

SibEL



INSTRUCTIONS FOR USE



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Section 1. Introduction to Discovery RA

This section describes the Discovery RA product and provides an overview of the sensors.

1.1 Overview of Instructions for Use

This Instructions For Use (IFU) document is for researchers to use Sibel Health Discovery Sensors - including the ANNE Chest, ANNE Limb, and ADAM Sensors. The intended use of the Sibel sensors with the Discovery RA App are for data collection applications in Clinical Research. This document includes an overview of Discovery RA, use of the Sibel Health sensors, and key information necessary for successful operation.

1.2 Overview of Discovery RA

Discovery RA is a mobile application developed by Sibel which allows researchers to stream and download raw physiological vitals data as well as select advanced digital clinical measures. The system consists of one or more wireless sensors, adhesives, a wireless charger, and a mobile application. The system sent to the researcher will include all relevant hardware and instructions that will allow them to use Discovery RA for their needs.



1.3 Overview of Sensors

1.3.1 ANNE Chest Sensor



The ANNE Chest Sensor is an epidermal patch worn below the suprasternal notch. The device includes accelerometer, temperature, and electrocardiogram sensors from which key vitals such as heart rate, ECG, respiratory rate, central skin temperature, cough, talk, swallow, sleep, snoring, activity, and body position can be measured. The device is secured to the skin via a biocompatible adhesive.

1.3.2 ANNE Limb Sensor



The ANNE Limb Sensor is a flexible device that conforms to the fingers or toes. The device includes a temperature sensor and a transmission mode PPG sensor from which key vitals such as pulse rate, SpO2, perfusion index, and peripheral skin temperature can be measured.

1.3.3 ADAM Sensor



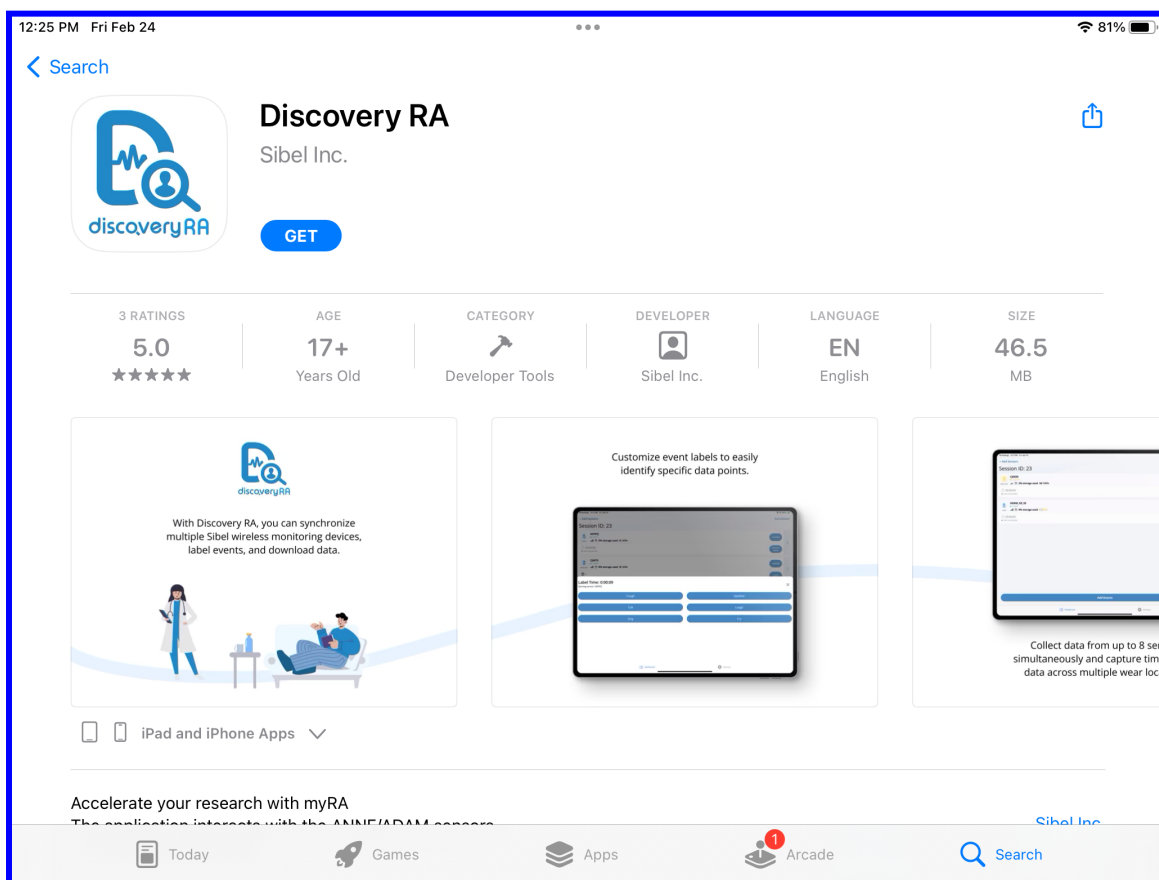
The ADAM device is an epidermal patch that can be worn on the suprasternal notch, hand, and other body parts. The device includes accelerometer and temperature sensors from which key metrics can be measured such as scratch indications and sleep metrics.

Section 2. System Set-up

This section describes the instructional steps needed to set up the sensors before starting data collection.

2.1 Downloading the Discovery RA App

The Discovery RA App is available on Apple iOS. If not provided with a tablet from Sibel, the app can be downloaded from the Apple App Store. Navigate to the Apple App Store and enter “Discovery RA” in the search bar to locate the app. Once found, click “Get” to download it.



2.2 Discovery RA Kit Unpacking

To open the package, remove the white lid of the package.

There are two layers inside the box. Each layer contains the components as listed below:

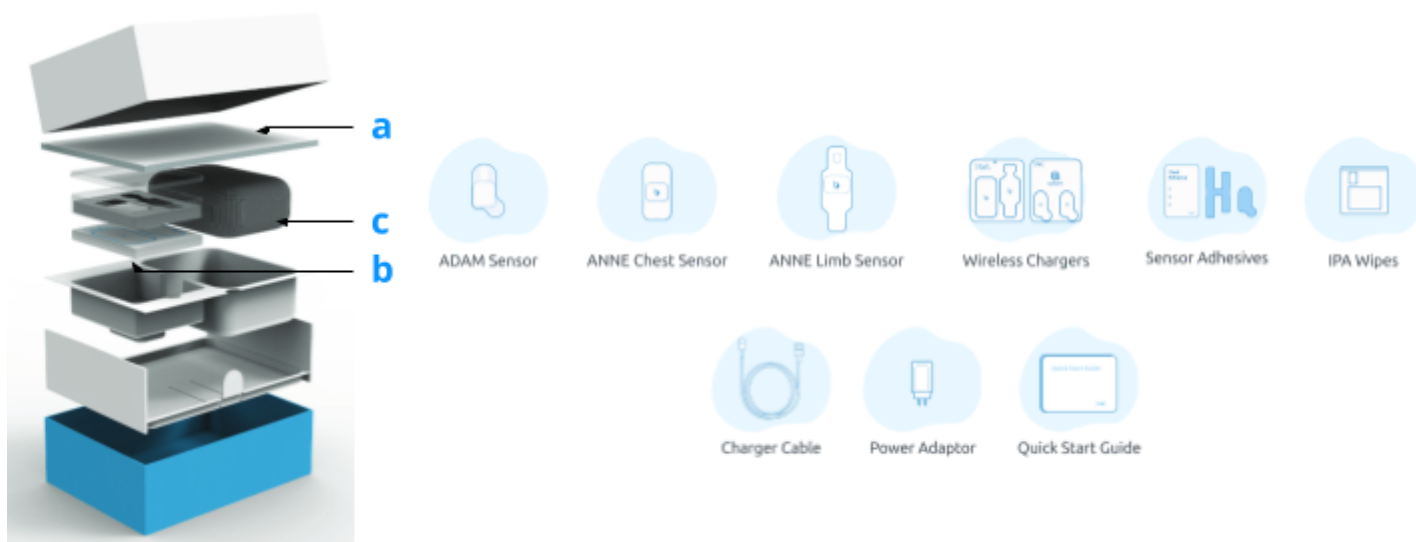
Top layer:

- a. Envelope containing Quick Start Guide

Middle layer:

- b. **Sensor container:** ANNE Chest Sensor and/or ANNE Limb Sensor and/or ADAM Sensor, ANNE Wireless Charger and/or ADAM Wireless Charger
- c. **Pouch:** ANNE Chest Adhesives and/or ANNE Limb Adhesives and/or ADAM Adhesives, IPA Cleaning Wipes, Wireless Charger Cable (USB-A to USB-C), Regional Power Adapter

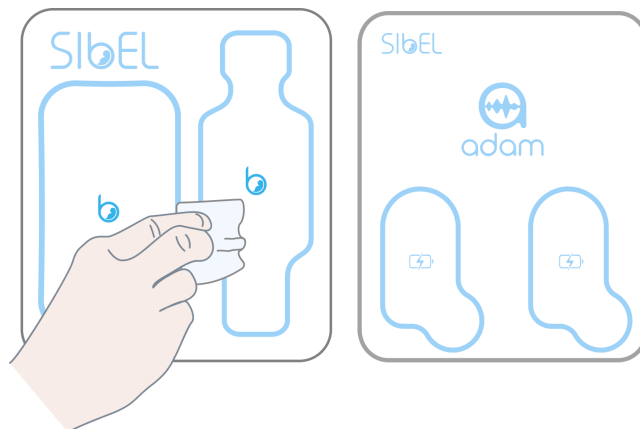
Note: Additional consumables can be ordered separately. Keep the packaging for future storage and shipment after use.



2.3 Setting Up the Wireless Charger

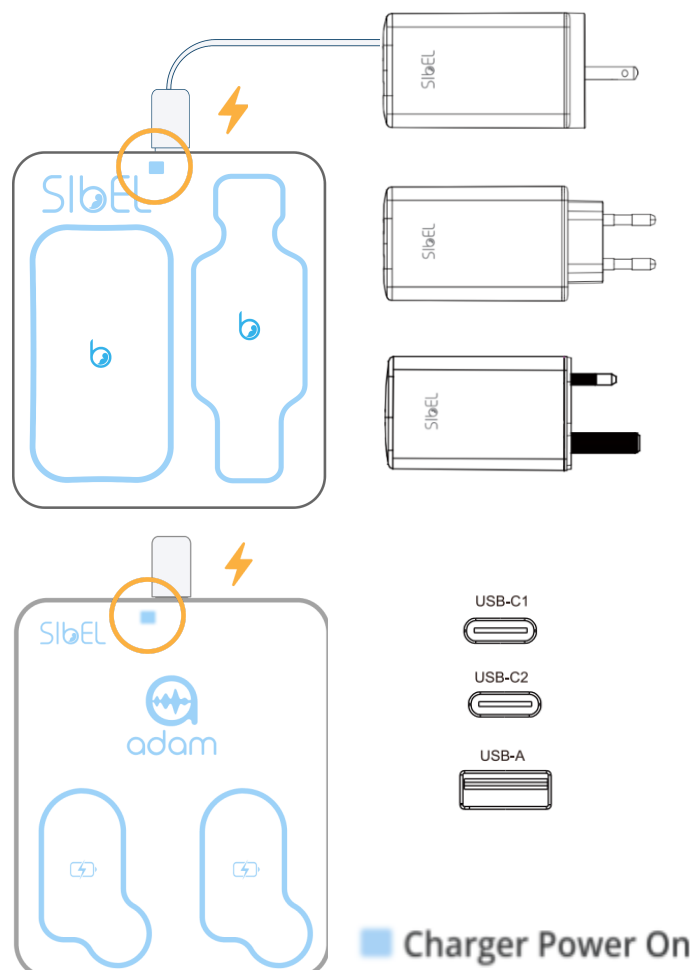
2.3.1 Sanitize the Charger Pad

Whenever first receiving a kit, before charging the sensor, wipe the top of the ANNE Wireless Charger or ADAM Wireless Charger with an IPA cleaning wipe to sanitize. Visually inspect the charger and repeat the cleaning process until it is visibly clean.



2.3.2 Plug in the Power Adapter

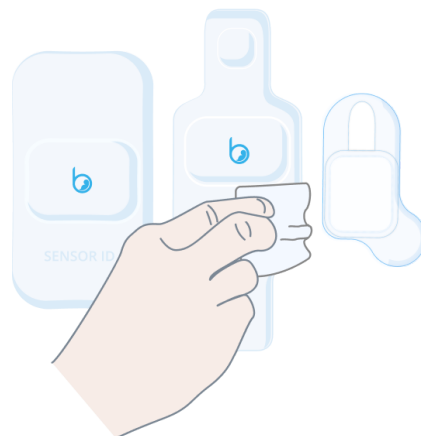
Plug the USB-C to USB-A cable into the Wireless Charger using the USB-C end. Then, plug the USB-A end into the USB-A port on the provided power adapter. A blue light indicates that the wireless charger is on. Note that the Wireless Charger is incompatible with USB-C to USB-C cables and will not function if used.



2.4 Setting Up the Sensor

2.4.1 Sanitize the Sensor

Wipe both sides of the sensor with an IPA cleaning wipe to sanitize. Visually inspect the sensor and repeat the cleaning process until it is visibly clean.



2.4.2 Wake up the Sensor

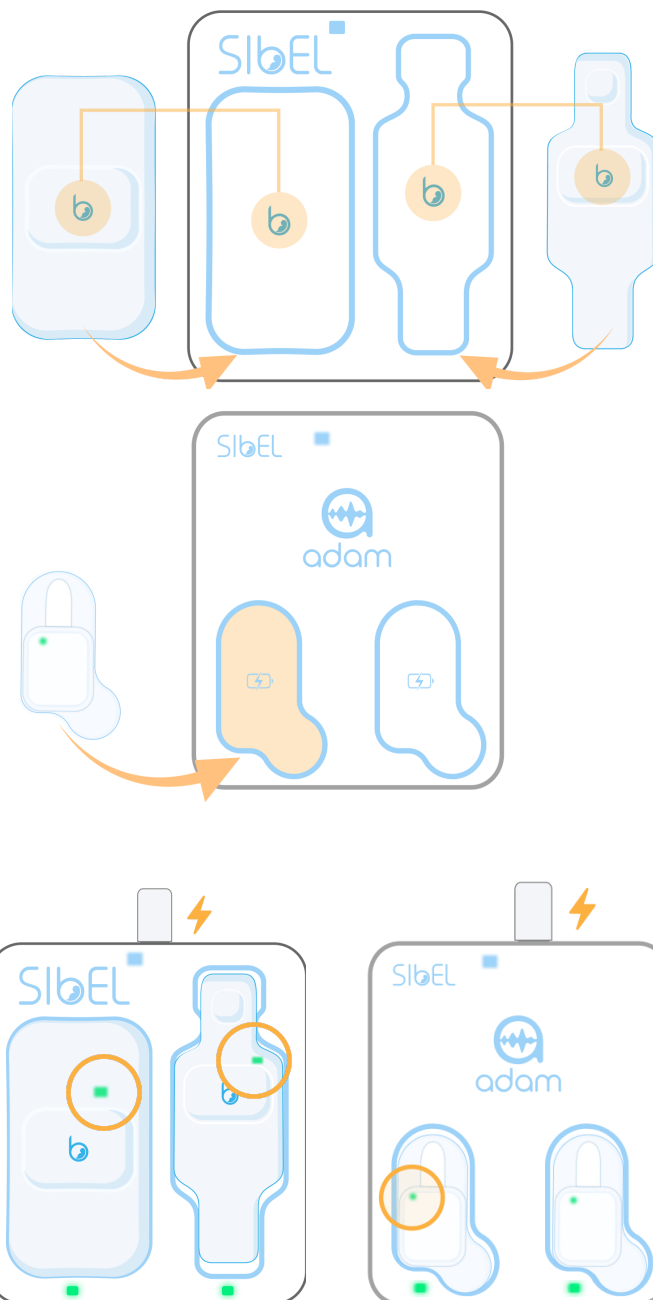
Step 1

Place the sensor on the Wireless Charger according to the outlines on the charger's surface. The shape and "b" logo on the sensor should match the sensor outline and "b" logo on the Wireless Charger.

Step 2

A green LED light on the Wireless Charger will turn on below the sensor indicating the sensor is positioned properly. The light may take up to 8 seconds to turn on. A green LED light on the sensor will blink every five seconds indicating that the sensor is charging. If the sensor is waking up from Ship Mode or very discharged, it may take a few seconds before the green LED turns on. If the sensor is turning on after reaching 0%, the green LED will slowly pulse, indicating very low battery. A full charge from 0% to 100% takes approximately 5 hours.

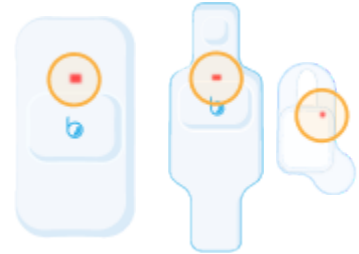
The sensor's battery level can be monitored using the Discovery RA app on the tablet.



2.5 LED Pattern Interpretations

The Red LED Blinks:

- Every 1 second to indicate poor skin contact during wear (ANNE Chest and ANNE Limb only)
- Every 3 seconds to indicate low battery OR low memory
- Solid to indicate sensor failure



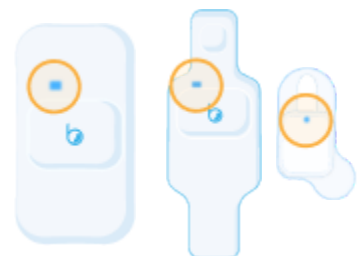
The Green LED Blinks:

- Every 3 seconds to indicate that the sensor is able to connect via bluetooth
- For 1 second every 5 seconds to indicate that the sensor is charging
- With a slow pulse (3 seconds to brighten, 3 seconds to dim) to indicate that the sensor is charging, but it has too low battery to be used
- Solid when on the charger to indicate that the sensor is fully charged
- Solid when pairing to indicate which sensor is being paired



The Blue LED Blinks:

- Every 1 second to indicate that the sensor was woken up from ship mode but not yet connected to the Discovery application



2.6 Discovery RA Sensor Workflow

Sibel sensors for Discovery RA will collect data when prompted by the app while configured to “Manual” mode. When configured to “Automatic” Mode, they will automatically start collecting data when they are removed from the charger and being worn (except for ADAM sensors, which will always start recording data once removed from the charger regardless of whether they are being worn). Putting the sensors in Ship Mode when they are off the charger (explained in [Section 8.1](#)) turns off the sensor so they are not collecting data. Sensors are taken out of Ship Mode by placing the sensor on the charger again. For the data from the sensor to be properly labeled, the sensor must connect to the application one time before starting data collection after taking the sensor out of Ship Mode (If not connected first, the sensor will flash a blue LED, as explained in [Section 2.5](#)). When not using the sensor, keep it in Ship Mode, and recharge it every 6 months so the battery quality does not degrade.

When a sensor is being worn and is collecting data, it stores all of the data on the sensor. When the data collection is completed and the sensor is returned to the charger, use the Discovery RA application to sync its data to the tablet (explained in [Section 5.4](#)). Once data is successfully synced from sensor to tablet, it can be transferred to a personal computer for processing. After data is successfully synced to the tablet it will be removed from the sensor and the sensor will be ready for the next data collection.

A summary of the workflow for data collection with a Discovery RA Kit is as follows:

1. Place the sensor on the charger when ready to wake the sensor from Ship Mode for use
2. Connect the Sensor to the Discovery RA Application (As explained in [Section 3.2](#))
3. Data Collection is initiated and the subject wears the sensor over a specified time period
4. The sensor is returned to the charger and the application is opened
5. The sensor recharges and syncs data to the tablet (As explained in [Section 5.4](#))



Section 3. Pair Sensors

This section describes the steps needed to open the Discovery RA App and pair the sensors with the App for data collection.

3.1 Starting the Discovery RA App

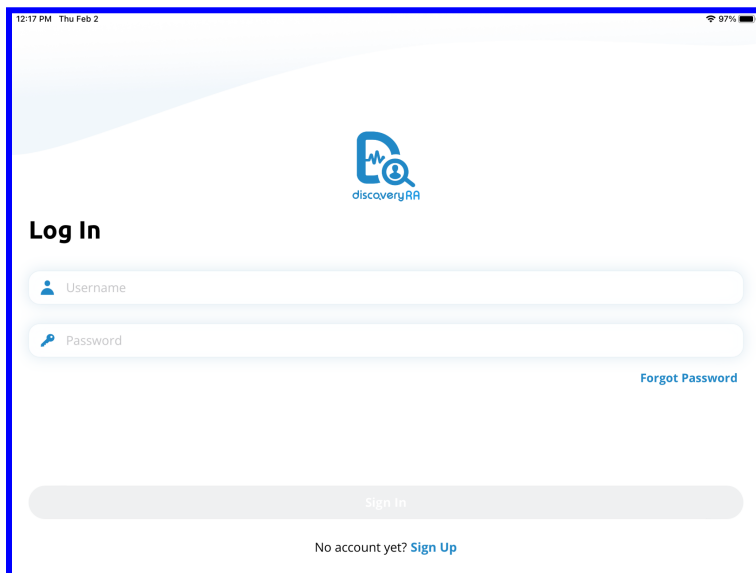
Step 1

Open the Discovery RA App from the tablet's home screen.

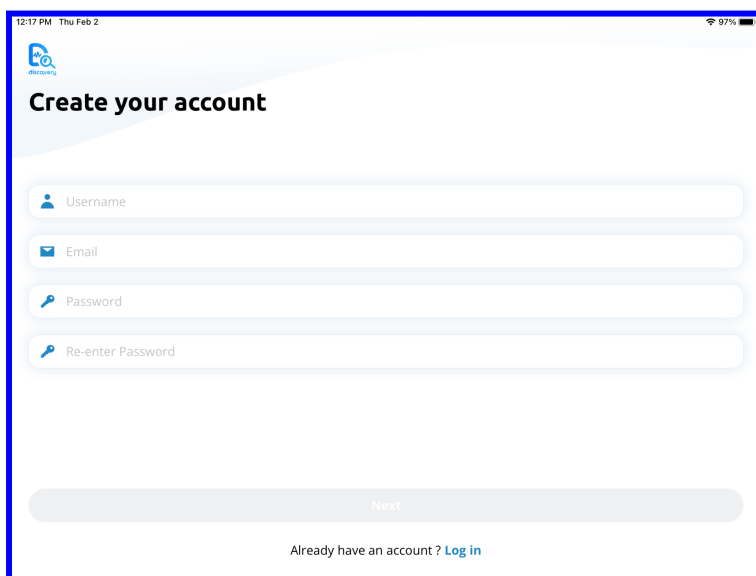
Step 2

If you do not have an account, create an account by clicking "Sign Up" on the bottom of the screen, and enter a username, an email address, and password.

Note that an internet connection is required to complete this step.



The screenshot shows the 'Log In' screen of the Discovery RA App. At the top, the status bar displays '12:17 PM Thu Feb 2' and '97%' battery. The app logo is centered. Below it, the title 'Log In' is displayed. There are two input fields: 'Username' and 'Password'. A 'Forgot Password' link is located to the right of the password field. A 'Sign In' button is at the bottom. Below the button, it says 'No account yet? Sign Up'.

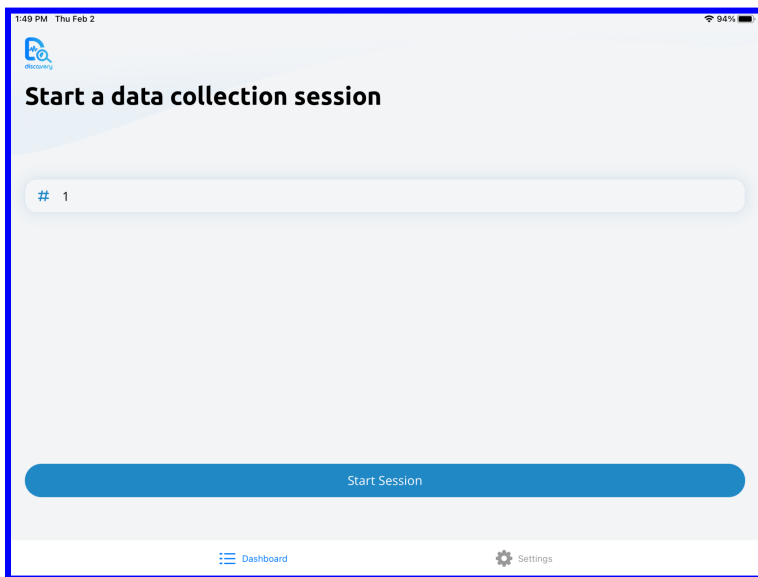


The screenshot shows the 'Create your account' screen of the Discovery RA App. At the top, the status bar displays '12:17 PM Thu Feb 2' and '97%' battery. The app logo is in the top left corner. Below it, the title 'Create your account' is displayed. There are four input fields: 'Username', 'Email', 'Password', and 'Re-enter Password'. A 'Next' button is at the bottom. Below the button, it says 'Already have an account? Log in'.

Step 3

After logging in, you will be prompted to start a new data collection session by entering a Session ID. Note that data will be identified using this Session ID, so enter an ID that is meaningful to you or your study.

Press the “Start Session” button below to be taken to the main screen.



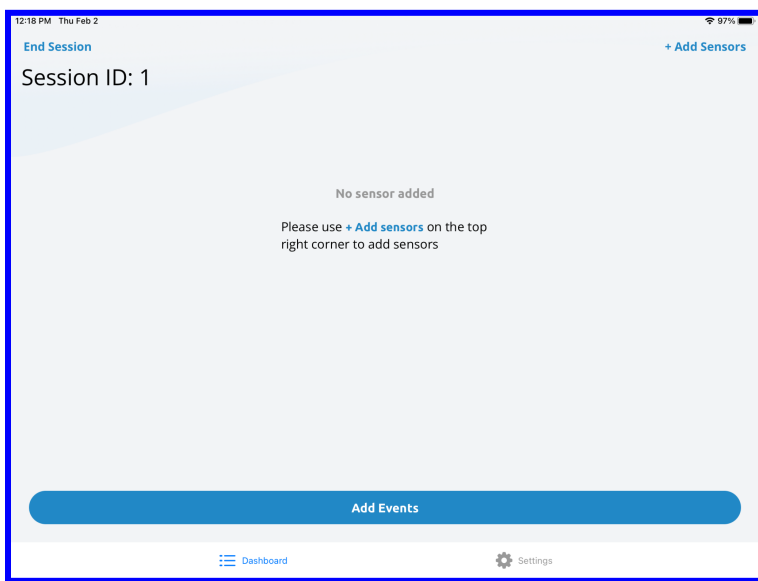
1:49 PM Thu Feb 2

Start a data collection session

1

Start Session

Dashboard Settings



12:18 PM Thu Feb 2

End Session + Add Sensors

Session ID: 1

No sensor added

Please use + Add sensors on the top right corner to add sensors

Add Events

Dashboard Settings

3.2 Pairing the Sensors

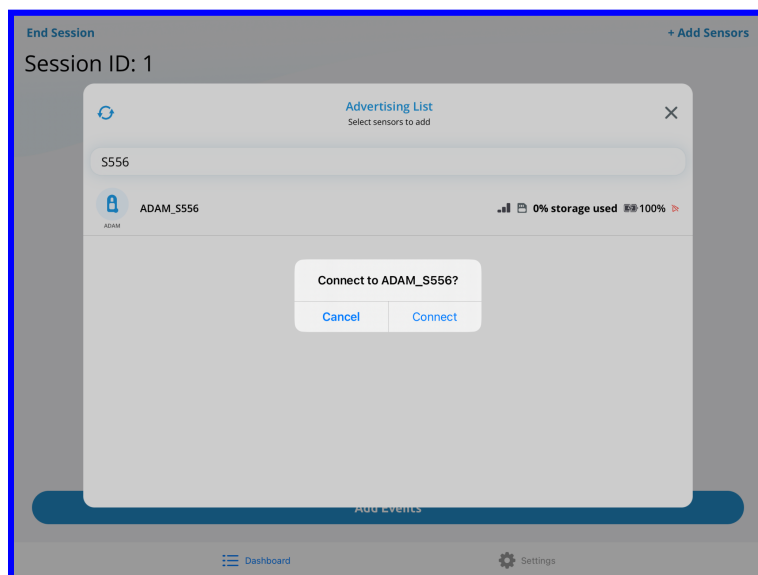
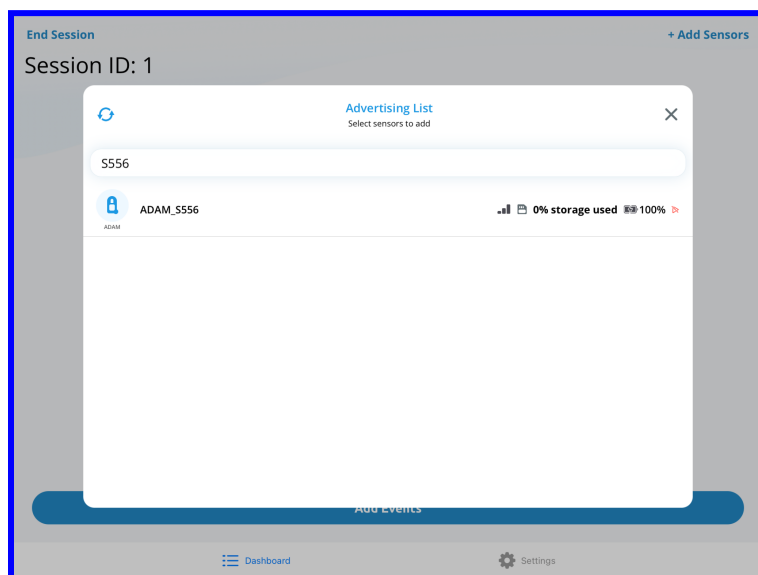
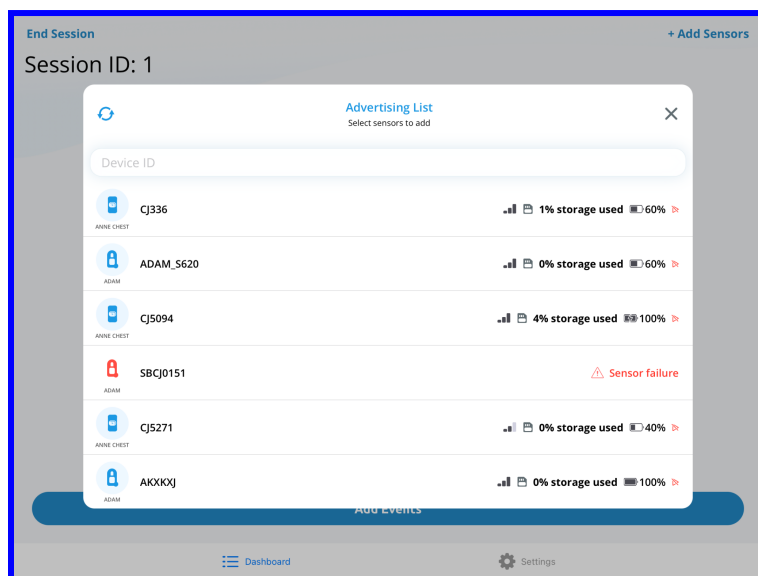
Press “+ Add Sensors” on the top right corner to bring up the advertising devices list window, which displays all Discovery Sensors currently advertising.

You can search for a specific sensor to connect with by typing the serial number of the sensor in the Device ID search bar on top of the window.

Click on the sensor and a window will display prompting confirmation to connect to the sensor. If prompted to pair the device via bluetooth, select “Pair”.

Up to 8 sensors can be paired at the same time, and can simultaneously collect data, while only one can stream at a time.

Note: The sensor must be within 2 meters of the tablet to pair. Do not attempt to connect to any devices that you do not recognize and are not included with the system.



Section 4. Applying and Removing the Sensor

This section describes the steps needed to apply the Discovery sensors to the subject.

The following application instructions include best practices Sibel has found for sensor wear to prevent skin irritation and ensure sensor adhesion to the skin. Some steps may not be necessary for users that have good adhesion of the sensors and users may not experience skin irritation even if not following all steps.

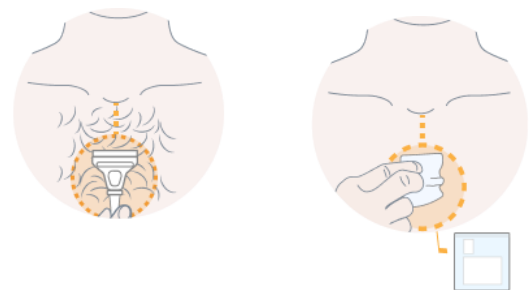
Best practices for all sensor wear:

- Sensors should be applied to healthy, intact skin only. A sensor should not be applied to skin that is broken, damaged, diseased or irritated.
- Users should utilize an IPA cleaning wipe on the site of sensor placement and let it completely dry (30 seconds) prior to putting on the sensor.
- Users should be advised not to use hydrating soaps or lotion at the site of sensor wear.
- If skin irritation occurs, the user should remove the sensor and inform the researcher. The site of irritation can be gently cleaned with unscented soap and water and have lotion applied. Irritation usually subsides within 24 hours of sensor removal.
- Users that experience poor adhesion of the sensors may benefit from gentle skin cleansing and exfoliation at the site of sensor wear.
- If foreign matter sticks to the Adhesive prior to use, discard it and apply a new one.
- Damaged sensors should not be used and should be returned to Sibel for replacement.

4.1 Applying the ANNE Chest Sensor

4.1.1. Preparing the Chest Area

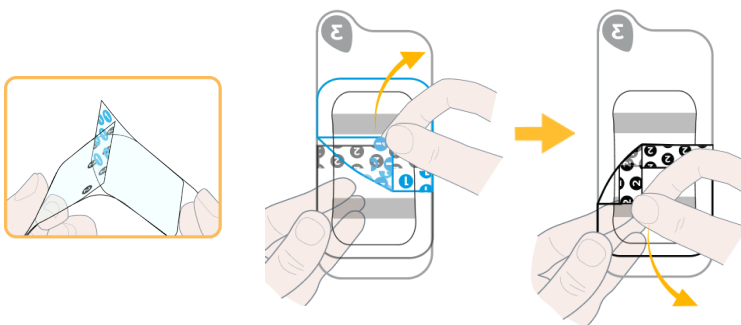
Prep the skin at the location of the Chest Sensor application site, which is directly under the collarbones on the sternum. First, shave any hair. Then use an IPA cleaning wipe to gently scrub away any lotion, oils, previous adhesives, dirt, dead skin, etc. Proper skin prep will improve sensor adhesion and signal quality.



4.1.2. ANNE Chest Adhesive Preparation

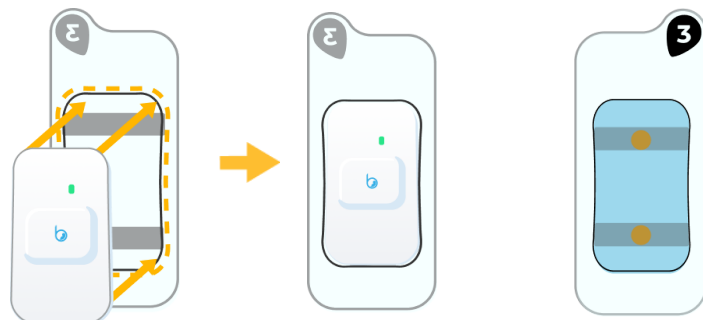
Step 1

Remove the Chest Adhesive from the pouch. Orient it so that the liners labeled "1" and "2" are facing towards you, then peel the "1" liner from the center, followed by "2".



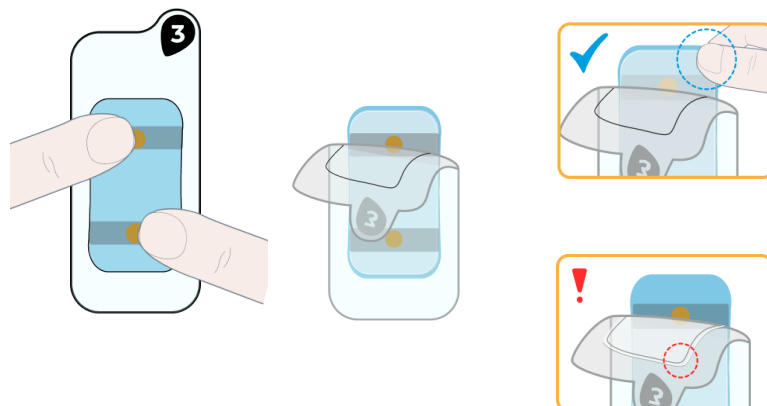
Step 2

Orient the ANNE Chest sensor with the logo facing towards you, and attach the back side of the chest sensor to the adhesive gel area. Then, gently press the adhesive to ensure that it properly adheres.



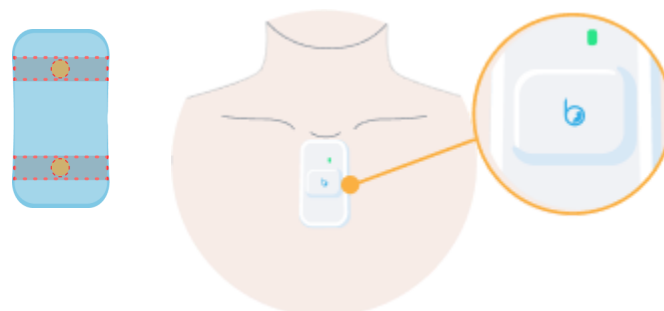
Step 3

Flip the sensor over and check that the gray stripes on the adhesive are aligned with both gold plates on the sensor. Then remove the clear liner labeled "Step 3" from the adhesive. Hold the adhesive on the sensor while peeling.



4.1.3. Placing the ANNE Chest Sensor

Position the sensor upwards facing away from you and with the Sensor ID and letter "b" of the **logo oriented up**. Place the ANNE Chest sensor directly underneath the collarbones, with the very top of the sensor/adhesive meeting the bottom of the suprasternal notch. Gently apply pressure on the top and bottom parts of the sensor when placing it to make sure it is stuck on correctly.

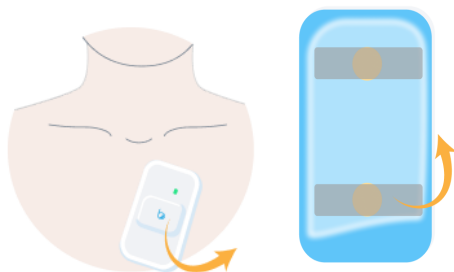


Note: The temperature module is directly under the lower gold plate of the sensor.

4.1.4. Removing the ANNE Chest Sensor

Step 1

Gently remove the ANNE Chest Sensor from the skin by peeling it off slowly. Gently peel the ANNE Chest Adhesive from the sensor and discard it.



Step 2

Gently wipe away any residual adhesive from the skin with an IPA cleaning wipe or a damp cloth



Step 3

Wipe the front and back of the sensor with an IPA cleaning wipe.



Step 4

Check that the sensor is clean and repeat the cleaning process until it is visibly clean.

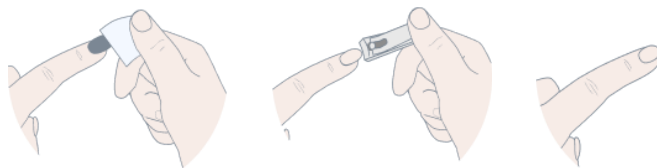
Step 5

Inspect the sensor for damage and return it to the wireless charger so it can sync data.

4.2 Applying the ANNE Limb Sensor

4.2.1. Preparing the Index Finger

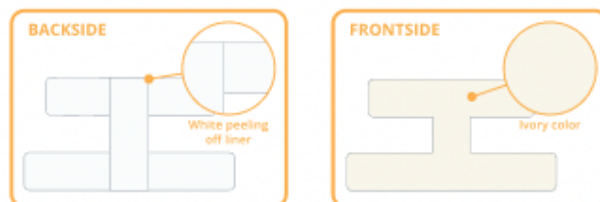
Remove any nail polish and clip the nail to a short length. The ANNE Limb sensor will not be able to fit if the nails are too long.



4.2.2. ANNE Limb Sensor Placement

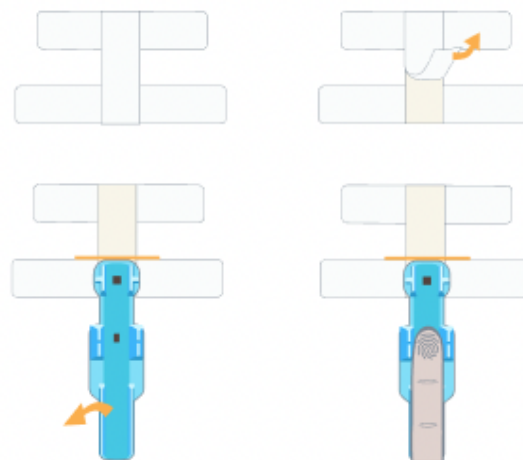
Step 1

Lay out the ANNE Limb Adhesive with the white side facing up. Peel off the middle section of the liner.



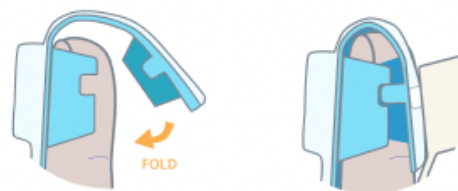
Step 2

Place the limb sensor with the ivory-colored side facing up as shown, with the top of the sensor lining up with the top edge of the bottom wing of the adhesive in the center. Place the finger onto the sensor so that the top is level with the extrusions with the notch, and ensure that the nail is facing down, covering the bottom square window.



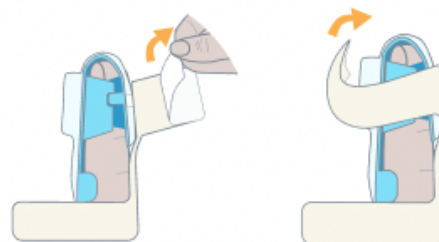
Step 3

Fold the top of the sensor along with the adhesive over the fingertip. Make sure that the notches and bumps on the side of the sensor fit together.



Step 4

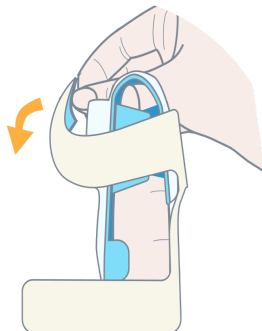
Remove the white liners from the longer wings of the adhesive and wrap them around the bottom of the finger. Repeat with the shorter wings on top.



4.2.3. Removing the ANNE Limb Sensor

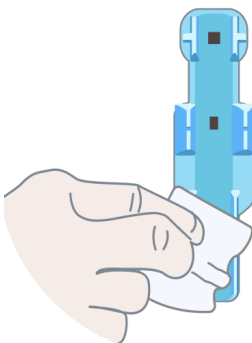
Step 1

Unwrap the ANNE Limb Adhesive, first peel off the lower wings, and then the upper wings.



Step 2

Remove the limb adhesive from the sensor and discard it. Sanitize the sensor with an IPA wipe.



Step 3

Adhesive residue on the fingernail is common. You can wipe it off using the cleaning wipe.

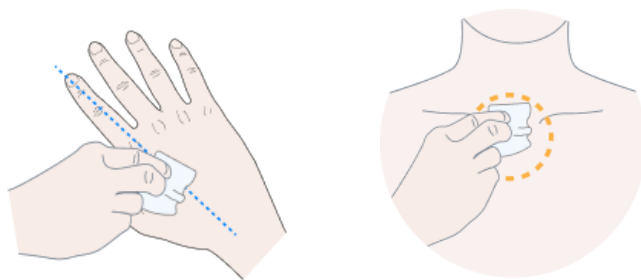
Step 4

Inspect the sensor for damage and return it to the wireless charger so it can sync data.

4.3 Applying the ADAM Sensor

4.3.1. Preparing the Application Site

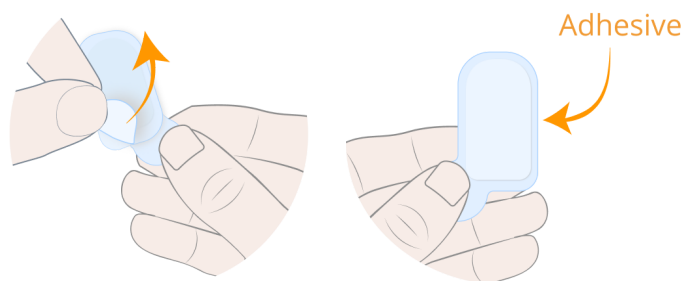
The ADAM Sensor can be applied to the suprasternal notch, the back of the hand, and other body parts. Shave any hair and then clean the target site if necessary to ensure proper adhesion.



4.3.2. ADAM Adhesive Preparation

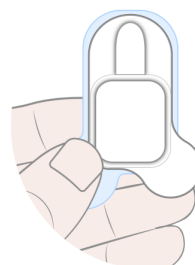
Step 1

Peel off one side of the clear liner by the flap and expose the adhesive attached to the remaining liner.



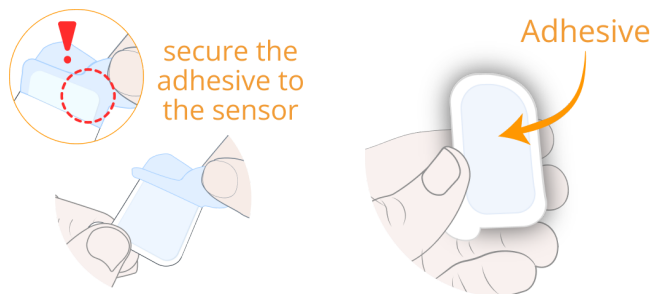
Step 2

Attach the ADAM Sensor to the adhesive, orienting the tab on the ADAM Sensor on the opposite side of the flap on the adhesive.



Step 3

Peel off the remaining adhesive liner, leaving the adhesive attached to the ADAM Sensor. Hold down the adhesive if necessary.



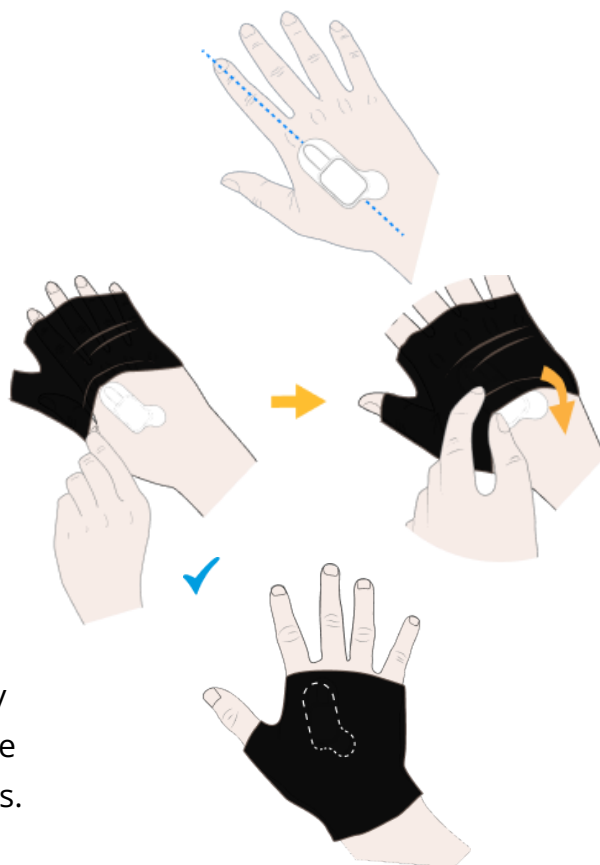
4.3.3. Placing the ADAM Sensor

Placing the ADAM Sensor on the Hand:

Align the ADAM Sensor with the center of the index finger and place it just below the knuckle, applying pressure to ensure proper adhesion. Line up the top of the sensor with the index finger.

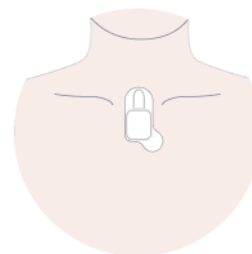
It is highly recommended to use the provided glove over the sensor to ensure sensor adhesion. Put on the glove by sliding it over the hand, making sure to pull the glove over the sensor.

Gloves can be machine washed by subjects (on cold temperature) and reused as many times as needed by that study subject. Once returned, dispose of the glove and replace it with a new glove for future deployments.



Placing the ADAM Sensor on the Suprasternal Notch:

Align the ADAM Sensor vertically between the two collar bones and press down to ensure proper adhesion.



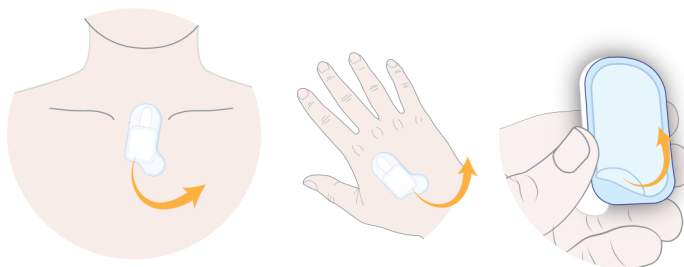
Placing the ADAM Sensor on Other Body Parts:

The ADAM Sensor may be attached to other areas on the body. For best adhesion, remove any hair at and around the sensor location, clean area prior to attaching the sensor. Some sensor locations may require an additional oversensor solution such as another adhesive or wrap to keep the sensor secure if it rubs against clothing or other areas of the body. Ensure it is placed in a method compatible with data collection needs. If you would like more recommendations on sensor wear in other areas of the body, please contact SibEL to discuss.

4.3.4. Removing the ADAM Sensor

Step 1

Gently remove the ADAM Sensor from the skin by peeling it off slowly using the tab on the bottom of the device. Gently peel the ADAM Adhesive from the sensor and discard it.



Note: Make sure to always remove the ADAM Sensor by pulling on the bottom tab, this impacts the long term reliability of the sensor.

Step 2

Gently wipe away any residual adhesive from the skin with an IPA cleaning wipe or a damp cloth.



Step 3

Wipe the front and back of the sensor with an IPA cleaning wipe.



Step 4

Check that the sensor is clean and repeat the cleaning process until it is visibly clean.

Step 5

Inspect the sensor for damage and return it to the wireless charger so it can sync data.

Section 5. Data Collection

This section describes the process for viewing live streamed data from the sensor and then collecting data using the Discovery RA app.

5.1 Viewing Data Streaming

From the dashboard, press the right arrow on the sensor row to display the live data stream, as well as sensor options.

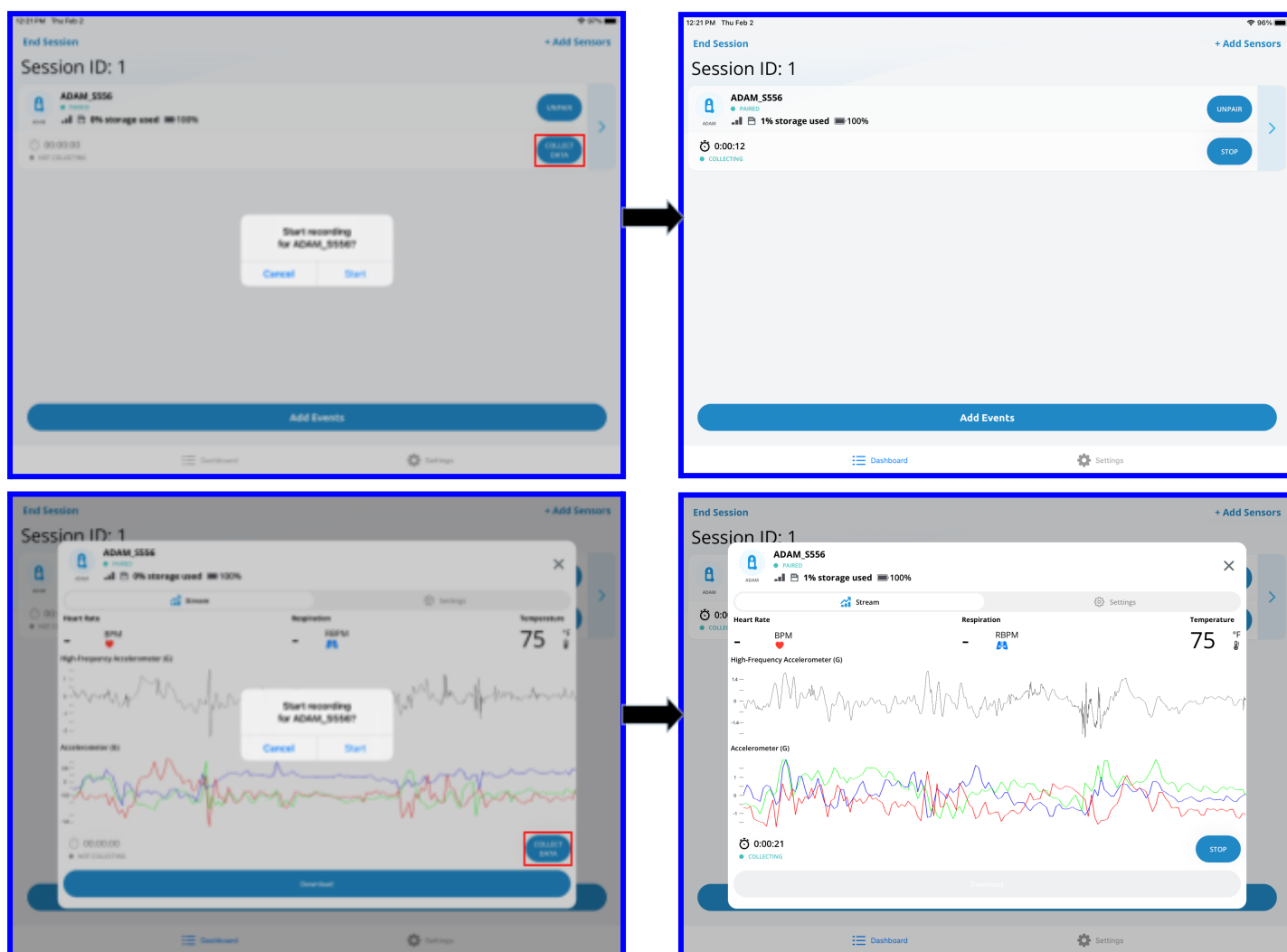
Click on the “Stream” section to view the sensor data being live streamed to the tablet. The type of data displayed will depend on the capabilities of the sensor.



5.2 Starting a Data Collection Session

If the sensor is configured to “manual” mode, data collection must be manually initiated. On either the main dashboard or the streaming window, press “Collect Data”. You will then be prompted to confirm, select “Start”. Once started, data will be recorded and saved to the memory on the sensor. Repeat the process with each connected sensor you wish to record data with. You can view the session duration via the clock on the lower left hand side of both the dashboard and the streaming window. Note that if the sensor is configured to “automatic” mode, it will automatically start recording data once it is removed from the Wireless Charger.

Note: If using sensors that have a time sync configuration, start data collection on the “Tx” sensor first, and then the “Rx” sensor(s).

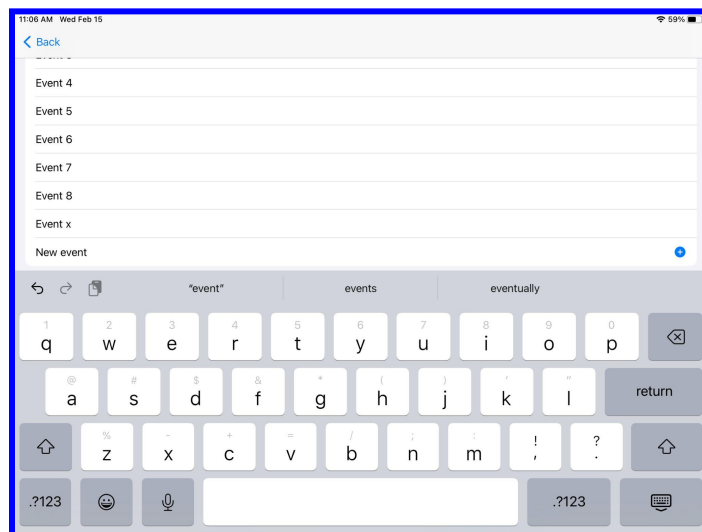
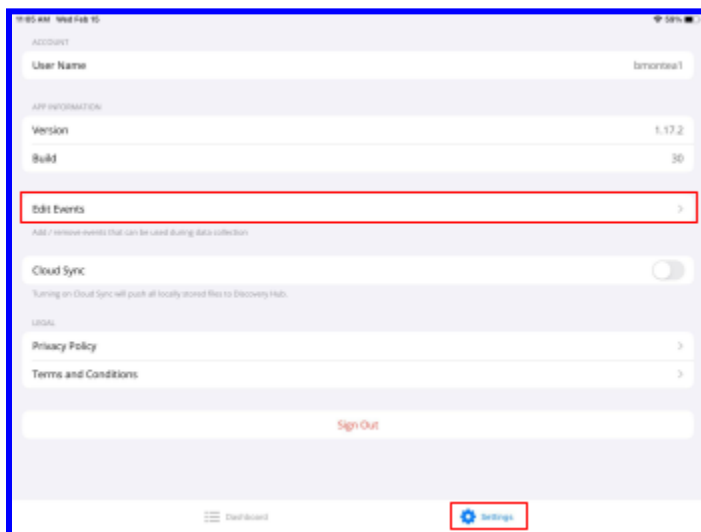
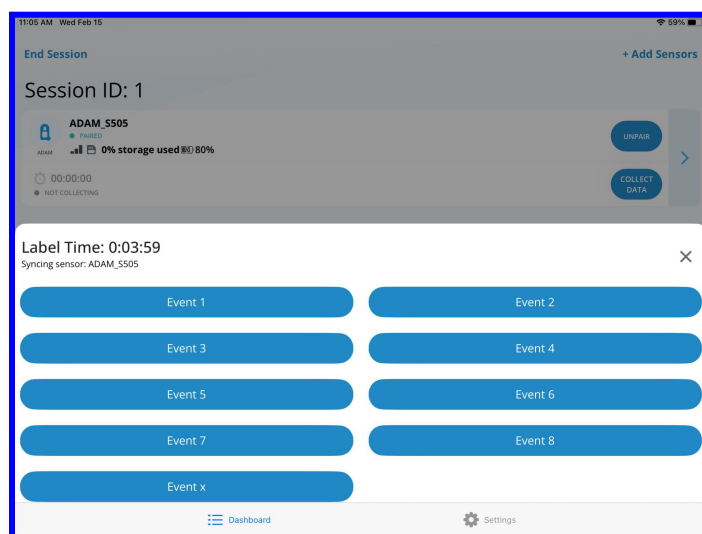
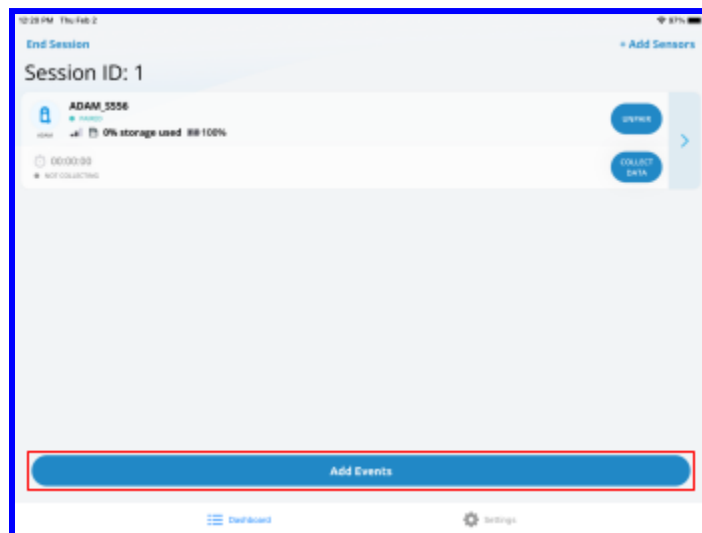


5.3 Marking and Adding Events

Discovery RA allows users to label “Events”. Use events to mark specific occurrences of interest throughout data collection. These are tracked in a separate csv file that notes the epoch times at which the event occurred. This file can be downloaded alongside the collected data.

To record an event during data collection, Click “Add Events” on the bottom of the dashboard. Then, press the button corresponding to the correct event and it will be logged.

To add new events as options to mark, click on the Dashboard settings page and click “Edit Events”. There, type in a new event on the bottom of the event list and press “+”. The new event will now be displayed under the event list.



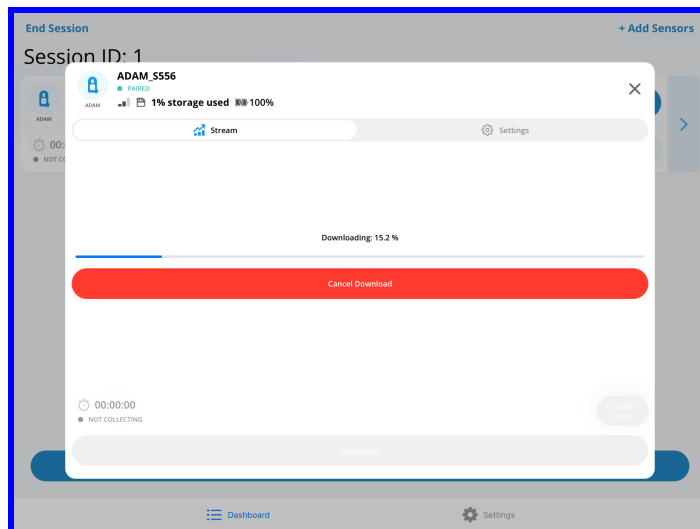
5.4 Ending a Data Collection Session and Downloading Data

If the sensor is configured to “manual” mode, data collection must be manually stopped. Press “Stop” on either the dashboard to stop all actively recording sensors or the streaming window of an individual sensor to end data collection. Press “Stop” once prompted to confirm on the popup window. Once confirmed, the sensor will stop recording data. It is advised to place the sensor on the wireless charger while downloading.

If the sensor is configured to “automatic” mode, data collection will automatically stop once the sensor is returned to the Wireless Charger, and the download must be initiated while the sensor is on the Charger.

To download the data stored on the sensor to the tablet, navigate to the streaming window and press “Download” on the bottom of the screen.

Once the download is complete, the sensor’s memory will be cleared. The binary data file will now be stored on the tablet.



Section 6. Discovery RA App Alert Handling

This section describes troubleshooting steps to take when facing errors in the Discovery RA App.

6.1 Sensor Alert Messages & Handlings

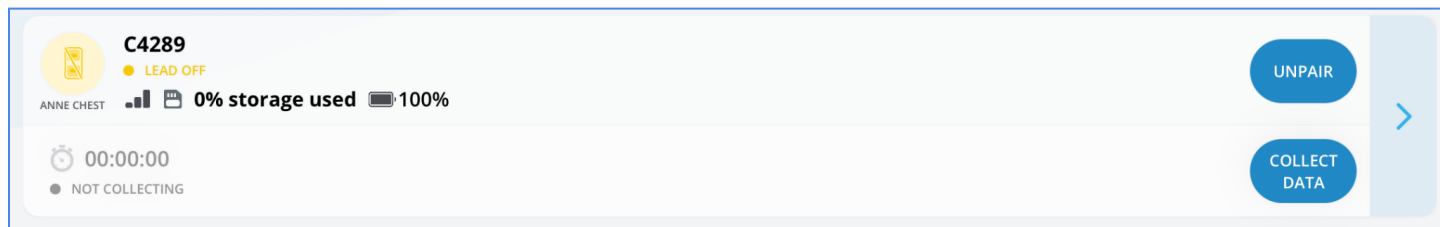
This section includes the resolution procedures for the following issues:

- Lead Off (ANNE Chest Sensor)
- Poor Skin Contact (ANNE Limb Sensor)
- Sensor Out Of Range
- Low / Critical Battery Level
- Low / Critical Memory Storage Level
- Sensor Failure

All of these error states will be represented on the user interface. Each error has a specific icon to indicate different meanings. Being familiar with the icon glossary table in [Section 6.2](#) with the descriptions and recommended user action is necessary to quickly solve the problem for future use.

6.1.1. Lead Off (ANNE Chest Sensor)

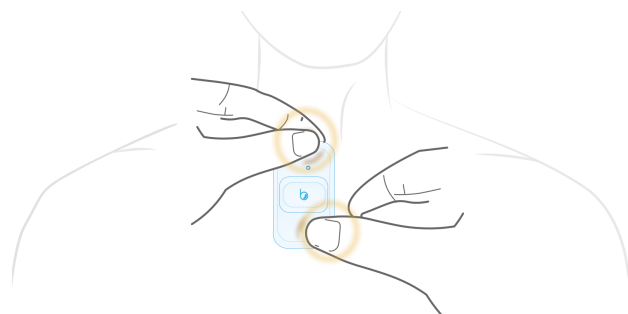
If the ANNE Chest Sensor is not detecting good skin contact, then a “Lead Off” alert will be displayed in the sensor status section of the sensor list. **If recording data while in Automatic Mode and the Lead Off is not resolved within 30 minutes, the ANNE Chest Sensor will stop automatically recording data until it detects proper skin contact.**



Solution

Option 1

Readjust the sensor placement to ensure that it is properly attached. Gently apply pressure on top of the sensor over the electrodes.



Option 2

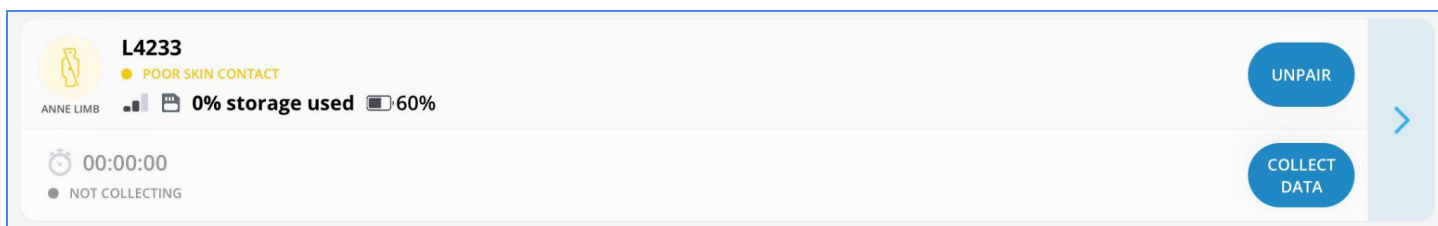
If the first step does not work, replace the Chest Adhesive.

Option 3

If there is still an alert after replacing the ANNE Chest Adhesive, then replace the sensor.

6.1.2. Poor Skin Contact (ANNE Limb Sensor)

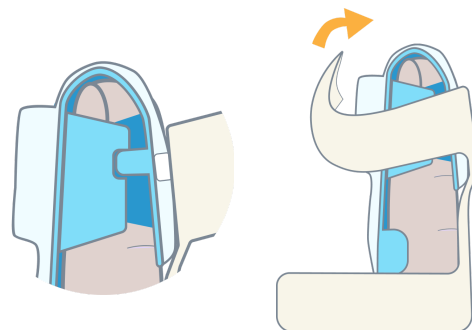
If the ANNE Limb Sensor is not detecting good skin contact, then a “Poor Skin Contact” alert will be displayed in the sensor status section of the sensor list. **If recording data while in Automatic Mode and the Poor Skin Contact is not resolved within 30 minutes, the ANNE Limb Sensor will stop automatically recording data until it detects proper skin contact.**



Solution

Option 1

Readjust the ANNE Limb Sensor and Limb Adhesive location to ensure that it is properly attached. Check that the notch and bump on the side of the sensor are aligned.



Option 2

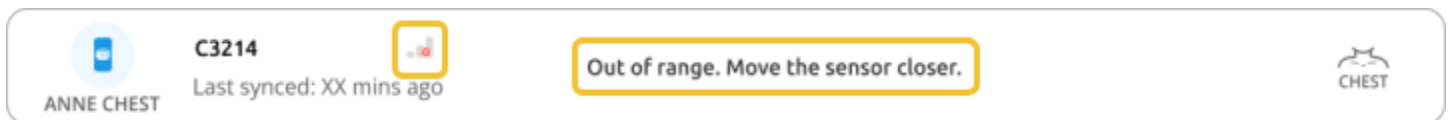
If the first step does not work, replace the Limb Adhesive.

Option 3

If there is still an alert after replacing the ANNE Limb Adhesive, then replace the sensor.

6.1.3. Sensor Out of Range

If the sensor is not detected nearby, then an “Out of Range” alert will be displayed in the sensor status section of the sensors list. The application will automatically attempt to reconnect to the sensor after the signal is detected.



If the sensor is out of range

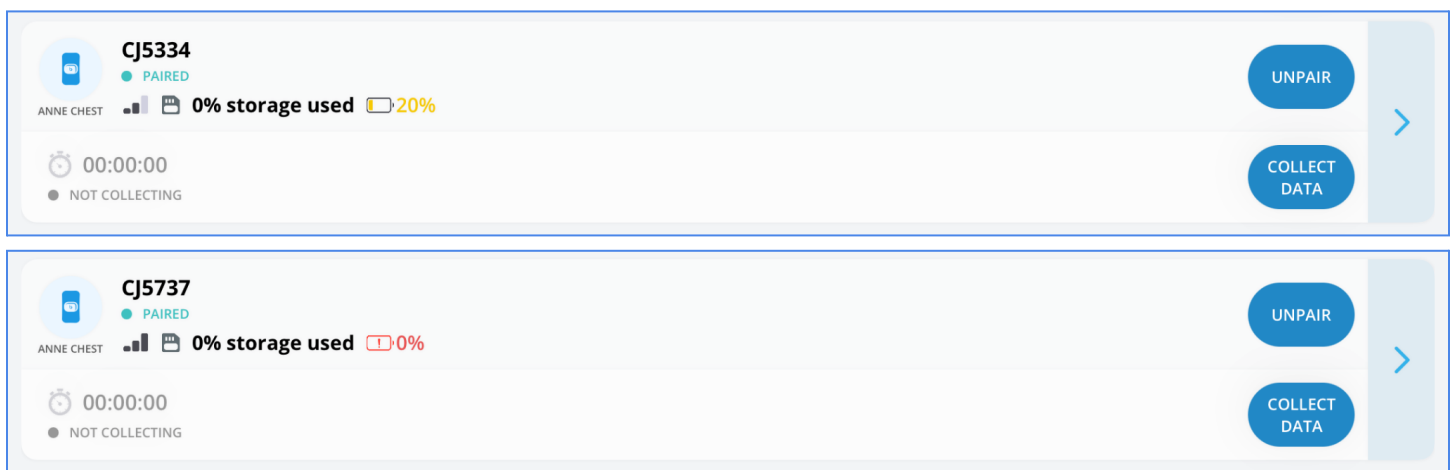
Bring the tablet and sensor closer together. Make sure there is no physical barrier between the sensor and the tablet (e.g. a wall). After they are close to each other, the App will automatically attempt to reconnect to the sensor.



6.1.4. Low / Critical Battery Level

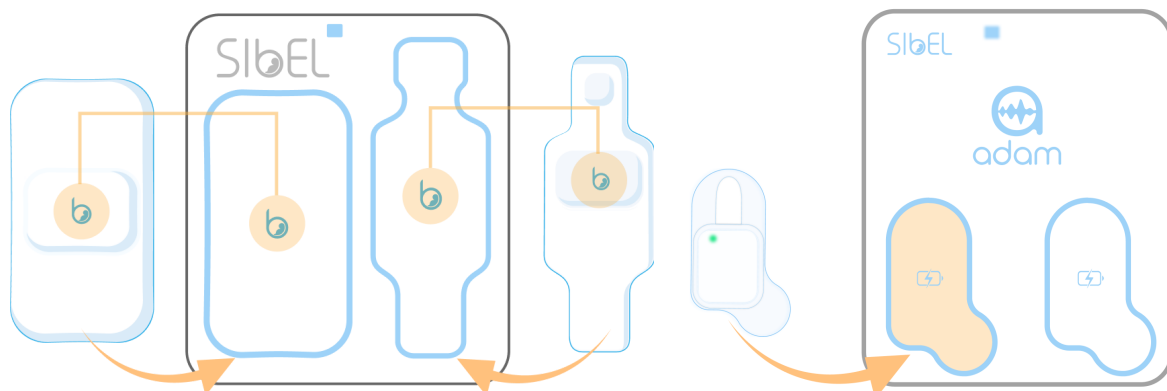
If the sensor has a low battery, then the battery icon displayed in the sensor status screen of the sensor list will turn yellow. The alert will show up when the battery level of the sensor has fallen to 20% or below.

If the sensor battery level has fallen below 5%, the “Critical Battery” alert will show up. **This is a high-priority issue, so please address the problem IMMEDIATELY if there is a “Critical Battery” warning.** A sensor with a completely depleted battery may also fail to function and connect by bluetooth (Out of Range) until recharged.



If the sensor has a low or critical battery,

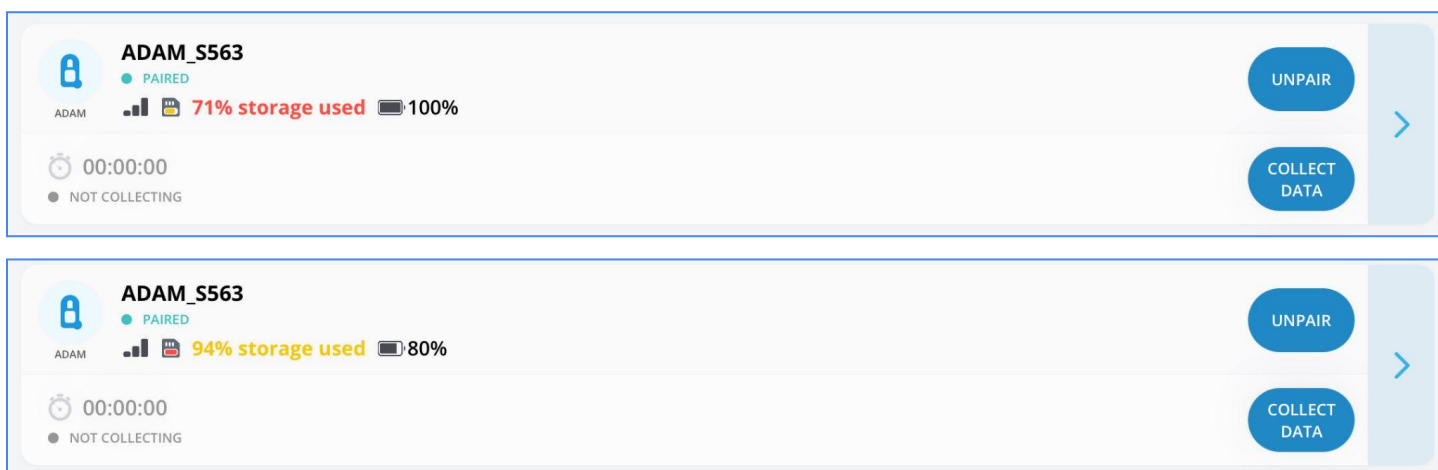
- Remove the Discovery Sensor from the Subject and pause or stop data collection.
- Clean the sensor using an IPA cleaning wipe.
- Check that the sensor is clean and repeat the cleaning process until it is visibly clean .
- Charge the sensor on the wireless charger.
- Once the sensor is charged, you can continue collecting data.



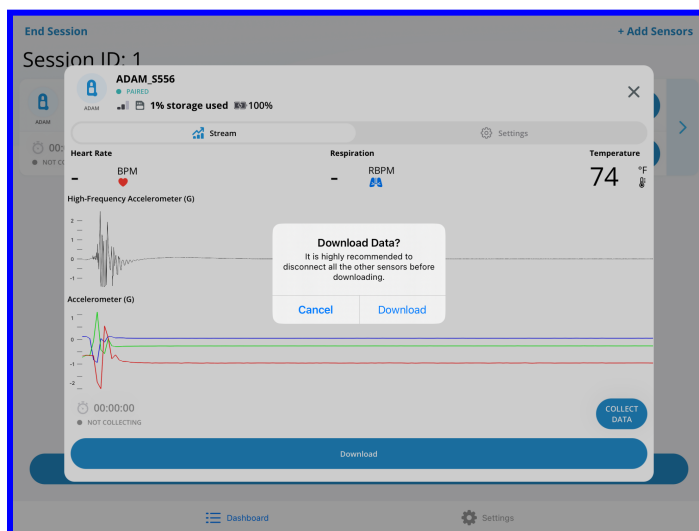
6.1.5. Low / Critical Memory Storage Level

If the sensor's storage is nearly full, then the memory icon alert will be displayed in the sensor status screen of the sensor list. The alert will show up when the storage of the sensor is more than 70% full.

If the sensor's storage is more than 90% full, the "Sync needed immediately" alert will show up. **This is a high-priority issue, so please address the problem IMMEDIATELY if there is a "Sync needed immediately" warning. A sensor that has reached 100% capacity will no longer collect data.**

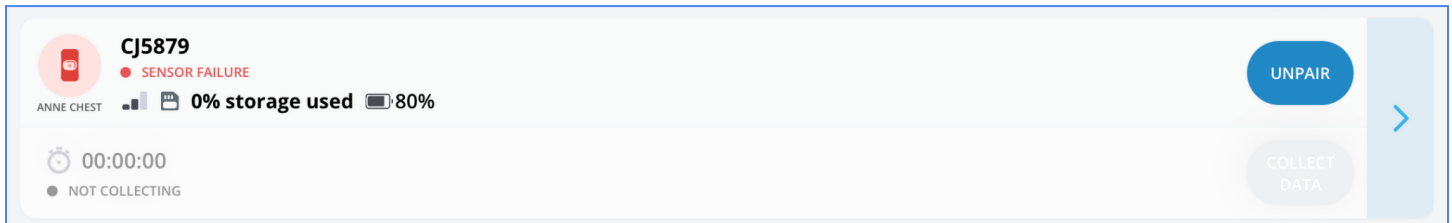


If the sensor has low or critical storage, download the data from the sensor. First, stop the data collection session and place the sensor on the wireless charger. Then, navigate to the streaming window and press "Download" to download the data onto the tablet. Note that the app must be open and the sensor must be connected. Alternatively, reset the memory by pressing "Reset Memory" in the options window (As explained in [Section 7.5](#)).



6.1.6. Sensor Failure

The “Sensor Failure” Alert appears in the sensor status screen of the sensor list when the Discovery sensor reports a sensor failure. **A “SENSOR FAILURE” warning indicates that the sensor will not function appropriately for wear or data collection.**



If there is a sensor failure,

- Notify Sibel Health of the sensor failure issue and request a replacement sensor.
- Take off the current sensor and replace it with a new sensor.

Note: Only the failed sensors need to be replaced.

6.2 Sensor Alert Icon Glossary

Alert Icon	Alert Name	Alert Description	Recommended User Action	Priority Level
	Lead off / Poor Skin Contact	Sensor is not detecting good contact with the skin (ANNE Chest and ANNE Limb Only).	1. Press the sensor to ensure the sensor is properly attached. 2. Adjust the sensor placement. 3. Replace the sensor adhesive. 4. Switch the sensor.	Medium
	Sensor failure	Sensor has reported a sensor failure. The sensor should be replaced immediately.	Replace the sensor with a functional one, contact Sibel for a replacement.	High
	Low sensor battery	Battery of the sensor has fallen below 20%. There is less than five hours of battery life remaining.	Place the sensor on the charger.	Medium
	Critical sensor battery	Battery of the sensor has fallen below 5%. There is less than one hour of battery life remaining.	Switch the sensor and put it on the charger.	High
	Sensor out of range	Sensor is not detected nearby. Data download will not be available. The application will automatically attempt to reconnect to the sensor after the signal is detected.	Bring the sensor closer to the tablet (Within 1 meter). Place the sensor on the charger to make sure it is on and charged (Only if not wearing the sensor).	Low
	Low Memory Level	Storage of the sensor is more than 70% full.	Download the data from the sensor to clear the storage.	Medium
	Critical Memory Level	Storage of the sensor is more than 90% full.	Download the data from the sensor to clear the storage.	High

Section 7. Miscellaneous Sensor Actions and Settings

This section outlines additional sensor-related actions that can be taken in the Discovery RA App on individual sensors in the Settings window.

Navigate to the Settings window by clicking the > for the selected sensor and view the available sensor actions. See the following sections listed for details on each action.



7.1 Changing Session Mode

Click "Change Session Mode" to change the sensor from manual mode to automatic mode or vice versa. In automatic mode, data collection will be initiated automatically when off the charger and will only end once the sensor is returned to the charger and will begin to sync data automatically. See [Appendix A](#) for more details on how this relates to configuring the sensor for use with the separate Discovery App.

Note: Make sure that no data is being collected when switching modes. For manual mode, stop data collection from the app before switching. For automatic mode, place the sensor on the charger before switching.

7.2 Changing Radio Mode

Click “Change Radio Mode” to change the sensor from Tx mode to Rx mode or vice versa. These modes control the time sync function of the sensors. All Rx sensors will sync their clocks when collecting data to the Tx sensor, syncing data as it is collected. As such, there can only be one Tx sensor and multiple Rx sensors when collecting time-synced data with multiple sensors. If data is collected on multiple sensors that are independent of each other and the data does not need to be time-synced, then Tx mode should be used on both sensors.

Note: Sibel configures Tx and Rx modes before shipping the sensors, so only use this if changes to the data collection procedures are required.

7.3 Resetting the Sensor Memory

Click “Reset Memory” to delete any data remaining on the sensor. Click “Reset” on the pop up window to confirm.

Note: Resetting the memory will permanently delete the data from the sensor! Make sure that all data has been downloaded before resetting the sensor’s memory.

7.4 Activating Low Power Mode

For ANNE Chest and ANNE Limb Sensors only, click “Low Power Mode” to change the sensor to Low Power Mode. The Green LED will blink three times and then switch modes. In this setting, the sensor will stay connected to Discovery RA but will not collect or stream data. To return the sensors to normal, place the sensors on the charger.

Note: Do not activate Low Power Mode on an ADAM sensor, it is not compatible.

7.5 Turning the Sensor LED On/Off

Click “Turn On LED” to activate the Green LED of the sensor, it will stay on until the “Turn Off LED” button is clicked, which will deactivate it.

7.6 Resetting Module Status

Click “Reset Module Status” to reset the functions of each individual module. This is usually used if any one module experiences a failure. Note that this is not a guaranteed fix and it is advised to refrain from pushing a module reset unless advised by Sibel.

7.7 Placing the Sensor in Ship Mode

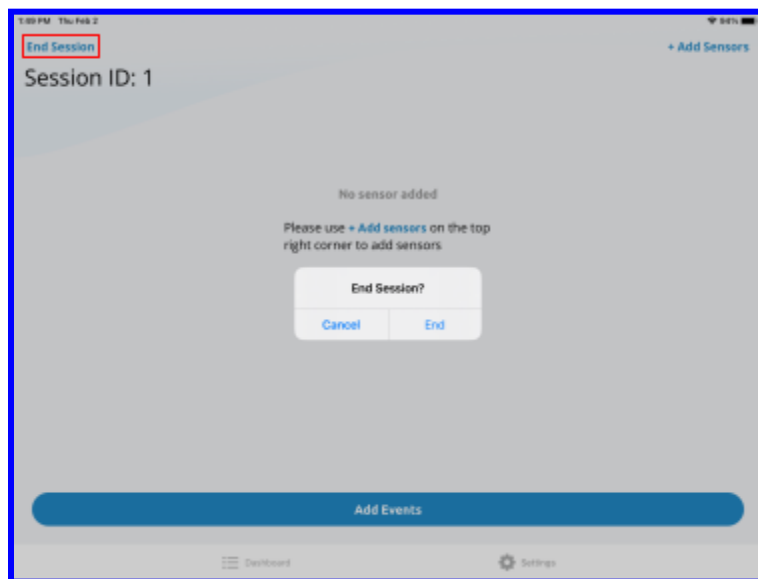
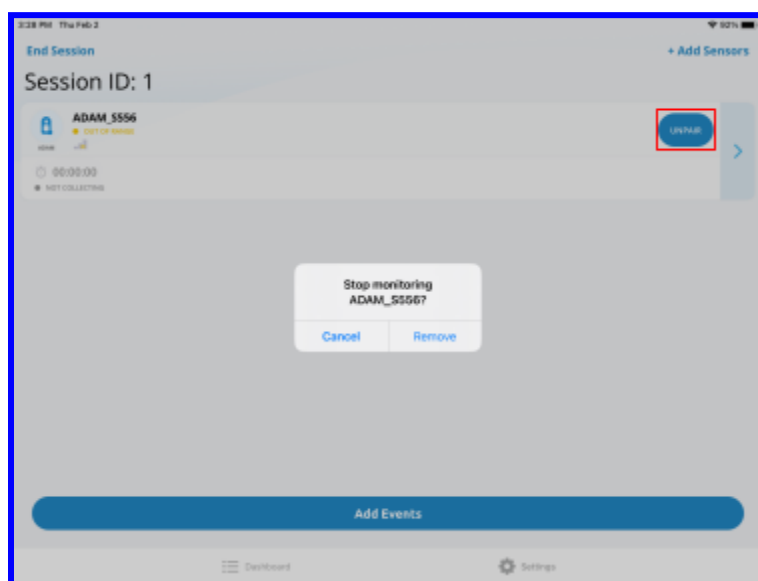
Click “Ship Mode” to turn the sensor off. Note that the sensor needs to be removed from the charger to be placed into ship mode. After being placed in ship mode, the sensor will not advertise to the Discovery RA app until it is placed on the charger to wake it up. Click “Yes” to confirm.

7.8 Unpairing the Sensor

Click “Unpair” on the main dashboard screen to unpair the sensor, then click “Remove” to confirm.

7.9 Ending the Session

Click “End Session” on the top left corner of the screen to log out of the current session and return to the “Start a Data Collection Session” screen.



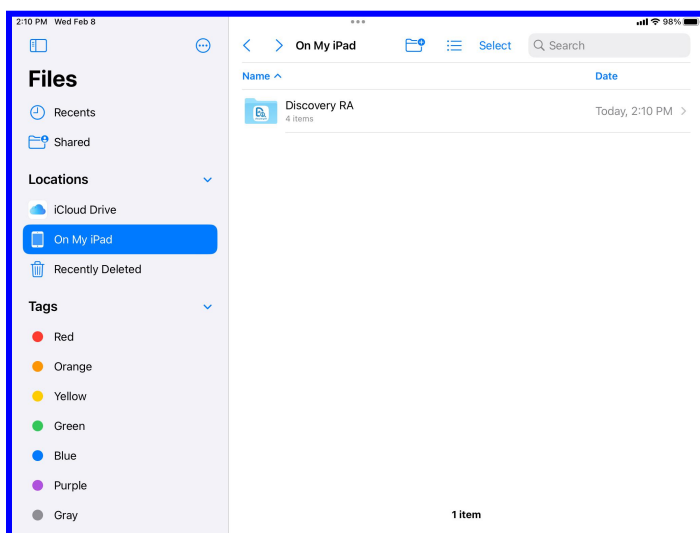
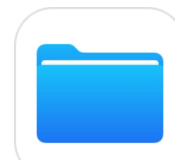
Section 8. Data Retrieval and Processing

This section outlines how to access and process data collected using the Discovery RA App.

8.1 Accessing the Data on the Tablet

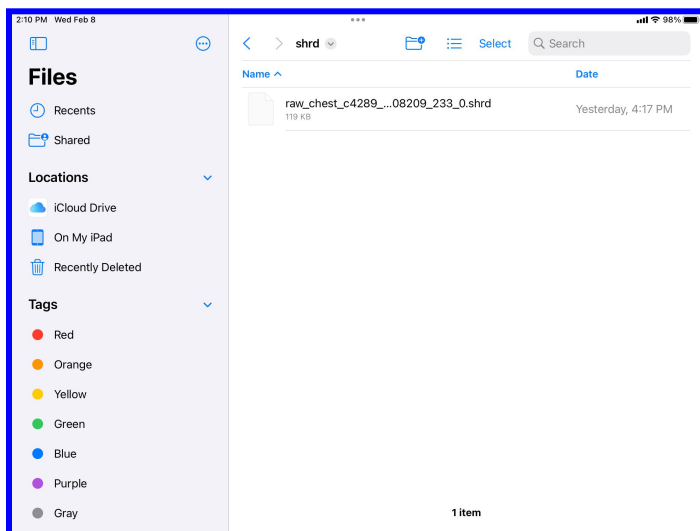
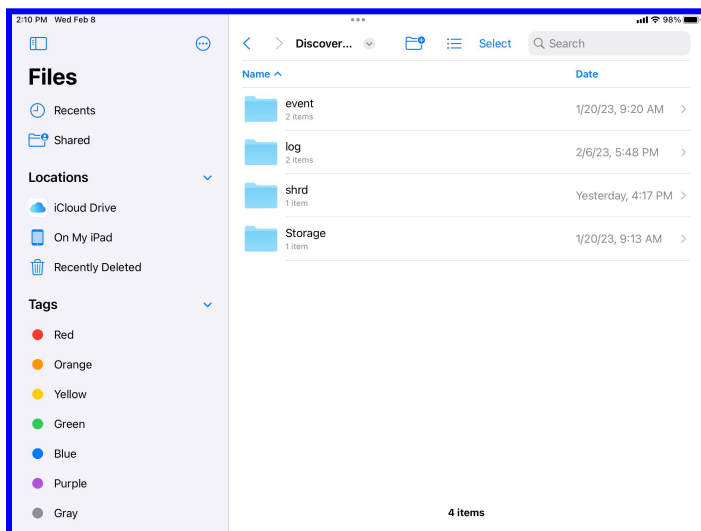
Navigate to the “Files” App on the tablet. Click on the “Discovery RA” Folder. In there, you will see four folders: “event”, “log”, “shrd”, and “Storage”. From these folders, the files can be retrieved via AirDrop or iTunes. Note that items in the “Storage” folder can be ignored.

Enter the “shrd” folder to view the downloaded raw data files (shrd is a Sibel Health Research Data binary file). Note that the shrd files must be processed using Sibel’s data parser (as explained in [Section 8.2](#)) to see the data.



The shrd files are named as follows:

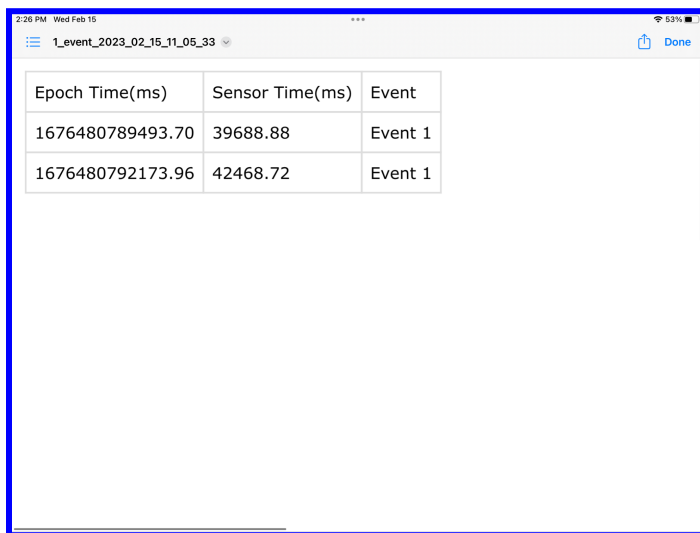
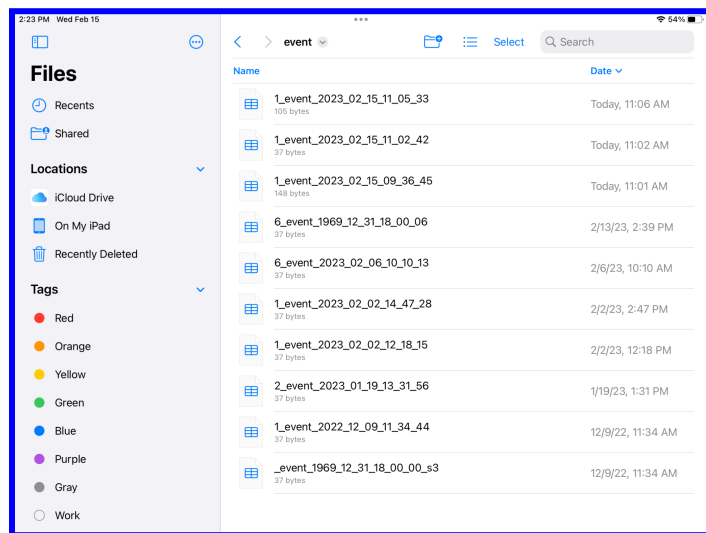
raw_[Sensor Type]_[Serial Number]_[Session Start Time]_[Data Recording Start Time]_[Session Number]_0.shrd



Enter the “event” folder to view csv files which contain the epoch time, the sensor time, and the type of event that was logged during data collection (as explained in [Section 5.3](#)). The epoch times in the event file are synchronized to the sensor data timestamps.

The event files are named as such:

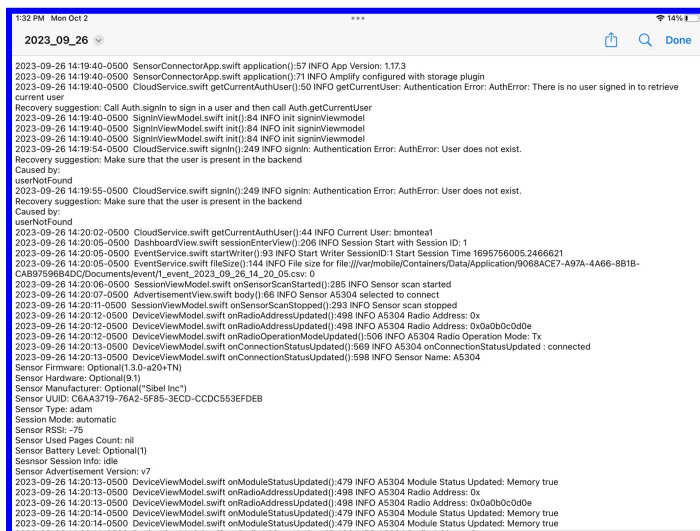
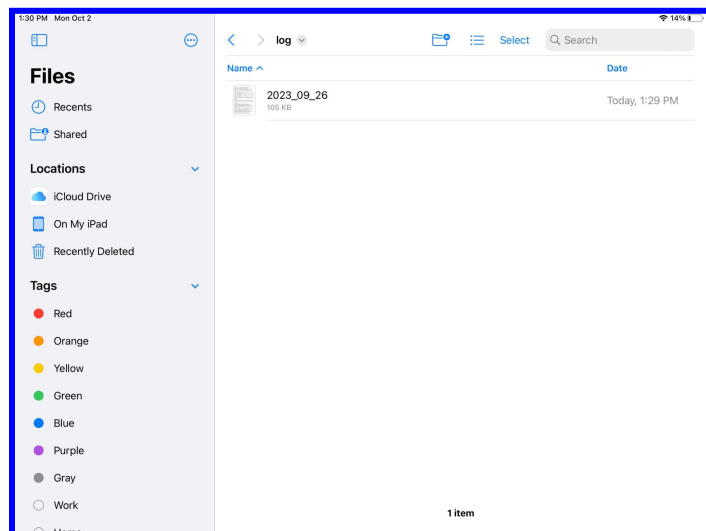
[Event Title]_[Year]_[Month]_[Day]_[Hour]_[Minute]_[Second].csv



Enter the “log” folder to view text files that track every action that occurred while using the app, allowing users to filter through the App’s history if needed.

The log files are named as such:

[Year]_[Month]_[Day].log

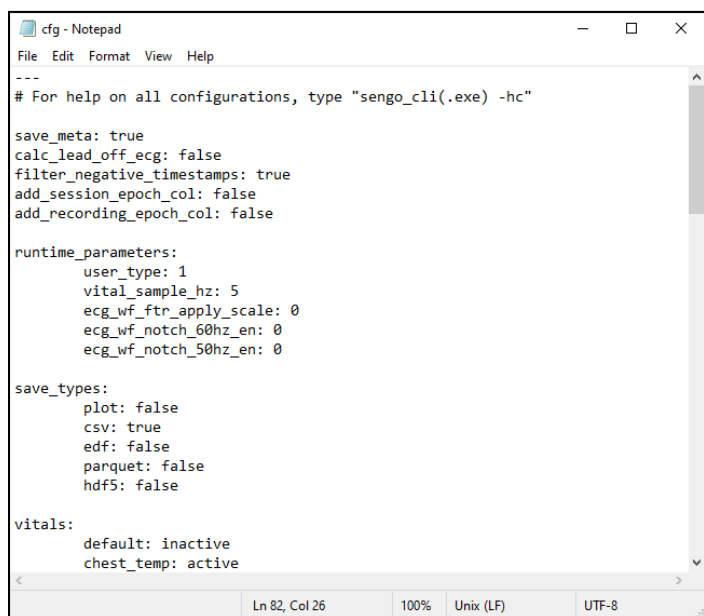


8.2 Processing the Data Using the Parser

To process the shrd file data, Sibel will provide a parser that will convert the shrd files to readable csv files and process other usable outputs. The parser has versions compatible for Windows, OSX, and Linux. Sibel will provide the parser for the proper operating system via a zip file. Unzip the file and you will see the parser executable and a Readme file. The parser is operated via command prompt. The Readme will provide instructions on how to use the parser, specific instructions for each operating system, and troubleshooting steps.

In addition, Sibel will provide a “config” file used by the parser: `cfg.yml`. By modifying parameters in this file with a text editor, you can change the output of the parser to meet your study needs.

To use the parser, open a command prompt and navigate to the folder containing the parser using the “`cd`” command plus the path. Place the shrd files to convert in the same folder.



```

---
# For help on all configurations, type "sengo_cli(.exe) -hc"

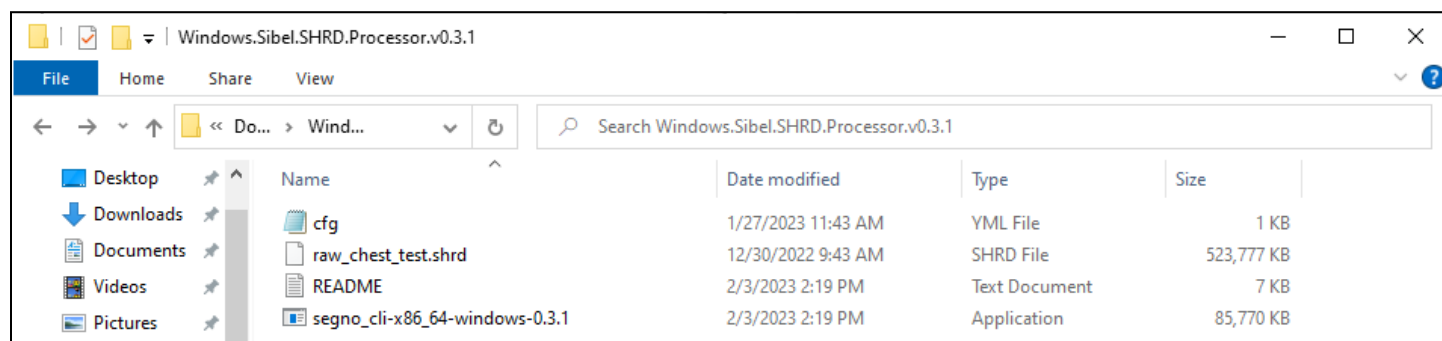
save_meta: true
calc_lead_off_ecg: false
filter_negative_timestamps: true
add_session_epoch_col: false
add_recording_epoch_col: false

runtime_parameters:
  user_type: 1
  vital_sample_hz: 5
  ecg_wf_ftr_apply_scale: 0
  ecg_wf_notch_60hz_en: 0
  ecg_wf_notch_50hz_en: 0

save_types:
  plot: false
  csv: true
  edf: false
  parquet: false
  hdf5: false

vitals:
  default: inactive
  chest_temp: active
  
```

```
cd C:\Users\<path>\Windows.Sibel.SHRD.Processor.v0.3.5
```



To see a list of all possible modifications to the config file, type the name of the parser followed by -hc to bring up the configuration manual. Follow the instructions to see all possible parameters that can be modified to generate the desired outputs.

```
Segno_cli-x86_64-windows-0.3.5 -hc
```

```
Segno Configuration Manual - Executable Version x86_64-windows-0.3.1

=====
This manual details the layout and parameters for the optional yaml configuration file.
To see the command line arguments rerun this executable with the option '-h'.
The format detailing how parameters and their values are described in this manual is listed below.
Format:
    parameter_name (acceptable values or datatype, {default value}): description
=====
Press v to toggle between verbose mode (currently active) and list mode at any time.
Press n to display the next message or q to quit at any time...
```

In addition, by entering the name of the parser followed by -h, you can bring up a manual that describes the available command line parameters and their operation. The command line parameters can also be viewed in the Readme file.

```
Segno_cli-x86_64-windows-0.3.5 -h
```

```
Sibel Processor Version x86_64-windows-0.3.1

segno_cli(.exe) [-v,--version] [-h, --help] [-hc --help-config]
                [-o, --output-dir <path>]
                [-n, --output-name <name>]
                [-c, --chest <path>] [-l, --limb <path>]
                [-cfg, --config <path>]

Optional arguments:
-h, --help          Show this help message and exit.
-v, --version       Show the processor version number and exit
-o, --output-dir    Set output directory (default: current directory)
-n, --output-name   Set name which is prepended to each output file (default: processed)
-c, --chest-dir     Set ANNE Chest or ADAM SHRD data directory for processing
-l, --limb-dir      Set ANNE Limb SHRD data directory for processing

-cfg, --config      Set the path to the config file for the CLI parameters
-hc, --help-config  Runs an interactive manual explaining the config file format and parameters.

Notes:
    At least one of --chest-dir or --limb-dir must be specified.
    If no config file is provided the configuration will match all default configuration values. Rerun
    with argument -hc for more information.
```

To initiate the processing, type:

- The name of the parser (Segno_cli-x86_64-windows-0.3.5)
- -cfg if you want to modify the output using the config file, and the path to the cfg.yml file
- -c for ANNE Chest or ADAM data, or -l for ANNE Limb Data, then the path to the shrd file
- -o to specify an output directory for the output file(s), and a path to that location
- -n to provide a specific name for the output file, and the output file name

Once finished, press enter and processing will begin. Note that the files will not appear in the output until all processing is complete, even if it displays "Processing Done!" or "CSV Done!" in the command window. Larger files may take several minutes to process.

```
Segno_cli-x86_64-windows-0.3.5 -cfg "<path>\cfg.yml" -c "<path>\[chest  
data]" -l "<path>\[limb data]" -o "<path>" -n "[title]"
```

```
Process Vital Signs..  
Vital Processing Done!  
Generating CSV...  
CSV Done!  
Generating CSV...  
CSV Done!  
Process Logs..  
Log Processing Done!
```

Section 9. Important Safety Information

This section describes important information related to safety regarding Discovery sensors.

9.1 Warnings

- Discovery Sensors may cause mild discomfort, skin irritation, redness, itching, rash, or contact dermatitis in some individuals. Histories of skin irritations should be considered prior to placing the sensors on a study subject. Sensors should be removed if any pain or discomfort occurs.
- Keep the wireless charger away from liquids . The sensors and tablet are splash resistant but are not waterproof. Do not submerge the sensors and avoid exposing the sensors to liquids for prolonged periods of time such as when bathing or showering.
- The sensors are NOT MRI safe  and should be removed prior to an MRI scan.
- The sensors are NOT defibrillator proof and should be removed prior to external defibrillation or cardioversion.
- Discovery Sensors should not be used in the presence of strong electromagnetic fields such as high frequency surgical equipment.
- WARNING - PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not use this device with pacemaker patients.

9.2 Precautions

- Discovery Sensors and adhesives are non-sterile.
- The adhesives are single-use only and should not be reused .
- Do NOT use this product if the silicone shell is damaged.  Return any broken or damaged devices to the manufacturer.
- Depending on wireless connectivity, temporary interruption of data sync is possible. Similar devices may cause signal interference during data transmission. If you experience this effect, avoid operating near interfering devices.

- Do NOT wear Discovery Sensors over regions of the body with excessive body hair. Excessive body hair should be shaved prior to wear. Adhesives should be applied to clean dry skin only. The site can be cleaned and prepped by gently scrubbing with an IPA cleaning wipe to remove loose skin, dirt, oils, lotions, etc prior to use to improve adhesion and signal quality.
- The devices should be applied to healthy, intact skin only. They should not be applied to skin that is broken, damaged, or irritated.
- Keep loose devices, accessories, and packaging materials away from small children as it may pose a choking hazard and may be harmful if swallowed.
- The battery used in the sensors and tablet may present a risk of fire, explosion, or chemical burn if mistreated. Do not expose the sensors or tablet to excessive heat or fire. Do not crush, puncture, or incinerate as doing so can result in fire, explosion, or the release of toxic gasses. Do not use or charge if the sensors appear to be leaking, discolored, deformed, or in any way abnormal.
- Return all non-consumable components to Sibel Health for disposal  following all state and federal laws governing the disposal of routine, non-hazardous electronic waste.
- DO NOT put unneeded mechanical stress (bending twisting, stretching, etc)  on the Discovery Sensors as it may damage the device.
- DO NOT attempt to disassemble, repair, or modify the devices.
- DO NOT plug in any unauthorized cables to the hardware ports located on the tablet device.
- Use only the sensors assigned to the system. If you see any devices you do not recognize within the software interface, do not attempt to connect or interact with the device.
- In case of emergency, unplug the wireless charger from the wall.
- Discovery Sensors have no cardiac arrhythmia detection capabilities.
- It is recommended that healthcare providers evaluate the underlying skin integrity after continuous use of 5 days and determine whether continued use is warranted and safe.

9.3 Symbols and Markings

Table 1: Symbols and Markings

Symbol	Title	Description
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	Type BF Applied Part	Type BF Applied Part
	Class II Equipment	Class II Equipment
	MRI Unsafe	This device is not safe for use with MRI equipment
Rx ONLY	Prescription Use Only	Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Does not contain natural latex rubber	Natural rubber latex was not used as a material in the manufacture of this medical device, its container, and/or packaging
	Manufacturer	Indicates the medical device manufactured, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient
	Direct current	Direct current
	Alternating current	Alternating current
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	Keep dry	Indicates a medical device that needs to be protected from moisture
FCC	Federal Communications Commission Mark	FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by the Federal Communications Commission
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot in which the device was manufactured can be identified
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Use-by-date	Indicates the date after which the medical device is not to be used
	Date of Manufacture	Indicates date when medical device was manufactured
REF	Catalog number	Indicates the manufacturer's catalog number so the medical device can be identified

	CE Marking	CE marking indicates that a product complies with applicable European Union regulations
	WEEE (Waste Electrical and Electronic Equipment)	Electrical and electronic items should not be disposed of in your dustbin or wheelie bin but should be recycled
	TELEC Certification	The classification and technical standards for the specified radio equipment listed in the official online technical regulations compliance certification system
IP	Ingress Protection	Degree of protection of electrical enclosures against foreign bodies and moisture
	UL (Underwriters Laboratories)	The product has successfully passed UL requirements
RoHS compliant	RoHS (Restriction of Hazardous Substances)	Regulates the use of toxic materials with the purpose of making electronics manufacturing safer at every stage of its life cycle
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	Bluetooth®	Indicates that the sensors use Bluetooth® as the wireless communication protocol
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Temperature limits	Operating temperature range
	Atmospheric pressure limitation	Operating pressure range
	Humidity limitation	Operating humidity range
	Non-ionizing electromagnetic radiation	Equipment includes RF transmitters that generate non-ionizing electromagnetic radiation
	Indoor use only	Identifies electrical equipment designed for indoor use

9.4 Storage and Handling

- Storage temperature range: -15°C – 43°C (5°F – 109.4°F)
- Storage relative humidity range: 5 – 95% RH (non-condensing)
- We recommend handling any subject-contacting system components with gloves.

9.5 Contact

- If a replacement is needed for any component, contact Sibel Health.
- Contact Sibel Health for any of the following issues:
 - Assistance in setting up, using, or maintaining sensors
 - To report unexpected operation or events

Address: 2017 N Mendell St, Chicago, IL 60614

Phone: (224) 251-8859

Website: www.sibelhealth.com

Email: support@sibelhealth.com

Section 10. Product Specifications

This section includes technical specifications for each item in Discovery.

10.1 ANNE Chest Technical Specifications

Table 1: ANNE Chest Sensor Specifications

Use type	For research use only, the sensors are reusable for up to 1 year. It is recommended that healthcare providers evaluate the underlying skin integrity after 7 days of continuous use and determine whether continued use is warranted and safe.
Safe Operating Environment Range	
Operation Time (per full charge)	36 hours
Battery Type	Rechargeable lithium polymer battery
Charging Time (to full charge)	5 hours
Charging Method	Wireless charging using custom ANNE Wireless Charger
Water Resistance	Sensors: IP47
Encapsulation Material	Low Durometer Silicone
Wireless Technology	Bluetooth® 5 Low Energy
Frequency Band	2402-2480 MHz
Maximum Connection Distance	10 meters
Dimensions (L x W x H, cm)	7.2 cm x 3.9 cm x 0.9 cm
Weight (grams)	17 grams
Attachment Method	ANNE Chest Adhesive
Sensor Capabilities	Single-Lead Biopotential AFE (Analog Front End) Range: ± 650 mV Sampling Rate: 256 Hz Thermometer Range: 23°C - 43°C

	Sampling Rate: every 4 seconds Accelerometer Range: $\pm 4g$ Sampling Rate: 25 Hz - 1.6 kHz
Heart Rate (beats/min)	30 - 270 bpm (the greater of $\pm 10\%$ or $\pm 5bpm$) (± 2 bpm RMSE)
Respiratory Rate (breaths/min)	8 - 35 bpm (± 3 bpm RMSE)
Step Count	0 - 65,535 steps (greater of 5% or ± 10 steps)
Fall Count	0 - 255 falls (90% sensitivity, 98% specificity)
Body Temperature*	93.2°F - 109.4°F ($\pm 0.54^\circ F$) 34°C - 43°C ($\pm 0.3^\circ C$)
Skin Temperature	73.4°F - 109.4°F ($\pm 0.54^\circ F$) 23°C - 43°C ($\pm 0.3^\circ C$)

*when placed under the axilla

Table 2: ANNE Chest Adhesive Specifications

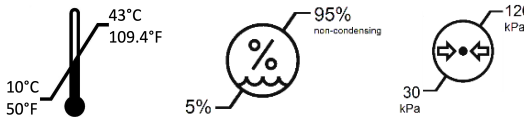
Dimensions (L x W, cm)	7.4 cm x 4.2 cm
Material	Biocompatible silicone gel adhesive
Use Type	Single use disposable
Shelf Life	2 years

Table 3: ANNE Wireless Charger Specifications

Dimensions (L x W x H, cm)	11.8 x 9.9 x 1.3 cm
Weight (grams)	102 grams
Power supply	USB-C 10W power adapter 5V, 2A
Water Resistance	Wireless Charger: IP20 
Charging Frequency Band	13.56 MHz

10.2 ANNE Limb Technical Specifications

Table 1: ANNE Limb Sensor Specifications

Use type	For research use only, the sensors are reusable for up to 1 year. It is recommended that healthcare providers evaluate the underlying skin integrity after 7 days of continuous use and determine whether continued use is warranted and safe.
Safe Operating Environment Range	
Operation Time (per full charge)	36 hours
Battery Type	Rechargeable lithium polymer battery
Charging Time (to full charge)	5 hours
Charging Method	Wireless charging using custom ANNE Wireless Charger
Water Resistance	Sensors: IP47
Encapsulation Material	Low Durometer Silicone
Wireless Technology	Bluetooth® 5 Low Energy
Frequency Band	2402-2480 MHz
Maximum Connection Distance	10 meters
Dimensions (L x W x H, cm)	9.4 cm x 3.5 cm x 0.9 cm
Weight (grams)	13 grams
Attachment Method	ANNE Limb Adhesive
Sensor Capabilities	Pulse Oximeter AFE Sampling Rate: 128 Hz Thermometer Range: 23°C - 43°C Sampling Rate: every 4 seconds
Pulse Rate (beats/min)	30-300 bpm (± 3 bpm RMSE)
Functional Oxygen Saturation (SpO2) (%)	70-100% ($\pm 3\%$ ARMS)

Perfusion Index	0.5 - 20%
Body Temperature*	93.2°F - 109.4°F (±0.54°F) 34°C - 43°C (±0.3°C)
Skin Temperature	73.4°F - 109.4°F (±0.54°F) 23°C - 43°C (±0.3°C)

*when placed under the axilla

Table 2: ANNE Limb Adhesive Specifications

Dimensions (L x W, cm)	13.0 cm x 5.7 cm
Material	Biocompatible medical foam adhesive
Use Type	Single use disposable
Shelf Life	2 years

Table 3: ANNE Wireless Charger Specifications

Dimensions (L x W x H, cm)	11.8 x 9.9 x 1.3 cm
Weight (grams)	102 grams
Power supply	USB-C 10W power adapter 5V, 2A
Water Resistance	Wireless Charger: IP20 
Charging Frequency Band	13.56 MHz

10.3 ADAM Technical Specifications

Table 4: ADAM Sensors Specifications

Use type	For research use only, the sensors are reusable for up to 1 year. It is recommended that healthcare providers evaluate the underlying skin integrity after 7 days of continuous use and determine whether continued use is warranted and safe.
Safe Operating Environment Range	 50 °F 10 °C 95 °F 35 °C 5% 95% non-condensing 30 kPa 120 kPa
Operation Time (per full charge)	36 hours
Battery Type	Rechargeable lithium polymer battery
Charging Time (to full charge)	5 hours
Charging Method	Wireless charging using custom ADAM Wireless Charger
Water Resistance	Sensors: IP47
Encapsulation Material	Low Durometer Silicone
Wireless Technology	Bluetooth® 5 Low Energy
Frequency Band	2402-2480 MHz
Maximum Connection Distance	10 meters
Dimensions (L x W x H, mm)	18.5 x 36.3 x 11.0 mm
Weight (grams)	6 grams
Attachment Method	ADAM adhesive
Sensor Capabilities	Thermometer Range: 23°C - 43°C Sampling Rate: every 4 seconds Accelerometer Range: ± 4g Sampling Rate: 1.6 kHz
Skin Temperature	73.4°F-109.4°F (±0.54°F) 23°C - 43°C (±0.3°F)

Table 5: ADAM Adhesive Specifications

Dimensions (L x W, cm)	4.4 cm x 1.9 cm
Material	Biocompatible medical-grade silicone gel adhesive
Use Type	Single use disposable
Shelf Life	2 years

Table 6: ADAM Wireless Charger Specifications

Dimensions (L x W x H, cm)	11.8 x 9.9 x 1.3 cm
Weight (grams)	102 grams
Power supply	USB-C 10W power adapter 5V, 2A
Water Resistance	Wireless Charger: IP20 
Charging Frequency Band	13.56 MHz

10.4 Electromagnetic Emissions Declaration

Discovery sensors are intended for use in the electromagnetic environment specified below. The end user of the device should ensure that it is used in such an environment.

Table 5: Electromagnetic Environment

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	Discovery sensors use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Discovery sensors are suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

10.5 FCC Compliance Notification (FCC ID: 2AAQS-ISP1807)

Discovery sensors have been verified for RF exposure and found to comply with Council Recommendation 1999/519/EC and FCC OET-65 RF exposure requirements. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

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. Additionally, 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.

The ANNE sensors comply with Part 15C of FCC Rules (FCC ID: 2AAQS-ISP1807). The included Discovery Tablet (FCC ID: A3LSMT547U) complies with Part 15 and Part 18 of the FCC Rules. Operation of each device 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.

10.6 Guidance and Declaration: Electromagnetic Immunity

(For ME equipment ME system that are not life-supporting)

Discovery sensors are intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Table 6: Discovery Sensors Electromagnetic Immunity

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 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	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	0.5 kV differential mode 1 kV common mode	0.5 kV differential mode 1 kV common mode	Mains 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	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip in 25 cycles >95% dip in 5 seconds	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip in 25 cycles >95% dip in 5 seconds	Mains power quality should be that of a typical commercial or hospital environment
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.
Conducted RF IEC 61000-4-6 Radiated RF	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Discovery than the recommended separation distance calculated from the

IEC 61000-4-3	2.5 GHz		equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800MHz to 2.7 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted disturbances induced by RF fields	Test levels: 3V 0.15-80 MHz 6 V ISM bands between 0.15 MHz to 80 MHz	Test levels: 3V 0.15-80 MHz 6 V ISM bands between 0.15 MHz to 80 MHz	Conducted disturbances induced by RF fields should be at levels characteristic of a typical location in a typical professional healthcare facility environment or domestic establishment.
Proximity Fields from RF wireless communications	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	Proximity fields from RF wireless communications should be at levels characteristic of a typical professional healthcare facility environment or domestic establishment

	27 V/m 385 MHz	27 V/m 385 MHz	
	28 V/m 450 MHz	28 V/m 450 MHz	
	9 V/m 710, 745, 780 MHz	9 V/m 710, 745, 780 MHz	
	28 V/m 810, 870, 930 MHz	28 V/m 810, 870, 930 MHz	
	28 V/m 1720, 1845, 1970 MHz	28 V/m 1720, 1845, 1970 MHz	
	28 V/m 2450 MHz	28 V/m 2450 MHz	
	9 V/m 5240, 5500, 6785 MHz	9 V/m 5240, 5500, 6785 MHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note 3: UT is the a.c. mains voltage prior to application of the test level.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

10.7 Recommended separation distance between portable and mobile RF communications equipment and Discovery Sensors

(For ME equipment/ME systems that are not life-supporting)

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

Table 7: Separation distance

Rated max output power of transmitter (W)	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 manufacturer.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix A. Switching Sensor to Discovery Configuration

This section outlines how to switch the sensor's settings for use with Discovery.

Discovery is Sibel's clinical research product wherein pharmaceutical companies and leading academic centers use Sibel sensors for the measurement of digital endpoints to quantify a study subject's reported outcome measures. Both Discovery and Discovery RA use the same sensors, but the sensors require a different data collection mode setting when using each app.

While Discovery RA is compatible with both automatic and manual mode, Discovery only uses automatic mode. In automatic mode, the sensor will automatically record data whenever it is off of the charger, while in manual mode, data collection sessions are manually initiated by the user from the Discovery RA app.

To switch the sensor to automatic mode from manual mode, navigate to the "Settings" window for the sensor, and press "Change Session Mode". The sensor will automatically restart upon switching. For more information, refer to the instructions in [Section 7.1](#).

Next, follow the instructions in [Section 7.8](#) to unpair the sensor. The sensor can only be paired with the Discovery App once it has been unpaired from the Discovery RA App.



To return the sensor to using Discovery RA, the sensor will also need to be unpaired from the Discovery App. The sensor can then be re-paired with Discovery RA and if desired, the mode can be changed back to manual so data is not automatically collected when it is removed from the charger.