CS System 3

User Manual

CardiacSense

Watching Over You

DMS-21987 Version B1

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About this User Manual

This manual provides the information necessary to operate and use the CS System safely and effectively.

Please read the manual before operating CS System 3 and its application. If any part of this manual is unclear, contact your local distributor for support.

User manuals in different languages can be found at https://www.cardiacsense.com/user-manual/.

Conventions

The Conventions section explains basic symbols and navigation concepts used in this manual.

Symbols

Three types of special messages appear in this User Manual:

Warning

A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

Caution

The term caution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices..

Note

A note provides other important information that may assist with operating the system.

Navigation

We have adopted the following shortened instruction form for navigating to the various application elements.

Shortened Instruction	Replaces
From any of the windows, select: **Menu > My profile > (login) > Personal information**	From any screen: 1. Tap the Menu icon. 2. Select My profile. 3. Log into the application. 4. Select Personal information. 5. Perform the action or edit the parameter value.

Important Notes

- The content of this manual is subject to change without notice.
- Some of the illustrations or descriptions in this manual may vary due to changes or improvements in the CS System and its application, Android device and OS version, iPhone device and iOS version.

1 Introduction

CS System 3 is a wrist-worn medical device, similar to a watch, that measures heart rate, Pulse Rate and detects atrial fibrillation (A-Fib) by reading the user's PPG and ECG values.

CS System 3 comprises a watch (CS Watch 3), a charging cradle, a mobile application (CS3 Mobile app), and a cloud application (CS3 Cloud app).

1.1 Proper Use of CS System 3

This manual provides the information necessary to operate and use the CS System 3. Please read the manual to understand CS System 3 and its mobile application setup process before using the device.

1.2 CS System 3 Overview

CS System 3 is a single-patient use wearable monitoring device that provides continuous monitoring of the user's Pulse Rate from its PPG (Optical) sensor. When prompted by an indication generated by the PPG sensor, or if feeling an A-Fib episode, the user can initiate a real-time ECG measurement.

The sensitivity and specificity of A-Fib detection by PPG are 95% and 95% respectively. Sensitivity for ECG analysis is 95% with specificity of 95%.

The real-time ECG measurements are saved on the smartphone once paired, and are automatically uploaded to the CS3 Cloud app.

The user can also initiate an ECG monitoring session which can be saved as a report and shared with physician or anyone else.

1.3 CS System 3 Technology

Combining off-the-shelf ECG electrodes and unique PPG sensors with proprietary algorithms, the device can detect the presence of A-Fib and notify the user. In addition to A-Fib detection, CS System 3 continuously monitors the user's Pulse Rate.

The CardiacSense unique PPG sensor compensates for the interference caused by hand, palm, and finger movement, which in most cases is the primary source of false notifications.

For more details on A-Fib, ECG, and PPG, see the Appendices in Chapter 13.

2 Intended Use

2.1 Indications for Use

CS System 3 is intended to measure beat-by-beat heart rate and Pulse Rate and detect the presence of atrial fibrillation lasting at least 5 minutes by using PPG and/or ECG signals.

2.2 Intended Users

CS System 3 is intended to be used by anyone who seeks to monitor their vital signs in medical facilities, ambulatory conditions, or at home.

The device is intended as a single patient use.

2.3 Contraindications

- The device has not been tested, and it is not intended for use by children under the age of 18.
- The device has not been tested, and it is not intended for use by pregnant and breastfeeding women, people with pacemakers, or ICD.
- The device should not be used by people with blood flow deficiency-related conditions.
- The device should not be worn over tattooed or injured skin.
- CS System 3 is not to be used in critical care situations.

2.4 Adverse Events

The device has been tested and found to be biocompatible. There are no known adverse events related to the use of CS System 3; however, there are possible adverse events related to monitoring systems that involve sensor application on the skin. These include the following:

- Edema
- Erythema
- Irritation
- Sensitization

Note

Any serious adverse event / incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

3 Safety

3.1 Data Privacy

Accessing your account data requires logging into the application using your account password (created while setting up an account).

To protect your privacy, the reports that are created through the mobile app are stored only on your smartphone. For subscribers, the reports are automatically stored in CS Cloud App. CardiacSense recommends locking your smartphone's display to avoid unauthorized access.

Your personal and measurement data is treated in a HIPAA and GDPR-compliant manner.

3.2 Warnings and Cautions

3.2.1 Warnings

DO NOT USE CS System 3 BEFORE READING AND UNDERSTANDING THIS MANUAL.

Do not use the device if you have an ICD or pacemaker or if you are pregnant or breastfeeding. The device has not been tested, and it is not intended for use by pregnant and breastfeeding women, people with pacemakers, or ICD

DO NOT adjust medication or delay medical care based on measurement results from this device. Take medication as prescribed by your physician.

To reduce the risk of suffocation, keep the device away from children and pets

To avoid the potential for electrical shock, the power supply must be disconnected from the power outlet while cleaning.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could occur.

To avoid the potential for electrical shock, use only the supplied charger.

This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as using the CS System 3 in a different location.

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this device could increase electromagnetic emissions or decrease the electromagnetic immunity of this device and result in improper operation.

MR unsafe: The device should not enter the MRI scanner room

3.2.2 Cautions

A too loose or too tight watch strap may affect measurement results.

Any adverse incident that has occurred in relation to the device should be reported to CardiacSense Ltd.

At the end of its useful life, the watch with its battery must be disposed of in accordance with local law and the local code concerning electrical and electronic equipment. Do not discard in a standard trash bin.

Before pairing the watch with the smartphone, ensure the date and time on your smartphone are correct.

Changes or modifications not expressly approved by CardiacSense Ltd. can affect the safety and effectiveness of the system and void the system’s warranty.

Do not operate with a damaged screen, cord, or plug. If damaged, have the cord or plug replaced immediately by a qualified service technician.

Do not use detergents to clean the watch and cradle.

Do not use the device if the package is damaged.

Do not use the device out of the defined environmental conditions.

If measurement is interrupted by a call, restart the app after the call has ended.

If you are unsure about your medical condition, enter "Don't know". Wrong medical information input will appear on the report and may lead to false diagnosis by your physician

If you notice any skin rash or any irritation is developing around the watch strap, remove the watch immediately from your wrist and inform your physician and/or medical staff.

Low skin temperature, restricted blood flow, or excessive movement may result in wrong measurement results or lack of results. In such cases, remove the watch from your wrist, warm your hands and place it back on.

The device is intended as a single patient use. The device should not be used by anyone other than you.

To avoid harm to the CS Watch 3, repair and maintenance should be performed by authorized personnel only.

Using the CS System 3 for unintended purposes may result in incorrect results and clinical misinterpretations

Verify you have selected the correct country of residence, as it is required for compliance with local regulatory requirements and new feature releases. Your country of residence cannot be changed without the aid of customer support.

To reduce the risk of wrong measurements, keep the device sensors clean from dirt or grease

Do not use the device to diagnose medical-related conditions. All interpretations should be reviewed by a medical professional for clinical decision-making

4 Know your CS System 3

4.1 Package Contents

The following items are included in the CS System 3 packaging*:

Figure 4-1. Package contents

* Only one type of charging cradle is supplied (item 2 or item 3)

Item	Description
1.	CS Watch 3
2.	Charging cradle with USB-C to USB-A cable
3.	Charging cradle with power supply
4.	Long replaceable strap
5.	Quick-start guide
6.	Warranty certificate

Do not use the device if the package is damaged.

4.1.1 CS Watch 3

Look at the watch to identify its physical controls:

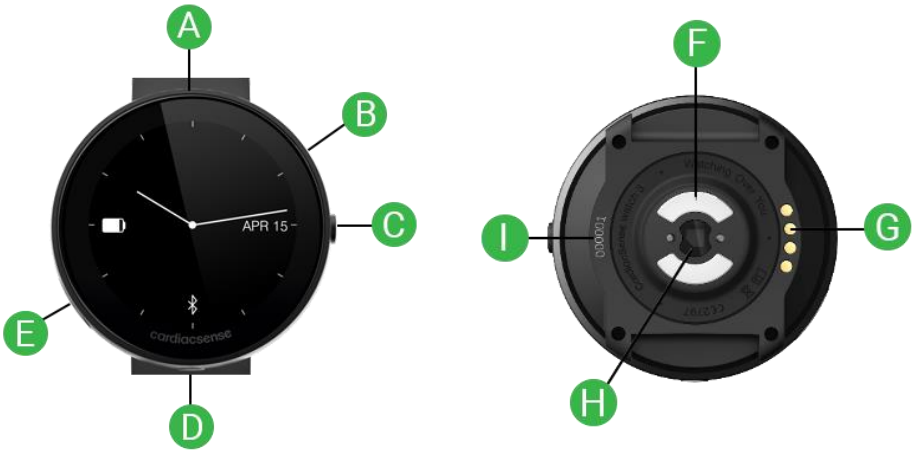


Figure 4-2. Watch front and rear view

A	Display
B	SpO_2 and Blood Pressure sensor (for use in future versions)
C	Watch display and on/off button (watch on/off: press for 3 seconds; display on/off: press momentarily)
D	Thermometer (for use in future versions)
E	ECG sensor used for real-time ECG measurement (by placing your finger and holding while ECG measurement is performed)
F	ECG sensor (takes various measurements through contact with your skin)
G	Charging contacts for charging the watch in the cradle
H	PPG sensor
I	Serial number, used for pairing and identifying the watch with a Smartphone

4.1.2 Charging Cradle

The cradle is used for charging the watch. It features four gold-plated pogo-pins for charging the watch and can be delivered in one of the following configurations:

- Cradle with connected power supply.
- Cradle with a USB-C to USB-A cable, to be used with a standard USB, CE marked adaptor.

4.2 Charging the Watch

The CS Watch 3 has an integrated rechargeable battery and is charged by placing the watch in the cradle.

Before first use, fully charge the watch until it reaches 100%.

> ***Warning***
>
> To avoid the potential for electrical shock, use only the supplied charger.

1. Plug the cradle charger into the power outlet.
2. Place the watch in the cradle, matching the 4 golden contacts on its back to the 4 golden pogo-pins in the cradle. The cradle has magnets that help with positioning the watch correctly.

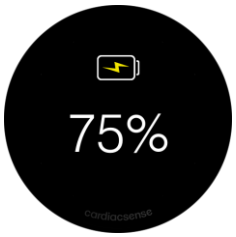


Figure 4-3. Watch in-charge display

While charging, the sensors are disabled, and the display shows the current battery level.

- Charging time (empty battery to fully charged battery) is around 2 hours.
- Under typical conditions, a fully charged battery provides up to 2 days (48 hours) of continuous usage.

When the low battery indicator turns on, charge the battery.

Figure 4-4. Battery low-level display

When the battery reaches 10%, the watch screen turns off, and the watch enters a deep-sleep mode.

In case of degraded battery performance, please contact CardiacSense or your local distributor.

> ***Note***
>
> The battery should be charged at least every 3 months, even when not in use.

4.3 Turning the Watch ON and OFF

Press the watch ON / OFF button for 2–3 seconds (the same button is used to turn the display On and Off by pressing it briefly).

Figure 4-5. Watch ON/OFF button

The watch vibrates momentarily, and its display turns on.

Figure 4-6. Watch face

The two green LEDs on the watch back turn on, indicating that the PPG sensors work properly.

Figure 4-7. Watch LEDs

5 Preparing the CS System 3

5.1 Charging the CS Watch 3

The CS Watch 3 battery must be charged before its first use.

For charging the watch, see Charging the Watch in section 4.2.

5.2 Installing the CS3 Mobile app

The CS3 Mobile app is an essential part of CS System 3.

1. Install the CS3 Mobile app on your smartphone in one of two ways:
   - Scan this QR code , also printed on the provided QSG.
   - On your smartphone, go to the Play Store (Android-based phones) or App Store (for iPhones), search for the CardiacSense app and install it.
2. Accept all terms and conditions displayed during the installation process to enable the app to operate properly.
3. Enable Location and Bluetooth on your smartphone.

5.3 Setting up your Account

Your account in the CS3 Mobile app holds the personal information needed to get personalized results from CS System 3. Your personal information is treated in a HIPPA - and GDPR-compliant manner.

Most of the personal and medical information entered at this stage may be changed later (see Chapter 9, Changing your Account Information).

Creating a new account and pairing the watch to your smartphone is a 6-step wizard-guided process comprising:

1. Registration.
2. Creating new account.
3. Entering personal information.
4. Entering medical information.
5. Setting preferences and agreeing to terms.
6. Pairing the watch.

A progress bar is displayed at the bottom of the screen during the process, indicating the steps performed and the current step. The step name is displayed at the top of the screen.

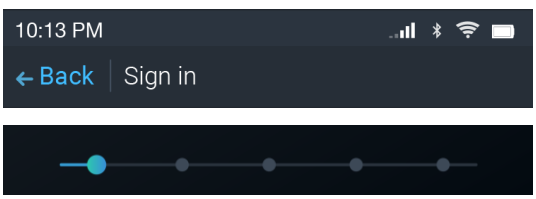


Figure 5-1. Account setup steps

5.3.1 Step 1: Registration

1. To register, open the CS3 Mobile app.

   The application opens with a splash screen, followed by the language selection screen.

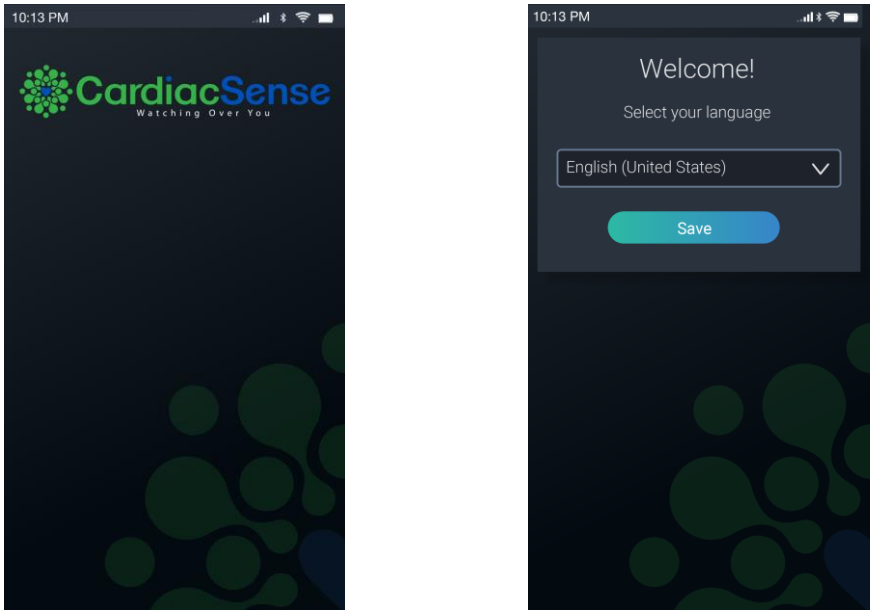


Figure 5-2. Splash and language screens

2. Select your language for the application interface from the preset list.

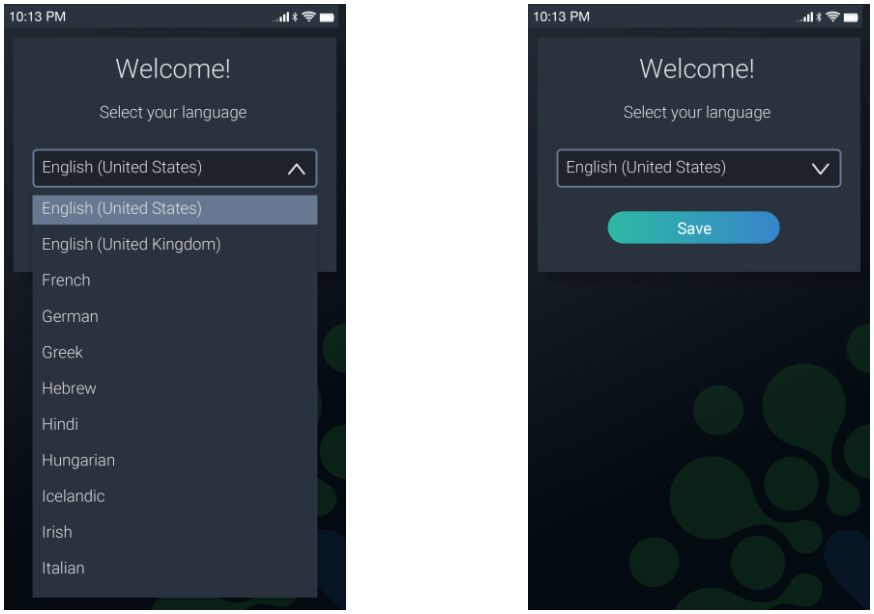


Figure 5-3. Language selection screens

3. Tap **Save**. The Login screen appears.

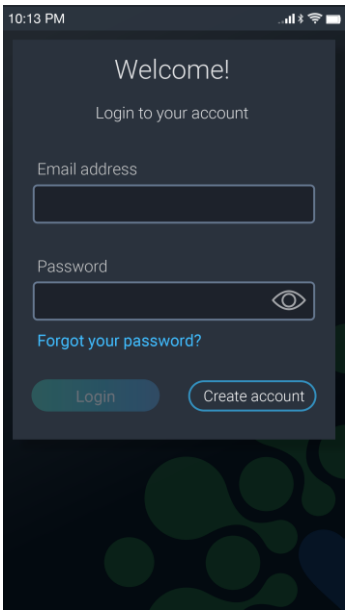


Figure 5-4. Create new account screens

4. Tap **Create new account**.

5.3.2 Step 2: Creating New Account

In this step, you create your CardiacSense account consisting of an email address and password.

> ***Note***
>
> The email address you enter here is part of your identification details and cannot be changed after completing the Sign-In process.

1. Enter your **Email address**. This address is used to login to the app and is used by CardiacSense to send you important information.
2. Tap the down arrow next to **Password policy** to display the rules for setting your password for the application.

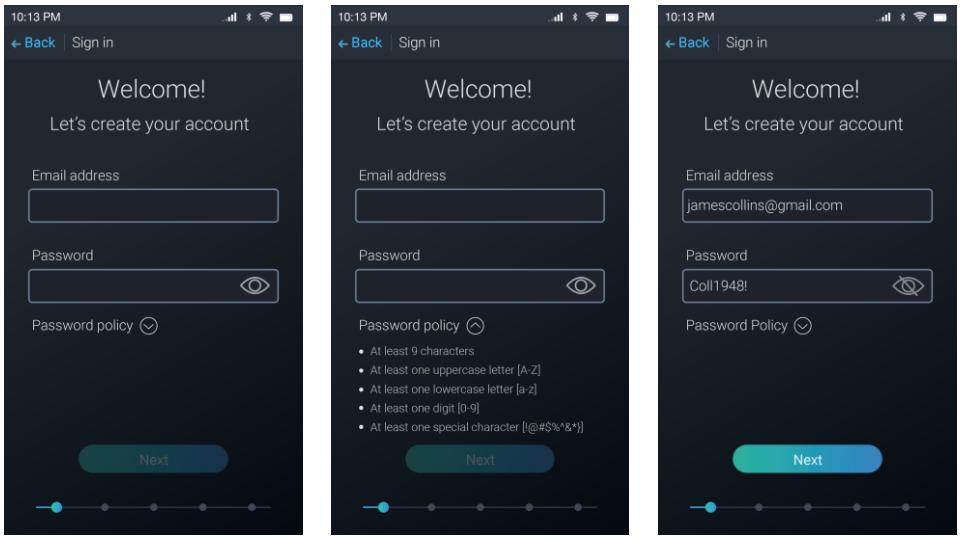


Figure 5-5. Email and Password screens

Invalid email addresses or passwords are indicated by a red rectangle or message.

3. Enter a **Password**. If required, tap the eye icon to replace the asterisks with visible characters to verify the password is what you intended it to be.

> ***Note***
>
> If a wrong email address or password were entered more than five times in a row, the system locks the login screen for 15 minutes.

When both the email address and password are typed correctly, the **Next** button becomes active.

4. Tap the **Next** button.

You will receive an email from CardiacSense requesting you to verify your email address and activate your account.

> ***Note***
>
> You must activate your account within 24 hours; otherwise, you will need to restart the registration process.

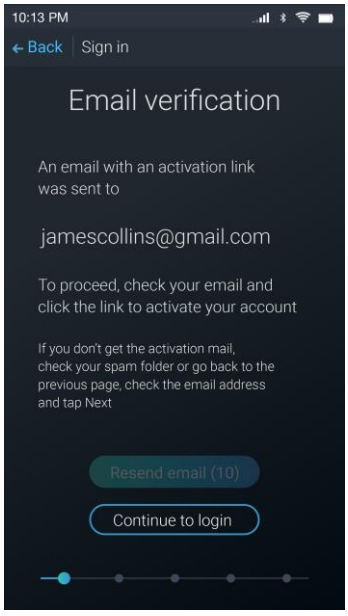
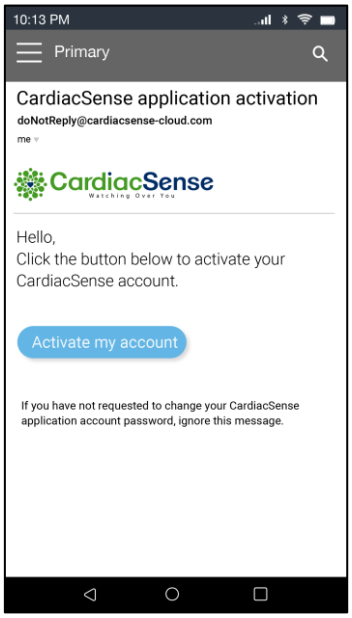


Figure 5-6. Email verification

To verify your email and activate your account:

1. Open your inbox and open the mail sent from CardiacSense mail.



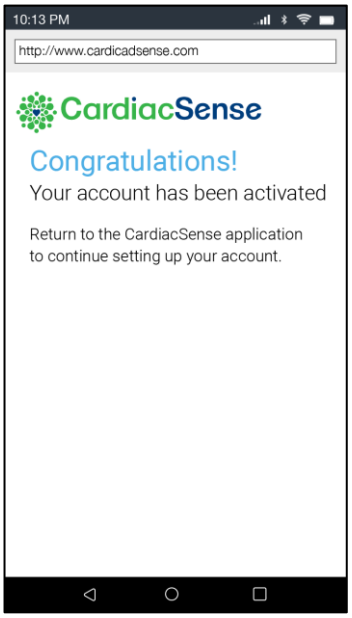


Figure 5-7. Email account activation

If you did not receive and, check on the CS3 Mobile app that your email address is correct, and tap **Resend email**.

2. Click **Activate my account**. The Congratulations! message is displayed, indicating your account has been activated.
3. Return to the CS3 Mobile app and tap Continue to log in.
4. Type your account credentials (**Email address** and **Password**) to log in to your account.
5. Tap **Next** to continue to the next step (Step 2: Personal Information).

5.3.3 Step 3: Entring Personal Information

In this step, you are requested to enter your personal information, which is essential for the CardiacSense algorithms to provide accurate results and personalize reports with your ID number.

1. Type in your first and last name.
2. Type your ID number.

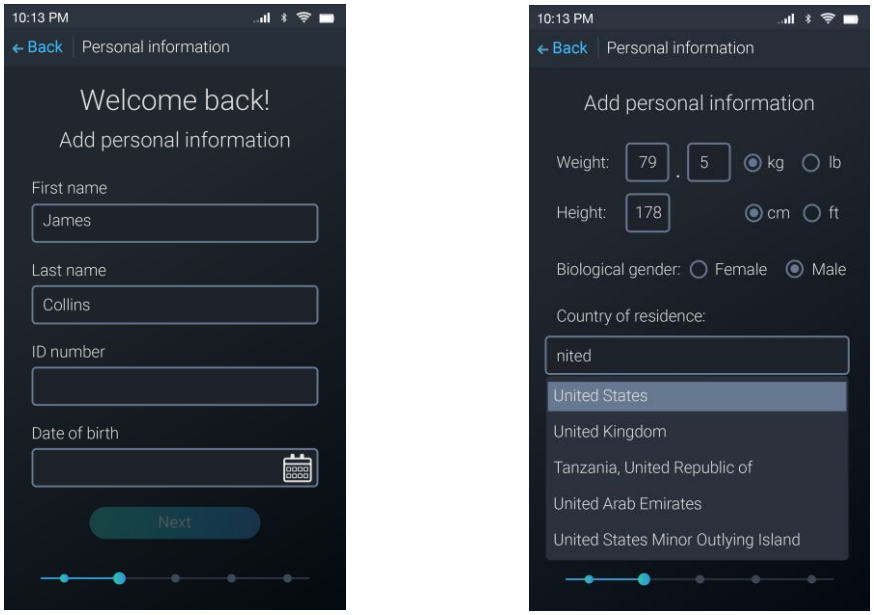


Figure 5-8. Personal information screens

3. Tap the calendar icon to select your date of birth. A confirmation screen with your age is displayed. Tap **Yes** to confirm your age.

> ***Note***
>
> Pay attention to the selected units of measure when entering your weight (kg/lb) and height (cm/ft).

4. Enter your weight, height, and select your biological gender.

> ***Note***
>
> Your weight can later be updated (see section 2).

5. Enter your country of residence using autocomplete.

> ***Caution***
>
> Verify you have selected the correct country of residence, as it is required for compliance with local regulatory requirements and new feature releases. Your country of residence cannot be changed without the aid of customer support.

6. After all the fields are filled, tap **Next** to proceed to the next step (Step 3: Medical Information).

5.3.4 Step 4: Entering Medical Information

In this step, you are requested to indicate your medical condition. It is important to be as accurate as possible, and if you are unsure, select “**Don’t know**”.

> ***Caution***
>
> If you are unsure about your medical condition, enter "Don't know". Wrong medical information input will appear on the report and may lead to false diagnosis by your physician

The app displays one condition at a time and indicates your progress (1 of 12 in the following example).

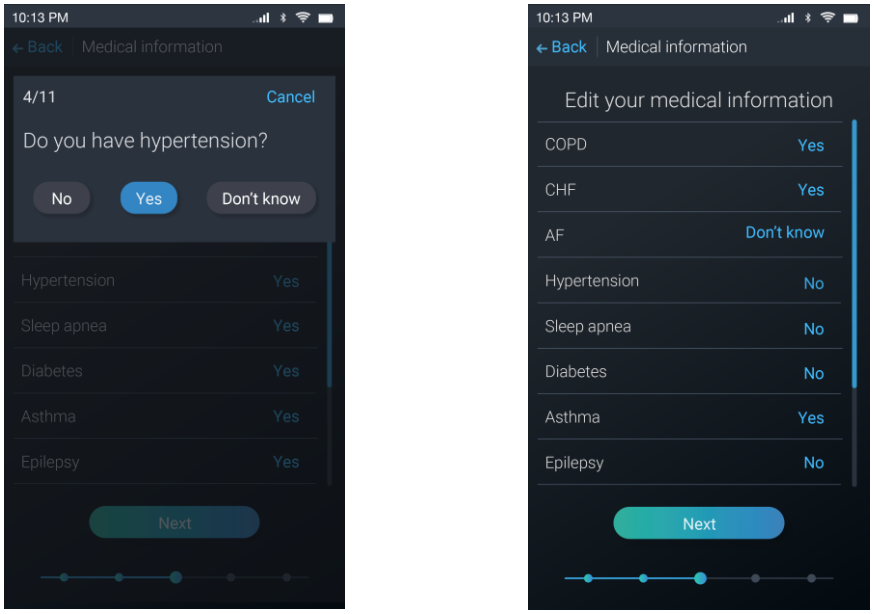


Figure 5-9. Medical information screens

1. Select your current medical state for the displayed medical conditions.

   After answering all questions, review your answers and edit them if needed by clicking the answer.

   The question is displayed again, and you may select a different answer.

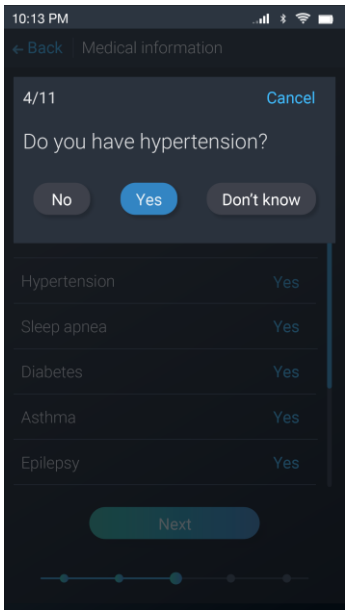


Figure 5-10. Changing a medical condition

2. After all medical conditions are filled in, tap **Next** to set thresholds for your medical measured and manually entered parameters.

   Thresholds are preset to default values that affect notifications. Before changing thresholds, consult your physician.

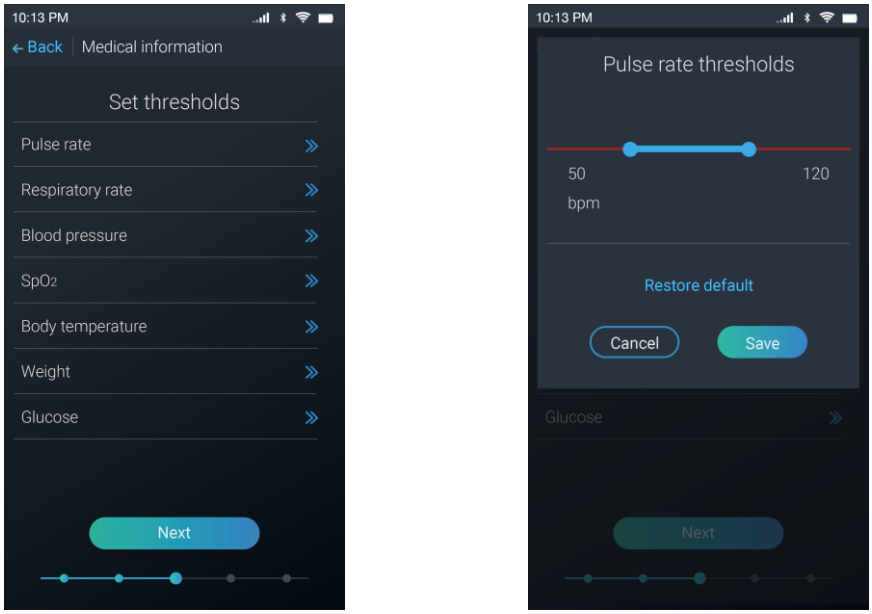


Figure 5-11. Setting thresholds

Note

The medical parameters have default thresholds. To continue without changing the default thresholds, tap **Next**.

The thresholds can later be updated (see section 2).

3. Tap the medical parameter to set its threshold.

4. Drag the handles or type values to set the upper and lower thresholds (tapping **Restore default** returns to the app default values).
5. Tap **Save** to save the change and continue to the next medical parameter.
6. After all medical conditions are filled, and your thresholds are set, tap **Next** to proceed to the next step (Step 4: Preference and Terms).

5.3.5 Step 5: Setting Preferences and Terms

In this step, you are asked if you allow CardiacSense to use your data for research purposes (optional) and to accept the terms and conditions for using the product (mandatory).

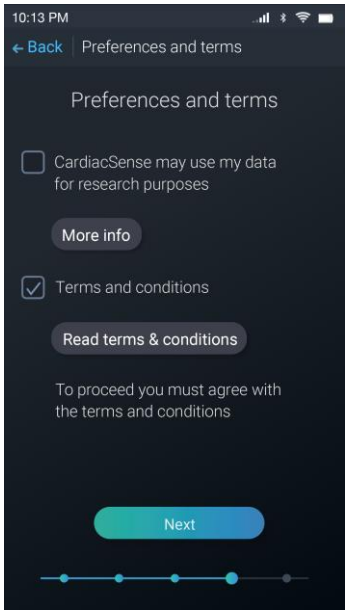


Figure 5-12. Preferences and terms

1. Select if to allow CardiacSense to use your data for research purposes.

   Data used for research purposes is anonymized, and no personal information is shared with any third party. The data is only used to improve the CardiacSense algorithms to benefit its users' health management.

2. Check the Terms and conditions checkbox (mandatory).

More information about using your data for research purposes and the terms and conditions is available by clicking **More info** and **Read terms & conditions**, respectively.

CardiacSense will inform you about any future changes to the privacy policy and ask you to agree to the revised terms.

3. After checking the Terms and conditions, tap **Next** to proceed to the next step (Step 5: Pairing the Watch).

5.3.6 Step 6: Pairing the Watch

The watch and the smartphone must be paired to work together. Once paired, they can only work with each other.

This operation needs to be performed only once.

Unpairing the watch and the app can be done from the setting menu in the app (see instructions in section Changing your Watch ID) and only then by tapping **Reset watch** on the **Factory reset** (described in section 11.2).

> ***Caution***
>
> Before pairing with the watch, ensure the date and time on your smartphone are correct.

1. Make sure that Bluetooth and the location are enabled on your smartphone and bring your watch and phone within 4m (13 feet) of each other.
2. Turn on the watch by pressing the watch ON/OFF button for 2–3 seconds.

   The watch vibrates momentarily, and its display turns on.

Figure 5-13. Turn on the watch

3. Tap **Scan for watches**.

   The watch displays its synchronization screen with the watch serial number.

Figure 5-14. Watch sync screen

Your smartphone searches for Bluetooth transmitting devices in its range and displays the list of watches it found.

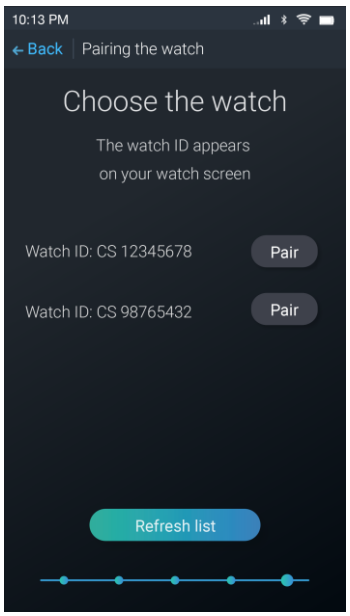


Figure 5-15. Choose watch

4. When found, tap **Pair** next to your watch's serial number.

   If your watch is not on the list, tap **Refresh list** for the phone to continue searching for additional devices.

5. Tap the blue approval ✓ sign on the watch within 1 minute to finish the pairing process.

Figure 5-16. Confirm pairing on watch

If there is no response from the watch within 1 minute, do one of the following on the next screen:

- Tap **Resend request**.
- Tap **Search for watches** to return to the list of watches.

After successfully paired, a message is displayed on the app.

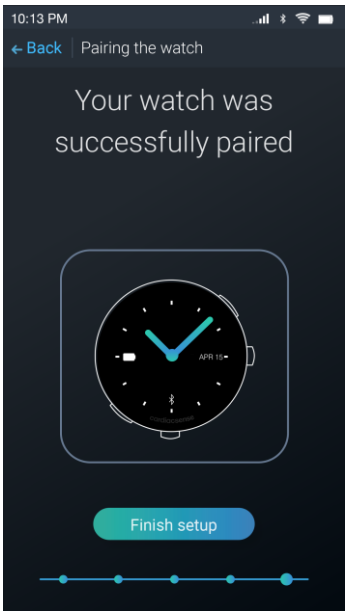


Figure 5-17. Watch paired with the smartphone

Figure 5-18. Watch paired with a smartphone

Note

To save battery power, the display automatically turns off after 3 seconds. To turn it back on, press the watch ON / OFF button, or turn your wrist with the watch towards you to view the watch face.

The watch display turns on by itself in case an A-Fib is detected.

The app displays the Main screen (Dashboard tab).

Note

The application screens are displayed in landscape orientation.

5.4 Mobile App Screen

The CS3 Mobile app screen includes a menu icon (see section 6.3.2) and two screen tabs.

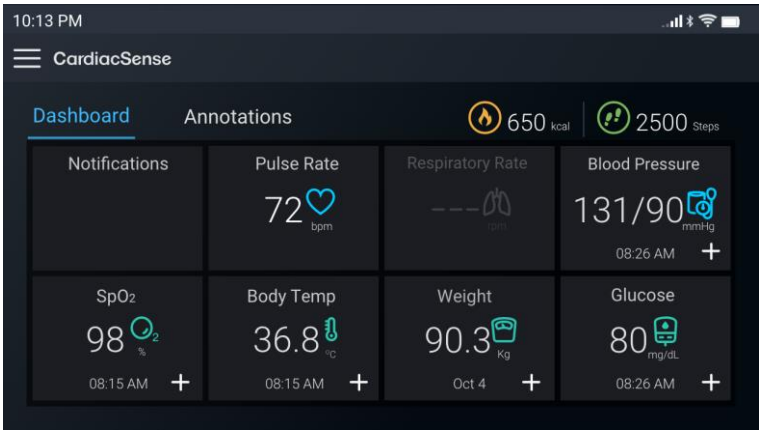


Figure 5-19. Main screen (Dashboard tab)

- **Dashboard** tab –displays notifications, the measured Pulse Rate, or manually entered medical information from external devices Pulse Rate(see details in section 6.3.1).

5.5 Wearing the Watch

When the watch is fully charged, wear it on your left or right wrist, just above the wrist bone, over intact skin.

Tighten the strap so that the watch is in full contact with your skin and feels comfortable. Do not overtighten the watchstrap.

A too loose or too tight watch strap may affect measurement results.

Once your CS Watch 3 and smartphone are paired, the watch starts monitoring your Pulse Rate. You may close the app; the watch continues monitoring your Pulse Rate even when the CS3 Mobile app is closed.

Low skin temperature, restricted blood flow, or exesive movement may result in wrong measurement results or lack of results. In such cases, remove the watch from your wrist, warm your hands and place it back on.

The CS Watch 3 is categorized as IP-67, meaning you may use the watch during exercise, rain, and while washing your hands or taking a shower.

Note

It is recommended to turn the watch off when not in use.

5.6 Replacing the Watch Strap

If the strap connected to the CS Watch 3 is too short, replace the strap with the longer strap provided with the CS System 3 (see item 4 Figure 4-1).

To remove the strap:

1. Turn the watch over to see its back side.

Figure 5-20. Watch back side

2. Slide the small silver spring lever inwards.

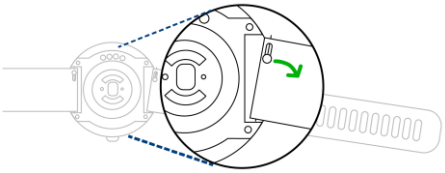


Figure 5-21. Strap silver spring lever

3. While under compression (spring-loaded), gently rotate the strap, pivoting around the stationary end.

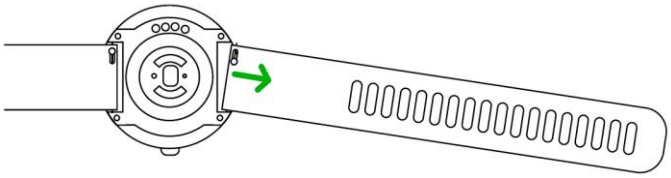


Figure 5-22. Rotating the strap

4. Remove the strap.

Figure 5-23. Watch strap removed

To connect the replacement strap:

1. Insert the pin on the far end from the silver lever into the small cavity in the watch strap holder/lug, as shown in Figure 5-22.
2. Slide the small silver spring lever inwards (as shown in Figure 5-21), and while under compression (spring-loaded), gently rotate the strap into place, pivoting around the stationary end (see Figure 5-22).
3. Insert the pin on the silver lever side into the other small cavity in the watch strap holder/lug. A click may sound when the pin enters the cavity. Gently push or pull the strap to hear a click and ensure the strap is firmly connected to the watch.

6 Using the CS System 3

The CS System 3 works best when the CS Watch 3 is on your wrist and is close to the paired smartphone.

6.1 Watch Display

The default watch display shows the time, date (month and day), watch battery status, and Bluetooth status.

To navigate through the watch display screens, swipe left to the next screen.

During operation, the following icons may appear on the watch display.

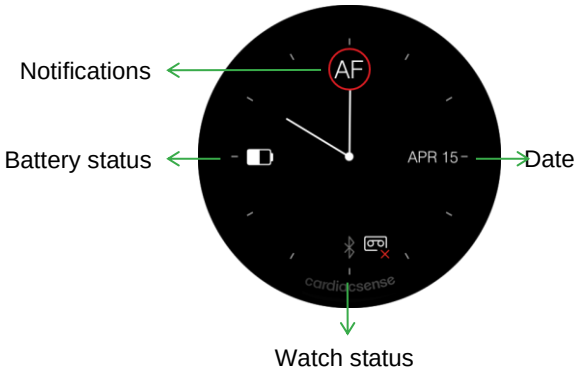
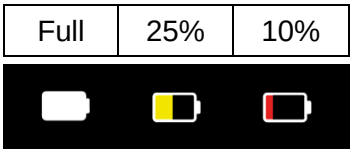


Figure 6-1. Watch face

The icons are also listed in the CS3 Mobile app (see section 6.4.2).

	**A-Fib detected**: CS System 3 detected A-Fib conditions. When the A-Fib episode starts (onset) and ends (termination), the watch vibrates. It is strongly recommended to notify your physician that your CardiacSense watch detected A-Fib arrhythmia.
	**Battery status**: At 40%, it is recommended that you charge the watch. At 10%, the watch should be charged. At 5%, the watch screen turns off, and the watch enters a deep-sleep mode.
	**Bluetooth status**: hardware failure/connected/disconnected. **Airplane mode** (see section 6.1.1).
	**Memory status**: low / very low / no recording

6.1.1 Pulse Rate

Swiping right from the main screen displays a screen showing the real-time measurements of your Pulse Rate.

Figure 6-2. Pulse Rate

6.1.2 Physical Activity

Physical Activity is tracked automatically in real time by CS System 3. The CS Watch 3 displays the number of steps taken and the number of calories burned. All physical activity measurements are reset every night at midnight.

Figure 6.3. Physical Activity

6.1.3 Settings

Swiping to the settings screen displays the CS Watch 3 serial number. The image below shows a sliding switch for toggeling from Bluetooth mode to Airplane mode, which disconnects the watch from the CS3 Mobile app.

Figure 6-4. Airplane mode

When in Airplane mode monitoring continues, but the measured results are only stored in the watch; they are not transferred to the app.

6.1.4 Factory Reset

Swiping to the Factory reset screen displays a **Confirmation** button.

Figure 6-5. Factory reset

Pressing the check sign erases the internal memory of the watch and deletes the pairing data with the app. It does not revert the watch firmware to its factory or previous version.

For details on resetting the watch to factory settings, see section 11.2.

6.2 Continuous Monitoring

Once the watch is placed on your wrist and turned on, it continuously monitors your Pulse Rate. Swipe the screen to the right to see the measured Pulse Rate.

Figure 6-6. Pulse Rate

When A-Fib is detected, the AF notification is displayed on the watch screen.

Figure 6-7. AF notification

It is advised to perform an ECG measurement (see instructions in Chapter 7).

Figure 6-8. ECG measurement

6.3 Application Screen

When opening the CS3 Mobile app, the Main screen appears. There is no need to log in.

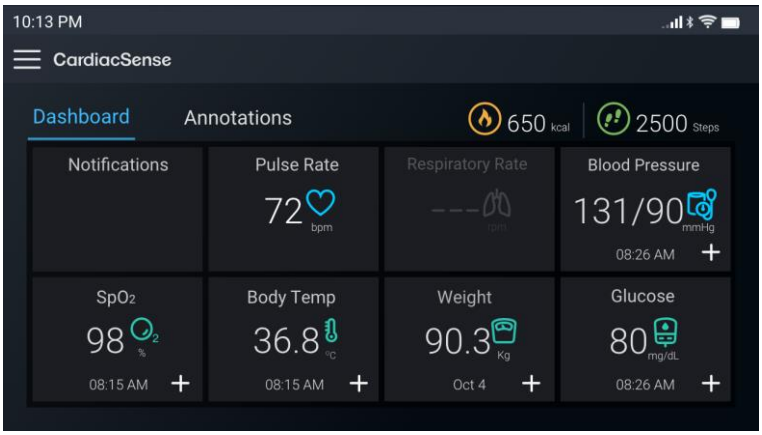


Figure 6-9. Main screen (dashboard tab)

6.3.1 Dashboard Tab

The Dashboard tab is the application's main screen. The screen displays real-time measured physical activity, Notifications (if any), the real-time measured Pulse Rate, and other measured or manually inserted medical parameters.

Note

Fields with a "+" sign are fields that their values are inserted manually. All other field values are updated by measuring with the watch.

- The Blood Pressure, SpO_2 and Glucose values are manually inserted by the user and are reset each midnight (see details in section 6.4.2).
- The Weight value is entered manually during the account setup process and displays the last entry date (it does not reset).

6.3.2 Main Menu

Tap the menu icon in the upper left corner of the screen to open a list of available menu options.

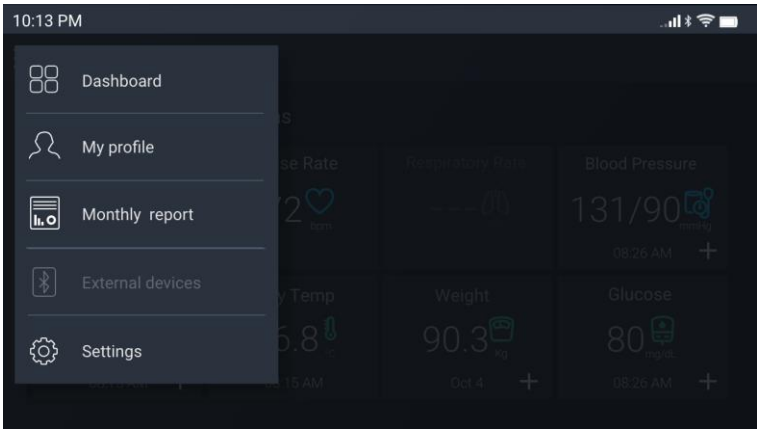


Figure 6-10. Menu

Note

To access My profile you must log into the application (explained in Chapter 9, Changing your Account Information).

- **Dashboard** – returns to the Dashboard screen.
- **My profile** – allows changes to the watch ID, personal and medical information, re-set thresholds and passwords, and access consent forms for preferences and terms (see Chapter 9).

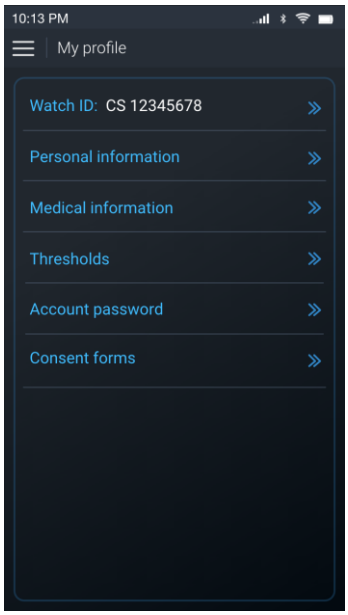


Figure 6-11. My profile

- **Settings** – allows changes to application-related settings such as the app interface language and measuring units. (For details, see Chapter 9, Changing your Account Information.)

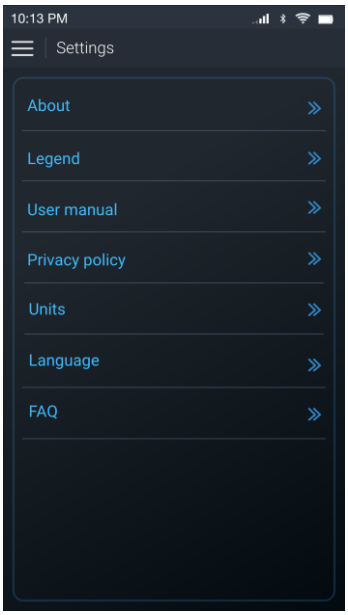


Figure 6-12. Settings

- **Monthly report** – used for requesting a 30-day history report from a selected date (see details in section 8.2).

6.4 Detected and Measured Data

The Dashboard tab displays notifications and medical parameters.

6.4.1 Notifications

When A-fib is detected, or if any of the medical parameters (e.g., Pulse Rate) exceeds the set thresholds, their values are displayed in red with a red border.

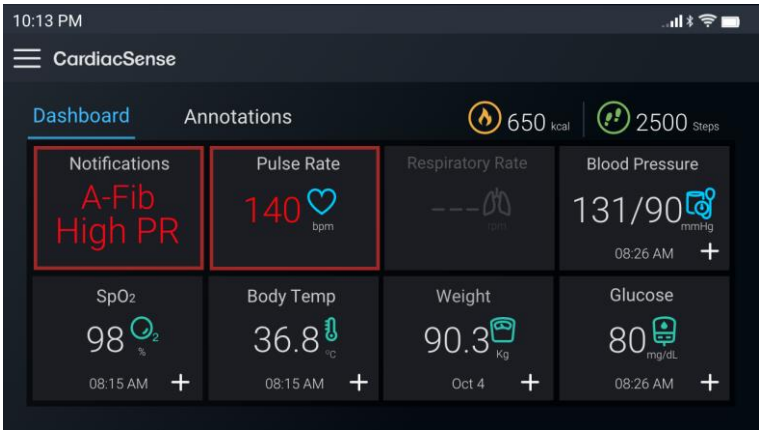


Figure 6-13. Notifications

6.4.2 Adding Externally Measured Data

Medical data not measured by the CS Watch 3 can be manually added to the CS3 Mobile app dashboard.

> ***Note***
>
> Adding externally measured medical data to the CS3 Mobile app requires an internet connection.

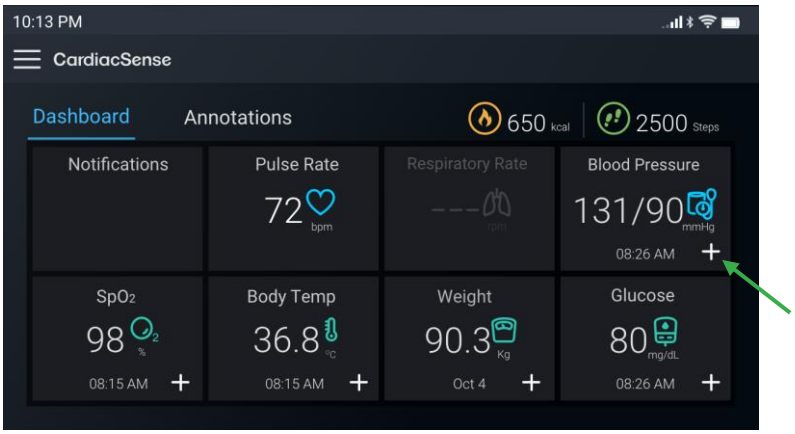


Figure 6-14. Adding external measured data

> ***Note***
>
> The added value includes the time of day it was added and is reset every day at midnight, except for weight.

To manually add a value:

1. Open the CS3 Mobile app in the Dashboard tab.
2. Tap the “+” symbol located in the lower-right corner of the relevant field.

   A window for updating the values appears.

Figure 6-15. Updating external measured values

3. Type in the measurement value or use the arrows to change the values.
4. Tap the **Update** button to save the changes.

   The screen returns to the Dashboard display.

Warning

DO NOT adjust medication or delay medical care based on measurement results from this device. Take medication as prescribed by your physician.

7 Performing an ECG Measurement

An ECG measurement can be initiated at any time from the watch or when prompted by the watch and app in case of A-Fib detection.

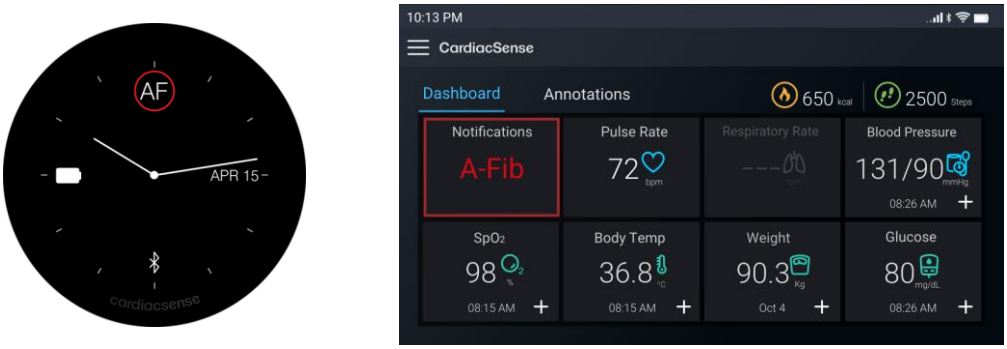


Figure 7-1. A-Fib notification

When the watch PPG sensor detects an A-Fib condition, the CS Watch 3 displays an AF notification, followed by an instruction screen to **Place your fingers on the ECG sensors**. The app displays the Real-time Data tab with the same instruction.

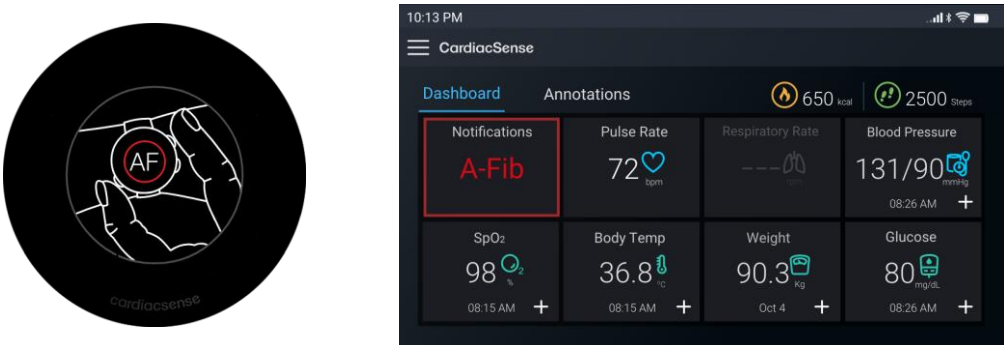


Figure 7-2. AF instruction for ECG

Note

Taking an ECG measurement does not require logging in to the app but does require a Bluetooth connection between the CS Watch 3 and the paired smartphone.

Note

Make sure your wrist is not sweaty or wet when performing ECG measurements, it may result in lack of measurement results.

Note

The watch touchscreen is disabled during ECG measurements.

The ECG measurement only works if your watch is on your wrist and your fingers are placed on the ECG sensors (see Figure 7-2. AF instruction for ECG).

7.1 ECG Measurement

ECG measurements are saved as Event Reports and can be shared with medical personnel or anyone of your choice.

A sample of an event report is shown in section 8.1.

> ***Note***
>
> The ECG measurement may take up to 5 minutes. Sit in an upright position and avoid moving while performing the ECG measurement.

If measurment is interupted by a call, restart the app after the call has ended..

To take an ECG measurement:

1. Swipe left on your watch face until you reach the screen shown below:

Figure 7-3. V-sign to start ECG

2. Tap the V sign.
3. Place your fingers on the ECG sensors and keep them on the sensors until the message "**You may remove your fingers**" is displayed on the app screen.

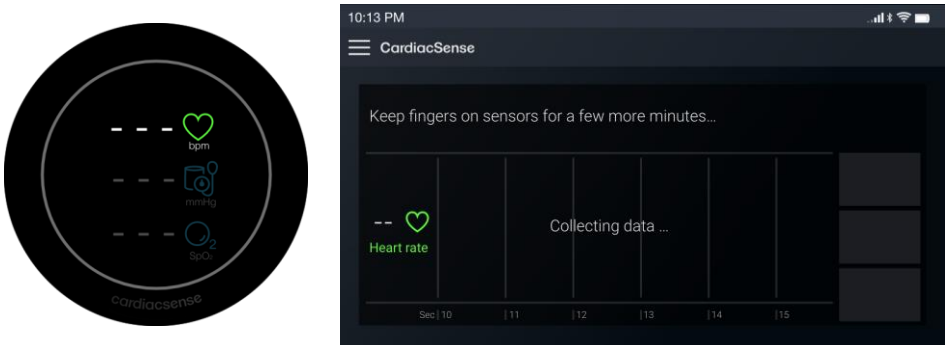


Figure 7-4. Watch ECG sensors

After around 20 seconds of data collection, the watch displays a blue progress line, and the CS3 Mobile app displays the Heart rate ECG measurement (on the upper right is a progress percentage).

Figure 7-5. ECG measurement (with a report)

Note

Removing your fingers during an ECG measurement pauses the measurement. Place them back to continue. Removing your fingers for more than 20 seconds ends the ECG measurement without a report.

At the end of a complete ECG measurement, the app displays the message "**Generating report… You may remove your fingers**".

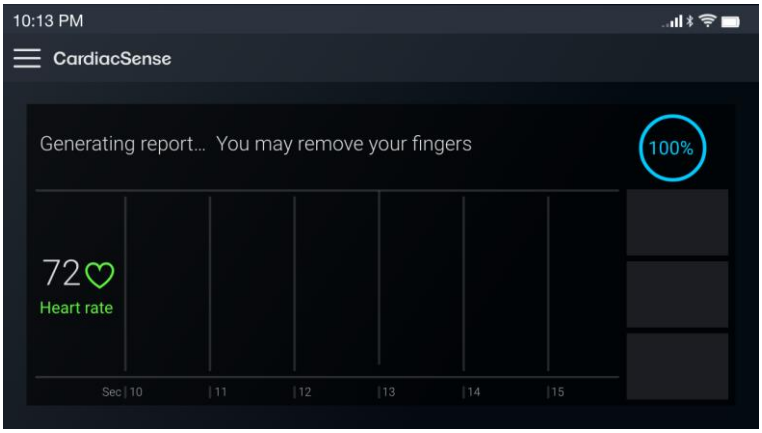


Figure 7-6. ECG measurement ended

4. Remove your fingers from the ECG sensors.
   - If A-Fib was not detected, the following watch and app screens are displayed.

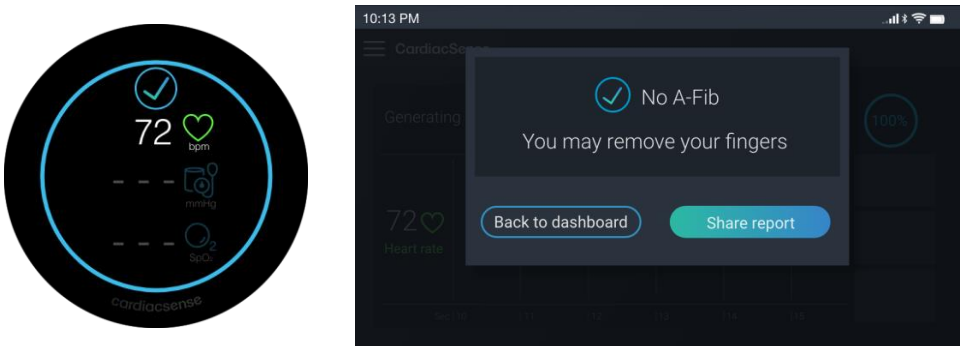


Figure 7-7. ECG complete message (No A-Fib)

- If A-Fib was detected, the following watch and app screens are displayed.

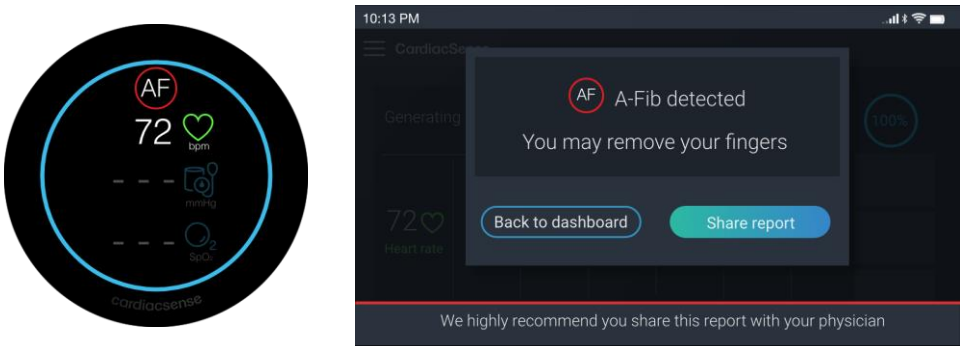


Figure 7-8. ECG complete message (A-Fib detected)

> ***Caution***
>
> Do not use the device to diagnose medical-related conditions. All interpretations should be reviewed by a medical professional for clinical decision-making

The measured data is saved on the smartphone (for Pro subscribers, the report is also uploaded to the CS3 Cloud app).

5. Select whether you want to share the report or return to the Dashboard

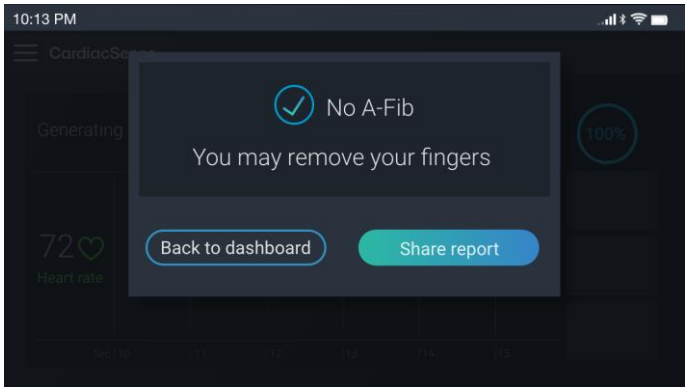


Figure 7-9. Share Report

- Tap **Share Report** to share the report and choose the app for sharing.

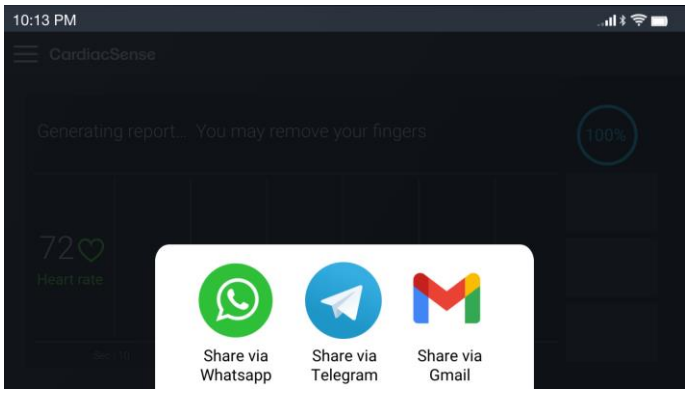


Figure 7-10. ECG report sharing

After sharing, the Main app screen is displayed.

- Tap **Back to dashboard** to discard sharing a report. A message asking if you want to leave without sharing the report is displayed.

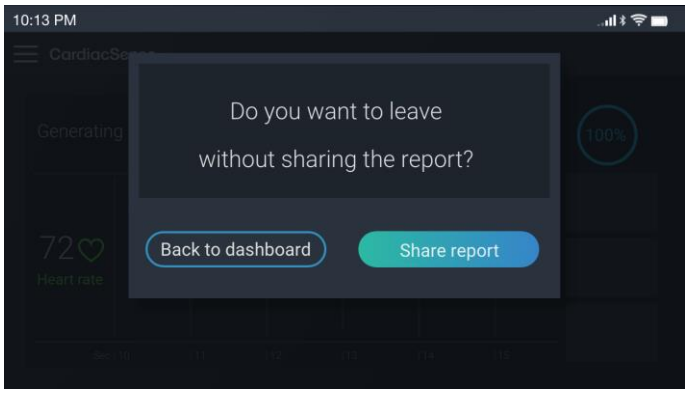


Figure 7-11. Leaving without sharing the report

7.1.1 Non-Successful ECG Measurement

If a measurement stops before successful completion, a notification is displayed on both the app and the watch, requesting to retake it.

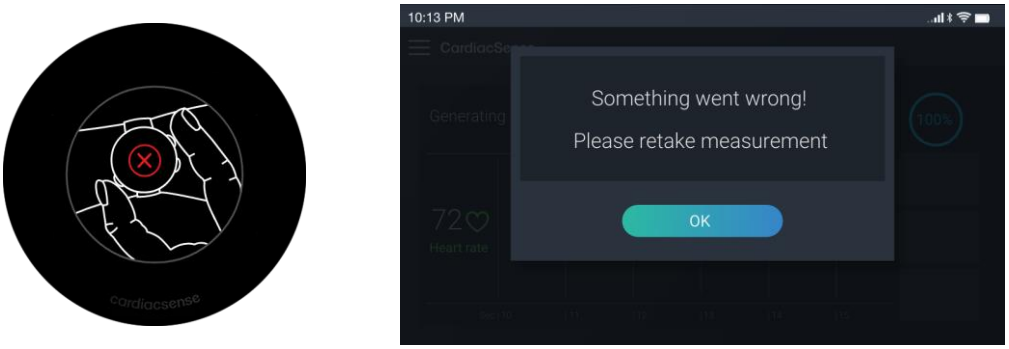


Figure 7-12. ECG measurement failed

The data is not saved, and no report is generated.

8 Event and Monthly Reports

8.1 Event Reports

Event reports are saved as PDF files in the /CardiacSense folder under the device's internal storage root folder:

- **Android** base smartphone: **My files > Internal storage > Android > data > com.cardiacsense > files > CardiacSense**
- **iOS** based smartphones: **Files > On My iPhone > cardiacsense**

The naming convention of report files is:

Results <DD-MM-YYYY> <Hour-minutes-seconds>.pdf.

The event report includes ECG measurement graphs and can be very long.

The /CardiacSense folder in your smartphone may contain many reports. Old reports can be removed using the File Manager.

8.2 Monthly Reports

The CS3 Cloud app automatically generates a monthly report of the last 30 days in a PDF file format and is sent to the user's email at the beginning of each month.

The user can also initiate a request to create a 30-day history report from a selected date. The PDF format report is sent to the user's email and can be shared with anyone the user chooses. This report is not shared via the CS3 Mobile app.

To initiate a monthly report:

1. Tapping the menu icon in the upper left corner of the screen.

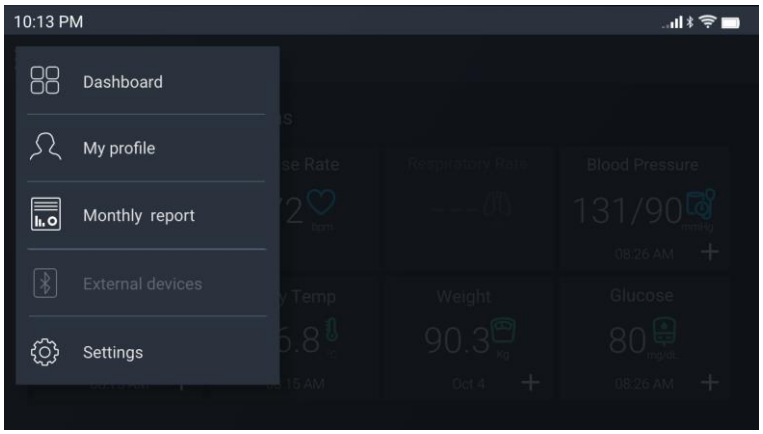


Figure 8-1. Initiating a monthly report

2. Select **Monthly report**.

   A screen requesting to select the date from which to create a 30-day history report is displayed.

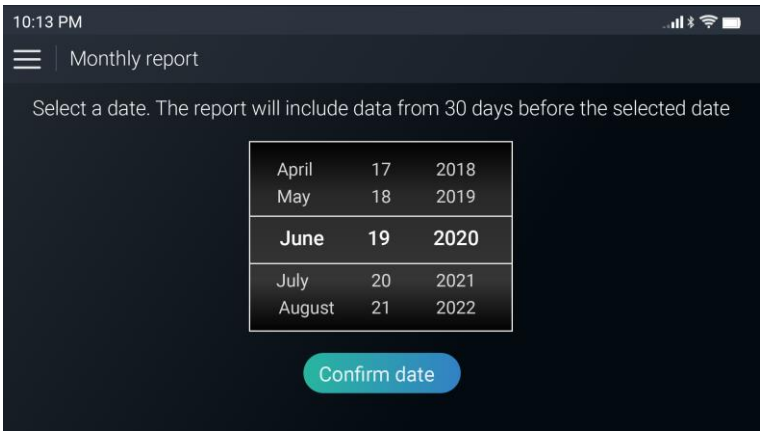


Figure 8-2. Selecting date for a monthly report

3. Select the date from the calendar and tap **Confirm date**.

   A confirmation message with the selected dates appears.

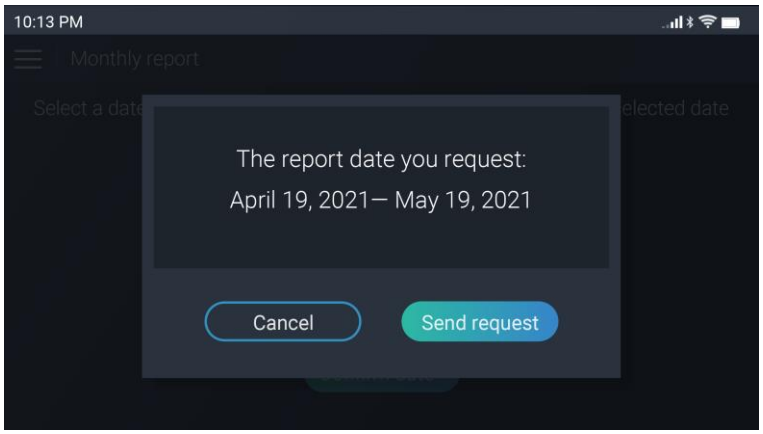


Figure 8-3. Selected date for the monthly report

4. Tap **Send request** to confirm the date and have CS System 3 send the monthly report to your email. A report is generated and sent to your email.

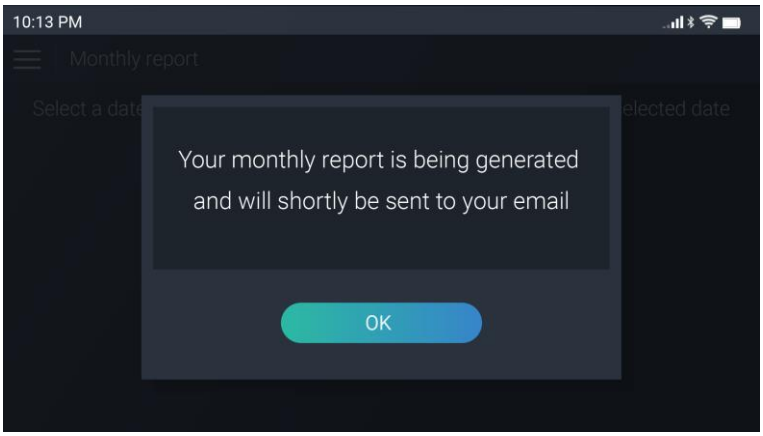


Figure 8-4. Confirmation a monthly report is generated

5. Tap **OK** to close the message.

9 Changing your Account Information

You can make changes to your account information to correct a mistake (e.g., your birthday), to reflect a change in your medical condition, or amend certain CS System 3 settings that require a password.

To view or change your account information, you must log into your account with your email address and password. If you have forgotten your account password, see Resetting Your Password.

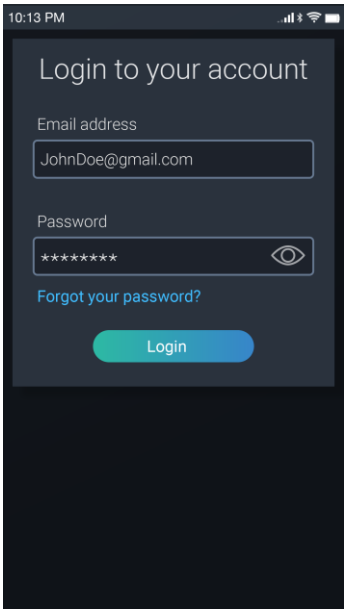


Figure 9-1. Login screen

1. Tap the **Menu** icon.
2. Select My profile.
3. Login to your account.

   The My Profile menu options become available.

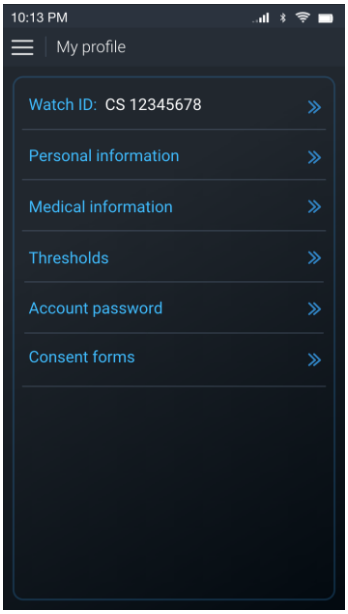


Figure 9-2. Account submenus

9.1 Changing your Watch ID

Both the CS Watch 3 and the CS System 3 app have unique IDs, and once paired, they can only work with each other. Before replacing your watch or smartphone with a new one, the old watch must be removed from the app and the new watch must be paired.

1. From the My profile menu, select Watch ID.

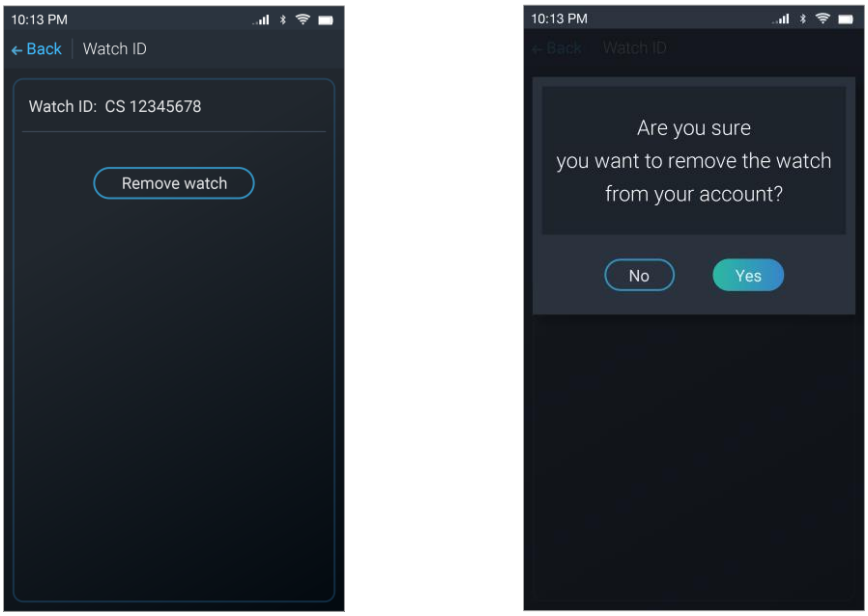


Figure 9-3. Removing the watch

2. Tap **Remove watch**.
3. Tap **Yes** when asked, "**Are you sure you want to remove the watch from your account**".

After removing, the app takes you to the "**Connecting the watch**" screen (see Figure 5-13 in section 5.3.6). Pair the new devices as described in Step 5: Pairing the Watch (section 5.3.6).

Resetting the Watch to Factory Settings (see section 11.2) also removes the watch from the app.

9.2 Changing your Personal Information

1. From the My profile menu, select **Personal information**.

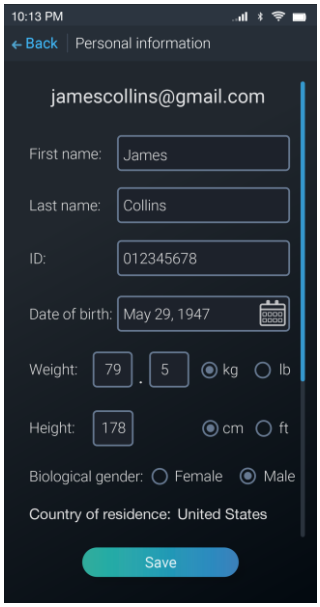


Figure 9-4. Personal information screen

2. Tap any field you wish to change (except your email address and country of residence).
3. Enter the desired change.
4. When done, tap **Save** to return to the My profile screen.

9.3 Changing your Medical Information

1. From the My profile menu, select **Medical information**.

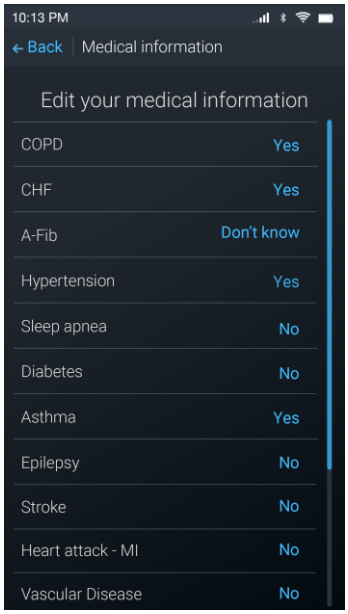


Figure 9-5. Medial information screen

2. Tap any of the blue values and select another value from the list.
3. When done, tap **Back** to return to **My profile**.

9.4 Changing the Thresholds

1. From the My profile menu, Select **Thresholds**.

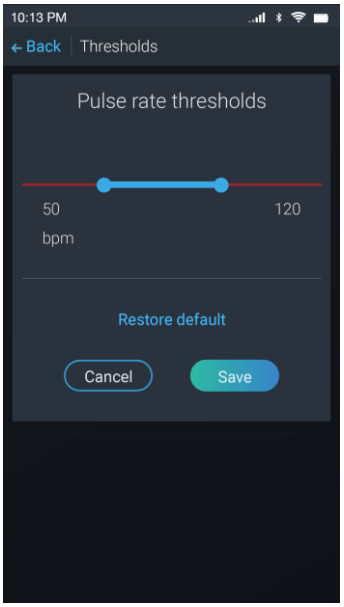


Figure 9-6. Thresholds screen

2. Modify the upper and lower rate thresholds.
3. When done, tap **Save** to return to **My profile**.

9.5 Changing your Account Password

CardiacSense recommends changing your account password from time to time for improved data security.

To change your account password:

1. From the My profile menu, select **Account password**.
2. Tap **Change Password**.

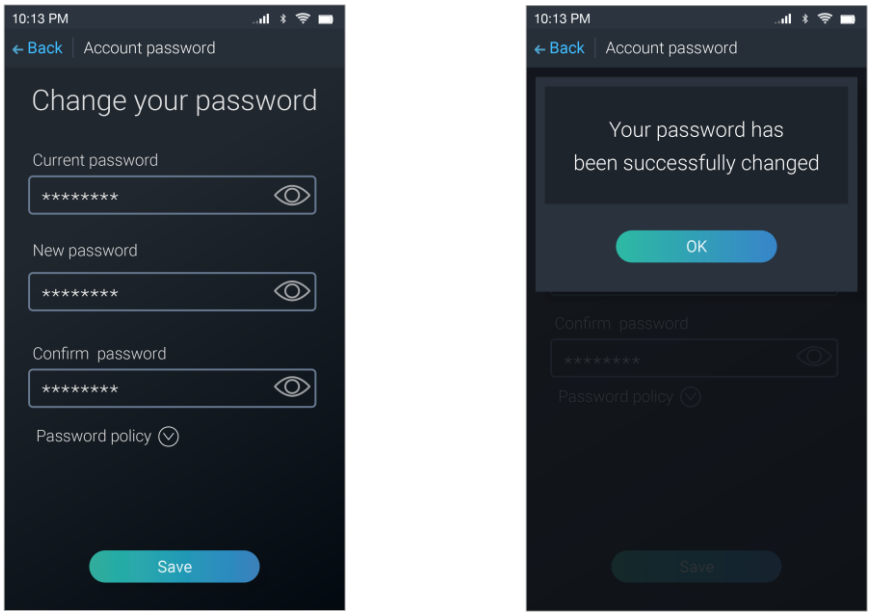


Figure 9-7. Changing account password

3. Enter your Current password, the New password (according to the password policy), and then re-type the new password to confirm.
4. Tap **Save.** You will see a message that **Your password has been successfully changed.**

9.6 Resetting your Password

If you have forgotten your password, you will need to choose a new one.

To reset your password:

1. Tap **Menu** and select **My Profile**.
2. In the **Login** screen, tap "**Forgot your password?**"

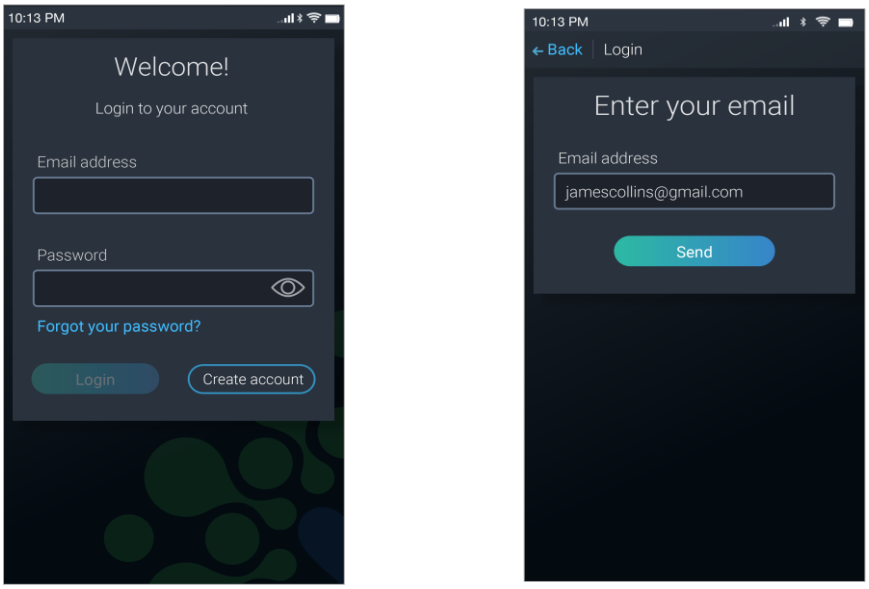


Figure 9-8. Resetting account password

3. In the next screen, type your email address (used by CardiacSense to send you a link to reset your password) and tap **Send**.
4. Go to your email inbox, open the mail with "**CardiacSense application password**" in the Subject and click **Reset My password**.

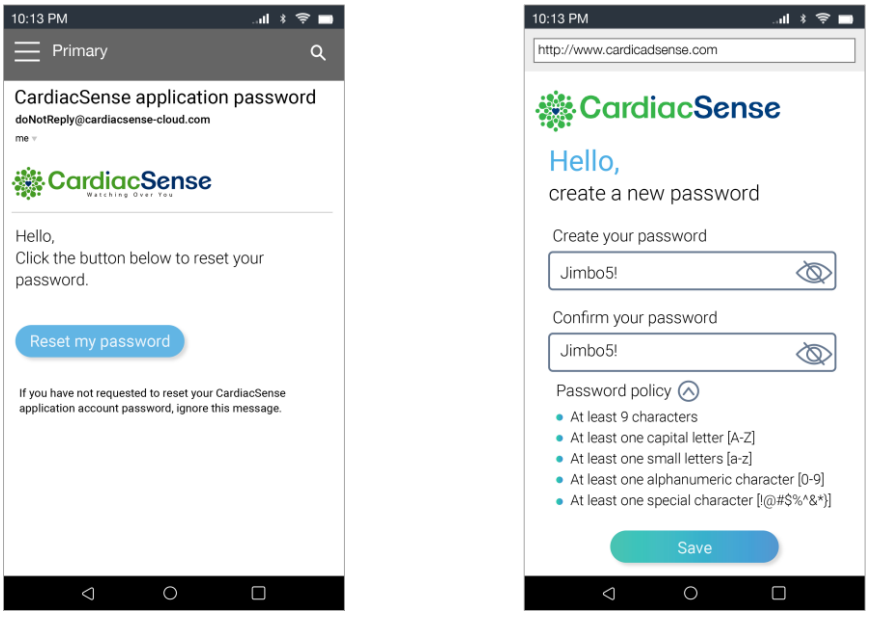


Figure 9-9. Create a new account password

5. Create a new password (observing Password policy rules), confirm your password, and click **Save**.

9.7 Changing your Consent Forms

Data used for research purposes is anonymized, and no personal information is shared with any third party. The data is used only to improve the CardiacSense algorithms for the benefit of its users' health management.

To change your consent to use your data for research purposes:

1. From the My profile menu, select **Consent forms**

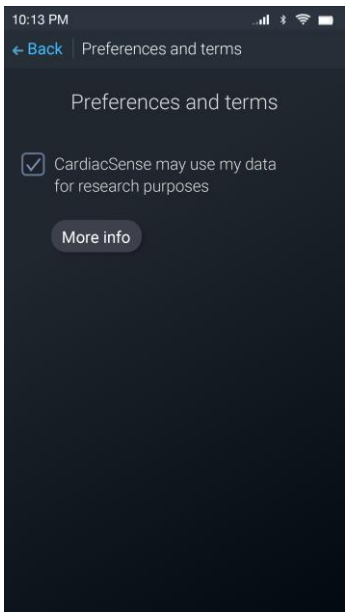


Figure 9-10. Preferences and terms screen

2. Check the checkbox if you agree that "CardiacSense may use my data for research purposes" or uncheck (clear) the checkbox if you disagree.
3. When done, tap **Back** to return to My profile.

9.8 Changing the Application Language

To change the application language:

1. Tap **Menu > Settings.**
2. Select **Language**.
3. Choose your preferred language from the preset list (see section 5.3 for reference).
4. Tap **Save**.

9.9 Changing the Units

To change the application units of measurement:

1. Tap **Menu > Settings**.
2. Select **Units**.

Figure 9-11. Preferences and terms screen

3. Choose the units of measurements to use in the CS4 Mobile app.
4. Tap **Save**.

10 The CS3 Cloud application

The CS3 Cloud app stores the user's personal information and medical data, and generates a monthly report that is sent to the user's email.

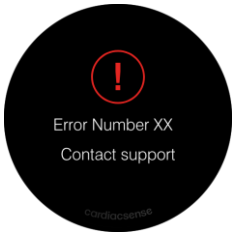
Note

The CS3 Cloud app communicates with the smartphone via the internet and is not accessible by the user.

11 Troubleshooting and Maintenance

11.1 Troubleshooting

11.1.1 Troubleshooting the CS Watch 3

Issue	Possible cause	Corrective action
The display is not working. The green LEDs on the back side are off.	Watch is turned off, or the battery is depleted.	Turn on the watch or charge the battery.
The display is on, but the green LEDs on the back side are off.	Possible issue with the sensors.	Contact CardiacSense support.
	There is a general problem with the watch or with its sensors.	Contact CardiacSense support.
	The watch did not detect contact with your fingers on the ECG sensors.	Release your fingers and place them again on the ECG sensors.
	Watch battery is only 20% charged.	Place the watch in the cradle and charge it.
	The watch has very limited memory storage.	Verify that your watch and smartphone are linked.
	The watch is not recording the measurements because it is out of memory storage.	Verify that your watch and smartphone are linked.
	Bluetooth is off on the watch or smartphone, or the distance/interference between them does not enable Bluetooth linkage.	Turn on the Bluetooth on the watch and the smartphone and verify they are paired.
	Bluetooth hardware failure.	Please contact support.

11.1.2 Troubleshooting the CS3 Mobile application

Symptom	Possible cause	Corrective action
No results are displayed.	There is no mobile communication with the watch.	Turn on Bluetooth and Location Services.
	Low battery on the smartphone is causing it to enter battery saving mode and turning off the Location Services and/or Bluetooth.	Charge the smartphone.
No signals are displayed, and the app moves to the background.	Incoming call or notification while viewing real-time signals.	Relaunch the app.
The report creation process is interrupted.	Low battery on the watch or smartphone, or incoming notification on the smartphone.	Repeat the process.
 (upper right corner of the screen)	No internet connection. Data is not saved in the app.	Check your smartphone internet connection.
 (upper right corner of the screen)	No connection with the watch.	Check your Bluetooth pairing with the watch. Verify that the distance between the watch and smartphone is less than 4 m (13 ft).

11.1.3 Troubleshooting the Cradle

Symptom	Possible cause	Corrective action
LED indicator failure.	Hardware failure.	Replace the cradle.
The watch is not charging.	Watch is placed backward on the cradle.	Place the watch in the cradle in the correct orientation. Use the cradle magnet to position the watch correctly in the cradle.

11.2 Resetting the Watch to Factory Settings

Resetting the watch is necessary if you get a new smartphone or reset your smartphone to its factory defaults.

The watch resetting process deletes the pairing data with the previous app. It erases its internal memory, where all the raw and processed data is stored but does not revert the watch firmware to its factory or previous version.

To reset the watch:

1. Swipe sideways until the Factory reset screen appears:

Figure 11-1. Factory reset screen

Tap **Reset Watch**.

Figure 11-2. Reset confirmation

Tap the blue approval ✓ sign to reset the watch.

A new watch and app pairing can be performed.

11.3 Updating the Watch Firmware

When a new firmware for the watch is available, it is automatically updated on the watch. The app displays a message that the watch software is being updated and to keep the Mobile app open during the update.

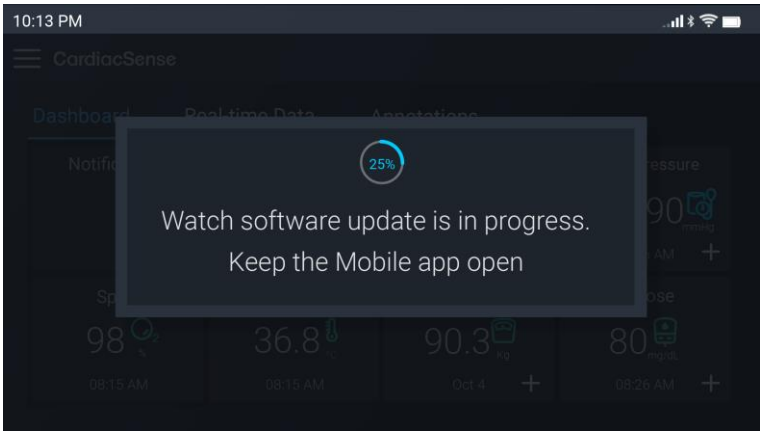


Figure 11-3. Updating watch firmware

11.4 Upgrading the Application

Whenever CardiacSense releases a new version of its CS3 Mobile app, the new version automatically replaces the current one on your smartphone (unless automatic app updates are not permitted on your smartphone). In any case, the app is updated the next time the application is launched and there is an internet connection.

The upgrade is performed in the background and does not affect the pairing of the watch and app. Your saved data, reports, and passwords are saved.

11.5 Cleaning the Watch and the Cradle

To ensure the good and long-lasting performance of the CS Watch 3 and its charging cradle, clean them regularly.

Wipe the watch and cradle with a nonabrasive, lint-free dry cloth.

Warning

To avoid the potential for electrical shock, the power supply must be disconnected from the power outlet while cleaning.

Caution

To reduce the risk of wrong measurements, keep the device sensors clean from dirt or grease

Caution

Do not use detergents to clean the watch and cradle.

If necessary, lightly dampen the cloth with fresh water.

11.6 Storing the Watch

Before storing the watch, make sure it is fully charged and turned off. The battery should be charged even when not in use.

12 Specifications

12.1 Supported Smartphones

The CardiacSense Mobile app was tested on the following smartphones:

- iOS version 12–14 based smartphones:
  - iPhone 6 Plus
  - iPhone 8 and more advanced
- Android version 7–10 based smartphones:
  - LG V40 ThinQ
  - Samsung Galaxy S8–S20
  - Xiaomi Redmi Note 8–20
  - Huawei P20
  - OnePlus 7

12.2 Communication Requirements

- **Wi-Fi**

  Wi-Fi (802.11g and up).
- **Bluetooth® Low Energy**

  Version 4.
- **Internet connection**

  Logging into the CS3 Mobile app and loading data to the CS3 Cloud app requires the smartphone to have access to the internet, either via a Wi-Fi network and a local router or via a cellular data network and a cellular network operator. It is recommended to use a Wi-Fi network.

12.3 Watch Specifications

12.3.1 Technical Specifications

Battery type	3.7V, 300 mAh Lithium-Ion
Expected battery life	24 months typical use
Expected operation time (fully charged battery to recharge)	~48 hours
Operation voltage	3.7V
Power consumption	<10 mA/h
Weight	40 grams (1.41 ounces)
Dimensions	Diameter 44mm (1.73 inches) Thickness 15mm (0.59 inches)
Wrist circumference	Min: 14 cm (5.5"), Max 20 cm (7.8")
Expected service life	2 years

12.3.2 Operational and Storage Environment

Atmospheric pressure	700 – 1060 hPa
IP rating (per IEC 60529)	Watch - IP67 Cradle - IP22
Operating Temperature	+5ºC to +50ºC
Storage Temperature	-15ºC to +60ºC
Relative humidity range	15% to 90%, non-condensing

Note: If the device have been stored or transported within the temperatures exceeding the specified operational temperatures, let the device reach its intended operational temperatures

12.3.3 PPG

Pulse Rate measurement	Continuous
Memory capacity	Min 72 hours of storage on the watch
Pulse Rate range	30–220 BPM
A-fib detection performance	Sensitivity of 95%, Specificity of 95%

12.3.4 ECG

A/D sampling rate	128 Hz
CMMR	80 dB
Common mode input impedance	5 GΩ
Differential range	±300 mV
ECG channel	Single lead
Frequency response	0.5–40 Hz
Heart rate range	30–220 BPM
Input dynamic range	10 mV peak to peak
Memory capacity	Min 72 hours of storage on the watch
Resolution	17 bit
User interface	3 stainless steel electrodes

Do not use the device out of the defined environmental conditions.

12.4 Electromagnetic Emissions

CS System 3 is intended for use in the electromagnetic environment specified in the following tables. It is not a life-sustaining device.

The user must ensure that it is used in such an environment.

12.4.1 FCC Radio Frequency Interference Statement

FCC ID: 2A4CTCS322

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CardiacSense Ltd. is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could occur.

12.4.2 Declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class B	CS System 3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	CS System 3 is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as using the CS System 3 in a different location.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

Warning

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this device could increase electromagnetic emissions or decrease the electromagnetic immunity of this device and result in improper operation.

12.4.3 Declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	Evaluated during AC/DC adapter approval	Power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Evaluated during AC/DC adapter approval	Power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Evaluated during AC/DC adapter approval	Power quality should be that of a typical commercial or hospital environment. If the user of the CS System 3 requires continued operation during power interruptions, it is recommended that CS System 3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. power voltage prior to application of the test level.			

12.4.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and CS System 3.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

12.5 Essential Performance

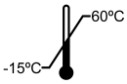
The essential performance of CS System 3 is defined as the ability of the System to continuously measure beat-by-beat heart rate and Pulse Rate and to detect the presence of atrial fibrillation lasting at least 5 minutes within the defined performance rates.

Essential performance is maintained by implementing an internal built-in test mechanism, which presents status and failure notifications to the user and allows for fail-safe operation.

12.6 Compliance

Basic safety and essential performance	ANSI/AAMI IEC/EN 60601- 1:2005/(R)2012 + A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Basic safety of electrocardiograph devices	IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
Batteries	IEC 62133-2:2017 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
Biocompatibility	ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process: permanent contact with intact skin
Clinical evaluation	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good clinical practice
Cybersecurity	Proprietary communication protocol with CRC is used to prevent unauthorized reading of measurement data and tampering of measurement and patient data. The watch software checks program flash checksum to prevent unauthorized firmware change. The app will not run if unauthorized software change is detected by integrity checks
Data privacy	CardiacSense is GDPR-compliant.
EMC requirements	IEC 60601-1-2:2014 Ed. 4 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
FCC	The Federal Communications Commission (FCC), Part 15. RADIO FREQUENCY DEVICES, 47 CFR Subpart B - Unintentional Radiators
Home care use	IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: 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
Labeling and symbols	EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirement
Optical safety	IEC 62471:2006 Safety analysis performed based on IEC 62471 or other lamp optical safety standards
Shock and vibration	ASTM D4332-14, ASTM D4169-16, ASTM D5276-98, ASTM D642-15, ASTM D999-08, ASTM D4728-17
Usability	IEC 62366-1:2015, Medical devices -- Part 1: Application of usability engineering to medical devices

12.7 Labels and Symbols

	Refer to instructions for use
	Consult instructions for use
 YYYY	Year of manufacture
	Special Requirements for Waste of Electrical and Electronic Equipment (WEEE) directive
 2797	Compliance with 2017/745 Medical Device Regulation (EU) and NB number
	Manufacturer
	Type BF applied part (IEC60601-1)
	Catalog Number
	Serial Number
	Medical Device
IP-67	Watch is protected from total dust ingress. Protected from immersion between 15 cm and 1 m in depth.
IP-22	Cradle is protected from touch by fingers and objects greater than 12 mm. Protected from water spray
	Storage temperature range
	BT SIG Membership Number
	Do not use if the package is damaged
	Compliance with FCC part 15 subpart B
 MR UNSAFE	Unsafe for Magnetic Resonance Imaging

13 Appendices

Appendix A. Medical Terms

A.1. About A-Fib

A-Fib is a reentrant cardiac arrhythmia marked by rapid randomized contractions of the atrial myocardium, causing an irregular, rapid atrial rate. It is recognizable on an electrocardiogram by the absence of P waves and an irregular ventricular response.

A-Fib is an independent risk factor for stroke and thromboembolism that cause mortality. Although A-Fib rates are increasing globally, improved outcomes may be achieved by successful although often complex treatment and by early detection.

A.2. About ECG and PPG

ECG and PPG are the two primary technologies for measuring heart rate.

- ECG (electrocardiography) uses electrodes to measure the bio-potential generated by electrical signals that control the expansion and contraction of heart chambers.
- PPG (photoplethysmography) uses light-based technology to sense the rate of blood flow as controlled by the heart's pumping action.

A.3. About HR and PR

Heart rate (HR) is the number of times your heart beats in a minute.

Pulse Rate (PR) is the number of times your arteries create a noticeable "pulse" due to an increase in blood pressure resulting from your heart contracting.