SIbEL

Anne Chest
INSTRUCTION FOR USE

IFU P/N 443-00002F

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Section 1. Important Safety Information

1.1 Device Description

Anne Chest is a skin-mounted, bio-integrated sensor that collects real-time biosignals including electrocardiography (ECG), 3-axis accelerometry, and temperature to measure vital signs such as heart rate, respiratory rate, body position, fall detection, and skin temperature. The sensor communicates via Bluetooth to the Sibel SDK, which may be integrated within software applications for the display and storage of data. The ECG signal obtained by Anne Chest is not intended for manual discrimination of any arrhythmias or cardiac conditions.

The Sibel Software Development Kit (SDK) is a software product integrated into Android-based mobile applications. The Sibel SDK alone cannot perform any clinical functions and needs to be integrated into a compatible software application for patient monitoring. The Sibel SDK is designed to communicate with and collect data from the Anne sensor to enable an application to request, retrieve, and process device data. The SDK communicates with sensors using the Bluetooth Low Energy (BLE) protocol.

Note: Refer to the Sibel SDK Integration Guide for instructions on the Sibel SDK.

1.2 Indications for Use

Anne Chest is a wearable, wireless sensor intended for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, activity, fall detection, body position, and skin temperature. Anne Chest is not intended to monitor or measure respiratory rate while the patient undergoes significant motion or is active. Anne Chest communicates with compatible software applications for the display, storage, and analysis of data. The device is intended to provide continuous physiological information as an aid to diagnosis and treatment by healthcare professionals in general care patients who are 12 years of age or older in clinical and home environments. The device is not intended for use on critical care patients.

1.3 Contraindications

- While the data may be applicable for use as an aid to diagnosis and treatment, Anne Chest does not provide diagnostic or interpretive statements to either the patient or the clinician.
- Anne Chest is NOT intended for use on critical care patients and is not a remote diagnostic device.
- Anne Chest is NOT intended for use on patients with implanted pacemakers or defibrillators.
- Anne Chest is NOT intended for use on patients with known allergies, or hypersensitivities to, adhesives or nickel.
- Anne Chest is NOT intended for patients with significant cardiorespiratory disease including patients that are oxygen dependent.
- Anne Chest is NOT intended for patients with significant respiratory muscle weakness due to an underlying neuromuscular condition (e.g., myasthenia gravis, amyotrophic lateral sclerosis, or muscular dystrophies)

1.4 Warnings

- Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner **Rx ONLY**
- Anne Chest 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 patient. Sensors should be removed if any pain or discomfort occurs.
- Keep the wireless charger away from liquids. The sensor is splash resistant but is 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.
- Anne Chest is NOT MRI safe and should be removed prior to an MRI scan.
- Anne Chest 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.
- Do not put Anne Chest directly on the patient after the sensors have been charging. Wait at least 5 minutes after removing the sensor from the charger before applying the sensors on the patient.
- Anne Chest is not intended to be used as an apnea monitor. Do not rely on the respiration monitoring to detect cessation of breathing.
- Anne Chest should not be used for real-time, remote monitoring when there is no attending medical professional present.
- Use of accessories and cables other than those provided by Sibel could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- DO NOT attempt to disassemble, repair, or modify the devices.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than the separation distances specified in this manual to any part of Anne Chest. Otherwise, degradation of the performance of Anne Chest could result.

1.5 Precautions

- Anne Chest and adhesives are non-sterile.
- The sensor 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 streaming is possible. Similar devices may cause signal interference during data transmission. If you experience this effect, avoid operating near interfering devices.
- Do NOT wear Anne Chest over regions of the body with excessive body hair. Excessive body hair should be shaved prior to wear. Adhesives should be applied to clean dry skin only.
- The sensors should be applied to healthy, intact skin only. They should not be applied to skin that is broken, damaged, or irritated.
- Keep loose sensors, 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 may present a risk of fire, explosion, or chemical burn if mistreated. Do not expose the sensor 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 sensors as it may damage the 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.
- Anne Chest is intended to be operated by a qualified healthcare professional. The patient is not an intended operator.
- In case of emergency, unplug the wireless charger from the wall.
- Anne Chest has no cardiac arrhythmia detection capabilities.
- It is recommended that healthcare providers evaluate the underlying skin integrity when replacing the adhesive for continued use and determine whether continued use is warranted and safe.
- Anne Chest does not provide alarms. Do not use the sensor in situations when alarms are required.
- Anne Chest sensors that are impacted in any way should be returned to Sibel Health for disposal and should not be used.

1.6 Glossary

Table 1: Glossary

Abbreviation	Definition
AFE	Analog Front End
NFC	Near Field Communication
LED	Light-emitting diode
IP	Ingress Protection
RH	Relative Humidity
ECG	Electrocardiogram
HR	Heart Rate
RR	Respiratory Rate
SpO2	Oxygen Saturation
ID	Identifier
RF	Radio Frequency
MRI	Magnetic Resonance Imaging
BPM	Beats Per Minute

ME	Medical Equipment

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
	Type CF Defibrillation Proof	Type CF Defibrillation Proof
	Class II Equipment	Equipment meets the safety requirements specified for Class II equipment according to IEC 61140
	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 manufacturer,
	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 Away From Rain	The transport package shall be kept away from rain and in dry conditions
	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
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Fragile, handle with care	Contents of the transport package are fragile and the package shall be handled with care.
	Use-by-date	Indicates the date after which the medical device is not to be used

	Date of Manufacture	Indicates the date when the medical device was manufactured
	Catalogue number	Indicates the manufacturer's catalogue number so the medical device can be identified
IP	Ingress Protection	Degree of protection of electrical enclosures against foreign bodies and moisture
	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 Security Recommendations

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

- Do not connect to sensors outside of the system components.
- Do not connect to sensors with sensor IDs you do not recognize.
- When pairing sensors with Bluetooth, always confirm the sensor ID displayed on the tablet with the one displayed on the system before use. Always confirm with the green led confirmation process before use.

1.9 Contact

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

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

Section 2. System Items

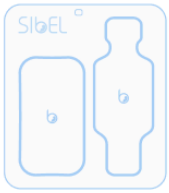
This section describes the items needed to start a monitoring session.

2.1 Anne Chest and Accessories

The system includes Anne Chest and the accessories listed below:

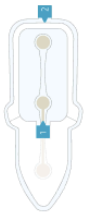
1. **Anne Chest**
2. **Anne Bedside Wireless Charger and Wireless Charger Adapter**
3. **Consumables: Anne Chest Adhesive, Standard Wear and/or Extended Wear**

Anne Chest



Anne Bedside Wireless Charger

Wireless Charger Adapter



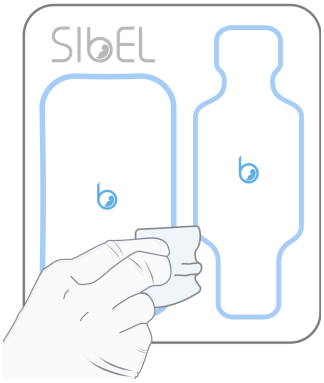
Anne Chest Adhesive, Standard Wear

Anne Chest Adhesive, Extended Wear

Section 3. Anne Chest System Setup

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

3.1 Setting up Anne Bedside Wireless Charger



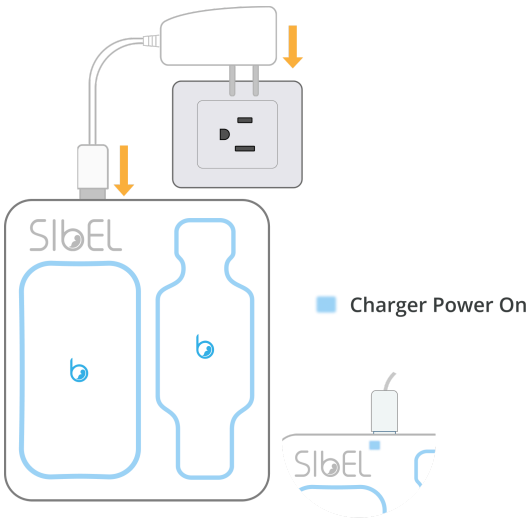
3.1.1 Sanitize the Anne Bedside Wireless Charger pad

Before charging the sensors, wipe the top of the Anne Bedside Wireless Charger with a Super Sani-Cloth® cleaning wipe to sanitize. Visually inspect the charger and repeat the cleaning process until it is visibly clean.

Note: Make sure to wear gloves if you use Super Sani-Cloth®.

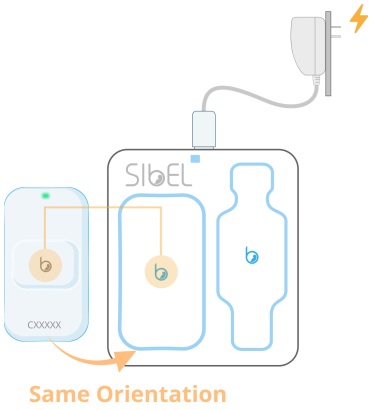
3.1.2 Plug in the Wireless Charger Adapter

Connect the Anne Bedside Wireless Charger to a power supply using the Wireless Charger Adapter.



3.2 Setting Up Sensors

3.2.1 Activate the Sensors

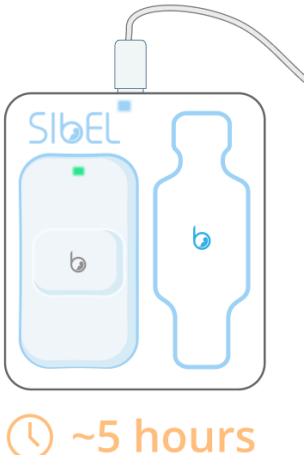


Step 1

Place the sensors on the Anne Wireless Bedside Charger,
guided by the outlines on the charging surface.
The logos of the sensors should match the logos on the wireless charging pad.

Step 2

A green LED light on the sensors will blink every five seconds indicating that the sensors are charging. The average duration for a full charge is 5 hours.

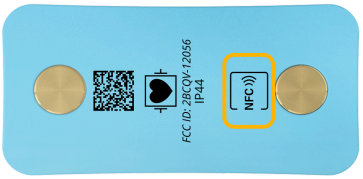


Note:

- In case of an emergency, unplug the Anne Wireless Bedside Charger from the wall.
- The sensor's battery level can be monitored using the ANNE View App on the tablet.

3.2.2 Pair the Sensor

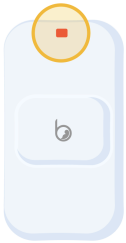
Pair the sensor to the monitoring system with Bluetooth or NFC.



Note: Anne Chest contains an NFC chip for NFC pairing.

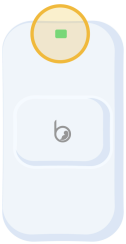
3.3 Anne Chest LED Pattern Interpretation

Red LED Status:



- Blinks every 1 second: lead-off / poor skin contact during wear
- Blinks every 3 seconds: low battery OR low memory
- Solid: sensor failure

Green LED Status:



- Blinks every 3 seconds: sensor is able to connect via bluetooth
- Blinks for 1 second every 5 seconds: sensor is charging
- Slowly pulses (3 seconds to brighten, 3 seconds to dim): sensor is charging, but it has too low battery to be used
- Solid (when on the charger): sensor is fully charged
- Solid (when pairing): indicates which sensor is being paired

Section 4. Anne Chest Application

This section describes the instructional steps needed to apply Anne Chest to the patient

4.1 Applying Anne Chest for Standard Wear Usage (up to 7 days)

4.1.1. Check the Adhesive

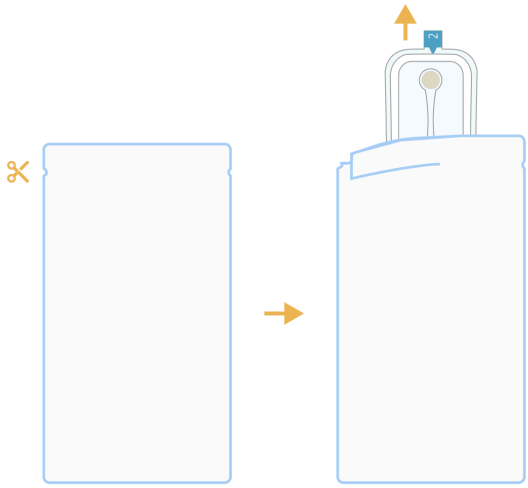
Check the expiration date on the adhesive box or pouch. Open Anne Chest Adhesive, Standard Wear pouch and take the adhesive out of the pouch. Check the condition of the adhesive before usage.

Pouch

Expiration Date

Side of the box

Expiration date



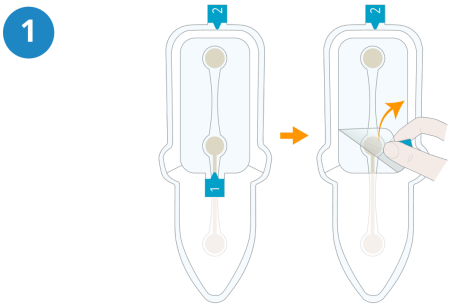
4.1.2. Prepare Chest Area

Prep the skin at the location of Anne Chest application site. Shave the application site if there is hair. Proper skin prep will improve sensor adhesion and signal quality.

4.1.3. Apply Adhesive and Sensor to Body

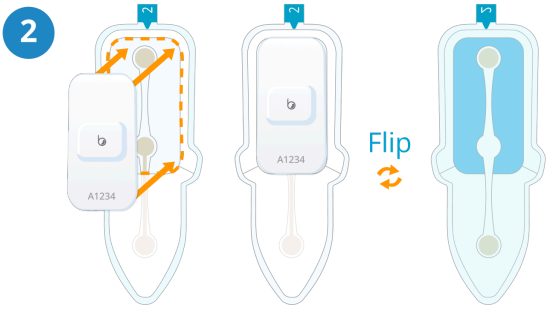
Step 1

Peel off the 1 liner.



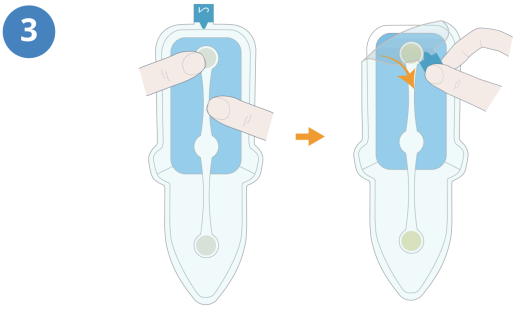
Step 2

Orient your Anne Chest sensor with the logo facing towards you. Press the sensor onto the adhesive, then flip the assembled sensor and adhesive.



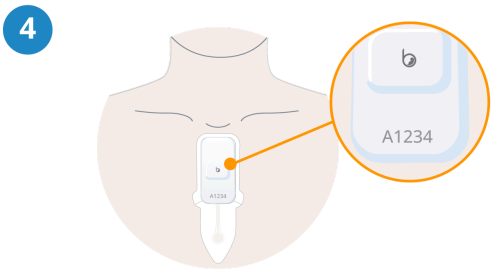
Step 3

Press down to ensure adhesion. Remove the 2 liner from the adhesive.



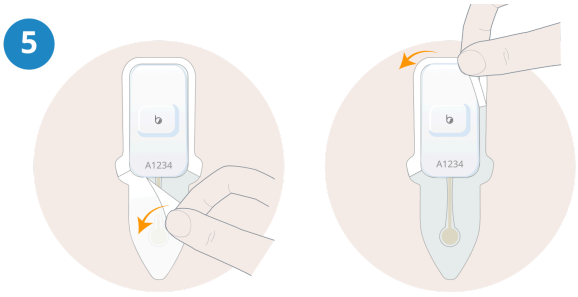
Step 4

Place the top edge of the chest sensor below the suprasternal notch, centered on the body, with the logo and sensor ID facing up. Ensure good contact by pressing evenly across the entire sensor and adhesive



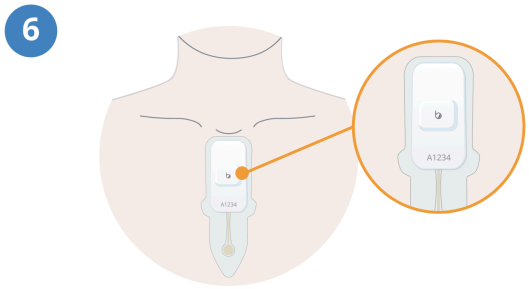
Step 5

Slowly remove the white liners from the adhesive.



Step 6

Ensure the logo and sensor ID are properly oriented.



Note:

- The sensors should be applied to healthy, intact skin only. They should not be applied to skin that is broken, damaged, or irritated.
- Sensors should be removed if any pain or discomfort occurs.
- Make sure the logo orientation is correct. See Section 4.1.3 Step 6.
- To ensure accurate chest sensor reading, gently apply pressure on the top and bottom of the sensor (This should also be done if the sensor shows lead-off on the software application).
- If foreign matter sticks to the adhesive prior to use, discard the adhesive and apply a new one.

4.2 Applying Anne Chest for Extended Wear Usage (5 days or longer)

4.2.1 Check the Adhesive

Check the expiration date on the adhesive box.Open Anne Chest Adhesive, Extended Wear box and take one adhesive out of the box. Check the condition of the adhesive before usage.

Side of the box

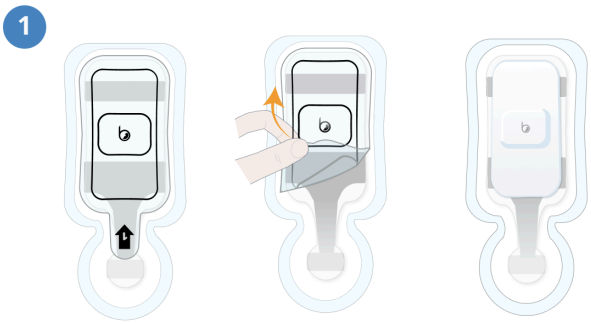
4.2.2 Prepare Chest Area

Prep the skin at the location of the Anne Chest application site. Shave the application site if there is hair. Proper skin prep will improve sensor adhesion and signal quality.

4.2.3 Apply Adhesive and Sensor to Body

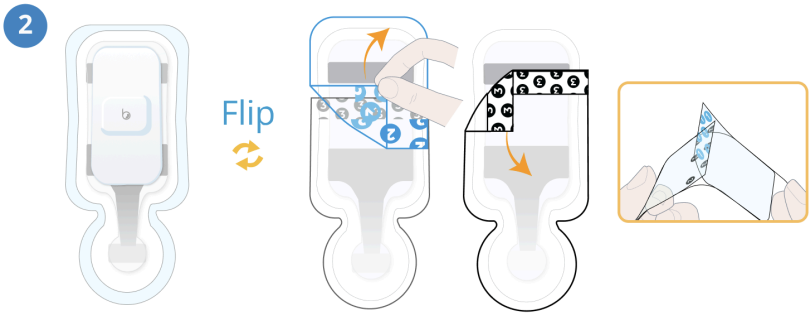
Step 1

Peel off the first clear liner that has Anne Chest outline. By following the location of the outline, attach the chest sensor on the top of the adhesive after the liner is off.



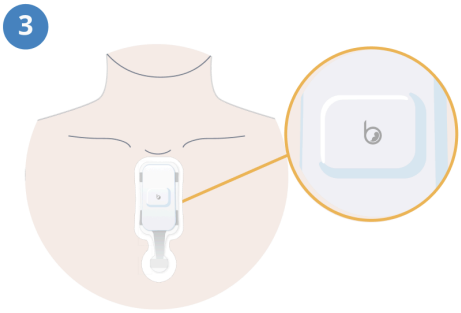
Step 2

Flip the adhesive (with the sensor) and peel off the second and third liner.



Step 3

Place the top edge of the chest sensor below the suprasternal notch, centered on the body, with the logo and sensor ID facing up. Ensure good contact by pressing evenly across the entire sensor and adhesive.



Note:

- The sensors should be applied to healthy, intact skin only. They should not be applied to skin that is broken, damaged, or irritated.
- Sensors should be removed if any pain or discomfort occurs.
- Make sure the logo orientation is correct. See Section 4.2.3 Step 3.
- To ensure accurate chest sensor reading, gently apply pressure on the top and bottom of the sensor (This should also be done if the sensor shows lead-off on the software application).
- If foreign matter sticks to the adhesive prior to use, discard the adhesive and apply a new one.

Section 5. Troubleshooting

Anne Chest detects when there is a technical issue and communicates that issue via Bluetooth. This section describes the instructional steps to handle the sensor's errors.

5.1 Handling Sensor Errors

This section includes the resolution procedures for the following issues:

- Anne Chest poor skin contact
- Low/critical battery
- Sensor failure

Note: When the system detects issues that may affect the quality of the data, the application may temporarily halt transmitting the data. Resolving the error states as soon as possible will aid in restoring the data quality and allow you to resume the use of the system.

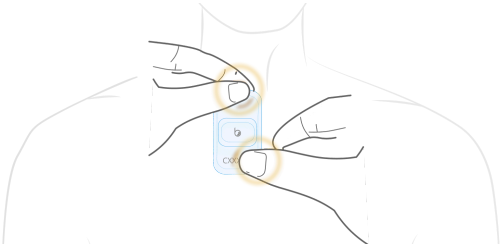
5.1.1. Anne Chest Poor Skin Contact

If Anne Chest is not detecting good skin contact, then a red light will be displayed on the sensor to indicate lead-off. The sensor will send a status via Bluetooth that there is a lead-off error, and will stop sending ECG, heart rate (HR), and respiratory rate (RR), skin temperature data while this status is occurring.

Solution

Option 1

Readjust the sensor placement to ensure that it is properly attached. Gently apply pressure over the electrodes on top of the sensor. Confirm the chest skin is properly prepared and in good condition.



Option 2

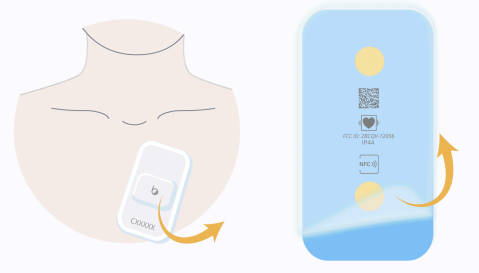
If the first option does not work, replace the Anne Chest Adhesive.

Option 3

If the second option does not work, try to un-pair and then re-pair the sensor.

Option 4

If the third option does not work, replace the sensor.



To replace the Anne Chest Adhesive,

Step 1 Remove the sensor from the body. Remove the Anne Chest Adhesive. Dispose the used Anne Chest Adhesive.

Step 2 Replace adhesive and apply following previous instruction per section 4.1.3. and 4.2.3

5.1.2. Low / Critical Battery

If the sensors have a low battery, the red LED blinks every 3 s to indicate low battery.

If the sensor has a low battery,

a) Remove the sensor from the patient.
b) Clean the sensor using a Super Sani-Cloth® cleaning wipe.
c) Check that the sensor is clean, and repeat the cleaning process until it is visibly clean.
d) Charge the low battery sensor.
e) Once the sensor is charged, you can pair the sensor and continue collecting data.

Note: Make sure to wear gloves if you use Super Sani-Cloth®.

5.1.3 Sensor Failure

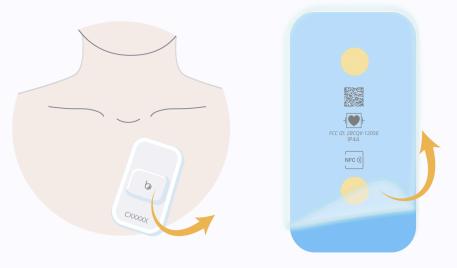
A solid red LED appears when Anne Chest reports a sensor failure. **This is a high-priority issue, so please address the problem immediately if there is a solid red LED on the sensor.**
If there is a sensor failure,

a) Notify your support representative of the sensor failure.
b) Take off the current sensor that is failing and replace it with a new sensor (See Section 4.1 or 4.2)

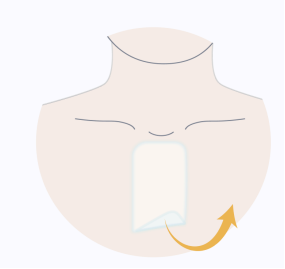
Section 6. Remove Anne Chest

6.1 Sensor Removal

First, gently remove the adhesive and from the skin, keeping the sensor on the adhesive. Second, gently peel the adhesive from the sensor and dispose of the used adhesive. The sensor is re-usable and should not be disposed.



If the adhesive remains on your skin after removing the sensor, gently remove the adhesive.



Note: Damaged sensors should not be reused. Notify your support representative of the sensor failure.

6.2 Sensor Cleaning

6.2.1 Cleaning Solution

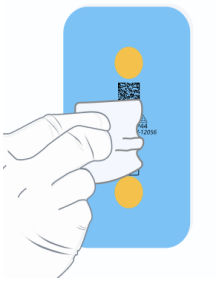
Super Sani-Cloth®

Note: Make sure to wear gloves if you use Super Sani-Cloth®.

6.2.2 Anne Chest Cleaning

Step 1 - Cleaning

Using Super Sani-Cloth(s), thoroughly wipe the device to remove all visible soil. Additional wipes may be used as needed until the device is visibly clean.



Step 2 - Low-level disinfection

Using new Super Sani-Cloth(s), wipe the device so that it remains visibly wet for at least 2 minutes. Additional wipes may be used as needed to ensure the device remains visibly wet for 2 minutes.

Note: Wipe the front and back of the device.

Step 3

Allow the sensor to air dry for 2 minutes and verify that there is no longer any soiling visible on the device.

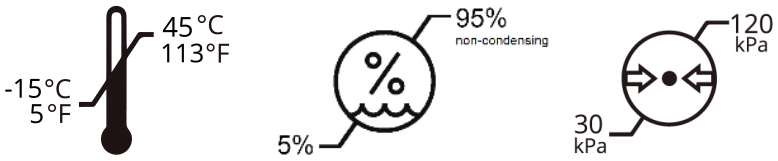
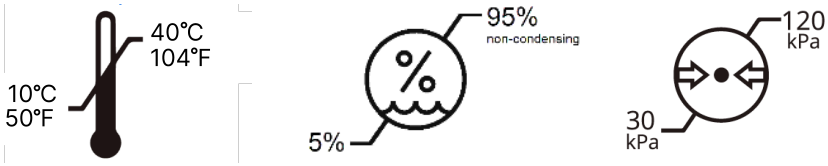
Note: Anne Chest may be used on new patients after the cleaning and disinfection process is complete.

Section 7. Product Specifications

This section includes the specifications of each item in the Anne Chest device.

7.1 Anne Chest Technical Specifications

Table 3: Sensor specifications

	Anne Chest
Storage/Transit Environment Range	 We recommend handling any patient contacting system components with gloves.
Safe Operating Environment Range	
Battery Type	Rechargeable lithium polymer battery Capacity: 70mAh
Charging Time (to full charge)	Less than 5 hours
Charging Method	Wireless charging using custom Anne Bedside Wireless Charger
Water Resistance	Sensors: IP44
Encapsulation Material	Low Durometer Silicone
Wireless Technology	Bluetooth® 5
Frequency Band	2402-2480 MHz
Maximum Connection Distance	100 ft (30.5 m)
Use Type	The sensor is multiple patient reusable up to 400 uses. It is recommended that the healthcare provider evaluate the underlying skin integrity after 7 days of continuous use and determine whether continued use is warranted and safe.
Defibrillation	Anne Chest has been tested to ensure that it does not reduce defibrillation energy to the patient and will recover immediately after defibrillation.
Electric Shock Protection	Internally powered medical electric equipment

Operation Time (per full charge)	Up to 7 days (Standard Configuration)
Dimensions (L x W x H, cm)	6.87 cm x 3.49 cm x 0.99 cm
Weight (grams)	17.6 grams
Attachment Method	Anne Chest Adhesive, Standard Wear Anne Chest Adhesive, Extended Wear
NFC Communication	OOB pairing through NFC
Signals	**Single-Lead Biopotential AFE** Range: ±650 mV Sampling Rate: 256 Hz **Accelerometer** Range: ±8g Sampling Rate: 26 Hz **Thermometer** Range: 23°C - 43°C Sampling Rate: every 4 seconds
Heart Rate (beats/min)	30 - 270 bpm (the greater of ±10% or ±5bpm)
Respiratory Rate (breaths/min)	8 - 35 BRPM (±3 BRPM RMSE)
Fall Detection (per session)	90% sensitivity, 98% specificity
Body Position	Supine, Prone, Upright, Right Lateral, Left Lateral
Skin Temperature	73.4°F - 109.4°F (±0.54°F) 23°C - 43°C (±0.3°C)
Transient Temperature Increase Response Rate	1.5°F/min
Transient Temperature Decrease Response Rate	-3.5°F/min
Thermometer Mode of Operation	Direct Mode
HR Response Time	The response time for a change in HR for a step increase from 80 to 120 bpm is 13 seconds. The response time for a change in HR for a step decrease from 120 bpm to 80 bpm is 16 seconds.
HR Averaging	The heart rate value represents an inverse of the average of the 11 most recent beats.
Tall T-Wave Rejection	The device is capable of tall t-wave rejection up to amplitudes of up to 170% of the QRS amplitude.

ECG - Lead off current	5 nA
ECG - Noise Surpression	0.650V

Table 4: Anne Chest Adhesive specifications

	Anne Chest Adhesive, Standard Wear	**Anne Chest Adhesive, Extended Wear**
Dimensions (L x W, cm)	14.7 cm x 6.0 cm	13.0 cm x 5.7 cm
Material	Biocompatible acrylic adhesive	Biocompatible medical gel with nonwoven lip adhesive
Use Type	Single use disposable	Single use disposable
Shelf Life	2 years	2 years
Wear Time	Anne Chest Adhesive, Standard Wear may be worn for periods up to 7 days. The adhesive may be replaced with a new adhesive for longer monitoring periods. It is recommended that the healthcare provider evaluate the underlying skin integrity after 7 days of continuous use and determine whether continued use is warranted and safe.	Anne Chest Adhesive, Extended Wear may be worn for periods up to 7 days. Users should not use Anne Chest 7 Day Adhesive for periods less than 5 days. It is recommended that the healthcare provider evaluate the underlying skin integrity after 7 days of continuous use and determine whether continued use is warranted and safe.

Table 5: Anne Bedside Wireless Charger specifications

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

7.2 Electromagnetic Emissions Declaration

Anne Chest 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 6: Electromagnetic environment

Emission test	**Compliance**	**Electromagnetic environment**
RF emissions CISPR 11	Group 1	Anne Chest 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 Chest 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.

7.3 FCC compliance Notification (FCC ID: 2BCQV-12056)

Anne Chest 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.

Anne Chest complies with Part 15C of FCC Rules (FCC ID: 2BCQV-12056). 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.

7.4 Guidance and Declaration – Electromagnetic Immunity

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

Anne Chest is 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 7: Anne Chest 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment

	±1 kV for input/output lines	Not applicable	
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 the Anne Chest device 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	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 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 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870,930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870,930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	

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.

7.5 Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and Anne Chest

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

Anne Chest 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 Chest as recommended below, according to the maximum output power of the communications equipment.

Table 8: 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.

7.6 Communication Specifications

Table 9: Bluetooth

Bluetooth	
Bluetooth Compliance	Version 4.2, 5.0
Operating Frequency	2.4 to 2.4835 GHz
Output Power	TX: +8 dBM
Operating Range	100 ft 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 10: 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 11: Radio Compliance

Radio Compliance	
FCC ID	2BCQV-12056

7.7 Essential Performance

The following is the essential performance of Anne Chest

- Measure heart rate per specification
- Measure temperature per specification
- Measure respiration rate per specification

Use of Anne Chest in electromagnetic environments beyond those specified in this manual may result in a degradation or loss of essential performance