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:

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

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

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

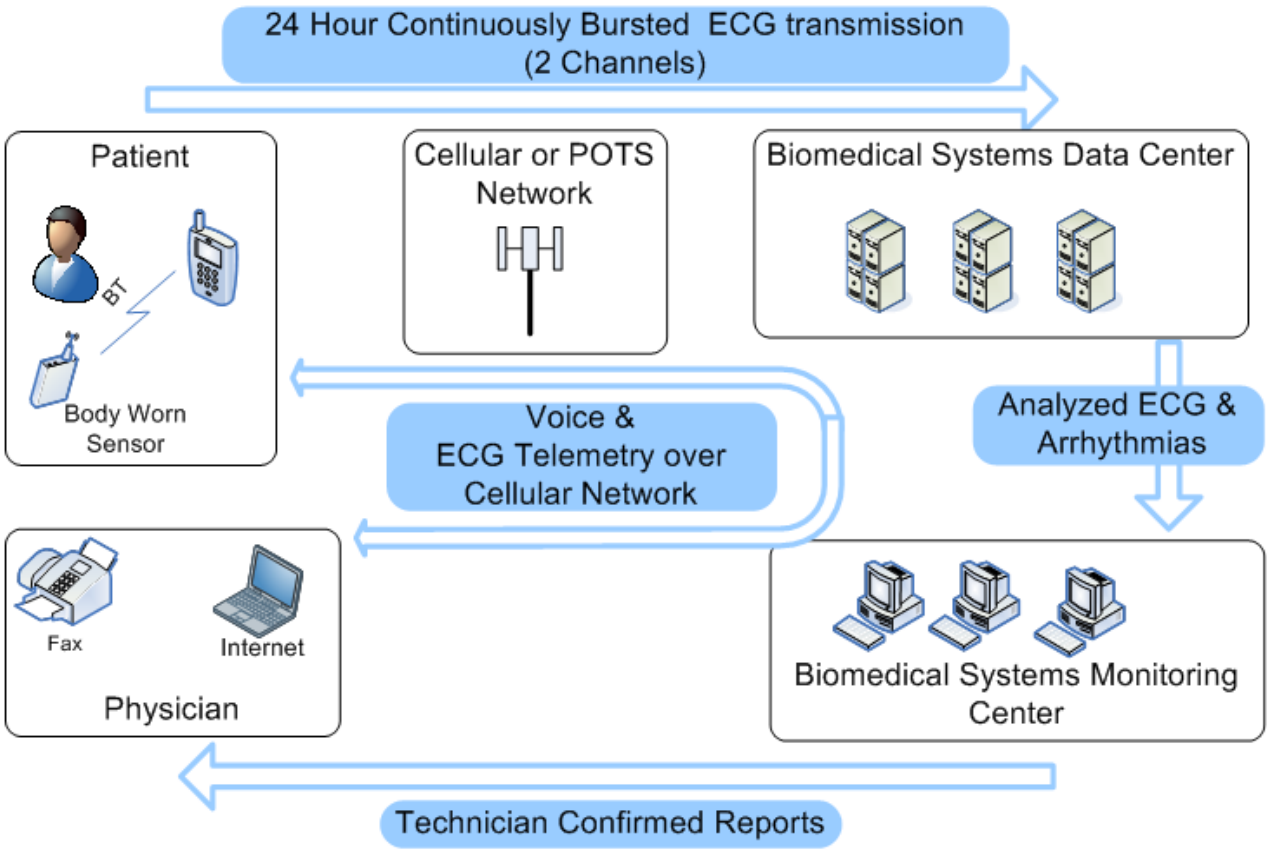
ECG data recorded by the device can be analyzed by other processing systems, such as the BMS Century Holter system to provide Holter style reports

Contraindications

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

System Overview

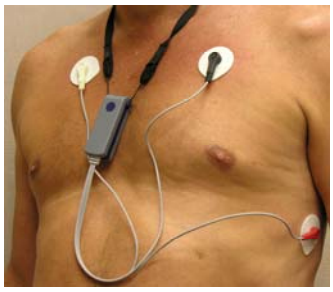
The TruVue system is a wireless ECG analysis and monitoring system used for the diagnosis of cardiac arrhythmia in ambulatory patients. ECG data is acquired at the patient on a body worn sensor, stored and then transmitted to a data center through a handheld device carried with the patient. No action 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.



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. 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.

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.

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.

Monitoring the Patient

While on service, you will receive daily reports for your patient that contain:

A) A full resolution HR Trend Graph
B) Atrial Fibrillation Burden Graph
C) Samples of all arrhythmic events

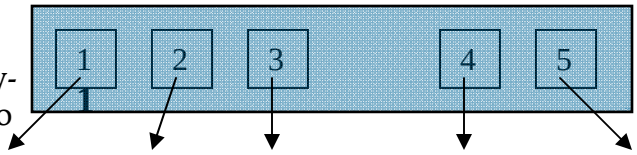
In addition, you will receive

HANDHELD USER INTERFACE SPECIFICATIONS

The handheld unit operates in three different modes:

1. Unassociated Mode - when the unit is not associated with a patient
2. Associated Mode - when the unit has been associated with a patient
3. Monitoring Mode - when the unit is associated with a patient and turned on for monitoring

When in monitoring mode, at the top of the LCD display is a 'Status Bar Layout' that provides the following information to the patient:



1	2	3	4	5
Sensor Battery	Sensor Connection	Upload Activity	Cell Strength	Handheld Battery

The interface incorporates six buttons below the LCD display screen. There are two soft keys, one on the right and the other on the left just beneath the LCD display. The other four keys are directional keys that allow the user to move left or right on the screen, or up and down.

INTRODUCTION

In monitoring mode, the main screen offers the user a list of six tasks to choose from. The six choices are as follows:

1. Record symptoms
2. Messages
3. Device Information
4. Battery levels
5. Volume
6. Wireless Settings

Main screen template

Main Screen Key Images
Key lit: Up, Down, Center, Right Softkey

In addition to the following screens in monitoring mode, there exists 'Call Screens' and 'Alert Screens'.

The 'Call Screens' is used to display an incoming call from the monitoring center, to show a call in progress with the monitoring center, and to adjust the volume (high, medium, low). The capabilities of the integrated microphone and speaker are limited to calls made from the monitoring center, and do not allow patient or user to utilize as a regular cellular phone.

The 'Alert Screens' show message alerts for a variety of things. The monitoring center number will be displayed on the screen for the patient to call for technical assistance.

Separate Items

A three electrode dual-channel lead set is included with the TruVue system. The lead wires are permanently attached to the sensor hardware.

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.

A separate charger is provided for the handheld unit.

Also included with the Truvue system is a complete step-by-step Patient Instruction Manual and DVD, and all accessories, such as electrodes and AAA alkaline batteries.

Insert picture of Truvue system
and all the contents of the box that ships
to the patient (including all accessories)

OPERATION

The following describes the essential elements of patient hook-up and the operation of the Truvue Mobile Telemetry system. If you have questions regarding any of the procedures mentioned herein, please contact Biomedical Systems Cardiac Lab at (1-800-000-0000).

PATIENT HOOK-UP

Electrodes

Good electrical contact between the electrodes, lead set and the skin is essential for a high quality ECG signal. Electrodes designed for long-term monitoring are included in Truvue packaging.

Biomedical Systems recommends that electrodes be changed every 24-hours, and that the skin be prepped with alcohol and hair removed from area where electrodes are placed. If an electrode becomes loose or falls off, it should be replaced with a new electrode after wiping the skin with a small of alcohol.

The lead set attached to the sensor is the only lead set that works with the Truvue system.

Determine Electrode Placement

Any standard lead configuration may be used with the Truvue; however, the diagram on page 12 shows an electrode placement that typically achieves good results when the electrodes are securely attached the skin. Optimal electrode placement varies according to patient body shape, size, cardiac history, and the desired view of ECG.

NOTE: Typically, patients will be applying the electrodes to their chest upon receipt of the Truvue system; however, there may be times when the patient will require hook-up in the clinical setting. It is recommended that all patients be demonstrated proper hook-up technique regardless of where the hook-up is being done.

NOTE: Before securing electrodes to skin, they should be attached to the sensor lead wires and a fresh battery inserted into the sensor. See page 13 for more information about the sensor.

ELELCTRODE PLACEMENT

Place diagram of recommended
electrode placement

(Use same diagram as in
Patient Instruction Manual)

Electrode Site Preparation and the Proper Positioning

- Skin surface should be clean, dry, and abraded before applying electrodes
- If hair is present in the area the electrode is being applied, the hair should be shaved and skin prepped as indicated in Step 1
- It is recommended that electrodes not be worn in the shower or bath, and should be removed and reapplied after bathing
- Any electrode which loosens during the monitoring period must be replaced with a new electrode
- When reattaching the lead wires to the electrodes, connect the lead wires and then secure them onto the skin

OPERATION

SENSOR

- Sensor battery should be replaced every 24-hours by removing battery compartment cover on back-side of sensor
- It is recommended that only a AAA alkaline battery be used (replacement batteries are included with the Truvue system)
- Upon insertion of a fresh battery, electrodes are then snapped onto lead wires, and then placed on the chest (as previously indicated).
- Sensor should be connected to the lanyard (neck cord) and then placed around neck (lanyard prevents sensor from dangling, which may cause electrodes to loosen or fall off)

HANDHELD

- Handheld is powered on by pressing and holding the power button (located on right side on unit) for approximately 5 seconds

NOTE: When unit powers on, a green light will appear and begin to blink. You may hear a 'beeping sound' approximately 10 seconds after powering unit on.

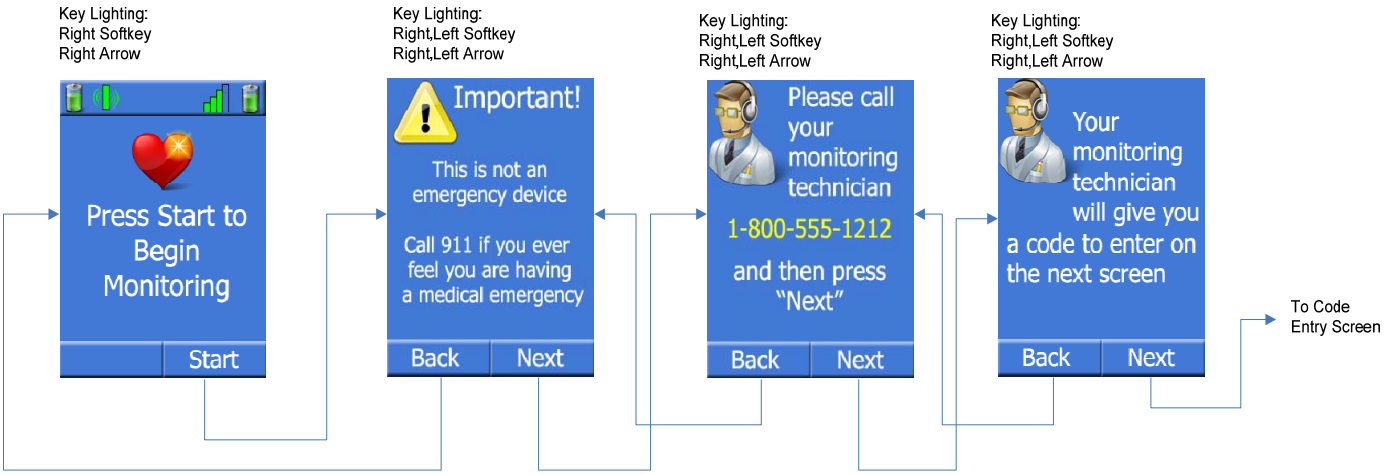
NOTE: Handheld unit must be charged each evening overnight.

Insert diagram of Handheld unit
that shows interface of unit depicting
the soft keys, up & down, and left & right arrow keys,
an arrow pointing to the 'power button', and the display screen

Include picture of charging cord

- Once the handheld unit is on, the display screen will direct user to 'press start to begin monitoring'.

NOTE: The diagram below shows the display screens as you use the 'soft keys' just beneath the words 'back' or 'next' at the bottom of the screen.



NOTE: The third screen will display a number for you to call for the code that is required to proceed forward with the monitoring. Certified Monitor Technician's (CMT's) are available 24 hours a day, 7 days/week, 365 days/year in order to assist with patient hook-up, handheld and sensor questions, technical difficulties, etc.

- The fourth screen will display the window for you to input the 4-digit code. You will use the up and down arrow keys to scroll through numeric digits 0-9, and the left and right keys to move between the digits.

- Upon entering the code, select the right soft key to indicate that you are 'done' as indicated on the display screen.

- Once the code is successfully entered, the screen will default to the main monitoring mode screen, which allows you to select between six different topics using the up and down arrows, and the center button to make a selection.

The topics include the following: (see diagram below)

1. View battery levels
2. Adjust volume
3. Record symptoms
4. View messages (sent from monitoring center)
5. View device information
6. Change wireless settings

Main screen template

Main Screen Key Images
Key lit: Up, Down, Center, Right Softkey

NOTE: Patients are instructed to contact Biomedical Systems prior to hook-up and initiating service, so that a CMT can guide them through the process and answer questions they may have.

CLEANING THE UNITS:

- Both the handheld and sensor units can be cleaned with a small amount of rubbing alcohol
- Do not submerse either unit in water or any liquid, as this may damage the unit and prevent it from working properly
- Sensor and electrodes should be removed and placed in a dry area prior to bathing , showering, or swimming

IMPORTANT DEVICE INFORMATION:

SENSOR:

- **Sensor is attached to a lanyard which should be worn by patient around neck**
- **Sensor is responsible for collecting the ECG data**
- **Sensor is powered by a 1.5V AAA alkaline battery that should be changed every 24 hours**

HANDHELD:

- **Handheld is powered by a rechargeable battery**
- **Handheld incorporates a speaker and microphone to enable communication between monitoring center and patient**
- **Handheld should be recharged every evening during sleep in order to provide up to 24-hours of battery life**

OPERATION

PATIENT INSTRUCTION PROCESS

Successful operation of the Truvue Mobile Telemetry system depends on thorough patient instruction. Biomedical Systems recommends that you explain to your patients the following before you order the Truvue system for them.

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
- To call Biomedical Systems immediately upon receipt of unit

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

NOTE: In the event you are performing the hook-up in your office or in a clinical setting, we recommend and strongly encourage you to guide the patient through the process in the order previously discussed in this manual (pages 11 - 16). Discuss thoroughly with your patient each step of the process and the significance of a good hook-up as described.

NOTE: Call Biomedical Systems immediately before allowing the patient to leave your office to ensure that ECG data is being collected and sent to the monitoring center.

ORDERING TRUVUE FOR YOUR PATIENTS:

- **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 you 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 #)**

MAINTENANCE AND SERVICE:

The TruVue monitor does not require any regular maintenance (other than electrode replacement, charging the handheld unit every 24-hours, and changing the AAA alkaline battery in the sensor every 24-hours), and has no user serviceable parts. **Do not** attempt to take units apart or service any internal components.

NOTE: See page 10 to view the contents of the TruVue box

OPERATION

PREVENTATIVE MAINTENANCE:

To ensure that the TruVue system continues to perform optimally, and to reduce the possibility of failure, perform the following preventative maintenance tasks on a regular basis (if you store the device in your office).

MECHANICAL INSPECTION

- **CAUTION:** Check lead wires for splits or cracks in the insulation or around the connectors. If the cable shows significant wear or damage, contact Biomedical Systems for a replacement.
- **CAUTION:** Do not store sensor with battery in place. Remove battery after each monitoring period.

HANDLING PRECAUTIONS**:**

The TruVue system is a valuable medical instrument and must be treated with care. Please follow the below guidelines to ensure proper handling and a successful monitoring experience.

- Do not drop the handheld or sensor units
- Do not dangle the sensor by the lead set wires
- Do not expose sensor or handheld to excessive dust or to extreme temperatures
- Do not immerse or otherwise allow any liquid to enter the sensor or handheld. Avoid pouring water or any other liquid over either unit, and do not use anything other than a damp cloth or alcohol pad to clean the unit
- Do not use abrasives such as wire wool or metal polish on either unit
- Do not store either unit in direct sunlight or near corrosive liquids

APPENDIX A

SENSOR SPECIFICATIONS

INSERT SENSOR SPECIFICATIONS

APPENDIX B

HANDHELD SPECIFICATIONS

Insert handheld specifications

APPENDIX C

TRANSMITTED DATA

Wireless ECG recordings transmitted to the central monitoring data center are dependent upon communication between the sensor and handheld units, as well as proper charging of the units. Various factors such as, loose electrodes, damaged lead wires, improper placement of electrodes, physical movement, or electrode noise, can affect the waveforms, and thus the quality of the processed ECG data.

Will need to add additional information on transmitted ECG data.

SENSOR SOFTWARE

ECG is acquired by the sensor, and noise rejection filtering and decimation is then performed. The ECG is stored in the sensor, and every 30 seconds the sensor initiates a transfer of the ECG to the handheld unit. If a connection with the handheld cannot be established, the sensor stores the ECG to its internal micro SD card for later transmission.

The sensor is always in one of three monitoring states:

- Associated
- Not associated
- Monitoring

In the associated state, the sensor is paired with a specific handheld, loaded with a patient ID. In this state it is acquiring, but is not storing ECG. On transition to the monitoring state, the sensor begins the storage and transmission of ECG to the handheld and monitors alert conditions. In the not associated state, all data is removed from the sensor and it is available for association with a handheld and patient.

In normal operation the sensor sets a 1 ms timer and enters 'sleep mode'. At each 1 ms tick the sensor acquires a new set of samples and runs the noise estimation and decimation filters. Alternatively, the sensor platforms noise estimation and decimation at a longer interval to take advantage of pipelining. Every 1 second, housekeeping tasks are performed (check battery voltage, alert state, etc.). Every 30 seconds a communication session with the handheld is initiated and ECG data is transferred.

The sensor also supports a real time streaming mode in which all ECG acquired is continuously transferred to the handheld for display on the handheld or streaming to the data center.

The sensor software can communicate with a configuration utility over USB, UART, or Bluetooth using the Serial Handheld Communications Protocol (SHCP). This software is used to configure, test the hardware, or transfer stored ECG data. Configuration information is stored on the internal flashcard.

The sensor software maintains an operation log that stores software or hardware fault information, alert conditions and system diagnostic information. When an alert condition (low battery, leads off, software or hardware fault) is detected by the sensor software, it transmits an alert packet to the handheld where an alert message can be displayed. The sensor LED turns red and an alert tone (or vibrate sequence) is played when an alert condition is present. This occurs even if the handheld cannot be connected to for message display.

HANDHELD SOFTWARE

Every 30 seconds the handheld stores ECG data received from the sensor. Every 2.5 minutes the handheld initiates a connection to the data center. The handheld utilizes the Device Communication Service Protocol (DCS) to communicate with the data center. The ECG data is compressed before transmission to the data center.

If a wireless network connection cannot be established for 5 minutes or more, the handheld switches to remote analysis mode until a wireless network connection can be reestablished. In remote analysis mode the handheld runs a Serious Arrhythmia Detection Algorithm (SADA) that monitors for serious arrhythmias only. If the SADA algorithm suspects a serious arrhythmia, the system will transfer the ECG to the data center for further analysis over the POTS modem if is is in range or notify the patient to move into a coverage area if it is not.

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. When the patient feels a symptomatic event, they can enter their symptoms and activity level from a list of predefined symptoms and activities. The user interface can also be used to adjust volume and place the sensor in stand alone mode (for areas where wireless transmissions are not allowed). When in stand alone mode, the sensor will automatically be removed from stand alone mode after 24 hours or when the user re-enables normal mode.

The handheld monitors for alert conditions and displays a message, plays a tone or vibrator sequence and flashes a red LED when in an alerting condition (low battery, SADA detection, software fault, etc.)

The handheld is capable of displaying text messages sent from the monitoring center. It also has capability of operating as a cellular telephone in mobile terminated mode only. Calls can only be placed to the handheld, outgoing calls cannot be placed from the handheld.

The handheld software is always in one of three monitoring states:

1. Associated
2. Not associated
3. Monitoring

In the associated state, the handheld is paired with a specific sensor, loaded with a patient ID, and is acquiring, but not storing ECG. On transition to the monitoring state, the handheld begins the storage and transmission of ECG to the data center and monitors alert conditions. In the not associated state, all data is removed from the handheld and it is available for association with a new sensor and patient.

The handheld also supports a rel-time streaming mode in which all ECG acquired from the sensor is continuously transferred to the data center on a technicians or physician's monitor.

Ecg Data is reliably stored before communicating to the handheld that the ECG has been successfully uploaded.

The Data Center Software (DCS) also supports a 'shoulder tap' method for directly contacting devices in the field. This functionality can be used to initiate a real time streaming session without waiting for the device to call in at its prearranged time. If the previous status message from the handheld indicates that the handheld has an open PDP context established, then the DCS can attempt to send an unsolicited 'phone home' message. This would primarily be used to start an immediate streaming ECG session. On receiving this message, the handheld would then initiate the standard communication sequence.

ECG ANALYSIS AND PROCESSING SUBSYSTEM (EAPS)

EAPS software operates in the data center and is responsible for coordinating the analysis and processing of ECG data.

The responsibility of EAPS is to ensure that every segment of data is processed reliably, and that common error modes can be recovered from gracefully. The EAPS processing sequence is as follows:

1. Uploaded ECG received by the DCS is stored in an ECG database

2. An EAPS instance checks the ECG processing queue to determine the next segment (30 seconds to 2.5 minutes) that needs processing. Upon accepting the ECG, the instance will save housekeeping information to mark the ECG as 'being processed'.

3. The EAPS instance will then connect to one of a pre-registered set of algorithm instances.

4. The EAPS instance will initialize the algorithm instance by sending any previously stored state data for the device/patient combination. In the event of a new patient, the algorithm will reset.

5. EAPS will then send ECG data to the selected algorithm instance and wait for a response synchronously. The algorithm instance will then send its data output using a simple protocol back to the calling socket.

6. EAPS then invokes the Global Cardio event generation interface for any events detected and returned in the output. It also stores annotation data generated by the algorithm.

7. The EAPS instance will finally mark the ECG queue entry as processed, and cleanup housekeeping information for the algorithm instance (marking it as available for use).

ALGORITHM SOFTWARE

Serious Event Processing

The algorithm subsystem is ran on EAPS servers in the data center.

When an algorithm instance processes ECG data, it also changes its own internal state. This state is not carried over for the next ECG packet., but rather stored and sent back to the EAPS system. When new ECG data arrive, the EAPS system sends this state information back to the algorithm instance along with the next set of ECG data. The algorithm instance itself does not hold a state associated with an ECG data.

Algorithm instances perform major tasks of processing ECG signal:

- Filtering
- QRS detection
- Morphology detection
- Heart rate calculations
- Event generation

Once the QRS detector processes the incoming ECG, the event generation system looks for the events listed in the table below.

Event Type	Default Critical Threshold	Critical Threshold Range
Pause/Asystole	> 3 second	2-5 seconds
Bradycardia	< 40 bpm	20-50 bpm
Tachycardia	> 180 bpm	120-220 bpm
SVT	> 30 seconds	5-60 seconds
VT	Rate: >110 bpm/3 or more beats	Rate: 80-150 bpm/3-10 beats
Idioventricular Rhythm	> 30 bpm	5-50 bpm
VF	Always	
AF	1st onset, then V-rate >150 or < 40 bpm	1-10 Onsets V-rate: 20-220 bpm
Patient initiated	Always sent	

Values for thresholds can be changed from defaults for any patient at any time. The algorithm receives threshold values from the EAPS system and generates events according to received thresholds.

Once per day, another algorithm runs on the collected annotation data and generates a set of events that represent the patient's condition for that day. The algorithm identifies the following strips:

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 arrhythmia class defined below the algorithm identifies the most serious, lowest noise sample

    - Tachycardia
    - Bradycardia
    - Atrial fibrillation
        First onset
        HR > 150 bpm
    - Pause
    - Ventricular runs

The algorithm will also identify alternate samples. These will be the next three best samples for each arrhythmia class. The technician can view these as part of the report generation process if the primary samples are not judged adequate for any reason.

SENSOR ALGORITHMS

Serious Events Detection Algorithm

This algorithm detects life-threatening conditions like high rate ventricular tachycardia, ventricular fibrillation, and asystole. The algorithm is estimating the ratio of slow movements of ECG (ventricular repolarization and baseline) vs. fast movements of ECG (R-wave). When the heart rate increases, this ratio also increases, because fast movements of ECG are happening more often compared to slow baseline moves. The ratio is also high for ventricular fibrillation because fast movements of ECG signal are happening all the time due to fibrillating ventricles.

The algorithm will trigger a serious event when the heart rate is close to or above 200 beats per minute.

ATRIAL FIBRILLATION ALGORITHM

Atrial fibrillation algorithm detects irregularity of R-R intervals, and, if certain irregularity is detected, performs additional checks to determine if the underlying rhythm is atrial fibrillation or atrial flutter.

A sub-algorithm is constantly performing a flutter wave check. If detected, flutter wave presence is used as a supporting indicator of atrial flutter.

Flutter wave check algorithm takes beat information structure, then based on known location of R and T wave takes part of T-R interval for analysis. Two indications are used for analysis: correlation between two waveforms in T-R interval, and power spectrum of these waveforms.

VENTRICULAR FIBRILLATION ALGORITHM

Ventricular fibrillation detection algorithm runs independently of QRS detector. The algorithm receives ECG samples at 250 Hz and processes both channels symmetrically. The logic of ventricular fibrillation detector is the same as for SADA running on a sensor. However, parameters of this algorithm are tuned to detect ventricular fibrillation only.

VENTRICULAR TACHYCARDIA ALGORITHM

Ventricular tachycardia trigger is required to have a very high sensitivity. At the same time, positive predictivity of this trigger is essential. TO satisfy these challenging requirements, there are additional processing steps for this type of trigger:

- If 3 V-beats in a row are detected, then noise level is checked (trigger is disabled for high noise level)
- 3 or more V-beats in a row with similar ECG axes considered to be a high probability V-tach; therefore, acceptable noise level is elevated
- Stable R-R interval is usually observed in V-tack rhythm; therefore, acceptable noise level is elevated if R-R intervals (between V-beats) are within small range

EVENT GENERATION SYSTEM

Once QRS detector processes the incoming ECG, the event generation system looks for events contained in the table below (also listed on page 27).

Generated Events include:

Event Type	Default Critical Threshold	Critical Threshold Range
Pause/Asystole	> 3 second	2-5 seconds
Bradycardia	< 40 bpm	20-50 bpm
Tachycardia	> 180 bpm	120-220 bpm
SVT	> 30 seconds	5-60 seconds
VT	Rate: >110 bpm/3 or more beats	Rate: 80-150 bpm/3-10 beats
Idioventricular Rhythm	> 30 bpm	5-50 bpm
VF	Always	
AF	1st onset, then V-rate >150 or < 40 bpm	1-10 Onsets V-rate: 20-220 bpm
Patient initiated	Always sent	

Values of thresholds could be changed from the default setting for any patient at any time. Algorithm is receiving threshold values from the EAPS system and generated events according to received thresholds.

REPRESENTATIVE EVENTS ALGORITHM

This algorithm is intended for post-processing of patient's data. The main purpose of this algorithm is to provide additional ECG samples for the daily generated report. These additional ECG samples are not chosen in a way that would be 'representative' for a particular patient: e.g. these data would reflect lowest and highest heart rates in the previous 24 hour period.

There are three types of Representative Events:

1. Tachy
2. Brady
3. Pause

Representative events are generated for previously processed data: annotations and events are assumed to be available for the time interval of interest (the last 24 hours).

The severity of events is calculated according to the event type:

- Highest heart rate for tachy trigger
- Lowest heart rate for brady trigger
- Longest pause for pause trigger

NOTE: Representative events do not have a predefined threshold as a criterion for event generation.

ECG PERFORMANCE STANDARDS

The system complies with the following ECG performance standards:

AAMI EC 38:1998, Ambulatory Electrocardiographs

ANSI/AAMI EC 57:1998, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms

May need to include the following:

ANSI/AAMI EC-13:2002, Cardiac monitors, heart rate meters, and alarms

AAMI EC 11-1991, Diagnostic Electrocardiographic Devices

The algorithm meets the following analysis performance measures on the MIT arrhythmia database:

	Sensitivity	Positive Predictivity (+P)
QRS detection (MIT)	99.9%	99.8%
V-beat detection (MIT)	90%	90%
V-Fibrillation (AHA)	95%	95%
Atrial Fibrillation (MIT)	90% (all events)	90% (all events)

GLOBAL CARDIO SOFTWARE

The monitoring and patient management software is based on the Global Cardio web application currently used for event monitoring.

A real time ECG viewer has been added to allow initiation of a streaming session.

For additional information on the Global Cardio software system, refer to the Global Cardio User Manual available upon request through Biomedical Systems.

OPERATION

ARRHYTHMIA MONITORING SYSTEM

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