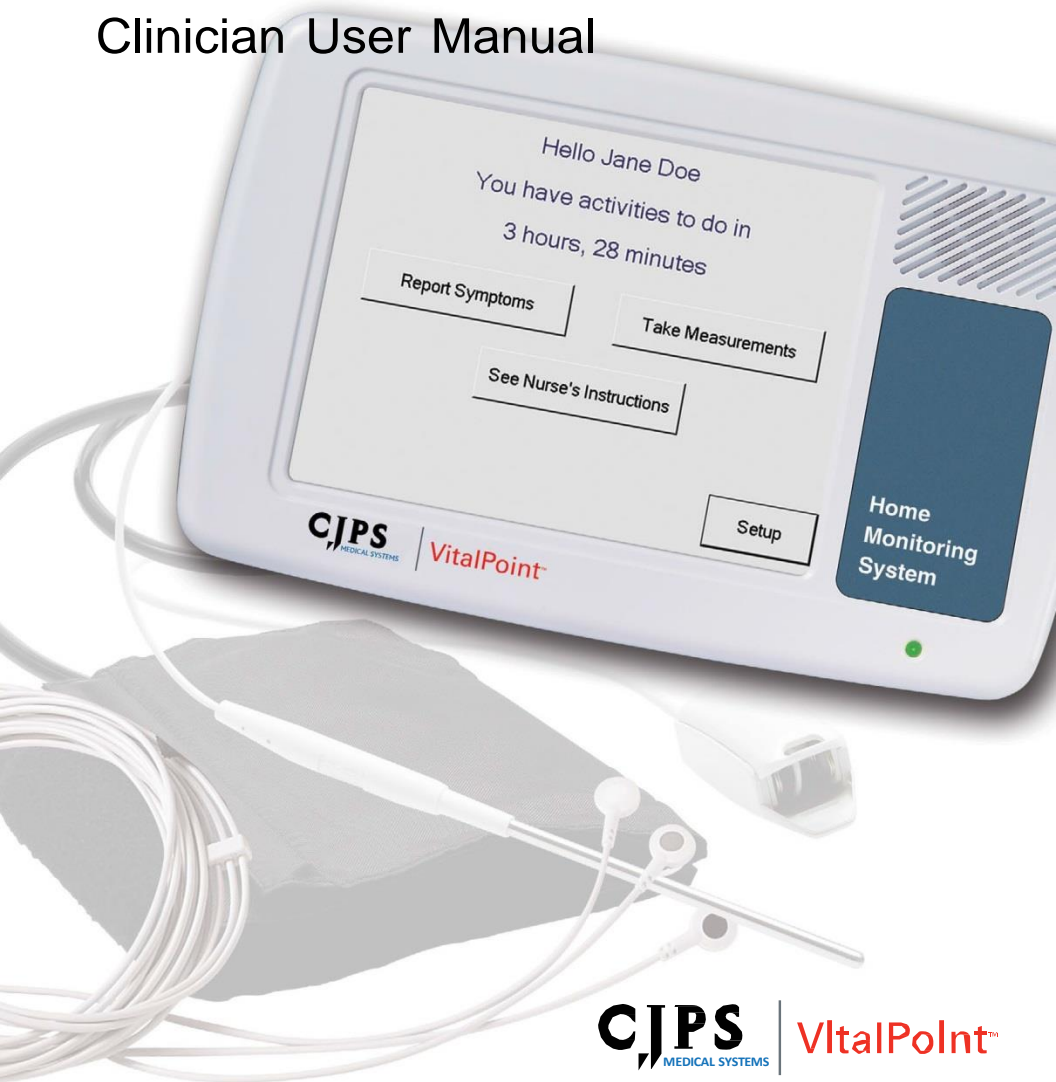# CJPS Medical Systems
VitalPoint Home Monitor
Clinician User Manual

Manufactured by:

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CJPS Medical Systems makes no warranty of any kind on this material, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. CJPS Medical Systems shall not be liable for errors contained herein or for incidental or consequential damages concerning the furnishing, performance, or use of this material.

Before using any CJPS Medical Systems product, be sure to read carefully and understand all manuals provided with the product.

CJPS Medical Systems Remote Device Connectivity complies with the U.S. Health Insurance Portability and Accountability Act (HIPAA) protecting the security and privacy of health data. It is recommended that the healthcare facility ensures that patients complete all necessary paperwork so that the facility complies with the HIPAA requirements.

This equipment complies with Part 68 of the U.S. Federal Communications Commission (FCC) rules and the requirements adopted by the American Council for Terminal Attachments (ACTA). On the back of the CJPS Medical Systems VitalPoint™ Home Monitor is a label that contains, among other information, a product identifier in the format US:AAAEQ##TXXXX. If requested, this number must be provided to the telephone company.

The Universal Services Ordering Code (USOC) jack used to connect the VitalPoint Home Monitor to the premises' wiring and telephone network must comply with the applicable FCC Part 68 rules and requirements adopted by the ACTA.

The ringer equivalence number (REN) is used to determine the number of devices that may be connected to a telephone line. Excessive RENs on a telephone line may result in the devices not ringing in response to an incoming call. In most, but not all, areas the sum of RENs should not exceed five (5). To be certain of the number of devices that may be connected to a line, as determined by the total RENs, contact the local telephone company. For products approved after July 23, 2002, the REN is part of the product identifier that has the format US:AAAEQ##TXXXX. The digits represented by ## are the REN without a decimal point (i.e., 03 is a REN of 0.3). For earlier products, the REN is separately shown on the label.

If this VitalPoint Home Monitor causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it's necessary.

The telephone company may make changes in its facilities, equipment, operations, or procedures that could affect the operation of the VitalPoint Home Monitor. If this happens, the telephone company will provide advance notice in order for you to make necessary modifications to maintain uninterrupted service.

Connection to party line service is subject to state tariffs (U.S.). Contact the state public utility commission, public service commission, or corporation commission for information.

If installed in a building with specially wired alarm equipment connected to the telephone line, ensure the installation of the VitalPoint Home Monitor does not disable the alarm equipment. If you have questions about what will disable alarm equipment, consult the telephone company or qualified installer.

Electrical safety advisory: Parties responsible for equipment requiring AC power should consider including an advisory notice in their customer information suggesting the customer use a surge arrestor. Telephone companies report that electrical surges, typically lightning transients, are very destructive to customer terminal equipment connected to AC power sources. This has been identified as a major nationwide problem.

Classification
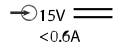
This equipment is ETL listed and classified with respect to electric shock, fire, and mechanical hazards per the following:

- Conforms to UL Standard 60601-1 (2003), First Edition, Medical Electrical Equipment, Part 1: General Requirements for Safety

- Certified to CAN/CSA Standard CSA C22.2 No. 601.1-M90 (1990), Medical Electrical Equipment, Part 1: General Requirements for Safety

- IEC 60601-1 (2004), Medical Electrical Equipment, Part 1: General Requirements for Safety, with A1 and A2

- IEC 60601-1-1 (2000), Second Edition, Medical Electrical Equipment, Part 1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems

- IEC 60601-1-2 (2001), Medical Electrical Equipment, Parts 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

- IEC 60601-1-4 (1996), Medical Electrical Equipment, Parts 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems

- IEC 60601-2-27 (1994), First Edition, Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Electrocardiographic Equipment

- IEC 60601-2-30 (1999), Second Edition, Medical Electrical Equipment, Part 2: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment

- IEC 60601-2-49 (2001), Medical Electrical Equipment, Parts 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment

- ISO 9919 (2005): Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use

- UL 1950 Third Edition, Clause 6 only

- FCC 47 CFR, Part 68: Connection of Terminal Equipment to the Telephone Network

This equipment is classified as:

- Class II
- Type CF
- IPX0
- Continuous operation

Explanation of Packaging and Labeling Symbols

Symbol	Meaning
(house icon)	For indoor use only
⚠	Caution, consult accompanying documents
(factory icon) (month/year)	Manufacture date (mm/yyyy)
(package icon)	Do not use if package damaged
⊖15V ⎓ <0.6A	Direct current power input, 15 V, 600 milliamperes
SN	Serial number
REF	Catalog number
R_x only	U.S. federal law restricts this device to sale by or on the order of a physician
⊙ ON	On
○ OFF	Off
▢	Class II device
↑↑	This end up
(glass icon)	Fragile/breakable
(pressure icon)	Atmospheric pressure limitation 0.3 bar to 1.0 bar
(thermometer icon)	Storage temperature limitation -4°F to 122°F (-20°C to 50°C)
(humidity icon)	Humidity limitation 10% to 95%
IPX0	Ordinary protection
♥	Type CF

Intended Use

The CJPS VitalPoint Home Monitor is intended to be used as a clinical tool for remotely monitoring a patient's health status at home or in another healthcare facility. The system is intended to guide patients through a set of scheduled activities whereby medical data (vital signs, symptoms, and medication compliance) is collected. The system is intended to transfer the collected data to a remote site where it is stored and reviewed by a clinician. The system is also intended to allow the clinician to modify the patient's scheduled activities in response to the collected medical data or other information available to the clinician. The intent is to provide clinicians caring for patients outside the hospital with a means for keeping track of how the patients are doing without the patients having to come in for a checkup or requiring the clinicians to go to the patients.

The CJPS VitalPoint Home Monitor provides periodic remote monitoring of the patient's self-reported symptoms or vital signs, including:

- Non-invasive blood pressure
- Oxygen saturation
- Pulse rate
- Temperature
- Weight

- Blood glucose level
- Fluid status
- Prothrombin time
- ECG and heart rate monitoring

-

WARNING:
THE VITALPOINT HOME MONITOR IS NOT AN EMERGENCY RESPONSE SYSTEM. THE DEVICE LABELING ADVISES PATIENTS TO CONTACT THEIR CAREGIVER, NURSE, OR DOCTOR; CALL LOCAL EMERGENCY NUMBER AS APPROPRIATE; OR GO TO THE EMERGENCY ROOM WHENEVER THEY FEEL THE NEED TO DO SO. THE VITALPOINT HOME MONITOR DOES NOT ANALYZE PATIENT INFORMATION, NOR DOES IT OFFER MEDICAL ADVICE.

CONTRAINDICATIONS OVERVIEW

CONTRAINDICATION:
• USE OF THIS DEVICE IS CONTRAINDICATED IN APPLICATIONS REQUIRING AUTOMATED ARRHYTHMIA DETECTION. • THIS DEVICE IS NOT TO BE USED AS AN APNEA MONITOR. • THIS DEVICE IS NOT TO BE USED IN AN MRI ENVIRONMENT. • THIS DEVICE IS NOT TO BE USED IN AN OPERATING ROOM OR SURGICAL ENVIRONMENT.

Manual Version
Please refer to this manual for detailed instructions on warnings, precautions, specifications, and additional information. Printed in U.S.A.

Electronic copies of the current version of the *CJPS Medical Systems VitalPoint Home Monitor Clinician User Manual* can be found at www.CJPS-MedicalSytems.com.

General Information

This user manual provides information for users of the VitalPoint Home Monitor.

Some information in this manual is valid only when the monitor is in single-patient mode. This information is indicated by the 👤 icon. Other information in this manual is valid only when the monitor is in multi-patient mode. This information is indicated by the 👥 icon.

For the sake of brevity, the terms "VitalPoint," "monitor," or "device" are sometimes used in this document to refer to the VitalPoint Home Monitor.

IMPORTANT
Users should read this entire manual before operating the VitalPoint Home Monitor. Failure to do so could result in personal injury and/or death.

If you have questions about the information in this user manual or about the safe operation of this system, contact your distributor.

TYPOGRAPHICAL CONVENTIONS IN THIS USER MANUAL
This guide contains warnings, precautions, and notes to help call your attention to the most important safety and operational aspects of the system. To help identify these items when they occur in the text, they are shown using the following typographical conventions:

WARNING:
STATEMENTS THAT DESCRIBE SERIOUS ADVERSE REACTIONS AND POTENTIAL SAFETY HAZARDS.

PRECAUTION:
STATEMENTS THAT CALL ATTENTION TO INFORMATION REGARDING ANY SPECIAL CARE TO BE EXERCISED BY THE PRACTITIONER AND/OR PATIENT FOR THE SAFE AND EFFECTIVE USE OF THE DEVICE.

IMPORTANT:
Statements calling attention to additional significant information about the device or a procedure.

Note: Statements that provide supplemental information.

Warnings and Precautions

WARNINGS OVERVIEW

CRITICAL! EXPLOSION HAZARD. DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS. DO NOT INCINERATE UNIT.

WARNING:

1. PACEMAKER PATIENTS: RATE METERS MAY CONTINUE TO COUNT THE PACEMAKER RATE DURING OCCURRENCES OF CARDIAC ARREST OR SOME ARRHYTHMIAS. DO NOT RELY ENTIRELY UPON RATE METER ALARMS. KEEP PACEMAKER PATIENTS UNDER CLOSE SURVEILLANCE. SEE "SPECIFICATIONS" (PAGE 79) FOR DISCLOSURE OF THE PACEMAKER PULSE REJECTION CAPABILITY OF THIS INSTRUMENT.

2. THE VITALPOINT HOME MONITOR IS NOT AN EMERGENCY RESPONSE SYSTEM. THE DEVICE LABELING ADVISES PATIENTS TO CONTACT THEIR CAREGIVER, NURSE, OR DOCTOR; CALL LOCAL EMERGENCY NUMBER AS APPROPRIATE; OR GO TO THE EMERGENCY ROOM WHENEVER THEY FEEL THE NEED TO DO SO. THE VITALPOINT HOME MONITOR DOES NOT ANALYZE PATIENT INFORMATION, NOR DOES IT OFFER MEDICAL ADVICE.

3. DO NOT USE THE MONITOR NEAR SOURCES OF LIQUIDS SUCH AS SINKS, SHOWERS, OR BATHTUBS.

4. UNPLUG THE MONITOR BEFORE CLEANING. DO NOT SPRAY CLEANERS INTO THE RECEPTACLES.

5. DO NOT USE A MONITOR OR ANY ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE.

6. DO NOT USE THE MONITOR IF THE MAIN MENU SCREEN IS NOT DISPLAYED PROPERLY WHILE CONNECTED TO AC POWER.

7. DEVICE INTERCONNECTIONS: THROUGH ITS OMD (OTHER MEDICAL DEVICE) PORT, THE VITALPOINT HOME MONITOR CAN BE CONNECTED TO

WARNING:

9. NON-INVASIVE BLOOD PRESSURE WARNINGS:

   • THE NON-INVASIVE BLOOD PRESSURE (NBP) CUFF SHOULD BE AT THE SAME LEVEL AS THE PATIENT'S HEART. IF THE NBP CUFF CANNOT BE PLACED AT THIS LEVEL, ADD TO MEASURED PRESSURE VALUES 1.4 mmHg FOR EACH 2 cm ABOVE HEART LEVEL, OR SUBTRACT 1.4 mmHg FOR EACH 2 cm BELOW HEART LEVEL.

   • IN SOME CASES, FREQUENT AND PROLONGED MEASUREMENTS CAN RESULT IN PETECHIA, ISCHEMIA, PURPURA, OR NEUROPATHY. CHECK THE CUFF SITE REGULARLY WHEN TAKING FREQUENT MEASUREMENTS OVER AN EXTENDED TIME PERIOD. ALSO CHECK THE PATIENT FOR ANY SIGNS OF RESTRICTED CIRCULATION IN THE EXTREMITIES OF THE LIMB WHERE THE NBP CUFF IS WRAPPED.

   • BE SURE THE NON-INVASIVE BLOOD PRESSURE HOSE IS NOT BLOCKED OR KINKED DURING A MEASUREMENT. A BLOCKED OR KINKED HOSE COULD LEAD TO EXCESSIVE PRESSURE IN THE BLOOD PRESSURE CUFF, WHICH COULD CAUSE LIMB DAMAGE TO THE PATIENT. IN THE EVENT THE CUFF NEEDS TO BE STOPPED DURING OPERATION DUE TO AN ERROR CREATED BY A BLOCKED OR KINKED HOSE, THE CUFF SHOULD BE REMOVED FROM THE PATIENT'S ARM BY RELEASING THE VELCRO® STRAP OR PULLING/CUTTING THE HOSE OFF OF THE CONNECTOR.

10. PULSE OXIMETRY WARNINGS:

    • REPOSITION THE PULSE OXIMETRY SENSOR AT LEAST EVERY 4 HOURS (2 HOURS FOR POORLY PERFUSED PATIENTS). MOVE THE SENSOR IF YOU SEE ANY SIGNS OF SKIN IRRITATION OR IMPAIRED CIRCULATION.

    • ELEVATED LEVELS OF CARBOXYHEMOGLOBIN OR METHEMOGLOBIN IN MONITORED PATIENTS CAN RESULT IN INACCURATE PULSE OXIMETRY READINGS.

    • A PULSE OXIMETER SHOULD BE CONSIDERED AS AN EARLY WARNING DEVICE. AS A TREND TOWARD PATIENT DEOXYGENATION IS INDICATED, BLOOD SAMPLES SHOULD BE ANALYZED BY A LABORATORY CO-OXIMETER.

11. PROBES AND CABLES ARE DESIGNED FOR USE WITH SPECIFIC MONITORS. VERIFY COMPATIBILITY AND USE ONLY APPROVED ACCESSORIES WITH VITALPOINT. USING NON-APPROVED ACCESSORIES MAY RESULT IN DEGRADED PERFORMANCE, DAMAGE TO THE MONITORING EQUIPMENT, OR IN HARM TO THE PATIENT, AND MAY VOID WARRANTY COVERAGE.

12. TO AVOID AN ELECTRICAL SHOCK HAZARD, THE CONDUCTIVE PART OF THE ELECTRODES SHOULD NOT BE ALLOWED TO COME IN CONTACT WITH OTHER CONDUCTIVE OBJECTS, INCLUDING EARTH.

13. DO NOT INTRODUCE ANY ADDITIONAL PATIENT CONNECTION THAT MAY PRODUCE ELECTRICAL CURRENT. VITALPOINT APPLIES APPROXIMATELY 2 MICROAMPERES (2 µA).

14. ACCESSORIES SHOULD BE DISPOSED OF ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS ON PACKAGING.

PRECAUTIONS OVERVIEW

PRECAUTION:

1. U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

2. THE VITALPOINT HOME MONITOR IS NOT INTENDED TO BE A PRIMARY SOURCE OF MEDICAL INFORMATION. PATIENT SHOULD CONTACT CLINICIAN WITH QUESTIONS.

3. A HEALTHCARE PROFESSIONAL MUST VERIFY THAT THE PATIENT IS CAPABLE OF OPERATING THE MONITOR AND UNDERSTANDS HOW TO USE THE MONITOR.

4. IT IS RECOMMENDED A HEALTHCARE PROFESSIONAL BE PRESENT AND PREPARED TO ASSIST A PATIENT USING A MONITOR IN MULTI-PATIENT MODE.

5. WHEN CHANGING BETWEEN SINGLE- AND MULTI-PATIENT MODES IN REMOTE DEVICE CONNECTIVITY, ALL DATA STORED IN THE MONITOR MUST BE UPLOADED TO THE CENTRAL SERVER BEFOREHAND. DATA NOT UPLOADED WILL NOT BE LOST IF THE MODE IS CHANGED, HOWEVER, THE MONITOR WILL BE UNABLE TO UPLOAD THE DATA UNTIL IT IS REVERTED TO THE MODE IT WAS IN AND ASSIGNED TO THE SAME PATIENT(S) WHEN THE DATA WAS COLLECTED. SEE THE REMOTE DEVICE CONNECTIVITY USER MANUAL FOR MORE INFORMATION.

6. THIS MANUAL WILL NOTE WHICH FEATURES ARE AVAILABLE ONLY IN SINGLE-PATIENT MODE. SELECT SINGLE-PATIENT MODE IN REMOTE DEVICE CONNECTIVITY IF THE FEATURE IS REQUIRED FOR PATIENT CARE. SEE THE REMOTE DEVICE CONNECTIVITY USER MANUAL FOR MORE INFORMATION.

7. FOR CONTINUED OPERATION, ALWAYS CONNECT THE MONITOR TO A WALL OUTLET. FAILURE TO DO THIS CAN LEAD TO AN INTERRUPTION OF MONITORING.

8. THERE ARE NO USER-SERVICEABLE PARTS IN THIS DEVICE.

9. THE VITALPOINT HOME MONITOR NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT INTO SERVICE ACCORDING TO EMC INFORMATION PROVIDED IN THIS MANUAL.

PRECAUTION:

10. PORTABLE AND MOBILE RADIO-FREQUENCY (RF) COMMUNICATIONS EQUIPMENT CAN AFFECT THE VITALPOINT HOME MONITOR. IF THE VITALPOINT HOME MONITOR DOES NOT APPEAR TO BE WORKING NORMALLY, TRY TO RELOCATE OR REORIENT THE VITALPOINT HOME MONITOR.

11. USE OF ACCESSORIES NOT APPROVED FOR USE WITH THE VITALPOINT HOME MONITOR MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE VITALPOINT HOME MONITOR. REFER TO THE APPROVED ACCESSORIES LIST FOR THE VITALPOINT HOME MONITOR.

12. THE VITALPOINT HOME MONITOR SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT; AND THAT IF ADJACENT OR STACKED USE IS NECESSARY, THE VITALPOINT HOME MONITOR SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION.

13. DO NOT CLEAN, DISINFECT, OR STERILIZE ANY PART OF THE MONITOR WITH ETHYLENE OXIDE GAS OR BY AUTOCLAVING. THIS MAY DAMAGE THE DEVICE AND WILL VOID THE WARRANTY.

14. THESE CHEMICALS MAY DAMAGE THE MONITOR'S FRONT PANEL: ACETALDEHYDE, ACETONE, AMMONIA, BENZENE, HYDROXYTOLUENE, METHYLENE CHLORIDE, OR OZONE. DO NOT USE THOSE CHEMICALS OR CLEANSERS CONTAINING N-ALKYLDIMETHYLBENZYLAMMONIUM CHLORIDE.

15. NON-INVASIVE BLOOD PRESSURE PRECAUTIONS:

• DO NOT APPLY THE NON-INVASIVE BLOOD PRESSURE CUFF ON THE SAME LIMB AS THE PULSE OXIMETRY SENSOR. DURING BLOOD PRESSURE MEASUREMENTS, THE PERFUSION IS TEMPORARILY REDUCED, WHICH CAN RESULT IN INACCURATE PULSE OXIMETRY READINGS.

• DO NOT ALLOW THE NON-INVASIVE BLOOD PRESSURE CUFF OR HOSE TO COME IN CONTACT WITH FLUIDS. IF THIS OCCURS, ALLOW TO DRY THOROUGHLY BEFORE USE. CHECK THE HOSE AND CUFF FREQUENTLY FOR SIGNS OF DAMAGE OR DEBRIS. AN OBSTRUCTION IN THE HOSE MAY INTERFERE WITH INFLATION AND DEFLATION, RESULTING IN INACCURATE NON-INVASIVE BLOOD PRESSURE READINGS.

• TO OBTAIN ACCURATE BLOOD PRESSURE READINGS, KEEP THE LIMB AND THE CUFF AS STILL AS POSSIBLE.

• NON-INVASIVE BLOOD PRESSURE MEASUREMENTS MAY NOT BE ACCURATE IF THE PATIENT IS CONVULSIVE, EXPERIENCING TREMORS, OR IS DEFIBRILLATED DURING THE MEASUREMENT.

16. PULSE OXIMETRY PRECAUTIONS:

• READ INSTRUCTIONS PROVIDED WITH THE PULSE OXIMETRY SENSOR TO UNDERSTAND THE BEST APPLICATION TECHNIQUE AND ALL RELEVANT SAFETY INFORMATION.
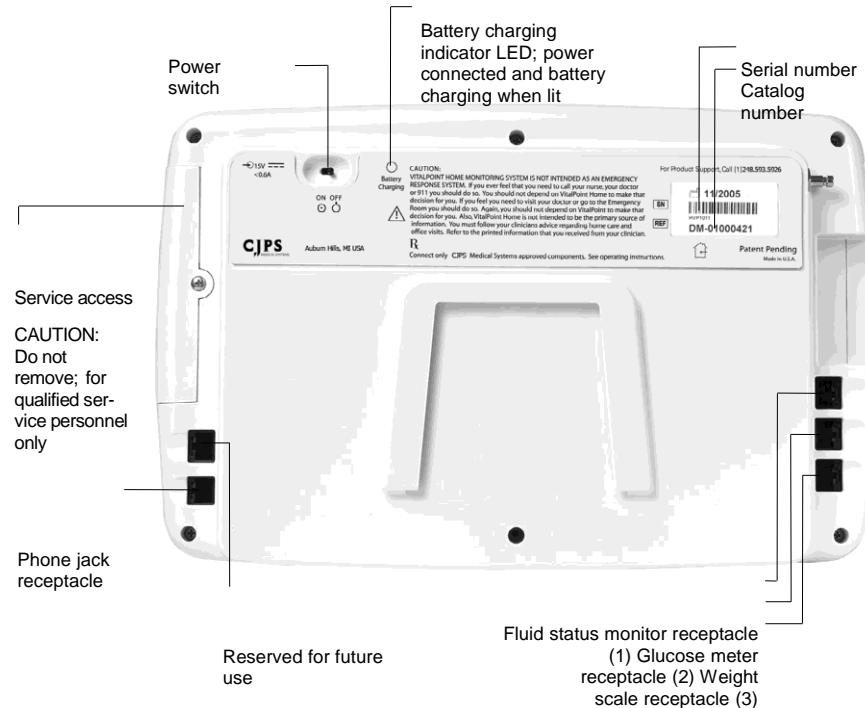
PRECAUTION:

- DO NOT APPLY THE PULSE OXIMETRY SENSOR ON THE SAME LIMB AS THE NON-INVASIVE BLOOD PRESSURE CUFF. DURING BLOOD PRESSURE MEASUREMENTS, THE PERFUSION IS TEMPORARILY REDUCED, WHICH CAN RESULT IN INACCURATE PULSE OXIMETRY READINGS.

- BRIGHT LIGHT CAN CREATE PROBLEMS WITH THE PULSE OXIMETRY MEASUREMENTS, RESULTING IN INACCURATE PULSE OXIMETRY READINGS. IF THE SENSOR IS IN A PLACE WHERE IT MAY BE EXPOSED TO BRIGHT LIGHT, COVER THE SENSOR WITH SOME OPAQUE MATERIAL TO BLOCK THE LIGHT.

- PULSE OXIMETRY READINGS MAY BE INACCURATE IN THE PRESENCE OF TOO MUCH MOTION OR IF THE PATIENT HAS TREMORS. IF QUESTIONABLE READINGS ARE OBTAINED, RE-CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS BEFORE ADMINISTERING MEDICATION.

17. SHOULD THE AC ADAPTER'S GREEN LIGHT NOT REMAIN ON WHILE PLUGGED INTO AN AC OUTLET, REPORT THE PROBLEM TO CJPS MEDICAL SYSTEMS OR AUTHORIZED DISTRIBUTOR AND DISCONTINUE MONITOR USE UNTIL THE PROBLEM CAN BE IDENTIFIED AND CORRECTED.

18. PATIENT SHOULD NOT RELY SOLELY ON THE MONITOR REGARDING WHEN TO TAKE MEDICATIONS. PATIENT SHOULD CONSULT PHYSICIAN BEFORE TAKING ANY PRESCRIPTION OR NON-PRESCRIPTION MEDICATION OR CHANGING ANY MEDICATION REGIMENS. VITALPOINT IS INTENDED AS A REMINDER SYSTEM ONLY.

19. ECG/RESPIRATION PRECAUTIONS:

- LINE ISOLATION MONITOR TRANSIENTS MAY RESEMBLE ACTUAL CARDIAC WAVEFORMS AND THUS INHIBIT HEART RATE ALARMS. TO AVOID THE RISK OF THIS HAPPENING, FOLLOW THE DIRECTIONS FOR PROPER ELECTRODE PLACEMENTS, AND KEEP THE ECG LEAD WIRES AWAY FROM SOURCES OF LINE NOISE.

- TO AVOID LARGE OFFSET POTENTIALS DUE TO POLARIZATION OF ELECTRODES, BE SURE TO USE ONLY ELECTRODE TYPES SPECIFIED FOR THIS DEVICE, AND BE SURE THAT ALL ELECTRODES USED ON A PATIENT ARE OF THE SAME TYPE.

20. FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR USE WHEN USING A GLUCOSE METER AND STRIPS.

21. FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR USE WHEN USING A FLUID STATUS MONITOR.

22. FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR USE WHEN USING A PROTHROMBIN TIME METER.

Contents

Monitor Features and Controls

Main screen

Power on indicator LED; "on" when lit

Power switch

Battery charging indicator LED; power connected and battery charging when lit

Serial number Catalog number

Service access

CAUTION: Do not remove; for qualified service personnel only

Phone jack receptacle

Reserved for future use

Fluid status monitor receptacle (1) Glucose meter receptacle (2) Weight scale receptacle (3)

Pulse oximeter receptacle

(SpO$_2$) Blood pressure

receptacle (NBP)

Electrocardiogram receptacle
(ECG)

Temperature probe receptacle
(TEMP)

Fluid status monitor receptacle (1)

Glucose meter receptacle(2)

Weight scale receptacle (3)

Power receptacle

USB port for CJPS
approved accessories only

Reserved for future use

Phone jack receptacle

Initial Monitor Setup

BEFORE YOU GET STARTED
Each VitalPoint Home Monitor is produced to exacting quality standards.
However, handling in transit could result in damage to the monitor.
Always inspect the monitor and its accessories for any sign of
damage before using. If the monitor or any accessory shows
any sign of damage, notify the shipping carrier immediately.
Contact the product distributor to obtain authorization for
equipment return for repair.

Contact the product distributor for a list of accessories.

WARNING:

DO NOT USE A MONITOR OR ANY ACCESSORY THAT
SHOWS ANY SIGN OF DAMAGE.

Important things to note before using the VitalPoint Home Monitor:

Necessary Equipment
- VitalPoint Home Monitor
- VitalPoint power supply with integral power cable
- Accessories, including:
    - SpO$_2$ sensor/extender (if you will be monitoring SpO$_2$)
    - Temperature probe and covers (if you will be monitoring temperature)
    - Non-invasive blood pressure cuff (if you will be monitoring
      non-invasive blood pressure)
    - Weight scale (if you will be monitoring weight)
    - Glucose meter and adaptive cables (if you will be monitoring
      glucose levels); any glucose meter may be used by entering the
      information manually
    - ECG monitor, electrodes, and cable lead set (if clinician will be
      performing ECG testing)
    - Prothrombin time meter (if you will be entering prothrombin time
      measurements)
    - Fluid status monitor (if you will be monitoring fluid levels)

Transport and Storage
The monitor should be transported and stored in a clean, dry environment:
- -4°F to 122°F (-20°C to 50°C)
- 10% to 95% relative humidity (non-condensing)
- Altitude 0 to 39,370 feet (0 to 12,000 m)

Selecting a Blood Pressure Cuff

To accurately measure blood pressure, an appropriate size cuff must be used. Measure arm circumference to determine which blood pressure cuff is appropriate.

Entering Patient Information

👤 Patient information and all monitor setup activities will be completed in Remote Device Connectivity. This data will be stored and distributed by the Central Server. Each VitalPoint Home Monitor is identified by a serial number that is used for each transmission to and from the Central Server. See your *CJPS Medical Systems Remote Device Connectivity User Manual* for more information.

👥 Most setup activities will take place in Remote Device Connectivity. However, in multi-patient mode, patient information can be entered via the monitor interface. See "Main Menu Screen – Multi-Patient Mode" on page 19 for more information. This data will be stored and distributed by the Central Server. Each VitalPoint Home Monitor is identified by a serial number that is used for each transmission to and from the Central Server. This serial number is printed on the back of the monitor.

> **PRECAUTION:**
>
> WHEN CHANGING BETWEEN SINGLE- AND MULTI-PATIENT MODES IN REMOTE DEVICE CONNECTIVITY, ALL DATA STORED IN THE MONITOR MUST BE UPLOADED TO THE CENTRAL SERVER BEFOREHAND. DATA NOT UPLOADED WILL NOT BE LOST IF THE MODE IS CHANGED, HOWEVER, THE MONITOR WILL BE UNABLE TO UPLOAD THE DATA UNTIL IT IS REVERTED TO THE MODE IT WAS IN AND ASSIGNED TO THE SAME PATIENT(S) WHEN THE DATA WAS COLLECTED. SEE THE REMOTE DEVICE CONNECTIVITY USER MANUAL FOR MORE INFORMATION.

SETTING UP

Choosing a Location for the Monitor

Carefully consider the following points when deciding where the VitalPoint Home Monitor should be placed. The location must be:

- Near a power outlet and a phone jack. Extension cords may be used if necessary.
- Flat and stable. A tabletop is a good choice.
- Away from common areas. Avoid areas with a lot of foot traffic to help prevent injury from tripping on cords and to prevent the cords from being disconnected.
- Away from a water source. Avoid areas near sinks, showers, and bathtubs.

Turning the Monitor On

Turn the monitor on by flipping the switch located on the back of the monitor. A green light on the front is lit when the monitor is powered on.

Power Supply

Use only the power supply that came with the VitalPoint Home Monitor. Do not use any other power supply with VitalPoint and do not use the VitalPoint Home Monitor power supply with any other devices.

Connect the AC adapter to the monitor by plugging the round connector into the receptacle on the right side of the monitor. Plug the other end of the AC adapter into an AC power outlet. The green light on the plug indicates proper connection of the adapter.

> **WARNING:**
>
> PROBES AND CABLES ARE DESIGNED FOR USE WITH SPECIFIC MONITORS. VERIFY COMPATIBILITY AND USE ONLY APPROVED ACCESSORIES WITH VITALPOINT. USING NON-APPROVED ACCESSORIES MAY RESULT IN DEGRADED PERFORMANCE, DAMAGE TO THE MONITORING EQUIPMENT, OR IN HARM TO THE PATIENT, AND MAY VOID WARRANTY COVERAGE.

👤 **Sleep Mode**

The monitor should always be turned on while in single-patient mode. In the event the monitor is disabled at Remote Device Connectivity, the monitor will remain on and the screen will display "Monitor in sleep mode."

While in sleep mode, the monitor will continue to dial in to the Central Server at its regularly scheduled intervals. It will only be able to come out of sleep mode when it dials in to the Central Server at its regularly scheduled interval.

Note: When it is known that the monitor will go into sleep mode, the time interval for scheduled call-ins should be reduced. This will minimize the time spent in sleep mode. For information on adjusting the call-in intervals, see "Setup Tasks" on page 14.

Battery Notes

The VitalPoint Home Monitor contains a lithium-ion rechargeable battery. The battery will charge when the monitor is connected to a live wall out-let. An indicator light on the back of the monitor shows that the battery is charging. The monitor can operate on battery power for up to 5 hours. For each hour of battery use, 1 hour of recharge time is needed.

If the battery is no longer holding a charge or the monitor is to be stored for an extended period of time, it is recommended that trained service person-nel remove the battery. For more details, contact the product distributor.

> **PRECAUTION:**
>
> SHOULD THE AC ADAPTER'S GREEN LIGHT NOT REMAIN ON WHILE PLUGGED INTO AN AC OUTLET, REPORT THE PROBLEM TO CJPS MEDICAL SYSTEMS OR AUTHORIZED DISTRIBUTOR AND DISCONTINUE MONITOR USE UNTIL THE PROBLEM CAN BE IDENTIFIED AND CORRECTED.

Phone Connection

The VitalPoint Home Monitor must dial in to the Central Server to download patient information (single-patient mode) and monitor setup data.

Connect the phone line by plugging one end into the receptacle on the right-hand side of the monitor and the other into a wall phone jack.

Note: The monitor must be connected to a standard (single) analog phone line (i.e., fax machine compatible).

The monitor's connection settings must be set up so it can dial in to the Central Server. To set up the monitor, follow these steps:

1. Set up monitor in Remote Device Connectivity. (See *CJPS Medical Systems Remote Device Connectivity User Manual* for more information.) Ensure that the monitor's serial number has been entered into the program correctly and single- or multi-patient mode has been selected.
2. Access the hidden Setup Tasks menu by tapping the screen four times in the upper-right corner. (For more information, see "Setup Tasks" on page 14.)
3. Enter the phone number to be dialed to connect with the Central Server.

   Note: It may be necessary to enter digits required to obtain an outside line on some telephone systems, e.g., a 9, and a slight delay added to the sequence, accomplished by adding a comma, which causes a two-second pause before the number is dialed. Therefore, the number may look like: 9,5550100. More than one comma may be used to create a longer pause, if necessary.

   a. Initial system installation must be performed by an authorized CJPS agent or representative. If you encounter the following message during setup: "A RDC User Name and PIN have not been specified for the Central Server. Please enter a valid RDC User Name and PIN.", contact you local representative for further instructions.

   b. There are 4 symbols included on the Set Phone Number screen (This screen is found from the main menu with 4 taps in upper right hand corner of screen, then select Set Phone Number). These symbols are used when determining proper dialing string and are defined as follows:

   - "Dial Tone" button = wait for dial tone before continuing
   - "Silence" button = wait for quiet answer
   - "Sound" button = wait for calling card "bong" tone.
   - "Pause" button = pause 2 seconds before continuing

   c. For example, the dialing sequence shown below is required when using a calling card from Brazil to the Central Server. Specifically, the required sequence for this particular case is as follows in order to successfully connect:

- Agency A enters "08008900288" for their phone card access number
- Agency A requires a short delay prior to sending phone card access number
- Agency A enters ",,," delay characters necessary so modem will wait until a voice prompt occurs as the voice prompt must occur before the modem should continue dialing (approximately 6 seconds).
- Agency A enters "8009616319$," which instructs the modem to wait for the calling card "bong" sound and then to wait for 2 additional seconds before entering (dialing) the calling card number and PIN.

4. Choose "Dial Central Server Now" from the Setup Tasks menu.

5. If using single-patient mode, verify the patient's name is accurate on the monitor's Main Menu screen. If using multi-patient mode, verify the sign-in screen appears and a patient can be signed in.

It is important to ensure that the information has been properly downloaded from the Central Server. If the patient's name or sign-in screen is not seen on the Main Menu screen (see page 17), the setup process should be retried.

During communication sessions, the monitor will use the phone line. It is important to avoid using the phone during the dial-in session until the confirmation screen appears on the monitor to ensure good communication with the Central Server.

PRECAUTION:
IT IS RECOMMENDED A HEALTHCARE PROFESSIONAL BE PRESENT AND PREPARED TO ASSIST A PATIENT USING A MONITOR IN MULTI-PATIENT MODE.

Installing Peripheral Measurement Devices

BLOOD PRESSURE MONITORING

To begin non-invasive blood pressure monitoring, use the following procedure:

1. To get good quality non-invasive blood pressure measurements, use a cuff that is the appropriate size for the patient.
2. Connect the non-invasive blood pressure cuff hose to the monitor.
3. Follow the instructions on page 29 to complete the measurement.

Note: This device functions according to specifications in the presence of common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.

Note: This device can be used to determine blood pressure over a heart rate range of 30 bpm to 240 bpm.

Checking the Blood Pressure

VitalPoint uses an oscillometric method to measure the patient's blood pressure. In this method, a blood pressure cuff is quickly inflated above the patient's systolic pressure, and then the cuff pressure is slowly released in a series of steps.

At each cuff pressure step, oscillations in the cuff pressure are measured. These oscillations are made by the underlying blood vessels that are pushing on the cuff during the cardiac cycle. From these oscillations, the patient's blood pressure can be derived.

When the measurement is complete, the monitor should display the blood pres- sure. The patient's systolic and diastolic pressures are displayed.

Hypertensive Considerations

For hypertensive patients (e.g., systolic pressure greater than 220 mmHg), it may be necessary to repeat a non-invasive blood pressure measurement if the first attempt is unsuccessful. VitalPoint will "learn" the patient's blood pressure profile from the first attempt, even if it is unsuccessful, and use a higher inflation pressure on a subsequent measurement attempt.

PULSE OXIMETRY MONITORING

Pulse oximetry equipment is calibrated to display functional oxygen saturation. To begin pulse oximetry monitoring, use the following procedure:

1. Select an appropriate sensor.
2. Connect the sensor cable to the SpO_2 connector on the monitor.
3. Follow the instructions on page 32 to complete the measurement.

Checking the Pulse Oximetry Signal
Pulse oximetry monitoring works by shining light of two different wavelengths through the patient's tissues (such as a fingertip) and measuring the absorption of the light by the hemoglobin in the patient's arterial blood. The way the blood absorbs the different wavelengths indicates the amount of oxygen in the blood. Since this amount is constantly changing during each beat of pulse as new blood comes in and old blood returns to the heart, it is also possible to detect a pulse rate from this signal. When the measurement is complete, the monitor should display the blood oxygen saturation level and pulse rate.

PRECAUTION:

READ INSTRUCTIONS PROVIDED WITH THE PULSE OXIMETRY SENSOR TO UNDERSTAND THE BEST APPLICATION TECHNIQUE AND ALL RELEVANT SAFETY INFORMATION.

PRECAUTION:

DO NOT APPLY THE PULSE OXIMETRY SENSOR ON THE SAME LIMB AS THE NON-INVASIVE BLOOD PRESSURE CUFF. DURING BLOOD PRESSURE MEASUREMENTS, THE PERFUSION IS TEMPORARILY REDUCED, WHICH CAN RESULT IN INACCURATE PULSE OXIMETRY READINGS.

PRECAUTION:

BRIGHT LIGHT CAN CREATE PROBLEMS WITH THE PULSE OXIMETRY MEASUREMENTS, RESULTING IN INACCURATE PULSE OXIMETRY READINGS. IF THE SENSOR IS IN A PLACE WHERE IT MAY BE EXPOSED TO BRIGHT LIGHT, COVER THE SENSOR WITH SOME OPAQUE MATERIAL TO BLOCK THE LIGHT.

PRECAUTION:

PULSE OXIMETRY READINGS MAY BE INACCURATE IN THE PRESENCE OF TOO MUCH MOTION OR IF THE PATIENT HAS TREMORS. IF QUESTIONABLE READINGS ARE OBTAINED, RE-CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS BEFORE ADMINISTERING MEDICATION.

TEMPERATURE MONITORING
To begin temperature monitoring, use the following procedure:
1. Connect the temperature probe cable to the monitor.
2. Follow the instructions on page 33 to complete the measurement.

Checking the Temperature
When the measurement is complete, the monitor should display the temperature. The patient's temperature is displayed in both degrees Fahrenheit and degrees Celsius.

GLUCOSE MONITORING
Using the LifeScan OneTouch® Ultra® Blood Glucose Meter
To begin glucose monitoring, use the following procedure:
1. Connect the glucose meter adapter cable to port 2 on the monitor.
2. Connect the glucose meter 9-pin cable to the adapter cable.
3. Connect the glucose meter to the 9-pin cable.
4. Follow the instructions on page 34 to complete the measurement.

For Subsequent Measurements
The patient may take the glucose meter off of the cable for portability. To reattach the meter:
1. Connect the glucose meter to the 9-pin cable.
2. Follow the instructions on page 34 to complete the measurement.

Note: After initial setup of the two cables, these should remain connected to the monitor at all times. Only the glucose meter should be removed and reconnected as needed.

Manual Entry
Glucose levels can also be monitored using other glucose meters. Instead of direct connection to VitalPoint, the user can manually enter glucose level and unit of measurement. The patient should follow the instructions on page 34 for entering glucose level.

Checking Glucose
When the glucose information is entered, the patient will be asked to confirm that the entry is correct.

Note: It is recommended that VitalPoint be used with the LifeScan OneTouch® Ultra® Blood Glucose Meter. If this meter is not used, it is important to remind the patient of the importance of entering the correct information to present an accurate view of the patient's medical record.

WEIGHT MONITORING
To begin weight monitoring, use the following procedure:
1. Connect the weight scale cable to port 3 on the monitor.
2. Follow the instructions on page 36 to complete the measurement.

Checking Weight
When the weight measurement is complete, the monitor should display the patient's weight. The weight is displayed in both pounds and kilograms.

FLUID STATUS MONITORING
To begin fluid status monitoring, use the following procedure:
1. Connect the cable from the fluid status device to port 1 on the monitor.
2. Follow the instructions on page 38 to complete the measurement.

Checking the Fluid Status
When the measurement is complete, the monitor should display the fluid status. The patient's fluid status is displayed in ohms.

PROTHROMBIN TIME MONITORING
The patient should follow the instructions on page 38 for entering a prothrombin time measurement.

ECG MONITORING
Only a clinician or patients instructed by their clinician should perform an ECG measurement. The measurement will report automatically on the monitor.

To begin ECG monitoring, follow the instructions on page 39.

Testing Peripheral Measurement Devices
To test each measurement device, press "Take Measurements" on the main screen and enter each of the measurement options to take a reading. For more information, see "Monitor Maintenance/Cleaning" on page 53.

Note: Any measurements recorded during testing will become a part of the patient's medical record. Please take these test measurements on the patient.

Suggested Discussion Topics With Patient
SINGLE-PATIENT MODE ONLY:
- The monitor should be left on at all times. The patient should always see that the screen is on in their home, whether the monitor is active or in sleep mode. If the monitor is not functioning, the patient should contact the clinician immediately.
- Emphasize the importance of recording the patient's data and not anyone else's to present an accurate view of the medical record. Instruct the patient to not allow others to use the monitor.
- Emphasize the patient should not rely solely on the monitor regarding when to take medications. The patient should consult a physician before taking any prescription or non-prescription medication or changing any medication regimens. VitalPoint is intended as a reminder system only.
- Alert chimes will sound when it is time to perform a scheduled activity. The chime will continue to sound every 5 minutes until the activity is completed. If the activity is not completed within approximately 30 minutes (or a designated amount of time) after the reminder, the monitor will send a message alerting the clinician that the activity has been missed.

SINGLE-AND MULTI-PATIENT MODES:
- VitalPoint is not intended for emergency response. Advise the patient to contact their caregiver, nurse, or doctor; call local emergency number as appropriate; or go to the emergency room whenever they feel the need to do so.
- Emphasize the importance of entering the correct information on the monitor to ensure vital signs are being accurately reported to the clinician.

- The monitor will need to use the phone line for very brief periods to send any reported data to the Central Server. While the monitor is communicating with the Central Server, the screen displays: "Sending Data Now. This may take a few minutes. Please do not use your telephone while the data is sent." Instruct the patient to remain off of the phone while the device is communicating and until the confirmation message is received on the monitor.

IMPORTANT:

The patient should be reminded that in emergency situations, they can interrupt a monitor that is uploading data by turning the monitor off in order to use the phone immediately. No data will be lost.

- The monitor is intended for indoor use only.
- The patient should discuss all medications with their physician.
- Contact the clinician immediately for the following (see "Troubleshooting" on page 58):
    - Activities do not appear or patient name is no longer on the main screen (single-patient mode only)
    - Data is no longer displayed (i.e., the screen is not functioning)
    - Data on the screen is no longer heard (i.e., the speaker is not functioning)
    - Data cannot be input (i.e., the touch screen is not functioning)
    - The device does not start up or does not function
- The patient should never attempt to repair a malfunctioning monitor. All repairs should be completed by trained service personnel. Advise the patient to contact clinician immediately if monitor needs service.
- Accessories such as blood pressure cuffs, temperature probes, and SpO_2 sensors should be disposed of according to manufacturer's instructions on packaging.

SETUP TASKS

The Setup Tasks menu is accessed by tapping the Main Menu screen four times in the upper-right corner, as indicated by the arrow below.

> Hello New Patient
>
> Patient data cannot be collected until Patient ID has been entered

— Tap Here
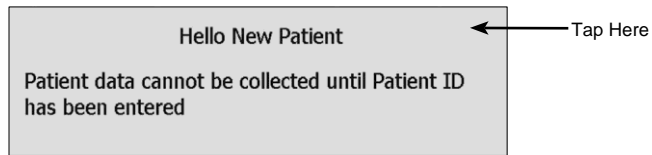
Setup tasks are used to perform additional setup functions, as listed below.

> What would you like to do?
>
> Set Phone Number   Set Speaker Volume
>
> Set Language   Dial Central Server Now
>
> Run Manufacturing Test
>
> Main Menu
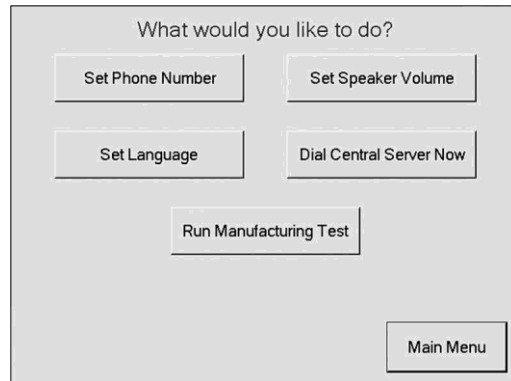
Note: At any time, you may return to the Main Menu screen by pressing "Main Menu" in the lower right corner.

Note: When the user presses "Setup" on the Main Menu screen, the following screen is displayed:

> What would you like to do?
>
> Set Speaker Volume
>
> Dial Central Server Now
>
> Main Menu
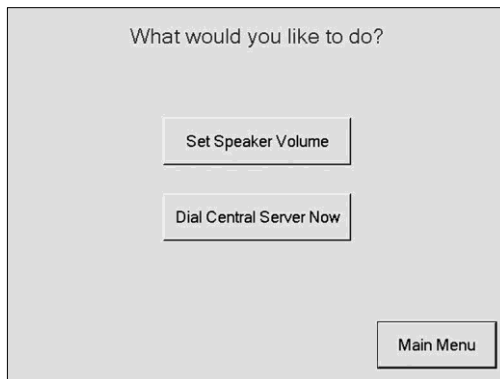
The patient can only adjust speaker volume or dial the Central Server.

Set Phone Number/Monitor Serial Number

This screen allows you to enter the phone number of the Central Server this monitor should call. Using the numeric display, enter the correct phone number, including all necessary preceding digits and area code.

Note: It may be necessary to enter digits required to obtain an outside line on some telephone systems, e.g., a 9, and a slight delay added to the sequence, accomplished by adding a comma, which causes a two-second pause before the number is dialed. Therefore, the number may look like: 9,5550100. More than one comma may be used to create a longer pause, if necessary.

This number can be tested by following the instructions in "Phone Connection" on page 6.

The monitor's serial number is also displayed on this page. The serial number is also printed on the monitor's rear label. The serial number is used to identify each monitor for all transmissions to and from Remote Device Connectivity and may also be requested by CJPS Customer Support.

Set Language

This screen allows you to select the language displayed on the monitor's screen and used in the voice prompts.

Run Manufacturing Test

Manufacturer use only; password required.

Set Speaker Volume

This screen allows you to adjust the monitor's voice prompt volume and alarm volumes.

The voice prompt volume can be set on a scale of 0 (off) to 9 (loudest). Press the desired setting; the monitor will automatically go to the "Set Alarm Volume" screen.

The alarm volume can be set on a scale of 1 (quietest) to 10 (loudest). The alarm volume cannot be turned off for the safety of the patient. Press the desired setting; the monitor will automatically return to the Setup Tasks menu.

Note: It is recommended that the clinician work with the patient to determine the appropriate volume level for the monitor's voice prompt and alarm levels.

Dial Central Server Now

This screen is used to call in to Remote Device Connectivity (Central Server) to upload the initial data to the monitor, to test the connection, or to upload data immediately. Press this button to continue. If the connection is successful, the monitor returns to the Setup Tasks menu, otherwise it will continue to attempt to dial the Central Server every 5 minutes. See "Communication" on page 49.

Note: Using this function on a monitor in single-patient mode will download the latest list of scheduled activities to the monitor. Using this function on a monitor in multi-patient mode will enable the monitor to receive the latest list of patients assigned to that monitor so they may begin entering measurements and symptoms.

Intentionally
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The following instructions should be reviewed with the patient (single-patient mode) or clinician operating the device (multi-patient mode) as appropriate. When the device is being used in single-patient mode, the patient should also be given the *CJPS Medical Systems VitalPoint Home Monitor Patient Guide*, which also outlines this information, and a phone number to call to report any problems or ask questions.

SELECTING OPTIONS

The VitalPoint Home Monitor operates by displaying a set of options that may be selected through the touch screen interface. A voice prompt also reads each option. To select an option on the screen, simply press the button on the screen with your finger.

Note: At any time, you may press "Go Back" to review the previous menu screen or "Main Menu" to return to the Main Menu screen.

MAIN MENU SCREEN – SINGLE-PATIENT MODE

After turning on a monitor set to single-patient mode in Remote Device Connectivity (see the *CJPS Medical Systems Remote Device Connectivity User Manual*), the Main Menu will appear with a personal greeting and the current time.

The Main Menu will also tell the patient if there are activities to do right away.

Hello Jane Doe

You have activities to do now!

Begin Activities

👤 Or lets the patient know when activities are scheduled.

Hello Jane Doe

You have activities to do in

3 hours, 28 minutes

Report Symptoms   Take Measurements

See Nurse's Instructions

Setup

The Main Menu screen includes options to:
• Report symptoms
• Take measurements
• See nurse's instructions

To report symptoms, press "Report Symptoms" and follow the instructions on the screen.

To take measurements, press "Take Measurements" and follow the instructions on the screen.

To check the nurse's instructions, press "See Nurse's Instructions" and follow the instructions on the screen.

Note: This option will not exist if nurse's instructions have not been entered in Remote Device Connectivity.

👥 MAIN MENU SCREEN – MULTI-PATIENT MODE
After turning on a monitor set to multi-patient mode in Remote Device Connectivity (see the *CJPS Medical Systems Remote Device Connectivity User Manual*), the following screen is displayed:

Hello New Patient

Patient data cannot be collected until Patient ID has been entered

Enter Patient ID   Setup

Press "Enter Patient ID" to identify the patient you would like to monitor. (See "Entering an Existing Patient" on page 20 or "Entering a New Patient" on page 23)

Once VitalPoint has identified the patient, the monitor will display the Take Measurements screen. Proceed with taking measurements and symptoms reporting as in single-patient mode. To report symptoms, press "Main Menu" from this screen, then "Report Symptoms."

What measurement would you like to take?

Blood Pressure   Pulse Oximetry   Temperature

Blood Glucose   Protime   Fluid Status

Weight   ECG

Main Menu

Entering an Existing Patient

The Patient Identification screen allows the user to select the "Existing" tab and search for a patient already entered in the system via their patient ID number, date of birth, or name.

Patient Identification
`<<Existing>>` | New

Search existing patient by:

[Patient ID]

[Date of Birth and/or Patient Name]

[Cancel]

To search by patient ID, follow these steps:

1. Press "Patient ID" from the Patient Identification screen.
2. Tap the "Patient ID" field to activate it, then enter the patient's ID number using the alphanumeric keypad.

Patient Identification
`<<Existing>>` | New

Patient ID: [   ]

Keypad:
1 | 2 ABC | 3 DEF
4 GHI | 5 JKL | 6 MNO
7 PQRS | 8 TUV | 9 WXYZ
CLEAR | 0 . , | SPACE

[OK] [Cancel]

3. Press "OK."
4. VitalPoint will match the patient ID with a patient name and display a confirmation screen:

Patient Identification

Please confirm

Patient Name:
JOHN TEST

Patient Date of Birth (m/d/y):
11/11/1918

Patient ID#:
111111

[OK] [Cancel]

5. Press "OK" to begin taking measurements and reporting symptoms for this patient, or press "Cancel" to return to the Main Menu screen.

To search by patient date of birth, follow these steps:

1. Press "Date of Birth and/or Patient Name" from the Patient Identification screen.
2. Tap on the "Month" field to activate it, then use the alphanumeric keypad to enter the month's numeric value (one or two digits, 1-12).

Patient Identification
`<<Existing>>` | New

Enter Patient's Date of Birth:
Month / Day / Year

[Search]

Keypad:
1 | 2 ABC | 3 DEF
4 GHI | 5 JKL | 6 MNO
7 PQRS | 8 TUV | 9 WXYZ
CLEAR | 0 . , | SPACE

and/or Patient Name:
Last Name, First Name
[▼]

[OK] [Cancel]

3. Tap on the "Day" field, then use the alphanumeric keypad to enter the day value (one or two digits, 1-31).
4. Tap on the "Year" field, then use the alphanumeric keypad to enter the four-digit year.
5. Press "Search."

Single-patient mode only   Multi-patient mode only

Single-patient mode only   Multi-patient mode only

6. VitalPoint will display all patients with the designated date of birth in a drop-down menu:

Note: Sample shows just one patient has the designated date of birth; if more than one patient has this date of birth, actual screen will display all those patients.

7. Select the desired patient from the drop-down menu by tapping the name.
8. Confirm the patient selected is correct by pressing "OK" to begin taking measurements and reporting symptoms, or press "Cancel" to return to the Main Menu screen.

To search by patient name, follow these steps:

1. Press "Date of Birth and/or Patient Name" from the Patient Identification screen.
2. Tap on the "Patient Name" field to activate it, then use the alphanumeric keypad to enter the patient's name, last name first, with a comma separating the last and first names.

Note: Entering a fragment of the name (beginning with the first letter) generates a list of names matching the search criteria. Select the desired name by tapping on it.

3. Press "Search."
4. VitalPoint will display all patients with the designated name in a drop-down menu:

Note: Sample shows just one patient has the designated name; if more than one patient has this name, actual screen will display all those patients.

5. Select the desired patient from the drop-down menu by tapping the name.
6. Press "OK" to begin taking measurements and reporting symptoms for this patient, or press "Cancel" to return to the Main Menu screen.

Entering a New Patient
The Patient Identification screen allows the user to select the "New" tab and enter information for a new patient into the system by following these steps:

1. Tap on each field to activate it, then use the alphanumeric keypad to enter the patient's first name, last name, date of birth, and assign a patient ID number.

2. When complete, press "OK." A confirmation screen will appear.

Patient Identification

Please confirm

Patient Name:
TEST,JO
Patient Date of Birth (m/d/y):
1/1/1987
Patient ID#:
411111

OK   Cancel

3. Press "OK" to begin taking measurements and reporting symptoms for this patient, or press "Cancel" to return to the New Patient screen, where the patient's information can be edited or the entry cancelled. (A confirmation screen will appear first.)

REPORTING SYMPTOMS

When "Report Symptoms" is selected, the monitor will display a reminder that this device is not an emergency response system.

If you feel the problem you are reporting is an emergency or requires you to call your nurse, your doctor or 911, please do so.

Please do not rely on the monitor to make this decision for you.

Go Back   Continue

WARNING:

THE VITALPOINT HOME MONITOR IS NOT AN EMERGENCY RESPONSE SYSTEM. THE DEVICE LABELING ADVISES PATIENTS
TO CONTACT THEIR CAREGIVER, NURSE, OR DOCTOR; CALL LOCAL EMERGENCY NUMBER AS APPROPRIATE; OR GO TO THE EMERGENCY ROOM WHENEVER THEY FEEL THE NEED TO DO SO. THE VITALPOINT HOME MONITOR DOES NOT ANALYZE PATIENT INFORMATION, NOR DOES IT OFFER MEDICAL ADVICE.

Press "Continue."

The VitalPoint Home Monitor allows the patient to report symptoms related to:
- Breathing
- Swelling
- Heart
- Stomach/bowel
- Urine
- Wound
- Pain
- General

Within each of the eight main problem categories, the patient can choose from multiple sub-problems to report. While only one problem category can be addressed at a time, the patient will be able to report problems in as many categories as desired as each is completed.

For each sub-problem, the monitor will display a series of questions. As the patient answers each one, the monitor advances to the next screen until all sub-problems have been reported. See "Appendix 1: Report Symptoms Text" on page 63 for a detailed description of each screen and what options the patient will have for each sub-problem.

Once all questions have been answered for each sub-problem to be reported in a problem category, the monitor will ask the patient if there are more problems to report. A "Yes" response will result in a return to the Choose a Problem to Report screen. (If multiple problems are reported using the "report more problems" option, the data will be stored and listed on the Confirming Problems screen.) A "No" response will take the patient to the Confirming Problems screen.

Confirming Problems
You reported the following problems. Is this correct?

Breathing
Swelling

Yes, send the problems to my clinician now

Yes, but I would like to record measurement(s)

No, I would like to report more problems

👤 At the Confirming Problems screen, the monitor will display the problems that have been reported and ask if they are correct. The listed problems include the eight main categories (e.g., "Breathing") and do not include any of the sub-problems.
   • If the reported problems are correct, press "Yes" to send the problems report to the clinician.
   • If the reported problems are incorrect, press "No" to return to the Choose a Problem to Report screen.

👥👥 Once all questions have been answered for each sub-problem to be reported in a category, the monitor will ask the patient if there are more problems to report. A "Yes" response will result in a return to the Choose a Problem to Report screen. (If multiple problems are reported using this option, all data will be stored and listed on the Confirming Problems screen.) A "No" response will take the patient directly to the Confirming Problems screen.

```
┌─────────────────────────────────────────┐
│          Confirming Problems            │
│   You reported the following problems.  │
│          Is this correct?               │
│  ┌──────────────┐  ┌──────────────┐     │
│  │ General      │  │              │     │
│  │ Heart        │  │              │     │
│  │              │  │              │     │
│  │              │  │              │     │
│  └──────────────┘  └──────────────┘     │
│     ┌─────────────────────────────┐     │
│     │ Yes, send the problems to   │     │
│     │ my clinician now            │     │
│     └─────────────────────────────┘     │
│     ┌─────────────────────────────┐     │
│     │ Yes, but I would like to    │     │
│     │ record measurement(s)       │     │
│     └─────────────────────────────┘     │
│     ┌─────────────────────────────┐     │
│     │ No, I would like to report  │     │
│     │ more problems               │     │
│     └─────────────────────────────┘     │
└─────────────────────────────────────────┘
```

At the Confirming Problems screen, the monitor will display the problems that have been reported and ask if they are correct. The listed problems include the eight main categories (e.g., "Breathing") and do not include any of the sub-problems.
   • If the reported problems are correct, press "Yes" to send the problems report to the Central Server immediately.
   • If the reported problems are correct, but the patient has additional measurements to take, press "Yes, but I would like to record measurement(s)" to go to the Take Measurements screen. All data will be sent when sending measurements.
   • If the reported problems are incorrect, press "No" to return to the Choose a Problem to Report screen.

If the patient selects a problem that has already been reported, a warning will appear.
   • If the patient selects "Yes," the prior reported problems in this category will be deleted and the monitor will provide the option to select the sub-problems in this category and answer the selected questions.
   • If the patient selects "No," the monitor will ask if there are more problems to report. A "Yes" response will result in a return to the Choose a Problem to Report screen. A "No" response will take the patient to the Confirming Problems screen.

```
┌─────────────────────────────────────────┐
│   You have already reported problems     │
│    for this category.  Would you like to │
│      change what you have reported?      │
│                                          │
│        ┌───────┐      ┌───────┐          │
│        │  Yes  │      │  No   │          │
│        └───────┘      └───────┘          │
│                                          │
│  ┌─────────┐                             │
│  │ Go Back │                             │
│  └─────────┘                             │
└─────────────────────────────────────────┘
```

TAKING MEASUREMENTS
When "Take Measurements" is pressed, the monitor will provide options as to what will be measured. The VitalPoint Home Monitor allows patients to take the following measurements:

   • Blood pressure
   • Pulse oximetry/pulse rate
   • Temperature
   • Blood glucose
   • Weight
   • ECG (respiration rate)
   • Prothrombin time
   • Fluid status

👤 Single-patient mode only   👥👥 Multi-patient mode only

The monitor displays:

What measurement would you like to take?

Blood Pressure	Pulse Oximetry	Temperature
Blood Glucose	Protime	Fluid Status
Weight	ECG	Main Menu

Note: All accessories necessary to take the required measurements should be installed by the clinician. The patient should not have to install or reinstall the accessories on the device, with the exception of the glucose meter. It is recommended that the patient leave the glucose cables attached and only the glucose meter be detached for transport.

For each measurement, the monitor will provide detailed instructions on how to take each measurement. Information on taking measurements will also be available in the *CJPS Medical Systems VitalPoint Home Monitor Patient Guide*.

After completing the instructions, the patient must press "Take Measurement." A voice prompt will tell the patient: "Please remain still, measurement may take some time." After the measurement is completed, the measurement results will be displayed on the screen.

🧍 After each measurement is completed, the monitor will ask if additional measurements are desired.

Would you like to take additional measurements at this time?

| Yes |
| No, but I would like to REPORT SYMPTOM(S) |
| No |

- If there are additional measurements to take, press "Yes" to return to the Take Measurements screen.
- If there are no additional measurements to take, but there are symptoms to report, press, "No, but I would like to report symptom(s)."
- If there are no additional measurements to take and no symptoms to report, press "No" to send the data to the Central Server immediately.

👥 After each measurement is completed, the monitor will ask if the patient has more measurements to take.

Would you like to take additional measurements at this time?

| Yes |
| No, but I would like to REPORT SYMPTOM(S) |
| No |

- If there are additional measurements to take, press "Yes" to return to the Take Measurements screen.
- If there are no additional measurements to take, but the patient has symptoms to report, press "No, but I would like to report symptom(s)."
- If there are no additional measurements to take and no symptoms to report, press "No" to send the measurement data to the Central Server immediately.

Blood Pressure
The monitor will display the following instructions to apply the cuff and take a blood pressure measurement:
1. Sit down in a chair next to the monitor.
2. Roll up the sleeve on your arm or remove any tight clothing.
3. Slide the cuff onto your arm.
4. Make sure that the bottom edge of the cuff is 1" (2.5 cm) above the crease of your elbow.
5. Make sure that the tubing is on the inside of your elbow.
6. Secure the cuff by using the Velcro® wrap to make the cuff snug, but not too tight.
7. Place your arm, raised to the level of your heart, on a table, remain still and do not talk while your blood pressure is being taken.

The patient must then press the "Take Measurement" button.
When complete, the measurement will be displayed on the screen.

The following errors may occur if the blood pressure cuff is not correctly applied or if there are issues with the blood pressure cuff accessory:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Reapply the cuff and try again	Cuff was not applied correctly to receive a good reading.	• Repeat the measurement. • Instruct the patient how to apply the cuff for a good measurement.
Weak signal; please contact your clinician	This error appears when the pulsations are too small to detect. This may be caused by: • Poor limb perfusion • Improper cuff placement • Cuff size too large for the patient	• Check the patient and provide any necessary clinical care. • Check to make sure the cuff is wrapped properly, with the artery mark (Ø) lined up over the brachial artery. • Check the limb circumference against the recommended range as printed on the cuff, to ensure the cuff is not too large.
Measurement time exceeded; please contact your clinician	The measurement time limit (2 minutes) was exceeded, usually due to motion artifact.	• See suggestions for "Artifact error." • Repeat the measurement.
Please remain still and try again	The patient moved during the measurement.	• Instruct the patient to remain still, with the blood pressure cuff remaining at the same level as the heart.
Artifact error; please contact your clinician	Additional information was gathered during the measurement. This may be caused by: • Persistent patient movement or coughing • Hemodynamic interference (varying pulse amplitudes due to breathing or valvular problem) • Hose is clogged or leaking	• Check the patient and provide any necessary clinical care. • Calm the patient. • Reattach the cuff to another limb with less movement. • If no obvious patient motion, switching to the other limb may still help in the case of hemodynamic interference. • Check the cuff and hose for signs of damage; replace cuff if necessary.

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Cuff leak or hose disconnected; please contact your clinician	The cuff or hose may be damaged or have become disconnected from the monitor. The cuff may not be applied to the patient.	• Check for leaks in the cuff or hose and replace if necessary. • Check that cuff and hose are connected to the monitor. • Check that cuff is applied to patient.
Overpressure; please contact your clinician	Monitor has detected a hardware problem. This could include an overpressure in which the cuff has inflated over 290 mmHg. If the patient tries to take their measurement again, they will receive an additional message: "Disabled due to previous overpressure."	• Check the patient and ensure that the cuff is deflated. • Turn the monitor off, then on. • If message persists, contact the product distributor.
Cannot measure; please contact your clinician	Initial inflation pressure may not have been high enough (if patient's systolic pressure is above 200 mmHg) or the patient may have been moving during the measurement.	• Repeat the measurement (monitor will automatically adjust to using a higher initial inflation pressure if needed). • Check the patient and ensure that the cuff is deflated. • Turn the monitor off, then on. • If message persists, contact the product distributor.
Line blocked; please contact your clinician	The hose may be pinched or kinked.	• Check the patient and ensure that the cuff is deflated. • Check for kinks or obstructions in the hose and replace if necessary.

WARNING:

A BLOCKED OR KINKED HOSE COULD LEAD TO LIMB DAMAGE.

Pulse Oximetry

The monitor will display the following instructions to apply the pulse oximetry sensor and take an oxygen level measurement:

1. Place the finger sensor on your middle or index finger.
2. Fit the sensor as shown.

The patient must then press the "Take Measurement" button. When complete, the blood oxygen saturation level and pulse rate will be displayed on the screen.

Note: Visually inspect the pulse oximetry sensor frequently and follow the cleaning instructions on page 55 as needed.

The following errors may occur if the pulse oximetry sensor is not correctly applied or is not communicating:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Hardware fault; please contact your clinician	Hardware issues may include artifacts, bad sensor placement, or bad SpO2 sensor.	• Check the patient and provide any necessary clinical care. • Calm the patient. • Move the sensor to another finger with less movement. • Replace the SpO2 sensor.
Weak signal; please contact your clinician	The sensor has not been applied correctly to receive a strong signal. Causes may include: • Poor perfusion • Large tissue mass • Nail polish • Bad SpO2 sensor	• Check the patient and provide any necessary clinical care. • Warm the patient's extremities if needed. • Move the sensor to a smaller finger. • Remove any nail polish that may be interfering with the red light. • Replace the SpO2 sensor.
Unplugged; please contact your clinician	The sensor has become disconnected.	• Check to make sure the SpO2 sensor is securely connected to the SpO2 connector on the monitor.

Temperature

The monitor will display the following instructions to use the temperature probe and take a temperature measurement:

1. Put the tip into a new disposable plastic cover, if one is available. If you do not have a plastic cover, clean the pointed end (probe) with soap and warm water or rubbing alcohol. Rinse it with cool water.
2. With your mouth open, put the covered tip under your tongue.
3. Close your lips gently around the temperature probe.

The patient must then press the "Take Measurement" button. The result will be displayed in both degrees Fahrenheit and degrees Celsius.

Note: Visually inspect the temperature probe frequently and follow the cleaning instructions on page 55 as needed.

The following errors may occur if the temperature probe is not used correctly or is not communicating:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Temp too high; please contact your clinician	There is a problem with the connections or with the hardware.	• Check the patient and provide any necessary clinical care. • Check the temperature cable connections. • Turn the monitor off, then on. • If message persists, contact the product distributor.
Hardware fault; please contact your clinician	A hardware problem has been detected.	• Turn the monitor off, then on. • If message persists, contact the product distributor.
Unplugged; please contact your clinician	Temperature probe has become disconnected.	• Check to make sure the temperature cable is connected to the monitor.

Blood Glucose

The blood glucose meter that connects directly to the monitor is the LifeScan OneTouch® Ultra® Blood Glucose Meter. For all other glucose meters, the information from the meter can be entered manually.

PRECAUTION:
FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR USE WHEN USING A GLUCOSE METER AND STRIPS.

The blood glucose level will appear in the same units as programmed on the OneTouch® Ultra® meter.

For manually entered information, the patient will be asked to verify that the glucose level entered is correct. The patient can enter the blood glucose level in mg/dL or mmol/L, depending on personal preference or meter type.

The following errors may occur if the glucose meter is receiving incorrect readings or is not communicating:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Glucose too high; please contact your clinician	Glucose level exceeded range determined by meter manufacturer.	• Check the patient and provide any necessary clinical care. • Check the glucometer cable connections. • Turn the monitor off, then on. • Recheck the glucose level. • If message persists, contact the product distributor.
Glucose too low; please contact your clinician	Glucose level was below range determined by meter manufacturer.	• Check the patient and provide any necessary clinical care. • Check the glucometer cable connections. • Turn the monitor off, then on. • Recheck the glucose level. • If message persists, contact the product distributor.

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
No readings are available; please measure your glucose level and try again	There are no records available in the meter's memory.	• Check the patient and provide any necessary clinical care. • Check the glucometer cable connections. • Turn the monitor off, then on. • Recheck the glucose level. • See glucometer user manual for directions regarding "Coding the Meter" to ensure that the meter has been coded appropriately. • If message persists, contact the product distributor.
Problems communicating with the glucose meter; please contact your clinician	This error occurs when the communication with the meter times out, when there is an invalid checksum, when greater than 150 records are received, or when no records are received.	• Check the glucometer cable connections. • Turn the monitor off, then on. • If message persists, contact the product distributor.

Weight

The monitor will display the following instructions to take a weight measurement:

1. Please make sure you are wearing no clothing or similar light clothing and your shoes are removed.
2. Make sure your bladder is empty.
3. Please do not step onto the scale yet.

   It is very important that there is no weight on the scale when the weight sequence is started. This enables the scale to re-zero itself and become prepared to take the patient's weight.

   Press "Continue."

4. Step on the platform and remain as still as possible without leaning on anything.

The patient must then press the "Take Measurement" button. The weight will appear on the screen in both pounds and kilograms.

The following errors may occur if the scale is not properly reset or the instructions are not followed:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Please step off the scale and try again	The auto-zero process failed. It is important that the scale starts with no weight on it to take a good measurement.	• Instruct the patient to step completely away from the scale. • Recheck weight by having the patient step on the scale. • If message persists, contact the product distributor.
Problems communicating with the scale; please contact your clinician	The scale may be disconnected.	• Check the cable connections to the scale. • Turn the monitor off, then on. • Recheck weight by having the patient step on the scale. • If message persists, contact the product distributor.

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Scale overload or scale was not at zero on power up; please contact your clinician	The scale was overloaded or there was weight on the scale when it was powered up.	• Instruct the patient to step completely away from the scale. • Recheck weight by having the patient step on the scale. • If message persists, contact the product distributor.
Please re-zero the scale and try again; please contact your clinician	The auto-zero process failed. It is important that the scale starts with no weight on it to take a good measurement.	• Instruct the patient to step completely away from the scale. • Recheck weight by having the patient step on the scale. • If message persists, contact the product distributor.
Unable to receive stable weight; please stand still and try again	The patient was moving when standing on the scale.	• Instruct the patient to step away from the scale, then have the patient step back on and remain still. • Check the cable connections to the scale. • Turn the monitor off, then on. • If message persists, contact the product distributor.

Fluid Status

The VitalPoint monitor will display the following diagram and instructions to take a fluid status measurement:
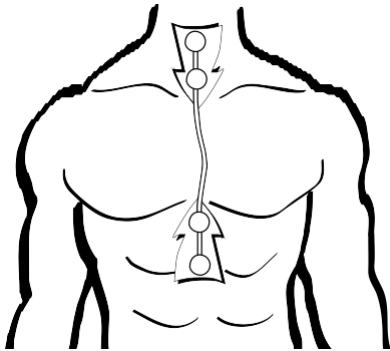
1. Snap the new electrodes to the cable.
2. Place the first electrode just above the top of your breastbone, with the arrow pointing down.
3. Place the second electrode just below the bottom of your breast-bone, with the arrow pointing up.
4. Press the Start button on the fluid status machine.
5. Remain still and do not talk while your fluid status is taken. The measurement may take some time.

The VitalPoint monitor will record and display the data displayed on the fluid status device.

The following error may occur if the fluid status monitor is not correctly applied or is not communicating:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Corrupt input from instrument	Fluid status monitor has sent data that doesn't make sense to VitalPoint.	• Instruct the patient to reconnect fluid status monitor and try again. • If message persists, contact the product distributor.

Prothrombin Time

The patient must enter the reading from the prothrombin meter into the monitor.

The monitor will display the following instructions:

1. Enter your prothrombin time reading.
2. Is this PT (prothrombin time) or INR (internationalized normalized ratio)?
3. Press "Complete" when data is entered.

The following errors may occur if the prothrombin time reading is not correctly entered or is not communicating:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Empty unit field	Patient has attempted to submit a prothrombin time measurement without entering a unit.	• Instruct the patient to enter a corrected unit. • If message persists, contact the product distributor.
Invalid value	Patient has attempted to submit a prothrombin time measurement with an invalid value.	• Instruct the patient to enter a corrected unit. • If message persists, contact the product distributor.

ECG and Heart Rate Monitoring (performed by clinician or patient as directed by clinician)

The ECG monitoring capabilities of the VitalPoint Home Monitor include:

- Displaying four waveforms of ECG
- Displaying respiration rate

To begin monitoring ECG, use the following procedure:

1. *Select and prepare the electrodes.*
   Pregelled, Ag/AgCl disposable electrodes are recommended. Depending on the situation, you may want to use either the short-term (foam-backed) or long-term (cloth-backed) electrodes. Do not use electrodes after their expiration date, or if the gel has dried out.
2. *Prepare the patient's skin for applying the electrodes.*

   Getting a good quality ECG signal depends largely on how good the contact is between the electrodes and the patient's skin. To help assure this, you should first clip or shave any excess hair and remove any skin residue or oils using an alcohol pad. For diaphoretic patients, use a benzoin prep to assure tighter adherence of the electrode.

3. *Apply the electrodes to the patient.*
   Apply the pad by using a circular motion on the adhesive area first, then pressing on the gel area gently to avoid squeezing out the gel. Please refer to the following diagrams for guidance about proper electrode placement. You should change the electrodes every 24-48 hours to maintain a good quality ECG signal.

4. *Connect the ECG cable lead set to the electrodes and to the monitor.*

5. *Press the "Take Measurement" button.*
   After 10 seconds of data is recorded, waveforms will be displayed. As a result of this measurement, the respiration rate will also be displayed.

6. *Accept measurement.*
   In order to send the measurements to the Central Server, they must be verified. On the wave display screen, press the "Accept" button to save the measurement.

STANDARD ELECTRODE PLACEMENT (AHA)
For ECG cable lead sets with AHA (USA) lead designations, position the electrodes as shown in the following diagram:
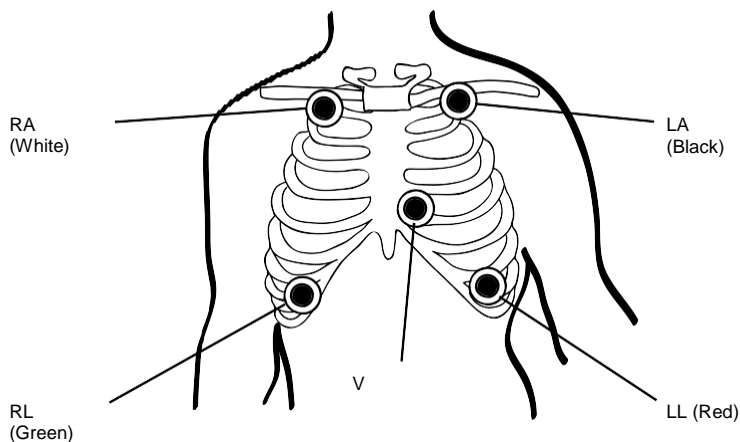
RA
(White)

LA
(Black)

V

RL
(Green)

LL (Red)

1. Position the right arm (RA) electrode on the right mid-clavicular line, directly below the clavicle.
2. Position the left arm (LA) electrode on the left mid-clavicular line, directly below the clavicle.
3. Position the right leg (RL) electrode on the right mid-clavicular line, 6th and 7th intercostal space.
4. Position the left leg (LL) electrode on the left mid-clavicular line, 6th and 7th intercostal space.
5. Position the chest (V) electrode on the 4th intercostal space, left sternal border.

ELECTRODE PLACEMENT FOR PACED PATIENTS (AHA)
For ECG cable lead sets with AHA (USA) lead designations, the optimal electrode placement for patients with pacemakers may be as illustrated in the following diagram:

LA (Black)

RA
(White)

LL (Red)

V

RL
(Green)
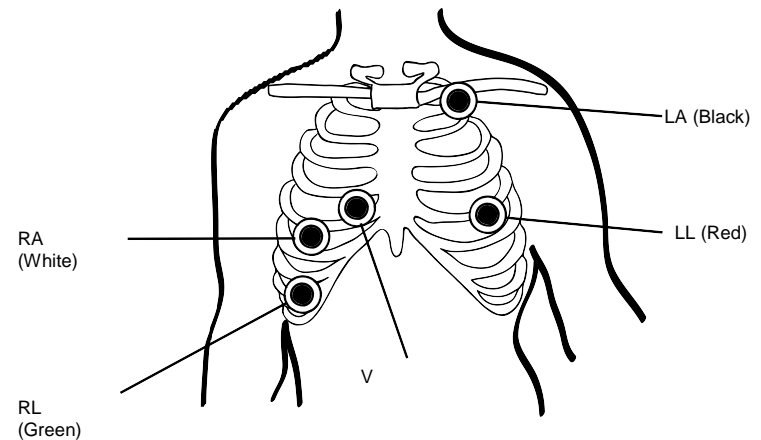
1. Position the right arm (RA) electrode on the right mid-clavicular line, 5th intercostal space.
2. Position the left arm (LA) electrode on the left mid-clavicular line, directly below the clavicle.
3. Position the right leg (RL) electrode on the right mid-clavicular line, 6th and 7th intercostal space.
4. Position the left leg (LL) electrode on the left mid-clavicular line, 5th and 6th intercostal space.
5. Position the chest (V) electrode on the 4th intercostal space, right sternal border.

VERIFYING PROPER PACEMAKER HANDLING

For paced patients, proper electrode placement results in pacer tick marks along the top of each ECG waveform channel on the monitor. These tick marks occur at the point where the monitor detects a pacer pulse.

VitalPoint rejects pacer pulses rather than calling them QRSs. However, it is important to keep paced patients under close surveillance and not to entirely rely on rate meters for these patients (as indicated in the warning at the start of this manual).

CHECKING THE ECG SIGNAL

The ECG electrodes sense the electrical signals generated by the electrical activity of the heart as it beats. The monitor amplifies the signals so they can be displayed on the screen. The monitor uses a 5-lead ECG cable set that allows you to choose from among the following four ECG leads: I, II, III, and V.

When you have connected the patient following the steps listed above, you should be able to see a clean ECG signal on the monitor display. VitalPoint should also be displaying a number for the patient's respiration rate (RR).

Note: Visually inspect the ECG cables on a daily basis and follow the cleaning instructions on page 55 as needed. Also, check for an inoperable ECG circuit, which would manifest itself as a blank ECG waveform and "RR lead off" message.

WARNING:

TO AVOID AN ELECTRICAL SHOCK HAZARD, THE CONDUCTIVE PART OF THE ELECTRODES SHOULD NOT BE ALLOWED TO COME IN CONTACT WITH OTHER CONDUCTIVE OBJECTS, INCLUDING EARTH.

WARNING:

DO NOT INTRODUCE ANY ADDITIONAL PATIENT CONNECTION THAT MAY PRODUCE ELECTRICAL CURRENT. VITALPOINT APPLIES APPROXIMATELY 2 MICROAMPERES (2 µA).

PRECAUTION:

LINE ISOLATION MONITOR TRANSIENTS MAY RESEMBLE ACTUAL CARDIAC WAVEFORMS AND THUS INHIBIT HEART RATE ALARMS. TO AVOID THE RISK OF THIS HAPPENING, FOLLOW THE DIRECTIONS FOR PROPER ELECTRODE PLACEMENTS, AND KEEP THE ECG LEAD WIRES AWAY FROM SOURCES OF LINE NOISE.

PRECAUTION:

TO AVOID LARGE OFFSET POTENTIALS DUE TO POLARIZATION OF ELECTRODES, BE SURE TO USE ONLY ELECTRODE TYPES SPECIFIED FOR THIS DEVICE, AND BE SURE THAT ALL ELECTRODES USED ON A PATIENT ARE OF THE SAME TYPE.

The following errors may occur if the electrodes are not used correctly or if there are issues with the ECG accessories:

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
ECG lead off	Monitor has detected an unplugged cable, broken cable, loose lead wire, faulty lead wire, dried out electrode, or inoperable ECG circuit.	• Check to make sure electrodes are still securely attached to the patient, and reattach if necessary. Remember the importance of good skin preparation techniques. • Check to make sure all the lead wires are still connected to the electrodes. • Check to make sure the lead wires are securely connected to the monitor. • Check to make sure there are no broken lead wires. • Turn the monitor off, then back on. • If message persists, contact the product distributor.

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
ECG sample corrupt	There is a serious issue with the monitor.	• Try to take measurement again. • Turn the monitor off, then back on. contact the product distributor.
ECG artifact error	Could be caused by patient movement or coughing, electrical noise from auxiliary equipment, or bad electrode contact.	• Calm the patient. • Isolate the patient from auxiliary equipment if possible. • Check to make sure electrodes are still securely attached to the patient and reattach if necessary. Remember the importance of good skin preparation techniques. • If message persists, contact the product distributor.
Respiration artifact error	Could be caused by patient movement or coughing, electrical noise from auxiliary equipment, or bad electrode contact.	• Calm the patient. • Isolate the patient from auxiliary equipment if possible. • Check to make sure electrodes are still securely attached to the patient and reattach if necessary. Remember the importance of good skin preparation techniques. • If message persists, contact the product distributor.

Remote Device Connectivity and Monitor Error	Error Explanation	Troubleshooting
Respiration lead off	Monitor has detected an unplugged cable, broken cable, loose lead wire, faulty lead wire, dried out electrode,	• Check to make sure electrodes are still securely attached to the patient and Remember the importance of good skin preparation techniques. • Check to make sure all the lead wires are still connected to the electrodes. • Check to make sure the lead wires are securely connected to the monitor. • Check to make sure there are no broken lead wires. • Turn the monitor off, then back on. • If message persists, contact the product distributor.
Respiration too high	Patient's respiration rate has risen above the current upper alarm limit; or lead placement may be incorrect.	• See suggestions for "artifact error."

ACTIVITIES TO DO

With programming from Remote Device Connectivity, the monitor can notify the patient to perform certain activities at designated times. These activities can include:

- Taking measurements
- Medication reminders
- Nurse's instructions

From a sequencing perspective, the requested activities will follow the sequence of completing measurements, then medication reminders, and then nurse's instructions, as each of these categories is available.

Note: When each activity is completed, the monitor will automatically go to the next scheduled activity on the list.

Take Measurements

For the selected measurements, the patient will be walked through the instructions on each measurement to be taken and asked to take the measurement. Each measurement included in the designated schedule will follow each other directly as the preceding measurement is completed.

Medication Reminder

Medication reminders can be set up in Remote Device Connectivity for each medication on the patient's medication list and includes information about the medication, dose, and frequency. A record of the patient's response will be uploaded to Remote Device Connectivity.

PRECAUTION:

PATIENT SHOULD NOT RELY SOLELY ON THE MONITOR REGARDING WHEN TO TAKE MEDICATIONS. PATIENT SHOULD CONSULT PHYSICIAN BEFORE TAKING ANY PRESCRIPTION OR NON-PRESCRIPTION MEDICATION OR CHANGING ANY MEDICATION REGIMENS. VITALPOINT IS INTENDED AS A REMINDER SYSTEM ONLY.

Medication: aspirin
Dose: 162 mg
1 tab(s) orally
Frequency: once a day

Consult with a physician before taking any prescription or non-prescription medication.

Have you taken your medication?

Yes   No

Please specify the reason for not taking the medication:

I am out of my medication

I am having difficulty taking my medication

I don't want to take the medication right now

The patient will be asked if they took their medication.

- If the patient answers "Yes," the screen will advance to the next activity, if scheduled. The screen will return to the Main Menu after sending the data if no additional activities are scheduled.
- If the patient answers "No," the monitor will ask for the reason why the medication was not taken. After the patient answers this question, the screen will display the next activity, if scheduled. The screen will return to the Main Menu after sending the data if no additional activities are scheduled.

Your clinician will be informed.

Continue

Note: An alert is created in Remote Device Connectivity for each medication non-compliance, including the reason for the non-compliance.

Questions and Answers
Up to three questions with up to three corresponding answers can be set up in Remote Device Connectivity and be scheduled to appear on the monitor as a scheduled activity. After the patient answers a question by tapping on the appropriate response, the screen will display the next question, if applicable, or the next activity, if there is one. The screen will return to the Main Menu after sending the data if no additional activities are scheduled.

Nurse's Instructions
If nurse's instructions are designated to appear with the other reminders, they will appear after all other activities are completed. Nurse's instructions can also be viewed at any time by pressing the "See Nurse's Instructions" button on the Main Menu screen.

These are your Nurse's Instructions:

Please drink 8 glasses of water each day

Main Menu
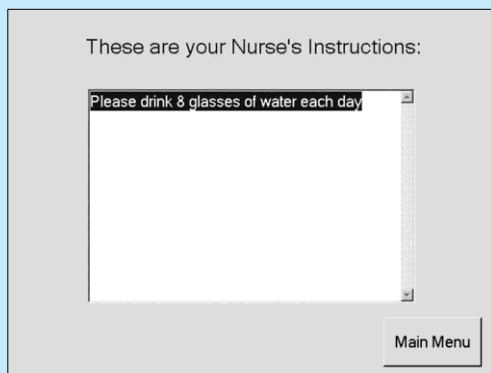
Completing Activities
Once all scheduled activities have been completed and there are no more activities scheduled, the monitor will send the data to the Central Server and display the Sending Data Now screen.

Communication

When the patient chooses to send information after reporting problems, taking measurements, or completing activities, the following message will appear on the monitor:

Sending Data Now.

This may take a few minutes. Please do not use your telephone while the data is sent.
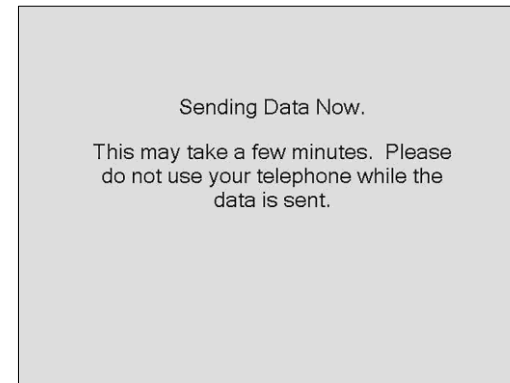
SUCCESSFUL COMMUNICATION WITH THE CENTRAL SERVER
Upon successful communication with the Central Server, the following message will appear:

"Confirmation. Monitor successfully communicated with the Central Server!"

Receipt of this message confirms that the monitor communicated with the Central Server and received confirmation of connection. All data that was sent will reside on the Central Server and will no longer be available on the monitor.

FAILED COMMUNICATION WITH THE CENTRAL SERVER
If the phone line is busy while the monitor is trying to send data, or telephone connection to the server is interrupted for some reason, the following message will appear on the monitor: "The Monitor could not communicate with Central Server. You will be returned to the Main Menu. Monitor will keep trying to dial Central Server about every five minutes." Data will be stored until successful communication is complete.

IMPORTANT:

The patient should be reminded that in emergency situations, they can interrupt a monitor that is uploading data by turning the monitor off in order to use the phone immediately. No data will be lost.

The Monitor could not communicate
with Central Server.

You will be returned to the Main Menu.
Monitor will keep trying to dial Central
Server about every five minutes.

Continue
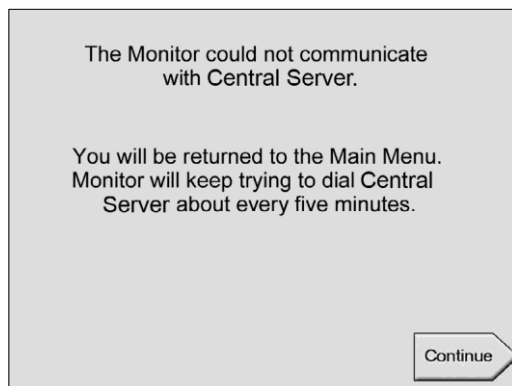
The patient can return to the Main Menu and interact with the monitor as usual. In the background, the monitor will keep trying to dial the Central Server. If it is successful after repeated tries, the successful communication message will appear.

If the monitor continues to not be able to communicate with the Central Server, a new message will appear:

"Monitor has not been able to communicate with the Central Server for a long time. Please contact your clinician for help."

Possible causes for failed communication with the Central Server include:

- Monitor serial number has been entered incorrectly in Remote Device Connectivity. Verify that the serial number has been entered correctly and try again.
- Monitor has been switched from single-patient to multi-patient mode or vice versa without uploading data first. Switch monitor back to previous mode (in Remote Device Connectivity), reassign patient(s) whose data is still in the monitor, and dial-in via the Setup menu to upload data.

See "Troubleshooting" on page 58 for more information.

VERIFYING COMMUNICATION

To check if the monitor has communicated with the Central Server, log in to Remote Device Connectivity and verify the last communication time. See your *CJPS Medical Systems Remote Device Connectivity User Manual* for more information.

The monitor should dial in at least every 8 hours (set through the "Setup Tasks" instructions on page 14). An alert will be generated in Remote Device Connectivity if the monitor does not call in within the designated time period set in Remote Device Connectivity.

If a missed dial-in alert is generated, there could be a problem. The clinician/healthcare provider should call the patient/assistant immediately and follow the steps below:

1. Make sure the device is on.
   - Ask what is displayed on the screen. If the screen is blank, the device might not be on.
   - Check to see if the green light on the right side of the device is on. If not, the device might not be on.
   - Check to make sure the power plug is connected properly to the wall outlet.
   - Check to make sure the power connector is connected properly to the monitor.
2. Check to make sure software is running. Ask what is displayed on the screen.
3. Check to see if the phone jack is properly plugged into the wall jack and into the device.
4. Ask the user to turn the monitor off and then on again.

After completing these steps, hang up and force the monitor to dial the Central Server by using the Setup Tasks menu option "Dial Central Server Now." Check Remote Device Connectivity again in about 5-10 minutes. If no communication has been made, a staff member should be sent to the patient's home or monitor location to conduct the checks above and/or replace the monitor. When replacing a monitor, be sure to have the monitor dial in to the Central Server to verify it communicated successfully and that the patient has been properly set up in the monitor before leaving.

IMPORTANT:

This step should be completed by a clinician; it is not recommended to share the setup menu with patients.

Troubleshooting for Remote Device Connectivity error codes related to the vital signs measurement can be found in "Taking Measurements" on page 27.

Discharging and Preparing for Next Patient

👤 When a patient's certification period for the VitalPoint Home Monitor has ended, collect all of the components for return. Before the monitor is removed from the existing patient's home, force the monitor to dial the Central Server (using the "Setup Tasks" instructions on page 14) to ensure all patient data is recorded. The patient information must also be removed from the monitor. The patient's information is removed by removing the serial number of the monitor from the patient's file in Remote Device Connectivity. Check that the patient has been removed in the same way that a patient is confirmed (see "Phone Connection" on page 6).

Note: If the monitor is removed from a patient's home prior to the end of their certification period entered in Remote Device Connectivity, the end date for that patient needs to be truncated to the date that the monitor was removed from the patient's home.

👥 The most common method to end a patient's session in multi-patient mode is to respond "No" to the question "Would you like to take additional measurement(s) at this time?" or "Yes" to the question "You reported the following problems. Is this correct?" on the respective screens. These selections will automatically send data to the Central Server and return the user to the Main Menu, where a new patient can be entered.

An alternative way to end a patient's session with the monitor (whether data was completed/sent or not), is to select "Enter Patient ID" from the Main Menu to begin the process of exiting the current session. The monitor will display a patient ID confirmation screen. Select "OK" to continue the session, or "Cancel" to end the session. (A confirmation screen will appear; select "OK" to end the session and return to the Patient Identification screen, where a new session can be started for a different patient.)

The monitor can also be forced to dial the Central Server (using the "Setup Tasks" instructions on page 14) to ensure all patient data is recorded.

If a patient will not be participating in any additional sessions, the patient information can be removed from the monitor by removing the serial number of the monitor from the patient's file in Remote Device Connectivity. Verify the patient has been removed by attempting to enter the patient ID as described in "Main Menu Screen – Multi-Patient Mode" on page 19.

Note: If the patient's information is removed from the monitor before the end of their certification period entered in Remote Device Connectivity, the end date for that patient needs to be truncated to the date the information was removed from the monitor.

Monitor

It is recommended that maintenance be performed every six months.

If there is evidence of damage/malfunction at any time, the monitor must be returned to the product distributor.

Check	Action (performed by trained service personnel only)
Device	• Clean as recommended in this section if needed. • Check for cracks, abrasive edges, and other signs of damage.
Labels	• Check for readability or missing labels.
AC adapter cord	• Check the cord and molded connectors for damage.
Power LED	• Verify that the green power LED is illuminated on the front of display when powered on.
Battery charging LED (optional)	• Verify that the green recharging LED is illuminated on the back of the device when connected to a live wall outlet. • Verify that the green recharging LED is not illuminated when disconnected.
Battery	• Connect monitor to a live wall outlet. • Power up the monitor. • Disconnect monitor from wall outlet. • Verify that the monitor continues to run (on battery power).
Speaker	• Using the monitor Setup Tasks menu, adjust the speaker volume and verify that the speaker quality is good at the softest and loudest volume settings.
Touch panel	• Verify that the monitor responds to touch panel presses.
SpO$_2$/pulse rate	• Apply pulse oximeter probe to finger. • Collect SpO$_2$/pulse rate information using the Take Measurements menu. • Verify that the reported pulse rate matches pulse rate as measured on wrist and that the SpO$_2$ rate seems reasonable (about 95% for a healthy non-smoker).

Check	Action (performed by trained service personnel only)
Blood pressure	• Apply the appropriate-sized blood pressure cuff to arm. • Collect blood pressure information using the Take Measurements menu. • Verify that the reported blood pressure is reasonably close in comparison to a manual blood pressure reading.
Scale	• Collect weight information using the Take Measurements menu. • Verify that the reported weight is reasonably close to typical weight.
Temperature	• Collect temperature information using the Take Measurements menu. • Verify that the reported temperature is reasonably close to typical temperature.
ECG/respiration	• Connect ECG leads to patient simulator. • Verify proper heart rate at 30 and 300 bpm (±2 bpm or ±1%) • Verify 1 mV test pulse (lead II). • Verify proper respiration rate at 15 and 120 bpm (±3 bpm).
Prothrombin time	• Consult prothrombin time meter manufacturer's instructions.
Fluid status	• Consult fluid status meter manufacturer's instructions.
Glucose meter	• Consult glucose meter manufacturer's instructions.

EXTERIOR CLEANING

These instructions apply to the VitalPoint monitor, SpO2 cable, NBP cuff, NBP hose, ECG cables, power supply, power cord, and OMD cable. Clean with alcohol or soapy water. Consult manufacturer instructions for information on prothrombin time meters and fluid status monitors.

WARNING:

UNPLUG THE MONITOR BEFORE CLEANING. DO NOT SPRAY CLEANERS INTO THE RECEPTACLES.

PRECAUTION:

DO NOT CLEAN, DISINFECT, OR STERILIZE ANY PART OF THE MONITOR WITH ETHYLENE OXIDE GAS OR BY AUTOCLAVING. THIS MAY DAMAGE THE DEVICE AND WILL VOID THE WARRANTY.

PRECAUTION:

THESE CHEMICALS MAY DAMAGE THE MONITOR'S FRONT PANEL: ACETALDEHYDE, ACETONE, AMMONIA, BENZENE, HYDROXYTOLUENE, METHYLENE CHLORIDE, OR OZONE. DO NOT USE THOSE CHEMICALS OR CLEANSERS CONTAING N-ALKYLDIMETHYLBENZYL- AMMONIUM CHLORIDE.

Before using the monitor, allow at least 1 minute for the cleaning solution to evaporate from the surface.

CLEANING THE SpO2 SENSOR
• Remove the sensor from the monitor
• Wipe off with 70% isopropyl pad
• Allow sensor to dry before placing it on a patient

CLEANING THE TEMPERATURE PROBES
Temperature probes should always be used with the disposable probe covers. Wipe probe with alcohol pads and allow to dry.

CLEANING THE ECG CABLES
• Disconnect the cables from the monitor
• Wipe off with 70% isopropyl pad
• Allow to dry before connecting to patient

DISPOSAL
Accessories such as electrodes, blood pressure cuffs, temperature probes, and SpO2 sensors should be disposed of according to the manufacturer's recommendations.

When the monitor has reached the end of its useful life, it should be disposed of according to all applicable regulations. Note that the monitor contains a lithium-ion battery pack and an electronic circuit board that should not be incinerated or exposed to extreme heat. Contact your local waste disposal agency for guidance on the proper recycling or disposal of these components. Follow your facility's procedures and/or guidelines for disposal.

WARNING:

THE VITALPOINT HOME MONITOR CONTAINS A LITHIUM-ION BATTERY. ONLY TRAINED SERVICE PERSONNEL SHOULD REMOVE OR CHANGE THE BATTERY.

Monitor Maintenance Record

Serial number:

Date	Maintenance Detail

Date	Maintenance Detail

Troubleshooting

Problem	Possible Causes	Troubleshooting
Alert has been generated on the Central Server or the user receives a failed communication message	• Monitor has become disconnected from phone line. • Phone line is not functioning. • Modem is not functioning. • Central Server is not functioning or is offline. • The patient may be using the phone while the device tries to dial in.	• Check that the phone line is connected; test the monitor communication using the Setup Tasks menu. • Instruct the patient on the importance of remaining off of the phone while the monitor is sending data and until the failed communication message is replaced by the confirmation screen. • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Monitor becomes inoperative	• Battery is depleted. • Monitor may be unplugged from the wall outlet. • Power connection to monitor may be loose or unplugged. • Monitor may be turned off. • Monitor has been exposed to liquids or mishandled.	• Check that the monitor is plugged in securely to the wall outlet and LED on back is lit. • Check that the monitor power cable is securely plugged in to the monitor. • Ensure the monitor is powered on and LED on front is lit. • Examine the monitor for damage or exposure to liquids. • If problem persists, contact the product distributor.
Loss of visual data presentation	• Monitor may be turned off or unplugged. • Display may not be functioning.	• See troubleshooting for "Monitor becomes inoperative." • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Loss of audio data presentation	• The volume may be set too low. • The speaker may not be functioning.	• Check the volume settings for the monitor using the Setup Tasks menu. • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Loss of device input	• The touch screen may not be functioning.	• Turn the monitor off, then on. • If problem persists, contact the product distributor.
Device fails to start up	• Monitor may be turned off or unplugged. • Monitor may not be functioning.	• See troubleshooting for "Monitor becomes inoperative." • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Device fails during operation	• Monitor may not be functioning.	• Turn the monitor off, then on • If problem persists, contact the product distributor.
Device becomes unreliable	• Operating system or data files may be corrupted. • Disk is full.	• Ensure that all recorded data has been sent. • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Reminders did not appear as scheduled	• System clock has been set incorrectly. • Reminder time has been set incorrectly. • Unit is turned off. • Unit is in sleep mode.	• Check the setup on Remote Device Connectivity, including the time zone selection and reminder setup. • Check that the monitor is not in sleep mode – the screen should indicate this. • If problem persists, contact the product distributor.
Invalid order has been sent to the patient	• Reminder time has been set incorrectly. • Reminder set up incorrectly.	• Check the reminder setup on Remote Device Connectivity, including the time zone selection. • Check the reminder setup details. • If problem persists, contact the product distributor.
Erroneous data recorded	• Someone other than the patient has used the device. • Patient may be confused about how to use the device.	• Instruct the patient on the importance of not recording anyone else's data to present an accurate view of their medical record. • Retrain the patient on the use of the device.

Problem	Possible Causes	Troubleshooting
Information is not being recorded	• Patient may not be using the device. • Monitor may not be functioning. • Patient may not be aware that activities are due.	• Instruct the patient on the importance of using the device as scheduled to ensure an accurate view of their medical record. • Ensure that the volume and chimes on the monitor are set to the appropriate level for the patient. • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Patient monitor not associated with the patient	Device ID may not be correct in Remote Device Connectivity. • Device may not have communicated with Remote Device Connectivity to receive the patient's information.	• Check the device setup in Remote Device Connectivity to ensure that the device ID is correctly entered for the patient, and there are no spaces before or after the serial number. • Dial in to connect with the Central Server and send the patient's information.
Loss of communication between the monitor and the Central Server	• Monitor has become disconnected from phone line. • Phone line is not functioning. • The patient may be using the phone while the device tries to dial in. • Central Server is not functioning or is offline.	• Check that the phone line is connected; test the monitor communication using the Setup Tasks menu. • Instruct the patient on the importance of remaining off of the phone while the monitor is sending data and until the failed communication message is replaced by the confirmation screen. • Turn the monitor off, then on. • If problem persists, contact the product distributor.
Flash card is corrupted.	Monitor software was interrupted – most likely turned off -- by the caregiver or the patient while it is executing a function, such as: - Sending/receiving data - Taking a measurement - Reporting a symptom - Storing data for transmission later	• Contact customer support because this can only be corrected in factory. • This is not a warranty item, so we strongly recommend that all users be made aware not to turn off or otherwise interrupt the monitor while it is executing a function. • Reminder: The "sending data now" may take several minutes to complete.

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APPENDIX 1: REPORT SYMPTOMS TEXT
When "Report Symptoms" is pressed, the monitor will first display a reminder that this is not an emergency response system:

"If you feel the problem you are reporting is an emergency or requires you to call your nurse, your doctor or 911, please do so. Please do not rely on the monitor to make this decision for you."

After pressing "Continue," the VitalPoint Home Monitor will display a series of options. The monitor allows users to report symptoms related to:
- Breathing
- Swelling
- Heart
- Stomach/bowel
- Urine
- Wound
- Pain
- General

The following pages outline the options that will appear based on user responses.

Note: These options are also communicated audibly to the user. See page 15 for information on changing the volume level.

BREATHING SYMPTOMS

Which of the following breathing problems would you like to report?
(Please select all that apply)
- o Shortness of breath
- o Breathing difficulties
- o Wheezing
- o Coughing

Shortness of breath
Are you experiencing more shortness of breath today than you were yesterday?
- o Yes
- o No

When do you get short of breath?
- o At rest
- o When lying down
- o With mild activity
- o With more tiring activity

Is this shortness of breath unusual for you?
- o Yes
- o No

Breathing difficulties
Did you wake up last night because of breathing difficulties?
- o Yes
- o No

Is it common for you to wake up in the night with breathing difficulties?
- o Yes
- o No

Do you need extra pillows to sleep comfortably?
- o Yes
- o No

How many pillows did you use last night?
- o 1
- o 2
- o 3
- o 4 or more

How many pillows do you normally use?
- o 1
- o 2
- o 3
- o 4 or more

Wheezing
When does your wheezing occur?
- o At rest
- o With mild activity
- o With more tiring activity

How bad is your wheezing?
- o Mild
- o Moderate
- o Severe

Is your wheezing better or worse than before?
- o Better
- o Same
- o Worse

Have you needed to use your inhalers more than usual?
- o Yes
- o No

How many times are you using your inhaler?
- o 0-2 times per day
- o 3-6 times per day
- o More than 6 times per day

Coughing
How would you describe your cough?
- o Dry, hacking
- o Congested without sputum (phlegm)
- o "Rattling," congested with sputum (phlegm)

What color is your sputum (phlegm)?
- o White/Clear
- o Yellow
- o Green
- o Pinkish/Red

Has the amount increased from your usual amount?
- o Yes
- o No

How frequent is your cough?
- o Persistent, all the time
- o Occasional, 3-5 times per day
- o With exertion or activity

When did your cough start?
- o Today
- o Yesterday
- o A few days ago
- o A week ago or more

SWELLING SYMPTOMS

Which of the following swelling problems would you like to report?
(Please select all that apply)
- New swelling
- Shoes feel tighter

New swelling
Where is your swelling? You may mark more than one location.
- Feet
- Ankles
- Hands
- Stomach

How bad is your swelling?
- Mild
- Moderate
- Severe

Shoes feel tighter
Did your shoes feel tighter when you put them on today?
- Yes
- No

HEART SYMPTOMS

Which of the following heart problems would you like to report?
(Please select all that apply)
- Chest pain
- Skipping beats or fluttering
- Beating rapidly or pounding

Chest pain
How would you describe your chest pain or chest discomfort?
- Stabbing, "knife-like"
- Pressure
- Crushing
- Squeezing
- Tightness
- Burning

How would you rate the pain? (options range from 1 to 10)
- 1: Minimal
- 10: Worst imaginable pain

Does your pain spread to other areas?
- Yes
- No

Please indicate the other areas where pain has spread.
You may mark more than one location.
- Jaw
- Neck
- Shoulders
- Back
- Upper arms

When does the chest pain occur?
- At rest
- With mild activity
- With exercise or tiring activity
- When anxious or upset
- After eating a meal
- When exposed to cold weather

Do you take nitroglycerin for chest pain relief?
- Yes
- No

Have you had to take a nitroglycerin pill in the past day?
- Yes
- No

Skipping beats or fluttering
Is your feeling that your heart is skipping beats or fluttering new or unusual?
- Yes
- No

How often does this feeling of skipping beats or fluttering occur?
- Frequently, every day
- Occasionally, a couple of times a week
- Rarely, a couple of times a month

Beating rapidly or pounding
Is your feeling that your heart is beating rapidly or pounding new or unusual?
- Yes
- No

How often does this feeling of beating rapidly or pounding occur?
- Frequently, every day
- Occasionally, a couple of times a week
- Rarely, a couple of times a month

STOMACH/BOWEL SYMPTOMS

Which of the following stomach/bowel problems would you like to report? (Please select all that apply)
- o Loss of appetite
- o Constipation
- o Diarrhea
- o Indigestion
- o Nausea

Loss of appetite
Have you noticed a decrease in appetite recently?
- o Yes
- o No

Constipation
Is constipation a common occurrence for you?
- o Yes
- o No

When was your last bowel movement?
- o Today
- o Yesterday
- o 2-3 days ago
- o 4-5 days ago
- o 6 or more days ago

Is your stool black or bloody?
- o Yes
- o No

Diarrhea
When did the diarrhea start?
- o Today
- o Yesterday
- o 2-3 days ago
- o 4-5 days ago
- o 6 or more days ago

How frequent is the diarrhea?
- o 1-2 times per day
- o 3-4 times per day
- o 5 or more times per day

Is your stool black or bloody?
- o Yes
- o No

Indigestion
Are you experiencing indigestion or stomach upset?
- o Yes
- o No

Nausea
Are you having any nausea today?
- o Yes
- o No

Are you vomiting?
- o Yes
- o No

URINE SYMPTOMS

Which of the following urine problems would you like to report? (Please select all that apply)
- o Frequency/Urgency
- o Burning/Odor
- o Discharge

Frequency/Urgency
Is urinating more frequently or with urgency a new problem?
- o Yes
- o No

Are you unable to hold your urine (incontinent)?
- o Yes
- o No

Have you been thirstier than usual or feel as if you cannot quench your thirst?
- o Yes
- o No

How many times a night do you get up to urinate?
- o 0
- o 1
- o 2
- o 3 or more

Burning/Odor
Have you noticed an odor in your urine?
- o Yes
- o No

Do you have a burning sensation while urinating?
- o Yes
- o No

When did the burning start?
- o Today
- o Yesterday
- o 2-3 days ago
- o A week ago or more
- o I don't know

Discharge

Do you have any discharge in your urine?
- o Yes
- o No

WOUND SYMPTOMS

Which of the following wound problems would you like to report?
(Please select all that apply)
- o Drainage
- o Odor
- o Size/Color
- o Difficulty with care

Drainage
Has the color of the drainage from your wound changed?
- o Yes
- o No

What color is the drainage?
- o White/Clear
- o Yellow
- o Green
- o Pinkish/Red
- o Other

Has the amount of drainage from your wound increased?
- o Yes
- o No

How much of an increase?
- o Small amount
- o Fair amount
- o Large amount

Odor
Have you noticed a change in odor from your wound?
- o Yes
- o No

Size/Color
How would you describe the change to the wound? (Please select all that apply)
- o Larger
- o Smaller
- o Color is pinkish/red
- o Color is white/clear
- o Color is yellow
- o Color is green
- o Color is dark or blackened

Difficulty with care
Are you having difficulty caring for your wound?
- o Yes
- o No

PAIN SYMPTOMS

Which of the following pain problems would you like to report?
(Please select all that apply)
- o Chest
- o Headache
- o Legs/Feet
- o Hands
- o Back
- o Stomach

Chest
How would you describe your chest pain or chest discomfort?
- o Stabbing, "knife-like"
- o Pressure
- o Crushing
- o Squeezing
- o Tightness
- o Burning

How would you rate the pain? (options range from 1 to 10)
- o 1: Minimal
- o 10: Worst imaginable pain

Does your pain spread to other areas?
- o Yes
- o No

Please indicate the other areas where pain has spread.
You may mark more than one location.
- o Jaw
- o Neck
- o Shoulders
- o Back
- o Upper arms

When does the chest pain occur?
- o At rest
- o With mild activity
- o With exercise or tiring activity
- o When anxious or upset
- o After eating a meal
- o When exposed to cold weather

Do you take nitroglycerin for chest pain relief?
- o Yes
- o No

Have you had to take a nitroglycerin pill in the past day?
- o Yes
- o No

Headache
Does your headache feel any different from a normal headache?
- o Yes
- o No

Do you have any vision changes such as blurred vision or any numbness or tingling?
- o Yes
- o No

How would you describe your headache?
- o Throbbing
- o Pressure
- o Stabbing
- o Dull
- o Sharp

How would you rate your headache? (options range from 1 to 10)
- o 1: Minimal
- o 10: Worst imaginable pain

Have you taken any pain medication for your headache?
- o Yes
- o No
- o I don't know

Are you getting any relief from the pain with the medication?
- o Yes
- o No
- o Somewhat

Legs/Feet
How would you describe the pain in your leg(s) or feet?
- o Sharp, "knife-like"
- o Throbbing
- o Aching
- o Cramping
- o Tingling/Numbness

How would you rate your pain? (options range from 1 to 10)
- o 1: Minimal
- o 10: Worst imaginable pain

Are you taking any pain medication?
- o Yes
- o No
- o I don't know

Are you getting pain relief with the medication?
- o Yes
- o No
- o Somewhat

Hands
How would you describe the pain in your hand(s)?
- o Throbbing
- o Aching
- o Stabbing, "knife-like"
- o Tingling/Numbness

How would you rate your pain? (options range from 1 to 10)
- o 1: Minimal
- o 10: Worst imaginable pain

Are you taking any medication for your pain?
- o Yes
- o No
- o I don't know

Are you getting pain relief with the medication?
- o Yes
- o No
- o Somewhat

Back
Is your back pain new for you?
- o Yes
- o No

How would you describe your back pain?
- o Throbbing
- o Aching
- o Stabbing, "knife-like"
- o Tingling/Numbness

How would you rate your pain? (options range from 1 to 10)
- o 1: Minimal
- o 10: Worst imaginable pain

Does the pain radiate down your leg(s)?
- o Yes
- o No

Do you have any numbness or tingling down your leg(s)?
- o Yes
- o No

Are you taking any medication for your back pain?
- o Yes
- o No
- o I don't know

Are you getting pain relief with the medication?
- o Yes
- o No
- o Somewhat

Stomach
When did the pain in your stomach or abdomen start?
- o Today
- o Yesterday
- o 2-3 days ago
- o 4 or more days ago
- o I don't remember

How would you describe your pain?
- o Cramping
- o Burning
- o Stabbing, "knife-like"
- o Other

How would you rate your pain? (options range from 1 to 10)
- o 1: Minimal
- o 10: Worst imaginable pain

Are you taking any medication for your pain?
- o Yes
- o No
- o I don't know

Are you getting pain relief with the medication?
- o Yes
- o No
- o Somewhat

GENERAL SYMPTOMS

Which of the following general problems would you like to report?
(Please select all that apply)
- o Tiredness
- o Weakness
- o Dizziness

Tiredness
Are you more tired and unable to do routine activities (like cooking, dressing, bathing) today?
- o Yes
- o No

Is your tiredness a new symptom in the last day or so?
- o Yes
- o No

Weakness
Have you felt weak in the past day or so?
- o Yes
- o No

Dizziness
Have you felt any new dizziness in the past day or so?
- o Yes
- o No

When is your dizziness occurring?
- o At rest
- o Upon standing up
- o With activity
- o All the time

APPENDIX 2: SPECIFICATIONS
GENERAL

Dimensions: 11.3" W x 7.2" H x 2.4" D (288 mm x 182 mm x 60 mm)

Weight: 4.5 lb (2.0 Kg)

Power requirements: 100–240 V AC, 0.7 A max; suitable for connection to the public mains

Mains frequency range: 50–60 Hz

Power consumption: 12 W nominal, 24 W (when charging battery)

Patient risk current (AAMI ES1-1993): Electromedical apparatus with isolated patient connection. Meets the following limits: Enclosure Risk Current < 100 µA; Patient-applied Risk Current < 10 µA; Patient Isolation Risk Current < 50 µA; Earth Risk Current < 500 µA

Type of protection (Electrical): Class II

Degree of protection (Electrical): Type CF

Degree of protection (Water): Ordinary equipment (IPX0)

Mode of operation: Continuous

BATTERY

Type: Lithium-ion rechargeable

Discharging time: 4 hours (minimum), 5 hours (typical)

Charging time: 5 hours

Charging method: Battery is charged while monitor is connected to the mains supply

ENVIRONMENTAL

Cooling: Convection (no fan)

Operating temperature: 59°F to 95°F (15°C to 35°C)

Storage temperature: -4°F to 122°F (-20°C to 50°C)

Operating humidity: > 30% to < 90% non-condensing

Storage humidity: > 10% to < 95% non-condensing

Operating altitude: 0 to 9842' (0 to 3000 m)

Storage altitude: 0 to 39,370' (0 to 12,000 m)

DISPLAY

Type: Active matrix LCD

Area: 6.7" x 5.1" (8.4" diagonal), 171 mm x 130 mm (213 mm diagonal)

Matrix: 640 x 480 pixels

Pixel dimension: 0.089 mm x 0.27 mm

ECG

Accessories: 5-lead cable

Input connector: 7-pin connector

Displayable leads: 5-lead cable: I, II, III, V

Lead-off detector: 3 V DC signal with current < 2 μA signal applied to patient to detect a lead-off condition

HR resolution: 1 bpm (beat per minute)

Measurement range: 15–300 bpm

Measurement accuracy: ±2 bpm or ±1%, whichever is greater

Response time: Step change from 80 to 120 bpm: < 7 seconds; step change from 80 to 40 bpm: < 11 seconds; per AAMI EC13-2002 4.1.2.1(f), response time is measured from the onset of the first QRS at the new rate to the time the measurement reads a value that is the original rate plus 63% of the change

Notch filter frequency: 50 Hz, 60 Hz, Off

Monitor bandwidth: 0.4 Hz to 50 Hz (-3 dB)

Dynamic range AC: ±20 mV

Dynamic range DC: ±300 mV

Electrode impedance: > 2.5 Mohm at 10 Hz

Defibrillation protection: Complies with IEC 60601-2-27

Pacemaker pulse detection: Lead II

Pacemaker pulse rejection: Rejects all pulses of amplitude ±2 mV to ±700 mV and duration 0.1 to 2 ms with no tail, per AAMI EC13-2002 4.1.4.1; rejects all pulses of amplitude ±2 mV to ±700 mV and
duration 0.1 to 2 ms with 10 ms time constant tail of < 2 mV, per AAMI EC13-2002 4.1.4.2 (Method A);
AAMI EC13-2002 4.1.4.3: 1.54 v/s

Tall T-wave rejection: Rejects all T-waves less than or equal to 120% of a 1 mV QRS and a Q-T interval of 350 ms, per AAMI EC13-2002 4.1.2.1(c)

HR response to irregular rhythm: HR is 82 bpm for a bigeminy rhythm consisting of 0.51 and 0.96 second RR intervals, HR is 76 to 82 for a trigeminy rhythm consisting of 0.51, 0.81, and 0.96 second RR intervals, HR is 76 to 80 for a frequent multifocal rhythm consisting of 0.63, 0.65, 0.75, 0.95, and 1.03 second RR intervals

Active noise suppression: RL drive (< 500 nA)

RESPIRATION

Method: Impedance Pneumography

Input connector: Same as ECG

Sensing lead: Lead II

RR resolution: 1 bpm (breath per minute)

Measurement range: 2–120 bpm

Measurement accuracy: ±3 bpm

Measurement sensitivity: 0.25 ohms (minimum)

Bandwidth: 0.17 Hz to 3.3 Hz (-3 dB)

Impedance measuring current: 40 μA @ 28 kHz square wave across lead II

PULSE OXIMETRY

Method: Absorption – Spectrophotometric (dual wavelength), (Functional oxygen saturation of arterial hemoglobin)

Input connector: 9-pin connector

SpO_2/PR resolution: SpO_2: 1 O_2%; PR: 1 bpm (beat per minute)

Measurement range: SpO_2: 20–100%; PR: 30–240 bpm

Measurement accuracy: SpO_2: from 70–100%: ±2% (O_2%), < 70%: unspecified PR: ±5%

Peak wavelength range: 660 nm ±3 nm 3 mW
Note: Wavelength range can be especially useful to clinicians.

Max optical output power of the light emitted by the SpO_2 probe: 895 ±8 nm 4 mW

Raw data sampling rate: 50 times per second

Data update period from acquisition to display: 20 seconds

Data averaging and signal processing: Sampling requires three valid consecutive heart-beats. System displays the average of the last 12 readings, discarding the two lowest and two highest readings.
> – 30 bpm, the 12 sample average spans 24 seconds
> – 240 bpm, the 12 sample average spans 3 seconds

Functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor unless there is an independent demonstration that a particular calibration curve is accurate for the combination of the pulse oximeter probe and monitor. The functional test can then measure how accurately a particular pulse oximeter monitor is reproducing the calibration curve.

Pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within the $+A_{rms}$ of the value measured by a co-oximeter.

TEMPERATURE

Input connector: 2-pin connector

Display units: °F and °C (user-selectable)

Measurement resolution: 0.2°F (0.11°C)

Measurement range: 32.0°F to 122.0°F (0.0°C to 50.0°C)

Measurement accuracy: ±0.1°F (±0.1°C) plus probe tolerance

NON-INVASIVE BLOOD PRESSURE

Method: Oscillometric

Input connector: Single lumen hose (quick-disconnect fitting)

Cuff: Pediatric, Regular adult, Large adult, Extra-Large/Thigh

Derived parameters: Systolic, mean, diastolic

Resolution: 1 mmHg

Measurement range: Systolic: 30 to 250 mmHg; Mean: 20 to 230 mmHg; Diastolic: 10 to 210 mmHg

Measurement accuracy: Systolic: ±5 mmHg (s < 8 mmHg); Mean: ±5 mmHg (s < 8 mmHg); Diastolic: ±5 mmHg (s < 8 mmHg)

Pulse rate range: 30–240 bpm

Pulse rate accuracy: ±5% or ±2 bpm, whichever is greater

Update interval: Upon measurement completion

Measurement time: 30 seconds (typical), < 135 seconds (maximum)

Initial cuff pressure: 160 mmHg (user-selectable)

Repeated cuff pressure: Previous systolic + 40 mmHg

Static cuff pressure accuracy: ±3 mmHg

Overpressure cutoff: 290 ± 3 mmHg (normal means), 300 ± 30 mmHg (back-up)

Measurement modes: Single measurement

APPENDIX 3: TECHNICAL INFORMATION
Electromagnetic Compatibility (EMC) Information
Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Portable and mobile radio-frequency (RF) communications equipment can affect devices such as the VitalPoint Home Monitor. As such, the monitor should not be used adjacent to other equipment. If this is not practical, then observe the monitor to make sure it is operating properly after installation.

PRECAUTION:
USE OF ACCESSORIES NOT APPROVED FOR USE WITH THE VITALPOINT HOME MONITOR MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE VITALPOINT HOME MONITOR. REFER TO THE APPROVED ACCESSORIES LIST FOR THE VITALPOINT HOME MONITOR.

Guidance and manufacturer's declaration: electromagnetic emissions
The VitalPoint Home Monitor is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment/guidance
RF emissions CISPR 11	Group 1	The monitor 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	The monitor 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 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration: electromagnetic immunity
The VitalPoint Home Monitor is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 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	<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 monitor user requires continued operation during power mains interruptions, the monitor should be powered from an uninterruptible power supply or a fully charged battery. If the supply mains is interrupted for more than 30 seconds, the monitor will operate on battery power.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration: electromagnetic immunity (cont.)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
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 VitalPoint Home Monitor, including cables, than the recommended separation
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:

$d = 1.2 \sqrt{P}$

$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 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.

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:

[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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the monitor.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the VitalPoint Home Monitor

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

Rated maximum output power of transmitter (W)	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

Warranty

CJPS Medical Systems warrants all monitors and accessory products ("Products") to be free of defects in material and workmanship, subject to the following conditions:

THE DURATION OF CJPS MEDICAL SYSTEMS' WARRANTY IS LIMITED TO ONE (1) YEAR FROM THE DATE OF SALE TO PURCHASER FOR MONITORS (INCLUDING BATTERIES) AND ACCESSORIES.

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