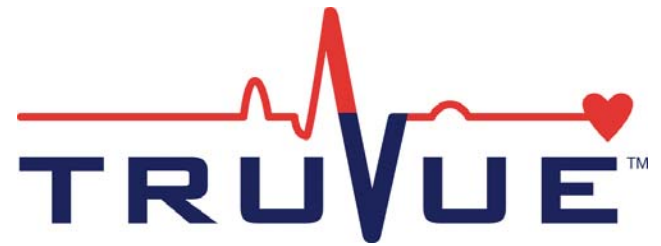




TruVue Mobile Telemetry



Patient Instruction Manual



**BIOMEDICAL SYSTEMS
WIRELESS AMBULATORY ECG**

Biomedical Systems
77 Progress Parkway
St. Louis, MO 63043
www.biomedsys.com



- *24-hour continuous ECG monitoring*
- *Patient friendly handheld unit that is easy to use*
- *Around the clock patient support and monitoring*



**CALL BIOMEDICAL SYSTEMS WITHIN
24-HOURS OF RECEIVING HEART MONITOR AND
BEFORE REMOVING MONITOR FROM THE BOX.**

1-800-000-0000

If you have questions regarding your monitor or about billing after your heart monitoring service begins, please call our Customer Service Department at **1-800-877-6334**.

When your physician decides the heart monitor can be removed, please return both units and any additional supplies to Biomedical Systems within 24-hours to avoid being billed.

**UPON COMPLETION OF MONITORING PERIOD
RETURN UNIT IN PREPAID BOX TO:**

Biomedical Systems
77 Progress Parkway
St. Louis, MO 63043

Customer Service 1-800-877-6334
(Monday -Friday 8:00am –5:00pm CST)

Mobile Telemetry Lab 1-800-000-0000
(24 hours/day, 7 days/week)



DISCLAIMER

Disclaimer:

Copyright Declaration:



Summary of Cautionary Statements

CAUTION: The TruVue Handheld device contains a cellular phone. If you have an implantable device follow your device manufacturers recommendations on the use of cellular phones with your device.

CAUTION: Take care not to get the sensor or handheld wet. Remove the sensor prior to bathing.

CAUTION: Do not drop the devices or dangle the sensor from the leadwires

CAUTION: When on an airplane, follow the instructions on the use of wireless devices. You can turn off the all wireless radios through the handheld user interface, the sensor will continue to monitor you.

CAUTION: There are no user serviceable parts in the TruVue device. Do not attempt to remove the cover from either the sensor or the handheld.

CAUTION: Use only AAA Alkaline batteries in the TruVue Sensor. Do not use rechargeable batteries in the sensor.

CAUTION: Use only the supplied wall charger to charge the handheld.

CAUTION: Always use the carrying case when carrying the handheld on your body.



Federal Law restricts this device to sale by or on the order of a physician

Note for patients with implantable devices such as a pacemaker or ICD:

CAUTION: The TruVue Handheld device contains a cellular phone. If you have an implantable device follow your device manufacturers recommendations on the use of cellular phones with your device.

CAUTION: The TruVue system is not an emergency response device. If you feel you are having a medical emergency call 911 and/or your local emergency medical service.



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Regulatory Statements

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.*

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.



Regulatory Statements

Federal Law restricts this device to sale by or on the order of a physician

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 System may void the FCC authorization to operate this equipment.



Mobile Telemetry

What is Mobile Telemetry?

Mobile Telemetry (MT) is a way for your physician to monitor your cardiac (heart) activity for an extended period of time. This is done by wearing a small sensor that includes wires and electrodes (patches) attached to your chest, that records your heart rhythm (activity) 24 hours a day while you continue with normal daily activities.

Why did my Doctor Prescribe Mobile Telemetry?

MT is often prescribed for patients who may have infrequent complaints of symptoms, such as dizziness, light headedness, feeling faint, or palpitations. It may also be worn by patients who have recently had cardiac (heart) surgery or other cardiac procedures. MT is useful for patients undergoing anti-arrhythmic medication changes or who may be starting anti-arrhythmic therapy. MT is also frequently prescribed to identify asymptomatic (without symptoms) cardiac (heart) arrhythmias (abnormal heart patterns).

How Does Mobile Telemetry Work?

Real-time MT automatically records and transmits (sends) cardiac rhythm data to an attended central data monitoring center. Therefore, it requires minimal (if any) patient interaction. Cardiac monitoring is occurring continuously whether the patient is experiencing symptoms or not, and this data is constantly being sent to the monitoring center. The data is analyzed by Certified Cardiac Monitor Technicians (CMT's) and sent to your physician for review. Your physician will receive a daily report of your cardiac activity, and will be notified immediately of any abnormal cardiac (heart) rhythm activity.



Methods of Payment

Biomedical Systems will verify and obtain authorization for payment from Medicare and/or your insurance provider. Depending on your coverage, you may be responsible for a co-payment and/or deductible amount.

In the event your insurance provider does not cover this procedure, Biomedical Systems will work with you to develop a payment plan and help you to understand your payment options.

Contents of Box



- Handheld unit (1) with carrying case
- Sensor unit with cable wires (1)
- Electrodes
- AAA Alkaline Batteries
- Patient manual (1)
- DVD (1)
- Charger
- Prep Pads



How to Return the Device

When your doctor decides your heart no longer needs to be monitored, promptly return the monitoring units and contents of the box to *avoid being billed*.

1. Place all items (handheld and sensor units, DVD, and any left over supplies) into the prepaid box provided.
2. Ensure that box is securely closed and place in mailbox for US postal service pick-up.

If you are unable to return the device for any reason, please call our Customer Service Department immediately so that we can make arrangements to have the units picked up via UPS.

Customer Service

(Monday – Friday 8:00am – 5:00pm)
1-800-877-6334

Mobile Telemetry Monitoring Lab

(24 hours/day, 7 days/week)
1-800-000-0000

Return Address:

Biomedical Systems
Attn: Mobile Telemetry
77 Progress Parkway
St. Louis, MO 63043

Non-returned MT units will be billed to patient.



Frequently Asked Questions

How do I return the Mobile Telemetry Sensor and Hand-held units, and other contents in the box?

Return the complete system to Biomedical Systems within 24 hours of being discharged from monitoring to avoid being billed for the units. Use the prepaid box sent to you with your initial shipment. In the event you are unable to return the MT units for any reason, please contact our Customer Service Department at 1-800-877-6334 so that we can make arrangements to have it picked up via UPS.

What should I do if I faint or if I experience symptoms that are more frequent than usual or don't seem to go away?

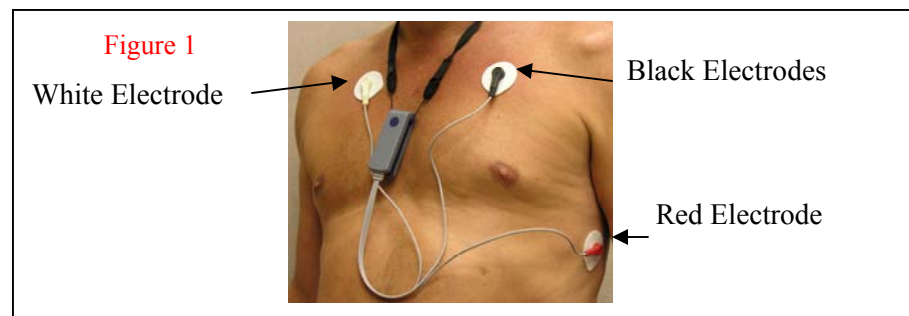
If you experience any new symptoms or your symptoms have worsened, you should contact your physician as soon as possible. If you feel that your symptoms are life threatening or require immediate attention, you should call 911 or go to the nearest emergency room immediately.

I have additional questions or concerns.

Please call the Customer Service Department at 1-800-877-6334.



Patient Instructions



ELECTRODE (PATCH) PLACEMENT:

Precaution: Shave any hair that is in the area the electrodes (sticky patches) are placed. If hair is not shaved, the recorded activity of your heart is difficult to read.

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



Electrode (Patch) Placement



Figure 3

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*.

Precaution: Press firmly all around electrode patches to secure them firmly to skin. If they are not secured firmly to skin the heart activity will not record well.

6. On the back side of the Sensor, remove the battery cover as shown in *Figure 4* and put (1) AAA Alkaline battery in place if not already done. Replace battery cover.



Figure 4



Frequently Asked Questions

I've already worn a Holter or Event monitor, so why did my doctor order Mobile Telemetry for me?

The holter monitor only captures 1-2 days of your heart's electrical activity. Often times this is not long enough to rule out cardiac arrhythmias that may occur less frequently than 24 to 48 hours. Event monitor's are typically only used for patient's who experience symptom's, and do not pick up on abnormal cardiac (heart) activity that may occur asymptotically (when you are not experiencing symptoms).

How will I be billed?

We will bill your insurance carrier, whether you have Medicare Part B, private insurance, or belong to an HMO. You will only be billed for the co-pay and/or deductible, if any.

The patches are irritating my skin, what should I do?

We have alternate electrodes (patches) with a skin prep available upon request. Please call Biomedical Systems Customer Service at 1-800-877-6334.

I am having difficulty using the Handheld unit and/or have questions about the unit?

The Cardiac Monitoring Technician's are available 24 hours a day, 7 days a week to answer any questions you may have and to monitor your heart's activity. Please call at any time of the day so that we can answer your questions.



Frequently Asked Questions

What should I do when I shower or take a bath?

Simply remove the device and patches. Throw away the old patches, and apply new ones to a clean area of skin. Be sure not to use lotions or creams on chest area, as this will prevent them from sticking securely to your skin. Shave hair in area of electrode.

I have used all of my supplies and need additional patches, etc.?

Contact our Customer Service Department at 1-800-877-6334.

What should I do if I forget my Handheld unit at home or somewhere else?

The Handheld and Sensor units are continuously communicating with one another. If it is not possible to return home to get the Handheld unit, the Sensor will continue to store your hearts activity until you find the Handheld. However, *your hearts activity will not be sent to monitoring center for evaluation until a connection between the Sensor and Handheld units is re-established or made.* Once you are able to retrieve the handheld, there is nothing that you need to do to reestablish this connection. Please call the monitoring center at 1-800-000-0000 as soon as possible if you have left your Handheld at home or another location. The monitoring center also has the capability to send a text message to the Handheld unit should you lose the device and someone else picks it up.



Lanyard Connection

- If sensor is not already attached to the lanyard (neck strap), then snap sensor onto lanyard as shown in *Figure 5*. Once lanyard (neck strap) is in place, put lanyard around your neck and wear as shown in *Figure 5*.



Figure 5

Important Notes:

- Every 24 hours you will need to change the AAA Alkaline battery in the sensor.
- Electrode patches should be changed every 24 hours or if they become loose or are not sticking well.
- Always wipe with alcohol before applying new patches, and shave hair if necessary.

When Showering or Bathing

- Remove lead wires attached to sensor from the electrodes (patches).
- Place sensor (attached to lanyard) in a dry secure place. **Do not allow sensor to get wet. It may cause sensor to stop working properly.**
- 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 in Steps 3 - 5 on pages 6 and 7.



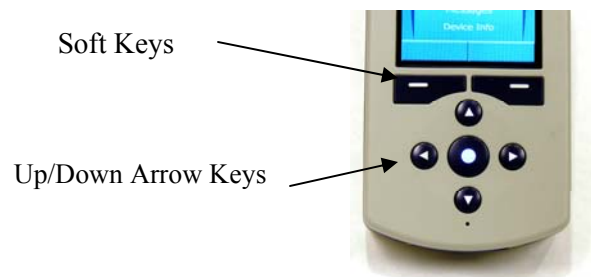
Handheld Unit Instructions

Figure 6



Figure 7 Power Button

1. Remove Handheld unit from box. (Handheld unit shown in **Figure 6** above).
2. **Press and hold** the Power button for five (5) seconds. (**Power button** is located on right side of unit)
See Figure 7.
Note: A green light will appear and will begin to blink after about 10 seconds. You may hear a 'beeping' sound.
3. After unit is 'Powered on', the following screens shown in **Figure 8 on page 10** will appear as you scroll through each screen on the Handheld unit screens. **See Figure 7** to view the buttons on the Handheld unit.



Frequently Asked Questions

Why did my doctor order a Mobile Telemetry test for me?

Mobile Telemetry (MT) will assist your doctor in determining if the symptoms you are having are related to your heart. If a problem with your heart is detected, the heart monitor will assist your doctor in determining the nature and severity of the problem. Doctors also prescribe MT for medication changes or post surgical procedures related to your heart.

How long will I have to wear the heart monitor?

The monitor must be worn at all times during the test period which can be *up to* 30 days. However, your doctor may discharge you from MT at any time upon making a diagnosis, or if he/she feels the cardiac (heart) monitoring is no longer necessary.

What if a patch is loose or comes off?

It is critical that the patches (electrodes) are securely attached at all times to your skin. If a patch is loose, remove the patch completely, ensure the area is free of hair, rub the area with alcohol, and then apply a new patch. Be sure to press firmly on the patch to ensure that it is secured to the skin.

Patches should be changed every day and when you bathe or shower. Remove the patches and device prior to bathing, and then reapply before dressing. (Refer to page 6 and 7 for electrode (patch) placement.



Things you should know

Cleaning the Unit:

Both the Handheld and Sensor units may be cleaned with a small amount of alcohol; however, *do not submerge the units in the alcohol, water, or any other liquid. If either unit gets wet, it may damage them and prevent them from working properly.*

IMPORTANT DEVICE INFORMATION:

SENSOR

- Sensor is attached to a lanyard which should be worn by patient around the neck
- Sensor is responsible for collecting the ECG data (heart activity) via lead wires and electrodes (patches)
- 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 while you sleep in order to provide up to 24-hours of battery life.



Handheld Unit Instructions

4. After turning Handheld unit 'Power On', you will see the following screens (Figure 8), as you scroll through the instructions on each screen. The first screen instructs you to press 'Start' to begin monitoring. The second screen has the word 'Important' at the top, and so on.

Select the 'Next' button after viewing each screen in order to move through the screens. The display screen will guide you through the process step by step.

Important Note: *Handheld unit should be charged every night while you sleep.* Plug in to charger in same room that you sleep. This will allow Sensor unit and Handheld unit to continue to communicate, and your cardiac (heart) activity will continue to be sent to the data center.

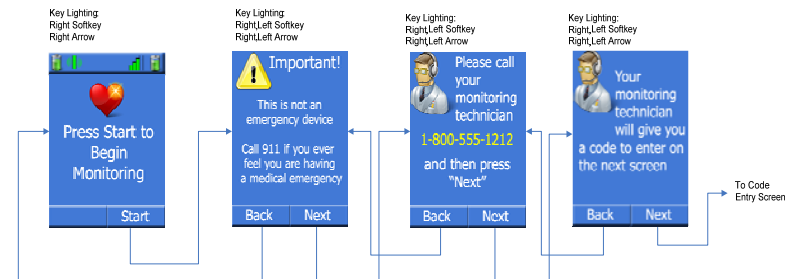


Figure 8

(Will need to make pictures much bigger and if possible, include picture of handheld with arrow to correct soft key to push).

Important Note: The third screen will display a number for you to call. If not already on the phone with the monitoring department, call the number listed. (1-800-000-0000).



Handheld Unit Instructions

- The fourth (4th) screen you will see is the ‘Code Entry’ screen (Figure 9). If not done so already, call the number listed on the previous screen to obtain your code (Mobile Telemetry Lab at 1-800-000-0000).

Precaution: Device will not work properly unless correct code is entered. You must call Biomedical Systems Mobile Telemetry Lab immediately.

NOTE: In the ‘Code Entry’ screen, the *right and left arrows* move between the four numbers. The *up and down arrows* scroll through the numerals 0 to 9.

When the code has been entered the *right soft-key* (refer to Figure 7 on page 9) will take you to monitoring mode if the code is correct.

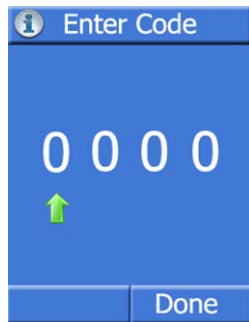


Figure 9

If code correct – to monitoring screen.
If incorrect, numeric entry is cleared and stay on code entry screen



Handheld Unit Instructions

- Once you have successfully entered your Code, the display screen will take you to the main monitoring mode screen (Figure 10).

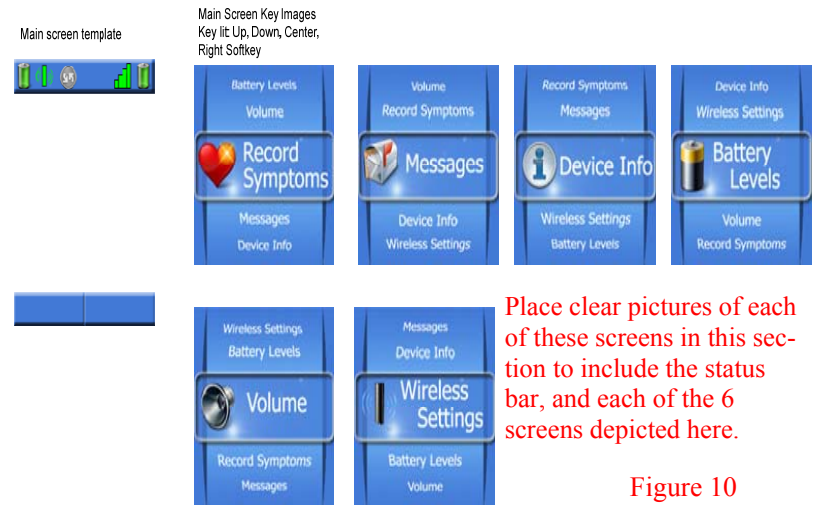


Figure 10

NOTE: The main monitoring mode screen allows you to:

- View battery levels
- Adjust volume
- Record symptoms
- View messages sent from monitoring center technicians
- View device information screen
- Change wireless settings

These screens will be reviewed with you by the Cardiac Monitoring Technician during the instruction process.