SIBEL

Anne Chest
INSTRUCTIONS FOR USE

support.sibelhealth.com

IFU P/N 443-00002I

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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.

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

- 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.

- Anne Chest is not intended to be used as an apnea monitor. Do not rely on the respiration monitoring to detect cessation of breathing.
- Use of accessories and cables other than those provided with or specified by the manufacturer 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.
- Do not use Anne Chest Adhesive, Standard Wear or Gentle Wear for durations longer than they are qualified, otherwise data loss resulting in delayed medical action could occur.
- Do not place the sensor in an undesignated location otherwise data loss or misattribution of data resulting in delayed medical action could occur.

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. Dispose of damaged devices in accordance with local regulations or return them to your authorized distributor.
- 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.
- 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.
- 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 gases. Do not use or charge if the sensors appear to be leaking, discolored, deformed, or in any way abnormal.
- The rechargeable lithium polymer battery is classified as hazardous waste. Do not dispose of batteries with household or unsorted municipal waste. At end of life, dispose of batteries in accordance with local regulations or return to your authorized distributor for proper recycling.
- Dispose of all non-consumable components in accordance with local regulations. Alternatively, components may be returned to your authorized distributor for recycling or proper disposal. Sibel Health's European distributors have been registered as a B2B (business-to-business) producer of Category 8 (Medical Equipment without implanted or infectious devices).
- 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 has no cardiac arrhythmia detection capabilities.

- Anne Chest does not provide alarms. Do not rely on the sensor as a standalone device in situations where alarms are required.
- Anne Chest sensors that are damaged in any way should not be used. Dispose of damaged sensors in accordance with local regulations or return them to your authorized distributor for proper disposal.

1.6 Glossary

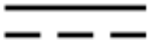
Table 1: Glossary

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

1.7 Symbols and Markings

Table 2: Symbols and markings

Symbol	Title	Description
	eIFU	Indicates the need for the user to consult the instructions for use or the electronic instructions for use.
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read
	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
IPN_1N_2	Ingress Protection	N1 0 Non-protected 1 Protected against solid foreign objects of 50 mm ⌀ and greater 2 Protected against solid foreign objects of 12.5 mm ⌀ and greater 3 Protected against solid foreign objects of 2.5 mm ⌀ and greater 4 Protected against solid foreign objects of 1.0 mm ⌀ and greater 5 Dust-protected 6 Dust-tight

		N2 0 Non-protected 1 Protection against vertically falling water drops 2 Protection against vertically falling water drops when enclosure tilted up to 15° 3 Protected against spraying water 4 Protected against splashing water 5 Protected against water jets 6 Protected against powerful water jets 7 Protected against the effects of temporary immersion in water 8 Protected against the effects of continuous immersion in water When a characteristic numeral is not required to be specified, it is replaced by the letter "X" ("XX" if both numerals are omitted).
	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
	WEEE Symbol	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	MD Symbol	Indicates the item is a medical device.
	Quantity Symbol	Indicates the number of units or pieces in the package.
	NFC Symbol	Indicate the sensor has the NFC feature.

	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
EC REP	Authorized representative in the European Union	Indicates the authorized representative in the European Union.
CE 2460	CE Mark	Indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.

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 software application with the one displayed on the system before use. Always confirm with the green LED confirmation process before use.

1.9 Manufacturer Information

- If a replacement is needed, contact your customer support representative.
- Contact your customer support representative 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, USA
Phone: (224) 251-8859
Website: www.sibelhealth.com

EC REP

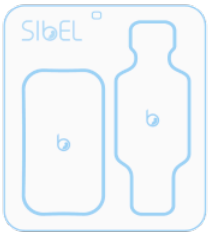
MDSS GmbH
Schiffgraben 41, Hannover 30175
Germany

Section 2. System Items

The system includes Anne Chest and the accessories listed below:

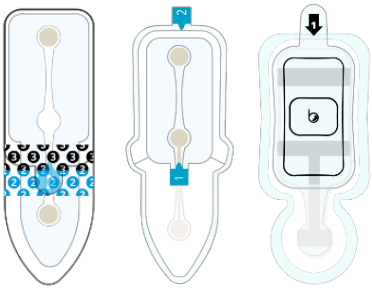
Anne Chest Sensor

Anne Bedside Wireless Charger



Wireless Charger Adapter

Anne Chest Adhesives

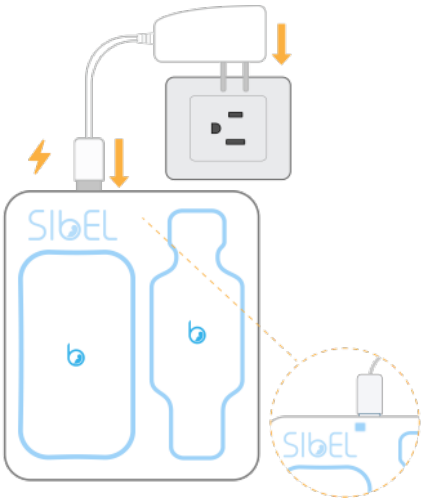


Note: Anne accessories are not sold in all countries. Contact your local sales representative for availability.

Section 3. Anne Chest System Setup

3.1 Setting up Anne Bedside Wireless Charger

Connect the Anne Bedside Wireless Charger to a power supply using the Wireless Charger Adapter. A blue LED light indicates that the charger power is on.



Note:

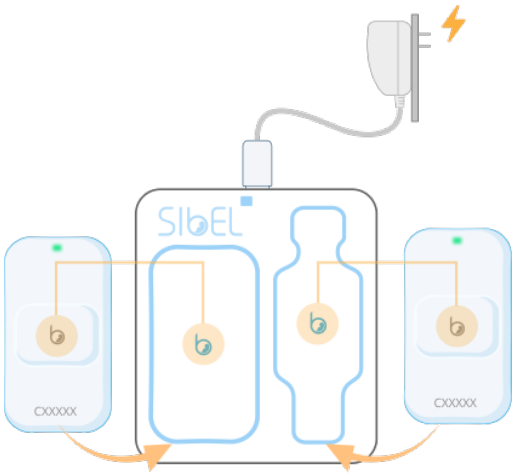
- Place the charger on a flat, stable surface.
- In clinical settings, the charger may be placed based on available space and unit workflow. Examples include the nurses' station or in patient rooms, including the patient bedside.
- In home settings, place the charger on a stable, accessible surface such as a nightstand or a table.

3.2 Setting Up Sensors

3.2.1 Activate the Sensors

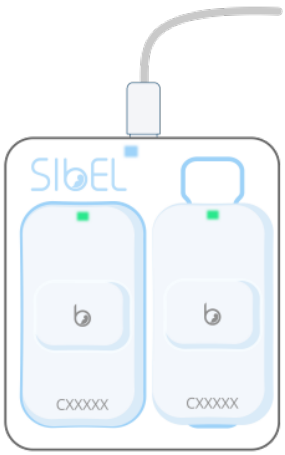
Step 1

Place the sensors on the Anne Bedside Wireless 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/red LED light on the sensors will show to indicate that the sensors are charging. The average duration for a full charge is 5 hours.



Note:

- The sensor's battery level can be monitored using a compatible software application.
- Charge the sensor to full before first use.

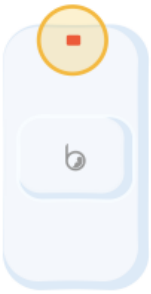
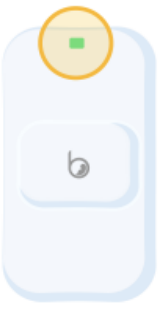
3.2.2 Pair the Sensor

Pair the sensor to the software application with Bluetooth or NFC.

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

3.3 Anne Chest LED Pattern Interpretation

Table 3: Anne Chest LED pattern

Color	Pattern	When	Status
No LED	N/A	On body	Normal operation
		On charger	Not charging
		Anytime	1. Not activated 2. Battery depleted 3. Sensor failure
Red 	Short blink (every 1 second)	After pairing	Lead-off
	Slow blink (every 3 seconds)	Anytime	Low battery
	Pulse (every 2.4 seconds)	On charger	Battery depleted, charging
	Solid	Anytime	Sensor failure
			Sensor end of life
Green 	Short blink (every 3 seconds)	Anytime	Ready to connect
	Blink	On charger	Charging
	Solid	On charger	Fully charged
	Solid	Pairing	Confirm sensor for pairing

Section 4. Anne Chest Application

4.1 Preparation

Step 1

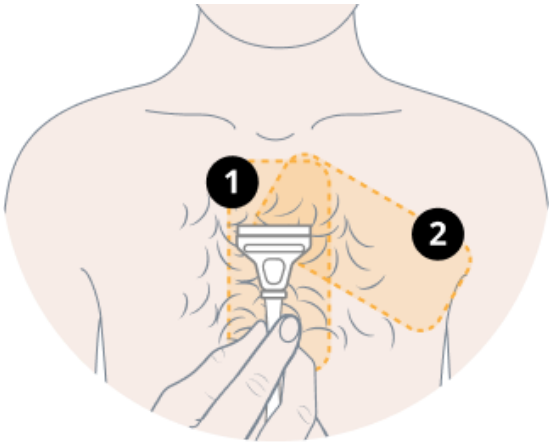
Before using the adhesive, check the expiration date on the box or pouch noted by the expiration icon ( ).
After taking out an adhesive, inspect it to ensure it is in good condition.

Step 2

Determine if the chest sensor will be applied to the **default**(①) or **alternative**(②) location. Prep the skin at the selected site, shaving any hair if necessary. Proper skin prep is critical for sensor adhesion and signal quality.

Note:

- Use Cavilon™ during skin preparation if needed. It is intended to serve as a protective film barrier to reduce skin reactions if irritation occurs. Follow Cavilon™ instructions when applying.
- Alternative(②) location has not been validated for use with ANNE View.

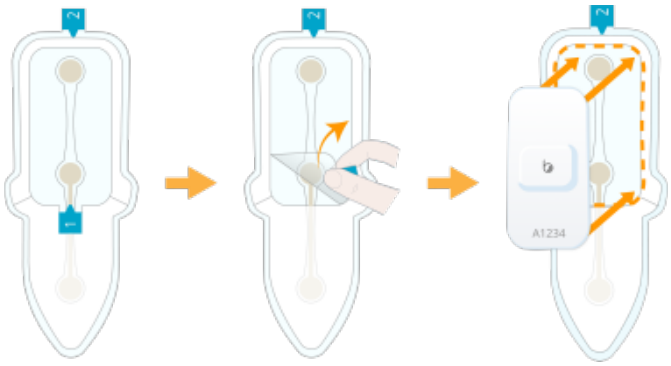


4.2 Apply the Adhesive and Sensor

4.2.1 Standard Wear Usage (Up to 7 Days)

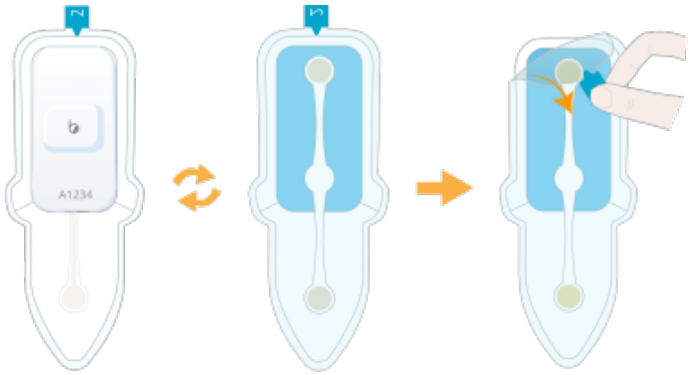
Step 1

Peel off the “1” liner. Orient the sensor so that the sensor ID is at the bottom. Place the sensor on the adhesive, then press down and rub the back to ensure proper adhesion.



Step 2

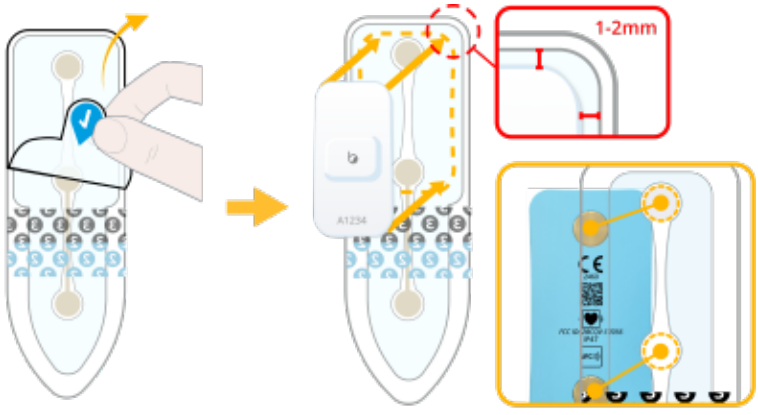
Flip the adhesive with the sensor and peel off the “2” liner.



4.2.2 Gentle Wear Usage (Up to 24 hours)

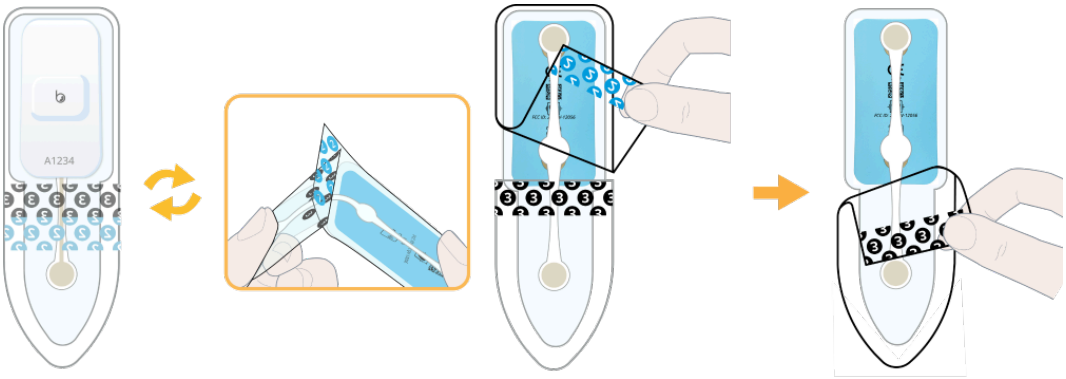
Step 1

Peel off the “1” liner. Orient the sensor so that the sensor ID is at the bottom. Place the sensor on the adhesive, then press down and rub the back to ensure proper adhesion between the sensor and adhesive.



Step 2

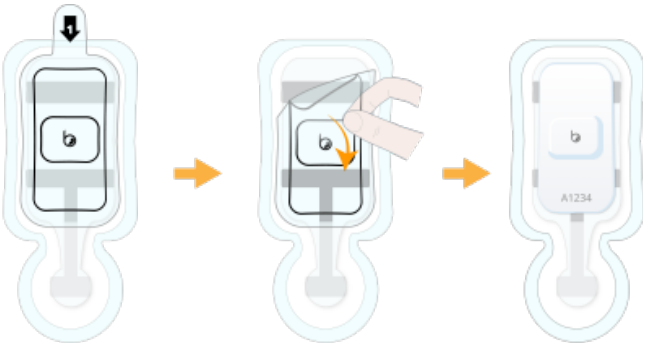
Flip the adhesive with the sensor and peel off the “2” and “3” liners.



4.2.3 Extended Wear Usage (5 Days or Longer)

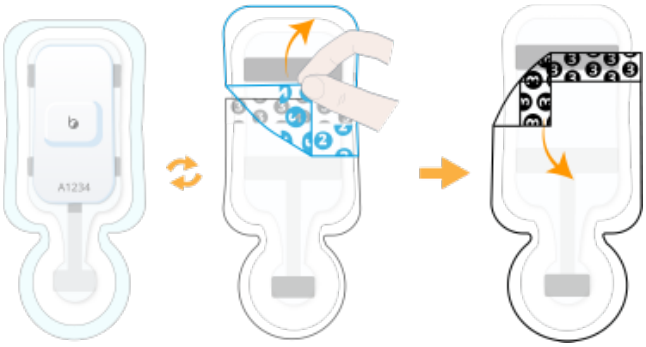
Step 1

Peel off the “1” 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. Press the sensor down firmly and evenly on the adhesive.



Step 2

Flip the adhesive with the sensor and peel off the “2” and “3” liner.



4.3 Apply to Chest

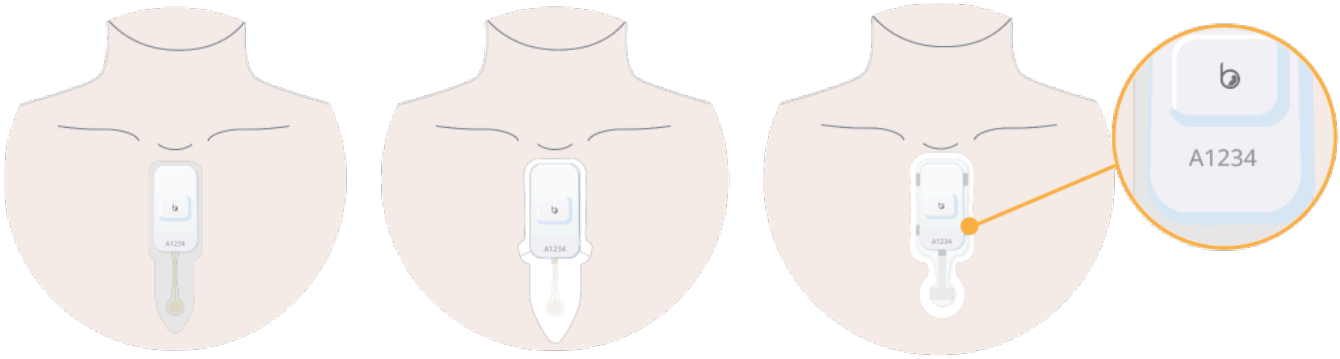
Note:

- 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.
- To ensure accurate chest sensor readings, firmly 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.

Step 1

Option 1: Default location

Place the top edge of the chest sensor below the suprasternal notch, centered on the body, with the logo and sensor ID facing front.

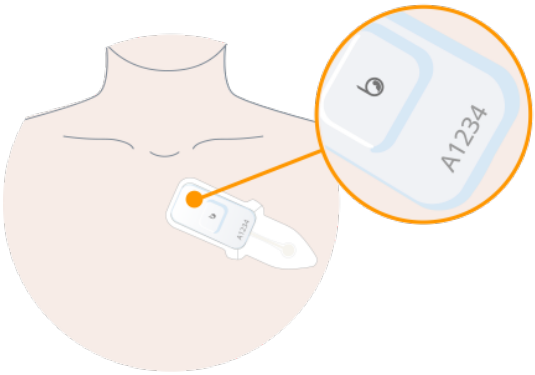


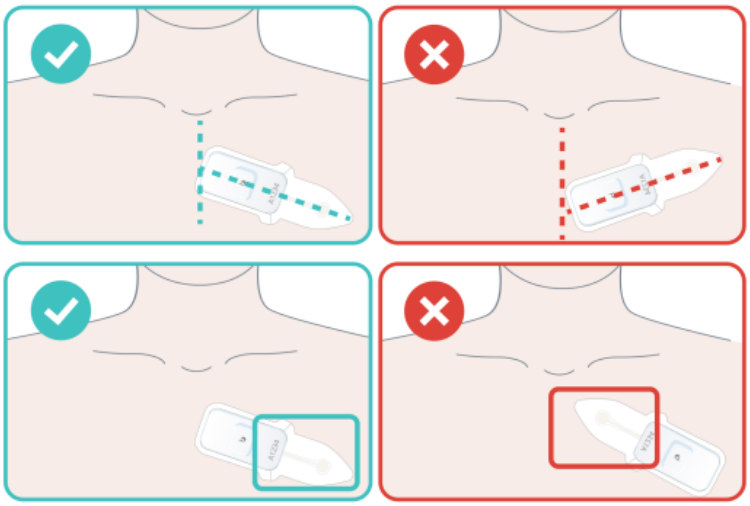
Gentle Wear Standard Wear Extended Wear

Default Location — All Adhesives

Option 2: Alternative location (Gentle Wear & Standard Wear adhesives)

Place the sensor 1-2 finger-widths below the left collarbone, with the tail of the adhesive pointed towards the left arm, slightly angled downwards.



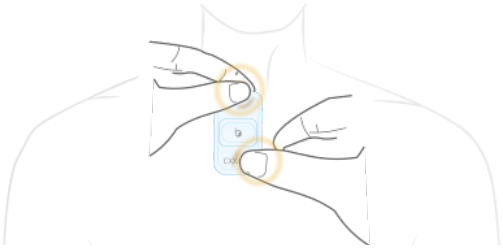


Alternative Location - Gentle Wear Adhesive, Standard Wear Adhesive

If using Standard Wear adhesive, slowly remove the white liners from the adhesive after it has been applied.

Step 2

Ensure good contact to the skin by pressing evenly across the entire sensor and adhesive.



Section 5. Troubleshooting

5.1 Anne Chest Lead-off

This section includes the resolution procedures for the following issues:

- Anne Chest lead-off
- Low/critical battery
- Sensor failure
- End of life
- No LED indication

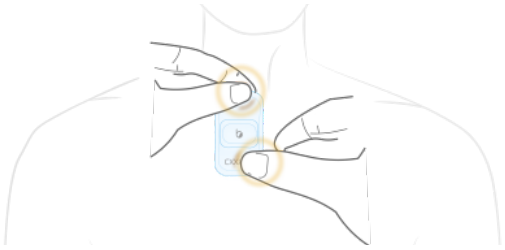
Note: When the system detects issues that may affect the quality of the data, the connected software application may temporarily halt transmitting the data. Resolving the error states as soon as possible will aid in restoring the data quality and allow you to resume the use of the system.

If Anne Chest is not detecting good skin contact, then a red LED light will be flashing on the sensor to indicate lead-off. The sensor will send a status via Bluetooth that there is a lead-off error.

Solution

Option 1

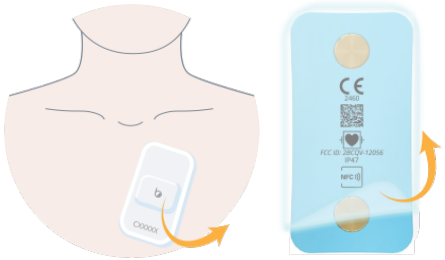
Readjust the sensor placement to ensure proper attachment. Verify that the electrodes are aligned with the adhesive and the sensor. Gently apply pressure over the electrodes on top of the sensor, and confirm the chest skin is properly prepared and in good condition.



Option 2

Replace the Anne Chest Adhesive.

1. Remove the sensor from the body. Remove the Anne Chest Adhesive. Dispose the used Anne Chest Adhesive.
2. Replace adhesive and apply following previous instructions per Section 4.2.



Option 3

Try to unpair and then re-pair the sensor.

Option 4

If none of the above options work, replace the sensor.

5.2 Low / Critical Battery

If the sensors have a low or critical battery, the red LED light blinks every 3 seconds to indicate low battery.

Charge the sensor as soon as possible.

5.3 Sensor Failure

A solid red LED light appears when Anne Chest reports a sensor failure. This indicates that the sensor is no longer transmitting data. Address the issue as soon as possible to restore data transmission.
Notify your support representative of the sensor failure.

5.4 End of Life

The sensor's life starts after the first use by connecting with the software application. End of Life indicates that the sensor has expired. This is not a sensor failure, but a normal expiration of the sensor's usage period.

If the sensor indicates end of life, the sensor cannot be used anymore. The service life of the sensor depends on various factors, including frequency of use, the method and duration of each use, as well as care and handling. Proper maintenance of the equipment is essential to achieve optimal performance over time. The expected service life of the Anne Chest sensor is 1 year. Any sensors that exceed the expected service life must be replaced.

5.5 No LED Indication

If the sensor shows no LED, its status depends on when it occurs.

- Anytime:
    - Not activated
    - Battery depleted
    - Sensor failure
- On body: Normal operation or above
- On charger: Not charging

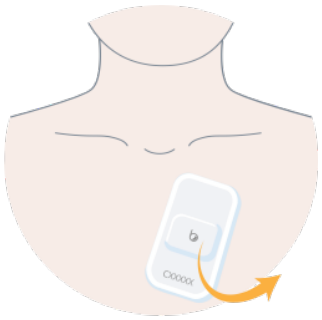
Solution

1. Check the software application to confirm if the sensor is connected.
2. If not connected, place the sensor on the charger and confirm the charger is powered.
3. Charge for 45–60 minutes. If there is still no LED indication, replace the sensor.

Section 6. Sensor Removal

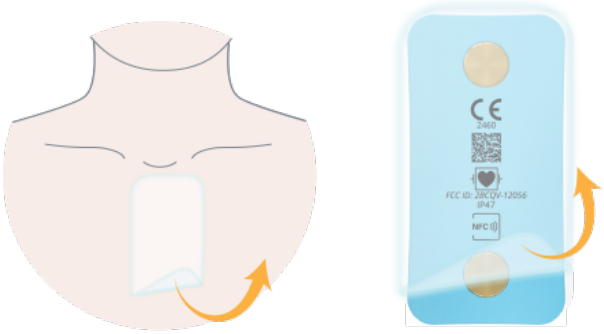
Step 1

Gently peel the sensor off the skin. Place the used sensor in a designated clean, dry location for cleaning prior to reuse. Follow your facility's cleaning protocol if applicable.



Step 2

Remove any adhesive left on the skin or sensor.



Step 3

Dispose of the adhesive as it is single use.

Note:

- The sensor is reusable. Do not discard sensors.
- Damaged sensors should not be reused.

Section 7. Cleaning and Disinfection

7.1 Cleaning and Disinfection Solution

The following procedures have been validated for the sensor and its components. Failure to perform every step of these instructions can lead to a risk of infection or cross-contamination.

Table 4: Validated reprocessing procedures

Component	Surface Disinfection with Cleaning	Description of Procedure
Anne Chest Sensor	Yes	See Section 7.2
Wireless Charger Pad	Yes	See Section 7.3

Anne Chest has been tested for material compatibility with the following solutions:

- CaviCide®
- Dismozon® plus
- Oxivir® Excel Wipes
- Super Sani-Cloth®
- Isopropyl Alcohol (70% solution)

The Wireless Charger Pad has been tested for material compatibility with the following solutions:

- CaviCide®
- Dismozon® plus
- Oxivir® Excel Wipes
- Super Sani-Cloth®
- Rely+On® Virkon
- Clorox™ Disinfecting Bleach (0.825% Sodium Hypochlorite solution)
- Isopropyl Alcohol (70% solution)
- Hydrogen Peroxide (0.5% solution)

Note:
- Avoid using chlorine-based or peroxide-based agents on the Anne Chest sensor as they may cause damage and can affect the sensor's performance.
- Follow the manufacturer's instructions when cleaning.

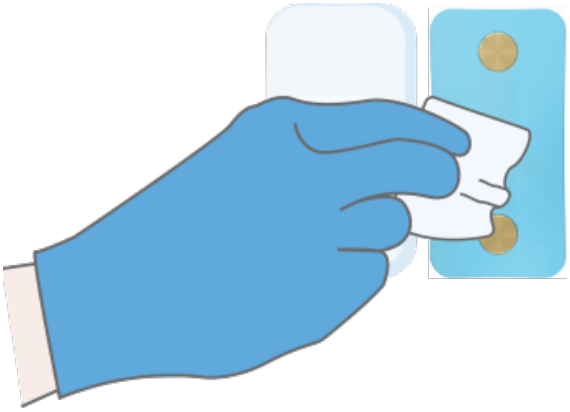
7.2 Sensor Cleaning and Disinfection Process

Prerequisites:
- Only validated cleaning and disinfection agents listed in Section 7.1 are used.

Surface Cleaning

Step 1

Thoroughly wipe the sensor with a validated cleaning solution to remove all visible soil. Additional wipes may be used as needed until the sensor is visibly clean.



Step 2

Allow the sensor to air dry for 2 minutes. Verify no soiling remains.

Surface Disinfection

Step 1

Using an appropriate cleaning solution, wipe the sensor until all visible soil is removed. Additional wipes may be used as needed until the sensor is visibly clean.

Step 2

Use a new wipe to wipe the sensor so it remains visibly wet for 2 minutes. Additional wipes may be used as needed to ensure the sensor remains visibly wet for 2 minutes.

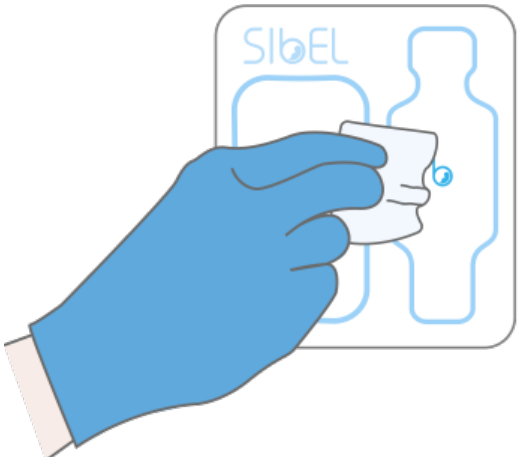
Step 3

Allow the sensor to air dry for 2 minutes. Verify the sensor is clean and dry.

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

7.3 Anne Bedside Wireless Charger Pad Cleaning

Before charging sensors, follow the surface cleaning process outlined above in Section 7.2 to clean the top of the Anne Bedside Wireless Charger.



Note: Ensure all contacts are thoroughly dry before use.

Section 8. Product Specifications

8.1 Anne Chest Technical Specifications

Table 5: Sensor specifications

	Anne Chest
Storage/Transit Environment Range	• Storage temperature range: -15°C to +45°C (5°F to 113°F) • Storage humidity range: 5 to 95% RH (non-condensing) • Storage atmospheric pressure range: 30 kPa to 120 kPa
Safe Operating Environment Range	• Operating temperature range: 10°C to 40°C (50°F to 104°F) • Operating relative humidity range: 5% to 95% (non-condensing) • Operating pressure range: 30 kPa to 120 kPa
Battery Type	Rechargeable lithium polymer battery Capacity: 70mAh
Charging Time (to full charge)	Up to 5 hours
Charging Method	Wireless charging using Anne Bedside Wireless Charger
Water Resistance	Sensors: IP47
Encapsulation Material	Low Durometer Silicone
Wireless Technology	Bluetooth® 5.1
Frequency Band	2402-2480 MHz
Maximum Connection Distance	Up to 100 ft (30.5m), line of sight
Use Type	The sensor is multiple patient reusable up to 1 year. 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.
Shelf Life	1 year
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 6 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, Gentle 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 *The ECG is a non-standard lead (e.g., I, II, III)
Heart Rate (beats/min)	30 - 270 bpm (the greater of ±10% or ±5 bpm)
Respiratory Rate (breaths/min)	8 - 35 brpm (±3 brpm RMSE)
Fall Detection (per session)	90% sensitivity, 98% specificity
Body Angle	Upright Body Angle Range: 0° to 180° Upright Body Angle Resolution: 1° Tilt Body Angle Range: -90° (left) to 90° (right) Tilt Body Angle Resolution: 1°
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 (0.8°C/min)
Transient Temperature Decrease Response Rate	-3.5°F/min (1.9°C/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 7 seconds. The response time for a change in HR for a step decrease from 80 bpm to 40 bpm is 15 seconds.
HR Averaging	The heart rate value represents an inverse of the trimmed mean of the 9 most recent R-R intervals.
Tall T-Wave Rejection	The device is capable of tall t-wave rejection up to amplitudes of up to 130% of the QRS amplitude.

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

Table 6: Anne Chest Adhesive specifications

	Anne Chest Adhesive, Standard Wear	**Anne Chest Adhesive, Gentle Wear**	**Anne Chest Adhesive, Extended Wear**
Dimensions (L x W, cm)	14.7 cm x 6.0 cm	13.9 cm x 4.5 cm	13.0 cm x 5.7 cm
Material	Biocompatible acrylic adhesive	Biocompatible silicone gel	Biocompatible medical gel with nonwoven lip adhesive
Use Type	Single use disposable	Single use disposable	Single use disposable
Shelf Life	2 years	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, Gentle Wear may be worn for periods up to 24 hours. 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 24 hours 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. 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.

Table 7: 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 *Power adapters provided may vary by country
Water Resistance	Wireless Charger: IP20 
Charging Frequency Band	13.56 MHz

8.2 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 8: 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.

8.3 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.

8.4 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 9: 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 ±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 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 $d = 2.3\sqrt{P}$ 800 MHz 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	Test levels: 3V 0.15-80 MHz	Test levels: 3V 0.15-80 MHz	Conducted disturbances induced by RF fields should be at levels characteristic of a typical location in a typical

induced by RF fields	6 V ISM bands between 0.15 MHz to 80 MHz	6 V ISM bands between 0.15 MHz to 80 MHz	professional healthcare facility environment or domestic establishment.
Proximity Fields from RF wireless communications	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870,930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870,930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	Proximity fields from RF wireless communications should be at levels characteristic of a typical professional healthcare facility environment or domestic establishment

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.

8.5 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 10: 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.

Note:

- 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.

8.6 Communication Specifications

Table 11: Bluetooth

Bluetooth	
Bluetooth Compliance	Version 4.2, 5.0
Operating Frequency	2.4 to 2.4835 GHz
Output Power	TX: +8 dBM
Operating Range	Up to 100 ft (30.5m), line of sight
Network Topology	Point-to-Point
Operation	Peripheral
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 12: Security

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

Table 13: Radio compliance

Radio Compliance	
FCC ID	2BCQV-12056

8.7 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.