Chest Sensor

Instructions For Use

Model CS2050

Vios Medical, Inc.

Vios Monitoring System

1 Introduction

Revision History

The cover page of this document has the revision letter at the bottom of the page. The revision letter identifies the document's level of revision. The revision history of this document is summarized below.

Revision	Description
A	Initial release.

Package Contents

- One (1) Chest Sensor
- One (1) Chest Sensor Instructions For Use

Vios Monitoring System Description

The Vios Monitoring System includes:

- **Chest Sensor:** A plastic encased, Bluetooth-enabled reusable sensor. The Chest Sensor is used in conjunction with the Adapter and BSM to monitor heart rate, respiratory rate, pulse rate, SpO_2, and patient posture.
- **Adapter:** A plastic encased, reusable adapter with four (4) patient ECG cables and a one (1) pulse oximetry cable. The Adapter is used in conjunction with the Chest Sensor and BSM to monitor heart rate, respiratory rate, pulse rate, SpO_2, and patient posture. The following Adapters may be used with the Chest Sensor:

Model: L2050F Adapter (Finger Pulse Oximetry)

Model: L2050E Adapter (Ear Pulse Oximetry)

Pulse Oximetry:
- Measurement Site: Finger
- Pulse Oximetry Cable Max Length: 36.75 inches

ECG:
- 7-Lead
- RA Cables Max Length: 9.05 inches
- LL Cable Max Length: 11.78 inches
- V Cable Max Length: 14.78 inches

Pulse Oximetry:
- Measurement Site: Ear
- Pulse Oximetry Cable Max Length: 22.5 inches

ECG:
- 7-Lead
- RA Cables Max Length: 9.05 inches
- LL Cable Max Length: 11.78 inches
- V Cable Max Length: 14.78 inches

- **Bedside Monitor (BSM) Software:** Analyzes and displays vitals data from one or more compatible sensors. May operate in stand-alone mode or communicate analyzed data across standard networking protocols.
- **Central Station Monitor (CSM) Software:** Simultaneously displays analyzed data from the Bedside Monitor software for multiple patients.
- **Central Station (CS) Software:** A communication hub that transfers data between the BSM software and CSM software.

Intended Use

The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of 7-Lead ECG, heart rate, respiratory rate, pulse rate, functional oxygen saturation of arterial hemoglobin, non-invasive blood pressure, and patient posture and activity. VMS allows for the input of body temperature, and can display data from peripheral devices. VMS can generate alerts when rate-based cardiac arrhythmias are detected and when physiological vital signs fall outside of selected parameters.

Intended Audience

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices, and terminology, as required for monitoring patients.

Equipment Symbols


Warning / Caution


Do not use if package is damaged


RoHS Compliant


Date of Manufacture


Manufacturer


Type CF applied part symbol for shock protection

	Non-ionizing radiation
	Not for general waste
IP22	Ingress Protection. First 2 – Protection against fingers or similar objects > 12.5 mm. Second 2 – Protection against dripping water when tilted up to 15°
	Serial Number
	Bluetooth Low Energy MAC Address
	Consult Instructions for Use
	Not for use with MRI
Rx Only	For prescription use only
	Refer to Instruction Manual
	Electrostatic Sensitive Device

Contraindications

- This device is contraindicated for use in the presence of Magnetic Resonance Imaging (MRI) devices.

Warnings

- The Vios Chest Sensor and Adapter may cause interference with pacemakers/ICDs that utilize minute-ventilation respiration detection
- The Vios Chest Sensor and Adapter to not detect pacing spikes generated from implanted pacemakers
- Remove the Vios Chest Sensor and Adapter from any patient prior to magnetic resonance imaging (MRI)
- Do not place the Vios Chest Sensor and Adapter on patients under the age of 18
- Federal Law (US) restricts this device to sale by or on the order of physician

- Do not apply the Vios Chest Sensor, Adapter, or electrodes on breached or compromised skin surfaces or on mucosal membranes
- Vios Medical recommends using Medico Electrodes MSGST-06 to adhere the Adapter and Chest Sensor to the patient
- No modification of this equipment internal or external is allowed
- Do not destroy this equipment without authorization of the manufacturer.
- Hazards can result from unauthorized modification of the equipment.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Pins of connectors identified with the ESD warning symbol should not be should and that connections should not be made to these connectors unless ESD precautionary procedures are used.
- This equipment is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orientating or relocating the ME equipment or shielding the location.
- Use of adaptor, cables other than those specified, may result in increased emissions or decreased immunity.
- The CS2050 should not be worn and used adjacent to another wireless device such as mobile phone.

⚠ Cautions

- The Vios Chest Sensor is a Bluetooth® low energy (BLE) device and should not be used in BLE sensitive areas
- The Vios Chest Sensor is a radio frequency (RF) emission device. Remove all components of the Vios Bedside Monitoring System in radio frequency sensitive areas.
- The VMS should not be used near direct X-ray exposure. The Vios Chest Sensor and Adapter must be removed from a patient prior to an upper torso X-ray
- The VMS should not be used near X-ray computed tomography (CT) equipment. The Vios Chest Sensor and Adapter must be removed from patient prior to a CT scan
- Never autoclave, sterilize, or immerse the Chest Sensor in liquid of any kind
- The following may degrade pulse oximeter performance:
    - Excessive ambient light
    - Excessive motion
    - Improperly applied sensor
    - Residue (e.g. dirt, dried blood) in the optical path
    - Blood pressure cuffs
    - Fingernail polish

Notes: The following notice safety messages apply to this monitoring system.

- If VMS components have been transported or stored outside operating temperature, allow them to stabilize back to the operating temperature range before use.
- Portable and mobile RF communications equipment can affect the Chest Sensor and its communication with the VMS.
- Service and repairs are allowed for authorized Vios personnel only.
- The Chest Sensor is Internally Powered ME Equipment per IEC 60601-1
-

FCC Compliance

FCC compliance statements,

This Device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, this including interference that may cause undesired operation.

FCC Caution!!!

• Any changes or modifications not expressly approved by the party

Responsible for compliance could void the user's authority to operate this

Equipment

Part 15B compliance statements for digital devices:

NOTE: 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. However, 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

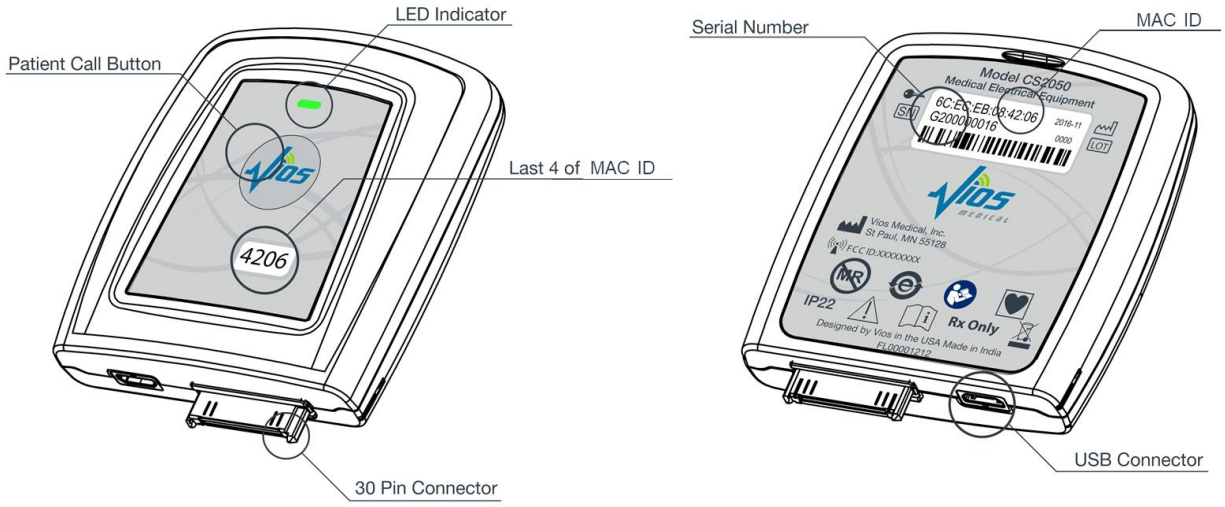
—Consult the dealer or an experienced radio/TV technician for help

2 Patient Application

Caution: Examine the product package upon receipt and do not use components if there appears to be any damage. Contact Vios for a replacement product. See Vios Customer Service section.

Notes: For instructions on how to use the Chest Sensor with the Vios Bedside Monitor Software (Model BSM2050), please refer to the Vios Bedside Monitor (Model BSM2050) Instructions For Use.

Overview



Component	Description
LED Indicator	Indicates various states of the Chest Sensor through red, yellow, green, and blue light with varying rates of blinking
Patient Call Button	User actuation of this button drives various functionalities of the device (turning the device on/off, sending a distress signal to the BSM)
Chest Sensor MAC ID (Last 4 Digits)	Provides the last 4 digits of the Chest Sensor MAC ID for pairing to the BSM
30-Pin Connector	Connector to which the Adapter is attached
USB Connector	Connector for charging the Chest Sensor battery
Back Label	Provides information pertaining to the MAC ID, serial number, manufacturing date, manufacturing lot, model number, and warning/cautionary symbols

Patient Preparation

Required Equipment:

- Vios Chest Sensor, Model CS2050
- Vios L2050F Adapter or L2050E Adapter
- Recommended electrodes
- Disinfecting wipes such as isopropyl alcohol or cleaning solution (not included)

Warning: Perform visual inspection of the Chest Sensor, Adapter, and electrodes for any signs of damage prior to use. The components should not have any damage. If any damage is observed, then use a new set of components and contact Vios to replace damaged parts.

Observe the chest and limb lead placement sites. Trim or clip hair if necessary. See Figure 1.

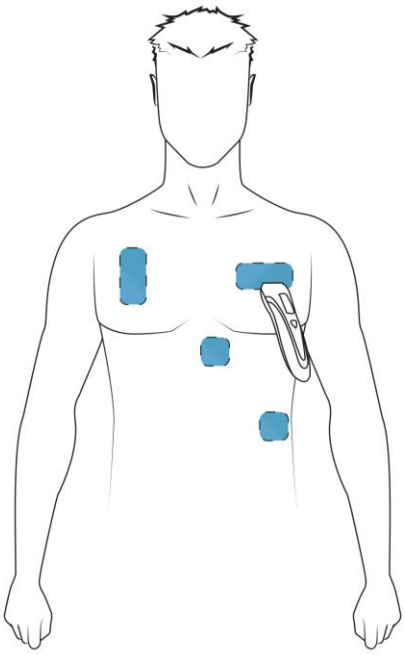


Figure 1

Use disinfecting wipes to clean the Chest Sensor placement sites and limb lead placement sites.

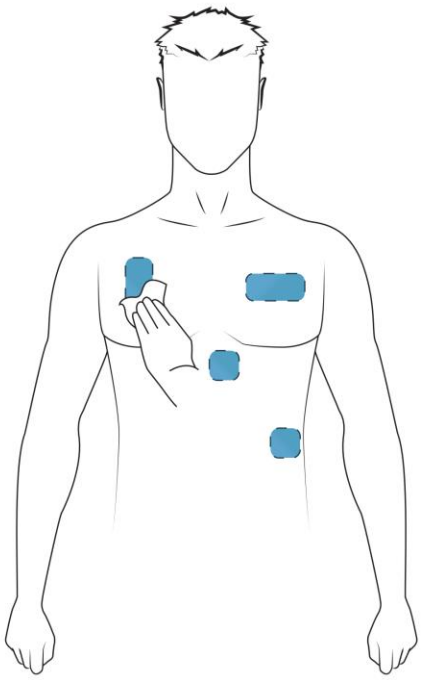
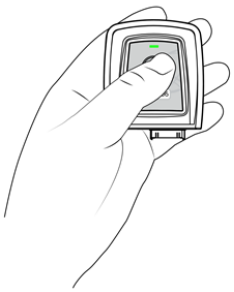


Figure 2

Check Chest Sensor Battery

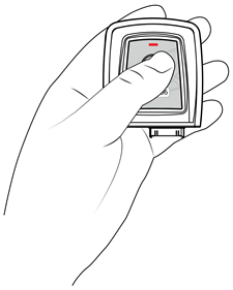
Always check the Chest Sensor battery status prior to monitoring a patient. You may check the Chest Sensor battery status by pressing the Patient Call Button when the device is off. Do not press and hold.

Briefly after pressing the Patient Call Button, the Chest Sensor LED will briefly display a color for 4 seconds. The displayed color will indicate the battery status – see the table below for the color representations:



SOLID GREEN
12 – 28 hours of use remaining

SOLID YELLOW
6 – 12 hours of use remaining



SOLID RED
3 – 6 hours of use remaining

BLINKING RED
0 – 3 hours of use remaining

Use the battery status indication to guide your decision about whether that Chest Sensor has enough charge to be used for a certain period of time. If the Chest Sensor indicates low battery (red or blinking red), please consider

charging the Chest Sensor or using a different device. See the 'Charging the Chest Sensor' section for instructions on charging.

Device Cleaning

Use disinfecting wipes to clean the Chest Sensor and Adapter prior to patient application. The following may be used for cleaning the Chest Sensor and Adapter:

- Isopropyl Alcohol (70% Alcohol/water mixture)
- Hydrogen Peroxide
- Ethyl Alcohol (50% Alcohol/water mixture)
- Water

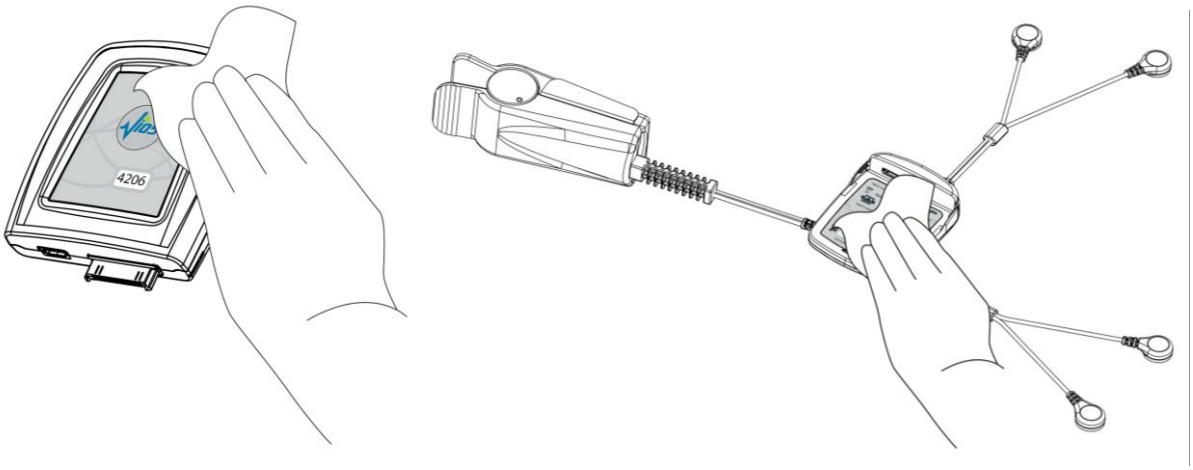


Figure 3

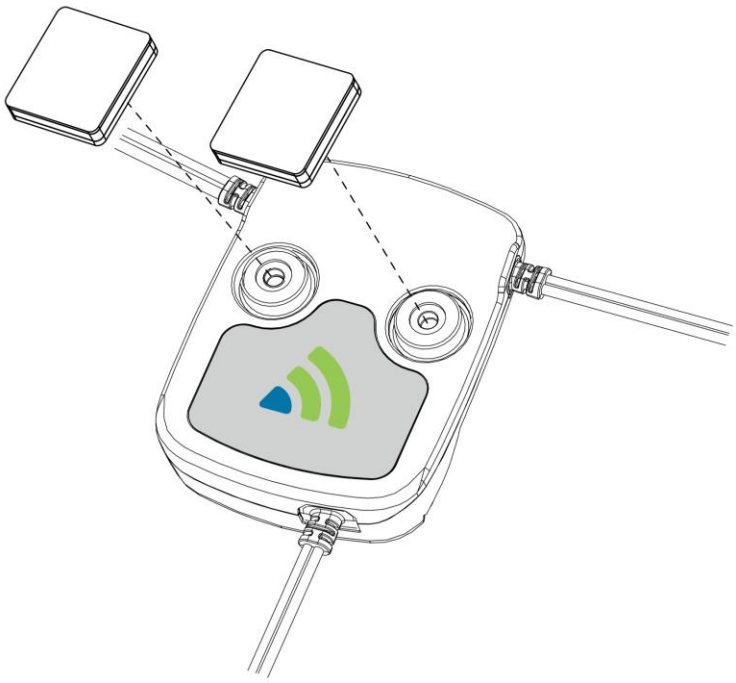
Attach an Adapter

Depending on where you want to monitor pulse oximetry, you may choose either a L2050F Adapter or L2050E Adapter. Slide the Chest Sensor into the Adapter so that the 30-Pin connectors mate. Ensure that the Chest Sensor is properly aligned on the Adapter rails.

Figure 4

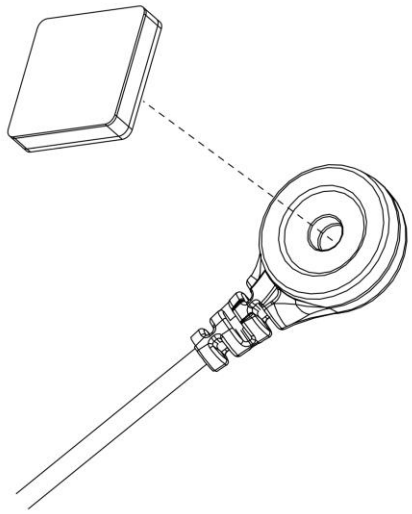
Caution: Ensure when sliding the Chest Sensor into the Adapter that the 30-Pin connectors are fully mated.

Snap two (2) electrodes into the back of the Adapter. Ensure there is no overlap between the two electrodes.



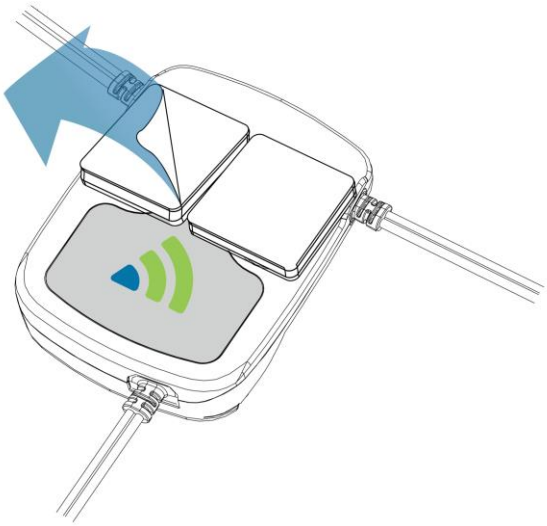
Caution: Ensure that when snapping the two (2) electrodes into the Adapter that there is no overlap between the electrodes.

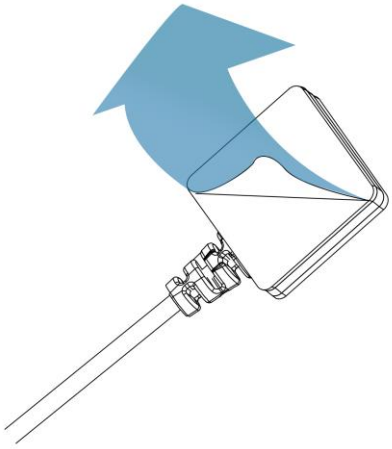
Snap four (4) electrodes into the RA, LL, and V lead snaps.



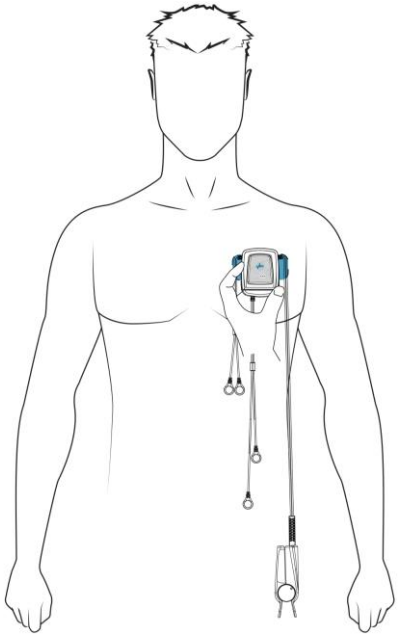
Device Placement

Peel off the adhesive liner from all six (6) electrodes.

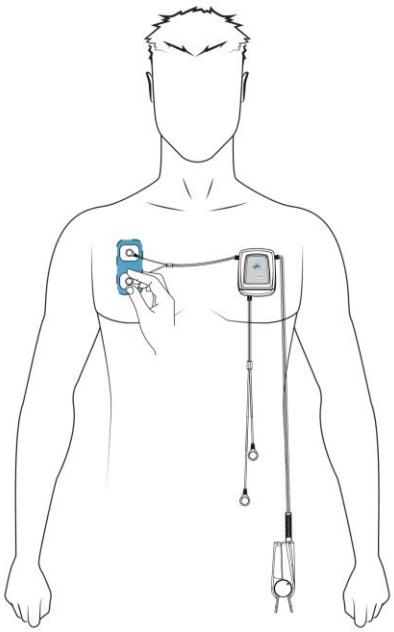




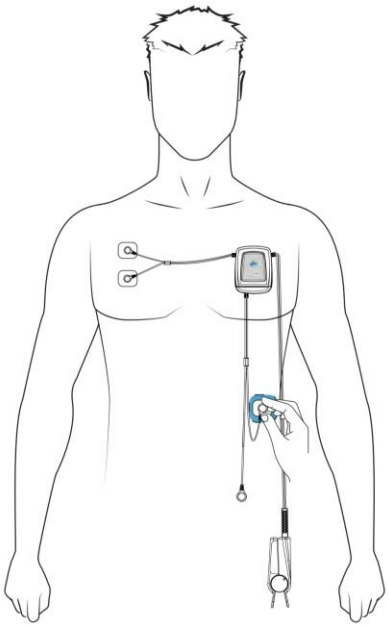
Attach the Chest Sensor with Adapter to the upper left pectoral area of the patient's chest. Ensure that the device is positioned correctly per the image below.



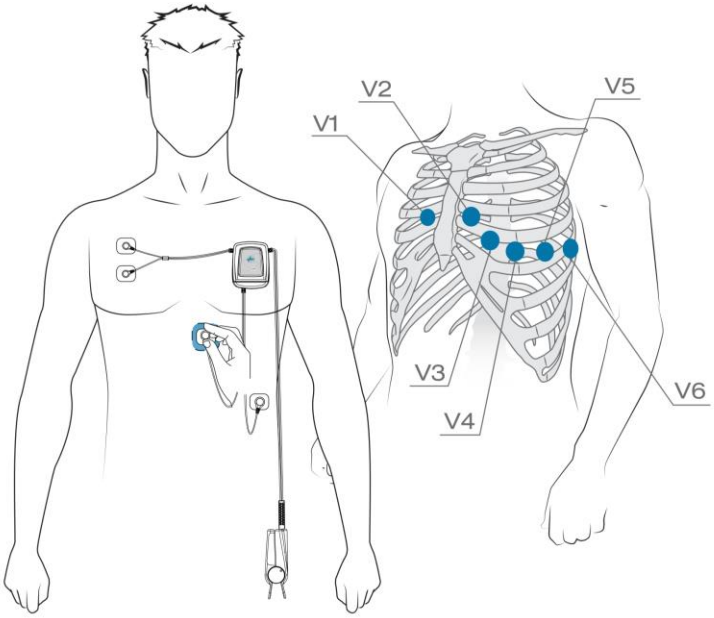
Affix the two Right Arm (RA) electrodes to the upper right pectoral area of the patient's chest. Ensure the leads are positioned correctly per the image below.



Affix the Left Leg (LL) electrode to the patient's left abdominal area, below the Chest Sensor. Ensure the lead is positioned correctly per the image below.



Lastly, affix the precordial (V) electrode to the patient. Placement of the electrode will determine which precordial lead is being monitored. The VMS may monitor one of the six (V1, V2, V3, V4, V5, V6) leads at a time – please see the image below for appropriate placement.

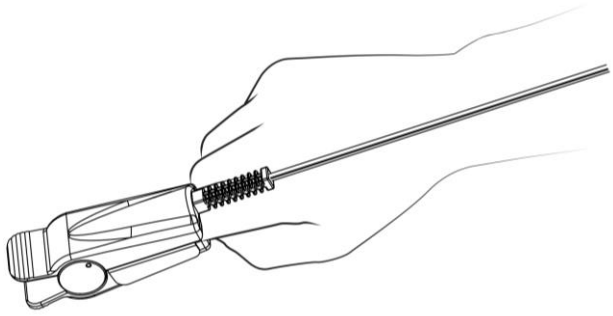


Pulse Oximeter Placement

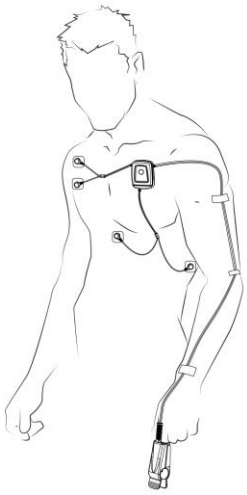
Next, place the pulse oximeter at the appropriate site. The site will depend on which adapter was connected to the Chest Sensor – please refer to the corresponding section below:

L2050F Adapter

Place the pulse oximeter finger clip over a finger on the patient's left hand (index finger preferred). Ensure that the patient's finger reaches the back of the pulse oximeter enclosure.

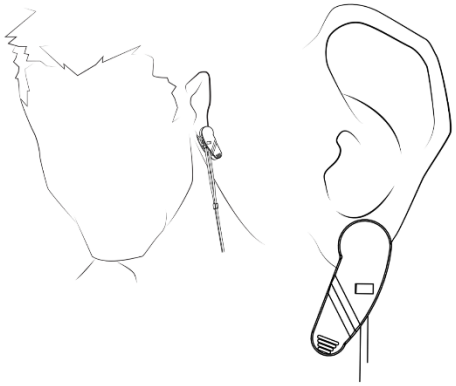


It is recommended to tape down the cable slack to prevent accidentally pulling or yanking of the cable. See the picture below for recommended tape sites.

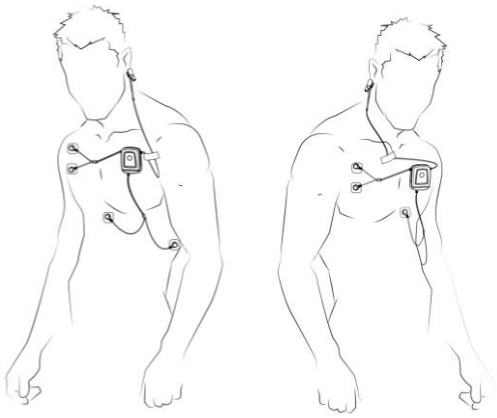


L2050E Adapter

Place the pulse oximeter ear clip over the patient's earlobe. Ensure that the ear clip fully covers the earlobe and is secure.



It is recommended to tape down the cable slack to prevent accidentally pulling or yanking of the cable. See the picture below for recommended tape sites.



3 Charging the Chest Sensor

Overview

The Chest Sensor uses a micro-USB connector for connecting to a charger. The charger must be connected to mains power to charge the Chest Sensor internal battery.

Vios recommends using the following power supplies for charging the Chest Sensor:

- TRUMPower Medical Grade Power Supply, Model TRM15-S05-E-UB-10F
- ASUS Switching Power Supply, Model PSM06A-050Q

Note: Please do not charge the Chest Sensor at temperatures less than or equal to 32°F.

LED Indications

When properly connected to a powered charger, the Chest Sensor LED will indicate a color based on the remaining battery life. See the images below for descriptions of each color representation.

Use the battery status indication to guide your decision about whether that particular Chest Sensor should be used or not. If the Chest Sensor indicates low battery (red), please consider waiting for the Chest Sensor to fully charge or use a different, fully charged device. See the 'Charging the Chest Sensor' section for instructions on charging.

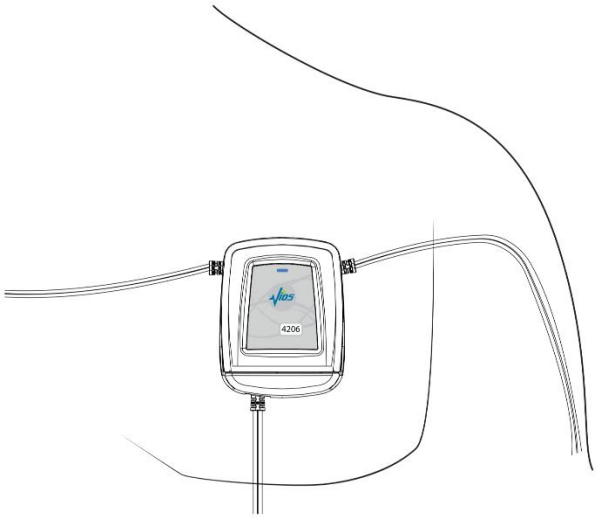
5 Pairing to a Bedside Monitor

Overview

Before pairing the Chest Sensor with a Bedside Monitor (BSM), you must initiate Bluetooth Low Energy (BLE) advertising on the Chest Sensor.

Initiating Bluetooth Low Energy (BLE) Advertising

To initiate Bluetooth Low Energy (BLE) Advertising, press and hold the Patient Call Button for at least seconds (4) seconds. For the first four (4) seconds, you will see the battery status indicated as described in the 'Battery Check' section. If you continue to hold the Patient Call Button for more than four (4) seconds, the Chest Sensor LED will begin blinking blue at a rate of once per second.

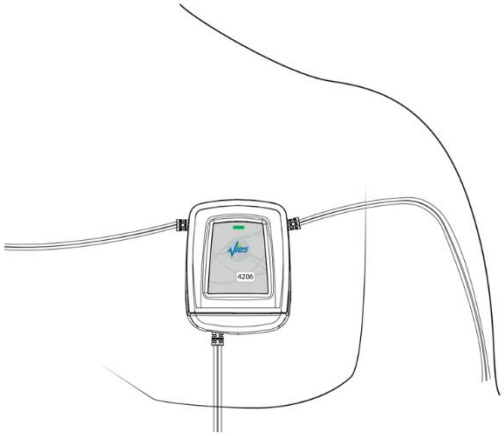


Pairing to a Bedside Monitor (BSM)

Once you have initiated Bluetooth Low Energy advertising, pair the Chest Sensor to the Bedside Monitor (BSM) using the Bedside Monitor software. For instructions on how to do this, please refer to the Bedside Monitor (BSM2050) Instructions for Use.

Confirmation of Pairing

After pairing the Chest Sensor to the Bedside Monitor (BSM), the Chest Sensor LED will slowly blink green (once per 10 seconds) to indicate that it is paired.



4 Troubleshooting

Overview

The troubleshooting section consists of several parts which should help you resolve the most common problems with the Chest Sensor. The 'Common Issues' section lists out the most likely issues you may encounter and the steps that should be taken to resolve them.

Common Issues

The Chest Sensor won't fit into the Adapter.
Ensure that the 30-Pin male connector on the Chest Sensor is properly aligned with the 30-Pin female connector on the Adapter. Ensure that the slots on the Chest Sensor are properly aligned with the rails on the Adapter.

The Chest Sensor / Adapter does not adhere to the patient.
Ensure that the steps in the 'Patient Preparation' section have been followed. Ensure that the Chest Sensor / Adapter have been placed per the 'Device Placement' section.

The Chest Sensor will not turn on.
Ensure that the steps in the 'Check Chest Sensor Battery' section have been followed. If the device is still not turning on, the battery may be depleted – try plugging it into a Vios recommended charger.

Service & Maintenance

If the device is damaged, please contact Vios for a replacement. Do not attempt to repair or service the device. See Customer Service information below.

If you are suspicious of damage to the device, please inspect the following:

- Ensure there are no breaks or tears in any of the cables
- Ensure the snaps (both on the leads and on the back of the adapter) are not loose
- Ensure the 30-Pin connector is not loose

To clean the Chest Sensor:

- Disconnect the Adapter from the Chest Sensor
- Dampen a clean cloth or gauze pad with appropriate cleaning solution and wipe all exposed surfaces including patient ECG cables and pulse oximetry cable/enclosure
- Dry all exposed surfaces with a clean, dry cloth or gauze pad

For proper disposal, please return the device to Vios at the end of its service life. See Customer Service information below.

5 Technical Specifications

Materials and Dimensions	
Materials	High impact PC, ABS, or a ABS/PC blend
Dimensions	74.6mm X 62.0mm X 14.5mm

Performance Specifications	
Minimum amplitude of QRS complex in the patient physiological signal	0.15 mV
Duration of use	At least 28 hours on a new, fully-charged battery
Use life	– The Chest Sensor shall have up to 365 attach/detach events with the Adapter. – The Chest Sensor shall have up to 365 attach/detach events with the Vios recommended charger.
Service Life	Expected to remain suitable for its intended use for up to 12 months
Degree of protection	Type CF applied part symbol for shock protection
Enclosure degree of Ingress protection	IP22

Caution: To prevent detection of P-waves or baseline noises as QRS complexes, the minimum detection level for QRS complexes as mentioned in the table above will be required for proper operation.

Operating Environment	
Operating Temperature	10°C to 40°C
Storage and Transport Temperature	-40°C to +70°C
Operating Humidity	Relative humidity range from 10% to 95% (Non-condensing)
Storage and Transport Humidity	Relative humidity range from 10% to 100%
Atmospheric Pressure	80 kPa to 100 kPa
Wireless Frequency and maximum radiated power	f = 2402 + k*2 MHz, k = 0, … , 39 power: 0.01 mW (-20 dBm) … 10 mW (+10 dBm)

Battery Specification	
Type	Rechargeable
Chemistry	Lithium-ion Polymer
Capacity	1250 mAh (Typical), 1150 mAh (Minimum)
Voltage	3.7 V (Nominal)

Dimension	52.0mm X 34.5mm x 7.3mm
Safety Certification	IEC 62133:2012
Battery Life	28 hours of continuous use

6 Customer Service & Contact Information

Vios Medical value's our Customer's feedback regarding our products, please call Vios Medical Inc. for any Customer Feedback, Complaints, or Return/Replacement Inquiries. Customer Service is available 24 hours a day, 7 days a week.

Vios Medical USA: +1-651-764-8467

Vios Medical India: +91-(0)80-4115-0546

Vios Medical Marketing: +91-8427439000

support@viosmedical.com

7 Safety & Compliance

Safety Notes

The Vios Chest Sensor:

- 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.
- Is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
- May need special precautions regarding EMC and needs to be installed and put into service according to the EMC information.

- ECG signals must have a minimum QRS amplitude of 5uV. ECG signal amplitude lower than this will be inhibited by the system
- May be affected by portable and mobile RF communications equipment.
- Should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Vios Chest Sensor should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emissions

Table A: Guidance and manufacturer's declaration – electromagnetic emissions – for all medical electrical equipment and medical electrical systems

Guidance and manufacturer's declaration – electromagnetic emissions		
CS2050 is intended for use in the electromagnetic environment specified below. The customer or the user of the **CS2050** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions EN 55011	Group 1	The **CS2050** 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 EN 55011	Class B	The **CS2050** 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.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Table B: Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The **CS2050** is intended for use in the electromagnetic environment specified below. The customer or the user of the **CS2050** should assure that it is used in such an environment.			
Immunity test	Error! Reference source not found. **60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge EN 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	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 EN 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of CS2050 requires continued operation during power mains interruptions, it is recommended that the CS2050 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table C: Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
CS2050 is intended for use in the electromagnetic environment specified below. The customer or the user of the **CS2050** should assure that it is used in such an environment.			
Immunity test	Error! Reference source not found. **60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Conducted RF EN 61000-4-6 Radiated RF EN 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 CS2050, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3{,}5/V1]\sqrt{P}$ $d = [3{,}5/E1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ 800 MHz to 2,5 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: 
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.			
[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 **CS2050** is used exceeds the applicable RF compliance level above, the **CS2050** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **CS2050**. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table D: Recommended separation distances between portable and mobile RF communications equipment and the medical electrical equipment and medical electrical systems – for medical electrical equipment and medical electrical systems that are not life-supporting

Recommended separation distances between **portable and mobile RF communications equipment and the CS2050**

The **CS2050** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **CS2050** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **CS2050** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [3{,}5 / V1]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3{,}5 / E1]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [7 / E1]\sqrt{P}$
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 1 At 80 MHz and 800 MHz, the separation distance for 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.

The Vios Monitoring System (VMS) has been designed in compliance with applicable Safety Standards given below.

Safety Standards

- 60601-1: Safety Requirements for Medical Electrical Systems
- 60601-1-2: General Requirements for Safety – Electromagnetic Compatibility
- 60601-2-27: 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
- ISO 80601-2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 10993-1: Biological Evaluation of medical devices
- EN 300 328 v1.8.1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
- ASTM D4169-14: Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 60529 standard Ingress Protection Marking – IP22
- EC53 ECG Trunk Cables and Patient Leadwires

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