

Personal Health Monitoring Services™



VITAL SIGNS TRANSMITTER™ • MODEL: VST<sup>3</sup>™

Instruction Manual



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## INTRODUCTION

Thank you for purchasing Biowatch Medical's vital signs transmitter, model number VST<sup>3</sup>. The vital signs transmitter is a comfortable, easy-to-use personal health monitoring device that may be worn continuously 24 hours a day.

The vital signs transmitter automatically transmits medical data via the cellular modem to the Clinical Monitoring Center whenever your electrocardiogram (ECG) or other monitored physiological parameters exceed normal limits. Critical care specialists at the Clinical Monitoring Center will analyze data as it is received from the vital signs transmitter and may then communicate directly with you and take whatever action is deemed most appropriate at that time. If for any reason you are unable to respond, Emergency Medical Service (EMS) personnel will be dispatched to your location using the information provided by the global positioning system (GPS).

The monitoring service also provides an Immediate Voice Response service option that allows you to depress the Event Button to alert and speak directly with the critical care specialists at the Clinical Monitoring Center at any time, for any reason.

Your vital signs and clinical reports are also available to authorized personnel (i.e., yourself, physician, relative, guardian, etc.) who may securely "log on" to [www.biowatchmed.com](http://www.biowatchmed.com) to view these reports for evaluation and tracking.

These items are included with your vital signs transmitter:

- |                                     |   |
|-------------------------------------|---|
| 1. Instruction Manual               | 6. Notice of Privacy Practices                  |
| 2. Guide to Getting Started         | 7. Personal Health Monitoring Services Brochure |
| 3. VST <sup>3</sup> Monitoring Belt | 8. Warranty Card                                |
| 4. Medium Elastic Strap             | 9. Products & Services Agreement                |
| 5. AC Power Adapter                 |   |

How the vital signs transmitter and Personal Health Monitoring Services should be used:

- To monitor ECG and heart rate
- The vital signs transmitter also captures:
  - body temperature

DO NOT use the vital signs transmitter and Personal Health Monitoring Services:

- To diagnose heart disease
- To replace physician check-ups



DO NOT use the vital signs transmitter in combination with an external cardiac defibrillator.

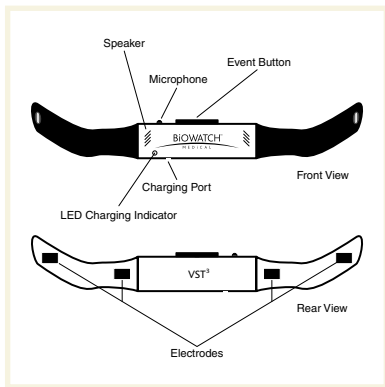


TYPE BF

The vital signs transmitter is intended for use by only the registered user and should NOT be shared with others.

## GET TO KNOW YOUR VITAL SIGNS TRANSMITTER

The vital signs transmitter uses built-in electrodes and other physiological sensors to monitor and capture two channels of electrocardiogram (ECG) including heart rate and body temperature. The built-in cellular data modem and phone provide both data and voice communications between you and Biowatch Medical's Clinical Monitoring Center. The vital signs transmitter also uses a rechargeable battery and a GPS.



## How the Vital Signs Transmitter Works

The vital signs transmitter automatically transmits a notification via its cellular modem to the Clinical Monitoring Center whenever your ECG or other physiological parameters exceed normal limits.



## Clinical Monitoring Center Intervention

If the Clinical Monitoring Center staff determines that it is necessary to contact you due to an abnormal ECG or other physiological abnormality, they will do so by placing a call to the vital signs transmitter. When an incoming call is received by the vital signs transmitter, it will vibrate to alert you of the incoming call. Within five seconds of this vibration, a voice channel is opened and allows the critical care specialists at the Clinical Monitoring Center to communicate directly with you and take whatever action is deemed most appropriate at that time.

## Emergency Medical Service (EMS) Intervention

If for any reason you are unable to respond, EMS personnel will be dispatched to your location using the information provided by the GPS.

## Event Button Intervention

The vital signs transmitter also provides an Event Button that allows you to alert the critical care specialists when you feel dizziness, pain, palpitations or other medical symptoms.

To send an alert, depress and release the Event Button. Once the Event Button has been fully depressed, the vital signs transmitter will vibrate to notify you that your medical data has been transmitted for review. The data is reviewed and analyzed by the critical care specialist who will initiate further interventional activities if needed.

## Immediate Voice Response Intervention\*

To use the Immediate Voice Response service option, depress the Event Button.

*\* This is an optional service feature that requires additional monthly and per-use fees.*

## Notifications

Any time that critical care specialists need to communicate with you or send a notification, they first notify you silently by sending a signal that causes the vital signs transmitter to vibrate. Approximately five seconds after the vibration, a brief message will be played for each of the following types of notifications:

- Occurrence of an event that has not been transmitted to the Clinical Monitoring Center because you are outside of cellular coverage area
- Low battery level
- Insufficient battery level for normal function
- Call from Clinical Monitoring Center
- Vital signs transmitter has become too loose for normal operation

To delay the automatic playing of a message following the vibration, depress the Event Button immediately following the notification vibration.

The message will be delayed 30 seconds before being played.

Please note that, for your safety, a 911 notification or similar type of Emergency Event cannot be delayed by the depression of the Event Button, and the incoming message will be played.

Message notifications that are received while you are not wearing your vital signs transmitter will be stored and automatically played back the next time you apply the vital signs transmitter to your body. Refer to the “How to Wear Your Vital Signs Transmitter” section for instructions on how to apply the transmitter.



## WHEN TO WEAR YOUR VITAL SIGNS TRANSMITTER

The vital signs transmitter should be worn any time you want your vital signs monitored. It is suggested that you wear the vital signs transmitter at all times, except when the belt could be subjected to water or other damaging environmental conditions or when the belt is being charged.

The vital signs transmitter can be worn during periods of physical exertion under which normal perspiration occurs without adversely affecting the transmitter.

Please see the “Technical Specifications” section for acceptable operating conditions.



When NOT to Wear: The vital signs transmitter should not be worn while you are bathing/showering, swimming or participating in any other activities that would require the belt to be submerged or continuously exposed to water.

The vital signs transmitter should not be worn while it is being charged.

The vital signs transmitter should not be worn onto any commercial aircraft. It can, however, be stored in baggage during air travel.

## USING THE VITAL SIGNS TRANSMITTER FOR THE FIRST TIME

- 1. Subscribe to Personal Health Monitoring Services.**  
In order to initiate the monitoring, you must subscribe to the Personal Health Monitoring Services. Refer to the section labeled “Getting Started” for more information.
- 2. Provide account set-up information.** Based on the service options you have purchased, additional account set-up information may be needed. Examples include emergency and physician contact information, setting/resetting passwords and setting family and physician access to reports. Refer to the section labeled “Getting Started” for set-up instructions.
- 3. Charge the vital signs transmitter.** The vital signs transmitter needs to be fully charged overnight prior to the first use. Refer to the section labeled “Charging the Vital Signs Transmitter” for charging instructions.
- 4. Put on the vital signs transmitter.** Refer to the section labeled “How to Wear Your Vital Signs Transmitter” to ensure that the vital signs transmitter is worn properly.
- 5. View reports and other account information.** To access and view activity reports and account information on the Internet, refer to the section labeled “Getting Started.”

## Getting Started

- 1. Subscribe to Biowatch Medical's Personal Health Monitoring Services.** You can subscribe by calling Biowatch Medical direct at 1-877-BIOWATCH (1-877-246-9282) or by completing the online subscription process at [www.biowatchmed.com/subscribe](http://www.biowatchmed.com/subscribe).

For more information on the available service options, please refer to the *Subscription Services and Options* brochure included in the vital signs transmitter packaging, visit our website, [www.biowatchmed.com](http://www.biowatchmed.com), or call our customer service center at 1-877-BIOWATCH (1-877-246-9282).

- 2. Provide account set-up information.** After you have subscribed to Biowatch Medical's Personal Health Monitoring Services, you are ready to enter account set-up information. This may be completed via our website at [www.biowatchmed.com](http://www.biowatchmed.com) or by calling our customer service center at 1-877-BIOWATCH (1-877-246-9282).

You will be asked to provide the information listed in the chart on the following page. Actual required information may vary based on the service options that were ordered as part of your monthly subscription agreement.

## Service Options that Require Information as Part of the Account

### Set-up Procedure

### Information Needed

Emergency contact(s)	Name, relationship to you, phone numbers
* Physician contact(s)	Name, type of physician, phone numbers
* Activity Reporting (Personal, Family or Physician)	Name, relationship to you, level of access (choose between daily activity reports or physician)
* Physician Access to Real Time Data	Name, type of physician

Passwords may also be reset during this process.

*\*Indicates optional features that have associated monthly fees.  
You will not be required to enter information for these options if you  
have not purchased them as part of your service agreement.*

Service subscription and account set-up is complete.  
Congratulations! You have completed the first steps to  
beginning your Personal Health Monitoring Services.

*Note: You can still add additional service options at any time, even after the  
initial service subscription and account set-up have been completed.*

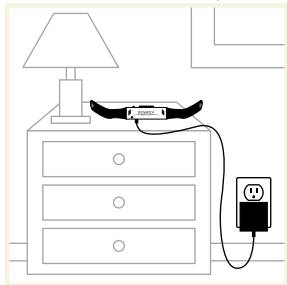
## Charging the Vital Signs Transmitter

### Charging for the First Time:

The vital signs transmitter needs to be fully charged overnight prior to its first use.

### Charging/Recharging the Battery:

1. Remove the vital signs transmitter from your torso.
2. Insert the AC adapter plug into the wall (standard US household electrical outlet: 120V AC outlet, 50-60 cycles).
3. Insert the AC adapter cord into the jack on the bottom edge of the vital signs transmitter.
4. The LED indicator located on the bottom right-hand side of the front label will light with a yellow indicator while the battery is being charged.



When the battery has been fully charged, the LED indicator light will change from yellow to green. Once the LED indicator light is green, you know your battery is fully charged and the vital signs transmitter is ready for use.

*\* If the LED indicator does not light when the AC adapter is in use, contact our customer service center at 1-877-BIOWATCH (1-877-246-9282) for further assistance.*



**The vital signs transmitter should never be charged while it is being worn.** Wearing the transmitter while the AC power adapter is plugged into the wall and the belt could result in serious personal injury

### Audible Low Battery Warning:

The vital signs transmitter has a rechargeable battery that typically, under normal use, maintains a charge for 32 hours. The vital signs transmitter provides a notification vibration, which, after an approximate five-second delay, is followed by a voice recording stating that the battery has reached the level where it needs to be recharged. This vibration/recording will be played when the battery level has dropped to 20% of its capacity.

### Audible Warning of Shutdown:

Once the battery has been depleted to a level where it can no longer maintain the function of the vital signs transmitter, it will provide a notification vibration. After a five-second delay, a final message will be played stating that the vital signs transmitter has insufficient battery level to maintain normal function and is turning itself off.

### Maintaining a Charged Vital Signs Transmitter:

In order to maintain an adequate charge, it is recommended that you charge the battery each day by charging the belt for a minimum of 20 minutes. Simply remove the vital signs transmitter from your torso, plug the adapter into the transmitter and leave it there for 20 minutes. If you do this once a day, your battery should remain adequately charged.

## AC Adapter:

To recharge your battery, use only the specific AC Adapter model #GTM21089-1305-W3 that was packaged with the vital signs transmitter.

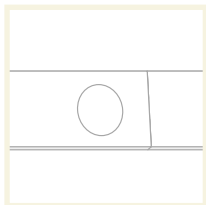
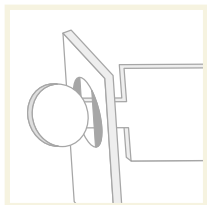
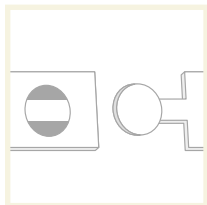
CAUTION: To avoid possible damage to the vital signs transmitter, use only the specific model #GTM21089-1305-W3 AC adapter that was packaged with the vital signs transmitter. This specialized adapter is only available from Biowatch Medical, Inc. Additional AC adapters may be purchased by calling 1-877-BIOWATCH (1-877-246-9282).

Other adapters may vary in output voltage and/or polarities and may damage the vital signs transmitter. Biowatch Medical, Inc. is not responsible for damage that occurs when other AC adapters are used.

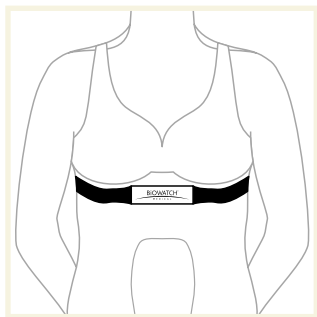
For replacement AC Adapters and other purchasing information, contact Biowatch Medical Inc. at 1-877-BIOWATCH (1-877-246-9282), or visit our website at [www.biowatchmed.com](http://www.biowatchmed.com).

## How to Wear Your Vital Signs Transmitter

1. To connect, insert circular plastic end of elastic strap into slot on the end of the vital signs transmitter and twist.



2. Adjust the strap length to fit snugly and comfortably around your chest, just below the chest muscles (sternum area). The vital signs transmitter should fit snugly so that you can only insert a small finger between the belt and your skin. If you hear a notification that the belt has become too loose to maintain normal operation, the strap should be adjusted and the vital signs transmitter should be reapplied as indicated here.





Lift the vital signs transmitter off your chest and moisten the four rectangular electrode areas on the back of the transmitter. Please refer to the diagram of the vital signs transmitter's components included in the "Getting to Know Your Vital Signs Transmitter" section to locate the electrode areas.

3. Ensure the electrode areas are firmly against the skin.  
The Biowatch Medical logo on front of the vital signs transmitter should be upright in the middle of the chest so that it can be read by a person standing in front of you.
4. Verify that the vital signs transmitter is working properly by listening for a message notification that will be automatically played within the first 10 seconds that the transmitter has been secured to your body as indicated above.

*\* If a notification message is not played, call our customer service center at 1-877-BIOWATCH (1-877-246-9282). **Do not** assume that the vital signs transmitter is functioning as intended if a notification message is not played.*

## CARE AND MAINTENANCE

The vital signs transmitter is very easy to maintain. Weekly cleaning is recommended and very little troubleshooting, if any, is ever required.

### Cleaning

1. Remove the elastic strap from the vital signs transmitter.
2. To clean the transmitter:
  - wipe with a cloth dampened with mild soap and water
  - next wipe with a cloth dampened with pure water to remove any remaining soap residue
  - thoroughly dry the vital signs transmitter with a soft towel
3. To clean the elastic strap:
  - hand wash in warm soapy water
  - lay strap flat and air dry

Store the vital signs transmitter, when not in use, in a clean, dry place that is within the specified storage temperatures published in the section labeled “Technical Specifications.”



DO NOT submerge the vital signs transmitter in water or any other liquid solution!

Avoid getting water or any other liquid in any of the device openings.

Biowatch Medical Inc. will not warranty vital signs transmitters that have been water damaged due to submersion.

## Troubleshooting

The vital signs transmitter does a daily diagnostic test with the Clinical Monitoring Center. No action is required by you to troubleshoot the transmitter.

If you are concerned that your vital signs transmitter is not functioning properly, please contact our customer service center at 1-877-BIOWATCH (1-877-246-9282).

Please see the “Limited Warranty” section for additional information on returning the vital signs transmitter while it is under the warranty protection period.

## LIMITED WARRANTY

Your vital signs transmitter is warranted, under normal use, to be free from manufacturing defects for one year from the date of purchase.

### Limitations related to this warranty are as follows:

- Tampering with the vital signs transmitter voids the warranty. The vital signs transmitter is explicitly **NOT** designed to be opened by anyone other than Biowatch Medical personnel.
- The warranty is only extended to the original purchaser (i.e. it is not transferable).
- To validate the warranty, you are required to return the enclosed registration card, or complete it online at [www.biowatchmed.com](http://www.biowatchmed.com), within 10 days of initiation of the monitoring service.

In the event of failure of your vital signs transmitter, first contact customer service at 1-877-BIOWATCH (1-877-246-9282). If it is confirmed that the vital signs transmitter is malfunctioning, then do the following:

1. Securely package the vital signs transmitter along with:
  - proof of purchase
  - a note including purchase date, a brief description of the malfunction and your name, address and phone number

2. Ship the package to the following address:  
(Insurance is recommended)

Biowatch Medical, Inc.

Attention: Warranty

1233 Washington Street, Suite 400

Columbia, SC 29201

FOR CUSTOMER SERVICE, CALL TOLL FREE:  
1-877-BIOWATCH (1-877-246-9282)

## TECHNICAL SPECIFICATIONS

### Vital Signs Transmitter

Model	VST <sup>3</sup>
FCC ID	SC7VST3
Vital Signs Monitored	ECG, body temperature
Data Storage	8 MB (up to 48 hrs w/o cellular transmission)
Material, strap	elastic
Material, vst	pellethane plastic
Battery Type	3.6V non-user replaceable lithium polymer cell
AC Adapter	5V 1A wall plug adapter module
Storage Humidity	0-95% relative, non-condensing
Storage Temperature	0-140 degrees F
Usage Temperature	40-110 degrees F
Usage Humidity	0-90% relative, non-condensing
Water Resistance	water resistant/NOT waterproof
Outer Dimensions	~ 21.75" x 1.6" x 0.5" (VST <sup>3</sup> ) ~ 14" x 1" x 0.2" expandable to ~ 33" x 1" x 0.1" (elastic strap)
Weight	~ 6 oz. (VST <sup>3</sup> ) ~ 1 oz. (elastic strap)

### Clinical Monitoring Center

Monitoring Services	
Availability	24 hours a day, 7 days a week, 365 days a year
Service Reliability	redundant backend systems
Data Storage	unlimited
Staff Certification	certified clinical care technicians
Facility Certification	CMS (HCFA)-Independent Diagnostic Testing Facility HIPAA-Compliant
Critical Events	special intervention for critical events
Online Reports	samples available upon request

It is recommended that the purchaser fill out the following information and retain for his/her files.

Purchaser Name \_\_\_\_\_

Date of Purchase \_\_\_\_\_

Serial Number \_\_\_\_\_

## NOTES

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1-877-BIOWATCH  
1-877-246-9282  
[www.biowatchmed.com](http://www.biowatchmed.com)