INSTRUCTIONS FOR USE

ANNE Link Mobile

IFU P/N 443-00027A

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Section 1. Important Safety Information

1.1 Device Description

The ANNE Link Mobile application is a remote patient monitoring (RPM) device that receives vital signs and physiological data from compatible devices for transmission to a partner cloud server. The ANNE Link Mobile application operates on the ANNE Link Phone.

When the ANNE Link Phone is connected to the internet, the vital signs and physiological data are uploaded from the ANNE Link Mobile application to a cloud server. The cloud server is maintained by active partners and is directly integrated with the ANNE Link Mobile application.

1.2 Indications for Use

The ANNE Link Mobile application is intended for the transmission of physiological data from the ANNE Chest devices. The ANNE Link Mobile application communicates to compatible customer cloud platforms, for the display and storage of multiple patients' physiological data.

The ANNE Link Mobile application is intended for use by RPM patients in the clinical or home healthcare environment. The device is not intended for use on critical care patients.

1.3 Contraindications

- While the data relayed by ANNE Link Mobile may be applicable for use as an aid to diagnosis and treatment, ANNE Link Mobile does not provide diagnostic or interpretive statements to either the patient or the clinician.
- ANNE Link Mobile is NOT intended for use on critical care patients and is not a remote diagnostic device.

1.4 Warnings

- Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner **Rx ONLY**
- ANNE Link Mobile should not be used in the presence of strong electromagnetic fields such as high frequency surgical equipment.

1.5 Precautions

- Do NOT use this product if the ANNE Link Phone is damaged. Return any broken or damaged devices to the manufacturer.

- Depending on wireless connectivity, temporary interruption of data relay is possible. Similar devices may cause signal interference during data transmission. If you experience this effect, avoid operating near interfering devices.
- The battery used in the phone may present a risk of fire, explosion, or chemical burn if mistreated. Do not expose the sensors or phone 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 sensor appears 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 attempt to disassemble, repair, or modify the device.
- DO NOT plug in any unauthorized cables to the hardware ports located on the phone 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 charger from the wall.
- ANNE Link Mobile has no cardiac arrhythmia detection capabilities.

1.6 Glossary

Table 1: Glossary

Abbreviation	Definition
RSME	Root mean square error
ADT	Admission Discharge Transfer
AFE	Analog Front End
PM	Patient Monitor
BLE	Bluetooth Low Energy
NFC	Near Field Communication
TEMP	Temperature
PR	Pulse Rate
PI	Perfusion Index
LED	Light-emitting diode
IP	Ingress Protection
RH	Relative Humidity
ECG	Electrocardiogram

HR	Heart Rate
RR	Respiratory Rate
SpO2	Oxygen Saturation
PLETH, PPG	Photoplethysmogram
ID	Identifier
NIBP	Non invasive Blood Pressure
SYS	Systolic
DIA	Diastolic
PIN	Personal Identification Number
EMC	Electromagnetic Compatibility
RF	Radio Frequency
MRI	Magnetic Resonance Imaging
BPM	Beats Per Minute
ME	Medical Equipment
BRPM	Breaths Per Minute
RPM	Remote Patient Monitoring

1.7 Symbols and Markings

Table 2: Symbols and Markings

Symbol	Title	Description
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	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 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

	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
	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
	Batch code	Indicates the manufacturer's batch code so that the batch or lot in which the device was manufactured can be identified
	Date of Manufacture	Indicates date when medical device was manufactured
	Catalogue number	Indicates the manufacturer's catalogue number so the medical device can be identified
	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
	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

1.8 Storage and Handling

- Storage temperature range: -15°C – 43°C (5°F – 109.4°F)
- Storage relative humidity range: 5 – 95% RH (non-condensing)

1.9 Security Recommendations

There are steps you can take to help make the operating environment more secure.

- Do not connect the ANNE Link Phone to sensors outside of the ANNE Chest Sensor.
- Do not connect the ANNE Link Phone to sensors with sensor IDs you do not recognize.
- Always confirm the sensor ID displayed on the phone with the one displayed on the system before use. For ANNE Chest Sensors, always confirm with the green LED confirmation process before use.

1.10 Contact

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

Sibel Health Inc.
Address: 2017 N Mendell St. Unit 2SE, Chicago IL 60614
Phone: (224) 251-8859
Website: www.sibelhealth.com

Section 2. System Unpack

This section describes the instructional steps needed before starting a monitoring session.

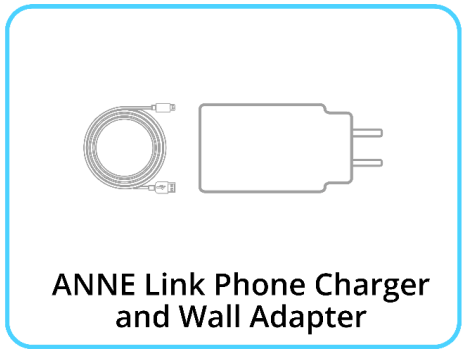
2.1 ANNE Link Mobile Package

2.1.1 Unpacking the ANNE Link Mobile

An ANNE Link Mobile system contains the components as listed below:

1. **ANNE Link Phone**
2. **ANNE Link Phone Charger and Wall Adapter**
3. **ANNE Link Phone Case**

ANNE Link Phone



ANNE Link Phone Charger and Wall Adapter

ANNE Link Phone Case

Section 3. ANNE Link Mobile System Setup

This section describes the instructional steps needed before starting a monitoring session.

3.1 Setting Up ANNE Link Mobile Phone

3.1.1 Phone Case Installation (Optional)

The system includes a phone case for the ANNE Link Phone. Users can choose to install it or not depending on the scenario. To install the phone case:

- Option 1: Refer to the instructions inside the phone case package.
- Option 2: Contact your care location's IT support on-site.

Note:

- Charge with ANNE Link Mobile Phone Charger if needed.

3.1.2 Turn On the Phone & Swipe Up to Unlock

Step 1

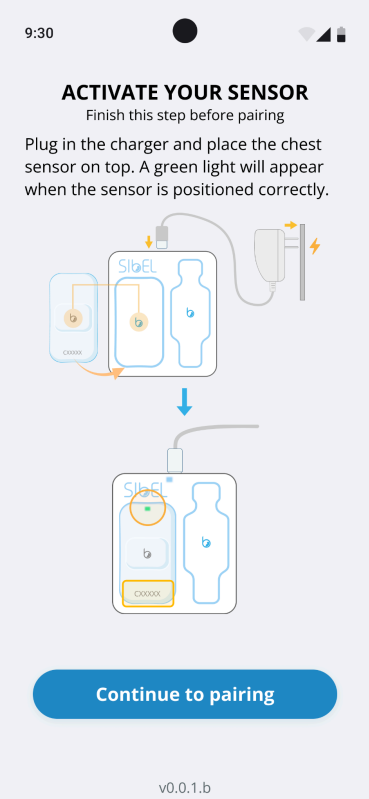
Turn on the phone by long pressing the power button.

Step 2

Place the finger on the center of the screen and swipe up.

3.1.3 Activate Your Sensor

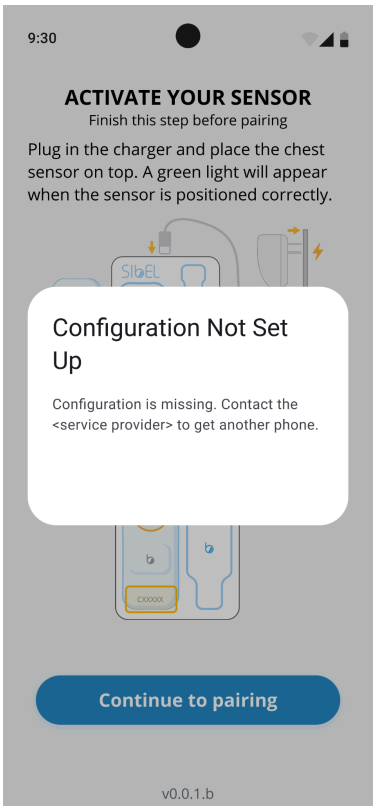
Follow the instructions on-screen to activate the sensor. Press “Continue to pairing”.



3.1.4 Start Session Error Handling

- **Configuration Not Set Up**

Occurs at the beginning of the application if no configuration has been set up. Contact the service provider to get another phone.



Section 4. Pair sensor with ANNE Link Mobile

This section describes the instructional steps needed to pair the sensor with the ANNE Link Mobile application.

4.1 Pairing the ANNE Chest Sensor

4.1.1 NFC Pairing

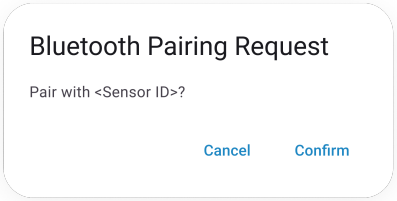
Step 1

Tap and hold the ANNE Chest Sensor near the phone in the area highlighted in the image to the right to pair the sensor via NFC.

Alternatively, the ANNE Chest Sensor can be manually paired by selecting the **TRY ANOTHER WAY** button on the bottom of the page and following instructions in Section 4.1.2.

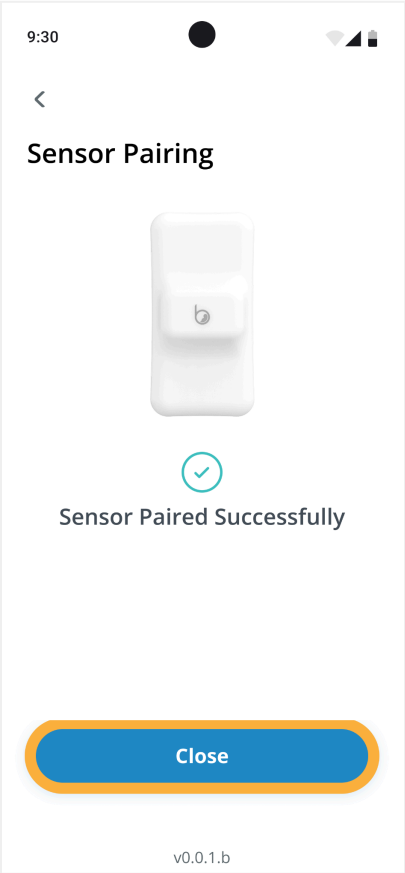
Step 2

A popup window will ask you to confirm the sensor ID for the ANNE Chest Sensor you would like to pair. Select the “CONFIRM” button if the sensor ID is correct.



Step 3

After pairing successfully, press the “Close” button to proceed.



4.1.2 Manual Pairing

Step 1

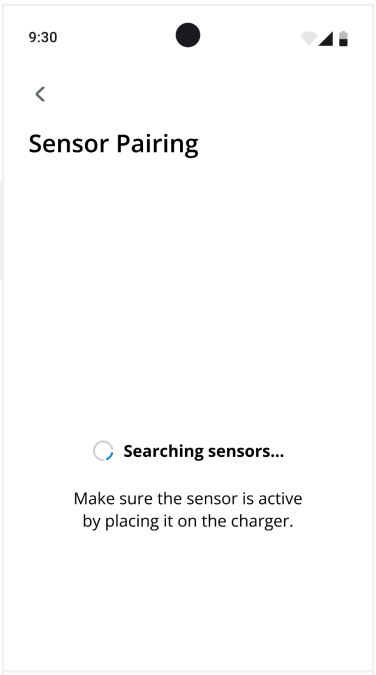
The ANNE Chest Sensor can be manually paired by pressing the

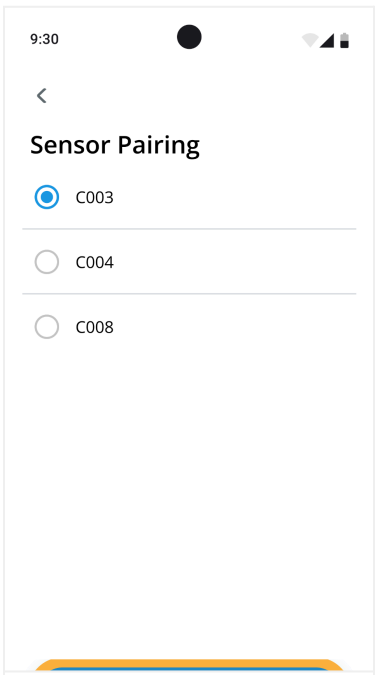
TRY ANOTHER WAY button on the bottom of the first screen.

Step 2

All advertising sensors near the phone will appear in a list shown on screen. Confirm that the sensor is sufficiently charged and then select the sensor that is to be paired. The sensor ID is located on the surface of the sensor.

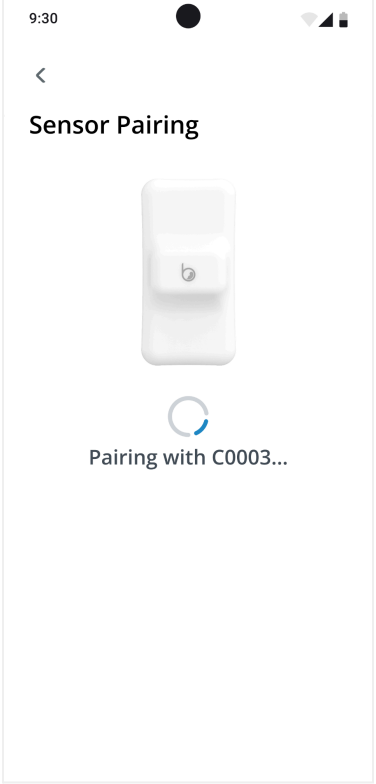
Note: If the sensor does not appear in the advertising sensors list, refer to Section 4.2.5.

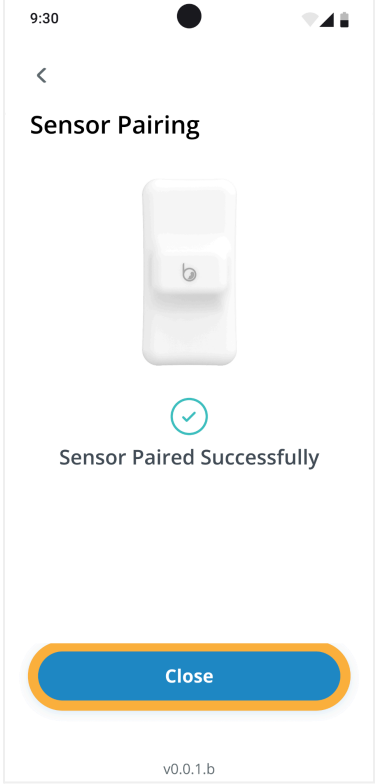




Step 3

During pairing, the system will present a pairing screen with the name of the sensor and the pairing status. After pairing successfully, press the “Close” button to proceed.



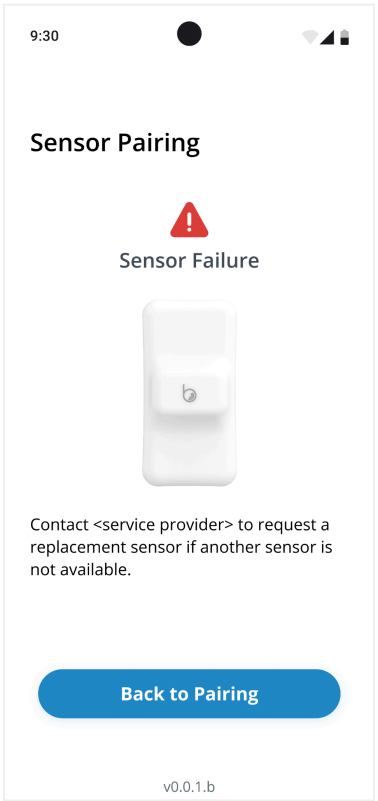


4.2 Troubleshooting During Sensor Pairing

4.2.1 Sensor Failure

If the sensor that needs to be paired has a sensor failure issue, notify Sibel Health to replace the failed sensor.

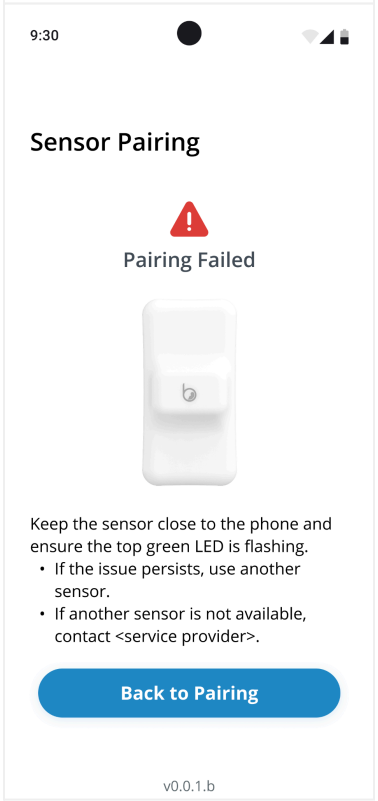
Note: ONLY the failed sensor needs to be replaced.



4.2.2 Pairing Failed

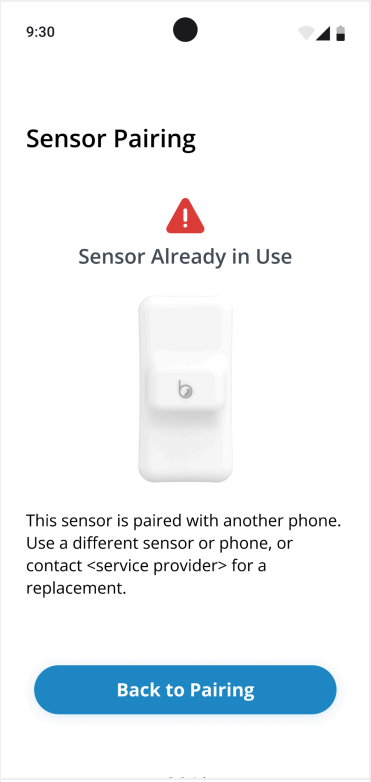
If the sensor fails to pair,

- Try again - Tap the Back to Pairing button to try to pair the sensor again.
- If it keeps failing, please notify Sibel Health and obtain a new sensor.



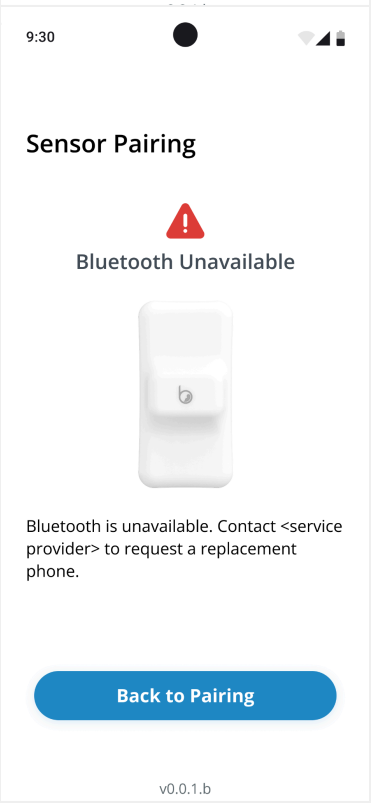
4.2.3 Sensor Already in Use

In this scenario, the sensor that the user is attempting to pair is already paired to a separate device. In this case, obtain a different sensor and pair it instead.



4.2.4 Bluetooth Unavailable

In this scenario, the ANNE Link Phone's bluetooth is unreachable. Restart the device and try again. If it continues to fail, obtain a new phone.



4.2.5 Sensor not in the list

If the sensor is not showing up in the advertising list:

Step 1

Check that the sensor is powered on and ready to pair by looking for the green LED on the top of the sensor. If it is not either a) blinking green every 3 seconds or b) solid green, place the sensor on the wireless charger to wake it up. If it is slowly pulsing green, wait a few minutes for the sensor to charge more before attempting to connect.

Step 2

Bring the phone close to the sensor and make sure there are no obstructions between the phone and the sensor.

Step 3

Scroll the list up and down to double-check if it is in the list.

Note: If the sensor still does not show up after trying Steps 1 - 3, contact Sibel Health.

4.3 Wear the sensor

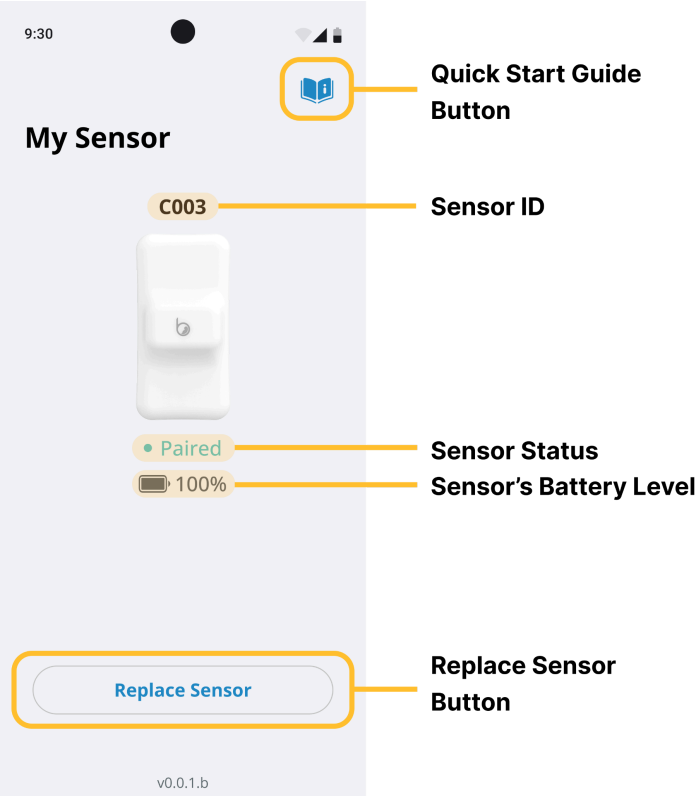
Wear the sensor following ANNE Chest Instructions for Use (443-00002).

Section 5. ANNE Link Mobile Paired Dashboard

This section describes the instructions needed for interpreting the information on ANNE View, the software application on the ANNE Link Phone.

5.1 ANNE Link Mobile Dashboard Screen

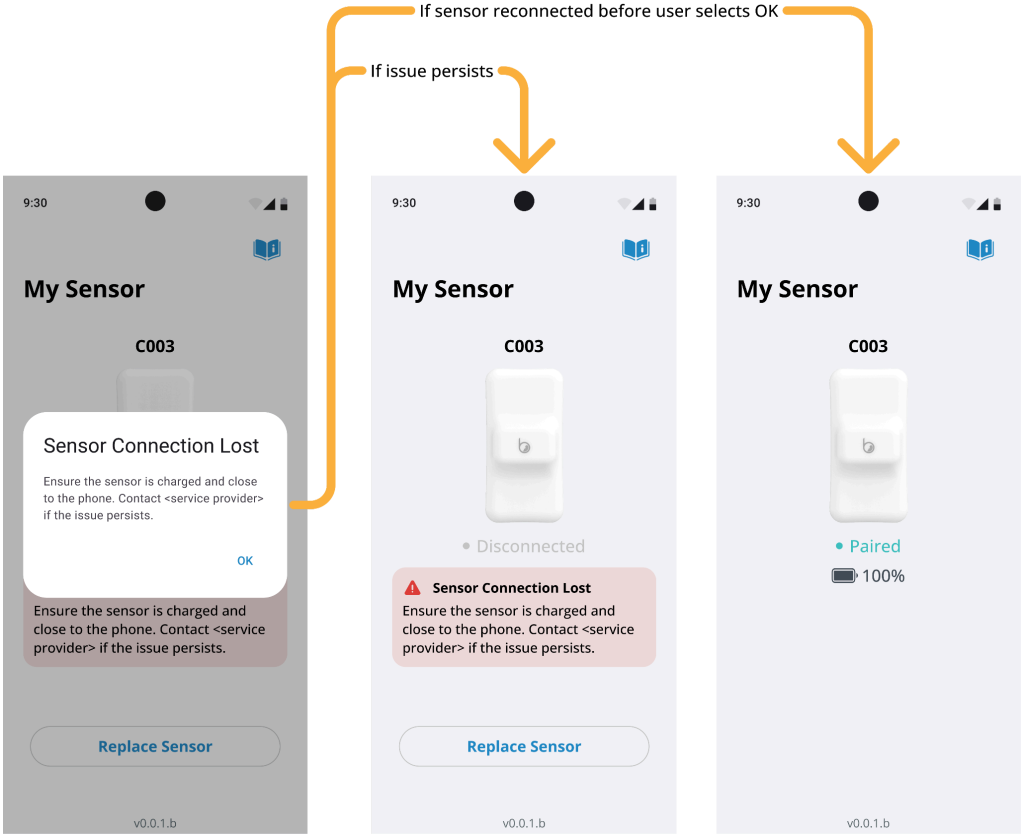
Once the system is paired, you will remain on this screen “My Sensor” as data is collected and relayed.



5.2 ANNE Link Mobile - Sensor Troubleshooting

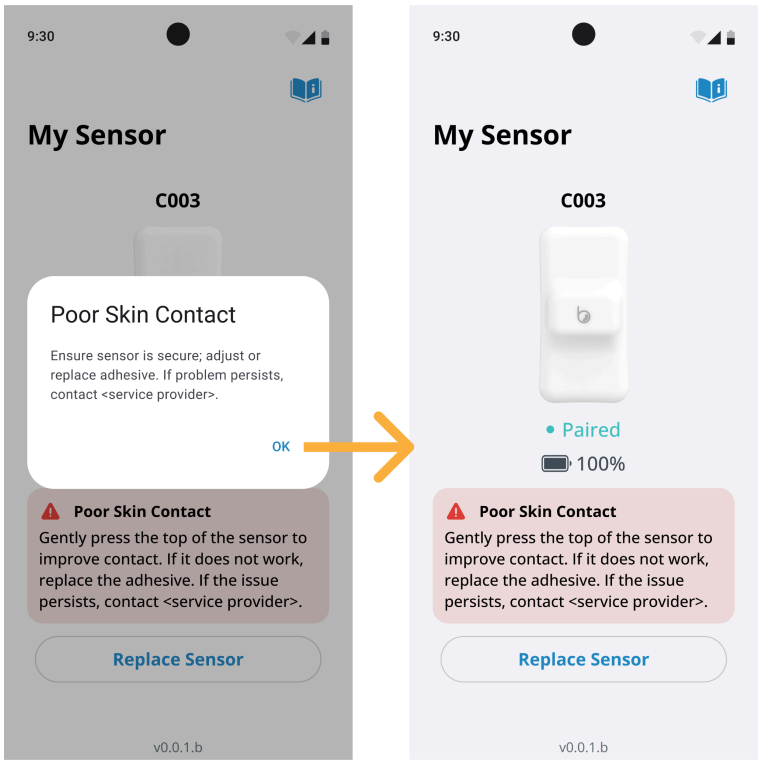
5.2.1 Sensor Connection Lost

If the sensor is not detected nearby, the app will display an alert indicating this. The application will automatically attempt to reconnect to the sensor if in range. Please reconnect the sensor as soon as possible. If unable to pair the sensor again, please contact Sibel Health to obtain a new sensor and follow the “Replace Sensor” workflow in Section 7.1.



5.2.2 Poor Skin Contact

If the sensor is not detecting good skin contact, then a “Poor Skin Contact” alert will be displayed in the sensor status section of the navigation bar. Re-adjust the sensor placement to obtain a better signal. Consult the ANNE Chest Instructions for Use (443-00002) document for guidance on re-adjusting the sensor if needed.



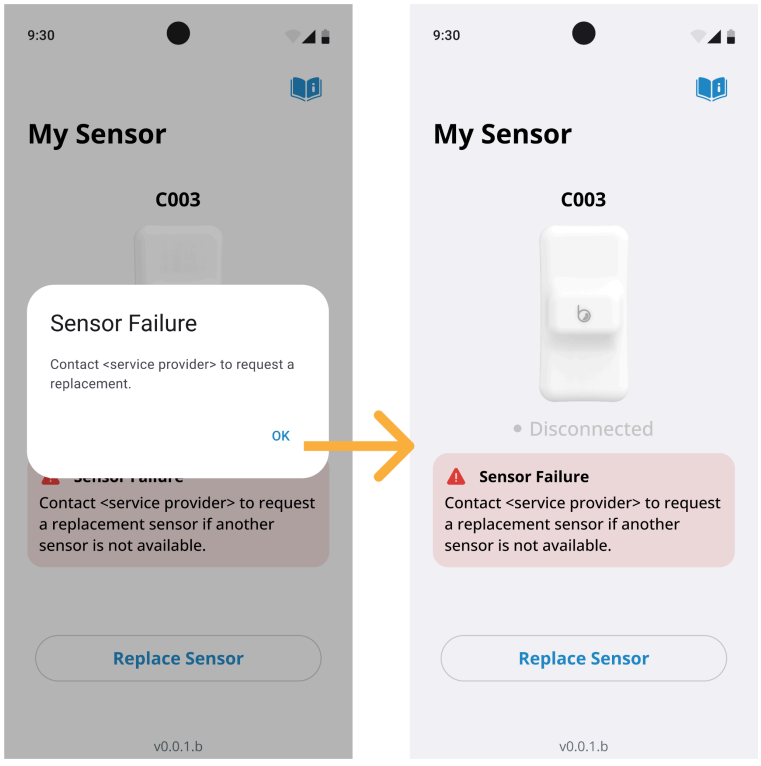
5.2.3 Sensor Failure

If the sensor experiences a Sensor Failure, a “Sensor Failure” alert will appear. **This is a high-priority issue, so please address the problem immediately if there is a “SENSOR FAILURE” notification.**

If there is a sensor failure,

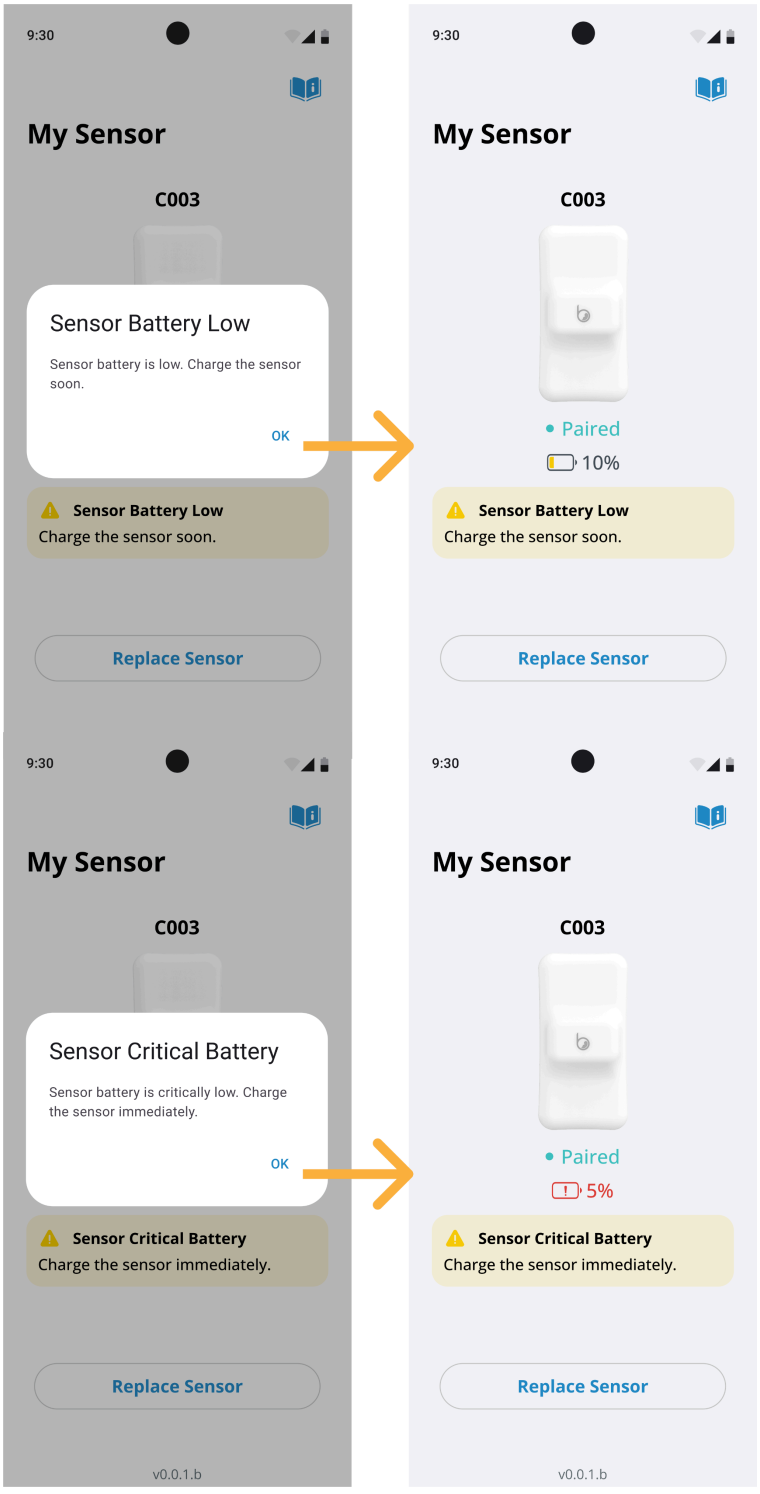
a) Notify Sibel Health of the sensor failure issue and ask for a replacement sensor.

b) Follow the “Replace Sensor” workflow in Section 7.1.



5.2.4 Sensor Battery Low

If the sensor battery falls below 20%, a “Sensor Battery Low” alert will appear. Remove the sensor and place it on the charger to charge it as soon as possible.

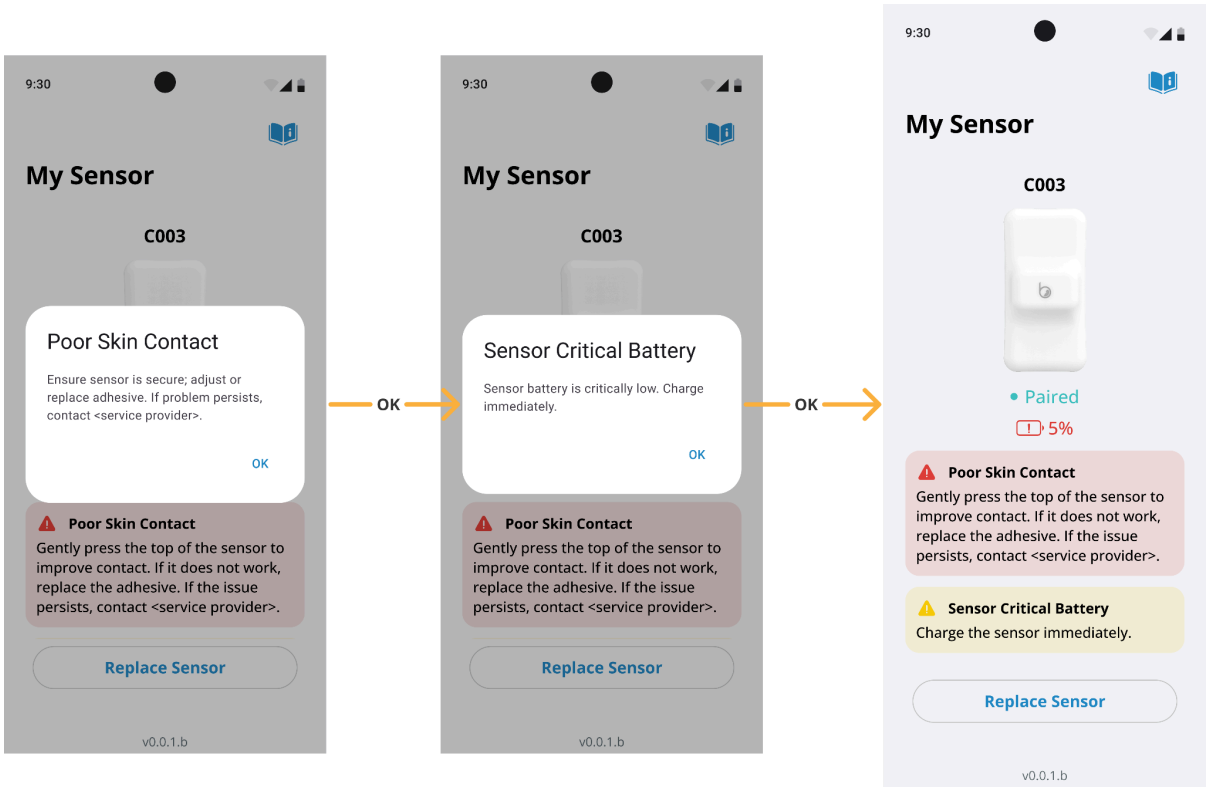


5.2.5 Sensor Critical Battery

If the sensor battery falls to 0%, the “Sensor Critical Battery” alert will appear. **This is a high-priority issue, so please address the problem IMMEDIATELY by removing the sensor and placing it on the charger to charge it.**

5.2.6 Multiple Errors at Once

If more than one error state appears, the latest popup stacks on the existing issue. The higher priority issues will display first.

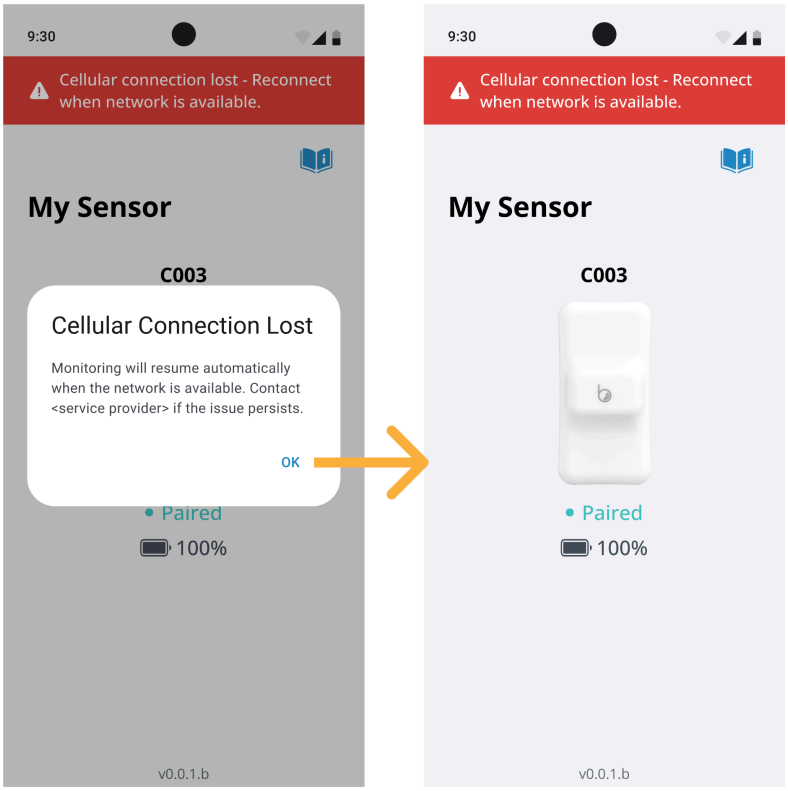


Note: Refer to the ANNE Chest Instructions for Use for sensor charging and reprocessing information.

5.3 ANNE Link Mobile - Phone Troubleshooting

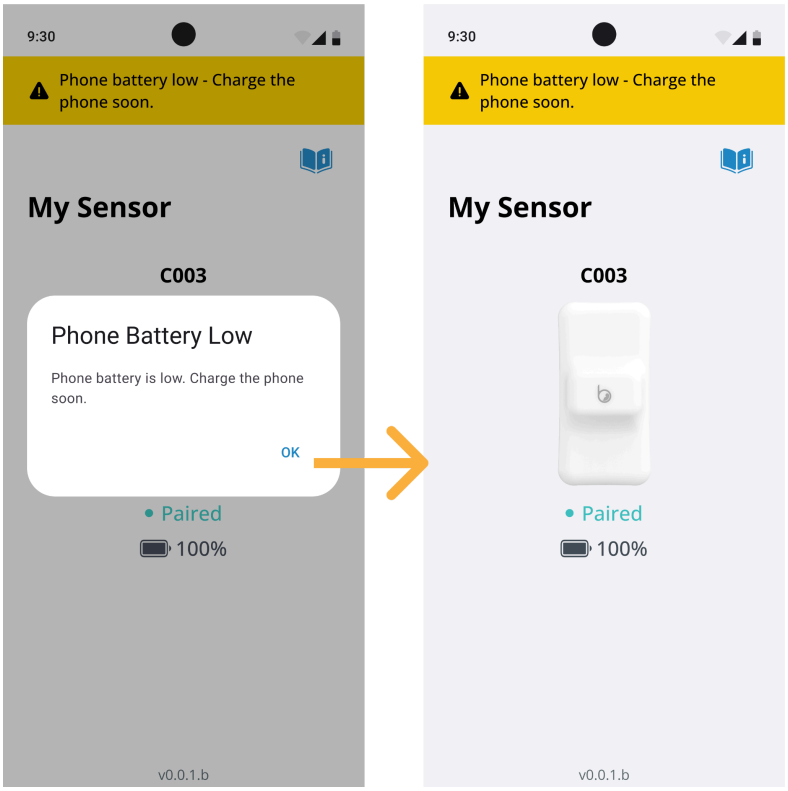
5.2.1 Cellular Connection Lost

If the phone loses connection to the server, a “Cellular Connection Lost” alert will appear. Reconnect the phone to the internet if possible or move to a location with a better connection.



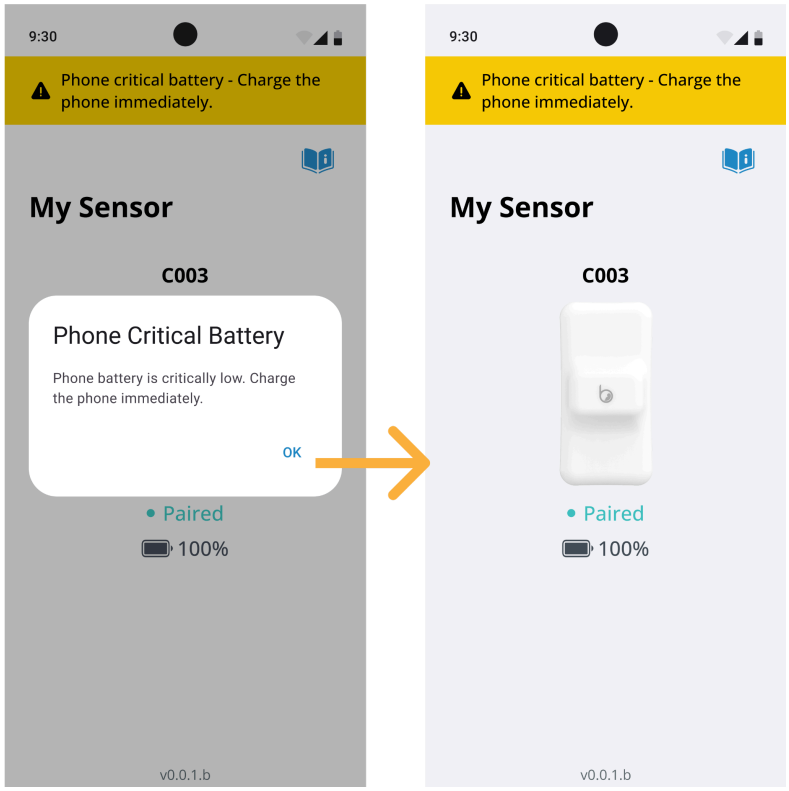
5.2.2 Phone Battery Low

If the phone battery falls below 20%, a “Phone Battery Low” alert will appear. Charge the phone as soon as possible to ensure data relay continues.



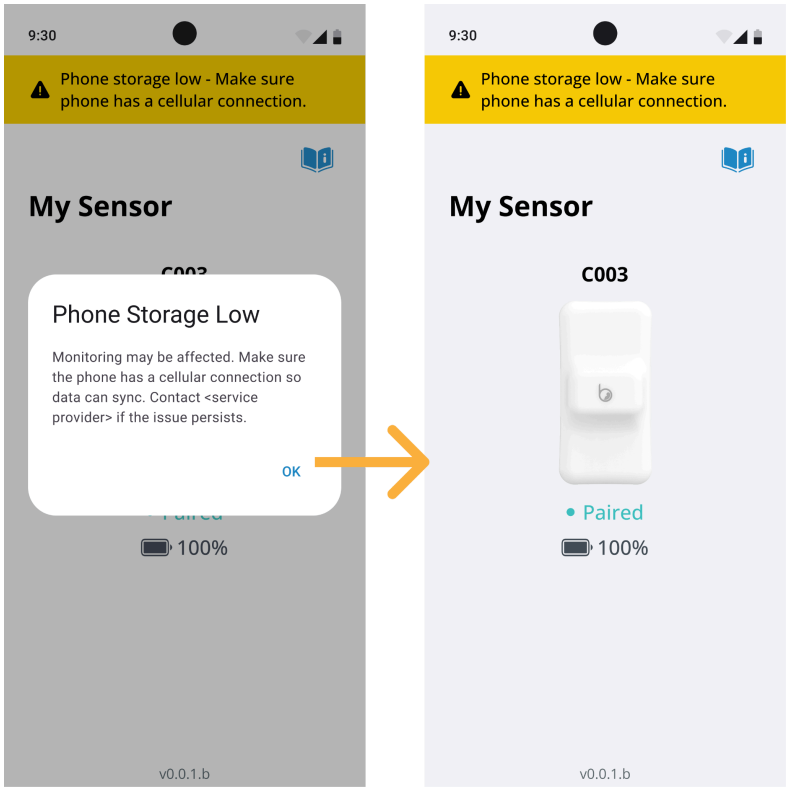
5.2.3 Phone Battery Critical

If the phone battery falls below 5%, a “Phone Critical Battery” alert will appear. Replace the phone to continue collecting data. **This is a high-priority issue, so please address the problem IMMEDIATELY by charging the phone.**



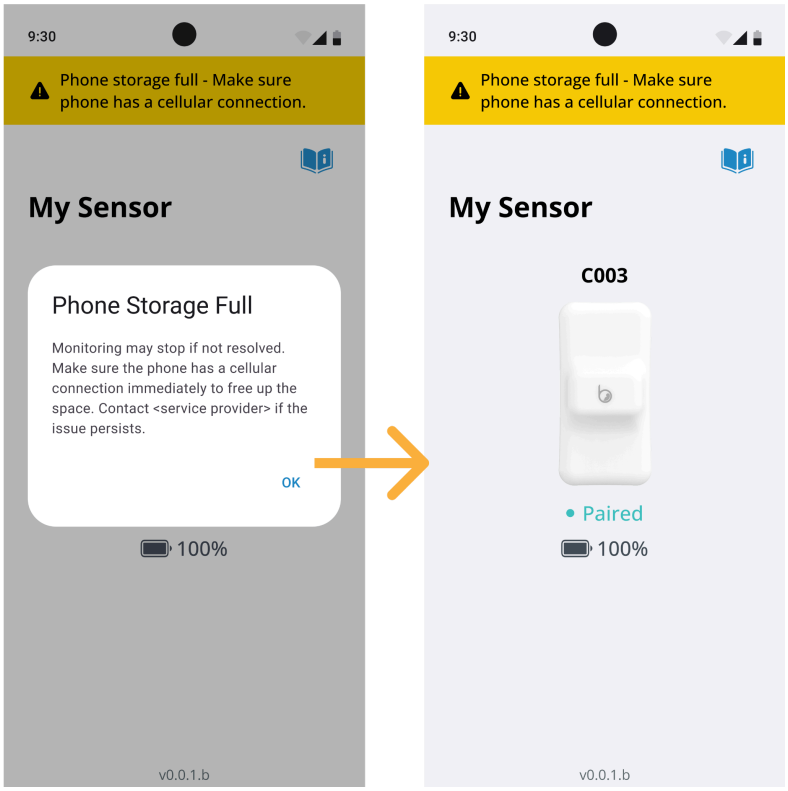
5.2.4 Phone Storage Low

If the phone has less than 80% disk space remaining, a “Phone Storage Low” alert will appear. Double check to make sure the device is connected to cellular so it can remain online and upload data.



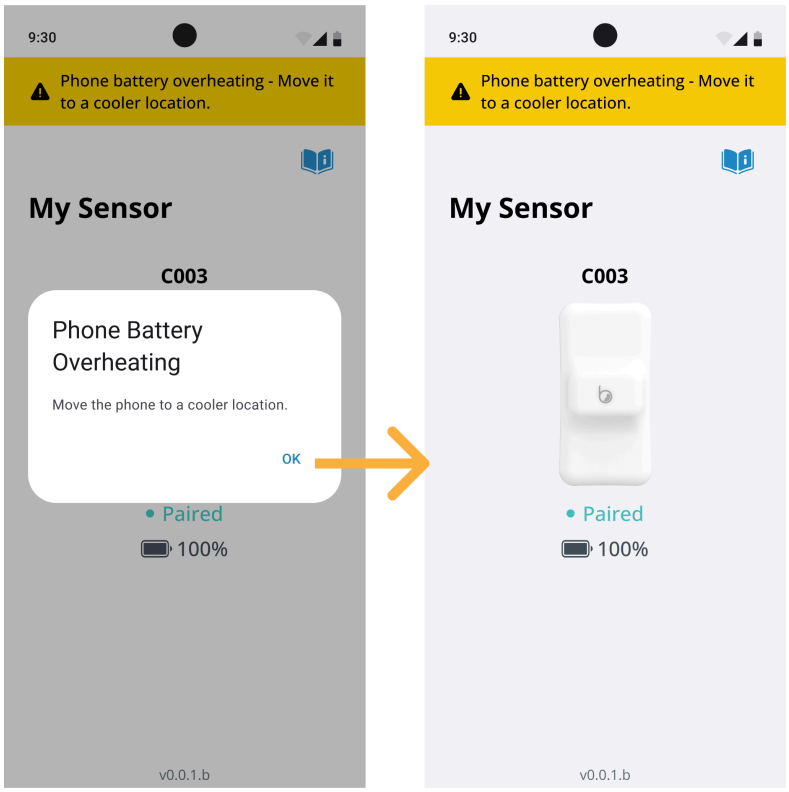
5.2.5 Phone Storage Full

If the phone has no available storage or is experiencing a hardware error, a “Phone Storage Full” alert will appear. **This is a high-priority issue, so please address the problem IMMEDIATELY by connecting the phone to cellular, or, contacting your service provider if the issue persists.**



5.2.3 Phone Battery Overheating

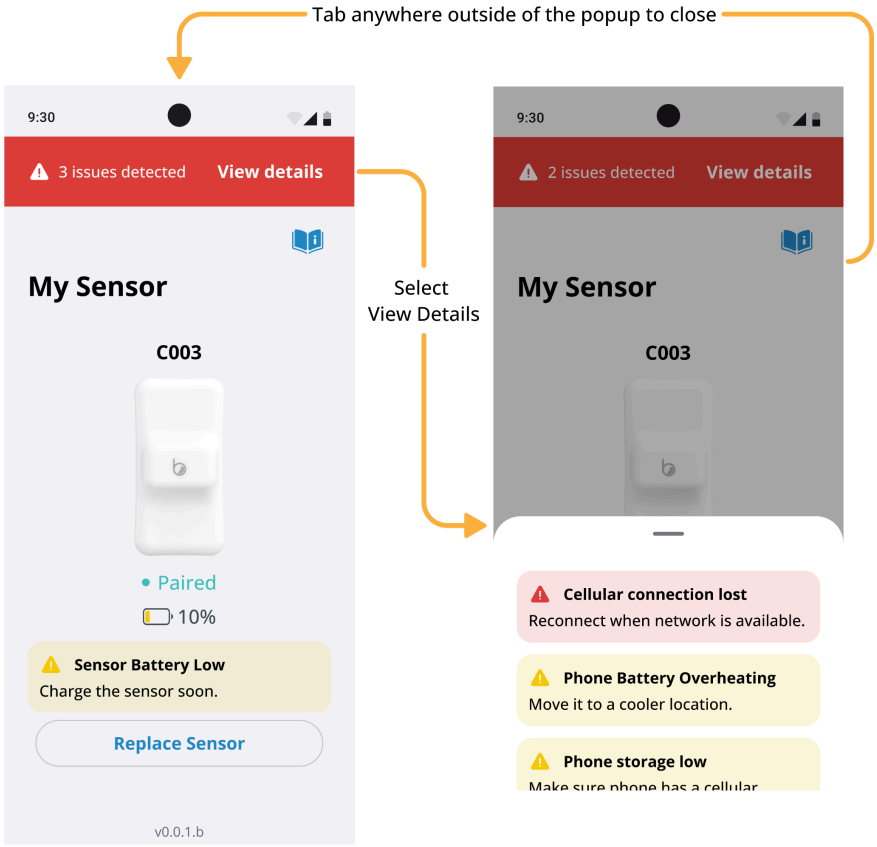
If the phone detects the battery is overheating, a “Phone Battery Overheating” alert will appear. Move the phone to a cooler location to resolve. If the issue persists, contact your service provider for a new phone.



5.2.6 Multiple Errors at Once

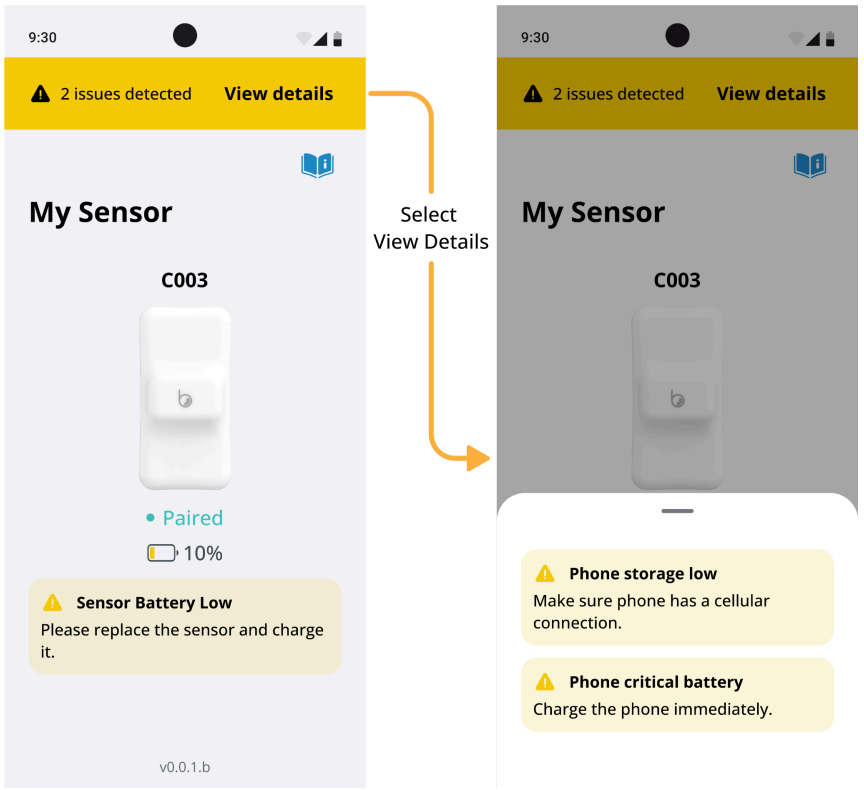
1. With both error and warning:

The Errors will display more prominently above the Warnings and the top bar will be colored Red.



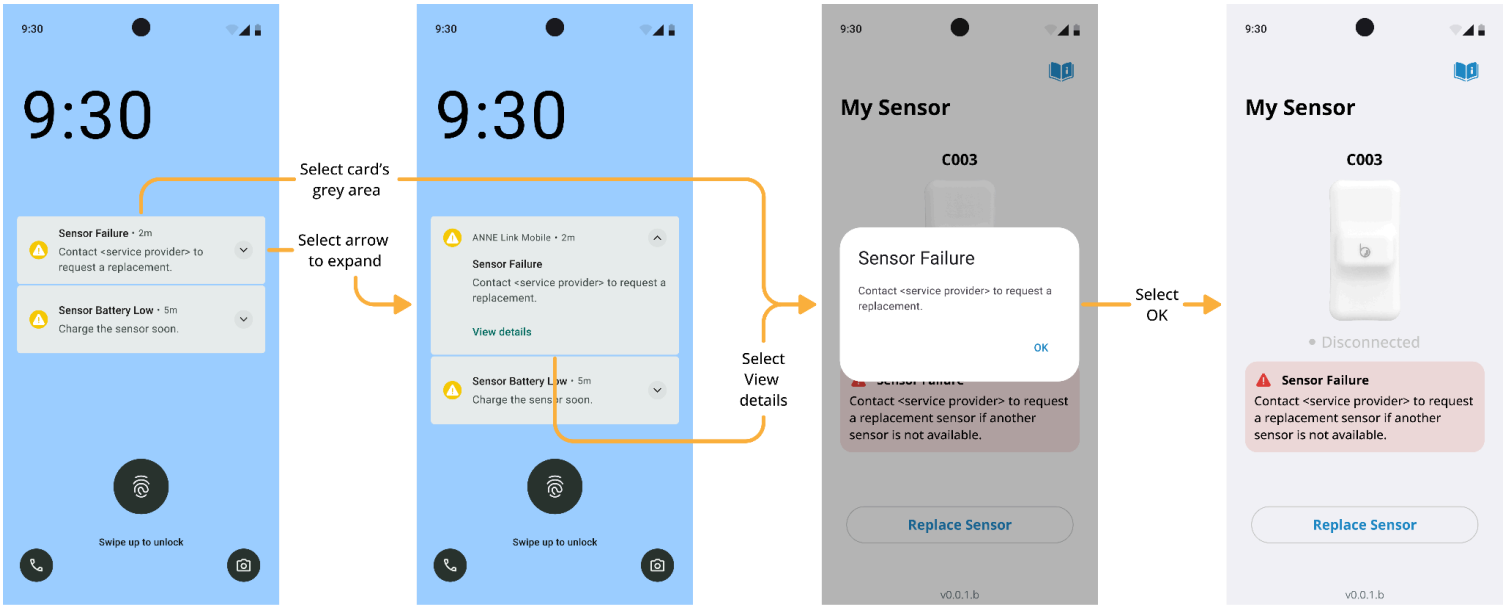
2. With warning only

The Warnings will all display together and the top bar will be colored Yellow.



5.4 Notification

The flow of notifications as they appear on the ANNE Link Phone is shown below:

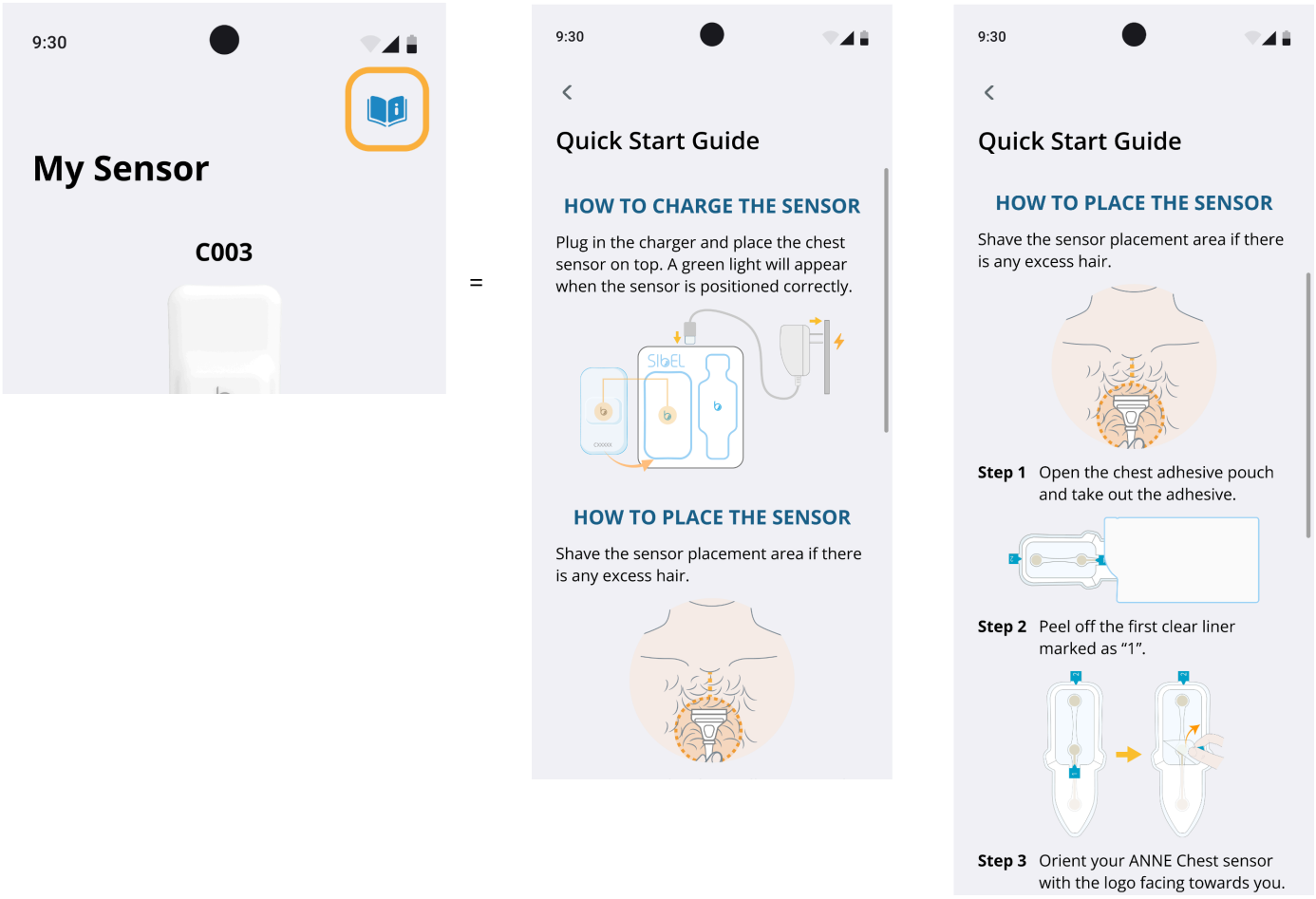


Section 6. ANNE Link Mobile - Quick Start Guide

This section describes the instructions for viewing the Quick Start Guide within the ANNE Link Mobile application.

6.1 Quick Start Guide

Press the Book icon on the top-right corner of the screen to open the Quick Start Guide. The Quick Start Guide includes the instructions of how to charge the sensor and how to place the sensor. Scroll up and down to see all contents.



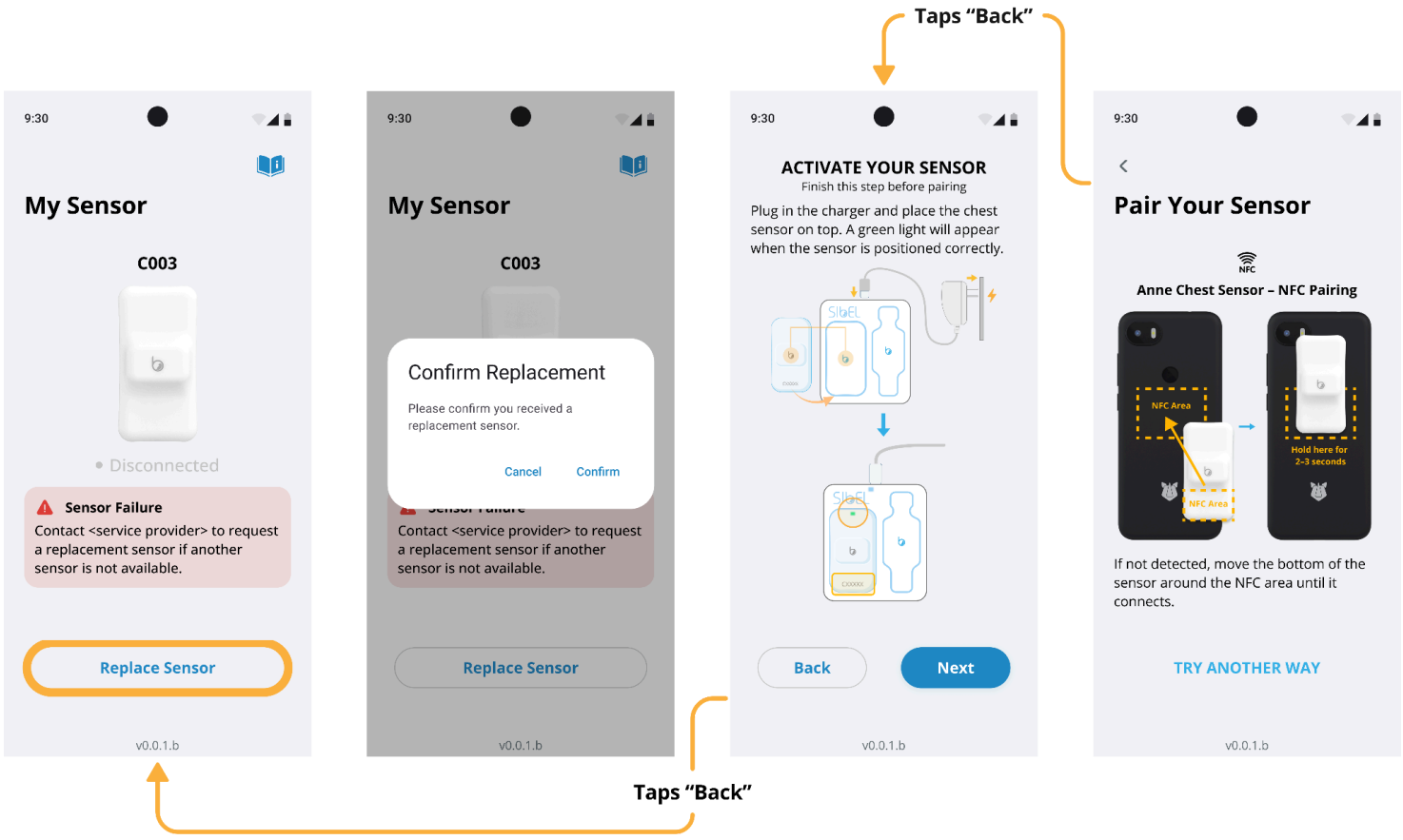
Section 7. ANNE Link Mobile - Sensor Replacement

This section describes the instructions for changing the sensor associated with the ANNE Link Mobile Phone.

Note: Make sure to have another replacement sensor ready.

7.1 Sensor Replacement

Click “Replace” on the Dashboard screen to initiate the sensor replacement process. From here, follow the same instructions as in Section 4.1 to pair the new sensor.



7.2 Sensor Replacement - Troubleshooting

Follow the troubleshooting instructions in Section 4.2 if facing an error.

Section 8. Product Specifications

This section includes the specifications of each item in ANNE Link Mobile.

8.1 ANNE Link Phone Technical Specifications

Table 3: ANNE Link Phone Specifications

	ANNE Link Phone
Dimensions (L x W x H, in)	6.4 x 2.9 x 0.4 inches
Weight (ounces)	5 ounces
Screen Size (inches)	6” Touchscreen
Screen Resolution (pixels)	720 x 1560
Wi-Fi	802.11 a/b/g/n/ac 2.4G+5GHz
Power supply	USB-C 10W power adapter 5V, 2A
Battery Type	Rechargeable lithium-ion battery
Operation Time (per full charge)	15 hours
Charging Time (to full charge)	6.5 hours
Water Resistance	Phone: IP68

8.2 Electromagnetic Emissions Declaration

ANNE Link Mobile is 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 4: Electromagnetic Environment

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	ANNE Link Mobile uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	ANNE Link Mobile is 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.

8.3 FCC Compliance Notification

ANNE Link Mobile has 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: 2BCQV-12056). The included ANNE Link Phone (FCC ID: A3LSMT545) 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.

8.4 Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and ANNE Link Mobile

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

ANNE Link Mobile is 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 ANNE Link Mobile as recommended below, according to the maximum output power of the communications equipment.

Table 5: 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.

8.5 Communication Specifications

ANNE Chest

Table 6: ANNE Chest - Bluetooth

Bluetooth	
Bluetooth Compliance	Version 4.2, 5.0
Operating Frequency	2.4 to 2.4835 GHz
Output Power	TX: +4 dBM
Operating Range	5-meter radius (line of sight)
Network Topology	Point-to-Point
Operation	Peripheral, slave
Antenna Type	Integrated Chip with Built-in Antenna
Modulation Type	Adaptive Frequency Hopping Spread Spectrum with Gaussian Frequency Shift Keying
Data Rate	1 Mbps
Bluetooth Profiles Supported	GATT-based proprietary ANNE profile

Table 7: ANNE Chest - Security

Security	
Data Integrity	24-bit CRC (Cyclic Redundancy Check) and 32-bit Message Integrity Check
Authentication and Encryption	Supported
Encryption Key Size	128 bits AES

Table 8: ANNE Chest - Radio Compliance

Radio Compliance	
FCC ID	2AAQS-ISP1807

ANNE Link Phone

Table 9: ANNE Link Phone - Bluetooth

Bluetooth	
Type	Version 5.1
Max. EIRP Output Power	13.73 dBm

Table 10: ANNE Link Phone - NFC

NFC	
Frequency	13.56 MHz
Max. Output Power	-19.00 dBµA/m at 10m

Table 11: ANNE Link Phone - Radio Compliance

Radio Compliance	
FCC ID	A3LSMT545
Model	C6

The following communication capabilities are included as part of the phone hardware and are enabled on the ANNE Link Phone for its use in the ANNE Link Mobile system:

- Bluetooth
- NFC
- Cellular (3G, 4G, 5G LTE)