

Surveillance Monitoring System



keeping an eye on life

Sotera
WIRELESS

ViSi Mobile® is a comprehensive surveillance monitoring system, designed to enhance patient safety, allowing early detection of patient deterioration and connecting clinicians with their patients anywhere, any time.

ViSi Mobile System Technical Specifications



Refer to the ViSi Mobile User Documentation [REF: 95-10134]

for Indications for Use, Contraindications, Warnings, Precautions, Description, Set-up, and Operation.






PATIENT-WORN DEVICES		SPECIFICATIONS						
<p>ViSi MOBILE MONITOR</p>  <p>[REF 92-10010]</p>	<p><i>Dimensions</i> 2.6 cm H x 4.9 cm W x 9.4 cm L 1.0 in H x 1.9 in W x 3.7 in L</p> <p><i>Monitor / Display</i> OLED, 160 x 128 pixels, full color, capacitive touch screen</p> <p><i>Waveforms</i> One waveform, user selectable (ECG, Pleth, Resp)</p> <p><i>Battery</i> Battery Type Li-Ion, 3.7 V., 2000 mAh, single cell Operating Time 12-24 hours (depending on use profile) Charge Time Less than 4 hours</p> <p><i>Liquid Ingress Rating: IPX7</i> <i>Cleaning Agent: Mild soap or detergent</i> <i>Disinfecting Agent: Super Sani-Cloth®</i></p>	<p><i>Weight</i> 110 g 3.9 oz</p> <p><i>Audio: Alarm annunciation (72dBA), QRS beep, Self-Test</i></p> <p>Wireless Connectivity <i>Network Standard: IEEE 802.11b/g/n</i> <i>Frequency: 2.412GHz – 2.462GHz</i> <i>Traffic generated (one Monitor): < 30 KBps (Numerics, Events, Waveforms)</i> <i>Wireless Network Security Support: WPA2-PSK AES</i> <i>Network Protocol: TCP/IP</i> <i>Power Output: 802.11b < 15.8 dBm(38.3 mW)</i> <i>802.11g < 12.9 dBm(14.5 mW)</i> <i>802.11n < 11.8 dBm(15.1 mW)</i></p>						
<p>ViSi MOBILE CUFF MODULE BLOOD PRESSURE</p>  <p>[REF 92-10011]</p>	<p><i>Dimensions</i> 3.1 cm H x 4.9 cm W x 12.2 cm L 1.2 in H x 1.9 in W x 4.8 in L</p> <p><i>Display</i> Eight LEDs: Six Green, One Yellow, One Red LEDs in array showing charge levels of onboard battery</p> <p><i>Battery</i> Battery Type Li-Ion, 3.7 V., 2000 mAh, single cell > 30 cuff inflations Charge Time Less than 4 hours</p> <p><i>Cleaning Agent: Mild soap or detergent</i> <i>Disinfecting Agent: Super Sani-Cloth®</i></p>	<p><i>Weight</i> 157 g 5.5 oz</p> <p><i>Audio</i> None</p>						
<p>ViSi MOBILE CHEST SENSOR RESPIRATION HEART RATE SKIN TEMPERATURE</p>  <p>3 Lead Wire Cable AAMI [REF 93-10014 & 93-10015] IEC [REF 93-10018 & 93-10019] 5 Lead Wire Cable AAMI [REF 93-10012 & 93-10013] IEC [REF 93-10016 & 93-10017]</p>	<p><i>Dimensions</i> 152.4 cm L 60.0 in L</p> <p><i>Liquid Ingress Rating: IPX7</i> <i>Cleaning Agent: Mild soap or detergent</i> <i>Disinfecting Agent: Super Sani-Cloth®</i></p>	<p><i>Weight</i></p> <table border="0"> <tr> <td><u>5-LEAD-WIRE</u></td> <td><u>3-LEAD WIRE</u></td> </tr> <tr> <td>72 g</td> <td>62 g</td> </tr> <tr> <td>2.5 oz</td> <td>2.2 oz</td> </tr> </table>	<u>5-LEAD-WIRE</u>	<u>3-LEAD WIRE</u>	72 g	62 g	2.5 oz	2.2 oz
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<p>ViSi MOBILE THUMB SENSOR SPO₂ PULSE RATE</p>  <p>[REF 92-10020]</p>	<p><i>Dimensions</i> 22.5 cm L 8.9 in L</p> <p><i>Liquid Ingress Rating: IPX7</i> <i>Cleaning Agent: Mild soap or detergent</i> <i>Disinfecting Agent: Super Sani-Cloth®</i></p>	<p><i>Weight</i> 8 g 0.3 oz</p>						

10020 Huennekens Street, Street, San Diego, California 92121, USA, +1 (858) 427-4620

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ACCESSORIES

SPECIFICATIONS

<p>ViSi MOBILE BATTERY CHARGER 8 POSITION</p>  <p>[REF 92-10023]</p>	<p>Charges up to eight ViSi Mobile Monitors / Cuff Modules</p> <p><i>Dimensions</i> 7.6 cm H x 6.0 cm W x 47.0 cm L 3.0 in H x 2.4 in. W x 18.5 in L <i>(exclusive of power supply & cable)</i></p> <p><i>Power Input: AC Adapter, Input: 100-240V, 50-60Hz</i></p> <p><i>Liquid Ingress Rating: IPX0</i></p>	<p><i>Weight</i> 670 g 1lb 7 oz <i>(exclusive of power supply & cable)</i></p>																								
<p>ViSi MOBILE BATTERY CHARGER 2 POSITION</p>  <p>[REF 92-10022]</p>	<p>Charges up to two ViSi Mobile Monitors / Cuff Modules</p> <p><i>Dimensions</i> 7.6 cm H x 6.0 cm W x 12.7 cm L 3.0 in H x 2.4 in W x 5.0 in L <i>(exclusive of power supply & cable)</i></p> <p><i>Power Input: AC Adapter, Input: 100-240V 50-60Hz</i></p> <p><i>Liquid Ingress Rating: IPX0</i></p>	<p><i>Weight</i> 240 g 8.3 oz <i>(exclusive of power supply & cable)</i></p>																								
<p>ViSi MOBILE POWER PACK & CRADLE</p>  <p>[REF 92-10083 & 92-10084]</p>	<p><i>Dimensions</i> 3.1 cm H x 4.9 cm W x 12.2 cm L 1.2 in H x 1.9 in W x 4.8 in L</p> <p><i>Display</i> Eight LEDs: Six Green, One Yellow, One Red LEDs in array showing charge levels of onboard battery</p> <p><i>Battery</i> Battery Type 2 each Li-Ion, 3.7 V., 2000 mAh, single cell > 30 cuff inflations Charge Time Less than 6 hours</p> <p><i>Cleaning Agent: Mild soap or detergent</i> <i>Disinfecting Agent: Super Sani-Cloth®</i></p>	<p><i>Weight</i> 157 g 5.5 oz</p> <p><i>Audio</i> None</p>																								
<p>MODE PLUGS</p> 	<p>Plug into ViSi Mobile Monitor to: Turn device off completely: <i>Shipping Plug [REF: 99-10025]</i> Secure Monitor into Wrist Cradle when not using Thumb Sensor, e.g. monitoring ECG only: <i>Locking Plug [REF 99-10026]</i></p>																									
<p>ViSi MOBILE PATIENT DISPOSABLES</p> 	<p>All disposable components are needed to set-up one individual patient, interchangeable left or right arm. Available in both starter kits and bulk.</p> <p><i>Disposable Components</i> Wrist Cradle incl. strap – holds ViSi Mobile Monitor on patient’s wrist</p> <p>Thumb Cradle – holds ViSi Mobile Thumb Sensor on patient’s thumb</p> <p>Welch Allyn Flexiport™ Disposable Blood Pressure Cuff – with ViSi Mobile Cuff Module adaptor</p> <p>Cable Securement packet – secures Chest Sensor modules to patient (chest and upper arm)</p> <p>Five (5) Pre-Packaged 3M Disposable ECG Electrodes</p>	<p><i>Sizing: Relevant to the BP Cuff and Wrist Cradle strap. All other components are one-size-fits-all.</i></p> <p><i>Wrist Strap Sizes - Wrist Circumference Ranges</i></p> <table border="1" data-bbox="1019 1402 1490 1541"> <tr> <td>Small</td> <td>4 ½-6 in.</td> <td>11.4-15.2 cm</td> </tr> <tr> <td>Medium</td> <td>5-7 in.</td> <td>12.7-17.8 cm</td> </tr> <tr> <td>Large</td> <td>6-10 in.</td> <td>15.2-25.4 cm</td> </tr> </table> <p><i>Blood Pressure Cuffs Sizes - Arm Circumference Ranges (follows Welch Allyn FlexiPort™ cuff sizing)</i></p> <table border="1" data-bbox="1019 1646 1490 1873"> <tr> <td>Small (10)</td> <td>7.9-10.2 in.</td> <td>20-26 cm</td> </tr> <tr> <td>Medium (11)</td> <td>9.8-13.4 in.</td> <td>25-34 cm</td> </tr> <tr> <td>Medium+ (11L)</td> <td>9.8-13.4 in.</td> <td>25-34 cm</td> </tr> <tr> <td>Large (12)</td> <td>12.6-16.9 in.</td> <td>32-43 cm</td> </tr> <tr> <td>Large+ (12L)</td> <td>12.6-16.9 in.</td> <td>32-43 cm</td> </tr> </table>	Small	4 ½-6 in.	11.4-15.2 cm	Medium	5-7 in.	12.7-17.8 cm	Large	6-10 in.	15.2-25.4 cm	Small (10)	7.9-10.2 in.	20-26 cm	Medium (11)	9.8-13.4 in.	25-34 cm	Medium+ (11L)	9.8-13.4 in.	25-34 cm	Large (12)	12.6-16.9 in.	32-43 cm	Large+ (12L)	12.6-16.9 in.	32-43 cm
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VITAL SIGNS MEASUREMENTS		SPECIFICATIONS		
ECG HEART RATE	<p><i>Display Range:</i> 0, 18 - 240 BPM</p> <p><i>Resolution:</i> 1 BPM</p> <p><i>Pacemaker:</i> Detects and rejects pacemaker impulses in accordance with ANSI/AAMI IEC60601-2-27:2011</p> <ul style="list-style-type: none"> - Displays pacer markers on ECG waveforms <p><i>Sampling:</i> 500Hz sampling, 19bit resolution</p> <p><i>Defibrillation Response / Protection</i></p> <ul style="list-style-type: none"> - Displays an ECG waveform < 10 seconds after a defibrillation event - Displays HR measurement < 30 seconds after a defibrillation event 	<p><i>Accuracy Range:</i> 30 to 240 BPM</p> <p><i>Accuracy:</i> 3BPM \pm3% of reading</p> <p><i>Heart Rate Averaging:</i> 20 second moving average</p> <p><i>Factory default alarm threshold:</i> High 200 BPM / Low 30 BPM</p>		
	RESPIRATION	<p><i>Method:</i> Impedance Pneumography</p> <p><i>Display Range:</i> 0 to 50 BR/MIN</p> <p><i>Resolution:</i> 1 BR/MIN</p>	<p><i>Accuracy Range:</i> 3 to 50 BR/MIN</p> <p><i>Accuracy:</i> \pm3 BR/MIN or 10% of reading, whichever is greater</p> <p><i>Factory default alarm threshold:</i> High 40 / Low 4</p>	
PULSE OXIMETRY (SpO₂, PULSE RATE)	<p><i>SpO₂</i></p> <p><i>Display Range:</i> 49 to 100%</p> <p><i>Accuracy Range:</i> 70 to 100%</p> <p><i>Accuracy (no motion):</i> \leq 2% from 70-100% / unspecified from 49-69%</p> <p><i>Resolution:</i> 1%</p> <p><i>Averaging:</i> Adaptive 60 second moving average</p> <p><i>Factory default alarm threshold:</i> Low 85%</p>	<p><i>Pulse Rate (from Oximetry)</i></p> <p><i>Display Range:</i> 0 to 240 BPM</p> <p><i>Accuracy Range:</i> 30 to 240 BPM</p> <p><i>Accuracy:</i> \pm 3 BPM; < 50 BPM @ \geq 0.6% Pulsatile Modulation / \geq 50 BPM @ \geq 0.4% Pulsatile Modulation</p> <p><i>Resolution:</i> 1BPM</p> <p><i>Averaging:</i> Adaptive 60 second moving average</p> <p><i>Factory default alarm threshold:</i> High 200 / Low 30</p>		
	NON-INVASIVE BLOOD PRESSURE (NIBP)	<p><i>NIBP</i></p> <p><i>Method:</i> Oscillometry</p> <p><i>Accuracy & Display Range:</i> 60 to 240 mmHg/8 to 32 kPa (SYS), 40 to 160 mmHg/5.3 to 21.3 kPa (DIA), 50 to 185 mmHg/6.7 to 24.7 (MAP)</p> <p><i>Accuracy:</i> Mean error of less than \pm 5 mmHg/.67 kPa and a standard deviation of \leq 8 mmHg/1.7 kPa</p> <p><i>Resolution:</i> 1 mmHg/.13 kPa</p> <p><i>Mode of Operation</i></p> <p>Manual mode – Single NIBP, max. 3 tries</p> <p>Automatic mode – NIBP taken automatically every 5, 10, 15, 30, 60, 90 or 120 minutes.</p>	<p><i>Pulse Rate (from Oscillometry)</i></p> <p><i>Display Range:</i> 0 to 240 BPM</p> <p><i>Accuracy Range:</i> 30 to 240 BPM</p> <p><i>Accuracy:</i> \pm 3 BPM</p> <p><i>Resolution:</i> 1BPM</p>	
CONTINUOUS NON-INVASIVE BLOOD PRESSURE (cNIBP)	<p><i>cNIBP</i></p> <p><i>Method:</i> Based on Pulse Arrival Time</p> <p><i>Accuracy & Display Range:</i> 60 to 240 mmHg/8 to 32 kPa (SYS), 40 to 160 mmHg/5.3 to 21.3 kPa (DIA), 50 to 185 mmHg/6.7 to 24.7 kPa (MAP)</p> <p><i>Accuracy:</i> Mean error of less than \pm 5 mmHg/.67 kPa and a standard deviation of \leq 8 mmHg/1.7 kPa</p> <p><i>Resolution:</i> 1 mmHg/ .13 kPa</p> <p><i>Averaging:</i> 60 seconds</p> <p><i>Mode of Operation:</i> Initial calibration required with ViSi Mobile Cuff Module</p>			
SKIN TEMPERATURE (at 102 kPa / 768 mmHg atmospheric pressure)	<p>^oCentigrade</p> <p><i>Accuracy Range</i></p> <p>0.0^o - 19.9^o</p> <p>20.0^o - 24.9^o</p> <p>25.0^o - 35.9^o</p> <p>36.0^o - 39.9^o</p> <p>40.0^o - 41.9^o</p> <p>42.0^o - 50.0^o</p> <p><i>Resolution:</i> \pm 0.1^o</p>		<p>^oFahrenheit</p> <p><i>Accuracy Range</i></p> <p>32.0^o - 67.9^o</p> <p>68.0^o - 76.9^o</p> <p>77.0^o - 96.7^o</p> <p>96.8^o - 103.9^o</p> <p>104.0^o - 107.5^o</p> <p>107.6^o - 122.0^o</p> <p><i>Resolution:</i> \pm 0.1^o</p>	
		<p><i>Accuracy</i></p> <p>\pm0.3^o</p> <p>\pm0.3^o</p> <p>\pm0.2^o</p> <p>\pm0.1^o</p> <p>\pm0.2^o</p> <p>\pm0.3^o</p>		<p><i>Accuracy</i></p> <p>\pm0.5^o</p> <p>\pm0.5^o</p> <p>\pm0.3^o</p> <p>\pm0.2^o</p> <p>\pm0.3^o</p> <p>\pm0.5^o</p>

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Transient Response: < 6 min (25.0° – 37.0°)

Transient Response: < 6 min (77.0° - 98.6°)

SYSTEM COMPONENTS [ALL SYSTEM COMPONENTS ARE PROVIDED, IMPLEMENTED AND CONFIGURED BY SOTERA WIRELESS]

APPLIANCE

Standard Server Configuration

Single 1u, redundant hardware and internal RAID 10, dedicated hardware
Processor: Single Intel Xeon 5620, 2.4 GHz, (or equivalent CPU), 8GB memory
Storage: Server contains (4) 500GB 7200 RPM Hard drives in RAID 10 array
Operating System

SUSE Linux Enterprise Server 11 Service Pack 3

Network Requirements

Static IP address or DHCP reservation required
Remote Access (SecureLink) – requires port 22 outbound
Unicast or Multicast configuration

Dimensions (single appliance, may vary):

4.3 cm H x 43.4 cm W x 62.7 L cm (w/o ear, w/o bezel)
1.7 in H x 17.1 in W x 24.7 L

Weight (single appliance): 35.0 lbs (15.9 kg)

[Maximum configuration weight]

Power Requirements (single appliance): w/Redundant Power supply 100-240 VAC, 50-60 Hz, 7A-3.5A

Backup Power Requirement (full system): Customer supplied Uninterruptable Power Supply required, Hospital Emergency Power recommended

**** This configuration is only recommended for systems 64 or fewer VIsi Mobile Monitors and up to 6 Remote Viewing Displays*

Recommended

Desktop PC - Touchscreen Display

All-in-One configuration

Patients per Remote Viewer: Max. 32

Display: 23-inch display, 1920x1080 resolution (screen is touch sensitive to issue commands alternative to mouse / keyboard)

Processor

Intel(R) Core(TM) i5-4460S Processor (6M Cache, up to 3.40 GHz)

Storage

One 500GB 7200RPM SATA

Operating System:

Windows 7 Professional x64 Bit

Network Requirements: Ethernet Connection, DHCP

Dimensions:

45.0 cm H x 58.5 cm W x 10.3 cm D
17.7 in H x 23.0 in W x 4.1 in D

Weight: 26.7 lb (12.1 kg)

Power Requirements: AC/DC Adapter, Input: 100-240V~3.5A, 50-60Hz, Output to Viewer: 19.5V/ 11.8A

Backup Power Requirement: Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended

REMOTE VIEWER (STATIONARY)

CUSTOMER NETWORK [NETWORK TO BE IMPLEMENTED AND MANAGED BY END USER IN ACCORDANCE WITH IEC 80001-1]

Wireless Network
Wireless Network Standard: IEEE 802.11b/g/n
Wireless Network Security Support: WPA2-PSK
Minimum Cell Coverage: -65dBm (edge coverage)
Output Transmit Power: AP output TX power 12 to 14 dBm
Wireless access point cell overlap: 15-20%
Signal-to-Noise Ratio: ≥ 25 db
IP Addressing: DHCP
SSID: Dedicated or shared with other medical devices

AGENCY COMPLIANCE

ANSI/AAMI:
EC13, Cardiac monitors, heart rate meters, and alarms
EC53, ECG cables and lead wires.
ISO:
80601-2-61:2011 (1st Edition) Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
81060-2, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

IEC:
60601-1(3rd Edition), Medical electrical equipment - Part 1: General requirements for safety+A11(2006) + AM1:2013
60601-1-2, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: EMC–Req. and tests.
60601-1-8, Medical electrical equipment – Part 1-8: General requirements – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
60601-2-27, Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.
60601-2-49, Particular requirements for the safety of multifunction patient monitoring equipment.
80601-2-30, Medical electrical equipment – Part 2-30: particular requirements for the safety, including essential performance, of auto-cycling NIBP monitoring equipment.
60601-1-6:2010 (3rd Edition) Part 1-6: General requirements for safety – Collateral standard: Usability including IEC 62366: Application of usability engineering medical devices
IEC 62471: Photobiological safety of lamps and lamp systems

RESEARCH AND EVALUATION SYSTEMS *[Customer Network does not apply]*

RESEARCH SYSTEM HARDWARE

Display:
1024x768 resolution

Processor:
Intel Core i5-3340M; 2.6GHz with Turbo Boost up to 3.3GHz, Intel® Smart Cache 3MB. 8GB RAM

Storage:
500GB HDD 7200 rpm running a 64 bit GNU/Linux distribution.

Operating System:
Linux

Wireless communication:
Intel® Centrino® Advanced-N 6235 802.11a/b/g/n.

Dimensions:
21.6 cm L x 27.2cm W x 4.8cm H (8.5 in L x 10.7 in W x 1.9 in H)

Weight:
5.1lbs (2.3 kg)

Power Supply
Lithium ion battery pack (10.65V, typical 5700mAh, minimum 5400mAh)
AC Adapter: AC 100V-240V 50/60Hz, auto sensing/switching worldwide power supply

Appliance

Processor
3.2GHz quad-core AMD Trinity Processor or equivalent ; 8Gb RAM

Storage
512 GB SSD running Windows 7 Pro 64 bits

Operating System:
Windows 8.1 Professional x64

Dimensions:
10.8 cm L x 9.29cm W x 9.29 cm H (4.27 in L x 3.656 in W x 3.656 in H)

Weight:
1.5 lb (0.68 kg)

Power Supply:
AC 100-240V 50/60Hz 1.5A max

EVALUATION SYSTEM HARDWARE

Viewer

Display:
23-inch, 1920x1080 (Full HD)

Dimensions:
60.0 cm W x 6.9 cm L x 40.90 cm H (23.60 in W x 2.70 in L x 16.10 in H)

Weights:
14.3 lb (6.5 kg)

Power Supply:
AC 100V-240V 50/60Hz

Uninterrupted Power Supply

Output Power Capacity:
330 Watts / 550 VA

Nominal Input/Output Voltage:
120V

Dimensions:
180cm W x 302cm D x 88cm H (70.9 in W x 118.9 in D x 34.7 in H)

Weight:
12.1 lbs (5.5 kg)

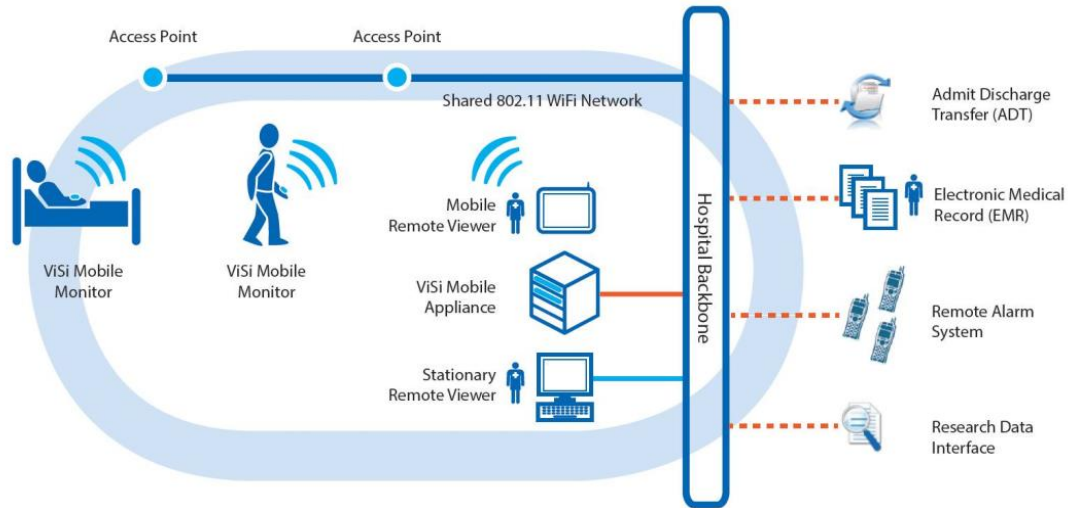
Access Point

Dimensions:
22.1cm W x 22.1 cm L x 4.7 cm H (8.7 in W x 8.7 in L x 1.84 in H)

Weights:
1.9 lbs (0.86 kg)

ViSi MOBILE SYSTEM ARCHITECTURE

(Interface to ADT, EMR or Remote Alarming not available for Research or Evaluation System)



The ViSi Mobile System has received CE mark and is currently FDA cleared for continuous monitoring of ECG, Heart/Pulse Rate, SpO₂, Blood Pressure (cuff-based and cuffless on a beat-to-beat basis), Respiration Rate, Skin Temperature and Posture/Activity.

For questions please call +1 (866) 232-6126 (from US) or +1 (858) 373-4870 (from intl.),
email Support@SoteraWireless.com or visit www.SoteraWireless.com



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