biomedical systems
35 YEARS OF ROCK SOLID PERFORMANCE

PHYSICIAN'S OPERATION MANUAL

TruVue Mobile Telemetry

Outpatient Cardiac ECG Monitoring

Biomedical Systems
77 Progress Parkway
Saint Louis, MO 63043
www.biomedsys.com
314-576-6800 Toll Free 1-800-877-6334

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

NOTE: *This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

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

Sensor FCC ID: YCVBRSA01
Handheld FCC ID: YCVBRHA01

NOTICE:
Changes or modifications made to this equipment not expressly approved by Biomedical Systems may void the FCC authorization to operate this equipment.

Radiofrequency radiation exposure Information:

For body worn operation, this phone has been tested and meets the FCC RF exposure guidelines when used with the Biomedical Systems accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

USA contact:
Biomedical Systems
77 Progress Pakway
Saint Louis, MO 63043
(314) 576-6800
(800) 877-6334
Fax:

TABLE OF CONTENTS

TABLE OF CONTENTS

TruVue Indications for Use

Indications for Use:

The TruVue System is intended for use by patients who experience or are suspected of transient events that may suggest cardiac arrhythmia

Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)

Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)

Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring

ECG data recorded by the device can be analyzed by other processing systems, such as the BMS Century Holter system to provide Holter style reports

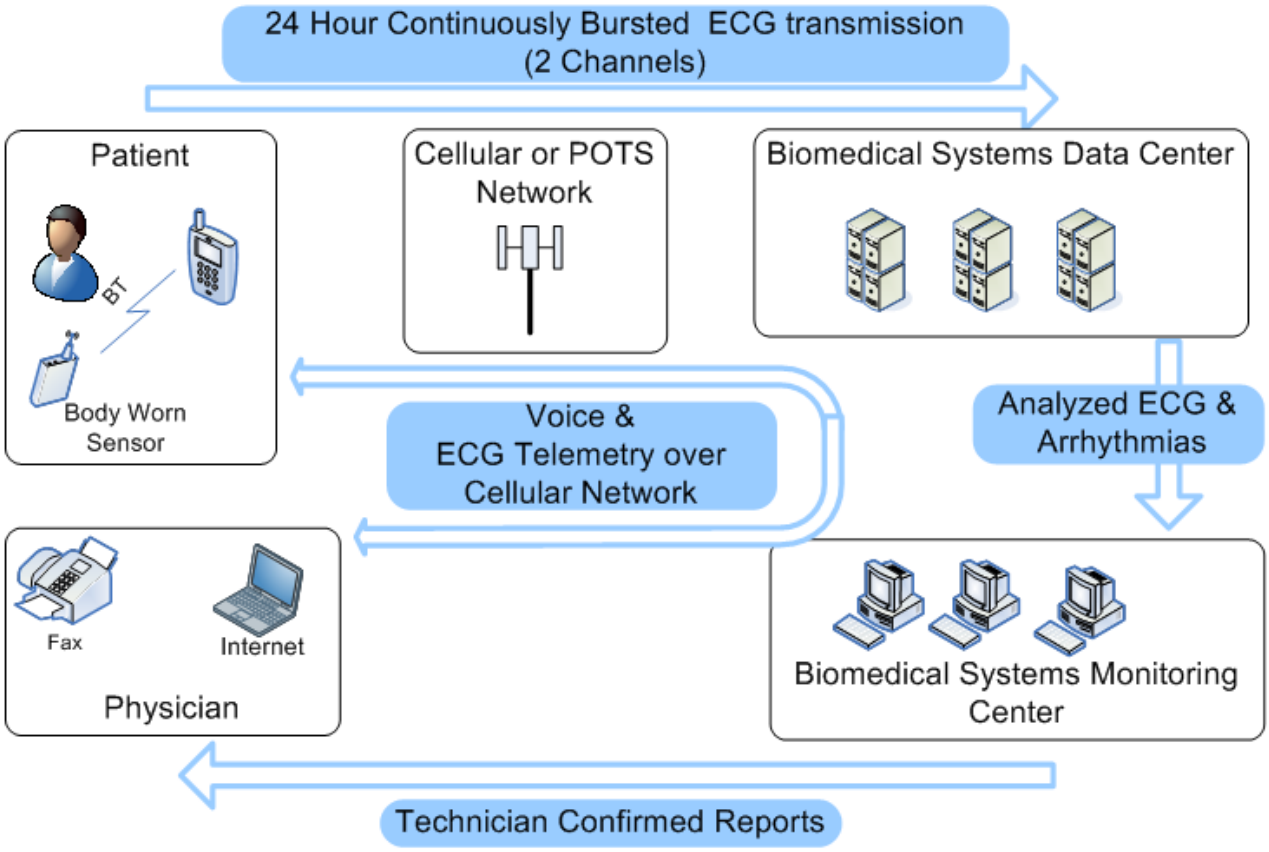
Contraindications

The TruVue System is contraindicated for those patients requiring attended, In-hospital monitoring for life threatening arrhythmias.

Note: The TruVue system does not provide interpretative statements. Interpretation and clinical diagnosis is the responsibility of the physician.

System Overview

The TruVue system is a wireless ECG analysis and monitoring system used for the diagnosis of cardiac arrhythmia in ambulatory patients. ECG data is acquired at the patient on a body worn sensor, stored and then transmitted to a data center through a handheld device carried with the patient. No action is required by the patient to transmit ECG data. At the data center, all ECG is stored and then analyzed for arrhythmia. Portions of the ECG containing arrhythmic events are transmitted to monitoring center for human confirmation before being compiled into a report and transmitted to the physician. The system also allows for real time 2-way communications of voice and data between the patient and the monitoring center or physician.

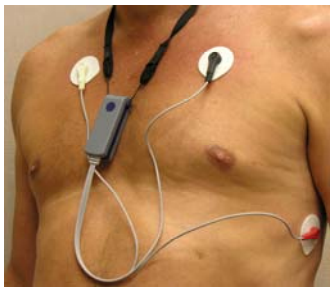


CAUTION: The TruVue system is not an emergency response device. The patient should call 911 and/or their local emergency medical service if they feel they are having a medical emergency.

Patient Devices

The patient devices consist of a body worn Sensor, a Handheld device that provides communication and the patient user interface, and a charger for the Handheld. A modem can optionally be supplied for those patients who lack cellular coverage in their homes.

TruVue Sensor



Applied Sensor

TruVue Handheld

The sensor acquires and stores 2 channels of full disclosure ECG data covering the entire monitoring period (up to 30 days). While acquiring ECG data, the sensor also continuously burst transmits the full disclosure data to the handheld over a radio link with a range up to approximately 30 feet.

The handheld continuously burst transmits the full disclosure ECG data over the cellular network to the 24/7 attended BMS monitoring center, where the ECG is analyzed. Any detected arrhythmias are confirmed by our certified monitoring technicians before being reported to the physician.

If the patient is symptomatic, they can enter their symptoms on the handheld. These symptoms are immediately transmitted to the monitoring center for review and correlation with the ECG data.

Text messages and voice calls can be placed to the patient handheld any time the device is in cellular coverage. Real time ECG can also be streamed from the patient device on request.

Data and Monitoring Center

Full disclosure ECG data transmitted from the handheld is stored in the BMS monitoring center, where arrhythmia analysis algorithms analyze for:

- Pause / Asystole
- Tachycardia
- Bradycardia
- Atrial Fibrillation
- Idioventricular Rhythms
- Supraventricular tachycardia
- Ventricular tachycardia and runs
- Ventricular Fibrillation

When one the above arrhythmias is detected, a certified monitoring technician confirms the arrhythmia and prepares and annotates a sample to be included on a physician report. A report is sent immediately to the physician if the arrhythmia meets the immediate report criteria specified for the patient, or sent on a daily summary report per the physicians orders.

A daily summary report is prepared per the prescribing physicians preference that can include:

- 24 hour HR Trend graph
- Atrial Fibrillation burden for 24 hours or covering the entire monitoring period
- Samples of any arrhythmias detected in the last 24 hours ,or normal ECG samples at the high and low HR for the day if there were no arrhythmias

Reports can be faxed, mailed, and/or viewed and printed online. Prior to printing your patients report, you may enter any comments or interpretations on the report.

The Truvue system allows you to view your patients monitoring record at any time, including all reports, samples and full disclosure ECG data since the inception of the monitoring period.

TruVue Service Overview

Ordering TruVue

The TruVue Mobile Telemetry system is provided as a service by Biomedical Systems. There is no need for the physician to manage an inventory of devices in the office.

- You may elect to enroll your patients online through Global Cardio, fax your order, or call us with the patient information.

NOTE: To place an order for your patient, call 1-800-000-0000. To fax your order, our fax number is 1-800-000-0000. If you wish to enroll your patients through the Global Cardio system, you will need the software installed in your office and user access set-up. If you do not currently have Global Cardio software on your office PC's, call Biomedical Systems to arrange set-up at 1-800-000-0000.

NOTE: When ordering TruVue for your patients, all physician orders require the following information to be provided to Biomedical Systems:

- Patient first, last, and middle initial
- Patient date of birth and social security number
- Patient demographics (primary address, telephone number, cell phone number, etc.)
- Patient primary and secondary insurance information (ID #, group #, address, telephone #)

On receipt of an order for the TruVue service Biomedical Systems will:

A) Confirm the insurance coverage for the patient.
B) Contact the patient and confirm the delivery address for the device kit
C) Configure the device for your patient and ship the device kit and all consumables required for the entire monitoring period.

Please discuss with your patients:

- Reason for ordering mobile telemetry
- Importance of proper hook-up and securing electrodes to skin
- Change sensor battery every 24-hours and charge handheld unit during times of sleep
- Anticipated monitoring time
- Instruct them to go to the nearest emergency room or call 911 in the event of a life-threatening Emergency

In addition to discussing the above with your patient, we encourage you to provide the patient with contact information for Biomedical Systems.

TruVue Service Overview

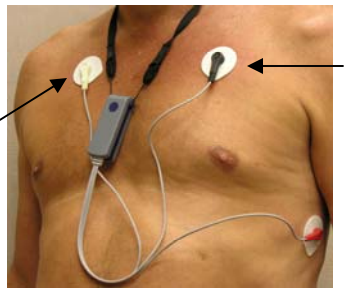
Initiating Monitoring

When the patient receives the device kit, Biomedical Systems will perform the hook up and verify the proper operation of the system. Our certified monitoring technicians will:

A) Confirm the identify of the patient
B) Review proper device operation with the patient.
C) Instruct the patient on the proper application of electrodes and hook up the patient
D) Take a baseline recording and verify proper operation of the device
E) Notify you that the patient is on service.

Electrode Site Preparation and the Proper Positioning

White Electrode (RA)



Black Electrodes (LA)

Red Electrode (LL)

Figure 1

CAUTION: Shave any hair that is in the area the electrodes are placed.

1. Shave area where electrodes (sticky patches) will be placed (if applicable). Wipe each area with alcohol in a circular motion and let dry. (*See Figure 1 for electrode placement*).

2. Remove the sensor (*See Figure 3*) from the box. Snap each lead wire onto an electrode. (*See Figure 2*)

3. Remove backing from the electrode attached to the black snap and place it on the left side of your upper chest just below your clavicle as shown in *Figure 1*.

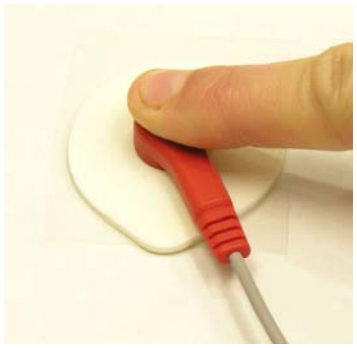


Figure 2

4. Remove backing from the electrode attached to the red snap and place it on the lower left portion of your chest as shown in *Figure 1*.

5. Remove backing from the electrode attached to the white snap and place it on the right side of your upper chest just below your clavicle as shown in *Figure 1*.

CAUTION: Press firmly all around electrode patches to secure them firmly to skin.

Concluding Monitoring

When the end-monitoring arrives Biomedical Systems will contact the patient and arrange for the device to be returned to BMS. Our monitoring staff will prepare a summary report for your review.

If you reach a diagnosis for your patient prior to the end-monitoring date or wish to extend the monitoring period past the date simply inform Biomedical Systems monitoring center.

Breaks in Monitoring

The monitoring period can be suspended and resumed later if the patient requires a hospitalization or a break in service for any other reason , such as out of the country travel. During a monitoring break you will not receive any daily reports.

Sensor Operation

ECG Acquisition and Storage
The Sensor acquires two channels of ECG through a three or four wire shielded cable connected to standard Holter monitoring electrodes. Standard leads II and III of the Einthoven triangle are sampled at 1000 samples per second (SPS) with +/- 40 mV of dynamic range with .05 to 150 Hz band pass. The data is then filtered and down sampled to 250 (SPS) before being stored on the sensor. The sensor retains up to 30 days of ECG data. ECG data is stored with the patient ID and an error detecting code.

ECG Transmission
The Sensor transmits the acquired ECG data to the handheld over an encrypted Bluetooth link with a range of approximately 10 meters. The range of this link can vary depending in environmental factors. If the sensor goes out of range of the handheld the patient will be alerted. The handheld and sensor are paired together prior to providing the kit to the patient and will only communicate with each other. Neither the sensor or handheld will communicate with other devices (they are "non-discoverable" and "non-connectable" per the Bluetooth specification). The ECG is protected from data corruption by an error detecting code that "travels" with ECG data throughout the TruVue system, ensuring that no corruption of the data occurs during transmission to and storage at the monitoring center.

The Sensor can be placed in "airplane mode" through the handheld user interface. This turns off all radios so the patient can continue to collect ECG data (but not transmit it to the handheld) in areas where wireless devices are not allowed. The stored ECG is transmitted to the monitoring center when the radios are turned back on. If the radios are turned off when the handheld is powered up the patient is prompted to turn them on again.

User Interface
The Sensor will alert the patient with a speaker tone (or vibration if selected by the patient) and a flashing led when the battery is low, if a lead falls off, or if the sensor is out of range of the handheld. The patient can silence an alert temporarily by using the large pushbutton on the sensor if they choose.

Algorithm
When communications between the Handheld and the BMS data center are interrupted for any reason the sensor runs a rhythm detector that detects potential significant arrhythmias that have a high heart rate or ventricular rhythm. If a potential arrhythmia is detected then an alert is presented to the patient that instructs them to move to an area with cellular coverage or closer to the modem so the ECG data can be transmitted to the data center for analysis and confirmation of the rhythm.

Powering the sensor
The sensor is powered by inserting the battery in the battery compartment. It is always on—there is no separated on/off switch. The patient replaces the battery in the sensor once a day with a standard AAA Alkaline battery

Sensor Operation

Leadset
The lead wires are permanently attached to the sensor hardware and are not user replaceable.

CAUTION: Do not attempt to remove the lead wires from the sensor.

CAUTION: Inspect the leadwires for any fraying and/or cracking in the insulation prior to use.

Note: BMS will perform this check before providing the equipment to the patient.

Lanyard
A lanyard (neck cord) is attached to the sensor for the convenience of the patient and to prevent the sensor and lead wires from dangling. The lanyard can be removed from the sensor if desired

Battery
The sensor is powered by a 1.5V AAA alkaline battery. 1.5V "advanced lithium" or "Oxyride" batteries can also be used to extend the battery life of the sensor, as long as are rated at 1.5 Volts.

CAUTION: Use only AAA alkaline batteries, or the batteries provided with the patient kit, in the sensor. Do not use rechargeable batteries.

CAUTION: Do not store sensor with the battery in place for extended periods of time. Remove the battery after each monitoring period

Cleaning
The sensor may be cleaned with Isopropyl Alcohol. Do not submerse the sensor in any liquid.

Sensor Operation

Handling precautions:
To ensure proper operation of the sensor please follow these handling precautions

CAUTION: Do not drop the sensor or handheld unit.
CAUTION: Do not pull or yank on the sensor lead wires
CAUTION: Do not expose sensor or handheld to excessive dust or to extreme temperatures
CAUTION: Do not immerse or otherwise allow any liquid to enter the sensor or handheld.
CAUTION: Do not store the sensor or handheld either unit in direct sunlight or near corrosive liquids

When Showering or Bathing

- Remove lead wires attached to sensor from the electrodes (patches).
- Place sensor (attached to lanyard) in a dry secure place.

CAUTION: Do not allow sensor to get wet.

- Remove electrodes (patches) from skin even if they have already been changed in past 24 hours.
- After showering or bathing, dry skin thoroughly. **Do not apply powder or lotion of any kind to chest area.**
- Wipe skin with alcohol in area where electrodes (patches) will be placed. Replace electrodes (patches) as previously instructed

Sensor Performance Specifications

Standards
The sensor complies with the following medical device standards:
-AAMI EC 38-1998, Ambulatory Electrocardiographs.
-EN60601 -1 Medical electrical equipment, Part 1: General requirements for safety
-EN60601 -1 Medical electrical equipment, Part 1-2: Electromagnetic compatibility

Sensor Performance Specifications

Parameter	Notes	Min.	Typ.	Max.	Unit
Physical:					
Length			3.1		in.
Width			1		in.
Thickness			.8		in.
Weight	With AAA Battery		60		gm
ECG Cable Lengths	Dual channel 3 electrode and Dual channel 4 electrode.		18		in

Parameter	Test Conditions	Min.	Typ.	Max.	Unit
Environmental:	Complies with AAMI-EC38 and EN60601 -1				
Operating Temperature		0		45	˚C
Storage Temperature		-10		60	˚C
Relative Humidity		10		95	%
Shock - Unpackaged Unit		36			in.
Water Resistance	Not Water Resistant				

Sensor Performance Specifications—Continued

Parameter	Test Conditions	Min.	Typ.	Max.	Unit
Electrical:	Complies with AAMI-EC38 and EN60601 -1				
Battery Voltage	1 x AAA Alkalines Eveready E92 or Equivalent	0.9	1.5	3.0	Volts
Battery Current	At 1.5V Battery Voltage, all circuits turned on			400	mA
Lithium Battery Voltage	Lithium-Ion Battery Not User Replaceable	2.0		3.1	Volts
VREF Voltage Reference		1.22	1.25	1.30	Volts
VREFAD Voltage Reference		2.45	2.55	2.60	Volts
Input Impedance	@ 5 Hz	1.0	1.5	1.6	MW
CMRR	@ 60 Hz	86			dB
CMR Range	AC + DC	-1.5		+1.5	Volts
Differential Range	AC DC + 80 mV AC @ 5 Hz	-40 -500		+40 +500	mV mV
Fast Baseline Reset – 3db Frequency	After Removing Overloading Signal	0.45	0.5	0.55	Hz
Bandwidth	+ 1 dB - 3 dB referenced to 15 Hz	0.05		150	Hz
Low Pass Filter Gain	@ 250 Hz	-18		-17	dB
Pacemaker Pulse Detection:	1usec max pulse rise and fall times				
Pacemaker Pulse Width		0.2		2.5	msec
Pacemaker Pulse Amplitude		1.0		250	mV
Communications					
Frequency	Bluetooth Class III		2.1		gHz
Communications Protocol	Bluetooth SPP Profile, non discoverable		2.2		Ver
Output power			0		dB
User interface	Complies with AAMI-EC38 and EN60601 -1				
Pushbutton	Used for silencing alerts				
LED	For device alerts				
Speaker	For device alerts		400-2500		Hz

Handheld Operation

Communications
The Handheld communicates with the sensor over an encrypted Bluetooth link with a range of approximately 10 meters. The range of this link can vary depending in environmental factors. If the sensor and handheld lose communication the patient will be alerted.

The Handheld transmits ECG data to the BMS data center over the cellular network. Transmissions are bursted with a maximum latency of 2.5 minutes when the Handheld is in coverage on the network. When out of coverage of either the cellular network or the optional modem, the handheld commands the sensor to run the potential arrhythmia detector algorithm (described under the Sensor Operation section)

The Handheld also can transmit data to the BMS data center over a optional modem attached to the patients home phone line. The handheld communicates with the modem over an encrypted Bluetooth link with a range of approximately 100 feet, allowing a single modem to provide coverage for the typical residence.

ECG data is transmitted to data center without modification and is protected from corruption by an error detecting code embedded in the ECG data.

Text messages can be sent from the BMS monitoring center for display on the patients handheld device.

The Handheld can also receive a voice call from the monitoring center in the event that monitoring staff wishes to speak with the patient and they cannot be reached at their regular phone numbers. Only the monitoring center can initiate a voice call, the handheld will only accept incoming calls from the monitoring center, and the patient cannot initiate an outgoing call. The Handheld can operate as a speakerphone when desired by the patient.

CAUTION: The handheld is a cellular phone. Follow your implantable device manufacturers recommendations on the use of the cellular phones with your implant.

Handheld Operation

Powering the handheld
The handheld is powered by an internal rechargeable LiIon battery. The on/off button is located on the right side of the unit and the handheld is powered on by pressing and holding the power button for approximately 5 seconds. The provided wall charger charges the battery. The handheld can be powered on whenever the wall charger is attached, regardless of whether the battery is depleted or not.

The handheld battery will typically power the handheld 16 hours without recharging. The patient should leave the handheld attached to the wall charger while they are sleeping.

CAUTION: Do not attempt to replace the handheld battery.

CAUTION: Use only supplied wall charger with the handheld.

Cleaning
The handheld may be cleaned with Isopropyl Alcohol. Do not submerse the handheld in any liquid.

Handling precautions:
To ensure proper operation of the handheld please follow these handling precautions

CAUTION: Do not drop the handheld unit.
CAUTION: Do not expose sensor or handheld to excessive dust or to extreme temperatures
CAUTION: Do not immerse or otherwise allow any liquid to enter the sensor or handheld.
CAUTION: Do not store the sensor or handheld either unit in direct sunlight or near corrosive liquids

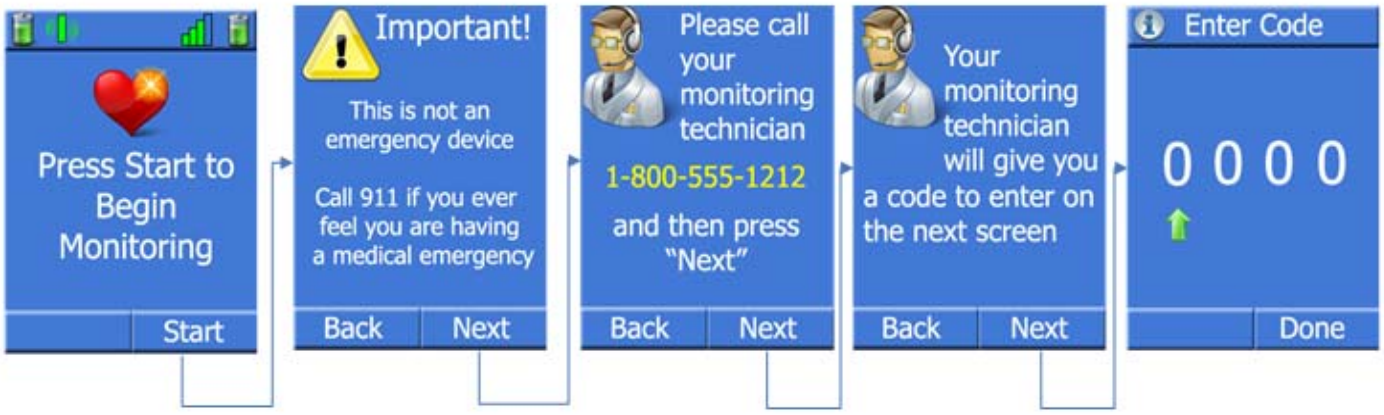
TruVue Handheld Operation

User Interface
A graphical user interface is incorporated for display of messages to the patient, input of symptoms and control of the system. A 5-way set of navigation keys and two soft keys are used to navigate the user interface. An Led is provided to indicate the status of the device when it is on and to indicate the charging status indication when the unit is off . The handheld incorporates a loudspeaker and vibrator for alerting the patient.

Operating modes

The TruVue device kit operates in two primary modes—monitoring and pre-monitoring. The unit is provided to the patient in pre- monitoring mode and is activated into monitoring mode by a BMS monitoring technician during the hook-up call from the patient. In pre-monitoring mode the patient kit does not record, store or transmit ECG data.

User Interface in Pre-monitoring mode
When the patient receives the unit and turns it on they will proceed the following sets of screens that instruct the patient to call the BMS monitoring center for the hook-up call:

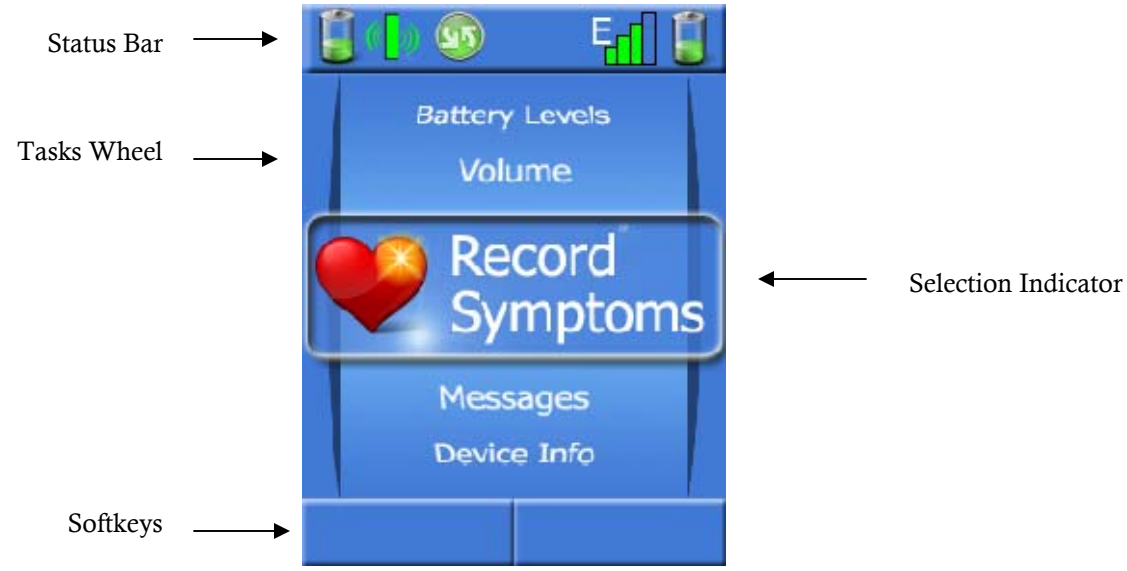


During the hook-up call, the BMS monitoring center technician will perform the hook-up (see "Initiating Monitoring" in the "TruVue Service Overview" section) and provide the patient with a code the enables the transition of the unit into monitoring mode. At this point the devices are actively monitoring the patient.

User Interface in Monitoring Mode

Main screen

The main screen is the top level screen for the user interface and is displayed when the device is turned on and whenever the LCD wakes up from power saving mode. It consists of the status bar, the tasks panel and softkey area. The status bar displays various indicators of device operation. The task panels scrolls using the up and down arrow keys and allows the patient to select various tasks to perform by selecting the center key. The softkey area contains two indicators that change depending on what state or screen the device is on.

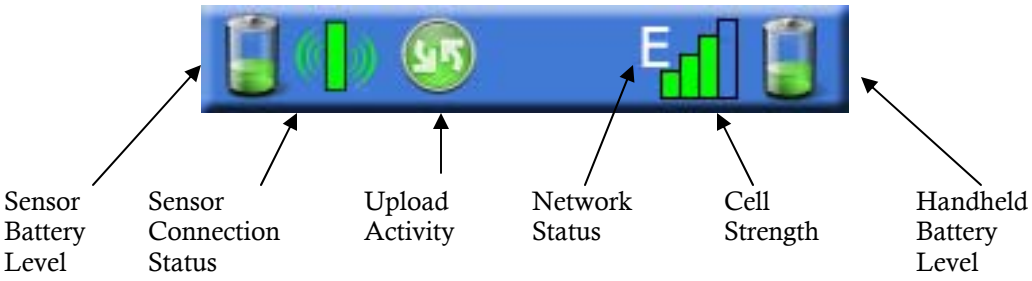


Task Wheel Options

Record symptoms and activity level	Read text messages from the monitoring center	Turn on or off wireless radios. Place the device in "flight mode"	View large battery level indicators for the handheld and sensor	Adjust the speaker volume and vibrator for both the sensor and handheld	View device information such as serial number, SW version levels, etc

User Interface in Monitoring Mode

Status Bar Indicators

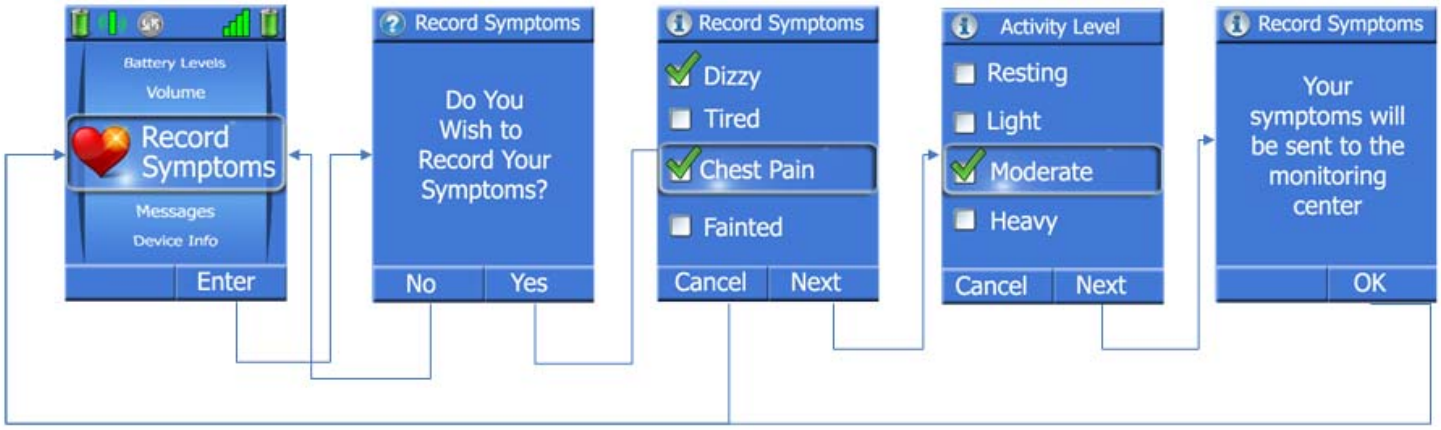


Full	Connected	Uploading	4 Bars	Full
			3 Bars	2/3
			2 Bars	1/3
Empty			1 bar	Empty
Absent or Unknown			No Bars, connected	Absent or Unknown
			Off	Charging

User Interface in Monitoring Mode

Record Symptoms Screens

Pressing the center key when the task wheel is on the Record Symptoms task allows the patient to enter both their current symptoms and their current activity level. This information is uploaded to the monitoring center and is available for correlation with the patients ECG at the time they recorded the symptoms.

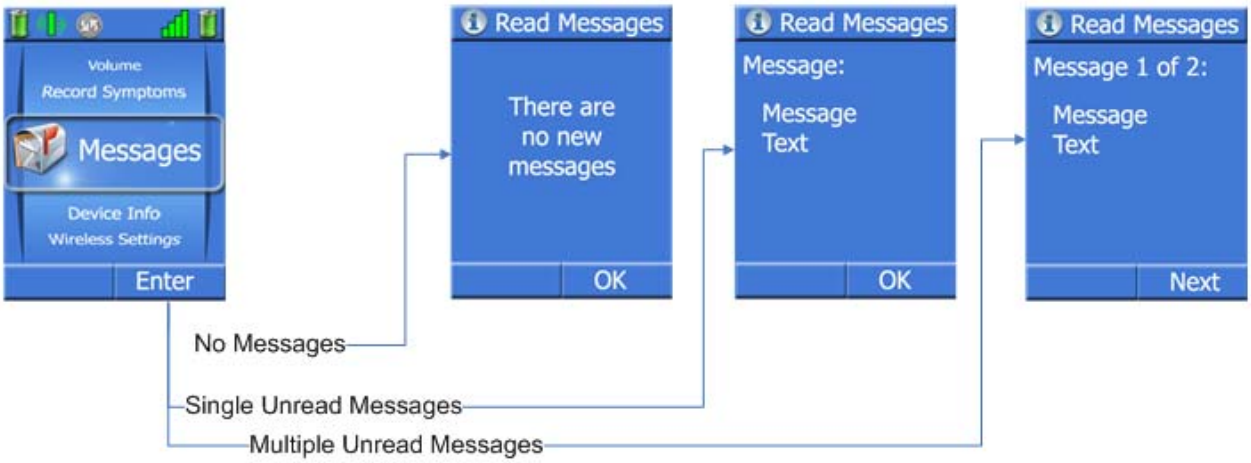


Messages Screen

Pressing the center key when the task wheel is on the Messages task allows the patient to read text messages sent from the center. Messages can be entered through GlobalCardio. The indicator on the main screen changes to indicate that there are unread messages waiting. Messages are deleted from the handheld once read


Unread message waiting


All messages have been read



User Interface in Monitoring Mode

Wireless Settings Screens

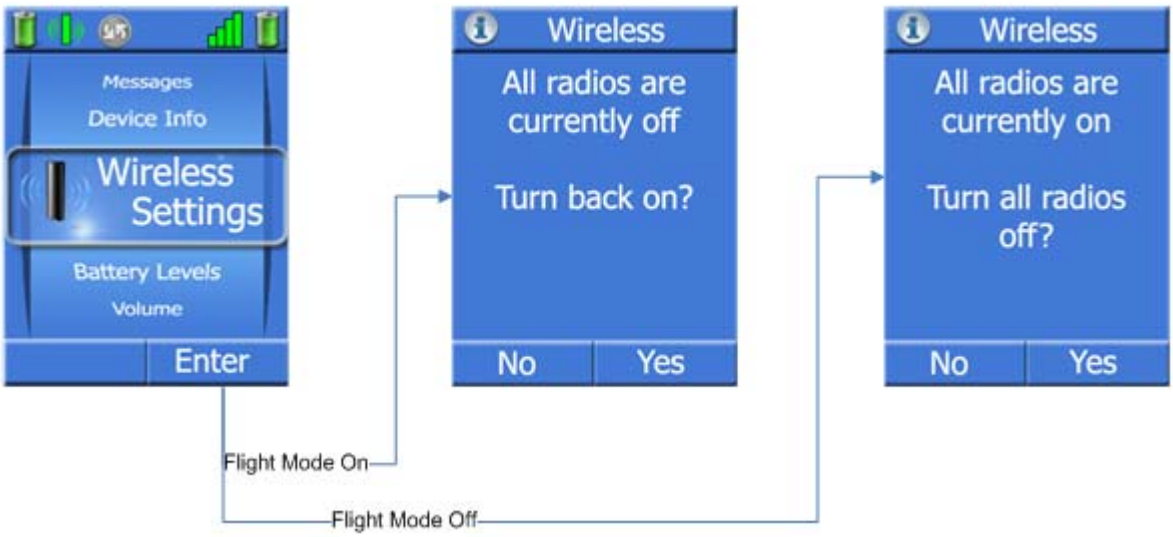
Pressing the center key when the task wheel is on the Wireless Settings task allows the patient to enter turn off all wireless radios in the system for a time. This is a useful feature if the patient is on an airplane or in some other area where cellular phones are not allowed. The sensor will continue to record all ECG data while the handheld radio is off.

When the radios are turned back on, all stored data will be transmitted to the monitoring center.

When the device is turned back on, the user is always prompted to turn on the radios if the handheld is on flight mode.

The user is also prompted every two hours to turn the radios on through an alert message.

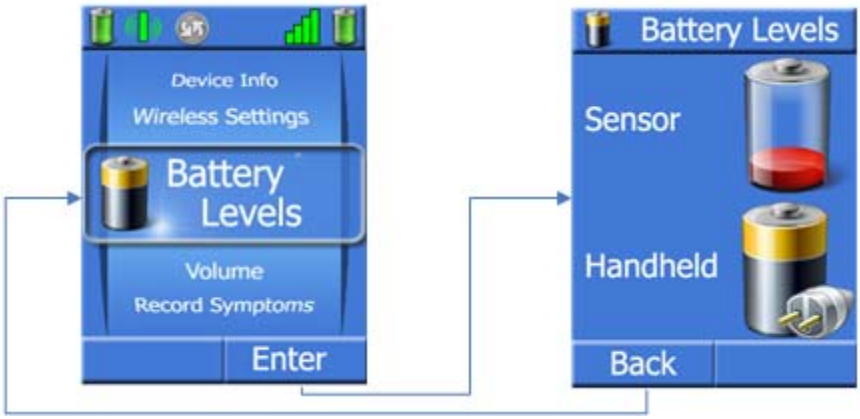
The potential arrhythmia detection algorithm does not run when the device is in flight mode, since it is assumed that the patient is unable to transmit any data due to their physical location.



User Interface in Monitoring Mode

Battery Level Screen

Pressing the center key when the task wheel is on the Battery Levels task allows the patient to view the large battery level indicators.



Volume Screen

Pressing the center key when the task wheel is on the Volume task allows the patient to set the volume and vibrate levels on the handheld and sensor. The sensor volume can only be set when the sensor is connected to the handheld. To set to vibrate only, the volume slider is moved to 0 and the vibrate indicator is automatically checked. Vibration can also be selected in addition to volume.

User Interface in Monitoring Mode

Device Info Screen
Pressing the center key when the task wheel is on the Device Info task allows the patient to view the following device information

- Handheld Serial Number
- Paired Sensor Serial Number
- Patient ID
- Handheld SW Version
- Sensor SW Version
- Wireless Setting (Normal or Off)

Handheld Performance Specifications

Standards
The handheld complies with the following medical device standards:
-AAMI EC 38-1998, Ambulatory Electrocardiographs.
-EN60601 -1 Medical electrical equipment, Part 1: General requirements for safety
-EN60601 -1 Medical electrical equipment, Part 1-2: Electromagnetic compatibility

Handheld Performance Specifications

Parameter	Notes	Min.	Typ.	Max.	Unit
Physical:					
Length			5		in.
Width			2.25		in.
Thickness			.8		in.
Weight			150		gm

User interface					
Display	240X320 QVGA OLED				
Keypad	5 way navigation + 2 softkeys				
Receiver / microphone	For voice call				
Loudspeaker	For device alerts				

Environmental:	Complies with AAMI-EC38 and EN60601 -1				
Operating Temperature		0		45	˚C
Storage Temperature		-10		60	˚C
Relative Humidity		10		95	%
Shock – Unpackaged Unit	Per AAMI-EC38	36			in.
Shock – Packaged Unit	Per AAMI-EC38				
Water Resistance	IPX 0				

Handheld Performance Specifications—Continued

Parameter					
Lithium Battery Voltage	Lithium-Ion Battery Not User Replaceable		4.2		Volts
Lithium Battery Current				1	Amp
Charger	EN60601 Approved direct plug-in Class II AC adapter power supply rated 100-240V~ Globtek Model GTM41076-0605	100		240	Volts

Communications					
Cellular	EGSM/GPRS/EGPRS 900/1800/850/1900 MHz				
Bluetooth	Bluetooth Class I				
Communications Protocol	Bluetooth SPP and DUN Profile, non discoverable		2.2		Ver

TruVue Algorithm Operation

Algorithm Operation and Performance Specifications

Serious Arrhythmia

The TruVue arrhythmia detection algorithm continuously process ECG transmitted from the patient deices and detects the following rate and rhythm based arrhythmias:

Tachycardia	Bradycardia	Pause/Asystole
Atrial Fibrillation	Idioventricular rhythm	Supraventricular tachycardia
Ventricular tachycardia	Ventricular Fibrillation	

When an arrhythmia is detected, it is flagged for immediate review by a BMS certified cardiac technician. The technician confirms the arrhythmia and prepares a report for immediate transmission if the arrhythmia meets the Serious Arrhythmia criteria specified by the physician.

Representative Samples, Trend and Arrhythmia Burden

Once per day, the TruVue algorithm scans all the entire ECG record transmitted from the patient and collates representative samples, HR trend information and Arrhythmia burden information and presents this information the monitoring center staff for review and transmission on the daily report. This information is also available for review at any time in GlobalCardio.

Representative samples are a set of samples that represent the patient's condition for that day. The algorithm identifies the following samples:

1. If no arrhythmia occurred, the algorithm identifies the lowest noise, highest heart rate and lowest noise, lowest heart rate samples

2. If arrhythmias did occur, for each serious arrhythmia class defined above the algorithm identifies the most serious, lowest noise sample.

The HR trend graph presents the patient HR represented as a moving average over every 6 beats

The arrhythmia burden graph presents the amount of time the patient was in Atrial Fibrillation with 10 minute resolution. If the patient was in Atrial Fibrillation for over 30 seconds during any 10 minute period then that period is marked as AF. This graph can selectably be presented for the current day or for the entire monitoring period to date.

Serious Arrhythmia Criteria

Any technician confirmed serious arrhythmia will be transmitted immediately to the physician on a serious arrhythmia report by the physicians preferred method of transmission.

The default criteria are:

Arrhythmia	Default Criteria	Criteria range
Pause/Asystole	> 3 seconds	2-5 seconds
Bradycardia	< 40 bpm	20-50 bpm
Tachycardia	> 180 bpm	120-220 bpm
Supraventricular tachycardia	>150bpm,>30 sec	100-200 bpm, 5-60 sec
Ventricular tachycardia	Rate: > 110 bpm (3 or more beats)	Rate: 80-150bpm Beats: 3-10
Idioventricular Rhythm	>30 beats	5-50 beats
Ventricular Fibrillation	Always	
Atrial Fibrillation	First onset for patient Then Vrate >150 or < 40 BPM	1-10 Onsets Vrate: 20-220 bpm
Patient Initiated	Always sent	

The default criteria above can be used or the physician can specify the criteria to be used as long as it falls within the criteria range specified above. The criteria can be specified for a particular patient, for all the physicians patients, for a particular office location or for the entire practice.

TruVue Algorithm Operation

Beat Detection and Classification
The TruVue algorithm can discriminate between normal and ventricular beat morphologies. For each beat complex the algorithm determines the R-point for HR calculation

The beat detection performance (as tested under ANSI/AAMI-EC 57:1998, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms) is:

	Sensitivity, %	Positive Predictivity, %
QRS detection (MIT DB)	99.92	99.90
QRS detection (AHA DB)	99.74	99.83
QRS detection (NST DB)	95.00	88.14
V-morphology detection (MIT DB)	91.15	93.25
V-morphology detection (AHA DB)	75.48	92.05
V-morphology detection (NST DB)	88.95	46.09

Heart Rate Averaging

The heart rate is averaged over 6 R-R intervals (HR = 360/duration of 6 consecutive RR intervals) and becomes the basis for rate based arrhythmia detection following the beat classification step. The HR calculation had a mean RMS error of 1.731 as tested per EC-57 on the MIT database.

Atrial Fibrillation Detection Algorithm

The Atrial fibrillation algorithm detects the irregularity of R-R intervals and examines the signal for flutter waves. When a certain irregularity is detected, the algorithm performs additional checks to determine if the underlying rhythm is bigeminy or trigeminy and looks at the presence of flutter waves as a secondary indicator.

Atrial Fibrillation detection performance as tested per EC-57 is:

	Sensitivity, %	Positive Predictivity, %
Atrial Fibrillation detection – all events (MIT DB)	92	100
Atrial Fibrillation detection – events longer than 30 seconds (MIT DB)	100	100

Ventricular Fibrillation Detection

The TruVue algorithm can detect VF rhythms with the following performance as tested under EC-57

	Sensitivity, %	Positive Predictivity, %
Ventricular Fibrillation detection (MIT DB)	100	100
Ventricular Fibrillation detection (AHA DB)	90	100
Ventricular Fibrillation detection (CU DB)	97	73

TruVue Algorithm Operation

Summary of Caution statements:

CAUTION: Do not attempt to remove the lead wires from the sensor.

CAUTION: Inspect the leadwires for any fraying and/or cracking in the insulation prior to use.

CAUTION: Do not drop the sensor or handheld unit.

CAUTION: Do not pull or yank on the sensor lead wires

CAUTION: Do not expose sensor or handheld to excessive dust or to extreme temperatures

CAUTION: Do not immerse or otherwise allow any liquid to enter the sensor or handheld.

CAUTION: Do not get the sensor or handheld wet.

CAUTION: Do not store the sensor or handheld either unit in direct sunlight or near corrosive liquids

CAUTION: Do not attempt to replace the handheld battery.

CAUTION: Use only supplied wall charger with the handheld.

CAUTION: The handheld is a cellular phone. Follow your implantable device manufacturers recommendations on the use of the cellular phones with your implant.

CAUTION: Press firmly all around electrode patches to secure them firmly to skin.

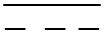
CAUTION: Shave any hair that is in the area the electrodes are placed.

CAUTION: The TruVue system is not an emergency response device. The patient should call 911 and/or their local emergency medical service if they feel they are having a medical emergency.

Description of Device Symbols

Type BF Electrical Isolation

Read Manual First



DC Current