts the displayed amplitude of the waveform. Affects the Y-axis of the waveform.
Duration		Adjusts the displayed frequency of the waveform. Affects the X-axis of the waveform.

5.3.4.3 Waveform data playback options

Table 10 - 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.
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.

5.4 Doctor tasks

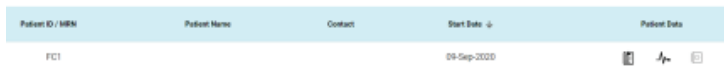
A Doctor can perform the following tasks in the Holter Connect Web Portal. A login is required to access the Holter Connect Web Portal. Contact the CFA for login details.

- Display a list of all the patients currently assigned to them.
- Filter the list of patients by hospital.
- View a patient's report, ECG waveforms and diary.

5.4.1 Display a list of patients

A Doctor can display a list of all the patients currently 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 all the patients currently assigned to them.







Patient ID / MRN	Patient Name	Contact	Start Date	Patient Data
FC1			09-Sep-2020	  

Figure 10- **Patient list** in the Holter Connect Web Portal

3. To filter the list of patients by hospital or report status, use the **Filter by hospitals** or **Filter by report status** drop-down list.










4. To view the patient report, select  .

5. To view Biosensor waveform data, select  .

6. To view the patient diary, select  .

5.4.2 View, edit and e-sign patient reports

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

1. Login to the Holter Connect Web Portal.
2. Select  and the **View Report** window will open.
3. Select  to view the report edit history.
4. Select  or  to download the report.
5. If the Doctor's e-signature is uploaded*, select , enter Username, select **Confirm**.
*If this icon is not displayed, then the Doctor's e-signature has not been uploaded by CFA.
6. 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.
7. To return to the patient list, select .

*Depending on the report layout, time stamps (blue hyperlinks) may be available above the waveform to navigate between the patient report and the waveform data.

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

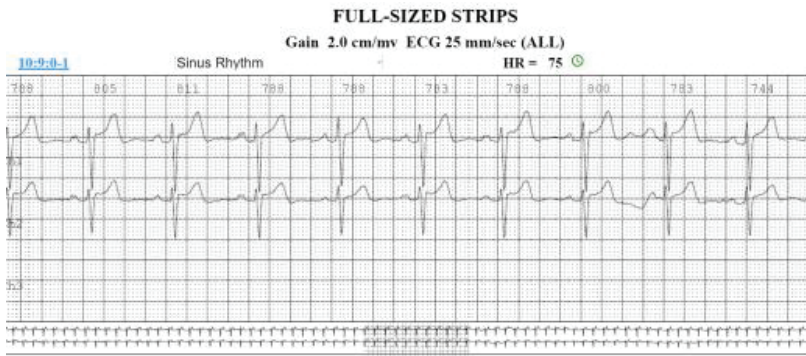


Figure 11 - Typical Biosensor waveform data and time stamp*

*Note: Report layout may vary between geographical locations.



Notice

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

5.4.3 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” on page 34.



6 Troubleshoot Holter Connect App notifications

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

Table 11 - Notifications in the Holter Connect App

Notification	Explanation	Resolution
Are you sure you want to clear all cached usernames?	User double taps on username.	Select OK to remove cached usernames. Select Cancel to 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.

Notification	Explanation	Resolution
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.
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 selected Change Relay from the menu, but the server key in the Download folder was invalid	Select PROCEED to continue with Holter test or DISCARD to discontinue Holter test.
Biosensor turned Off successfully.	Data retrieval has completed and Biosensor has turned Off.	Select OK .

Notification	Explanation	Resolution
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.
Data has already been uploaded.	Biosensor data has already been transferred to the Holter Server.	Select OK .

Notification	Explanation	Resolution
Do you want to stop data retrieval and retry later?	Back has been selected during data retrieval.	Select YES to stop data retrieval. Select NO to continue data retrieval.
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, assign to 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.

Notification	Explanation	Resolution
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.
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 License 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.

Notification	Explanation	Resolution
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 has no data. 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.

Notification	Explanation	Resolution
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
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 .



7 Specifications

This chapter details the specifications of the LifeSignals Biosensor.

7.1 Biosensor (LP1251 & LP1251E) Specifications

Table 12 - 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-MnO ₂
Battery Life	168 hours
Charging Mode	Not rechargeable
Wear Life	Up to 168 hours ¹

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

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
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 10 Hz
ADC Resolution	16 bits
ECG Electrode	Hydrogel
Wireless & Security	
Frequency Band (802.11b)	2.400 - 2.4835 GHz
Bandwidth	20 MHz (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°C to +45°C (32°F to 113°F)
Operational relative humidity	10% to 90% (non-condensing)
Storage temperature (< 30 days)	+0°C to +45°C (32°F to 113°F)
Storage temperature (≥ 30 days)	+10°C to +27°C (50°F to 81°F)
Transportation temperature (≤ 10 days)	-5°C to +50°C (23°F to 122°F)
Storage relative humidity	10% to 90% (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Shelf life	12 months



8 Regulatory

The Holter Connect complies with the following regulations.

8.1 Standards used in design, development, labelling and testing

Table 13 - 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
IE 62366-1C	2015	Medical devices – Application of usability engineering to medical Devices
ISO	2007	Medical devices – Application of usability engineering to medical Devices
FCC	2015	47 CFR 15

8.2 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.

8.3 Guidance and manufacturer's declaration – electromagnetic emissions

Table 14 - 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	

8.4 Guidance and manufacturer’s declaration – electromagnetic immunity

Table 15 - 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.

8.5 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.








8.6 Symbols

Table 17 - 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
	Catalog Number	Device Catalog number / Labeler Product number

Label	Identification	Description
	Quantity	Number of devices in pouch or multi-carton box.
	Prescription only device	To be used under prescription supervision by a medical practitioner.
	Electronic instructions for use	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed form.
 >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

Label	Identification	Description
	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
	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
	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).

Label	Identification	Description
	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
	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: LX1251A, LX1251, LX1251E, AB1251, AB1257, MA1251, MA1251E, KM1251E.

8.7 Declaration of conformity



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

Manufacturer	: LifeSignals, Inc. 426 S Hillview Drive Milpitas, California 95035 United States of America 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 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.
Quantity	:
Lot No .	:
Class	: Class IIa
Annexure No	: Annexure II

Notifying Body	: BSI, Netherlands (notified body No. 2797)
Applied Directive	: 1. Directive 93/42/EEC on medical devices, conformity assessment according to Annexure II, excluding Section 4 2. Radio Equipment Directive (RED) 2014/53/EU 3. RoHS Directive 2011/65/EU

The company, LifeSignals, Inc, herewith declares that the above- mentioned product meets all applicable provisions of the Directive 93/42/EEC (2007/47/EC amendment), 2014/53/EU and 2011/65/EU. 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
VP-Global Medical Technology and Regulatory Operations

8.7.1 Annex to Declaration of Conformity

No	Name of Medical Device	Part Numbers	GMDN Code
1	Holter Connect Platform	LX1251E	31733
	Consist of:		
	- Wearable Biosensor	LP1251E, MA1251E, KM1251E	35162
	- Holter Connect Relay Application	LA1252-R	64902
	- Holter Connect Secure Server	LA1252-S	36870
	Application	LA1252-C	65832
	- Holter Connect Business Logic		

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