



INSTRUCTIONS FOR USE

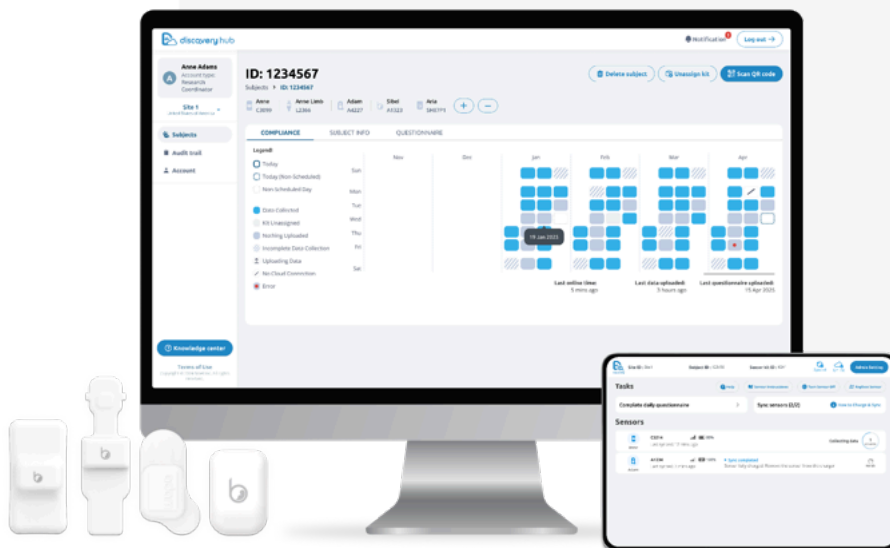


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Section 1. Introduction to Discovery

This section provides an overview of the Discovery product.

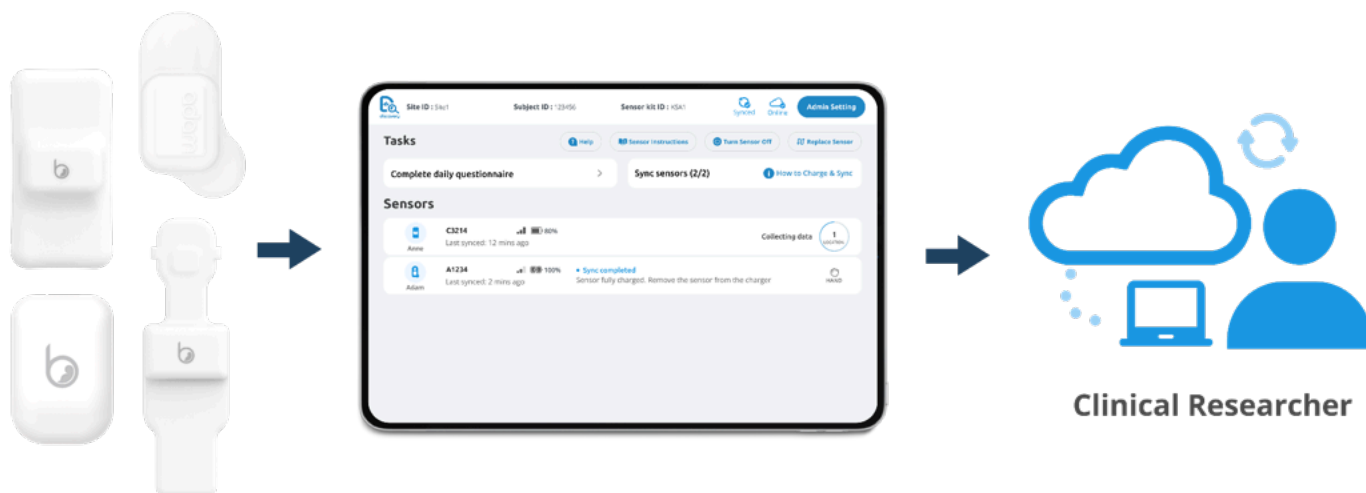
1.1 Overview of Instructions for Use

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

1.2 Overview of Discovery

Discovery is Sibel's clinical research product for clinical research applications.

The Discovery product allows researchers to collect raw physiological data as well as advanced digital clinical measures from study subjects. The system consists of wireless sensors, adhesives, a wireless charger, a mobile device, a mobile application, and a cloud portal. The system includes all hardware and instructions to complete data collection using Sibel's Discovery sensors.



1.3 Overview of Sensors

1.3.1 Anne Sensor



The Anne Sensor (Also sometimes referred to as “Anne Chest”) 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. The device is secured to the finger via a biocompatible adhesive.

1.3.3 Adam Sensor



The Adam Sensor is an epidermal patch that can be worn on the hand, suprasternal notch, 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. The device is secured to the skin via a biocompatible adhesive.

1.3.4 Aria Sensor



The Aria Sensor is an epidermal patch that can be worn on the hand, suprasternal notch, abdomen, and other body parts. The device includes accelerometer, microphone, barometer, and temperature sensors from which key metrics can be measured such as scratch indications, swallowing, and bowel movements. The device is secured to the skin via a biocompatible adhesive.

Section 2. System Unpack and Set-Up

This section describes steps to set up the Discovery Kit before starting monitoring with a Subject.

2.1 Discovery Kit Unpacking

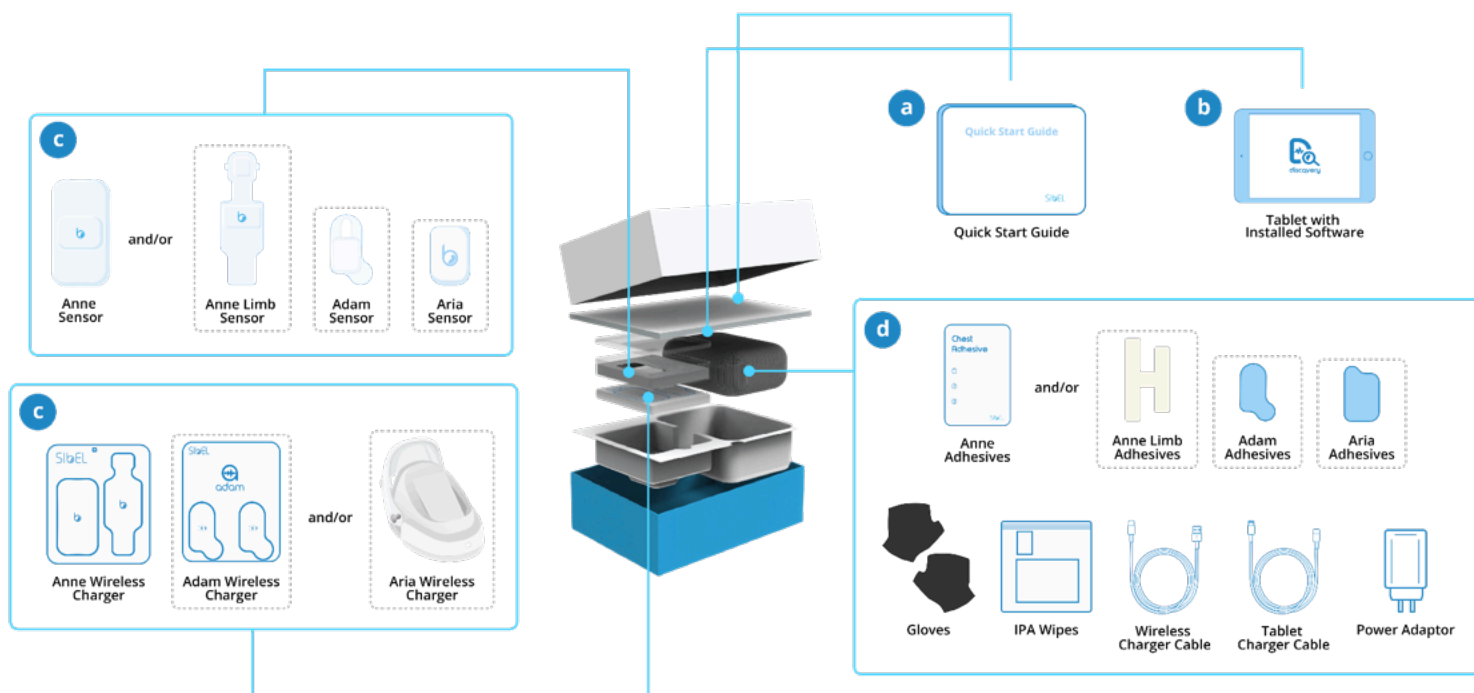
To open the package, remove the white lid to reveal two layers inside the box. Each layer contains the components as listed below:

Top layer:

- Envelope containing Quick Start Guide
- Discovery Tablet with Discovery App installed

Middle layer:

- Sensor container:** Sensor (Anne, Anne Limb, Adam, and/or Aria), Wireless Charger
- Pouch:** Adhesives (Anne, Anne Limb, Adam, and/or Aria), Gloves (For Adam or Aria), Cleaning Wipes (For Anne Only), Discovery Tablet Charger Cable (USB-C to USB-C), Wireless Charger Cable (USB-A to USB-C), Regional Power Adaptor



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

2.2 Turning On the Discovery Tablet

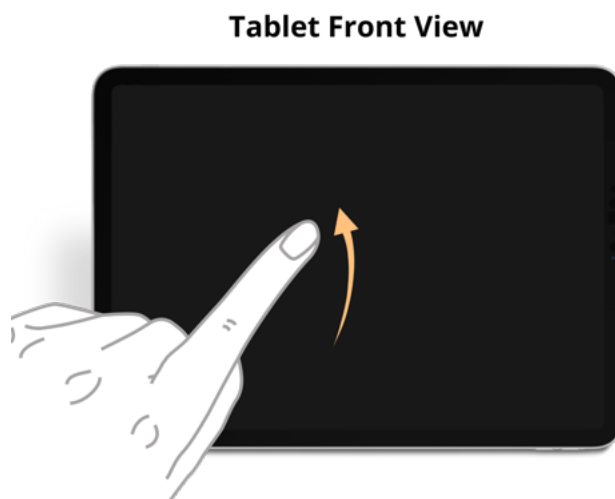
Step 1

Turn on the tablet by holding the power button on top of the tablet until the screen turns on.



Step 2

Press the power button, swipe upwards on the screen, and enter the password (if applicable) to unlock the tablet.



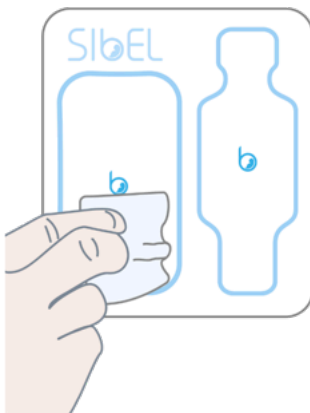
Step 3

Check the battery level. Charge with the Discovery Tablet Charger Cable (USB-C to USB-C) if needed.

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 Wireless Charger with a cleaning wipe to sanitize. Visually inspect the charger and repeat the cleaning process until it is visibly clean.



Anne Wireless Charger



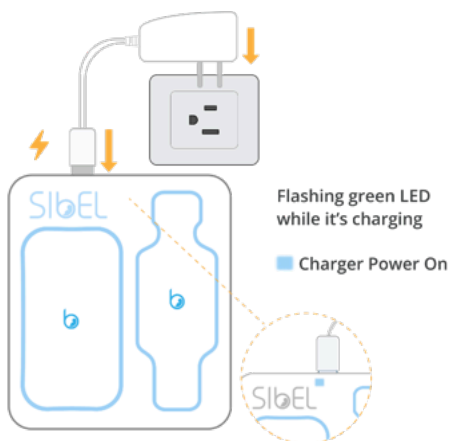
Adam Wireless Charger



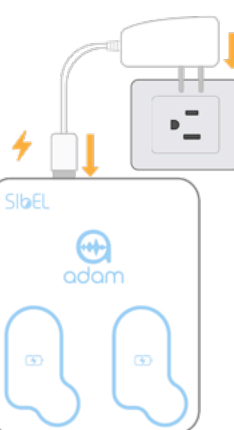
Aria Wireless Charger

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 USB-C to USB-C cable must be reserved for the Discovery tablet.**



Anne Wireless Charger



Adam Wireless Charger



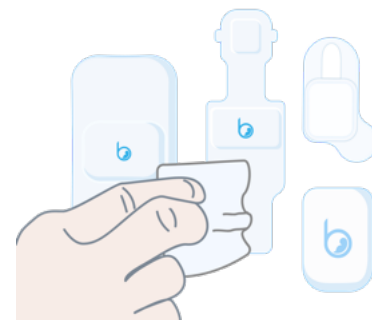
Aria Wireless Charger

2.4 Setting Up the Sensor

2.4.1 Sanitize the Sensor

Wipe both sides of the sensor with a cleaning wipe to sanitize.

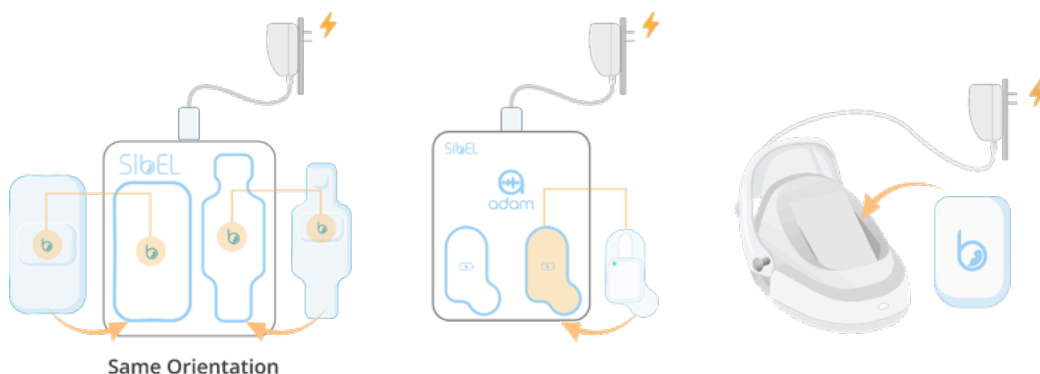
Visually inspect the sensor and repeat the cleaning process until it is visibly clean.



2.4.2 Wake up the Sensor

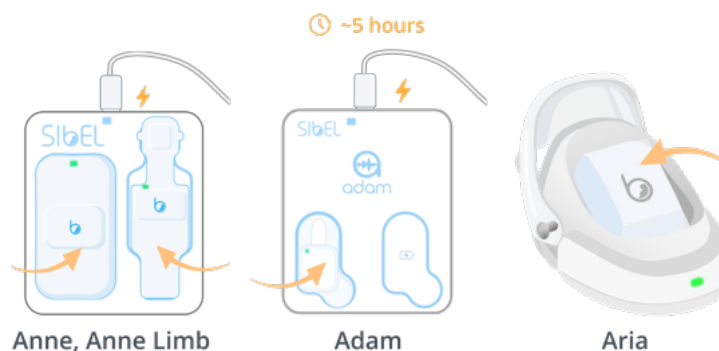
Step 1

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.

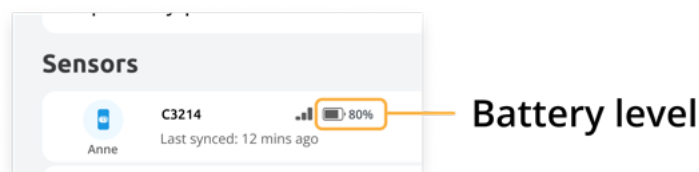


Step 2

A green LED light on the 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 app on the tablet.

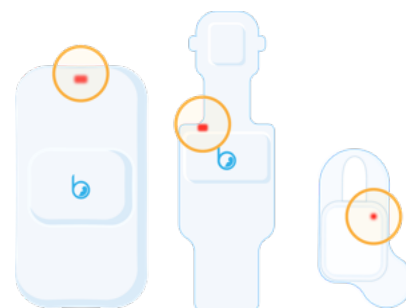


2.5 LED Pattern Interpretations

2.5.1 Anne, Anne Limb, and Adam LED Patterns

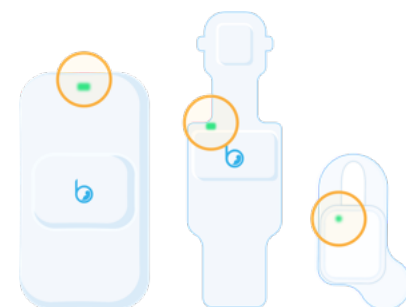
The Red LED Blinks:

- Every 1 second to indicate poor skin contact during wear
- Every 3 seconds to indicate low battery OR low memory
- Solid to indicate sensor failure



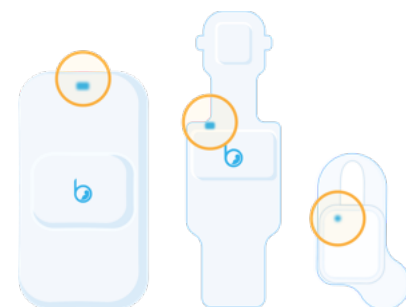
The Green LED Blinks:

- 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 one of two states:
 - a. The sensor has not yet connected to the Discovery app after turning on
 - b. Has data available for download and is on the charger



The LED is Off:

- When the sensor is off
- When the sensor is functioning normally collecting data

2.5.2 Aria LED Patterns

The Red LED Blinks:

- Every 1 second to indicate one of two states:
 - Sensor failure
 - Critical battery (4 hours remaining)



The Green LED Blinks:

- Solid when pairing to indicate which sensor is being paired



The Blue LED Blinks:

- Every 1 second to indicate one of two states:
 - a. The sensor has not yet connected to the Discovery app after turning on
 - b. Has data available for download and is on the charger



The Orange LED Blinks:

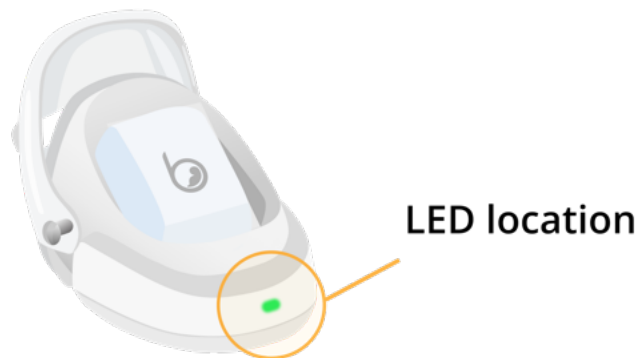
- Three times for 1 second each to indicate that the sensor is entering Ship Mode



The LED is Off:

- When the sensor is off
- When the sensor is functioning normally collecting data

2.5.3 Aria Charger LED Patterns



The Green LED Blinks:

- Solid when the sensor is fully charged

The Orange LED Blinks:

- Solid when the sensor is charging, but not fully charged

The Red LED Blinks:

- Solid when there is a Charger failure

The White LED Blinks:

- Solid when the charger is functional and ready to use, but the sensor is not on.

The LED is Off:

- When the charger is not plugged in

2.6 Discovery Sensor Workflow

Anne and Anne Limb sensors for Discovery will automatically start collecting data when they are removed from the charger and worn, while Adam and Aria sensors will always start recording data once removed from the charger regardless of whether they are worn. Putting the sensors in Ship Mode when they are off the charger (explained in [Section 8.3](#)) turns off the sensor so it is 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 (Indicated by a Blue LED as noted in [Section 2.5](#)).** When a sensor is worn and is collecting data, it stores all of the data locally on the sensor. When the data collection is completed and the sensor is returned to the charger, open the Discovery application and the sensor will automatically sync its data to the tablet. Once data is successfully synced from sensor to tablet, the tablet will sync to the cloud as long as there is an internet connection. 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. If data is not fully synced with the tablet and it is removed from the charger too early, this data will remain stored on the sensor and it can be downloaded during the next data sync.

Note: It is important to ensure that the tablet is always connected to the internet while using the Discovery application.

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

1. Put the sensor in Ship Mode until ready to be worn (As explained in [Section 8.3](#))
2. Place the sensor on the charger when ready to use or wear
3. The subject wears the sensor over time specified for the study (As explained in [Section 6](#))
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](#))

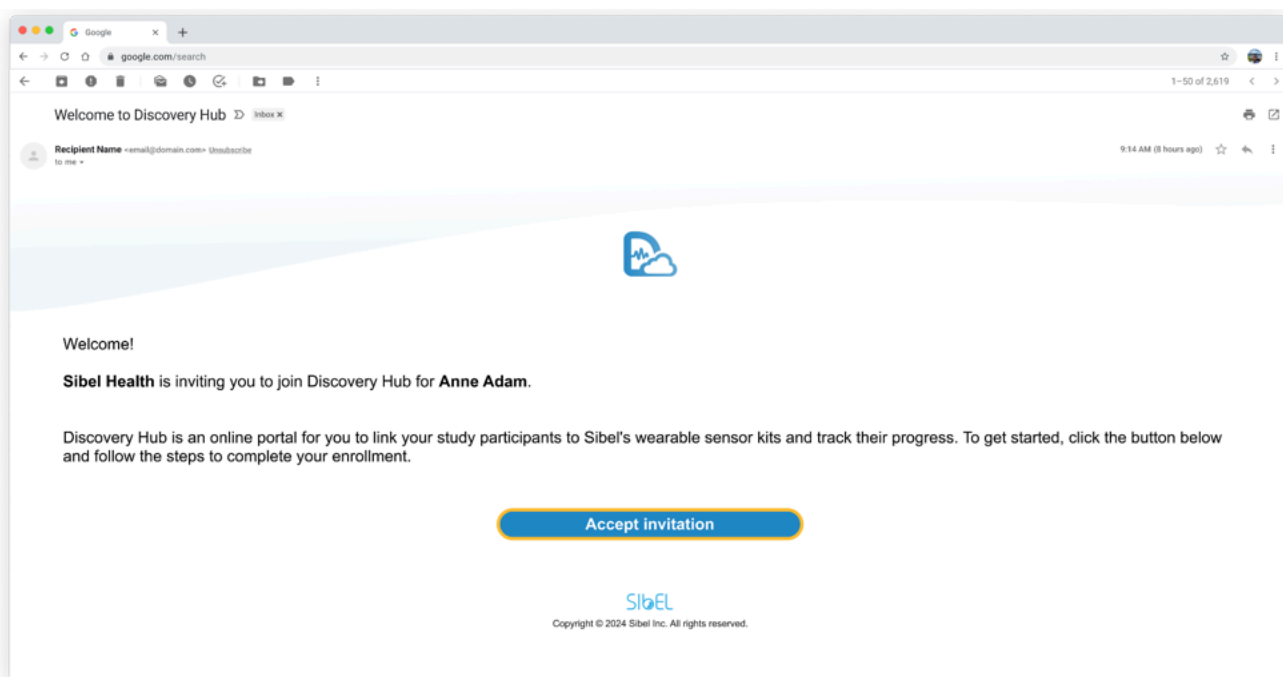


Section 3. Using Discovery Hub

This section describes the steps needed to use Discovery Hub, the cloud-based service used to manage Subjects and Discovery Kits.

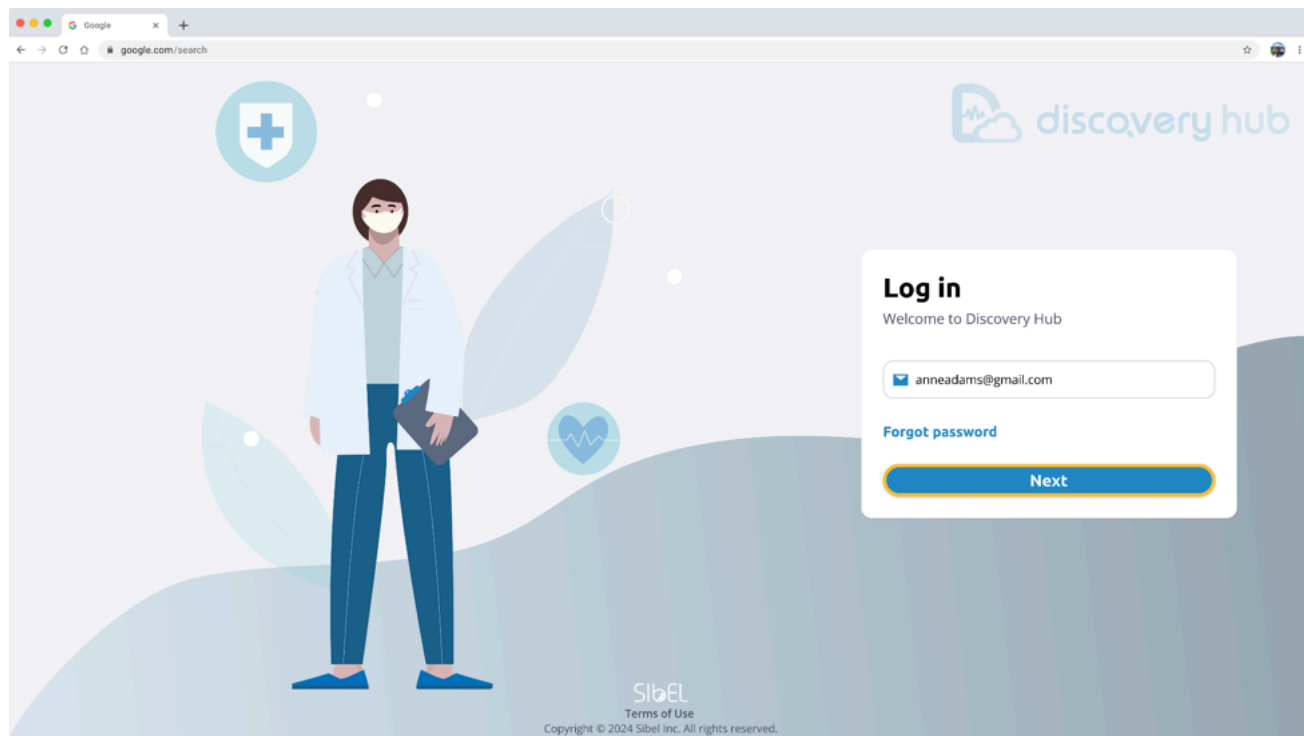
3.1 Logging into Discovery Hub

Users are invited to log in to Discovery Hub from an email sent by study personnel or Sibel support. Additional personnel can be added or removed by users with specific account types.

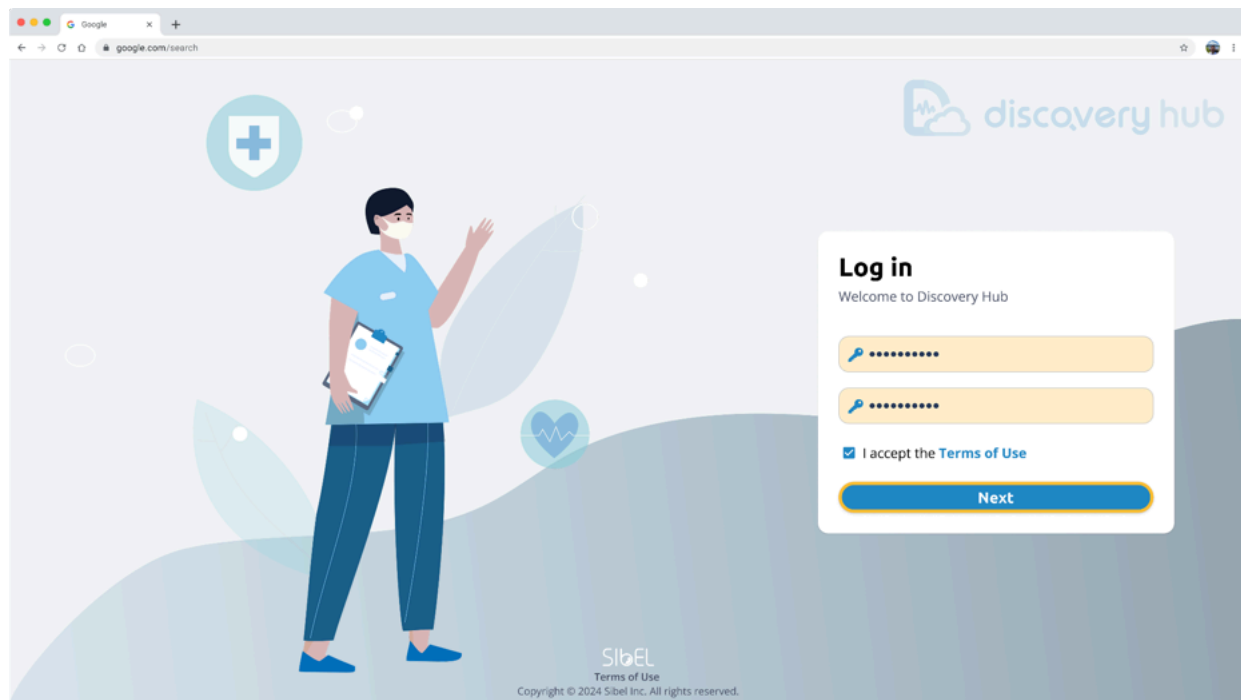


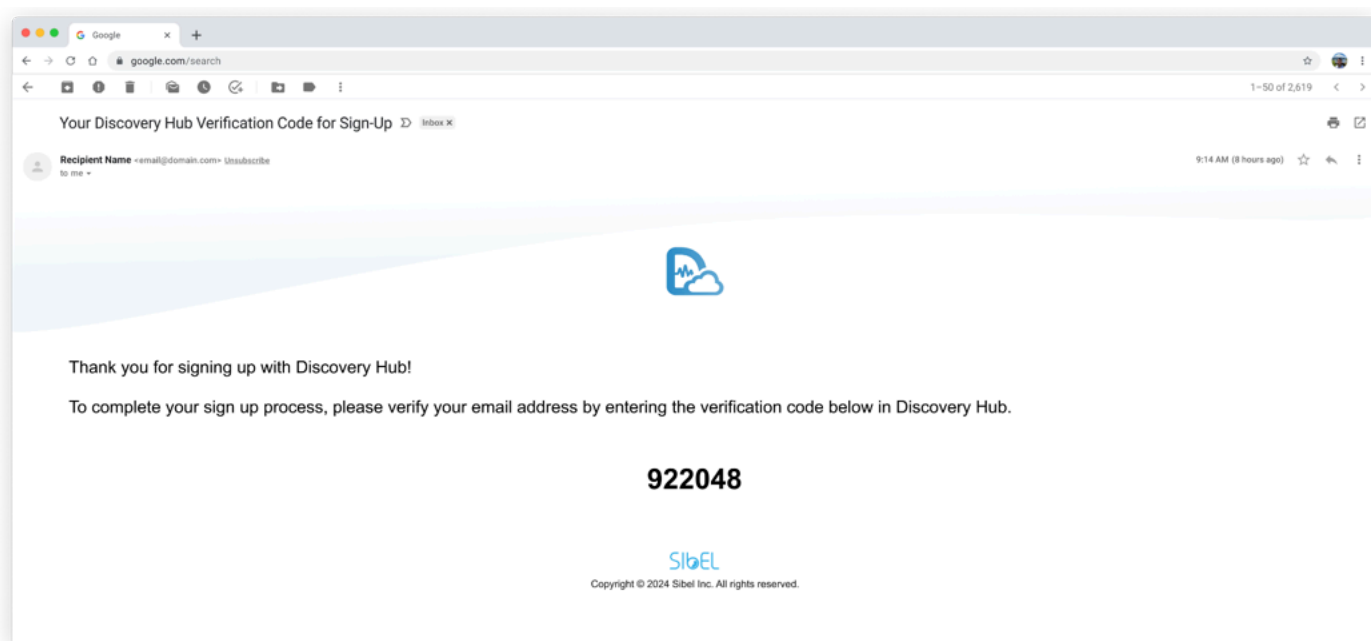
Note: You may need to work with your IT department to have them whitelist the Discovery Hub site to ensure that all users can access the site on their computers. You may also need to adjust your browser settings if you are not using Google Chrome.

When first logging in, enter your email address on the starting screen and then press “Next”.

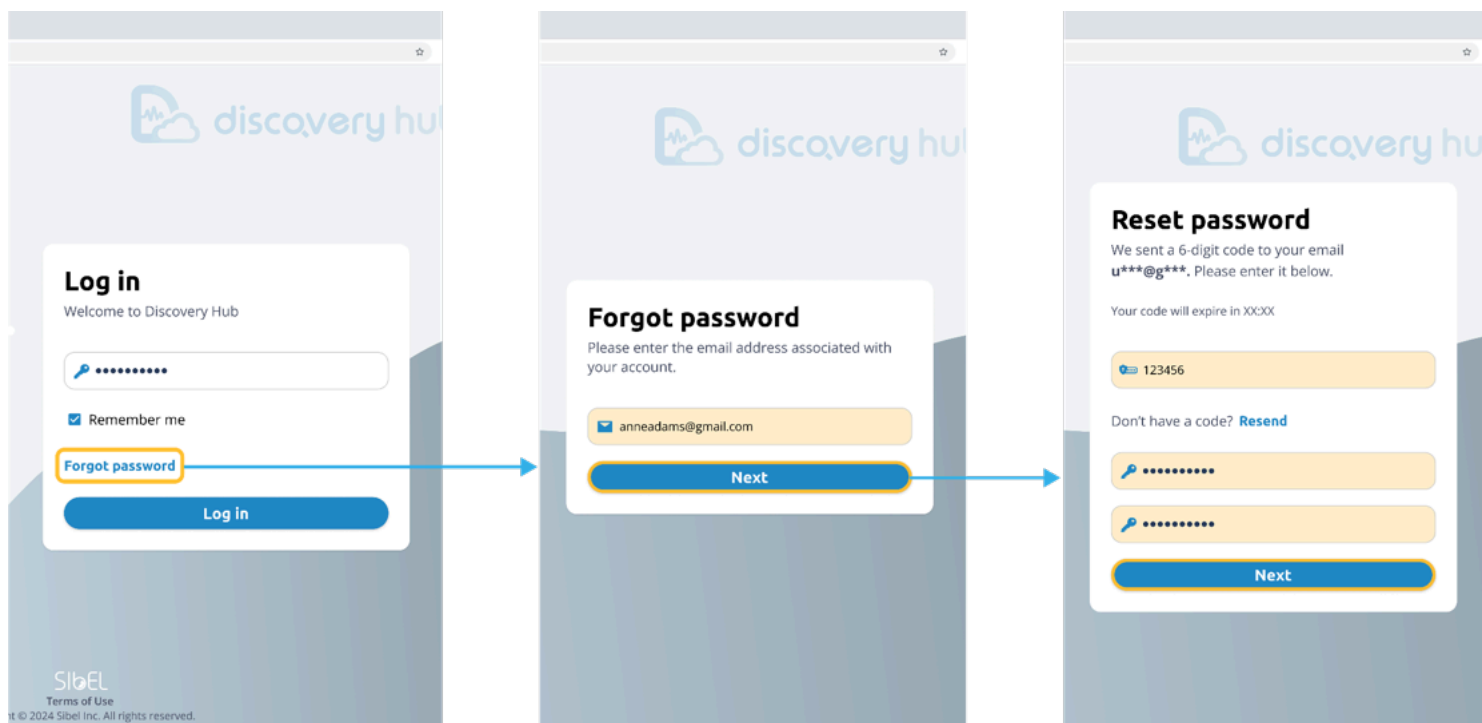


Next, create a password, and then you will receive an email with a verification code to complete the registration. Enter the code within 24 hours to log in.

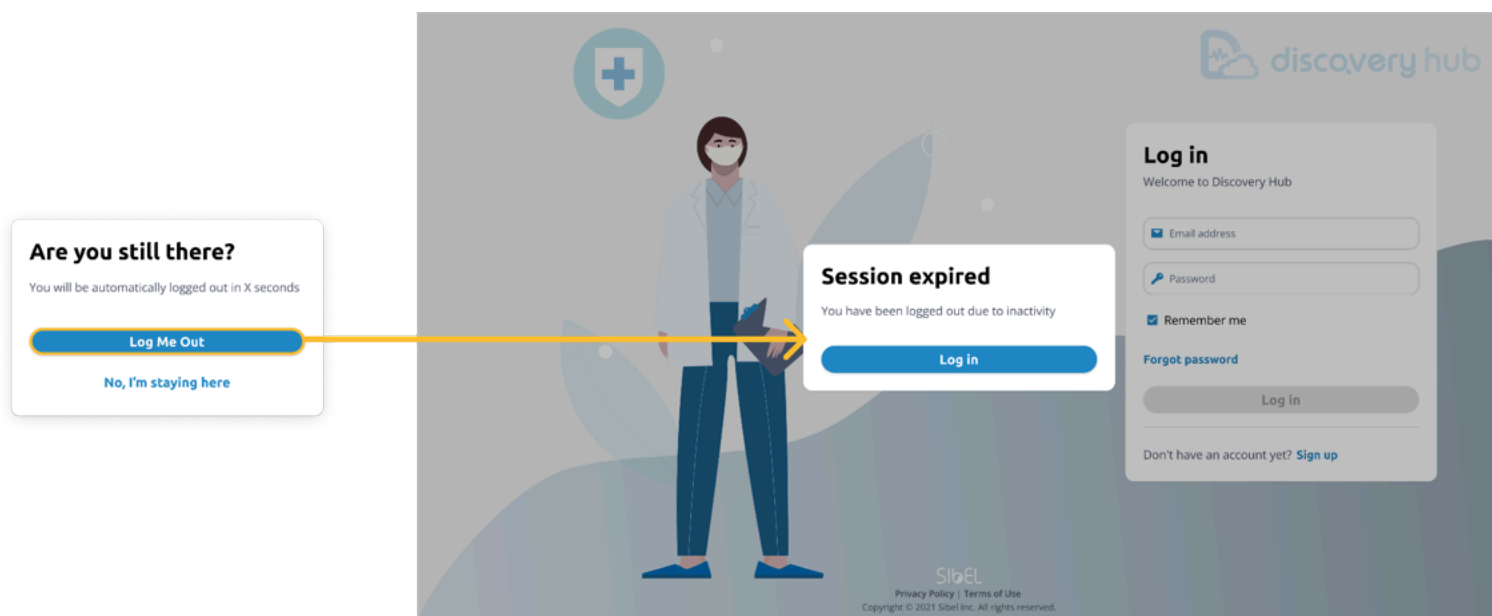




If your account is already configured, simply enter your email and then password on the login screen. You can also click “Forgot Password” to reset your password if needed.



Note: Discovery Hub will automatically log you out after 20 minutes of inactivity.



3.2 User Roles

A User's access and ability to use Discovery Hub depends on the type of account associated with their login. These include:

Admin:

- Can view every page in their assigned site(s)
- Can add, edit, remove and view QR codes for any subject in their assigned site(s)
- Can view the detailed view for any subject in their assigned site(s)
- Can view notifications
- Can add and remove research coordinators in their assigned site(s)
- Can view the audit trail for any subject in their assigned site(s)

Research Coordinator:

- Can view the subjects, audit trail and account pages for their assigned site(s)
- Can add, edit, remove and view QR codes for any subject in their assigned site(s)
- Can view the detailed view for any subject in their assigned site(s)
- Can view notifications
- Can view the audit trail for any subject in their assigned site(s)

3.3 Overview

Once logged into the Discovery Hub, you will be taken to the Subjects List page. On the top of the screen you will see your name and the type of account on the left side, and a notification button on the left to alert you to inactive subjects and sensor failures. Below this, you will see summary metrics for the selected site. This includes:

- Active Subjects
- Inactive Subjects
- Sensor Failures
- Hours of Data Collected

You can select the site from the site dropdown menu if your account has access to multiple sites. You can also access the following pages:

- Subjects List
- Audit Trail
- Study Personnel (Admins only)
- Account Information

You can also access the Knowledge Center from the blue button on the bottom of the screen.

The screenshot displays the Discovery Hub interface. At the top, there's a navigation bar with a notification bell icon and a 'Log out' button. Below this, four summary cards are shown: 'Active' (3), 'Inactive' (2), 'Sensor Failures' (1), and 'Hours of Data Collected' (59min). The main content area is titled 'Subjects' and features a table with columns for Subject ID, Last 7 Days Collection, Last Online, and Status. The table lists four subjects with their respective IDs and collection status. A sidebar on the left contains links for 'Account Type', 'Site Selection', 'Tab Selection', and 'Knowledge Center'. The 'Knowledge Center' link is highlighted with a blue button.

Subject ID	Last 7 Days Collection	Last Online	Status
1234567123456712345671234567123ddd 456712345671234567123456712345671...		Online	Collecting Data
12434567jkl		23 hours ago	!
24347p		14 Apr 2025	
99999			

3.4 Subject Management

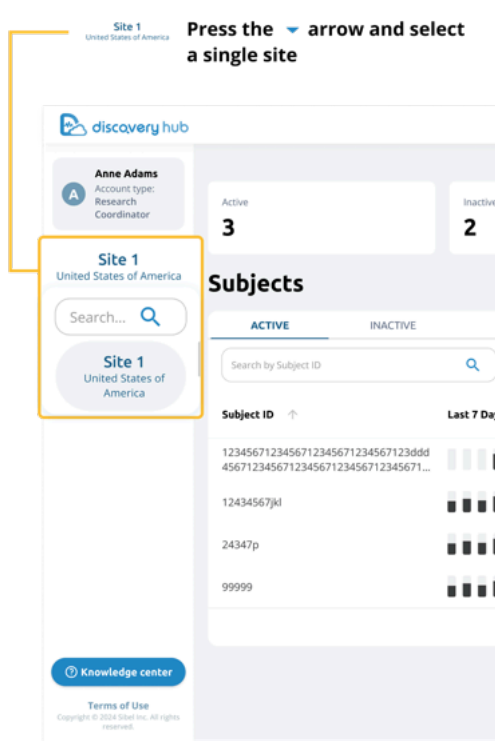
The Subjects page is viewable by anyone with any account type (for only the sites they have access to).

3.4.1 Selecting the Site

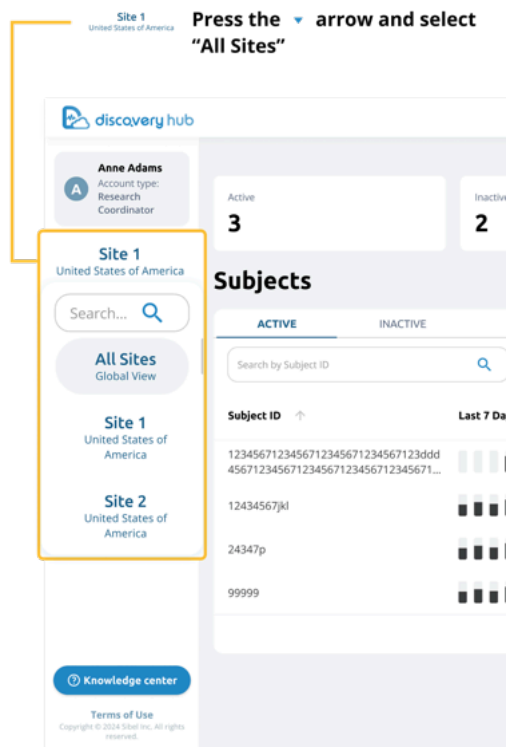
Before adding any study subjects, make sure the correct site is selected. Click on the down arrow near the subject list to bring up a dropdown menu to select the site. Note that any subjects added on one site cannot be moved to a different site.

Note: Research Coordinator can only access the site(s) assigned to them upon their registration in Discovery Hub, so this option will be restricted for them if they do not have access to more than one site. It is also possible to click the “All Sites” option to view all subjects across all sites when the user has access to multiple sites.

Note: A new subject cannot be added in the “All Sites” view.



Single site option



All Sites option

3.4.2.1 Active Tab



3.4.2.2 Inactive Tab

You can also see a list of Subjects who are no longer assigned a kit under “Inactive”. All of their data is still retained and viewable in this state.

discovery hub

Notification 1

Log out →

Anne Adams
Account type:
Research
Coordinator

Site 1
United States of America

Subjects

Audit trail

Account

Active
3

Inactive
2

Sensor Failures
1

Hours of Data Collected
239hr

Subjects

ACTIVE

INACTIVE

Subject ID ↑

Site ID ↑

12434567jkl

usa_01

⋮

2342342

usa_01

⋮

24347p

usa_01

⋮

Rows per page: 25

1-3 of 3

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>

Knowledge center

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Inactive tab

3.4.3 Adding a Subject

By clicking **+ Add subject** in the top-right corner, you will see a window appear where you can enter the Subject's information.

You must enter a Subject ID, which can be any number-letter combination of your choosing. The Site ID is automatically configured based on the site selected. In addition, you must register the Subject to a Kit. Under "Kit ID" enter the 4-digit Kit ID from the label on the bottom of the Kit. Also enter the date when the subject is expected to begin data collection.

If you do not enter all of the required information, you will be prompted to do so before continuing. After entering all of the required information, you will be prompted to confirm. Once you do so, the new Subject will be added to the "Active Subject" list. This information can be edited later under the "Subject Info" page.

+ Add subject

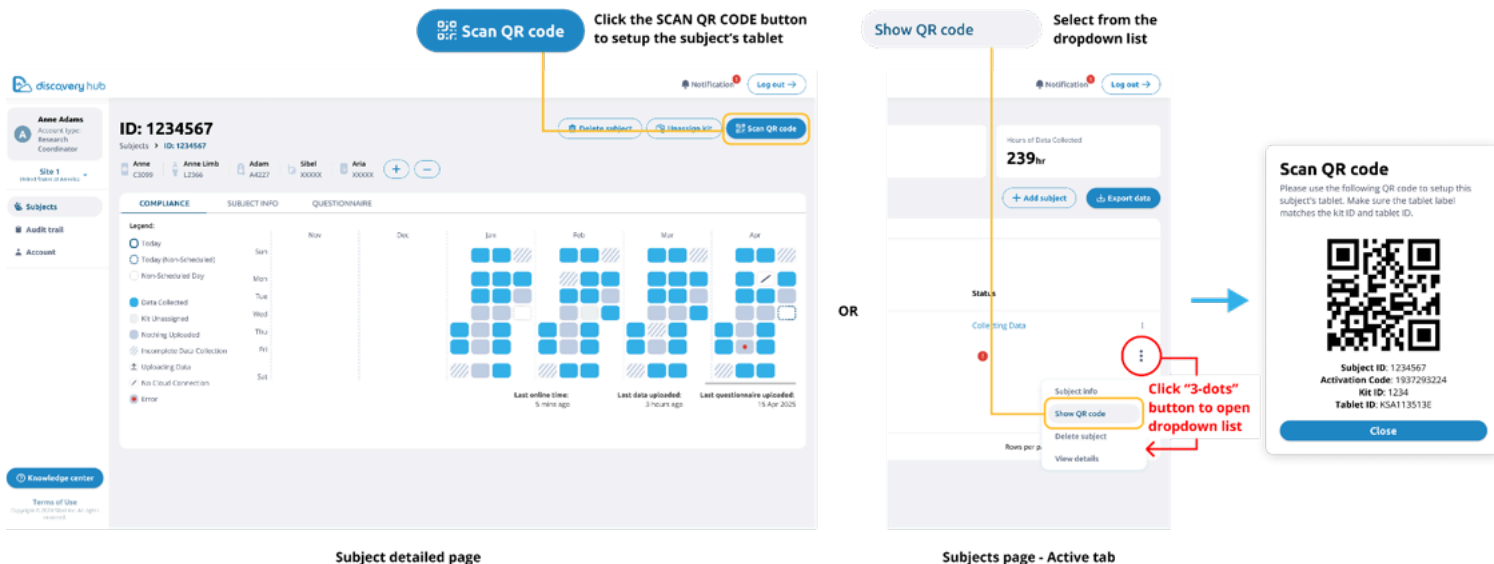
Click the ADD SUBJECT button to add a subject

Confirm

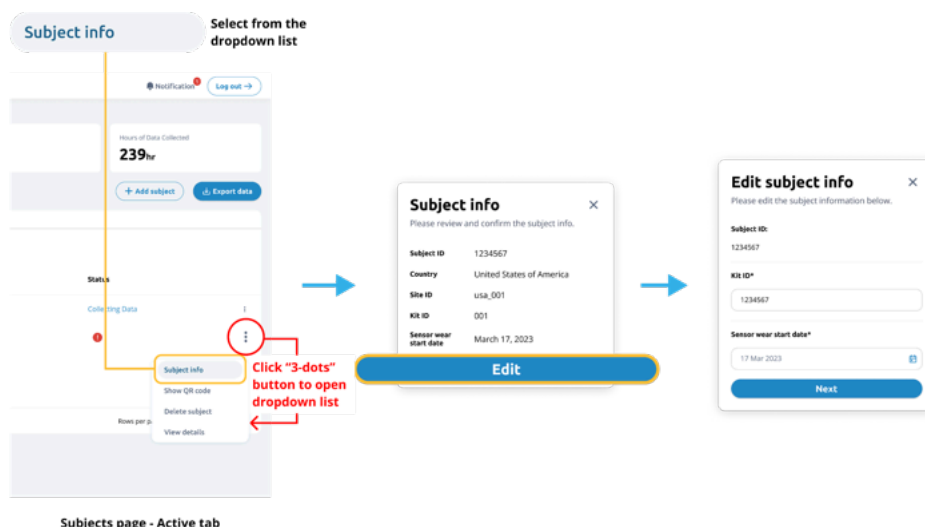
Click the CONFIRM button to add to the "Active Subject" list

3.4.4 Configuring a Subject in the Discovery App

Once a Subject is added, a window displaying a QR code appears. This QR code is used to load a Subject profile into the Discovery App running on the tablet contained in the Kit. This QR code window is also accessible by clicking the 3 dots on the rightmost side of the row on the list of Subjects, and then clicking “Show QR Code”. This QR Code will be referred to when it is scanned into the Discovery App in [Section 4.1 Step 2](#). Also displayed under the QR Code is the Subject ID, Activation Code, Kit ID, and Tablet ID.



In addition, you can click on “Subject Info” in this drop down menu to bring up a window that shows the Subject’s ID, Country they are registered in, Site ID, and the Kit ID assigned to them. You can also change the assigned Kit to this subject from this window by clicking on “Edit” and entering a new Kit ID when prompted. This menu also allows you to change the Sensor wear start date as well.



3.4.5 Exporting Data

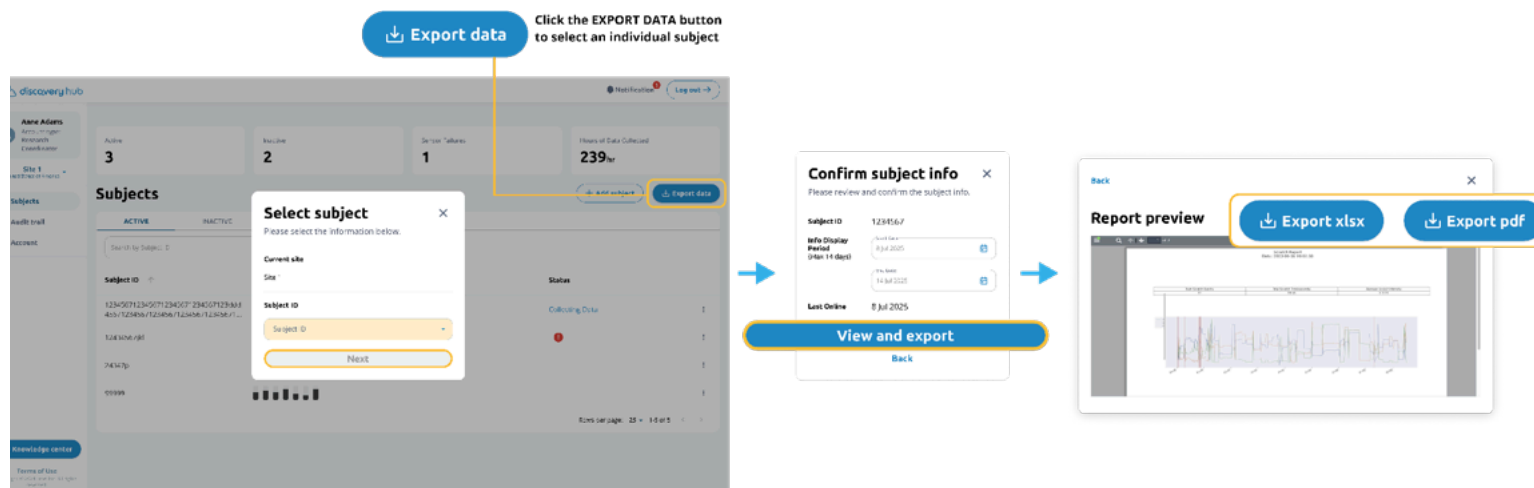
Discovery Hub allows users to download summaries of a Subject's data. This includes PDF reports of individual data collection sessions, and an Excel file summarizing all data collected. Click the blue [Export data](#) button on the top-right corner of the screen to begin.

The export feature allows for data downloads of only one subject. Select the individual subject desired under the "Subject ID" dropdown menu to choose which data to export. Then click the [Next](#) button.

On the next pop-up, select the start and end date of data to retrieve, and then click the [View and export](#) button. You will see a preview of all the PDF data reports from that desired date range from the subject. To download the PDF reports, click "Export pdf". To download the Excel file, click "Export excel".

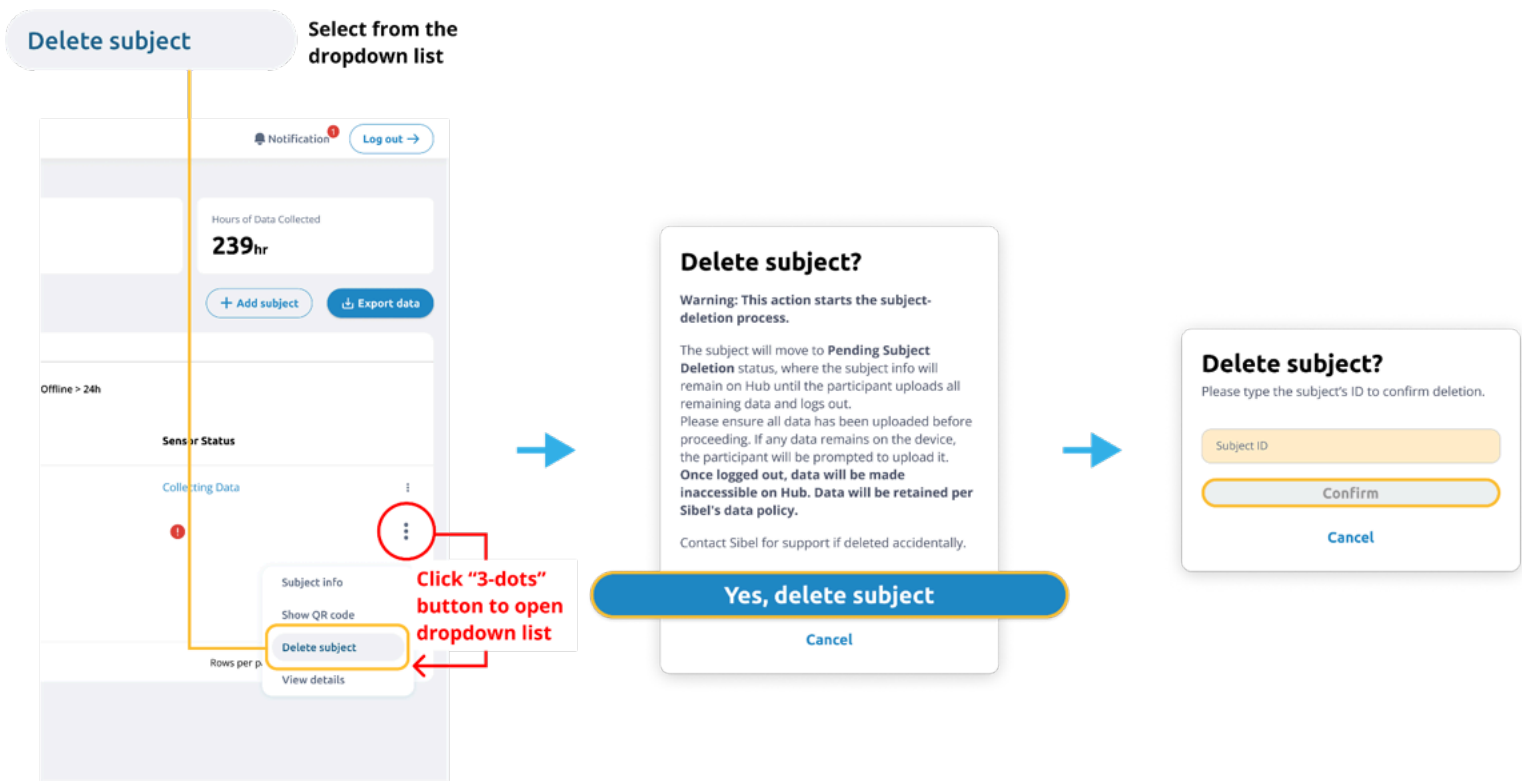
To interpret the PDF data reports and Excel files, please refer to the corresponding Algorithm Outline papers provided by Sibel.

Note: Access to the data collected by the Discovery system will be arranged with Sibel as part of the system deployment.

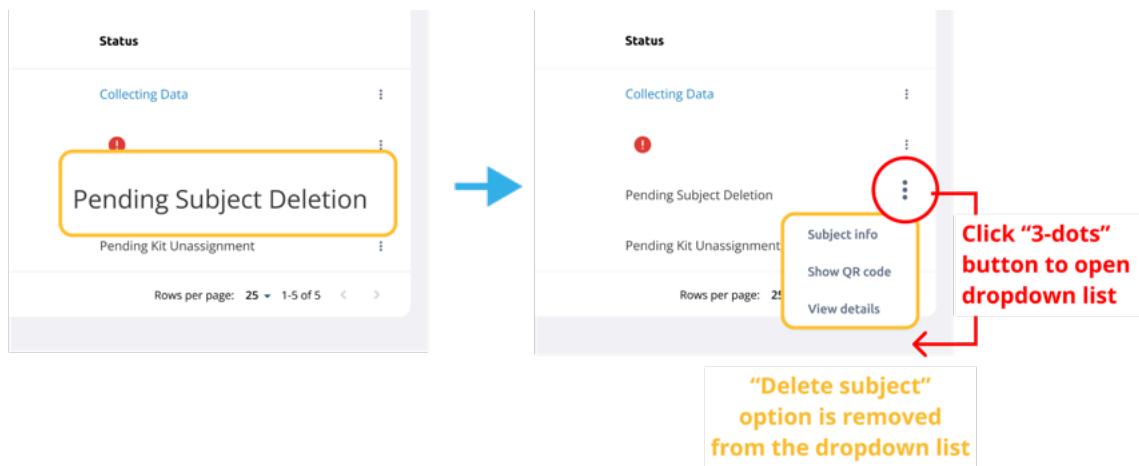


3.4.6 Deleting a Subject

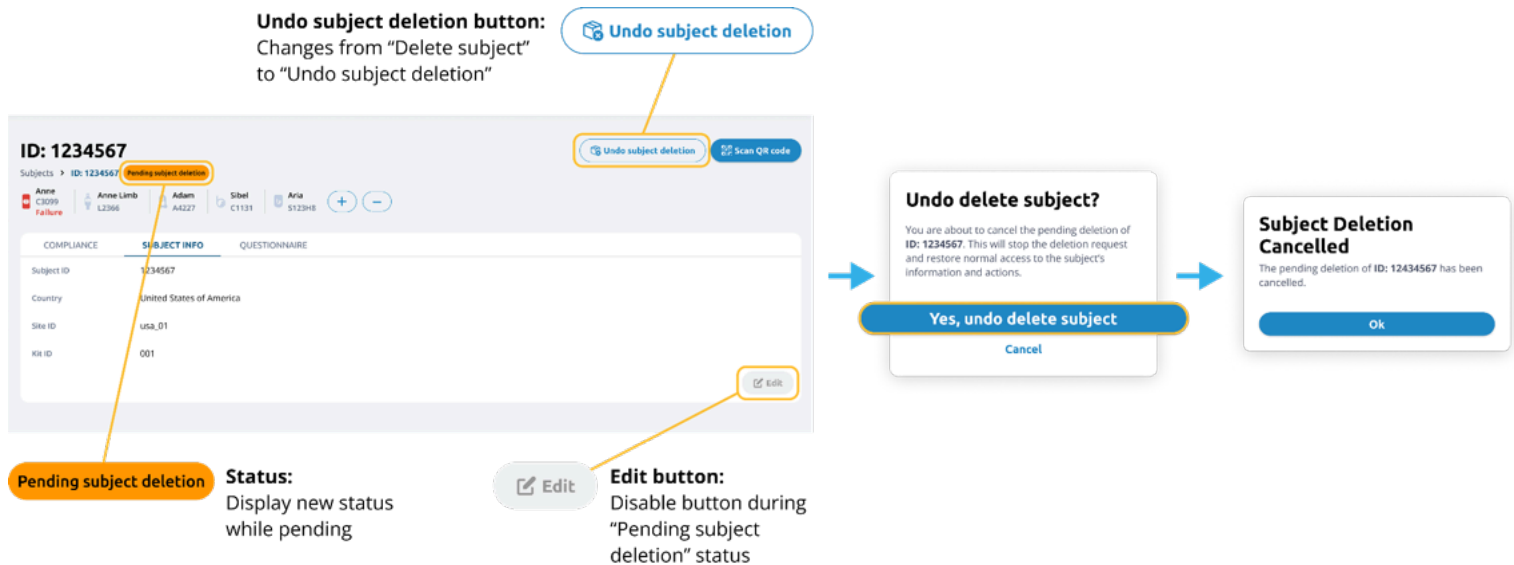
You can also delete a Subject from the system by selecting “Delete subject” from the same drop-down menu. Before doing so, you will be prompted to type out the subject’s ID to confirm. If accidentally deleted, contact Sibel to recover lost information.



Placeholder text for “Pending Subject Deletion” view in “Active” tab.

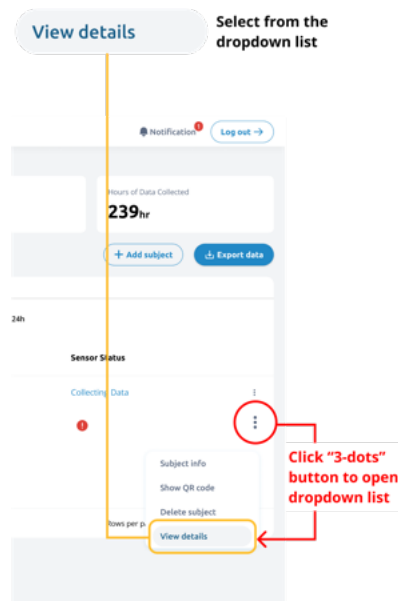


If it is no longer necessary to Delete the Subject, click “Undo subject deletion” and the subject will be returned to the normal status and the “Study Ended” workflow will be removed from the Discovery App.

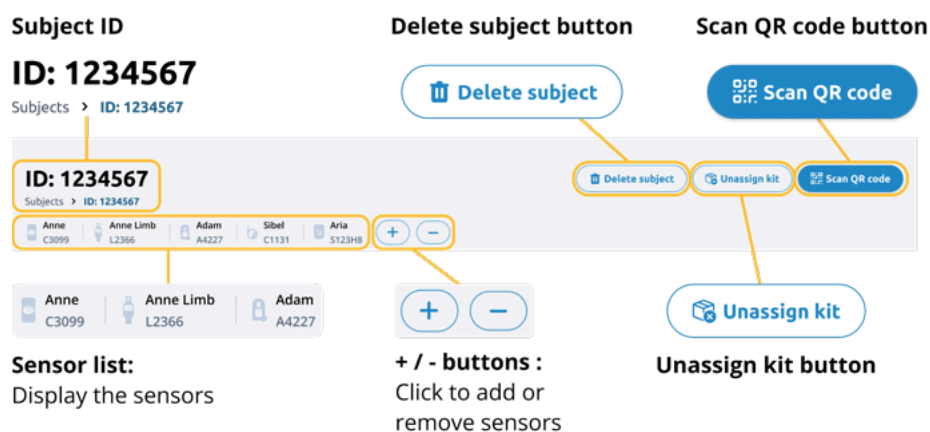


3.5 Subject’s Detailed View

By clicking on a Subject or clicking **View details** in the drop down menu (the “3-dots” icon), you can access the Subject’s Detailed View. On the top of the screen, you can access the Compliance, Subject Info and Questionnaire sections. The IDs of the Sensors assigned to this Subject are listed above. The sensor icon will be red if an error is detected, indicating it must be replaced. There are also buttons to delete the subject, unassign the kit, and to display the QR Code.

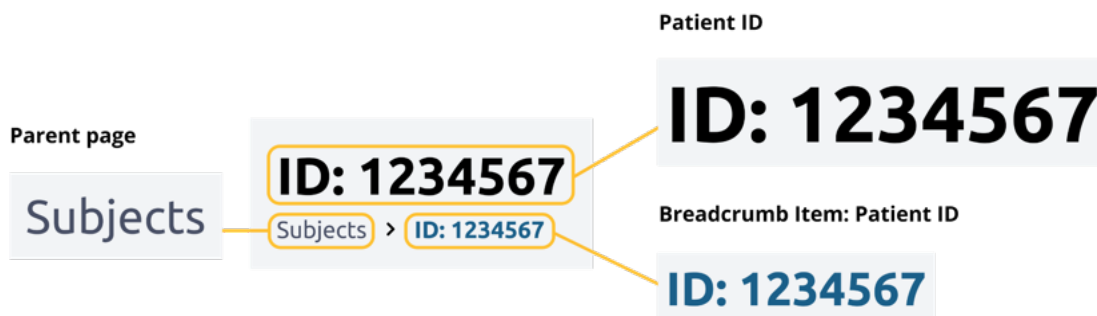


3.5.1 Top Bar

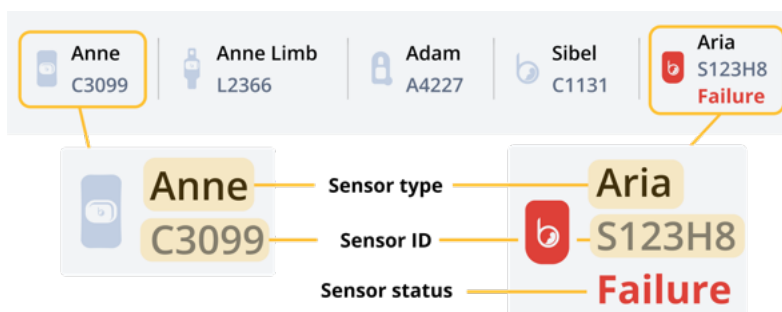


Top bar overview of Subject Detailed View Page

3.5.2 Subject Info



3.5.3 Sensor Info



3.5.4 Compliance

This tab contains a table that tracks the Subject's compliance. The table displays each day the Subject has had the kit, and will indicate days when the Subject collected data. Hovering the cursor over one of the cells displays the date.

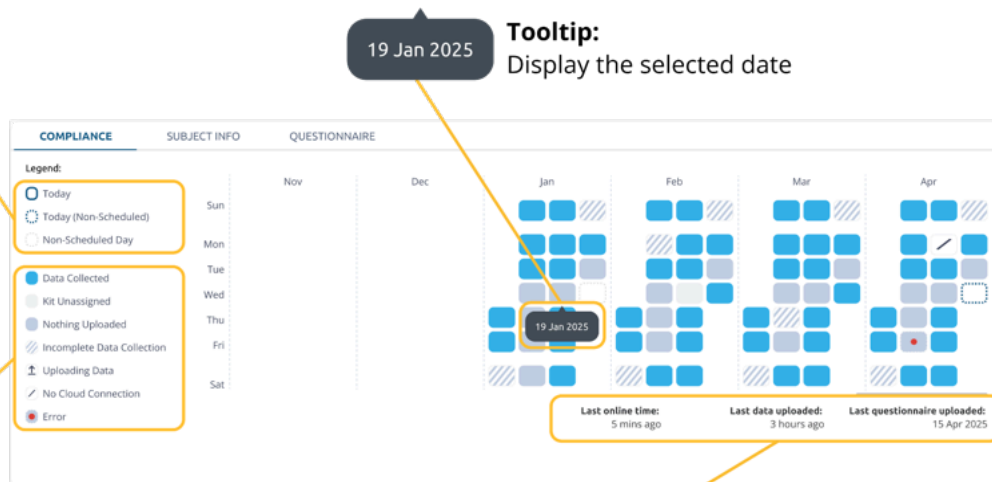
A legend is provided on the left side to differentiate the status of collected data over each day. The last online, last data upload, and last questionnaire upload statuses are also displayed.

Scheduling Status

- Today
- Today (Non-Scheduled)
- Non-Scheduled Day

Data Collection Status

- Data Collected
- Kit Unassigned
- Nothing Uploaded
- Incomplete Data Collection
- Uploading Data
- No Cloud Connection
- Error



Tooltip:
Display the selected date

Other statuses:

Display the last online, data uploaded, and questionnaire uploaded time

Last online time: 5 mins ago	Last data uploaded: 3 hours ago	Last questionnaire uploaded: 15 Apr 2025
--	---	--

3.5.5 Subject's Audit Trail

Clicking on a cell displays the Subject's Audit Trail. This tracks actions performed in the Discovery App by the subject.

Note: This is different from the Audit Trail explained in [Section 3.6](#), which covers actions performed in Discovery Hub by study personnel.

Subject's Audit Trail actions include:

- **Added a Subject** (Add kit to a subject)
- **Unassigned a Kit**
- **Started Survey**
- **Completed Survey**
- **Connected Sensor**
- **Uploaded Data**
- **Disconnected Sensor**
- **Replaced a Sensor**
- **Failed Sensor**

Audit trail for 16 Apr 2025

Filter: All Actions

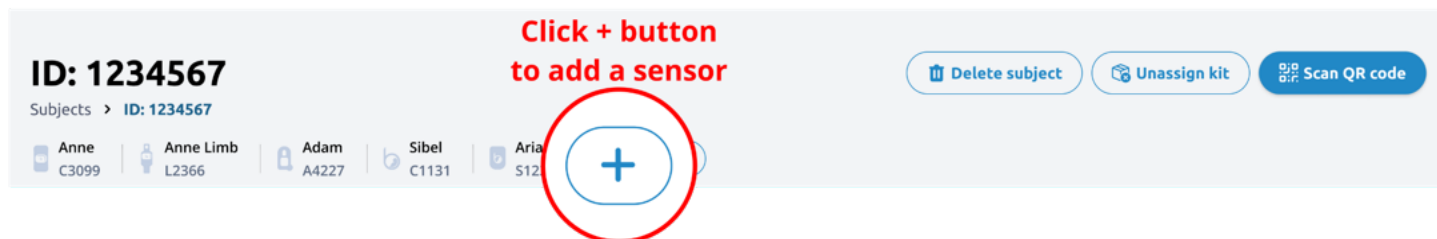
Action	Sensor ID	Time
Disconnected Sensor		16 Apr 2025 18:56
Uploaded Data	C3099	16 Apr 2025 16:33
Connected Sensor		16 Apr 2025 10:07
Completed Survey		16 Apr 2025 10:01
Started Survey		16 Apr 2025 09:44
Failed Sensor	C3099	16 Apr 2025 09:10

Full list of actions

- All Actions
- Added a Subject
- Unassigned Kit
- Started Survey
- Completed Survey
- Connected Sensor
- Uploaded Data
- Disconnected Sensor
- Replaced a Sensor
- Failed Sensor

3.5.6 Adding a Sensor

To add a new sensor to the kit, click the  button next to the sensor ID.



On the pop-up menu, under "Sensor ID" enter the ID of the new sensor to add to the kit.

Note: You must enter the EXACT Sensor ID of the new sensor, and any differences will result in the inability to pair the new sensor.

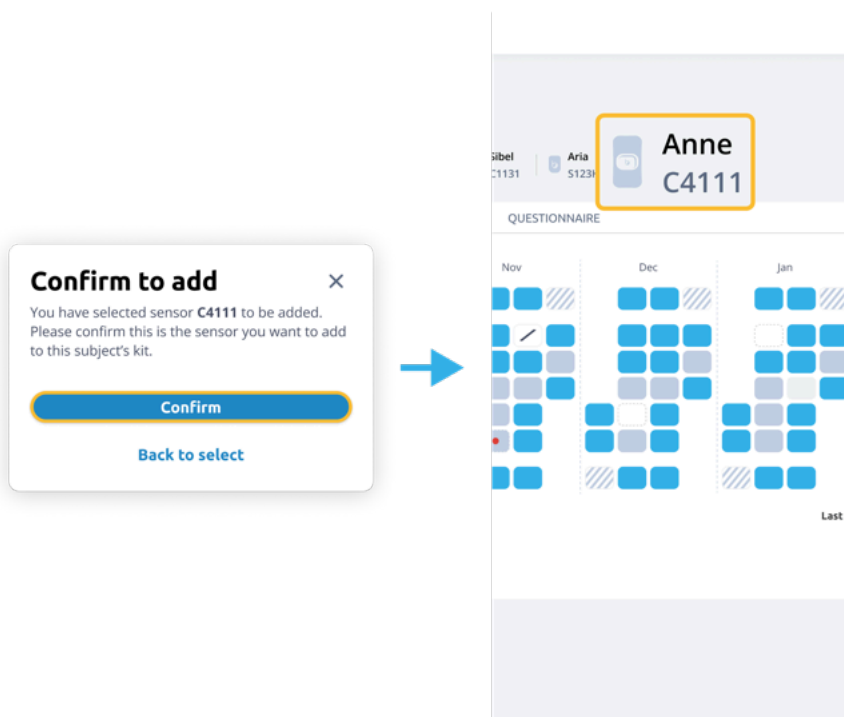
Under "Sensor Type" you will see a drop down for the type of sensor to add. You can add "Anne", "Anne Limb", "Adam", "Aria", or "Sibel" sensors. ("Sibel" sensor represents a generic sensor).

Under "Sensor Location", you will see a drop down menu to configure the location of the sensor.

- All types of sensors allow you to select a generic "Location 1-9"
- Anne Sensors also allows you to select "Chest", "Chest 24h", and "Chest 7 day" (These correspond to use of the Standard Wear, Gentle Wear, and Extended Wear adhesives respectfully. Please refer to [Section 6.1](#) for details on each)
- Limb also allows you to select "Finger"
- Adam also allows you to select "Hand" or "Suprasternal Notch"
- Aria also allows you to select "Hand" "Suprasternal Notch", or "Abdomen".

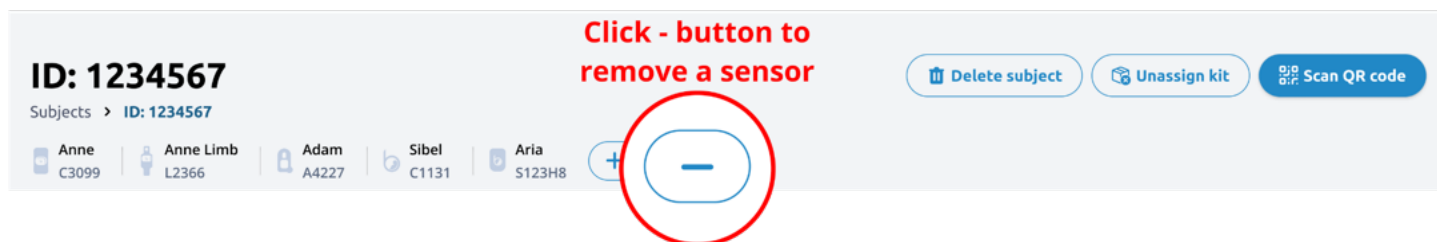
The 'Add sensor' pop-up menu is shown. It has a close button (X) in the top right corner. Below the title, it says 'Please enter the information below for the sensor you would like to add.' There are three input fields: 'Sensor ID*' with the value 'C4111', 'Sensor type*' with a dropdown menu showing 'Anne', and 'Sensor location*' with a dropdown menu showing 'Chest 24h'. At the bottom, there is a blue 'Next' button.

Once entered, click “Next” and you will be prompted to confirm, and then the new sensor will be paired. You will see the new Sensor ID on the Subject’s Detailed View page and if the kit is in use, the user will be able to see their App Screen Dashboard update to include the new sensor if connected to the internet. It may be necessary to restart the app if the sensor does not appear immediately.



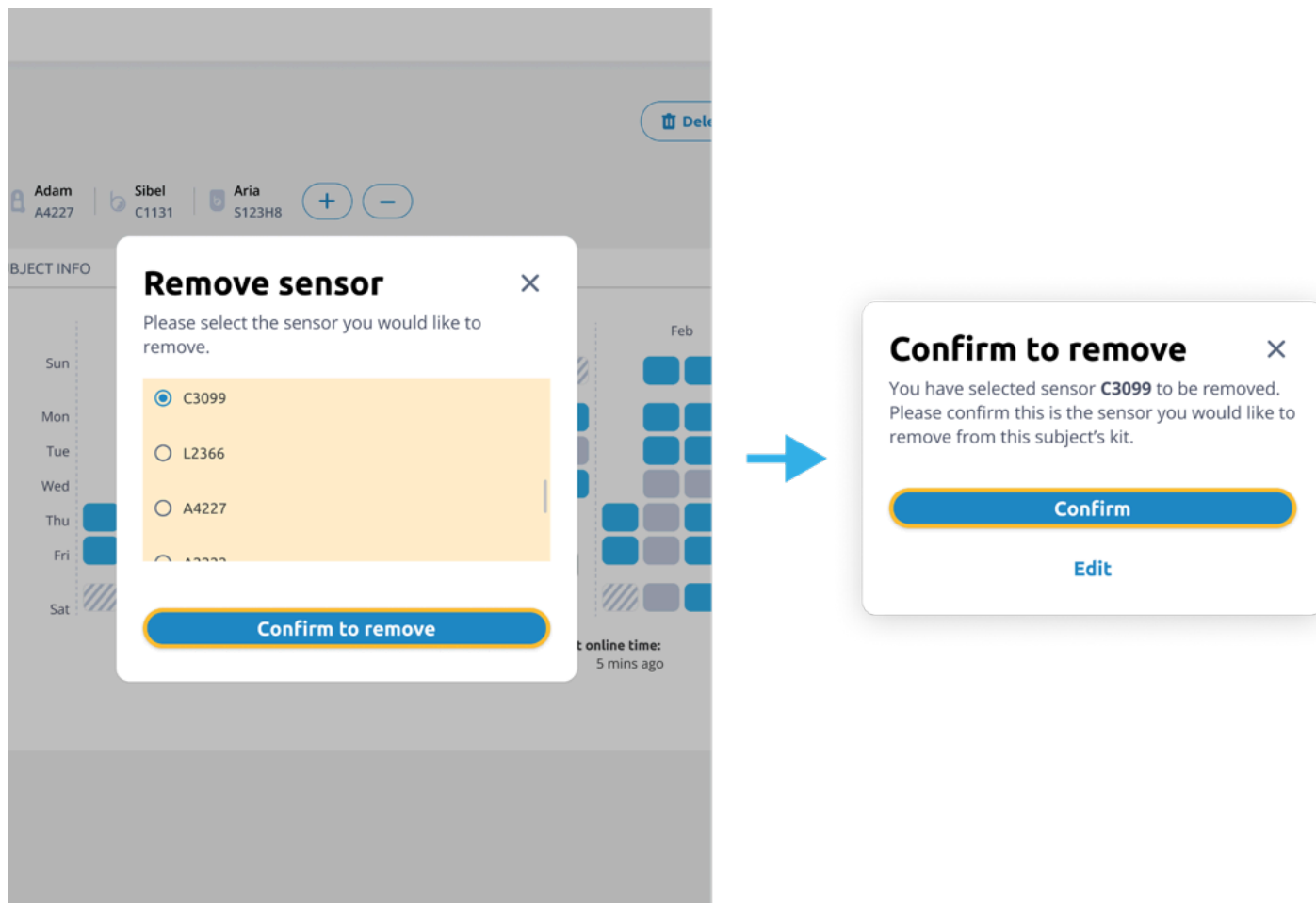
3.5.7 Removing a Sensor

To remove a sensor from the kit, click the  button next to the sensor ID.



On the pop-up menu, select the ID of the sensor to remove from the kit.

Once selected, proceed and confirm to remove the sensor. You will see that the Sensor ID is no longer present on the Subject's Detailed View page. If the kit is in use, the user will be able to see their App Screen Dashboard update to remove the old sensor if connected to the internet.



Note: There is also a way to replace a sensor in the app itself, this is described in [Section 8.1](#).

3.5.8 Subject Info

On this tab you can view the Subject's information, which shows their Subject ID, Country, Site ID, and Kit ID.

SUBJECT INFO

Subject ID	1234567
Country	United States of America
Site ID	usa_01
Kit ID	001

Edit button:
Click to edit subject info

You can also click “Edit” and enter the ID of a new Kit to change the Kit assigned to this Subject.

Edit subject info

Please edit the subject information below.

Subject ID:
1234567

Kit ID*
1234567

Sensor wear start date*
17 Mar 2023

Next

Confirm Information

Please review and confirm the subject info.

Subject ID 1234567

Country United States of America

Site ID usa_001

Kit ID 001

Sensor wear start date 17 Mar 2023

Edit

On this tab you can view the Subject's responses to the questionnaire. You can also arrange the responses by newest or oldest, and search for specific responses.

Contact Sibel to implement a questionnaire if needed as a part of the study protocol.

46-002 Rev. H Discovery IFU

3.5.10 Unassign a Kit

Once the subject is done using a kit, there are two ways to Unassign a Kit - one from the app (Refer to [Section 8.5](#)) and one from the Hub explained here.

Click “Unassign Kit” and confirm by entering the Subject ID. This will prompt the removal of the associated kit from the subject through the “Study Ended” workflow in the Discovery App (Please refer to [Section 8.6](#)). Until this is completed, the Subject will remain in the “Active” Subjects List with the status “Pending kit unassignment”.

Unassign kit

Click the UNASSIGN KIT button to unassign the kit from the subject

Unassign kit?

Warning: This action starts the kit unassignment process.

The subject will move to **Pending Kit Unassignment** status, where the subject info will remain on Hub until the participant uploads all remaining data and logs out. Please ensure all data has been uploaded before proceeding. If any data remains on the device, the participant will be prompted to upload it. **Once logged out, the kit will be fully unassigned and ready for use on a new subject.**

Contact Sibel for support if unassigned accidentally.

Yes, unassign kit

Cancel

Kit unassigned successfully

You can find the subject under active tab with the status “Pending Kit Unassignment”.

Ok

Subject will remain in the “Active” Subjects List

Status

Collecting Data

Pending Subject Deletion

Pending Kit Unassignment

Rows per page: 25 • 1-5 of 5

Status

Collecting Data

Pending Subject Deletion

Pending Kit Unassignment

Rows per page: 25

Subject info

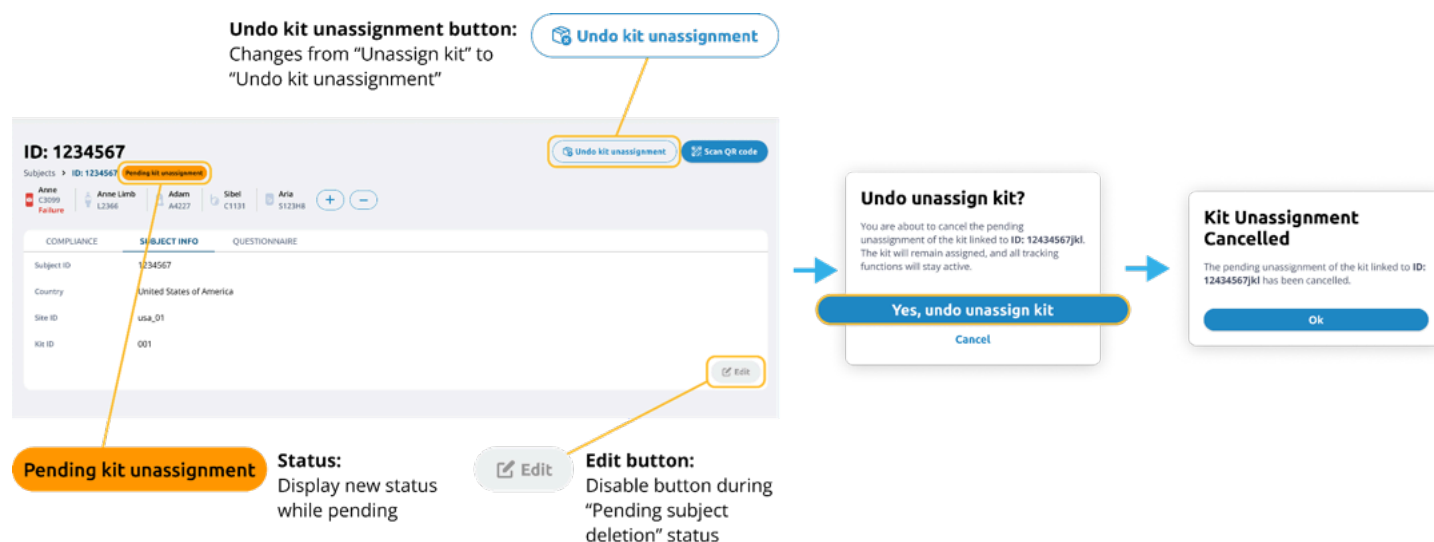
Show QR code

View details

Click “3-dots” button to open dropdown list

“Delete subject” option is removed from the dropdown list

Until the “Study Ended” workflow is completed, the new status “Pending kit unassignment” will be displayed next to the subject ID. If it is no longer necessary to Unassign the Kit, click “Undo kit unassignment” and the subject will be returned to the normal status and the “Study Ended” workflow will be removed from the Discovery App.



Once the “Study Ended” workflow is completed, the subject will automatically be moved to the “Inactive” Subjects List, and the kit can be associated with any new subject or other inactive subject as desired.

3.6 Personnel

The Personnel page is accessible by Admins (for their assigned site only), Research Coordinators cannot view this page or add/remove personnel.

3.6.1 Viewing Active Users

First, you may view a list of enrolled Personnel. Each user has an assigned account type, along with their email address and optionally, a phone number.

You will also be able to see a list of Personnel who have been invited to use Discovery Hub but have not yet accepted the invite under “Pending”.

ENROLLED

ENROLLED tab:
List of enrolled personnels

PENDING

PENDING tab:
List of personnels who have not yet accepted the invite

Account type:
Only accessible for Admin to the “Personnel” page

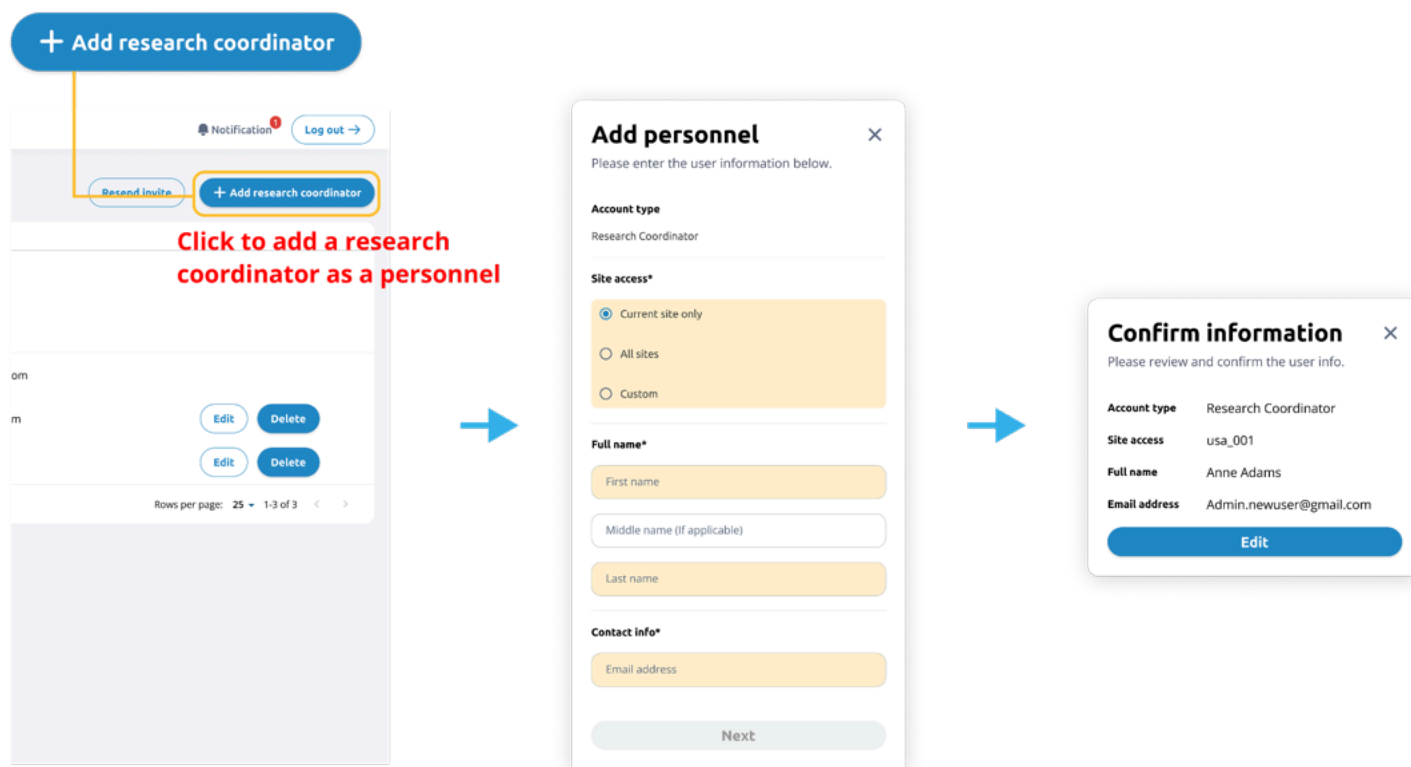
EDIT and DELETE button:
Edit or delete a “Research Coordinator” as a “Admin”

3.6.2 Adding New Personnel

Clicking “Add research coordinator” in the top-right corner will bring up a window where you will be prompted to enter a new user’s information to track.

You will then select their Site Access, deciding if they are to access all sites or only the currently selected site (from the site dropdown menu). You must enter the user’s First and Last Name, as well as a valid email address. Optionally, their Middle Name and Phone Number may also be added.

If you do not enter all of the required information, you will be prompted to do so before continuing. Once confirmed, the user will be invited. Their next step is to click on the link on the email sent to them and follow the steps to activate their account. Contact Sibel for help in inviting new personnel if needed.



3.6.3 Re-Inviting a User

To resend the invite email in case the invited user has trouble locating it, click “Resend Invite”. A window will open showing a list of all users that were invited to the Discovery Hub but have not yet accepted the invitation and their last invitation date.

Select all users to re-invite and then click “Confirm”. The invitation will be re-sent to everyone’s email addresses and they once again have a 30 day window to enroll.

Resend invite Click RESEND INVITE button to open pop up and select the user(s)

Resend invite

Choose user(s) to resend the invite email to.

☐ Email address	Last invitation date
☐ John.user@gmail.com	16 Mar 2024 18:56
☒ Kathryn1234@gmail.com	7 Mar 2024 18:56
☐ Devon.user@gmail.com	1 Mar 2024 18:56

Confirm

After selecting the user(s), click the CONFIRM button

3.6.4 Deleting a User

You can delete a user from the list by selecting “Delete” at the end of row and confirming the deletion by re-entering their full name.

Click DELETE USER button to open the popup and delete the user

Delete

Delete this user?
Please type the user's full name to confirm deletion of the user. All information related to this user will be deleted and can not be restored.

Leslie Alexander

Confirm
Cancel

Yes, delete user
Cancel

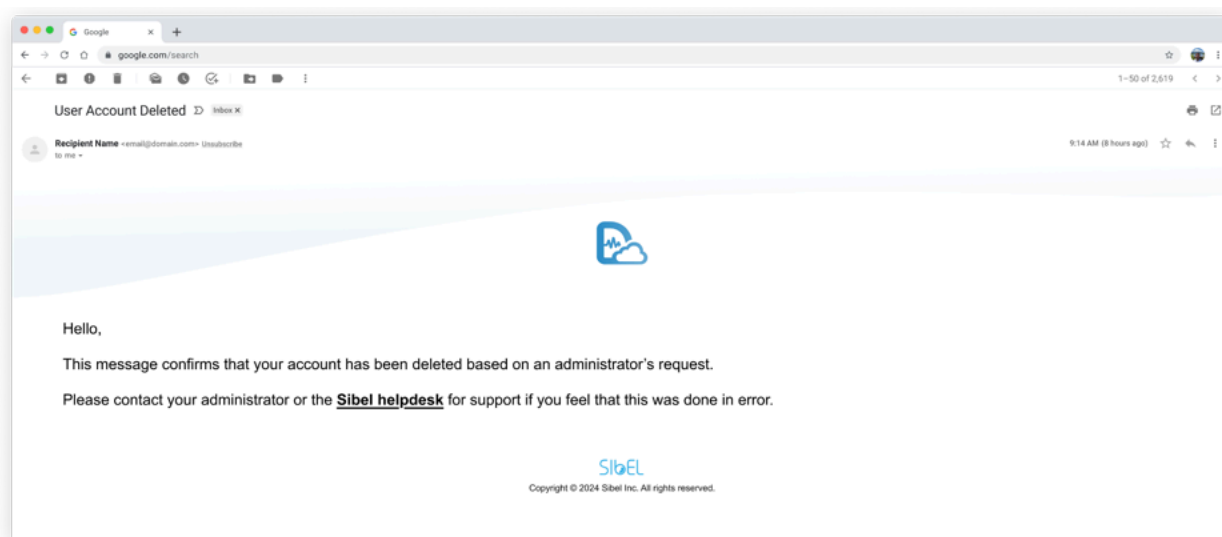
User has been deleted
All information related to **Leslie Alexander** has been removed.

Ok

After confirming the user's name, click the YES, DELETE USER button

Yes, delete user

Deleted users will receive an email confirming that they have been deleted per an admin's request.



Note: Admins may only delete Research Coordinators, not other Admins.

3.7 Audit Trail

The Audit Trail section is accessible by any user for their assigned site only. This page tracks actions performed by all enrolled personnel on Discovery Hub. This page also allows you to filter for specific actions, the users who performed the action, and the time when the action occurred.

Audit trail actions include:

- **Signed Up** (Enroll in Discovery Hub)
- **Reset Password**
- **Changed Password**
- **Changed Account Information**
- **Changed Summary Email Settings**
- **Added a Subject** (Add kit to a subject)
- **Edited a Subject** (Change kit)
- **Deleted a Subject**
- **Unassigned a Kit**
- **Added a Personnel**
- **Deleted a Personnel**
- **Added a Sensor**
- **Removed a Sensor**
- **Replaced a Sensor**
- **Exported Data**
- **Viewed Resource** (Knowledge Center)
- **Downloaded Resource**
- **Downloaded Report**

Actions: List of the actions from all enrolled personnels

User: List of the users who performed the action

EXPORT button: Click to download a csv file for listed items

Start date and End date: Filter the time when the action occurred

Action	User	Affected User	Time
Deleted a Subject	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Deleted a Subject	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Deleted a Subject	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Downloaded Resource	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Edited a Subject	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Signed Up	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Changed password	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Viewed Resource	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Added a Subject	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56
Deleted a Subject	username1@sibelhealth.com	username1@sibelhealth.com	17 Jul 2023 18:56

You can export a csv file of the filtered list by clicking the **Export** button on the top right corner. It will only export listed items into the csv.

3.8 Account

Account information for your Discovery Hub account is viewed here. This page allows the user to view their account information, change their password, edit any personal info, and opt in or out of summary emails.

The screenshot shows the 'Account' page for Anne Adams, a Research Coordinator. The page includes a sidebar with navigation links (Subjects, Audit trail, Account), a main content area with 'Account info' and 'Summary email settings', and a footer with 'Knowledge center' and 'Terms of Use'.

Callouts:

- Change password:** View account type and change the password. (Points to the 'Change password' link in the top header and the 'Change password' button in the 'Account info' section.)
- Account info:** View and edit user's full name and email address. (Points to the 'Edit' button in the 'Account info' section.)
- Summary email settings toggle:** Opt in or out of summary emails. (Points to the 'ON' toggle switch in the 'Summary email settings' section.)

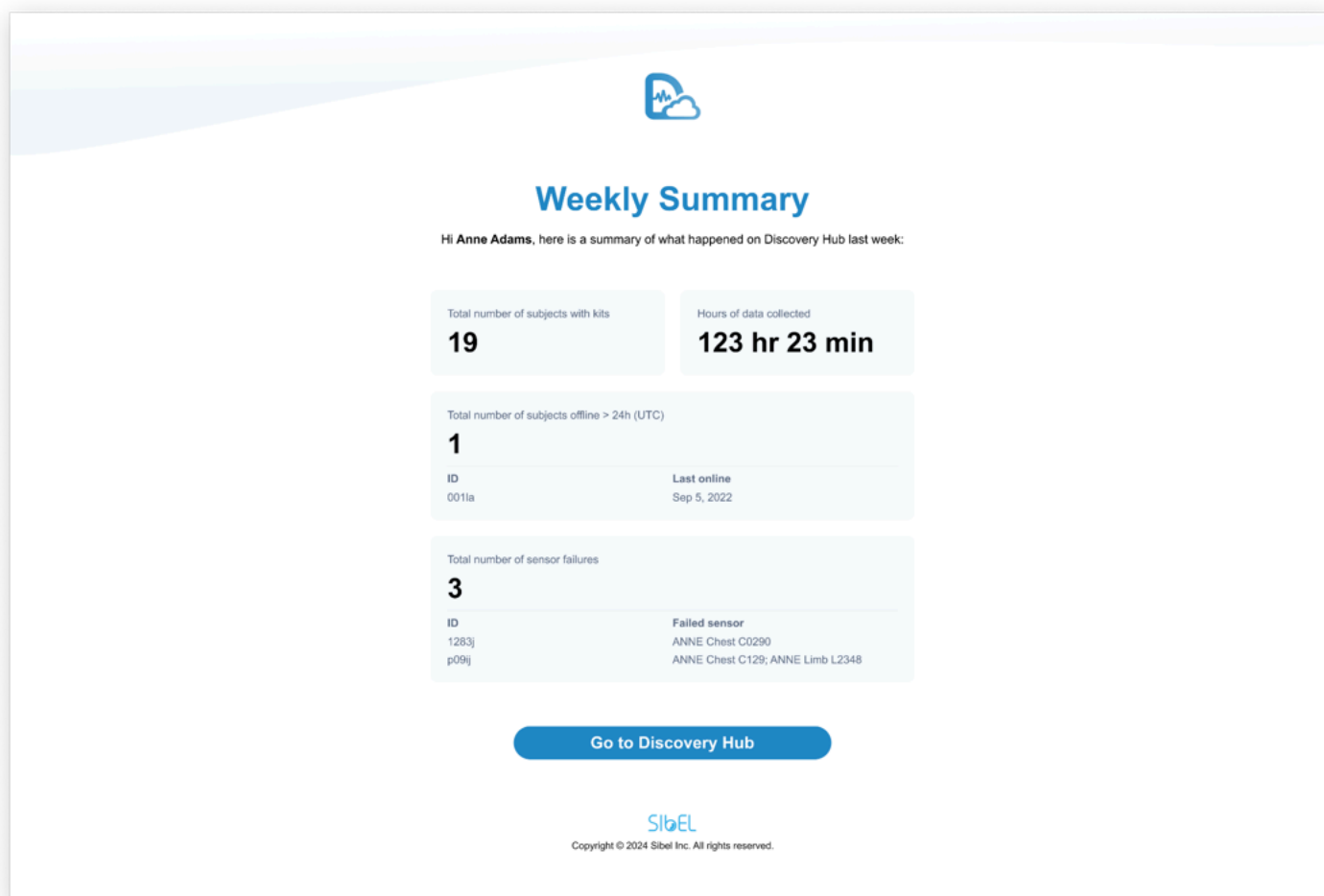
Account Info Details:

Field	Value
Full name	Anne Adams
Email	123321ANNE@gmail.com

Summary email settings:

Summary email on/off
 Summary emails will be sent to the email address linked to your account.
☒ ON ☐ OFF

Summary emails are sent once a week on Monday to any Admins or Research Coordinators who opted in, and include a summary of sensor issues, hours of data collected, active study subject compliance and online status.



The image shows a screenshot of a "Weekly Summary" email template. At the top, there is a blue header with a cloud and pulse icon. Below the header, the title "Weekly Summary" is displayed in blue. A greeting line reads: "Hi Anne Adams, here is a summary of what happened on Discovery Hub last week:". The main content is organized into three light blue boxes. The first box shows "Total number of subjects with kits" as 19 and "Hours of data collected" as 123 hr 23 min. The second box shows "Total number of subjects offline > 24h (UTC)" as 1, with a table listing the ID 001la and its last online date as Sep 5, 2022. The third box shows "Total number of sensor failures" as 3, with a table listing the IDs 1283j and p09lj, and the failed sensors as ANNE Chest C0290 and ANNE Chest C129; ANNE Limb L2348. At the bottom, there is a blue button labeled "Go to Discovery Hub" and a footer with the SibEL logo and copyright notice: "Copyright © 2024 SibEL Inc. All rights reserved."



Weekly Summary

Hi Anne Adams, here is a summary of what happened on Discovery Hub last week:

Total number of subjects with kits	Hours of data collected
19	123 hr 23 min

Total number of subjects offline > 24h (UTC)	
1	
ID	Last online
001la	Sep 5, 2022

Total number of sensor failures	
3	
ID	Failed sensor
1283j	ANNE Chest C0290
p09lj	ANNE Chest C129; ANNE Limb L2348

[Go to Discovery Hub](#)


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3.9 Knowledge Center

The Knowledge Center is accessible by pressing the  button on the bottom-left corner of any page. The Knowledge Center contains educational resources on the Discovery system, such as PDF copies of the Quick Start Guides included in each kit, an FAQ, and a checklist to fill out before deploying the kits. There are also videos demonstrating how to apply the sensor adhesive and other actions.

Additionally, you can access the Sibel Support website by clicking the [Support center](#) button. This site contains additional information for troubleshooting and answering frequently asked questions. Additionally, pressing [Submit request](#) will direct you to a page where you can submit a support ticket if you were not able to find the answer on this page. An agent from Sibel Health will respond within 1 business day to help.

The screenshot shows the Sibel Discovery Hub Knowledge Center. At the top, there are three tabs: "STUDY PARTICIPANT RESOURCES", "DISCOVERY HUB RESOURCES", and "ADDITIONAL RESOURCES". The "STUDY PARTICIPANT RESOURCES" tab is selected. Below the tabs, there is a search bar with the placeholder text "Search by Subject ID". To the right of the search bar, there are two buttons: "Support center" and "Submit request". Below the search bar, there is a grid of resource cards. Each card has a title "How to put on sensors", a description "Lorem ipsum dolor sit amet, consectetur adipiscing elit. Fusce a euismod arcu. Fus...", and a "Download" button. The first card in the grid is highlighted with an orange border. To the left of the grid, there is a sidebar with a user profile for "Anne Adams" (Research Coordinator) and a "Knowledge center" button. To the right of the grid, there is a legend for "List" and "Grid" views, and a section titled "Types of file format:" showing icons for Image, PDF, and Video. Annotations with orange lines point to the "Support center" and "Submit request" buttons, the "Knowledge center" button, and the "List" and "Grid" view icons.

Support center
Directs to Sibel Support website that has FAQs and troubleshooting

Submit request
Directs to the page to submit a support request ticket

Knowledge center
Click KNOWLEDGE CENTER button to view and download resources

List and grid view
List Grid

Types of file format:
Image, PDF, and video

Section 4. Pairing a Study Subject with the Discovery App

This section describes the steps needed to begin using the Discovery App with the sensor.

4.1 Starting the Discovery App

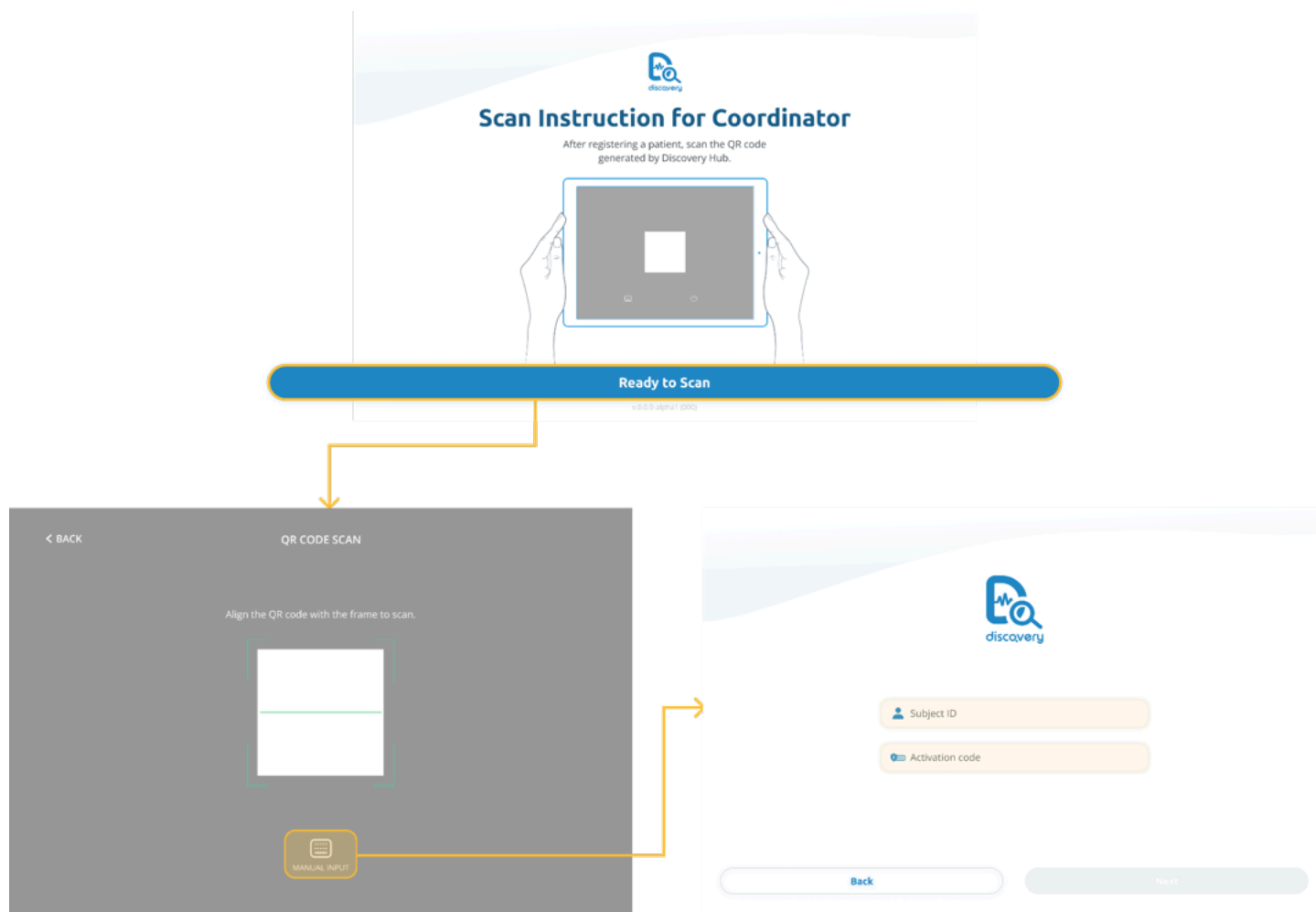
Step 1

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



Step 2

Scan the QR Code provided from Discovery Hub or Manually input the Subject ID and Activation Code. The Activation Code is viewable underneath the QR Code displayed on Discovery Hub.



Note: An internet connection on the tablet is required to complete this step.

After inputting a code, the Subject's data begins loading into the app, indicated by this icon next to the Subject ID and Site ID.

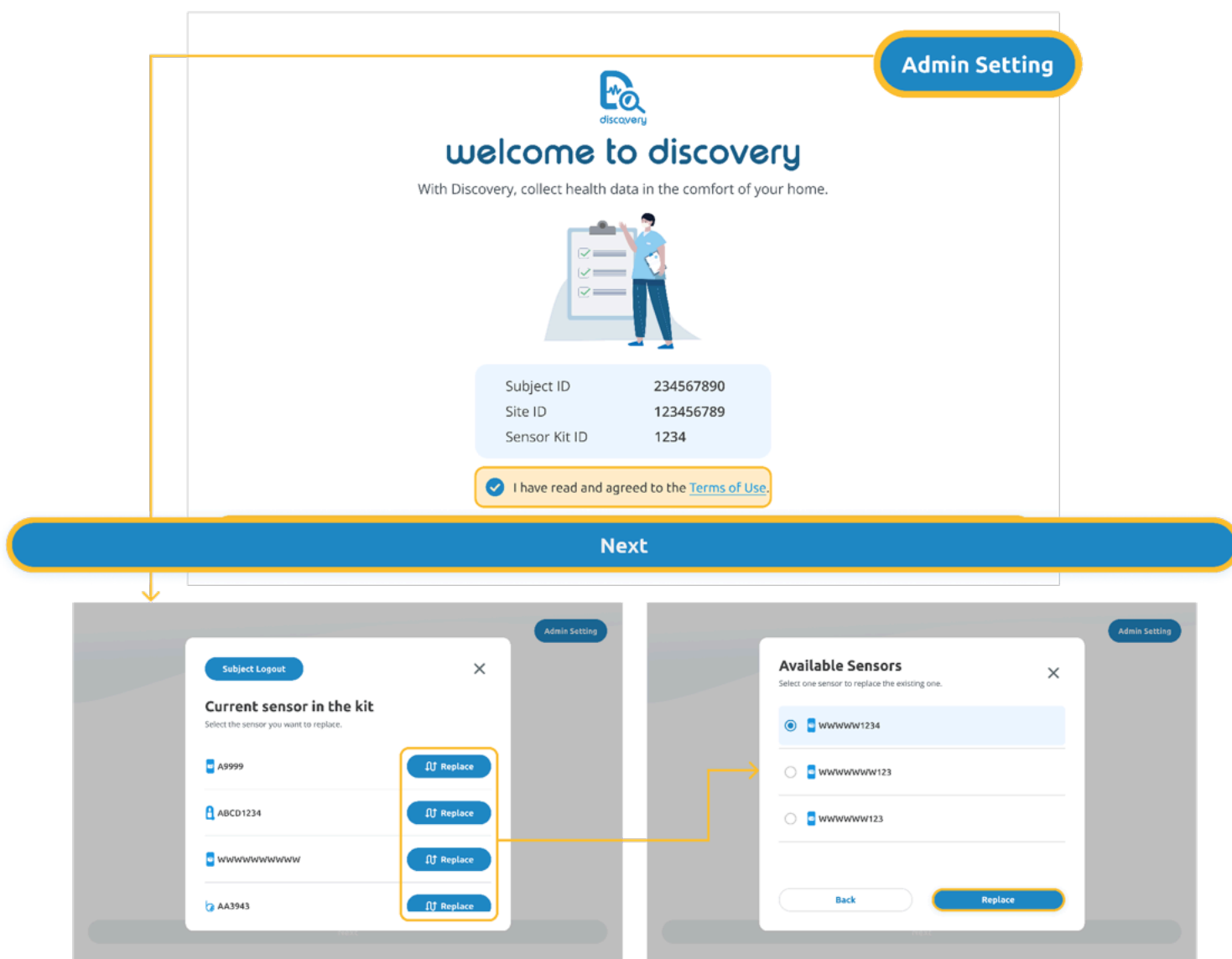


After loading completes, the configured Subject ID and Site ID will be shown.

Step 3

Agree to the Terms of Use. If the wrong QR code was scanned, click “Admin Setting” and follow the instructions in [Section 8.6](#) to log out. If a different sensor is needed, follow the instructions in [Section 8.2](#) to replace the sensor. Click the Next button to continue to the next step.

Note: This screen is what the App should display when Subjects begin using the Discovery Kit. When deploying a kit, close the app on this screen.



Step 4

Confirm the steps the Subject will be performing on the “What you will be doing” screen. Click the  button to continue to the next step.

What you will be doing



Wear the sensors
according to instructions



Collect and
sync data

BackNext

4.2 Pairing the Sensors

Wake up the sensors by placing them on the charger as described in [Section 2.4](#). Once the sensors are turned on, move them close to the tablet for pairing. Once they are paired, click “Next” to advance to the dashboard.



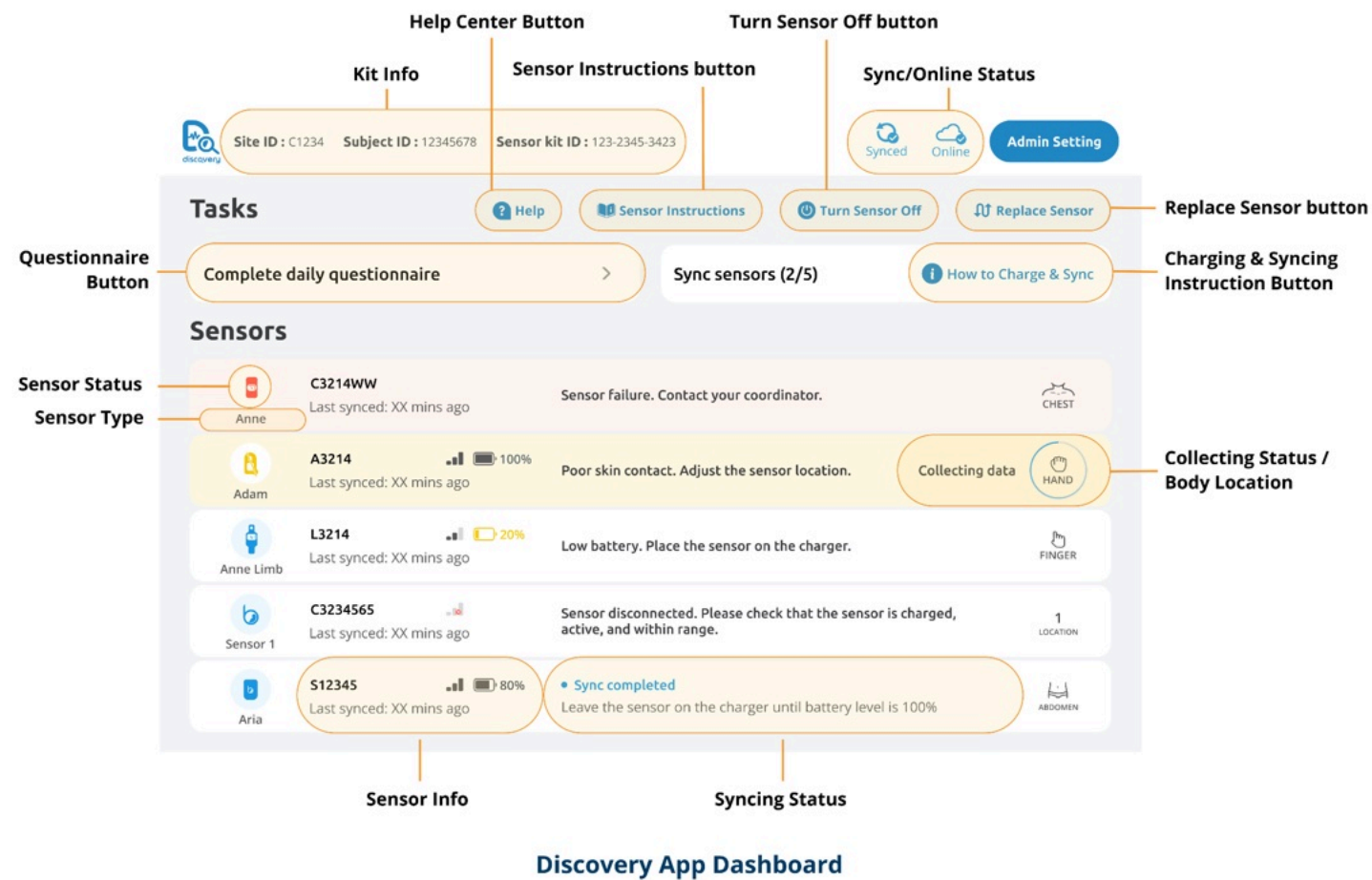
Note: The sensor must be within 2 meters of the tablet to pair.

Section 5. Discovery App Dashboard

This section describes the instructions for using the Discovery App, as well as interpreting information displayed on the app dashboard.

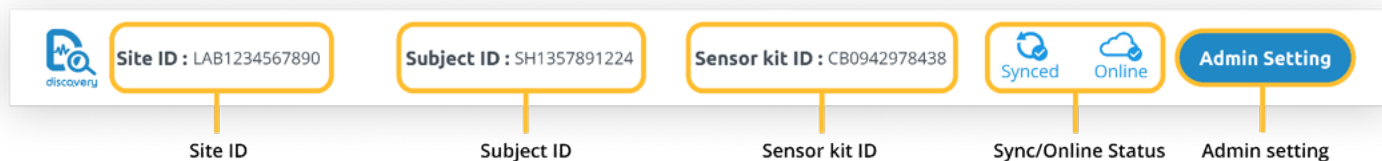
5.1 Discovery App Overview

The Discovery App Dashboard has three distinct sections: Top Bar, Tasks, and Sensors.



5.2 Top Bar

The Top Bar contains identification information for the Kit associated with the tablet (Site ID, Subject ID, Kit ID), as well as online status and access to admin settings.



Site ID:

ID for the site where this Kit will be used, as selected in Discovery Hub.

Subject ID:

ID for the Subject using this Kit, as configured in Discovery Hub.

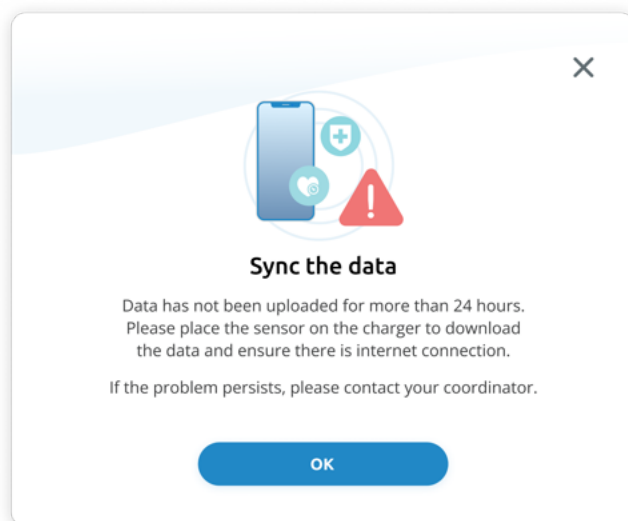
Sensor Kit ID:

ID for the Kit containing this tablet and app, as assigned in Discovery Hub.

Sync Status: Synced Syncing Unsynced

Sync Status can be one of the following:

- **Synced:** If all data from the tablet is synced with the cloud OR there is no data to sync.
- **Syncing:** If there is data synced from the sensor to the app and a cloud upload is in progress.
- **Unsynced:** If there is data locally on the tablet not synced with the cloud due to a connection issue. The pop-up message on the right appears when unsynced for over 24 hours.

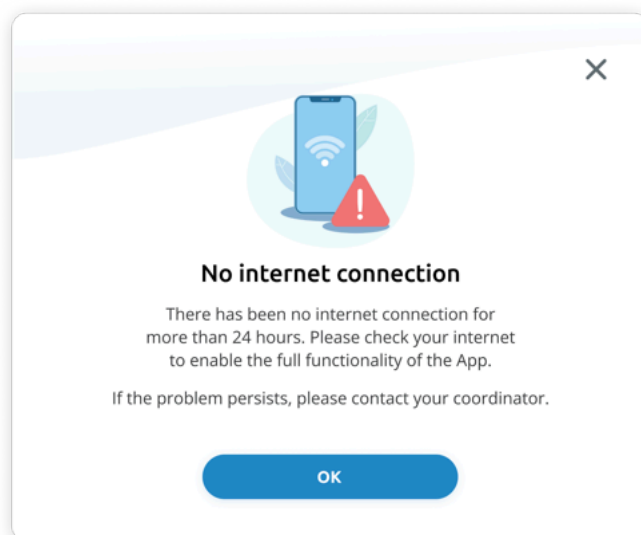


Note: For faster data syncing, we recommend connecting to WiFi if possible, as cellular data may be slower. If the sync icon stays gray for a long time, please contact Sibel.

Online Status: Online Offline

Online Status displays whether the tablet is connected to the internet or not:

- **Online:** Connected to the internet.
- **Offline:** Not connected to the internet. The pop-up message on the right appears when not connected for over 24 hours.

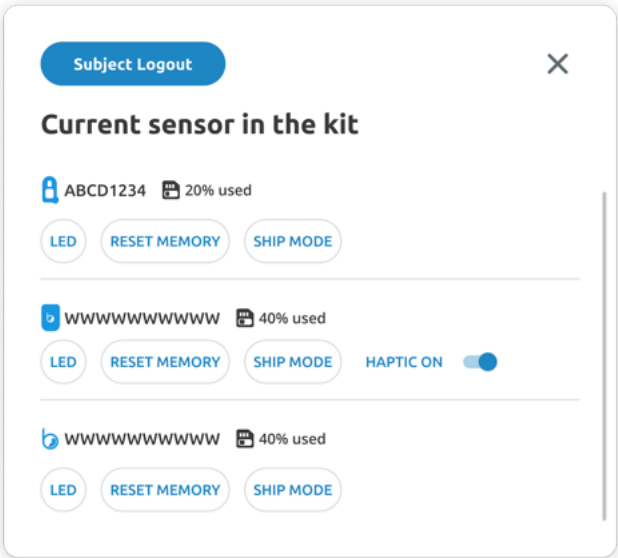


Admin Setting: Admin Setting

Enables access to admin settings:

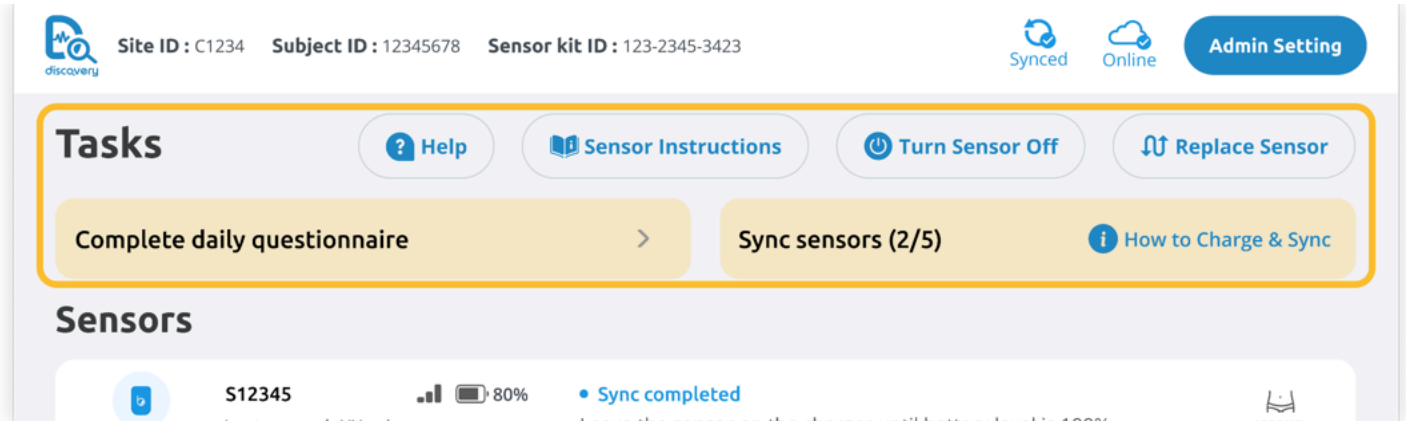
- **Subject Logout:** Unenrolls the subject and returns the app to the first screen
- **LED:** Toggles the Sensor LED On/Off
- **Reset Memory:** Deletes all data in the Sensor
- **Ship Mode:** Puts the sensor to sleep
- **Haptic On/Off:** Toggles Haptic On/Off (Aria Only)

Please refer to [Section 8.3](#) for more detailed information on Admin Settings.



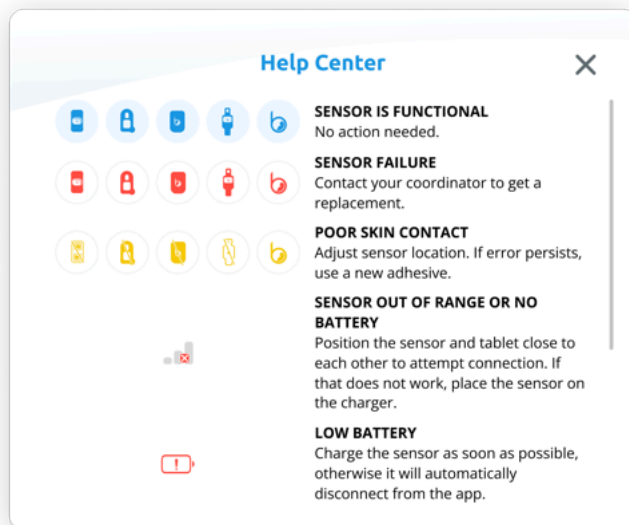
5.3 Tasks

The Tasks Section provides access to various instruction windows, as well as the questionnaire and a tracker for how many sensors have been synced.



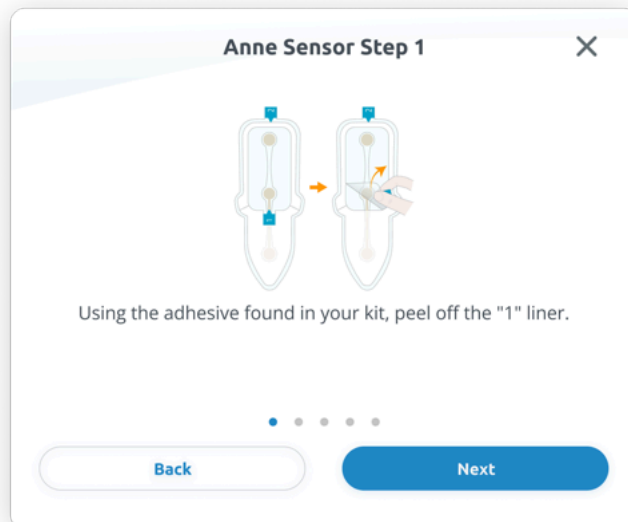
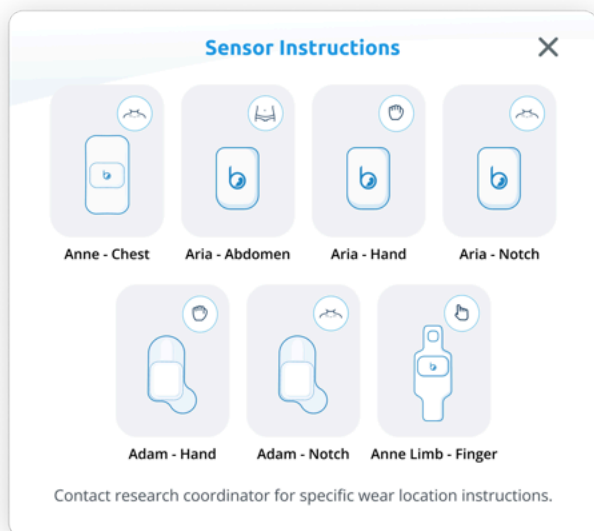
Help:

Displays the Help Center, which provides information on the meaning of each sensor icon and troubleshooting information.



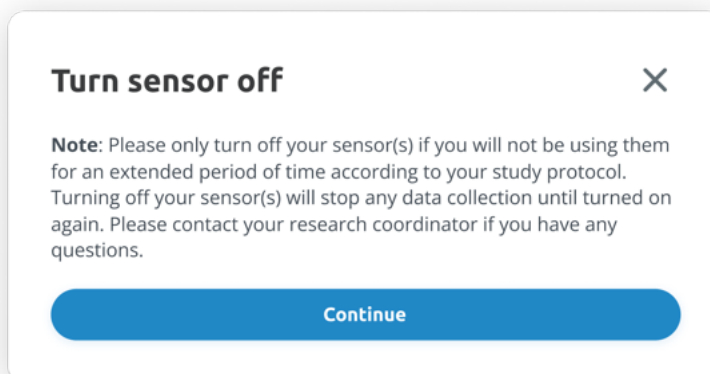
Sensor Instructions:

Provides instructions for how to apply and use each set of sensors.



Turn Sensor Off:

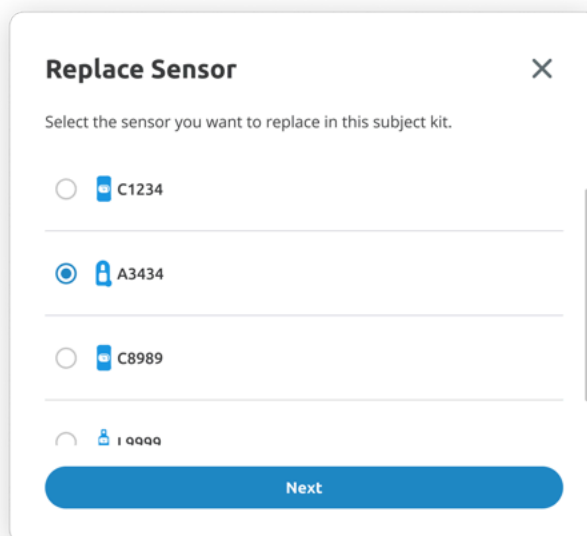
Allows the user to turn the sensor off when they are not using it to save battery.



Replace Sensor:

[↺↻ Replace Sensor](#)

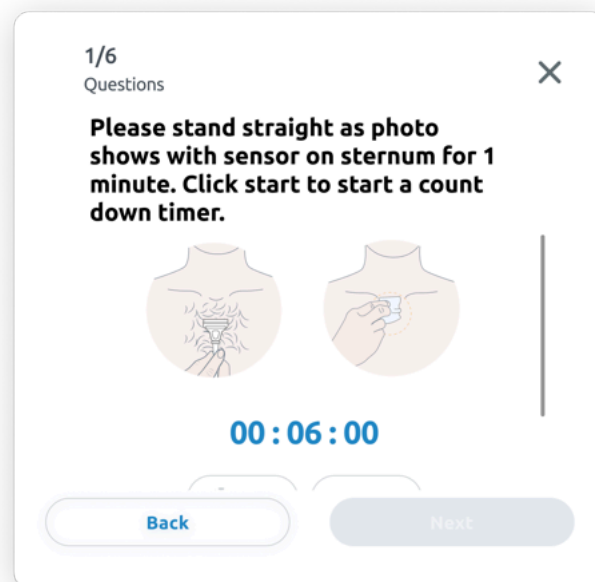
Enables the replacement of any sensor associated with the kit.



Complete Daily Questionnaire:

[Complete daily questionnaire](#) >

Brings up the questionnaire to be filled out as required by the study protocol. Note that this can only be selected if there is a questionnaire available for the Subject, otherwise it will be grayed out and the subject will not be able to select it. The questionnaire can be submitted multiple times within one day if desired.



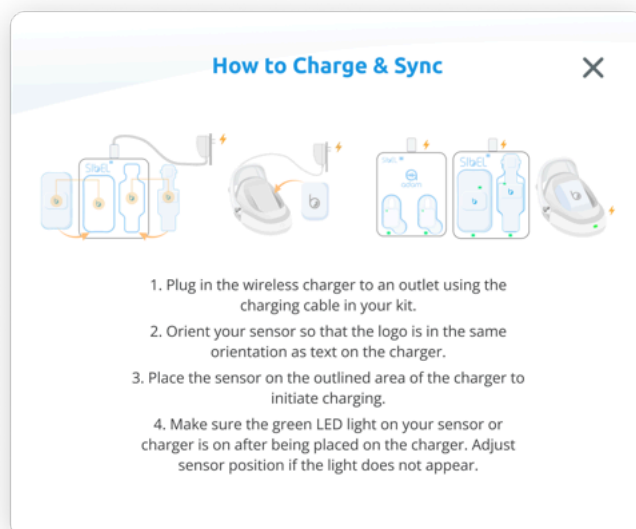
Sync Sensors:

Indicates how many of the sensors have synced their data with the tablet out of all registered sensors.

[Sync sensors \(1/2\)](#)[i How to Charge & Sync](#)

How to Sync & Charge: How to Charge & Sync

Displays instructions on how to place the sensor on the charger to sync the data.



5.4 Sensors

The Sensors Section displays all sensors paired with this Discovery Kit and their statuses, including the type of sensor, sync status, battery level, and its configured body position.

5.4.1 Icon Legend

Sensor Status/Type	Sensor Signal and Battery	Collecting Status / Body Location
Anne CJ1234 Last synced: 45 mins ago	80%	Collecting data
Anne CJ3214	100%	Syncing... 80% time left
Adam A7777 Last synced: 5 mins ago	40%	• Sync completed Leave the sensor on the charger until battery level is 100%
Sensor ID		Sync Status

Sensor Type:



Anne



Adam



Sensor



Aria

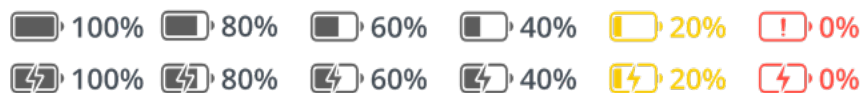


Anne Limb

Sensor Signal:



Sensor Battery:



Sync Status:

- Sync completed
- Sync the sensor
- Sync needed immediately



See Section 7.1.5 for explanation of the sensor sync statuses.

Body Location:



HAND



CHEST



LOCATION



ABDOMEN



FINGER

5.4.2 Alert Icons

High Priority:

- Sensor Failure

CJ3214

100%

Last synced: 45 mins ago

Sensor failure. Contact your coordinator.

- Critical Battery Level

CJ3214

0%

Last synced: 45 mins ago

Low battery. Place the sensor on the charger.

- Critical Storage Level

CJ3214

100%

Last synced: 45 mins ago

- **Sync needed immediately**

 Place the sensor on the charger

Medium Priority:

- Poor Skin Contact

CJ3214

100%

Last synced: 45 mins ago

Poor skin contact. Adjust the sensor location.

Collecting data

- Low Battery Level

CJ3214

20%

Last synced: 45 mins ago

Low battery. Place the sensor on the charger.

- Low Storage Level

CJ3214

100%

Last synced: 45 mins ago

- **Sync the sensor**

 Place the sensor on the charger to sync the data

Low Priority:

- Out of Range

CJ3214

Last synced: 45 mins ago

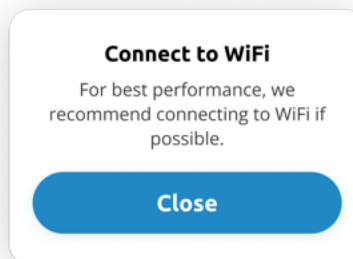
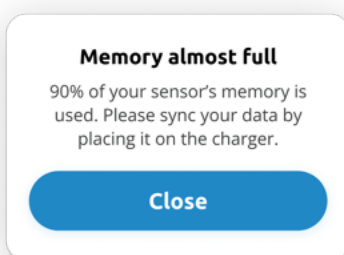
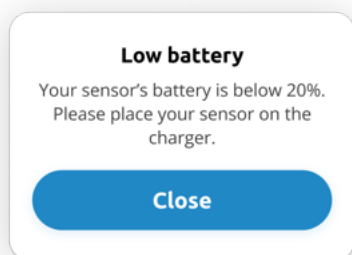
Sensor disconnected. Please check that the sensor is charged, active, and within range.

See [Section 7](#) for a detailed summary on how to respond to each type of sensor alert.

5.5 In-app Notifications

The following in-app notifications appear under the following conditions:

- **Low battery:** If the sensor's battery is below 20%.
- **Memory almost full:** If 90% of the sensor's memory is used.
- **Connect to WiFi:** If the mobile device detects it is not connected to WiFi (including if it is using cellular data).



Section 6. 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.

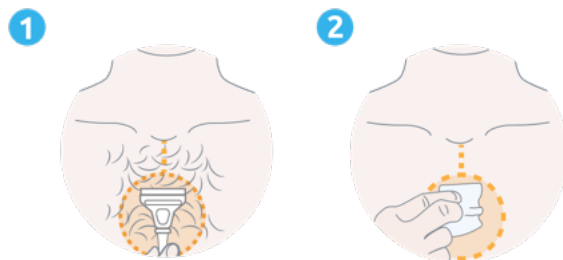
Best practices for all sensor wear:

- 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 a cleaning wipe on the site of sensor placement and let it completely dry (30 seconds) prior to putting on the sensor (Anne Sensors only).
- 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.

6.1 Applying the Anne Sensor

6.1.1. Preparing the Chest Area

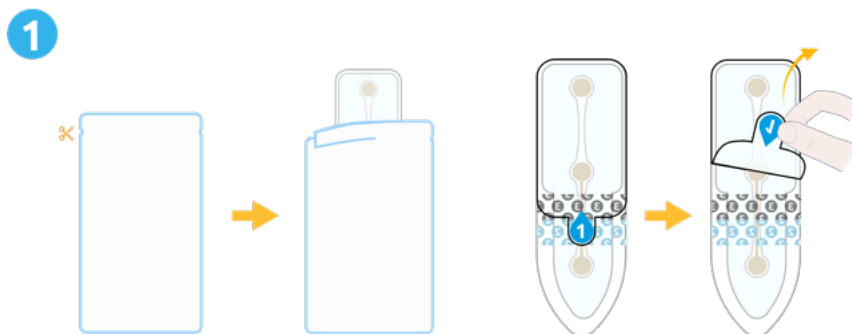
Prep the skin at the location of the Anne Sensor application site, which is directly under the collarbones on the sternum. First, shave any hair. Then use a cleaning wipe to gently scrub away any lotion, oils, previous adhesives, dirt, dead skin, etc. Proper skin prep improves sensor adhesion and signal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



6.1.2. Anne Sensor Adhesive Preparation (Gentle Wear Adhesive)

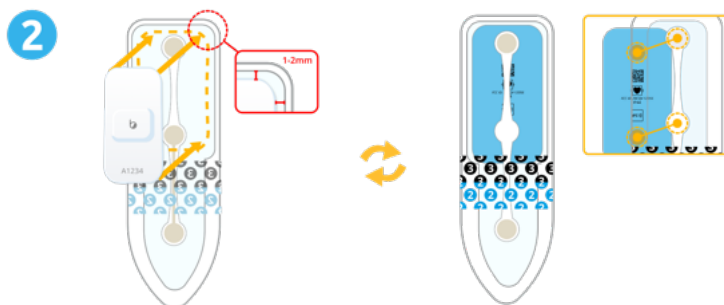
Step 1

Remove the adhesive from the pouch. Orient it so that the side with "1" is facing towards you. Peel off the "1" liner.



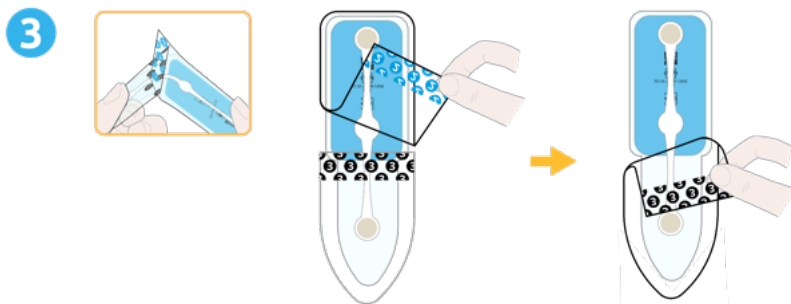
Step 2

Orient your Anne sensor with the logo facing towards you. Place the sensor onto the adhesive and line up the two leads (golden circles) with the circles on the adhesive. Press down to ensure adhesion. Flip the sensor to the other side.



Step 3

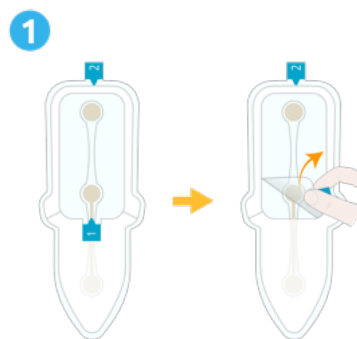
Flip the sensor over and check that the gray stripes on the adhesive are aligned with both gold plates on the sensor. Then remove the clear liner labeled "Step 3" from the adhesive. Hold the adhesive on the sensor while peeling



6.1.3. Anne Sensor Adhesive Preparation (Standard Wear Adhesive)

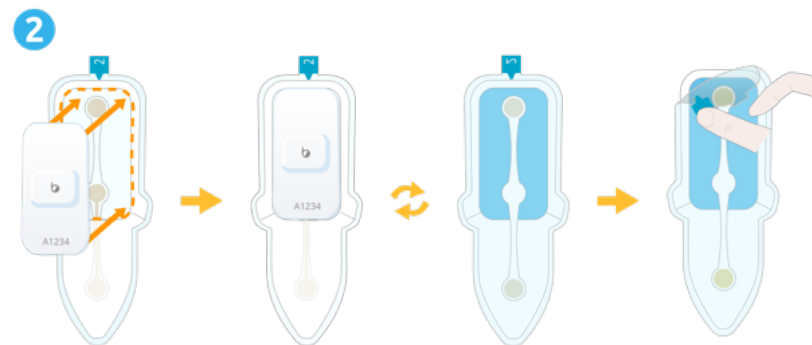
Step 1

Orient the adhesive so that the liner labeled "1" is facing you, then peel the "1" liner.



Step 2

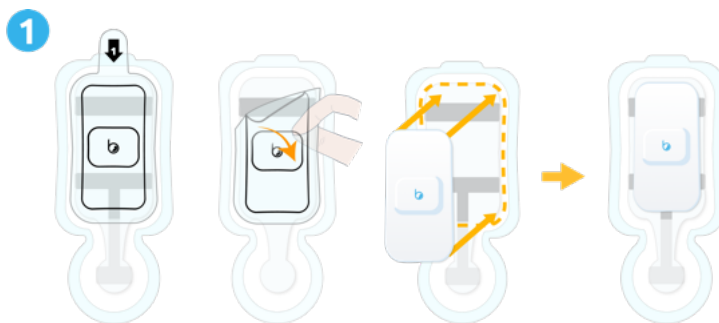
Attach the Anne sensor to the adhesive, aligning the circles on the adhesive with the gold plates on the sensors. Flip the adhesive (with the sensor) and peel off the "2" liner.



6.1.4. Anne Sensor Adhesive Preparation (Extended Wear Adhesive)

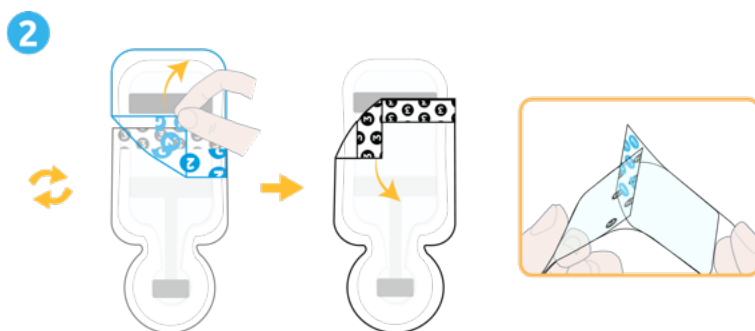
Step 1

Peel off the first clear liner labeled “1” that has the ANNE sensor outline. By following the location of the outline, attach the Anne sensor on the top of the adhesive after the line is off. Make sure that the sensor is oriented correctly with the logo.



Step 2

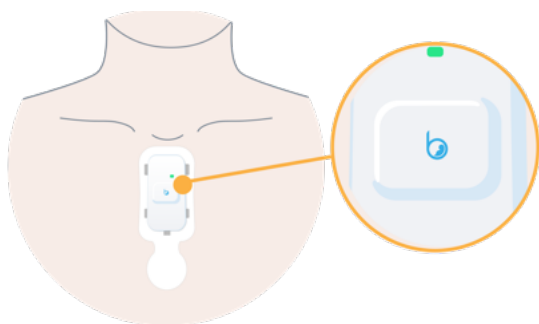
Flip the adhesive (with the sensor) and peel off the “2” and “3” liners.



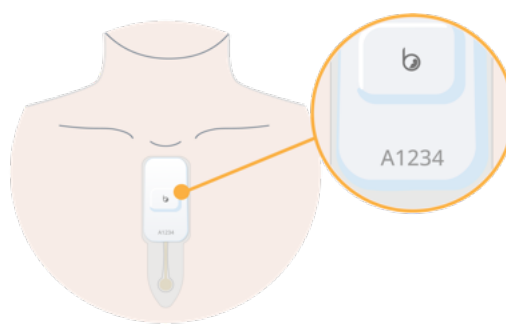
6.1.5. Placing the Anne Sensor

Position the sensor upwards facing away from you and with the Sensor ID and letter “b” of the **logo oriented up**. Place the Anne 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.

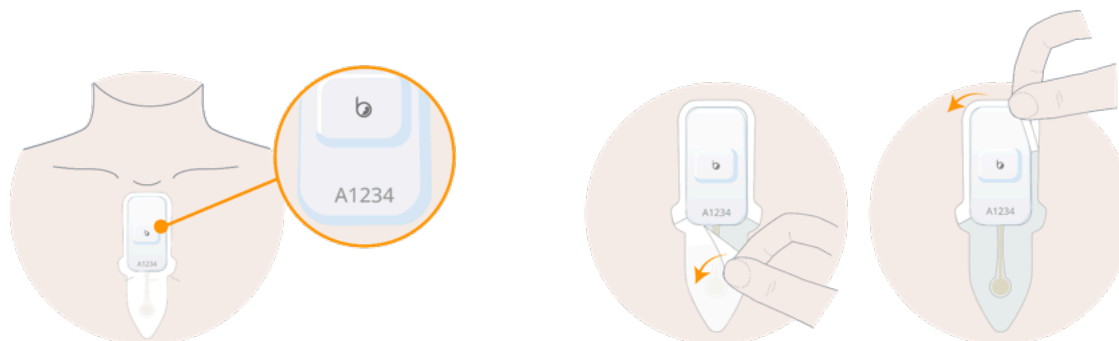


Extended Wear Adhesive



Gentle Wear Adhesive

For the 3-Day adhesive, after placing the adhesive on skin, gently peel off the white liner on the outline of the adhesive.

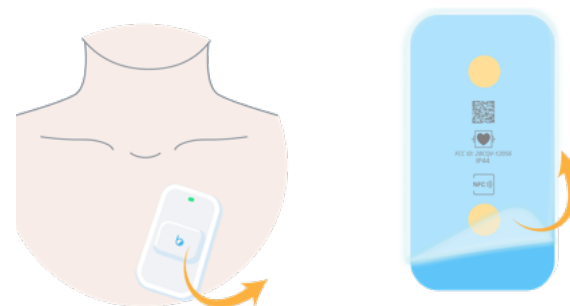


Standard Wear Adhesive

6.1.6. Removing the Anne Sensor

Step 1

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



Step 2

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



Step 3

Wipe the front and back of the sensor with a cleaning wipe.

Step 4

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



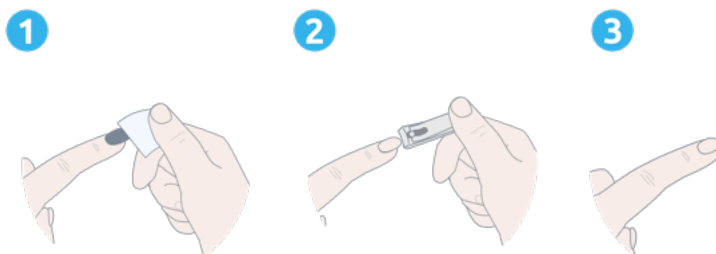
Step 5

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

6.2 Applying the Anne Limb Sensor

6.2.1. Preparing the Index Finger

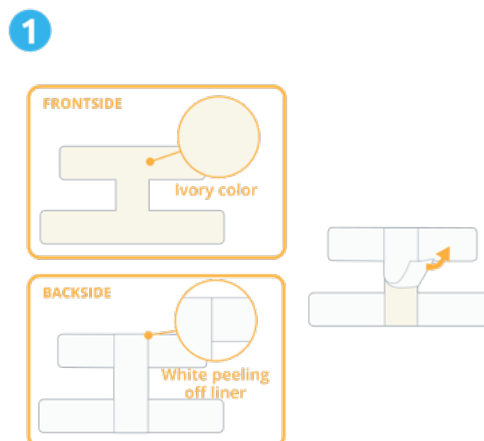
Remove any nail polish and clip the nail to a short length. The Anne Limb sensor will not be able to fit if nails are too long.



6.2.2. Anne Limb Sensor Placement

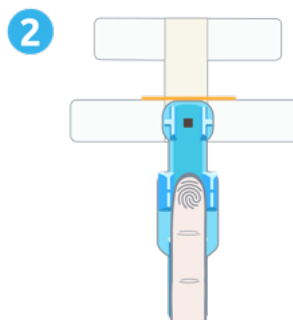
Step 1

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



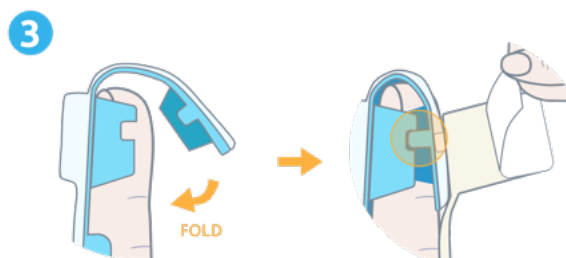
Step 2

Place the 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.



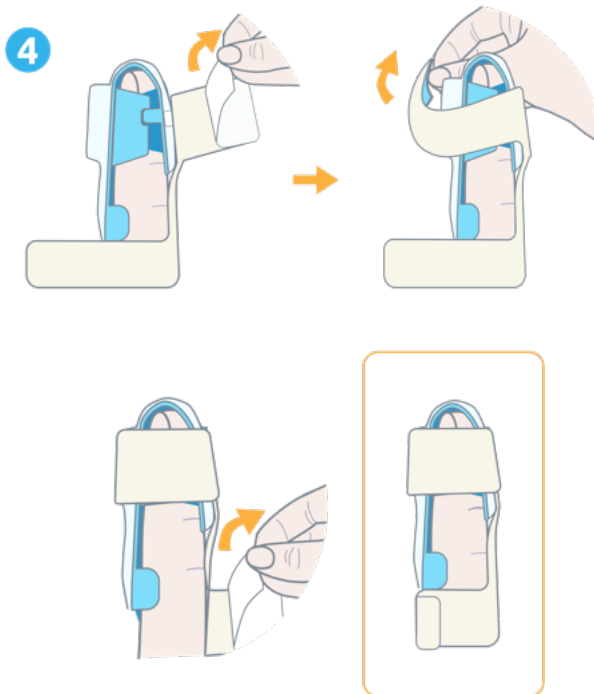
Step 3

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

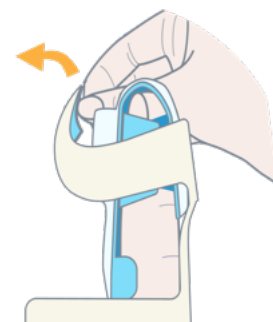
Remove the white liners from the longer wings of the adhesive and wrap them around the bottom of the finger. Repeat with the shorter wings on top.



6.2.3. Removing the Anne Limb Sensor

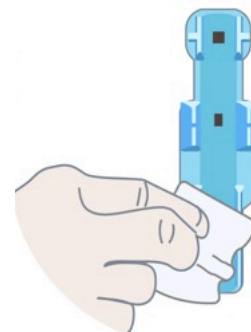
Step 1

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



Step 2

Remove the adhesive from the sensor and discard it. Sanitize the sensor with a cleaning wipe.



Step 3

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

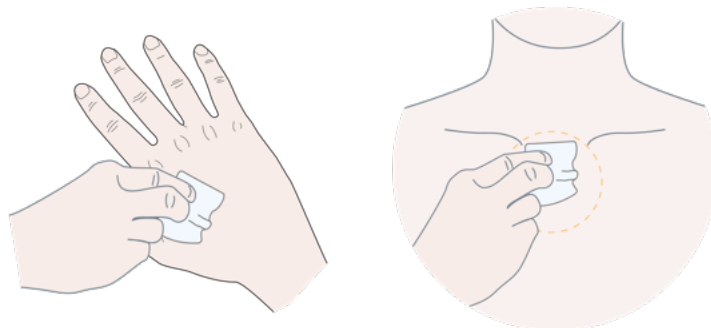
Step 4

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

6.3 Applying the Adam Sensor

6.3.1. Preparing the Application Site

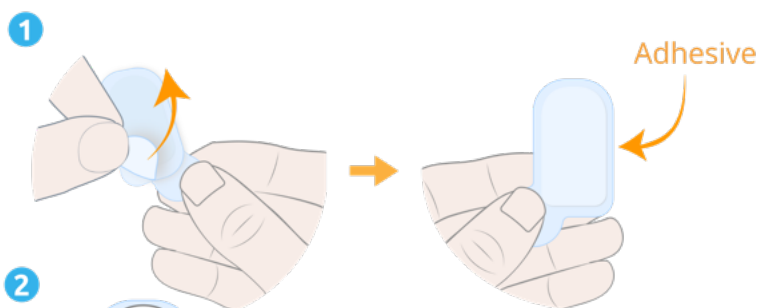
The Adam Sensor can be applied to the suprasternal notch, the back of the hand, and other body parts. Shave any hair and then clean the target site with a cleaning wipe to ensure proper adhesion.



6.3.2. Adam Adhesive Preparation

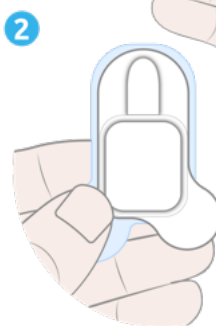
Step 1

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



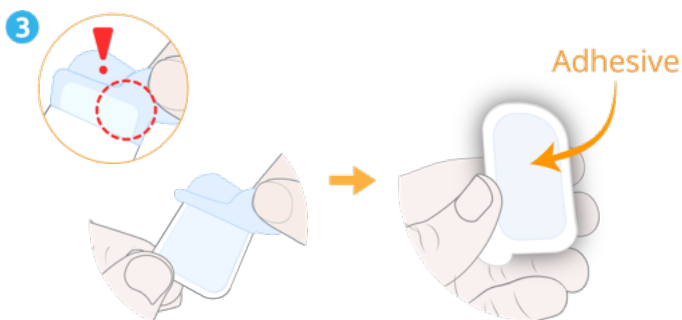
Step 2

Attach the Adam Sensor to the adhesive, orienting the tab on the 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 sensor. Hold down the adhesive if necessary.



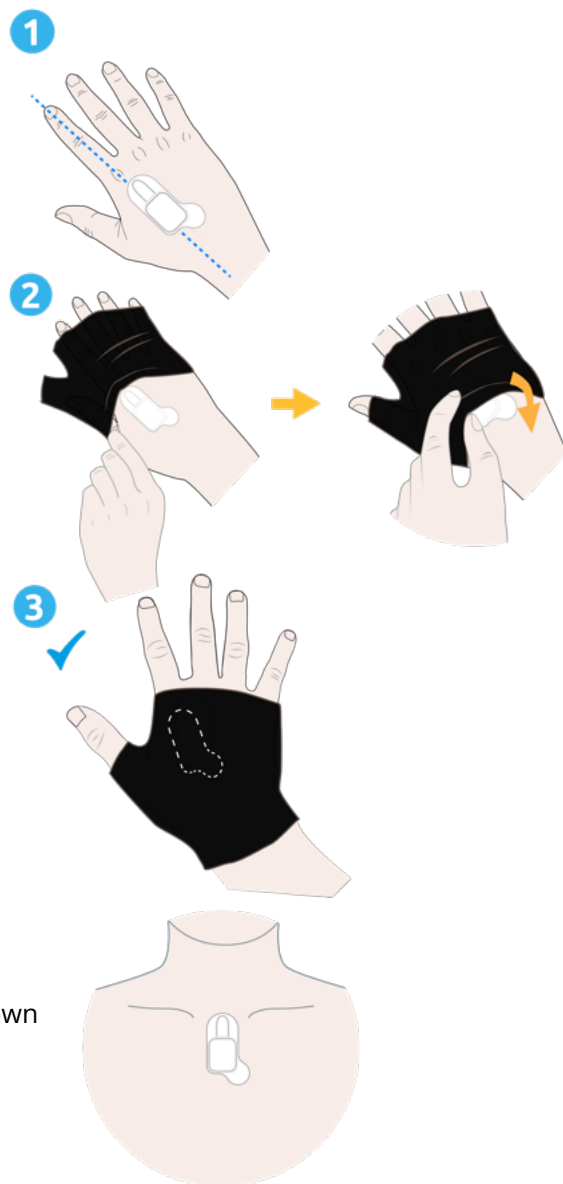
6.3.3. Placing the Adam Sensor

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.

6.3.4. Removing the Adam Sensor

Step 1

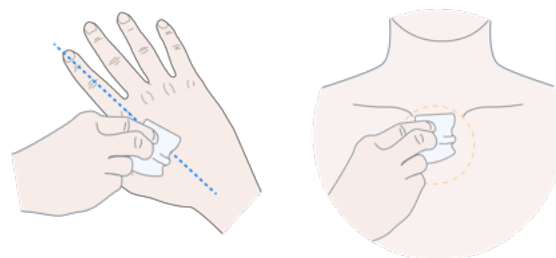
Gently remove the Adam Sensor from the skin by peeling it off slowly using the tab on the bottom of the device. Gently peel the Adam Adhesive from the sensor and discard it.



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 a cleaning wipe or a damp cloth.



Step 3

Wipe the front and back of the sensor with a cleaning wipe.



Step 4

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

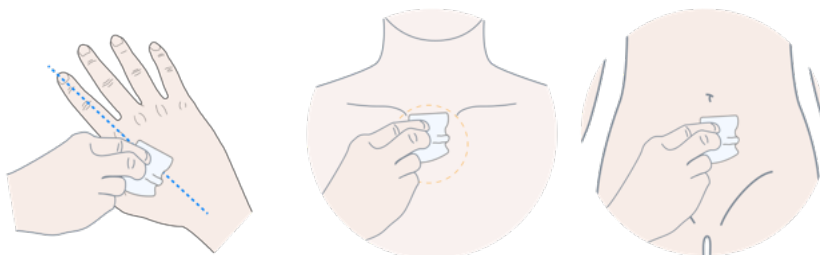
Step 5

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

6.4 Applying the Aria Sensor

6.4.1. Preparing the Application Site

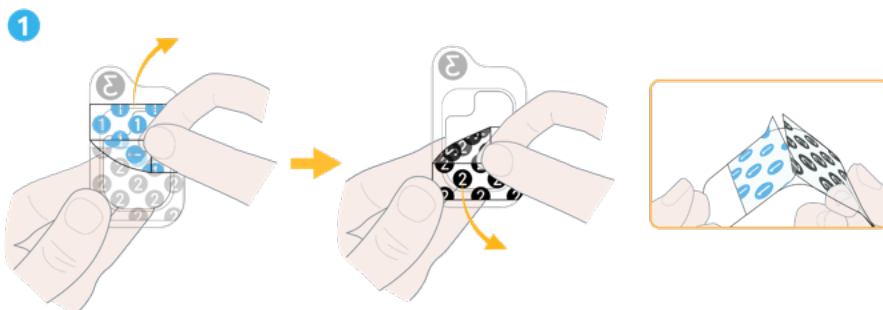
The Aria Sensor can be applied to the suprasternal notch, the back of the hand, abdomen, and other body parts. Shave any hair and then clean the target site with a cleaning wipe to ensure proper adhesion.



6.4.2. Aria Adhesive Preparation

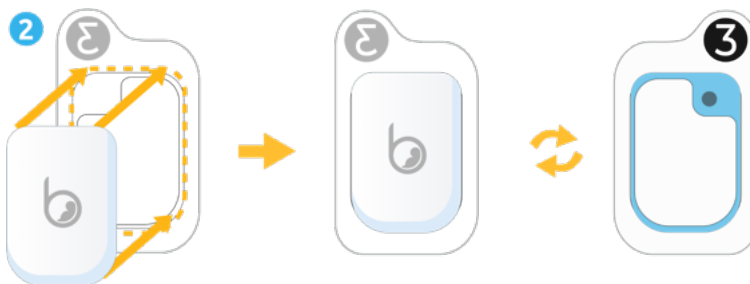
Step 1

Peel off the "1" liner. Then, carefully peel off the "2" liner.



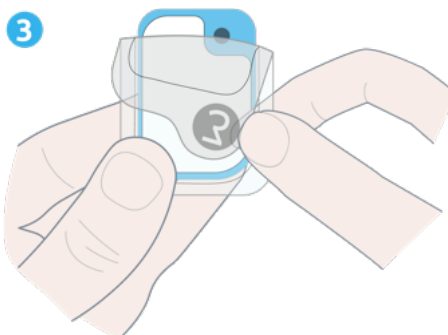
Step 2

Orient your Aria sensor with the "b" logo facing upright and towards you. Place the sensor onto the adhesive and press down to ensure adhesion. Make sure the dot is not covered by the adhesive.



Step 3

Flip the sensor to the other side. Remove the "3" clear liner from the adhesive.



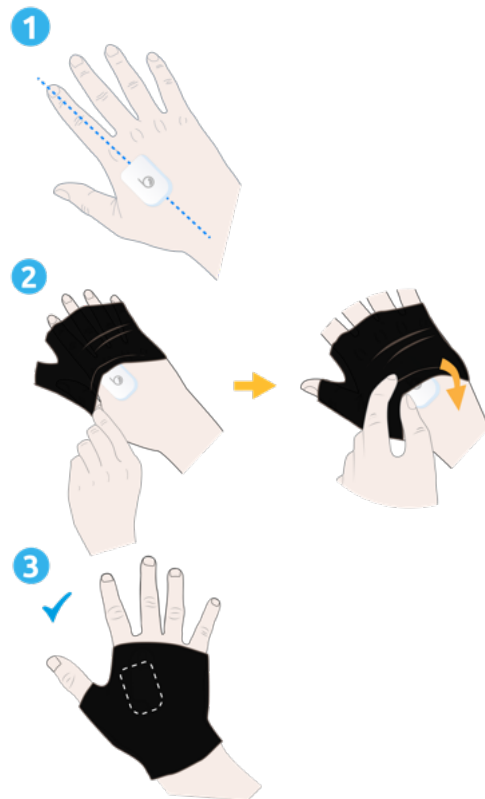
6.4.3. Placing the Aria Sensor

Placing the Aria Sensor on the Hand:

Align the Aria 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.

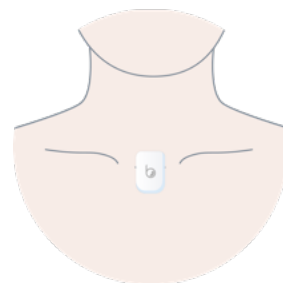
It is highly recommended to use the provided glove over the sensor to ensure sensor adhesion. Put on the glove by sliding it over the hand, making sure to pull the glove over the sensor.

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.



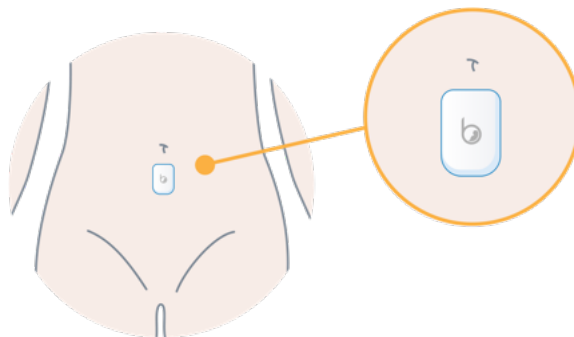
Placing the Aria Sensor on the Suprasternal Notch:

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



Placing the Aria Sensor on the Abdomen:

Align the Aria Sensor in the center of the abdomen (approximately 1 cm below the navel) and press down to ensure proper adhesion.



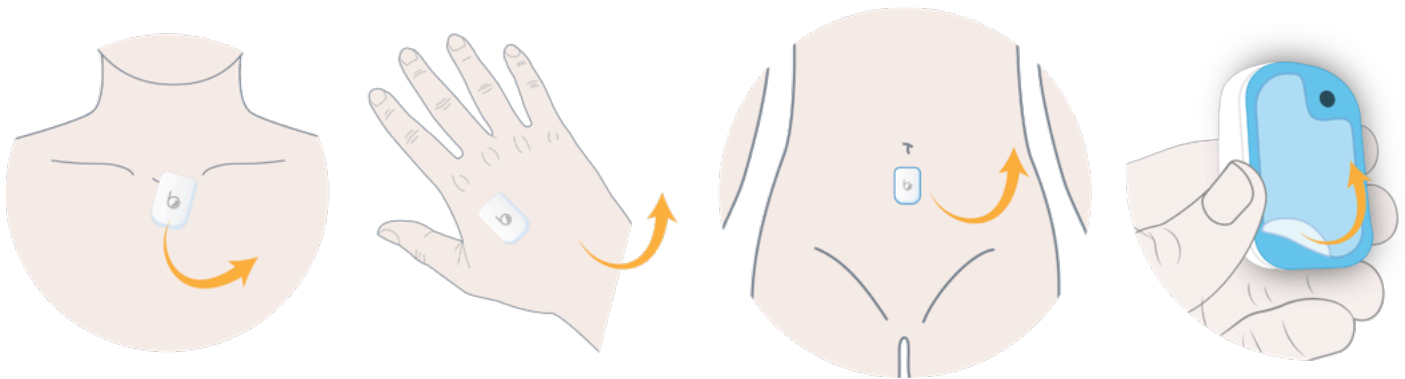
Placing the Aria Sensor on Other Body Parts:

The Aria 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.

6.4.4. Removing the Aria Sensor

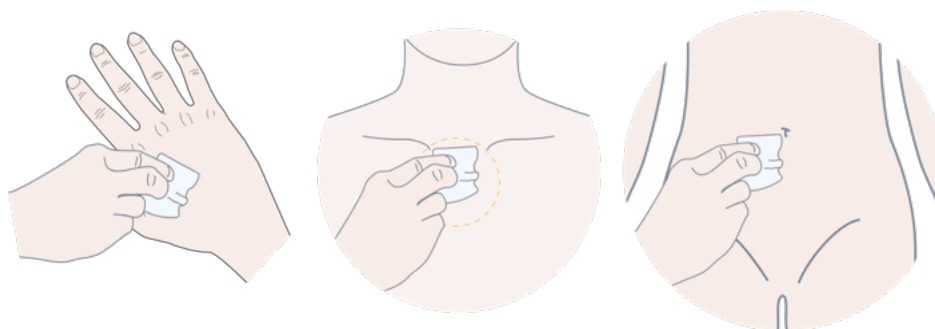
Step 1

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



Step 2

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



Step 3

Wipe the front and back of the sensor with a 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 7. Discovery App Alert Handling

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

7.1 Sensor Alert Messages & Handlings

This section includes the resolution procedures for the following issues:

- Poor Skin Contact
- 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. [Section 5.4.2](#) shows the user interface display of the error messages and the methods of recognition. Each error has a specific icon to indicate different meanings. Being familiar with the icon glossary table in [Section 7.2](#) with the descriptions and recommended user action is necessary to quickly solve the problem for future use.

7.1.1. Poor Skin Contact

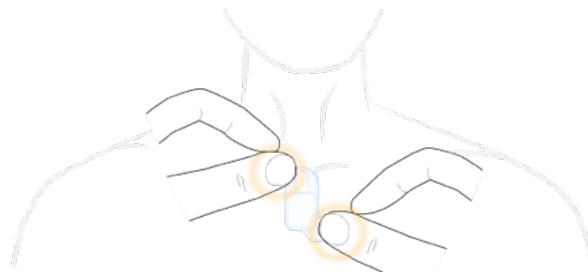
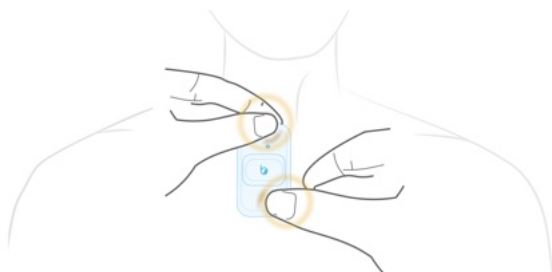
If the Anne or Anne Limb sensor is not detecting proper skin contact, a “Poor Skin Contact” alert will appear in the sensor status section of the sensor list. **If the alert is not resolved within 30 minutes, the sensor will stop recording data until it detects proper skin contact.** For the Adam or Aria sensor, the alert will appear after 3 hours of no movement being detected, and then **the sensor will stop recording data immediately until it detects movement again.**

	CJ3214 Last synced: 45 mins ago	100%	Poor skin contact. Adjust the sensor location.	Collecting data	
	A1234 Last synced: 45 mins ago	100%	Poor skin contact. Adjust the sensor location.	Collecting data	
	L1234 Last synced: 45 mins ago	100%	Poor skin contact. Adjust the sensor location.	Collecting data	
	S1234 Last synced: 45 mins ago	100%	Poor skin contact. Adjust the sensor location.	Collecting data	

Solution

Option 1

Readjust the sensor placement to ensure that it is properly attached. For the Anne, Adam, and Aria sensors, gently apply pressure on top of the sensor over the electrodes and contact areas. For the Anne Limb sensor, 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 adhesive.

Option 3

If there is still an alert after replacing the adhesive, then replace the sensor.

7.1.2. Sensor Out of Range

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

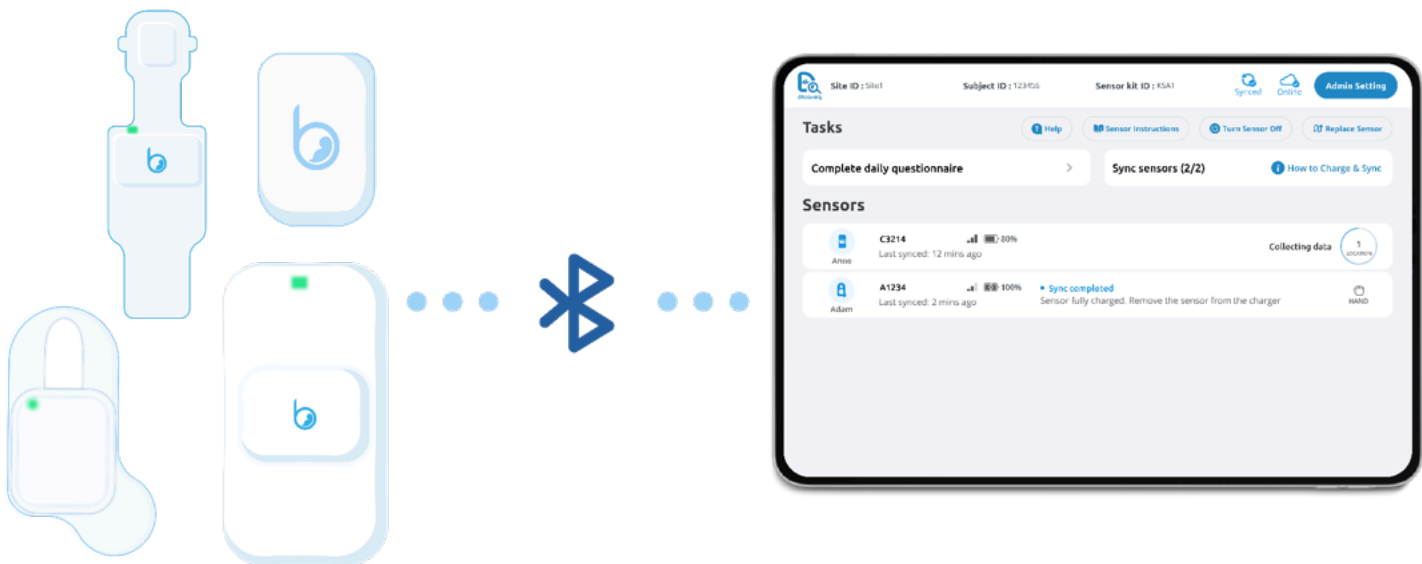
CJ3214

Last synced: 45 mins ago

Sensor disconnected. Please check that the sensor is charged, active, and within range.

If the sensor is out of range

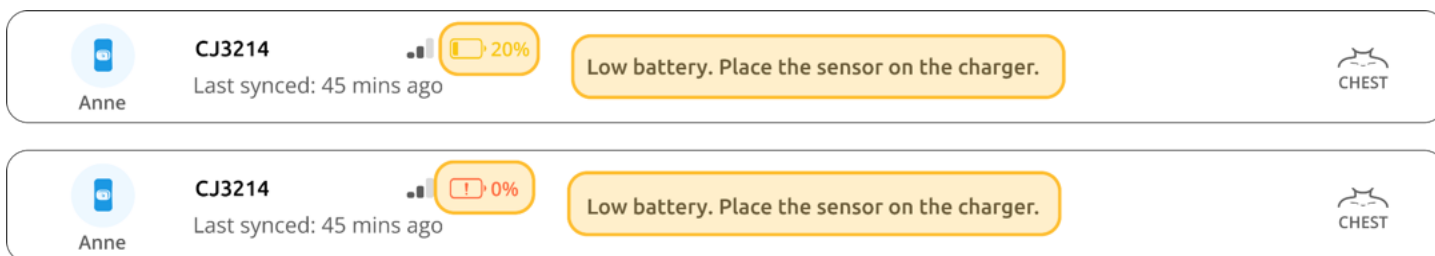
Bring the tablet and sensor closer together. Make sure there is no physical barrier between the sensor and the tablet (e.g. a wall). After they are close to each other, the App will automatically attempt to reconnect to the sensor.



7.1.3. Low / Critical Battery Level

If the sensor has a low battery, then a “Low Battery” alert will be displayed in the sensor status screen of the sensor list. The alert will show up when the battery level of the sensor has fallen below 20%.

If the sensor battery level has fallen below 5%, the “Critical Battery” alert will appear. **This is a high-priority issue, so please address the problem IMMEDIATELY if there is a “Critical Battery” warning.**



If the sensor has a low or critical battery,

- Remove the Discovery Sensor from the Subject.
- Clean the sensor using a 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.



7.1.4. Low / Critical Memory Storage Level

If the sensor has not synced its data with the tablet in over 1 day, then a “Sync the sensor” alert will be displayed in the sensor status screen of the sensor list. This indicates that the sensor has been collecting data for a long period of time and its memory storage level is getting filled up.

If the sensor has not synced its data with the tablet after 2 days, the “Sync Needed Immediately” alert will appear. **This is a high-priority issue, so please address the problem IMMEDIATELY if there is a “Sync needed immediately” warning, as the sensor’s memory will soon completely fill up.**

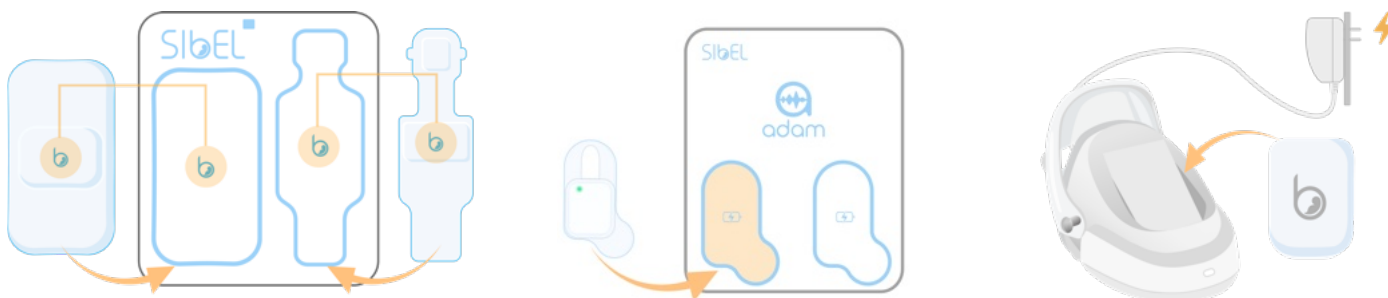
CJ3214
40%
• Sync the sensor

Last synced: XX mins ago
 Place the sensor on the charger to sync the data

CJ3214
100%
• Sync needed immediately

Last synced: XX mins ago
 Place the sensor on the charger

If the sensor has low or critical memory storage level, sync the data from the sensor by placing the sensor on the wireless charger. The sync will start automatically after placing the sensor on the charger. Note that the app must be open and the sensor must be connected.



CJ3214
100%
Syncing... 80%
time left

Anne

7.1.5. 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.**


Anne

CJ3214
Last synced: 45 mins ago

Sensor failure. Contact your coordinator.


CHEST

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 failed sensors need to be replaced.

7.2 Sensor Alert Icon Glossary

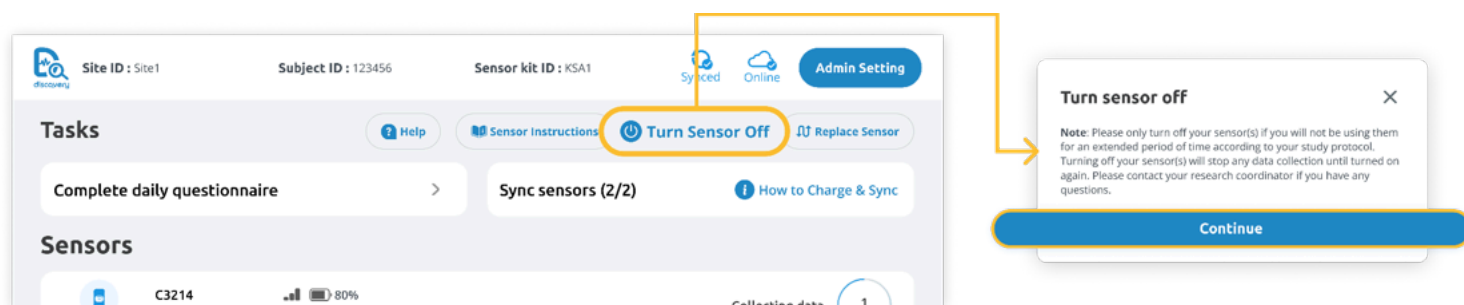
Alert Icon	Alert Name	Alert Description	Recommended User Action	Priority
	Poor Skin Contact	Sensor is not detecting good contact with the skin.	1. Press the sensor to ensure the sensor is properly attached. 2. Adjust the sensor placement. 3. Replace the sensor adhesive. 4. Switch the sensor.	Medium
	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 sync 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 storage	Storage of the sensor is over 80% full. (Visible in Admin Mode only)	Sync the data from the sensor to clear the storage.	Medium
	Critical storage	Storage of the sensor is 100% full. (Visible in Admin Mode only)	Sync the data from the sensor to clear the storage.	High
	Offline	App is not connected to the internet.	Connect the tablet to the internet and check connection.	High
	Unsynced	Data is unable to sync with the cloud.	Connect the tablet to the internet and check connection.	High

Section 8. Sensor Admin Settings and Turning Off Sensor

This section describes how to end the data collection process on the Discovery App.

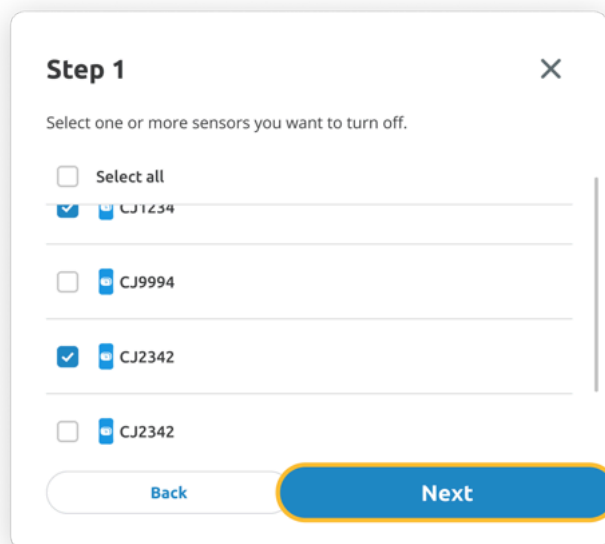
8.1 Turn Sensor Off

The Sensor(s) can be turned off from the main dashboard to save battery if desired. Press “Turn Sensor Off” on the top dashboard to begin this process.



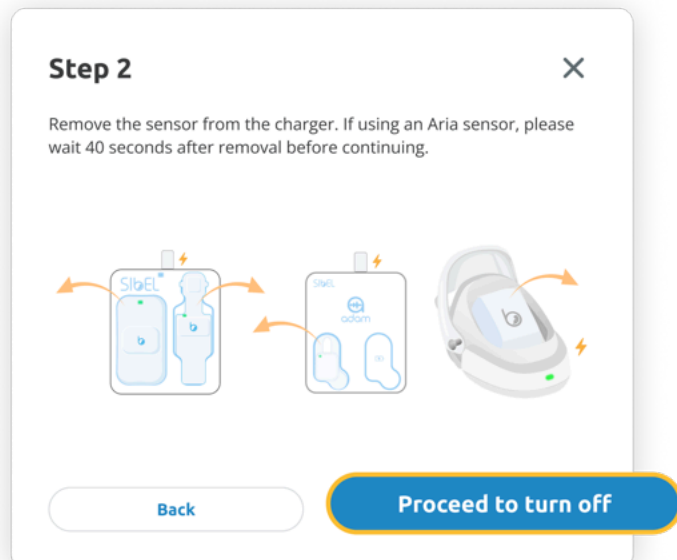
Step 1

Select the sensor(s) you want to turn off, then click “Next”.



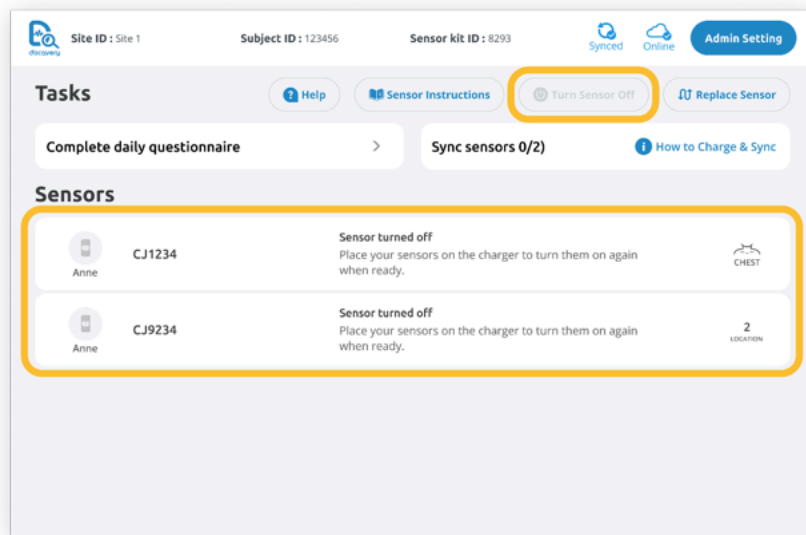
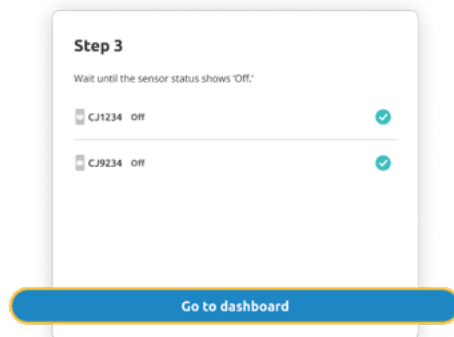
Step 2

Remove the sensor(s) from the charger.



Step 3

Wait for the App to confirm that the sensor(s) have turned off.



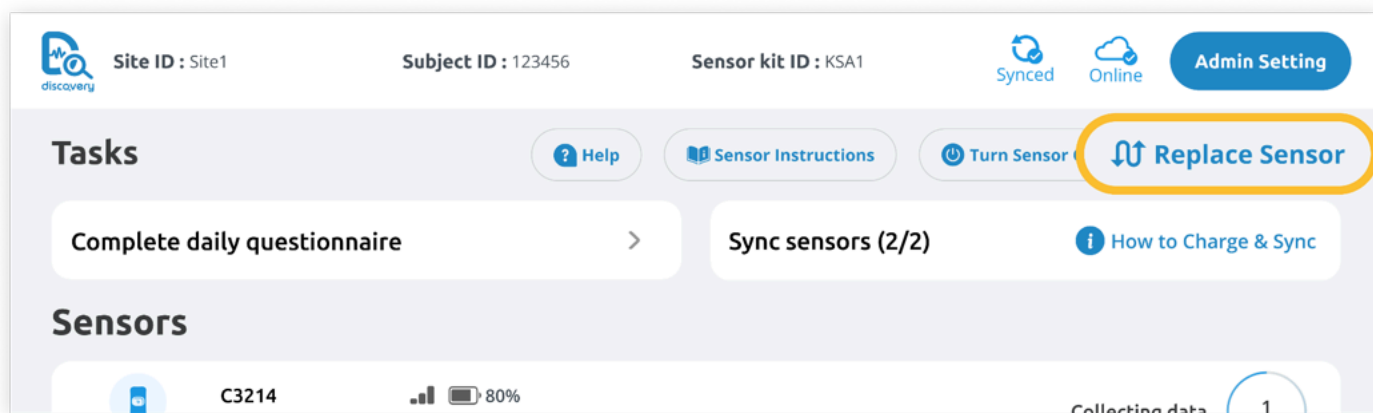
Note: A sensor can be turned on again by placing it on the charger. Remember to confirm that the sensor is once again paired with the tablet before attempting to collect data.

8.2 Replace Sensor

In addition to the method described in [Section 3.5.6](#) and [Section 3.5.7](#), sensors can be replaced with new ones if needed via Admin settings.

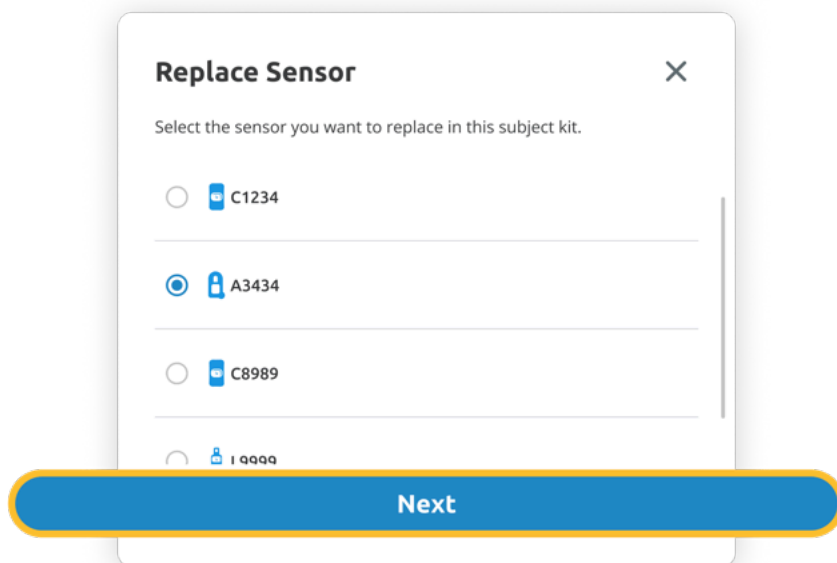
Step 1

Press the “Replace Sensor” button on the top bar of the dashboard.



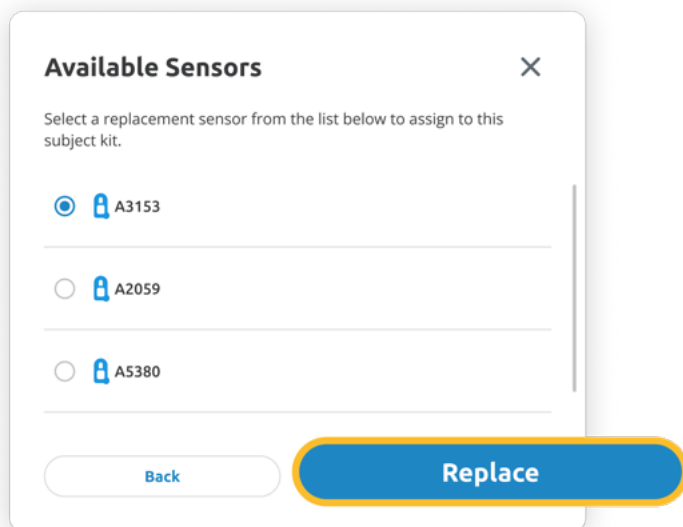
Step 2

Select the sensor to be replaced and press “Next”.



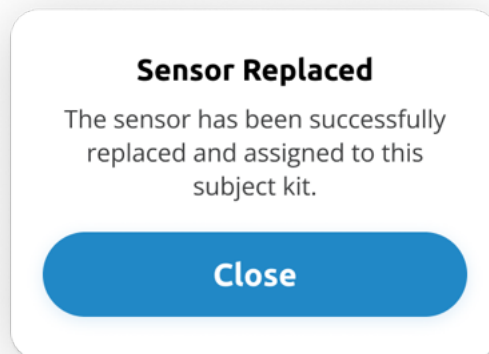
Step 3

The next screen displays nearby sensors to pair with the system. Locate the Sensor ID of the replacement sensor in the list and click “Replace”.



Step 4

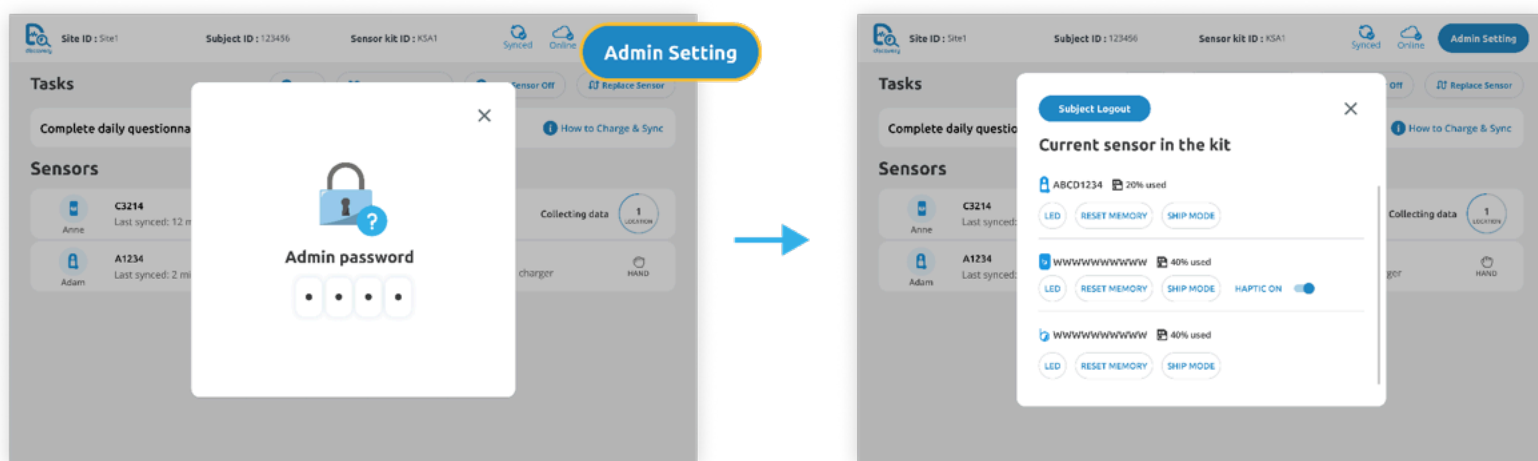
The new sensor will automatically connect and appear on the sensor dashboard. Confirm that the new sensor has connected and is functional.



8.3 Opening Admin Settings

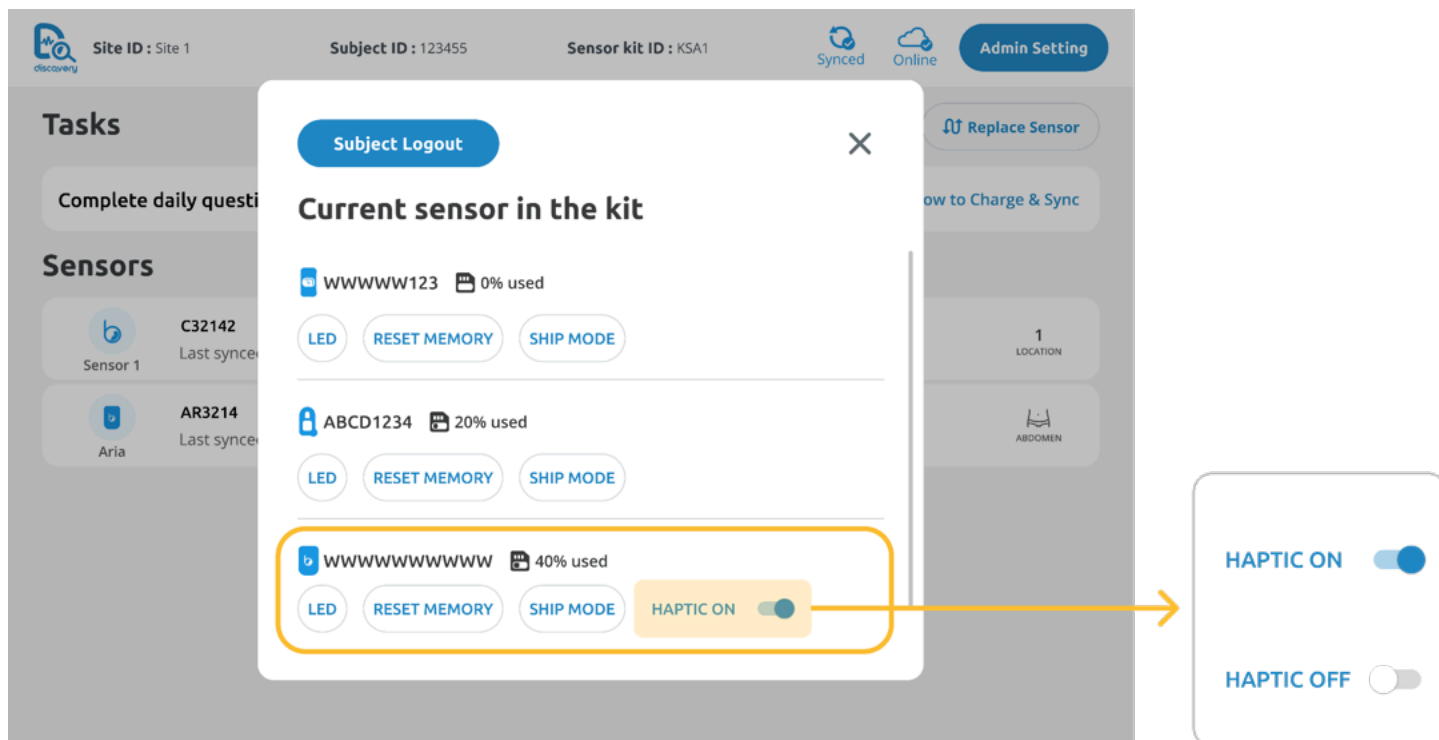
To open the Admin Settings window, click “Admin Settings” on the top-right corner of the screen and enter the password. The password will be the current month and date in that order (“MMDD” format). For example, on October 1st, the password will be 1001.

In most cases it is advised to not grant participants access to Admin Settings unless you provide a reason to do so, as they may inadvertently change settings that can affect data collection.



8.4 Enabling Haptic Feedback on an Aria Sensor

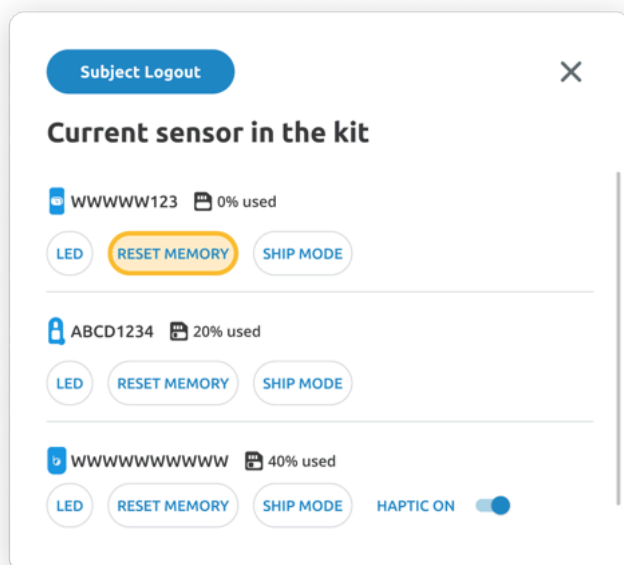
The Aria sensor has the capability to relay haptic feedback (vibration). This can be enabled or disabled by toggling the switch labeled “Haptic On” or “Haptic Off” next to the listed Aria sensor.



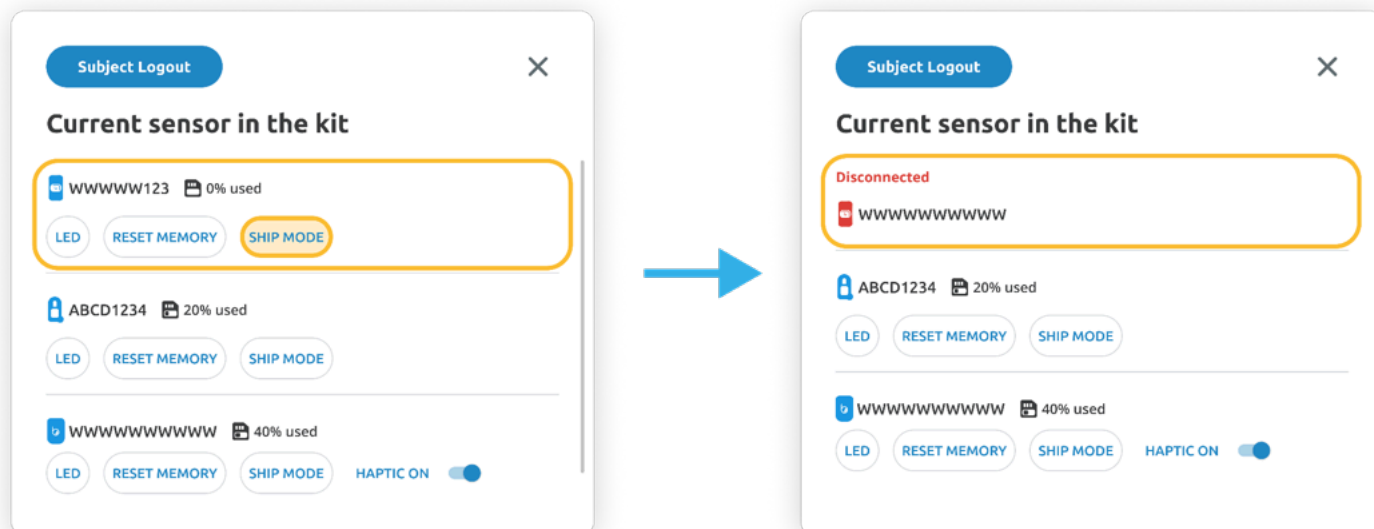
8.5 Resetting and Putting the Sensor in Ship Mode

If the sensor has recorded data not important to the study, such as test runs or empty data generated from leaving the sensor still while collecting, you can reset the sensor's memory to delete this data. In addition, the sensor can be put to sleep (referred to as "Ship Mode") when data is not being collected to save battery.

In Admin Settings, press "Reset Memory" to empty any remaining data from the sensors. After resetting the sensors, the data collection session will stop for approximately 3 seconds if it is not on the charger.



Press “Ship Mode” to put the sensor to sleep. While in Ship Mode, the sensor status will display “Disconnected”. Ship mode will stay active until the sensor is placed on the charger once again, this will wake up the sensor and it will automatically reconnect to the tablet.

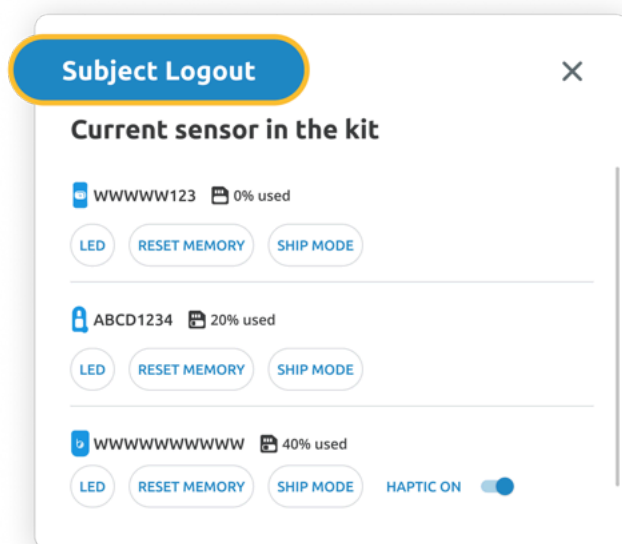


Note: Make sure that all data has been uploaded and synced to the cloud before resetting the sensor’s memory. Any data still on the sensor will be erased after resetting the memory.

8.6 Logging Out

Once the Subject's data collection period with the sensors is over, the research coordinator will unpair the sensors and log the Subject out.

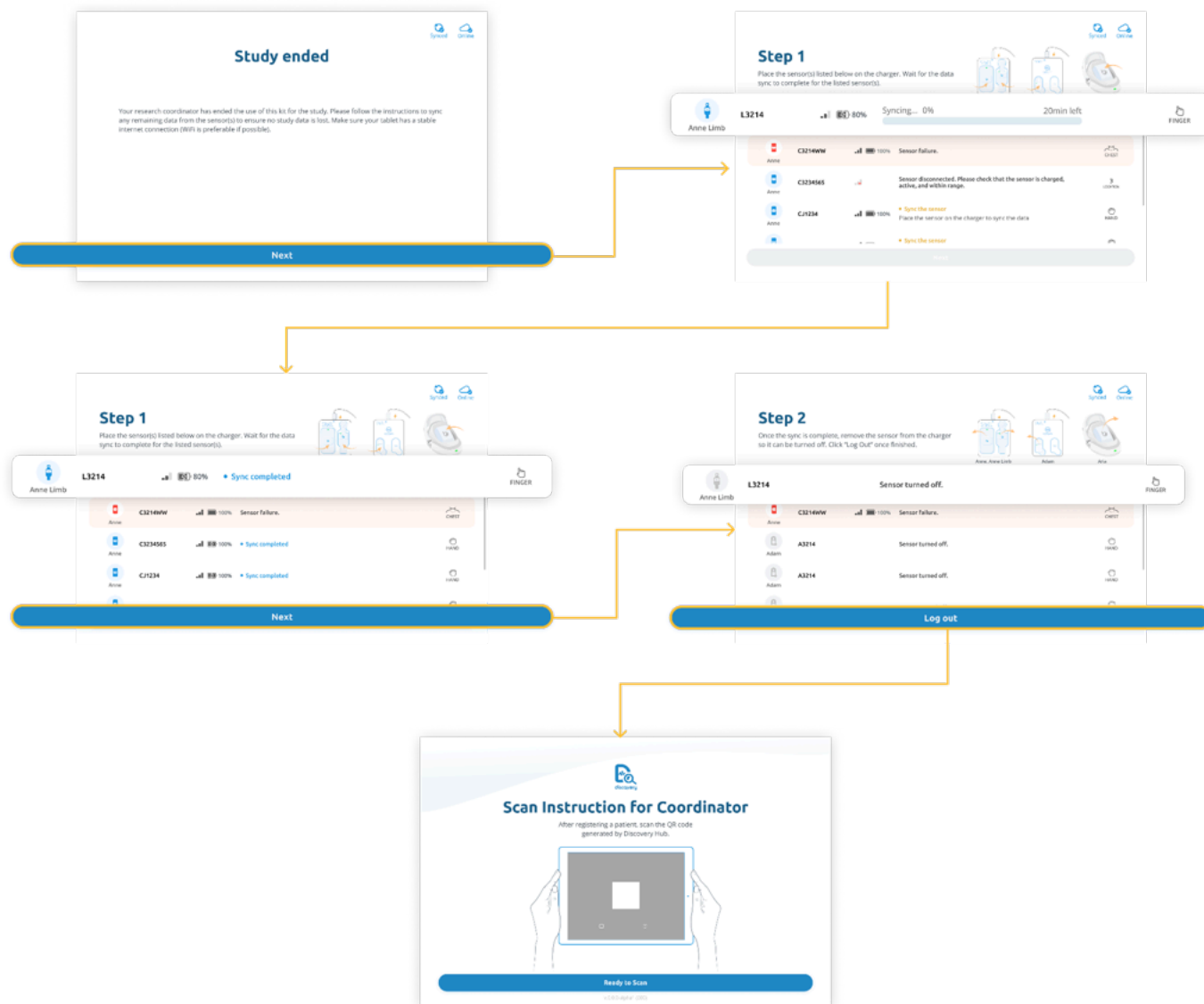
First, ensure that all data from the sensor is uploaded and synced with the cloud. Then, remove any sensors from the charger, and in admin settings, click "Subject Logout".



The Logout will not proceed unless:

- The Sensor is taken off of the charger
- The Sensor is connected to the tablet by bluetooth
- All data has been synced with the cloud and nothing remains on the tablet

Once the above conditions are met, the "Study ended" workflow will proceed. The app will automatically reset the sensor memory, put it in ship mode, and then it will return to the "Scan Instruction for Coordinator" screen, where you are prompted to scan a QR code to associate a new Subject to the Kit. Note that also this will cause the Subject's status on Discovery Hub to be moved to an "Inactive" subject and the kit will be unregistered from the subject.



Note: If granted access to Admin Settings, please make sure to point out to the Subjects not to perform the subject logout as this will require re-registering the subject to the kit and having them re-scan the QR code.

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 body hair. 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 a 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 has 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
	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 <i>compliant</i>	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 of Discovery, contact Sibel Health.
- Contact Sibel Health for any of the following issues:
 - Assistance in setting up, using, or maintaining Discovery
 - To report unexpected operation or events

Address: 2017 N Mendell St, Chicago, IL 60614

Phone: (224) 251-8859

Website: www.sibelhealth.com

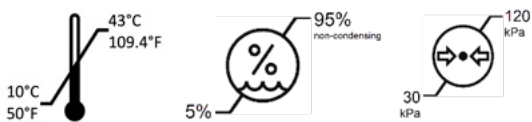
Email: support@sibelhealth.com

Section 10. Product Specifications

This section includes technical specifications for each item in Discovery.

10.1 Anne Technical Specifications

Table 2: Anne 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 - 7 days (Depending on Configuration)
Battery Type	Rechargeable lithium polymer battery
Battery Capacity	70 mAh
Charging Time (to full charge)	5 hours
Charging Method	Wireless charging using custom Anne Wireless Charger
Water Resistance	IP47 - Water-proof/Shower-proof
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)	7.2 cm x 3.9 cm x 0.9 cm
Weight (grams)	17 grams
Attachment Method	Anne 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: ±4g Sampling Rate: 25 Hz - 1.6 kHz
Heart Rate (beats/min)	30 - 270 bpm (the greater of ±10% or ±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 (±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 3: Anne Adhesive Specifications

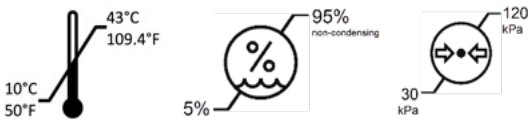
	Gentle Wear Adhesive	Standard Wear Adhesive	Extended Wear Adhesive
Dimensions (L x W)	13.9 cm x 4.49 cm	15.6 cm x 5.8 cm	14.9 cm x 6.7 cm
Material	Biocompatible silicone gel adhesive	Biocompatible acrylic adhesive	Biocompatible polyurethane gel with acrylic border adhesive
Use Type	Single use disposable	Single use disposable	Single use disposable
Shelf Life	2 years	2 years	2 years

Table 4: Anne Wireless Charger Specifications

Dimensions (L x W x H)	11.8 cm x 9.9 cm 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 5: 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	IP47 - Water-proof/Shower-proof
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)	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% (± 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 6: Anne Limb Adhesive Specifications

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

Table 7: Anne Wireless Charger Specifications

Dimensions (L x W x H)	11.8 cm x 9.9 cm 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 8: 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	The diagram illustrates the safe operating environment for the Adam sensors. It includes three circular icons: a thermometer for temperature (50 °F / 10 °C to 95 °F / 35 °C), a humidity gauge for humidity (5% to 95% non-condensing), and a pressure gauge for pressure (30 kPa to 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	IP44 - Splash-proof
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)	4.2 cm x 2.4 cm x 1.1 cm
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 9: Adam Adhesive Specifications

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

Table 10: Adam Glove Specifications

Dimensions (L x W)	15.8 cm x 11.9 cm (Adult L) 13.0 cm x 11.4 cm (Adult S) 11.9 cm x 10.5 cm (Pediatric L) 11.3 cm x 9.0 cm (Pediatric M) 7.5 cm x 8.0 cm (Pediatric S)
Material	88% polyester, 12% spandex
Use Type	Reusable
Shelf Life	2 years

Table 11: Adam Wireless Charger Specifications

Dimensions (L x W x H)	11.8 cm x 9.9 cm 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 Aria Technical Specifications

Table 12: Aria 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	
Operation Time (per full charge)	24 hours
Battery Type	Rechargeable lithium polymer battery
Charging Time (to full charge)	5 hours
Charging Method	Wireless charging using custom Aria Wireless Charger
Water Resistance	IPX4 - Splash-proof
Encapsulation Material	Medical Grade Plastic (Makrolon 2458)
Wireless Technology	Bluetooth® 5 Low Energy
Frequency Band	2402-2480 MHz
Maximum Connection Distance	10 meters
Dimensions (L x W x H)	3.0 cm x 2.1cm x 1.2 cm
Weight (grams)	6 grams
Attachment Method	Aria Adhesive
Sensor Capabilities	Thermometer Range: 0°C - 45°C Sampling Rate: every 4 seconds Accelerometer Range: ± 4g Sampling Rate: 1.6 kHz Acoustic Microphone (Inward): Range: 20Hz - 8kHz Sampling rate: 16kHz Acoustic Microphone (Outward):

	Range: 20Hz - 8kHz Sampling rate: 16kHz Barometer: Sampling rate: 80Hz 300 hPa to 1250 hPa measurement range (full accuracy) ±30 Pa absolute accuracy ±6 Pa relative accuracy pressure
Skin Temperature	73.4°F-109.4°F (±0.54°F) 23°C - 43°C (±0.3°F)

Table 13: Aria Adhesive Specifications

Dimensions (L x W)	3.0 cm x 2.1 cm
Material	Double Sided Spunlace Non Woven medical tape Double Sided Silicone/Acrylate medical tape
Use Type	Single use disposable
Shelf Life	1 year

Table 14: Aria Glove Specifications

Dimensions (L x W)	15.8 cm x 11.9 cm (Adult L) 13.0 cm x 11.4 cm (Adult S) 11.9 cm x 10.5 cm (Pediatric L) 11.3 cm x 9.0 cm (Pediatric M) 7.5 cm x 8.0 cm (Pediatric S)
Material	88% polyester, 12% spandex
Use Type	Reusable
Shelf Life	2 years

Table 15: Aria Wireless Charger Specifications

Dimensions (L x W x H)	5.9 cm x 3.8 cm x 4.8 cm
Weight (grams)	26.7 grams
Power supply	USB-C 10W power adapter 5V, 2A
Water Resistance	Wireless Charger: IPX4 
Charging Frequency Band	13.56 MHz

10.5 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 16: 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.

10.6 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.

10.7 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 17: 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 IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	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 equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

			$d = 2.3\sqrt{P}$ 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	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	Proximity fields from RF wireless communications should be at levels characteristic of a typical professional healthcare facility environment or domestic establishment

	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.

10.8 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 18: 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.