SIbEL

Anne Limb
INSTRUCTIONS FOR USE



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Section 1. Important Safety Information

1.1 Device Description

Anne Limb is a wearable, bio-integrated sensor that collects real-time biosignals including photoplethysmography (PPG) and temperature. Anne Limb has on-device processing of raw data for the calculation of SpO2 and pulse rate. 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 Limb is a pulse oximeter intended for continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature. Anne Limb communicates with compatible software applications for the display, storage, and analysis of data. The device is indicated for use 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

- Anne Limb is not intended for use as a stand-alone diagnostic monitor or as a replacement for standard-of-care patient monitoring practices. While the data may be applicable for use as an aid to diagnosis and treatment, Anne Limb does not provide diagnostic or interpretive statements to either the patient or the clinician.
- Anne Limb is not intended for use on critical care patients and is not a remote diagnostic device.
- Anne Limb is not intended for use on patients with known allergies or hypersensitivities to silicone or adhesives.

1.4 Warnings

- Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Anne Limb 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 sensor and avoid exposing the sensor to liquids for prolonged periods of time such as when bathing or showering.
- Anne Limb is not MRI safe and should be removed prior to an MRI scan.
- Anne Limb is not defibrillator proof and should be removed prior to external defibrillation or cardioversion.
- Anne Limb should not be used in the presence of strong electromagnetic fields such as high frequency surgical equipment.
- Anne Limb communicates with compatible software applications for the display, storage, and analysis of data. The responsible organization or operator must verify the compatibility of the monitor or patient injury can result.

- Use of accessories or materials not described in the instructions for use could be unsafe.
- Avoid securing Anne Limb too tightly on the finger. Misapplication of the sensor with excessive pressure for prolonged periods can induce pressure injury.

1.5 Precautions

- Anne Limb 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 or 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.
- 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 sensors or tablet to excessive heat or fire. Do not crush, puncture, or incinerate as doing so can result in fire, explosion, or the release of toxic gasses. Do not use or charge if the sensors appear to be leaking, discolored, deformed, or in any way abnormal.
- For US customers: 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.
- Do not attempt to disassemble, repair, or modify the devices.
- In case of emergency, unplug the wireless charger from the wall.
- It is recommended that healthcare providers evaluate the underlying skin integrity after 5 days of continuous use and determine whether continued use is warranted and safe.
- Nail polish and artificial nails should be removed prior to use of Anne Limb.
- Anne Limb does not provide alarms. Do not rely on the sensor as a standalone device in situations where alarms are required.
- A functional tester cannot be used to assess the accuracy of the oximeter or sensor.

1.6 Glossary

Table 1: Glossary

Abbreviation	Definition
AFE	Analog Front End
BPM	Beats Per Minute
ID	Identifier

IP	Ingress Protection
IR	Infrared
LED	Light-emitting diode
ME	Medical Equipment
MRI	Magnetic Resonance Imaging
NFC	Near Field Communication
PI	Perfusion Index
PLETH, PPG	Photoplethysmogram
PR	Pulse Rate
RF	Radio Frequency
RH	Relative Humidity
SpO2	Oxygen Saturation

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 BF Applied Part	Type BF Applied Part
	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 date when 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
	Quantity Symbol	Indicates the number of units or pieces in the package.
	NFC Symbol	Indicates 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.

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.

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 Manufacturer Information

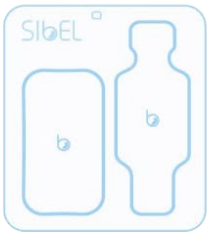
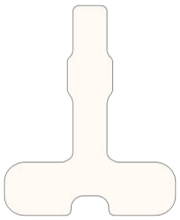
- If a replacement is needed, contact your customer support representative.
- Contact your customer support representative for any of the following issues:
    - Assistance in setting up, using, or maintaining Anne Limb
    - To report unexpected operation or events



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

Section 2. System Items

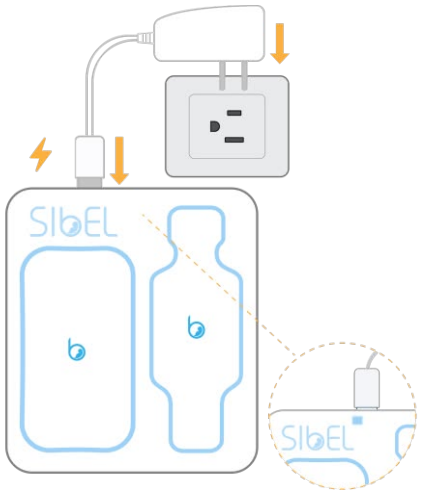
The system includes Anne Limb and the accessories listed below:

Anne Limb Sensor	Anne Bedside Wireless Charger	Wireless Charger Adapter	Anne Limb Adhesive
			

Section 3. Anne Limb 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:

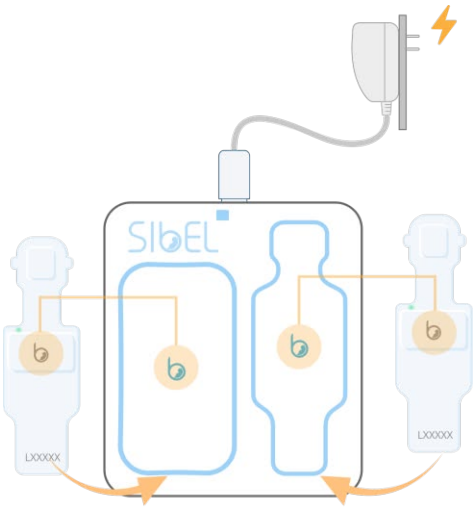
- Place the charger on a flat, stable surface.
- In clinical settings, the charger may be placed based on available space and unit workflow. Examples include the nurses' station or in patient rooms, including the patient bedside.
- In home settings, place the charger on a stable, accessible surface such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

3.2 Setting up Sensors

3.2.1 Activate the Sensors

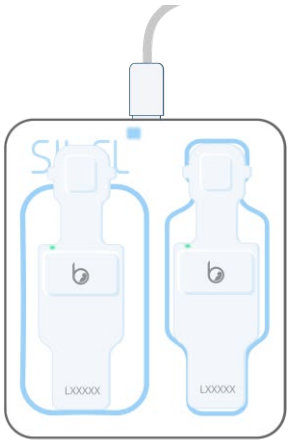
Step 1

Place the sensors on the Anne 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/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 host application.
- Charge the sensor to full before first use.

3.2.2 Pair the Sensor

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



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

3.3 Anne Limb LED Pattern Interpretation

Table 3: Anne Limb 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	Poor skin contact
	Slow blinks (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 Limb Application

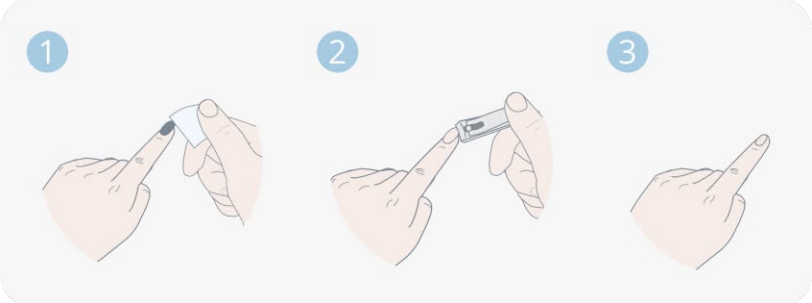
4.1 Preparation

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

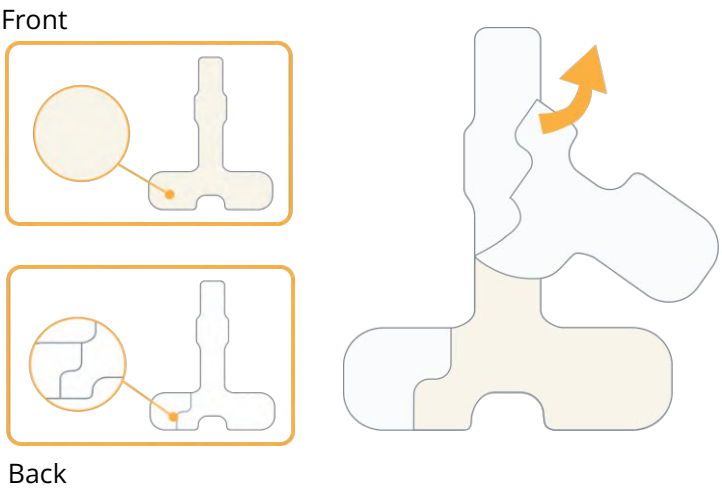
Before wearing the limb sensor, trim fingernails and remove any nail polish with your personal nail polish remover.



4.2 Apply the Adhesive and Sensor to the Index Finger

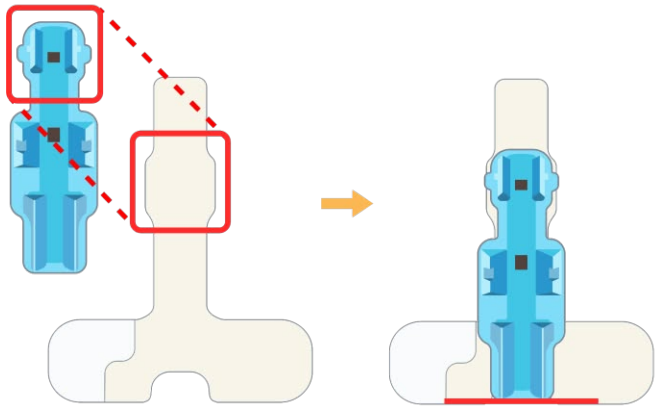
Step 1

Identify the backside of the Anne Limb Adhesive that shows the cut lines of the liner segments. Peel off the right side liner.



Step 2

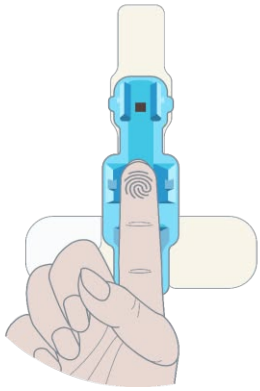
Place the limb sensor on the adhesive in the correct position, ensuring the sensor is centered between the side tabs and aligned with the bottom adhesive edge.



Step 3

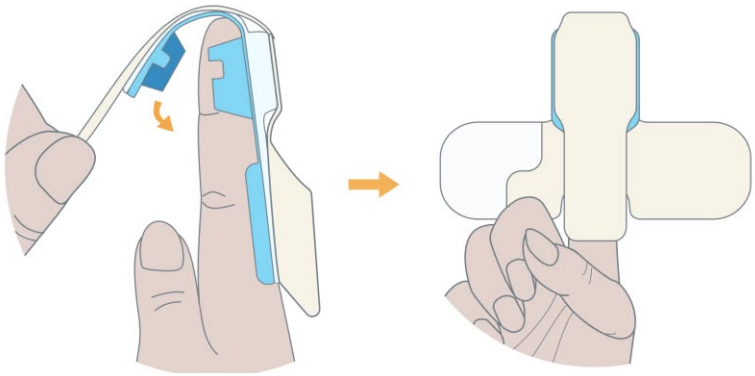
Then place the fingertip on the bottom square window.

Note: Fingernail should face down.



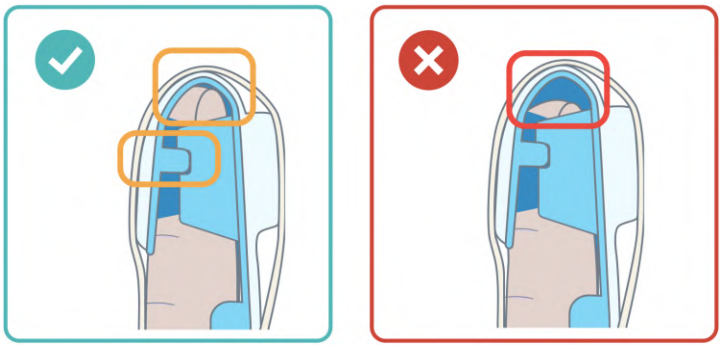
Step 4

Fold the top of the sensor and adhesive over the fingertip. Check the side view of the finger to confirm the notch and bump are aligned.



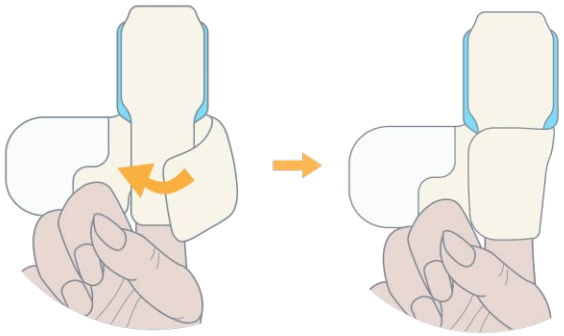
Note:

Avoid any air gap between the fingertip and the folded portion of the sensor.



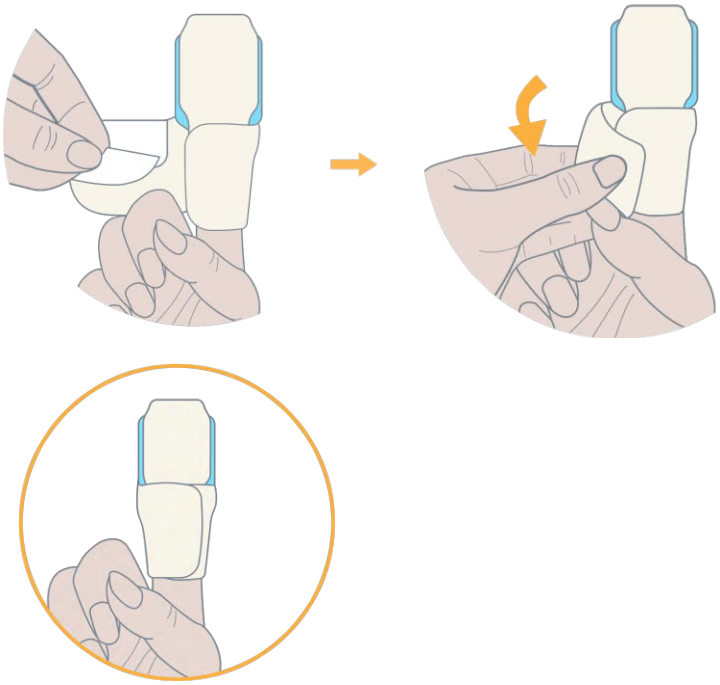
Step 5

Wrap the side adhesive tab firmly around the finger to secure the top portion of the sensor.



Step 6

Peel off the left liner from the adhesive tab and wrap it around the finger.



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.
- If foreign matter sticks to the adhesive prior to use, discard it and apply a new one.

Section 5. Troubleshooting

This section includes the resolution procedures for the following issues:

- Anne Limb poor skin contact
- 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 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.

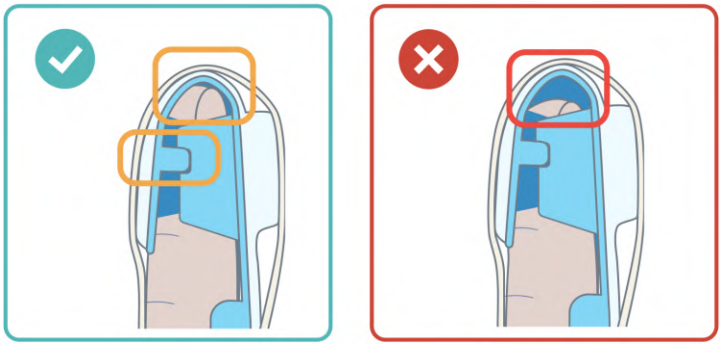
5.1 Anne Limb Poor Skin Contact

If Anne Limb is not detecting good skin contact, then a red LED light will be flashing on the sensor to indicate poor skin contact. The sensor will send a status via Bluetooth that there is a poor skin contact error, and will stop sending the PLETH waveform, SpO2, PI, PR, and Skin Temperature data while this status is occurring.

Solution

Option 1

Readjust the sensor placement to ensure that it is properly attached. Check that the notch and bump on the side of the limb sensor are aligned. Avoid any air gap between the fingertip and the folded portion of the sensor.



Option 2

Replace the Anne Limb Adhesive.

1. Unwrap the Anne Limb Adhesive from the sensor, remove the Limb Sensor from the finger, and discard the used Anne Limb Adhesive.
2. Replace adhesive and apply following previous instruction per Section 4.2.

Option 3

Try to un-pair and then re-pair the sensor.

Option 4

Try placing the sensor on a different finger (index, middle, or ring finger) to ensure optimal blood flow and fit.

Option 5

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

5.2 Low / Critical Battery

If the sensors have a low 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 Limb 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 device's usage period.

If the sensor indicates end of Life, the sensor cannot be used anymore.

5.5 No LED Indication

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

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

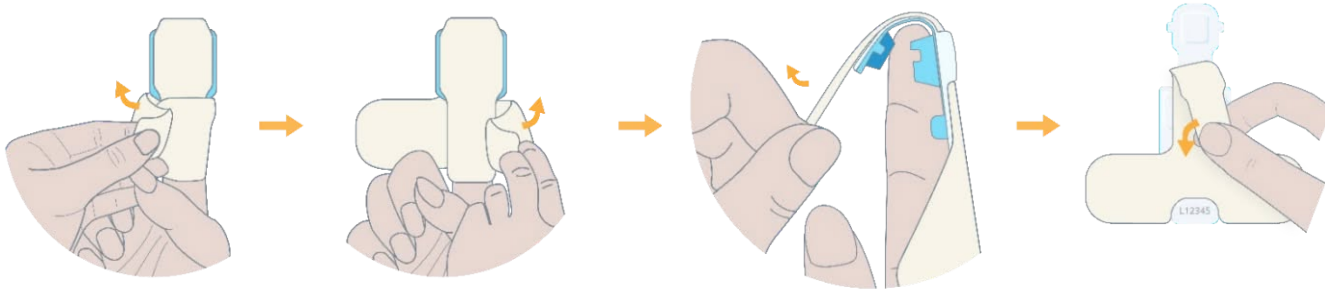
Solution

1. Check the software application to confirm 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, replace the sensor.

Section 6. Sensor Removal

Step 1

Unwrap the adhesive.



Step 2

Gently remove Anne Limb from the finger.

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 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 Limb Sensor	Yes	See Section 7.2
Wireless Charger Pad	Yes	See Section 7.3

Anne Limb and the Wireless Charger Pad has been tested for material compatibility with the following solutions:

Cleaning

- CaviCide®
- Dismozon® plus
- Oxivir® Excel Wipes
- Super Sani-Cloth®
- Rely+On® Virkon
- Isopropyl Alcohol (70% solution)
- Hydrogen Peroxide (0.5% solution)

Disinfection

- Clorox™ Disinfecting Bleach (0.825% Sodium Hypochlorite solution)

Note:
- Follow the cleaning agents' instructions when cleaning.

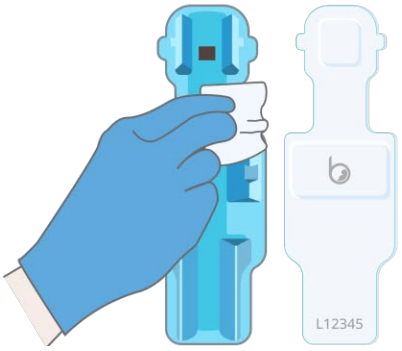
7.2 Sensor Cleaning and Disinfection Process

Prerequisites:
- Only validated cleaning and disinfection agents listed in Section 7.1 are used.
- Anne Limb must be cleaned before it is disinfected; do not disinfect a device that has not been cleaned.
- The disinfectant solution is defined as a 10% bleach (~8.25% sodium hypochlorite) to 90% water solution. The final solution should be .825% sodium hypochlorite. Do not use undiluted (~8.25% sodium hypochlorite) as permanent damage to the device may occur.

Surface Cleaning

Step 1

Using the appropriate cleaning solution, wipe the device to remove all visible soil. Additional wipes may be used as needed until the device is visibly clean.



Step 2

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

Note:

- Anne Limb may be used on new patients after both cleaning and disinfection processes are complete.

Surface Disinfection

Step 1

Place the sensor in the disinfectant solution, such that the sensor is completely immersed. If observed, dislodge air bubbles by gently shaking the sensor.

Step 2

Soak the sensor for 10 minutes.

Step 3

Remove from the disinfectant solution.

Step 4

Place the sensor in room temperature sterile or distilled water for 10 minutes.

Step 5

Remove from the water.

Step 6

Dry the sensor by wiping all surfaces with a clean, dry gauze pad.

Step 7

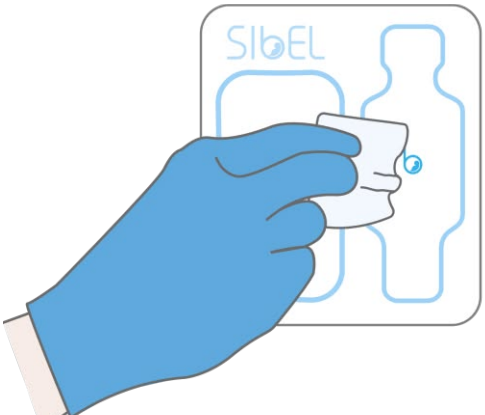
Allow the sensor to air dry for a minimum of 2 minutes.

Step 8

Verify that there is no soiling visible on the device.

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. Ensure all contacts are thoroughly dry before use.



Section 8. Product Specifications

8.1 Anne Limb Technical Specifications

Table 5: Sensor specifications

	Anne Limb
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 We recommend handling any patient contacting system components with gloves.
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: 30kPa to 120 kPa
Battery Type	Rechargeable lithium polymer battery Capacity: 60mAh
Charging Time (to full charge)	Less than 5 hours
Charging Method	Wireless charging using Anne Bedside Wireless Charger
Water Resistance	Sensors: IP44
Encapsulation Material	Low Durometer Silicone
Wireless Technology	Bluetooth® 5.1
Frequency Band	2402-2480 MHz
Maximum Connection Distance	100 ft (30.5m)
Electric Shock Protection	Internally powered medical electrical equipment
Use Type	The sensor is reusable up to 250 uses. It is recommended that the healthcare provider evaluate the underlying skin integrity after 5 days of continuous use and determine whether continued use is warranted and safe. The healthcare provider may also consider moving the sensor to another finger at this time.
Shelf Life	1 year
Operation Time (per full charge)	Up to 36 hours
Dimensions (L x W x H, cm)	9.99 cm x 3.33 cm x 2.03 cm
Weight (grams)	18.2 grams
Attachment Method	Anne Limb Adhesive

NFC Communication	OOB pairing through NFC
Signals	Pulse Oximeter AFE Sampling Rate: 84 Hz Thermometer Range: 23°C - 43°C Sampling Rate: every 4 seconds
Pulse Rate (beats/min)	30-300 bpm (±3 bpm RMSE)
Functional Oxygen Saturation (SpO2) (%)	70-100% (± 3% ARMS)
Perfusion Index (%)	0.1 - 20% Note: SpO2 and PR will be displayed when PI > 0.3%
Peak Wavelengths	Red LED: 660 ±10nm IR LED: 940 ±20nm
Maximum Optical Output Power	Red LED: ~10.3mW ±15% IR LED: ~12.7mW ±15%
Skin Temperature	73.4°F - 109.4°F (±0.54°F) 23°C - 43°C (±0.3°C)
Average Transient Temperature Increase Response Rate	1.4°F/min (0.9°C/min)
Average Transient Temperature Decrease Response Rate	-2.6°F/min (-1.4°C/min)
Thermometer Mode of Operation	Direct Mode
Displayed SpO2	SpO2 is exponentially averaged weighted over the last 2.5 seconds when all of the last 10 measurements are deemed “good quality” and over the last 5 seconds when any of the last 10 measurements are deemed "bad quality". SpO2 is updated each measurement (pulse) if the current and previous 2 measurements are deemed "good quality", otherwise the previous SpO2 value is maintained. SpO2 is blanked if an update has not been made for 30 seconds.
Averaged SpO2	SpO2 rolling averages are calculated over 15-minute, 30-minute, and 60-minute intervals.
Displayed PR	PR is exponentially averaged with a weight of 0.25 if the current and previous 2 measurements are deemed "good quality", otherwise the previous PR value is maintained. PR is blanked if an update has not been made for 30 seconds.

Table 6: Anne Limb Adhesive specifications

	Anne Limb Adhesive
Dimensions (L x W, cm)	13.0 cm x 10.0 cm
Material	Biocompatible medical foam adhesive
Use Type	Single use disposable
Shelf Life	2 years

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
Water Resistance	Wireless Charger: IP20 
Charging Frequency Band	13.56 MHz

8.2 Electromagnetic Emissions Declaration

Anne Limb 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 Limb 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 Limb 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 Limb 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). 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 Limb 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 Limb 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Anne Limb device than the recommended

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted disturbances induced by RF fields	Test levels: 3V 0.15-80 MHz 6 V ISM bands between 0.15 MHz to 80 MHz	Test levels: 3V 0.15-80 MHz 6 V ISM bands between 0.15 MHz to 80 MHz	Conducted disturbances induced by RF fields should be at levels characteristic of a typical location in a typical professional healthcare facility environment or domestic establishment.
Proximity Fields from RF wireless communications	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m	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	Proximity fields from RF wireless communications should be at levels characteristic of a typical professional healthcare facility environment or domestic establishment

	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	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.

8.5 Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and Anne Limb

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

Anne Limb 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 Limb 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.

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.

8.6 Pulse Oximeter Accuracy and Test Methods

Anne Limb collects photoplethysmography (PPG) data from the patient for the calculation of SpO2 and pulse rate. When the sensor is placed correctly on the finger, light from a red LED and IR LED are emitted through the finger, and the transmitted light is captured on the other side of the finger with a photodiode. The ratio of red light to IR light transmitted through the finger is then converted to SpO2, which is an estimate of the blood oxygen saturation. SpO2 is exponentially averaged weighted over the last 2.5 seconds when all of the last 10 measurements are deemed “good quality” and over the last 5 seconds when any of the last 10 measurements are deemed "bad quality". Anne Limb is calibrated to display functional oxygen saturation. A clinical desaturation study was conducted at Vital Signs Research Group, San Francisco, CA to evaluate the accuracy of Anne Limb in 14 healthy adult subjects over a range of oxyhemoglobin saturation from 70-100%.

8.6.1 SpO2 Accuracy - Overall

The average root mean square error (ARMS) of SpO2 values with Anne Limb is estimated to be 2.30% (95% CI: -4.22% to 4.83%) for the range of 70-100%. This ARMS value compares the pulse oximeter SpO2 value to arterial blood gas saturation and is typically within 2 to 3% for recently FDA-cleared pulse oximeters.

However, real-world accuracy may differ from accuracy in the lab setting. While reported accuracy is an average of all patients in the test sample, there are individual variations among patients, and the SpO_2 reading should always be considered an estimate of oxygen saturation. Performance of the device may be impacted by the physiological characteristics of the patients, particularly characteristics relating to the skin, as well as how the device was applied. For some subjects, the presence of certain chronic medical conditions, acute disease states, and device setup may also degrade performance. The following conditions may impact the performance of pulse oximeters:

- Conditions such as hypothermia, low cardiac output, increased systemic vascular resistance, profound anemia, etc.
- Arrhythmias or presence of pacemakers
- Carbon dioxide poisoning or other conditions causing high levels of dyshemoglobins (high Hb, CO), low hematocrit level, or elevated levels of bilirubin
- Skin temperature and skin pigmentation
- Excessive ambient light conditions

Overall, these factors are known limitations of pulse oximetry and do not raise safety and performance concerns regarding the accuracy of this device.

The plot below is the Bland-Altman plot for Anne Limb compared to reference SaO_2. Mean bias is represented by the solid horizontal line. 95% limits of agreement are shown by dashed horizontal lines.

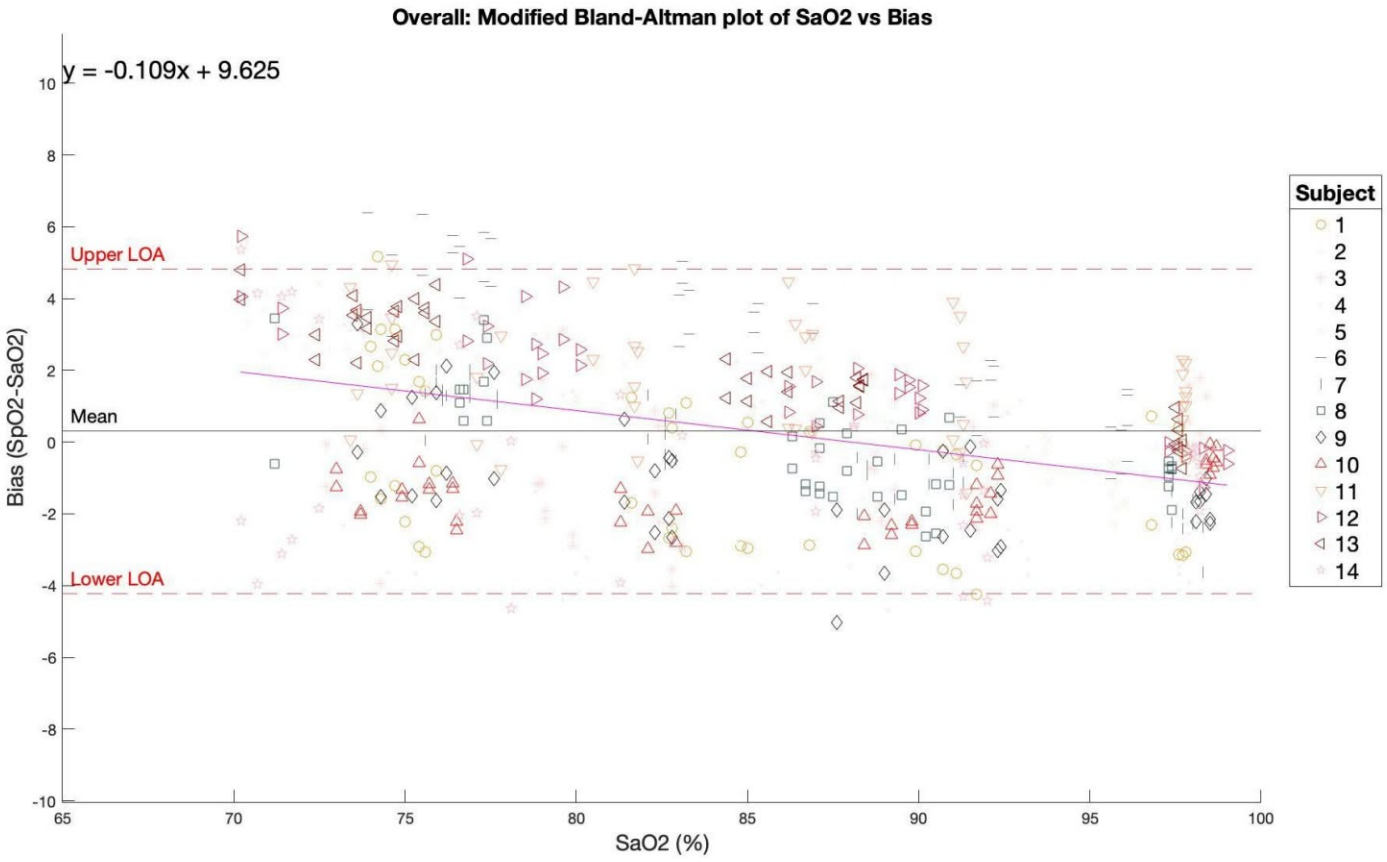


Table 11: Overall accuracy of Anne Limb SpO2 measurements to reference CO-Oximetry

Overall accuracy of Anne Limb SpO2 measurements to reference CO-Oximetry (14 subjects)				
SaO2 Range (%)	**70-100 (Overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	602	204	200	198
Mean Bias	0.31%	1.52%	0.09%	-0.72%
Arms	2.30%	2.91%	2.11%	1.67%

The pulse oximeter accuracy was tested in fourteen healthy subjects, aged 21-43, with skin tones varying from Monk 2-9. Five subjects had dark skin pigmentation with Monk 8 - 10. The following tables show the bias and accuracy among gender and skin pigmentation subgroups.

Table 12: Anne Limb accuracy for dark skin pigmentation

Anne Limb accuracy for dark skin pigmentation (5 subjects, Monk 8 - 10)				
SaO2 Range (%)	**70-100 (Overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	224	82	80	62
Mean Bias	0.83%	2.30%	0.44%	-0.64%
Arms	2.7%	3.47%	2.37%	1.80%

Table 13: Oximeter accuracy by gender

Anne Limb accuracy by gender (7 female subjects, 7 male subjects)		
	Female	**Male**
# of data pairs	184	97
Mean Bias	-0.46%	0.71%
Arms	2.38%	2.19%

8.6.2 SpO2 Accuracy - Motion

To obtain motion data, subjects during each stable plateau were guided in performing intermittent motions based on tapping (raising the 3 central fingers approximately 1 inch) and rubbing (moving the sensors along the surface from left to right and back again). The participant performed a tap, waited several seconds (2-3s), and performed a rub, wait several seconds (2-3s). The procedure was repeated through the 2nd, 3rd, and 4th data points of each plateau.

The average root mean square error (ARMS) of SpO2 values with Anne Limb is estimated to be 2.17% (95% CI: -3.88% to 4.68%) for the range of 70-100%. This ARMS value compares the pulse oximeter SpO2 value to arterial blood gas saturation and is typically within 2 to 3% for recently FDA-cleared pulse oximeters.

The plot below is the Bland-Altman plot for Anne Limb under motion conditions compared to reference SaO2. Mean bias is represented by the solid horizontal line. 95% limits of agreement are shown by dashed horizontal lines.

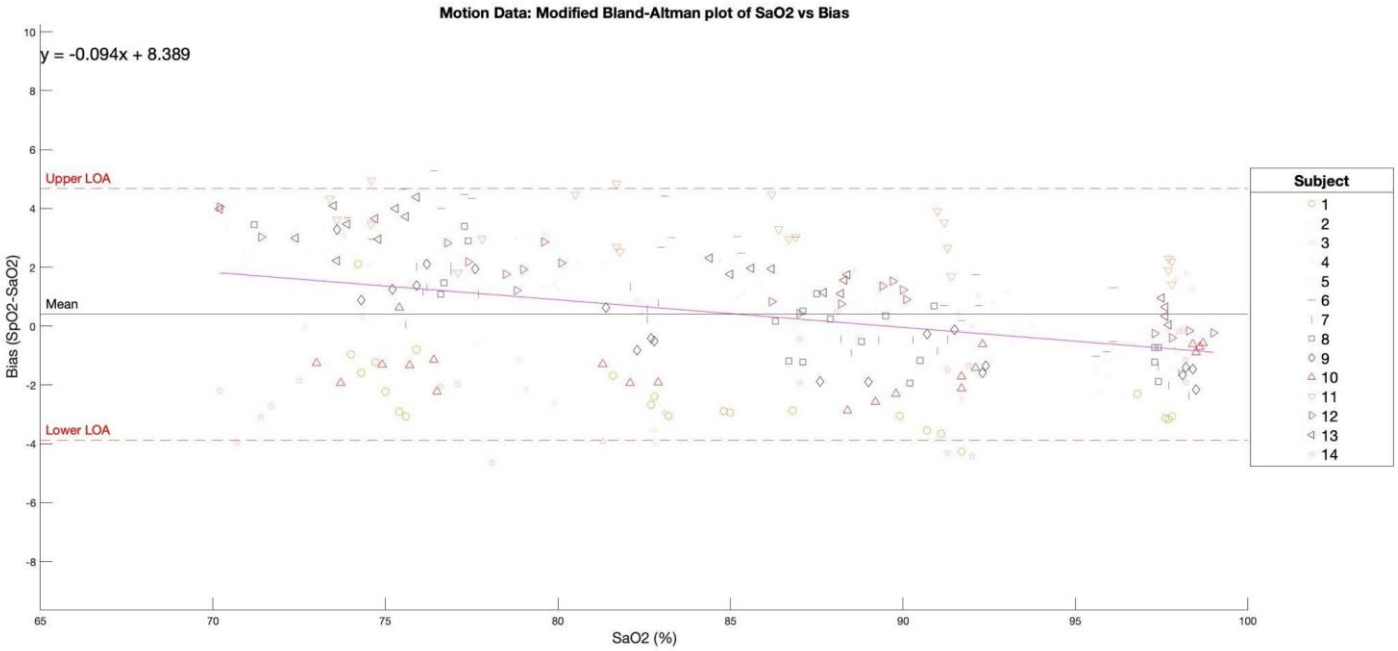


Table 14: Accuracy of Anne Limb SpO2 measurements to reference CO-Oximetry, motion

Accuracy of Anne Limb SpO2 measurements to reference CO-Oximetry, Motion (14 subjects)				
SaO2 Range (%)	**70-100 (Overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	301	102	100	99
Mean Bias	0.40%	1.39%	0.36%	-0.58%
Arms	2.17%	2.67%	2.03%	1.69%

8.6.3 SpO2 Accuracy - Low Perfusion

To obtain low perfusion data, a bench test was conducted using an SpO2 simulator/Pulse Oximeter tester. The perfusion index was set to 0.3% and data points in the SpO2 range were measured (70% - 100%). The SpO2 values measured by the Anne Limb Sensor at each test point met the accuracy requirement of 3 % Arms demonstrating the sensor's accuracy under low perfusion conditions.

Additionally, 31 samples (12 during motion, 19 during non-motion) across the range of 70%-100% SaO2 from subject 11 in the hypoxia study had low perfusion (PI <1%). The performance over these samples yields an overall Arms of 2.34% with a mean bias of 1.99%.

8.6.4 Pulse Rate Accuracy

To obtain low perfusion data, a bench test was conducted using an SpO2 simulator/Pulse Oximeter tester. The perfusion index was set to 0.3% and data points in the PR range were measured (30bpm - 300bpm). The PR values

measured by the Anne Limb Sensor at each test point met the accuracy requirement of ± 3bpm demonstrating the sensor's accuracy under low perfusion and normal conditions.

For pulse rate accuracy during motion, PPG data measured by the Anne Limb sensor from the motion portions of the clinical desaturation study was analyzed. The analysis compared the PR computed by Anne Limb to PR derived by reference pulse oximeters. Anne Limb maintained ± 3bpm PR accuracy under motion conditions.

8.7 Communication Specifications

Table 15: 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 16: 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 17: Radio compliance

Radio Compliance	
FCC ID	2BCQV-12056

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