

Dear LifeWatch Technologies Ltd. device owner:

Thank you for selecting the LifeWatch Technologies Ltd. Vital Signs Patch (VSP) device, CG-1101XX (models CG-1101U, CG-1101B, CG-1101UC).

Please read this user guide before you start using your new device. The guide contains important information about your device as well as clear instructions about how to use it.

If you have any questions about the new Vital Signs Patch, please contact:

Customer Service at:

Copyright Declaration

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Before using the *VSP System* please read the Warnings and Precautions in Appendix A and the Contraindications on pages 5 and 6.

Declaration of Conformity

The VSP System consists of a disposable patch, a reusable processing unit and a Smartphone based application.

- The VSP System is classified as internally powered equipment with type BF applied parts.
- The device is suitable for continuous operation.
- The Patch (CG-1101XX) is classified as type IP54 equipment which affords protection against dust and splashing water.
- The VSP System is classified by the MDD as a Class IIa device (Pulse oximeter; ECG; Heart Rate; Body Temperature)

The VSP System is compliant with IEC 60601-1:2005 and IEC 60601-1-2:2007; however this does not preclude the possibility of electronic interference from other equipment where the device will need to be activated at a distance from the source(s) of interference.

LifeWatch Technologies' Quality System (QS) is
certified to ISO-9001:2008, ISO 13485:2003
CE 93/42 MDD and Canadian QS Requirements



WARNING

No modification of this equipment is allowed
Refer servicing to qualified personnel only.

DANGER












Equipment not suitable for use in the presence of flammable
anesthetic mixture with air or with Oxygen or Nitrous Oxide.



Federal Law (USA) restricts this device to sale by
or on the order of a practitioner licensed by the
law of the State in which he/she practices to use
or order the use of the device.

Graphic Symbols on VSP System

Label	Description
	Warning
	Precaution
	Notes; indicates important general information for using the system successfully.
	Refer to instruction manual/ booklet NOTE: On ME EQUIPMENT "Follow instructions for use."
	Manufacturer and date of manufacture
	Type BF Applied Part
	Indicates the temperature limits for storage of the device.
	WEEE Directive for disposal of Electrical and Electronic Equipment
	Symbol for no SPO ₂ alarms

Warning

Under no circumstances should you interpret your heart rate, body temperature, saturation or respiration vital signs or accelerometer data nor take any actions of a medical nature based on your understanding UNLESS you are a medical professional.

Intended Use

The Vital Signs Patch system is intended to be used by patients for the continuous, non-invasive monitoring of ECG, Heart Rate (HR), respiration, body temperature and blood saturation, when prescribed by a physician or other qualified healthcare professional.

The VSP includes pacemaker detection to show pulses of pacemaker on the screen and can therefore be used by users with a pacemaker.



Readings obtained using the **non-standard** 3-lead vital sign monitoring **should not** be compared with readings obtained using the **standard** 12-lead vital signs via standard electrode placement.

Contraindications

- The Vital Signs Patch (VSP) is not intended for use by persons with any type of defibrillator, external or internal (ICD); the VSP must be detached from the patient before using a defibrillator on the patient.
- The VSP is not intended for the treatment or alleviation of disease
- The VSP is not to be used in a magnetic resonance imaging (MRI) environment; the VSP unit must be removed from the patient's skin before he/she undergoes MRI analysis.
- The VSP is not a "life-saving" or therapeutic device; the VSP supplies vital signs data to a doctor or technician for the purpose of diagnosis by such (or other qualified) personnel
- The VSP is not intended for use for patients who have undergone surgery on the chest and who still have a fresh incision on the chest
- The VSP is not intended for use on patients with any skin damage on the area where the VSP is placed (such as burns, irritation, infections, wounds, etc.)

Contraindications regarding ECG/Heart Rate

Due to the possible seriousness of the abnormal heart rhythms that can be associated with the following conditions, persons with these conditions should consult with their physician before using the VSP:

- Coronary heart disease
- Valvular heart disease
- Heart transplant
Heart failure

General conditions for use of the VSP

Before using the VSP, check that you comply with the following conditions:

- You understand the principles of operation described in this manual.
- You speak and understand English or have access to a fluent English speaker who can explain how to use the device.
- You can attach the VSP to your body or have access to someone who can attach the VSP to your body.
- You can operate the Gateway application software or have access to someone who can operate the Gateway application software.
- You can operate simple push-buttons.

Precautions:

- Use the device only for the purposes described in these instructions for use.
- User Manual Warning: To prevent fire, do not expose the unit unnecessarily to moisture, nor to or excessive heat. Refer servicing to qualified personnel only
- Do not use this device if it is not working properly, or if it has suffered any damage.

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1 GLOSSARY

BRAIN	Main Processing Unit, vital sign data communication device that collects the body vital signs and sends these signs to the gateway device. The BRAIN can receive settings updates from the Gateway
ECG	Electrocardiogram; a representation of the heart's electrical activity recorded from electrodes on the body surface
Gateway device	Device for receiving vital signs from the BRAIN and transmitting them on to the monitoring center; the gateway can receive settings updates from the monitoring center
Heart Rate	The number of heartbeats per unit of time, usually per minute.
Monitoring Center	Monitoring Center equipped with hardware and software that receives, analyzes and stores vital signs signals received from the VSP system, and can generate reports for the medical staff
Respiration Rate	The number of movements of the chest wall per unit of time, indicative of inhalation and exhalation
RF	A range of radio frequencies used for wireless transmission
Saturation	Blood's oxygen saturation level measured in percentage
Temperature	The patient's body temperature recorded from a thermistor on the body surface
VSP	Vital Signs Patch system
CG-1101XX	Internal Part Number indicating the type of Vital Signs Patch (CG-1101C, CG-1101B or CG-1101UC)

2 VSP SYSTEM INTRODUCTION

2.1 General Description

The VSP system is a medical device that allows recording of heart rate, ECG (up to 3 Lead), body temperature, oxygen blood saturation and respiration; the VSP also enables transmission of vital sign recordings to a Monitoring Center, thereby allowing your physician or other medical personnel to monitor your health condition anywhere, any time.

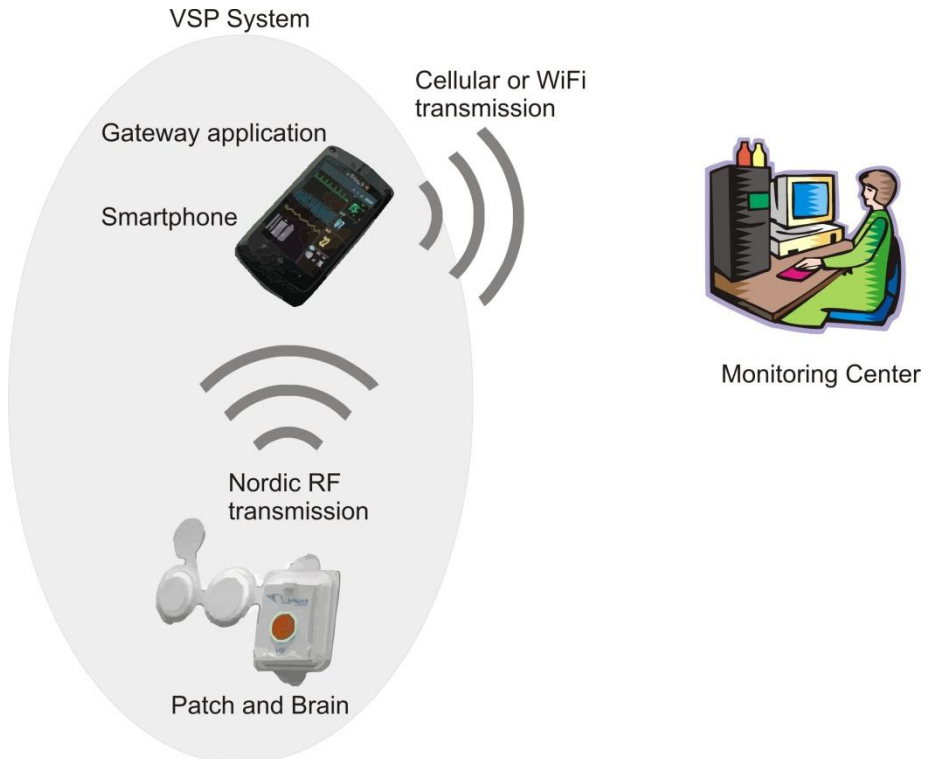


Figure 1 - Vital Sign Patch System

2.2 The VSP Kit

1. 3-lead Disposable Patch for upper placement
2. 3-lead Disposable Patch for lower placement
3. Brain
4. Gateway device
5. Gateway Charger
6. Quick User Guide (not shown)



Figure 2 - VSP Kit Components

3 PHYSICAL FEATURES

3.1 Parts

The VSP system includes the following components:

- Disposable Patch (CG-1101XX)
- Brain
- Gateway application

3.2 Patch

The Patch is a disposable unit that is attached to the body and contains the following sensors:

- ECG sensor
- Temperature sensor
- Blood oxygen saturation sensor
- Respiration sensor

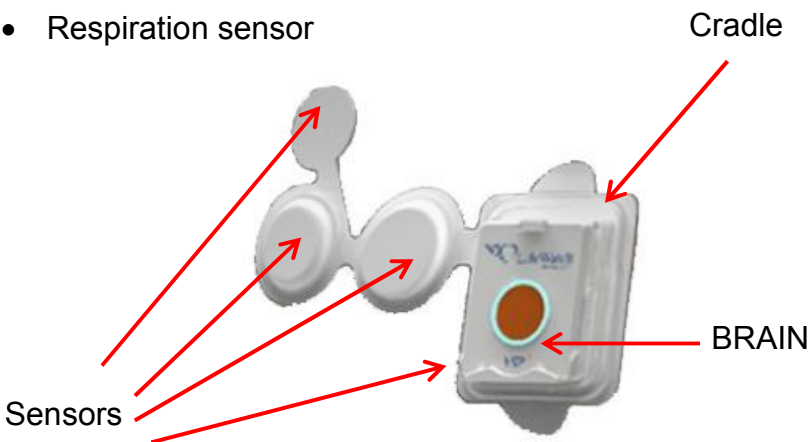


Figure 3 - Patch Components (general)

3.3 BRAIN

The BRAIN is a non-disposable part, containing an **RF transmitter** and a receiver for communicating with the Gateway. The BRAIN connects to the Patch via a dedicated cradle located on the Patch.

The BRAIN includes a processor unit, and receives power and vital signs data from the Patch. In addition, the Brain has an accelerometer for sensing when a patient falls.

The BRAIN has a centrally placed event **button** for recording and subsequent transmission of *manual events*. Events can also be triggered manually via an icon on the Gateway application.

A LED rim around the button blinks to indicate the status of the VSP system - a green light indicates that the VSP system is working properly, while a red light indicates a problem (refer to the troubleshooting section for details of possible problems).

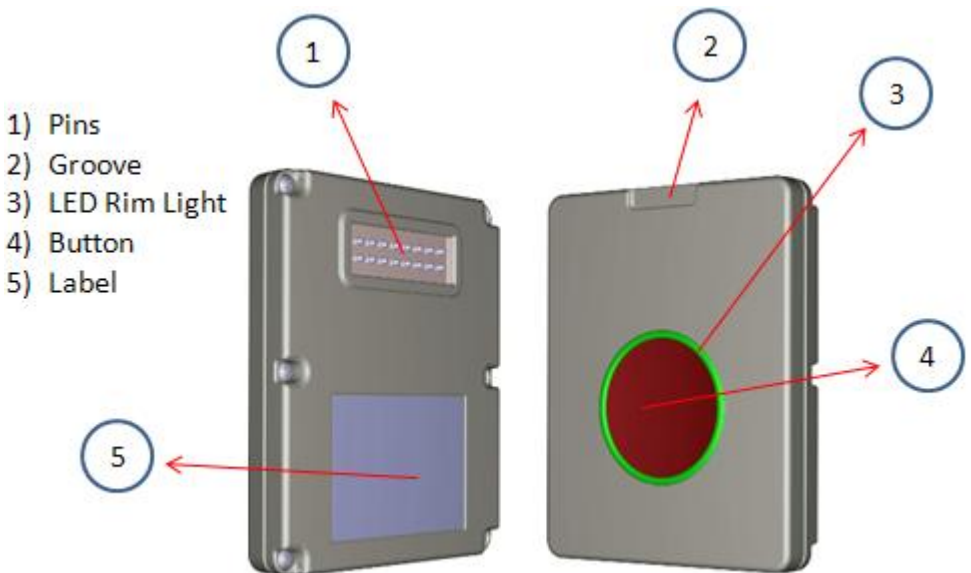


Figure 4 - Brain Components

3.4 Gateway Application

The Gateway application runs on a smartphone using the Android operating system, RF capabilities (Nordic), and a proprietary application.

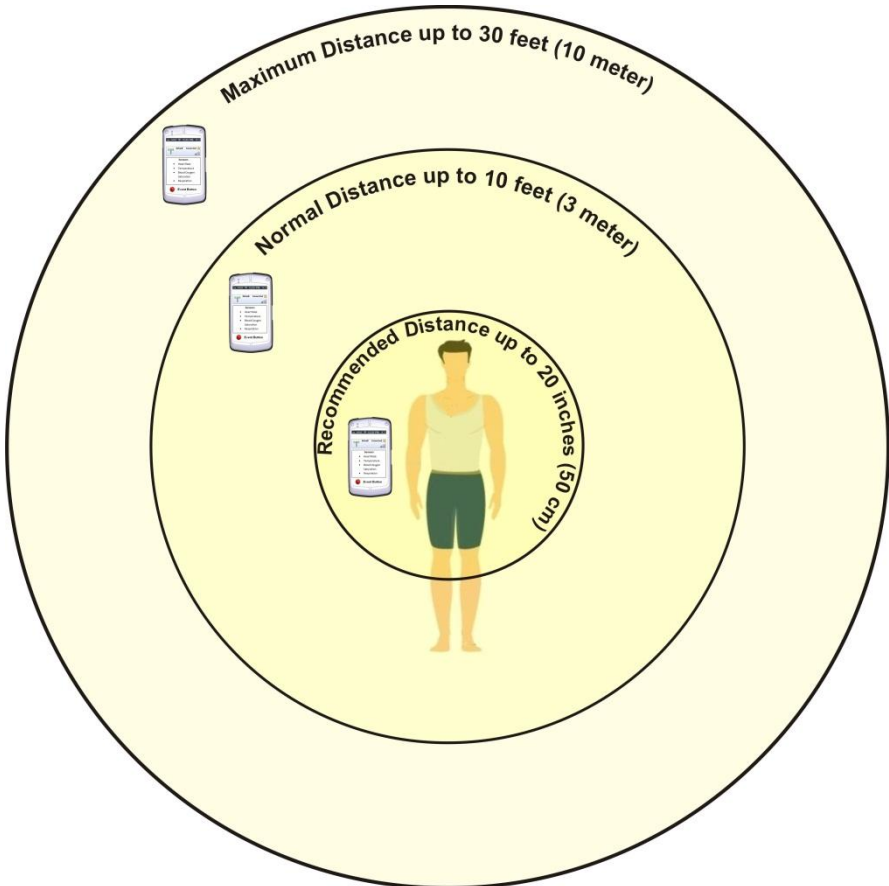


Figure 5 - Gateway Application

Gateway Placement



For optimal system performance, the recommended distances between the Gateway and Patch should be as follows:

- Within 20 inches (50 cm) for normal operation
- Within 10 feet (3 meters) during Gateway charging
- Within 30 feet (10 meters) maximum distance



3.5 Gateway Recharging Procedure

Charge the Gateway whenever possible during the day. In addition, charge the Gateway every night (regardless of battery level icon), making sure that the VSP is within 10 feet (3 meters) of the Gateway.

The Gateway battery level icon () indicates when charging is needed. When charging is complete, the battery level icon will indicate full charging ().

 Battery full	 Battery partially drained	 Battery very low	 Battery charging
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To Charge the Gateway

1. Plug the Gateway charger power cord into the power socket on the Gateway.
2. Plug the supplied Gateway charger unit into a standard wall outlet.
3. When finished, disconnect the Gateway charger from the wall outlet and then from the Gateway.

4 USING THE VSP SYSTEM

4.1 General

A certified clinician is responsible for dispensing the VSP to the patient. A trained and certified technician is responsible for maintaining and cleaning the reusable parts of the VSP System.

4.2 Patch

Before attaching the Patch you must prepare the skin.

4.2.1 *Preparing the Skin*

Skin Preparation

1. Wash the skin on the upper part of your chest using warm water and gentle soap if the Patch is placed in the top location.



Figure 6 - Skin Hair-removal Region

2. Wash the skin on the lower part of your chest using warm water and gentle soap, if the Patch is placed in the bottom location.
3. Remove excess hair from the areas by carefully clipping with scissors. Avoid shaving in order to minimize irritation.
4. Make sure that your skin is clean and fully dry before proceeding.
5. Do not apply the patch to skin that is broken or irritated.
6. Contact LifeWatch if you have any questions concerning the use of the device.

**Note**

There are physiological conditions that may affect the gateway from detecting the electrode connection for a certain period of time. Even though the sensors seem to be in good contact with the body, the alert message will continue to appear. Some examples that can cause delayed electrode recognition are very dry skin or contact immediately after attaching the electrodes. If the condition does not resolve, contact LifeWatch.

4.2.2 Placing the Upper 3-lead Patch

To place the patch

1. Peel off the plastic liner covering the adhesive from the back of the Patch contact pad.
2. Dispose of the plastic liner.
3. Place the Patch on the skin vertically aligned with the mid-point of the chest.

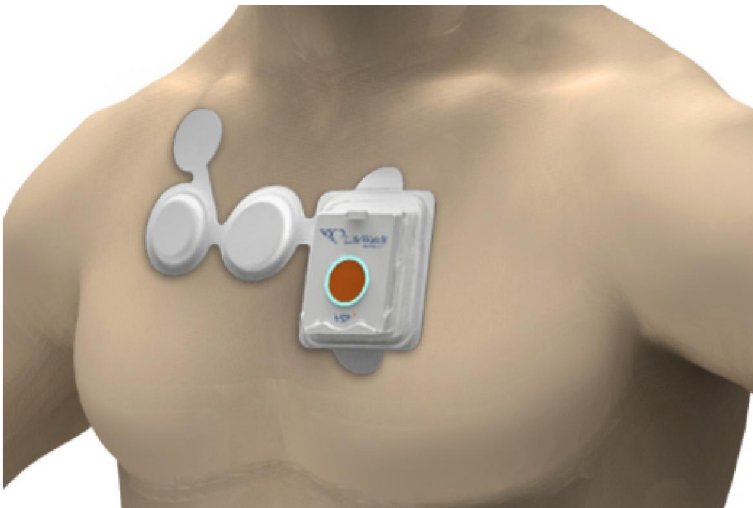


Figure 7 – Upper Patch Placement

4.2.3 Placing the Lower 3-lead Patch

To place the patch

1. Peel off the plastic liner that covers the adhesive from the back of the Patch contact pad.
2. Dispose of the plastic liner.
3. Place the Patch on the skin vertically aligned with the mid-point of the left half of the chest, approximately 5 cm (2 inches) below the left breast.
4. Place the upper electrode of the Patch approximately 5 cm (2 inches) above the right of the sternum.

In order to collect vital sign data the Patch must be placed on an area of the body containing veins. If the breast prevents the Patch from being placed in the correct location, lift the breast slightly.

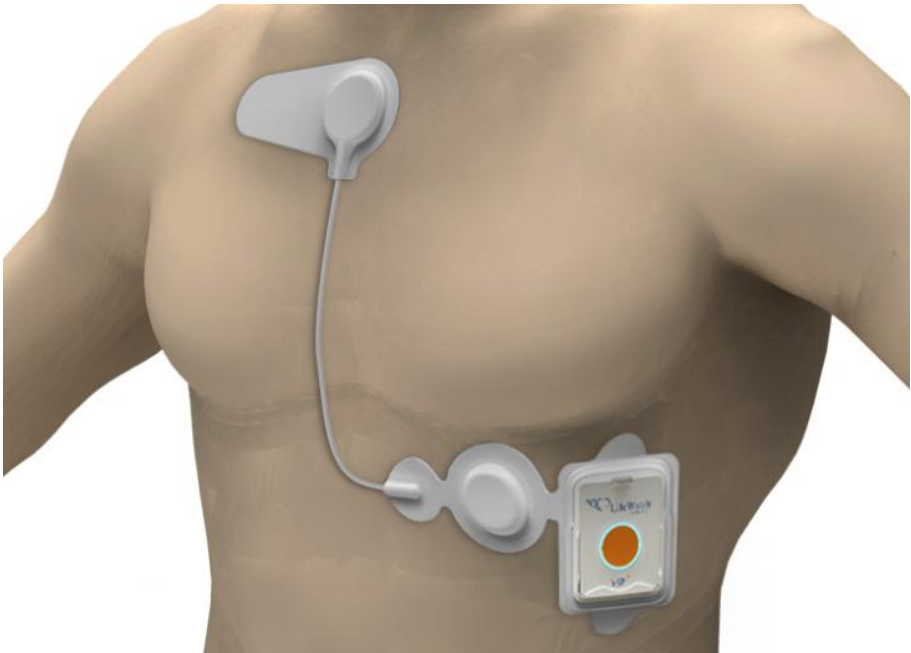


Figure 8 – Lower Patch Placement

4.3 Installing the Brain

To install the Brain

1. Position the Brain in the cradle with the groove facing upwards and the button facing outwards.
2. Push gently until the tab on the cradle locks into the groove on the Brain. If the brain is correctly installed it will start to receive signals from the sensors in the Patch (Brain/patch ON, removal of Brain OFF).

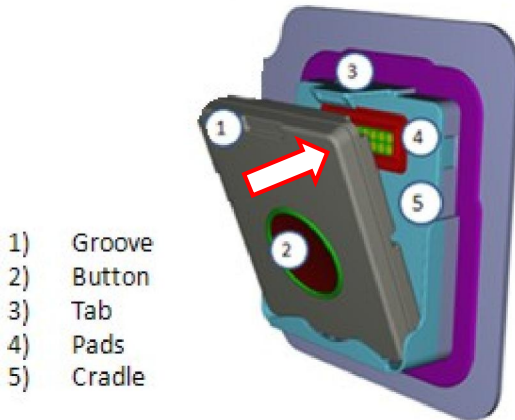


Figure 9 - Placing Brain into Cradle

Ensure that the Brain is positioned properly with the correct side up before pushing it into place.



Precaution: Using excessive force when putting the Brain in the cradle can cause the pins to bend, preventing the Brain from being installed or removed.

4.4 Removing the VSP

To remove the patch

- Peel the Patch contact pads from the skin.

If you experience difficulty in removing the Patch contact pads, use water to weaken the adhesive.

Do not use the VSP if you have a history of experiencing irritation to electrode adhesives.

To remove the Brain

1. Lift the tab (**Item 3** in Figure 9) holding the Brain in the cradle.
2. Place finger in the groove (**Item 1** in Figure 9) on the top of the Brain.
3. Gently pull the top of the Brain away from the cradle.
4. Remove the Brain from the cradle, remove the battery from the patch and place in the envelope to return to LifeWatch.

WARNING



The Patch is for single use only.

Dispose of the Patch after use in a place designated as for disposal of biomedical waste.

WARNING



Dispose of the battery in a battery disposal that meets WEEE requirements.



Note

Returning the Patch to LifeWatch Services ensures proper disposal.

5 USING THE GATEWAY APPLICATION

5.1 Starting the Application

To start the Gateway application

- Activate the device running the application. The application is automatically launched and the Main Screen is displayed.

The maximum unblocked distance between the Brain and the Gateway is 10 meters (30 ft.); walls and other obstructions will reduce this distance. Do not exceed this distance under any circumstances as this will prevent data transfer from the Brain.

5.2 VSP Screen

The VSP screen displays signal, connectivity, time, available battery power and the Gateway application functions and screens.

5.3 Gateway Application Functions

The Gateway application has the following functions:

- Displaying the main screen
- Displaying sensor data
- Displaying HW/SW version on the About screen
- Displaying alerts
- Creating manual events
- Displaying questionnaires

5.3.1 Displaying the Main Screen

To display the main screen

- Activate the device that contains the application. The main screen is displayed.

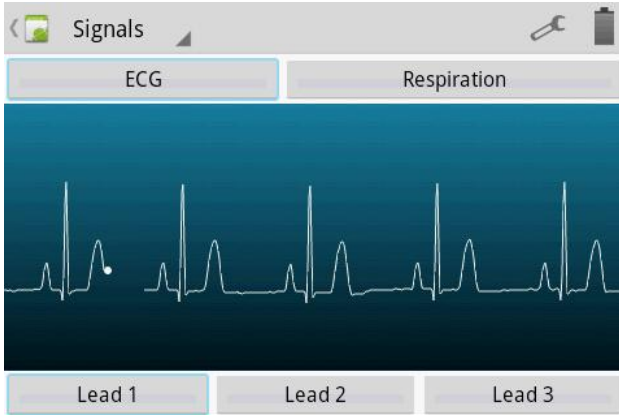


Figure 10 – Main screen

5.3.2 Displaying Sensor Data

To display data on the signal viewer

1. Select one of the vital sign signal viewers from the Main Screen.
2. Enter the password. The raw signal data is displayed.

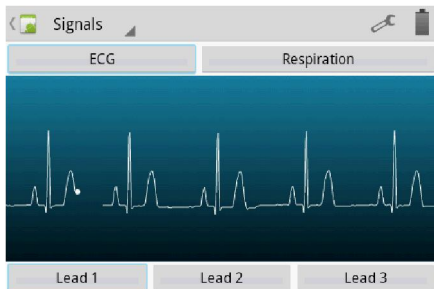


Figure 11 – ECG



Respiration

5.3.3 Displaying HW/SW Version on the About Screen

To display hardware/software information on the screen

- On the left bottom, press the Menu button. Then, click **About**.
The About screen is displayed with the hardware, software and Gateway application versions.

5.3.4 Displaying Alerts

An error initiates one of two types of alerts – one for the Brain and one for the Gateway.

5.3.4.1 Brain Error Alerts

A Brain error triggers the following alerts:

- LED rim light flashes red
- VSP system initiates sporadic beeping (1 sec beep)
- Gateway screen displays the error

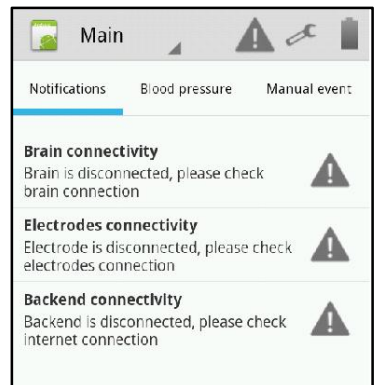
5.3.4.2 Gateway Error Alerts

A Gateway error triggers the following alerts:

- VSP brain initiates sporadic beeping
- Gateway screen displays the error

An alert will continue as long as the error exists. Any errors occurring during an initial alert will be indicated as well.

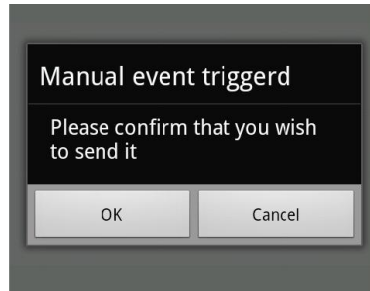
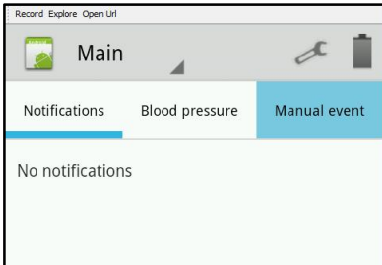
- Once an error has been corrected, the alert stops and the Main Screen is displayed.



5.3.5 Creating Manual Events

There are two methods for creating a manual event:

- Pushing the Manual Event button on the Brain.
- Tapping the Manual Event button in the Gateway application.



When a manual event is created, the following occurs:

1. The Gateway application notifies the Monitoring Center that a manual event was created.
2. A questionnaire appears in the Gateway application asking the patient to identify the symptom(s) being experienced by the patient.

The figure displays two screenshots of the Gateway Questionnaire interface. Both screens have a top bar with 'Main', a settings icon, and a battery icon. Below the bar are tabs for 'Notifications', 'Blood pressure', and 'Manual event'. A progress bar at the top of the questionnaire area indicates the time remaining.

Left Screenshot: The progress bar shows 'Questionnaire will be closed in 43 seconds'. The list of symptoms includes:

- ☒ Lightheadedness/Dizziness
- ☐ Passed
- ☒ Chest Pain/Tightness
- ☒ Palpitations/Rapid Heart Rate
- ☒ Fluttering in the chest
- ☐ No Symptoms
- ☐ Other

 At the bottom are 'Next' and 'Close' buttons.

Right Screenshot: The progress bar shows 'Questionnaire will be closed in 42 seconds'. The list of activities includes:

- ☐ Normal daily routine
- ☐ Sitting
- ☒ Laying down
- ☐ Sleeping
- ☐ Exercising
- ☐ Not sure

 At the bottom are 'OK' and 'Close' buttons.

Figure 12 - Gateway Questionnaire

5.3.5.1 Responding to the Gateway Questionnaire

To respond to the Gateway questionnaire

1. Tap to check the relevant symptom(s) from the predefined list.
2. Click **Send**. The questionnaire is closed, and the data is sent.

If the questionnaire is not completed in the allotted time, the responses are sent to the Monitoring Center. If the patient does not respond to the questionnaire after the allotted time, the blank questionnaire is sent to the Monitoring Center.

6 HEART RATE CALCULATION METHOD

6.1 Introduction

This section describes the heart rate (HR) calculation within the LifeWatch V. HR is defined as the number of heart beats during a GIVEN TIME INTERVAL (usually one minute). It is reported by the algorithm each time a QRS complex is detected.

6.2 Method of Calculation

The momentary HR is the inverse of the time lasting between two consecutive heart beats. As the momentary HR fluctuates due to inaccuracies in detecting the exact R wave timing eight momentary HR values are averaged to generate the displayed HR. Therefore the reported HR is the mean of the last momentary HR values WHICH CORRESPOND TO THE DETECTED R COMPLEXES FOR THE LAST 8 SECONDS.

OCCASIONS IN WHICH THE HR IS NOT REPORTED: If during a specific QRS complex the signal is considered as too low to be considered accurate or is considered as noise, the displayed HR will be 0.

7 PAUSE CALCULATION

Pause is considered a lack of Ventricular activity for more than 3 seconds. In order to detect a pause one of two conditions needs to be detected:

1. Lack of QRS detection for more than 3 seconds
2. A flat signal (P complexes can occur) for slightly less than 3 seconds.

Once one of the above conditions is detected a pause event is called.

8 MAINTENANCE

8.1 Conditions of Use

Your VSP conforms to international regulations insofar as it is used under normal conditions and in accordance with the instructions below.

8.2 Caring for your VSP

- Do not open or attempt to repair your VSP yourself. Only authorized service personnel may repair the product.
- Do not bend the Brain, which can damage the circuitry.
- Do not use extreme force when pressing the button on the Brain.
- Do not submerge the Brain in water.

8.3 Cleaning

The clinician should clean the Brain with a wet towel and 99% isopropyl alcohol after use between patients.

8.4 Environment

- Keep the VSP away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in any place that is extremely damp or dusty.
- Do not store the VSP in a place where it will be continuously exposed to moisture, steam or perspiration, etc. Extended exposure to moisture may cause malfunction.

The battery and electronics of the VSP are covered by the European Directive 2012/19/EC (WEEE) or by other local/national environmental regulations.



All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

You can also dispose of the Patch by returning it to LifeWatch as per their instructions. Correct disposal of the Patch will help prevent potential negative consequences for the environment and human health.

9 TROUBLESHOOTING

Problem	Possible Cause(s)	Solution
VSP system displays failure or an inaccurate reading.	Patch has become loose or detached. Electrodes not clean; skin is oily or with excessive hair.	Make sure Patch is correctly placed or detach and reattach. Restart Gateway. Clean electrodes, clean or shave skin. Contact LifeWatch customer service.
Data is not being transmitted to the smartphone.	Disconnected RF channel between Brain and Gateway.	1) Verify the smartphone is set for communication and the VSP system is listed as a paired device. 2) Move the Brain closer to the Gateway (Gateway has a range of 10 meters). 3) Replace Patch. 4) Contact LifeWatch customer service.
No display when Gateway is activated.	The battery is very low or depleted.	Connect the Gateway to charger to charge the battery.
Hardware error.	Hardware not functional.	Contact LifeWatch customer service.

If you are experiencing a critical error not included in this table, restart any running applications and then disconnect and reconnect the Brain. If the critical error is not resolved, contact LifeWatch Customer Service.

10 SPECIFICATIONS

10.1 VSP Brain Specifications

Parameter	Min	Max	Typical	Units
<i>Input Operating DC voltage</i>	2	3.3		V
<i>Average Current consumption</i>			10	mA
<i>Without SPO2</i>			7.5	mA
<i>Peak Current Consumption</i>			50	mA
<i>Manual event triggering</i>	N/A	N/A	Yes	None
Environmental and Operating conditions				
<i>Operating temperature</i>	10 (50)	45 (113)	N/A	°C (°F)
<i>Environmental Operation humidity</i>	10%	95%		
<i>Environmental atmospheric pressure</i>	70	106		kPA
<i>Transport & storage temperature</i>	-20 (-4)	65 (149)	N/A	°C (°F)
<i>Transport & storage humidity</i>	10%	85%		
<i>Transport & storage atmospheric pressure</i>	50	106		kPA
Dimensions				
<i>Dimensions (max.)</i>	N/A	N/A	59 x 47 x 9 (2.32 x 1.85 x 0.35)	mm (inch)
<i>Net Weight</i>			23 (0.811)	gr. (oz.)

Parameter	Min	Max	Typical	Units
ECG				
<i>ECG Input Impedance</i>	10			MΩ
<i>ECG Input dynamic range</i>	N/A	+/- 5	N/A	mV
<i>ECG ADC sample Rate</i>	250	250	250	Hz
<i>ECG DC offset correction</i>	0	+/-300		mV
<i>ECG HPF Cutoff Frequency</i>	N/A	N/A	131	Hz
<i>ECG System noise</i>	0	30		μV
Respiration				
<i>Respiration Impedance</i>	500	2000	N/A	Mohm
<i>Respiration Δ Impedance</i>	0.2	3	N/A	Mohm
<i>Respiration Sampling Rate</i>			25	/sec
Temperature				
<i>Temperature Range</i>	35 (95)	42 (107.6)	N/A	°C (°F)
<i>Temperature Accuracy</i>			0.3 (0.54)	°C (°F)
Accelerometer				
<i>Accelerometer Acceleration Range</i>	0.1	6.0	N/A	G
<i>Accelerometer Sampling Rate</i>			50	/sec
<i>Accelerometer resolution</i>			12bit A2D	

Parameter	Min	Max	Typical	Units
SPO2 specification				
Saturation LED Current	5	30		mA
Saturation Measurement Resolution			16bit A2D	
Saturation Noise (in darkness)			2bit A2D	
Saturation Sampling Rate			13	/msec
SPO2 parameters				
Oxygen saturation range:	70 to 100 %			
Pulse rate range:	18 to 300 pulses per minute			
Data averaging and update period	3 seconds; data is sent every 0.5 seconds			
Measurement wavelengths:	Red 660 nanometers Infrared 910 nanometers			
Alarm indication	The device does not have the capability to detect an SpO2 or pulse rate physiological alarm condition			
Pulse rate Accuracy	3 % ± 1 digits			
SPO2 Accuracy	Root Mean Square (RMS) error: 3.5%			
Note: because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a co-oximeter.				

10.2 VSP Patch Specifications

VSP Patch specifications are listed below:

Parameter	Min	Max	Typical	Units
<i>Dimensions (max.)</i>				
<i>Upper</i>	N/A	N/A	195 x 115 (7.7 x 4.5)	mm (inches)
<i>Lower</i>	N/A	N/A	192 x 110 (7.6 x 4.3)	mm (inches)
<i>Battery type</i>			lithium/ manganese dioxide	
<i>Battery voltage</i>			3.0	V
<i>Battery capacity</i>			1500	mAh
<i>Battery dimensions</i>			5.5x35x35	mm
<i>Battery life</i>	4	7	Use dependent	Days (dependent upon mode)
<i>Net Weight</i>			50 (1.76)	g (oz.)

10.3 Transmission Specifications

Parameter	Typical	Units
<i>Operating Frequency</i>	2.4GHz	MHz
<i>Output power</i>	0	dBm
<i>Crystal frequency</i>	16	MHz
<i>Frequency deviation @ 250kbps</i>	±160	kHz
<i>Frequency deviation @ 1Mbps</i>	±160	kHz
<i>Frequency deviation @ 2Mbps</i>	±320	kHz
<i>Air Data rate</i>		kbps
<i>Non-overlapping channel spacing @ 250kbps/1Mbps</i>	1	MHz
<i>Non-overlapping channel spacing @ 2Mbps</i>	2	MHz

APPENDIX A WARNINGS AND PRECAUTIONS

Declaration of RoHS Compliance

The VSP was designed by LifeWatch Technologies Ltd. to comply with Directive 2011/65 /EC of the European Parliament - RoHS (Restriction of Hazardous Substances) - with respect to use of the following substances in the device:

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent Chromium (Cr (VI))
- Polybrominated biphenyls (PBBs)
- Polybrominated diphenyl ethers (PBDEs)

Warnings



The VSP is not intended for use in the diagnosis of myocardial infarction or for chest pain monitoring.

Due to the risk of ignition or fire, the *VSP* is not intended for use in a hyperbaric chamber, within an oxygen tent or in the presence of flammable anesthetics / medical gases.

To prevent an allergic reaction, do not use the *VSP* or accessories if you have a known allergy to nickel, silver or other metals.

The *VSP* is not defibrillation-proof. Exposure to defibrillation may damage the *VSP*, or the *VSP* may interfere with the operation of the defibrillator.

The user of the *VSP* should not take any actions of a medical or clinical nature based on his/her understanding or interpretation of monitoring without consulting a healthcare professional.

The VSP System should not be used to monitor chest pain and it cannot predict or diagnose a heart attack (myocardial infarction).

Do not operate the VSP in combination with the following medical electronic devices as this may cause a malfunction of this device:

Electronic life support systems such as an artificial heart/lung.

Precautions



The VSP System generates, uses, and can radiate radio frequency energy and, if not used in accordance with the instruction manual, may cause harmful interference to radio communications.

The VSP System employs cellular technology. The location of the VSP System and the associated environment, including cellular phone coverage in the particular area, may cause transmission interruption or delay.

Do not open or attempt to repair the device. Only authorized service personnel may repair the system components.

To avoid damage to the system, the system and accessories should be kept away from extreme heat, including placement of the VSP on the dashboard of a car or near a heater.


The system should not be subjected to severe impact or bending force. Exposure to these types of stresses can damage the system components.

Do not use or store the VSP in a location where liquids such as water, juice, coffee can splash on it.

The VSP is intended to be used in conjunction with a monitoring service that reviews the transmissions and provides information to the physician for his/her final diagnostic interpretation.

The VSP is not intended for use as an emergency medical response system and should not be used by patients at risk for serious or life-threatening cardiac arrhythmias.

If you are experiencing symptoms that are not consistent with any of your monitoring, you should consult your healthcare provider, doctor or other appropriate medical professional.

	If you are taking medications you should consult your healthcare professional concerning the possible effect of the medications on the monitoring.
	Note: Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment. THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

IMPORTANT FCC Part 15

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.

FCC WARNING

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 the receiver.
- Connect the equipment into an outlet different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTE: THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

Gateway (Cellular Phone) Warnings

Using Your Gateway near Other Electronic Devices

Most modern electronic equipment is shielded from radio frequency (RF) signals.

However, certain electronic equipment may not be shielded against the RF signals from your wireless phone. Consult the manufacturer to discuss alternatives.

Implantable Medical Devices

A minimum separation of six (6) inches (15 cm) should be maintained between a handheld wireless phone and an implantable medical device, such as a pacemaker, to avoid potential interference with the device.

Persons who have such devices:

- Should ALWAYS keep the phone more than six (6) inches (15 cm) from their implantable medical device when the phone is turned ON;
- Should not carry the phone in a breast pocket;
- Should use the ear opposite the implantable medical device to minimize the potential for interference;
- Should turn the phone OFF immediately if there is any reason to suspect that interference is taking place.
- Should read and follow the directions from the manufacturer of your implantable medical device. If you have any questions about using your wireless phone with such a device, consult your health care provider.

Hearing Aid Compatibility with Mobile Phones

FCC Hearing-Aid Compatibility (HAC) Regulations for Wireless Devices

On July 10, 2003, the U.S. Federal Communications Commission (FCC) Report and Order in WT Docket 01-309 modified the exception of wireless phones under the Hearing Aid Compatibility Act of 1988 (HAC Act) to require digital wireless phones be compatible with hearing-aids. The intent of the HAC Act is to ensure reasonable access to telecommunications services for persons with hearing disabilities.

While some wireless phones are used near some hearing devices (hearing aids and cochlear implants), users may detect a buzzing, humming, or whining noise. Some hearing devices are more immune than others to this interference noise, and phones also vary in the amount of interference they generate.

The wireless telephone industry has developed a rating system for wireless phones, to assist hearing device users find phones that may be compatible with their hearing devices. Not all phones have been rated. Phones that are rated have the rating on their box or a label located on the box.

The ratings are not guarantees. Results will vary depending on the user's hearing device and hearing loss. If your hearing device happens to be vulnerable to interference, you may not be able to use a rated phone successfully. Trying out the phone with your hearing device is the best way to evaluate it for your personal needs.

M-Ratings: Phones rated M3 or M4 meet FCC requirements and are likely to generate less interference to hearing devices than phones that are not labeled. M4 is the better/higher of the two ratings.

T-Ratings: Phones rated T3 or T4 meet FCC requirements and are likely to be more usable with a hearing aid's telecoil than phones that are not rated. T4 is the better/higher of the two ratings.

Hearing devices may also be rated. Your hearing device manufacturer or hearing health professional may help you find this rating. Higher ratings mean that the hearing device is relatively

immune to interference noise. The hearing aid and wireless phone rating values are then added together. A sum of 5 is considered acceptable for normal use. A sum of 6 is considered for best use.

In the above example, if a hearing aid meets the M2 level rating and the wireless phone meets the M3 level rating, the sum of the two values equal M5. This should provide the hearing aid user with “normal usage” while using their hearing aid with the particular wireless phone. “Normal usage” in this context is defined as a signal quality that is acceptable for normal operation.

The M mark is intended to be synonymous with the U mark. The T mark is intended to be synonymous with the UT mark. The M and T marks are recommended by the Alliance for Telecommunications Industries Solutions (ATIS). The U and UT marks are referenced in Section 20.19 of the FCC Rules. The HAC rating and measurement procedure are described in the American National Standards Institute (ANSI) C63.19 standard.

Some digital wireless phones may interfere with some hearing aids. In the event of such interference, you may wish to consult your hearing aid manufacturer to discuss alternatives.

Other Medical Devices

If you use any other personal medical device, consult the manufacturer of your device to determine if it is adequately shielded from external RF energy. Your physician may be able to assist you in obtaining this information. Switch your phone off in health care facilities when any regulations posted in these areas instruct you to do so. Hospitals or health care facilities may be using equipment that could be sensitive to external RF energy.

Children Using Wireless Phones

The scientific evidence does not show a danger to users of wireless phones, including children and teenagers. If you want to take steps to lower exposure to radio frequency energy (RF), the measures described above would apply to children and teenagers using wireless phones. Reducing the time of wireless phone use and increasing the distance between the user and the RF source will reduce RF exposure.

Some groups sponsored by other national governments have advised that children be discouraged from using wireless phones at all. For example, the government in the United Kingdom distributed leaflets containing such a recommendation in December 2000. They noted that no evidence exists that using a wireless phone causes Brain tumors or other ill effects. Their recommendation to limit wireless phone use by children was strictly precautionary; it was not based on scientific evidence that any health hazard exists.

Body-worn Operation

To comply with RF exposure requirements, a minimum separation distance of 0.50 inch (1.5 cm) must be maintained between the user's body and the handset, including the antenna. Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-worn accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided.

Use only the supplied or an approved antenna. Unauthorized antennas, modifications, or attachments could impair call quality, damage the phone, or result in violation of regulations. Do not use the phone with a damaged antenna. If a damaged antenna comes into contact with the skin, a minor burn may result. Please contact your local dealer for replacement antenna.

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UG-00077 rev01 2013-03