

LifeWatch Technologies Ltd. Vital Signs Patch (VSP) Gateway

The LifeWatch Technologies Ltd. Vital Signs Patch (VSP) device is used with the VSP Gateway as part of the VSP System.

Before using the VSP Gateway, please read the sections of this guide that describe its method of use and operation.

The VSP Gateway model number FGL-00005, FCC ID: SMTLWVGW

The references to gateway within this user guide refer to the VSP Gateway.

If you have any questions about the use of 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.

Declaration of Conformity

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.



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

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
	WEEE Directive for disposal of Electrical and Electronic Equipment

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1 GLOSSARY

VSP TRANSMITTER	Main Processing Unit, vital sign data communication device that collects the body vital signs and sends these signs to the gateway device.
ECG	Electrocardiogram; a representation of the heart's electrical activity recorded from electrodes on the body surface
VSP Gateway	Device for receiving vital signs from the VSP TRANSMITTER and transmitting them on to 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 device (patch with transmitter and cradle)

2 VSP SYSTEM INTRODUCTION

2.1 General Description

The VSP system is a medical device that records heart rate, ECG (3 Lead), surface temperature, blood oxygen saturation and respiration; the VSP transmits the vital sign recordings to a Monitoring station for viewing by medical personnel.

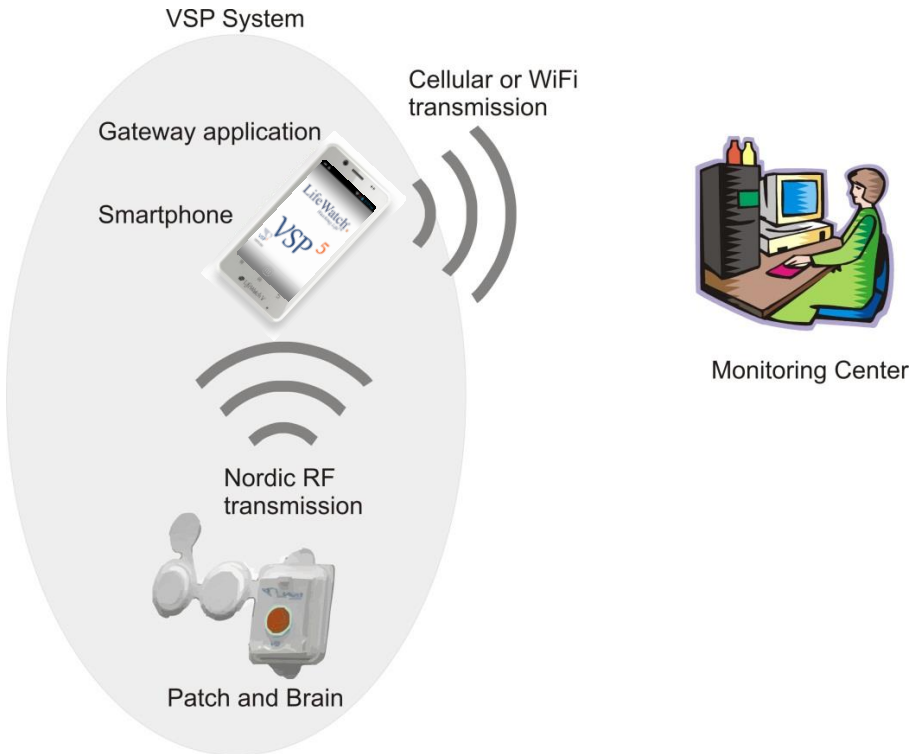


Figure 1 - Vital Sign Patch System

2.2 Physical Description

Front View

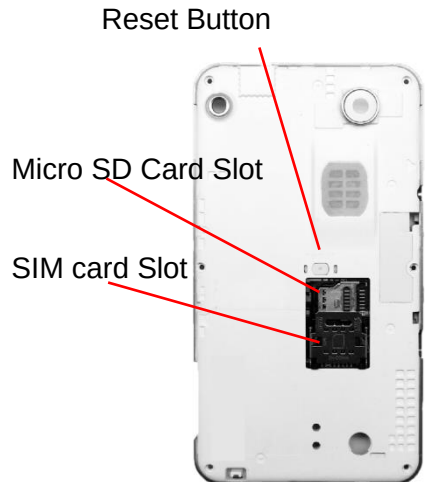


Rear View

Loudspeaker Rear Camera



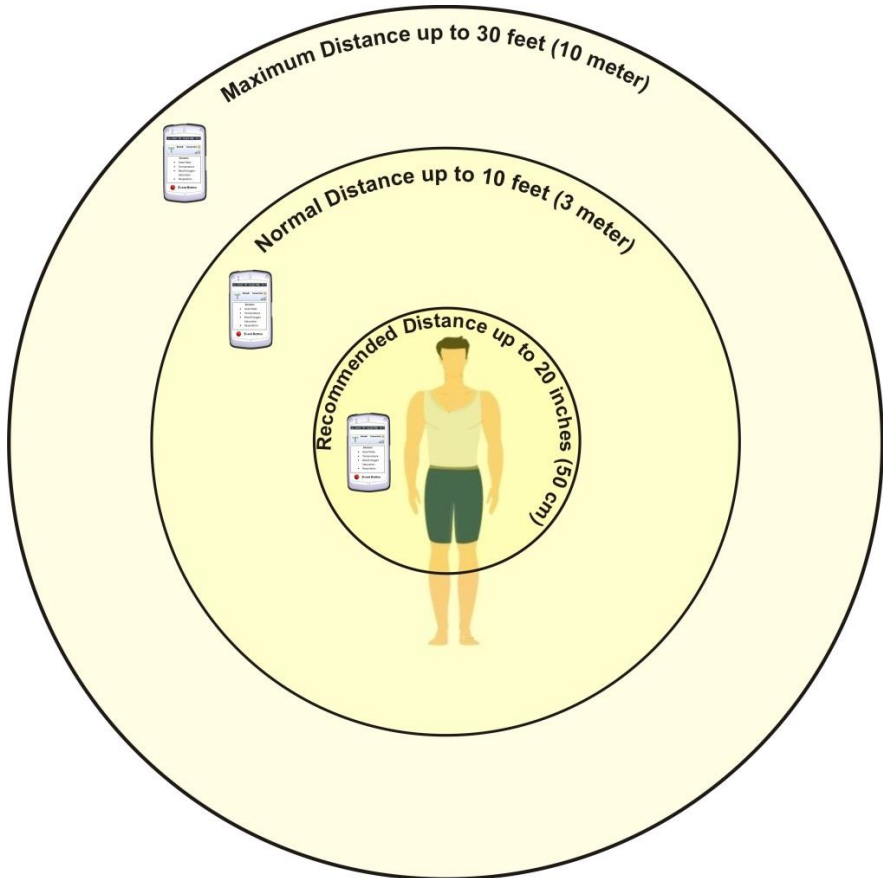
Rear Cover Removed



2.3 VSP Gateway Placement

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

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



1 VSP GATEWAY BASIC OPERATION

1.1 For Your General Safety

The *VSP Gateway* device is a cell phone used within a medical system.

	Do not make or receive handheld calls while driving; do not text while driving.		Keep the device away from pacemakers, ICDs and other electronic medical devices (at least 6 inches/15 cm).
	Do not use the device at gas/petrol stations.		Do not expose the device to extreme temperatures.
	Keep your phone at least 15 mm away from your ear or body while making calls.		Switch the device off when asked to in hospitals and medical facilities.
	Your phone may produce a bright or flashing light.		Avoid contact with liquids. Keep your phone dry.
	Small parts may cause choking.		Switch the device off when told to in aircrafts and airports.
	Don't dispose of your device in fire.		Don't take your device apart.
	Your device can produce a loud sound.		Switch your device off when near explosive materials or liquids.
	Avoid contact with anything magnetic.		Only use approved accessories.
	Do not rely on your device for emergency communications.		

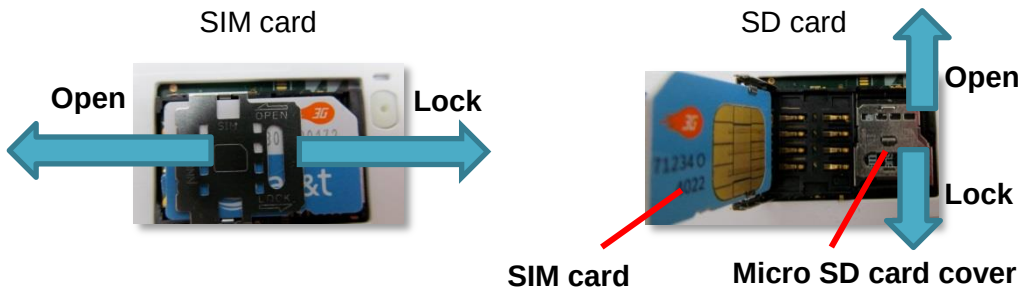


Before using the *VSP Gateway* please read Appendix A, Warnings and Precautions, thoroughly.

3 GETTING STARTED

3.1 Installing the SIM card/micro SD card

1. Switch off your device before installing SIM.
2. Open the SIM card holder by sliding it in the direction of the OPEN arrow.
3. Hold the SIM card by the cut corner and slip it into the card holder.
4. Pull the micro SD cover tag by sliding it in the direction of the OPEN arrow.
5. Hold your micro SD card with the metal contacts facing down and slide it in.
6. Press the micro SD cover gently back into place, sliding it in the direction of the LOCK arrow
7. Press the SIM card holder gently back into place, sliding it in the direction of the LOCK arrow, until you hear a click.



Rear cover removal – **Place your fingernail in the notch in the bottom of the device and pull the rear cover upwards.**

Note: Do not bend or twist the back cover excessively; doing so may damage the cover.

NOTE: micro SD logo  is a trademark of the SD Card Association.

3.2 Charging the Battery

1. Connect the supplied USB plug to the USB/adaptor jack. Ensure that you insert the plug with the correct orientation. Do not force the plug into the jack.

USB input is 5 VDC: maximum 5.25VDC to minimum 4.75VDC at 1A max.

2. Connect the USB cable's USB plug to the adapter.
3. Connect the adapter to a standard AC wall outlet.
4. Disconnect the adapter when the battery is fully charged.

NOTE: When you first receive your device you will need to charge the battery for 12 hours with the device turned off.



Use only the supplied adaptor PA1005-050UIB070.
Input is 100 to 240 V, ~50 to 60 Hz, 0.3A;
Output is 5 V, 0.7A, 3.5 W maximum

3.2.1 How much charge is in the battery?

If the battery is low, a message appears. When charging, there will be an indication of the battery level.

The VSP 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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When finished, disconnect the VSP Gateway charger from the power adapter and then from the VSP Gateway.

3.2.2 Switching Your Device On/Off

- ◆ Hold Power to switch on your device.
- ◆ To switch it off, hold Power to get the device options. Select Power off, and then tap OK.

Always place the adapter in easily accessible main plugs.



In case of electrical malfunction of the device during the connection to the adapter, remove the adapter from main plug immediately.

3.3 Setting up Your Device for the First Time will be done by LifeWatch Technical staff

3.3.1 Waking Up Your Device

1. Press **Power** to activate your screen display.
2. Drag the icon  to the right.

3.4 Getting Around Your Device

3.4.1 Touch Control

You can use finger gestures to control your device. The controls on your touchscreen change dynamically depending on the tasks you're performing.

1. Tap the buttons, icons, or applications to select items or to open applications.
2. Keep your finger on an item to see the available options.
3. Flick the screen to scroll up, down, left or right.
4. Point, drag and drop to move particular items across the screen.
5. Pinch with two fingers or double-tap the screen to zoom in/out on a web page or an image.
6. **NOTE:** You can view the device screen in portrait or landscape orientation simply by holding it upright or turning it on its side. Not all screens are viewable in landscape.

4 USING THE GATEWAY APPLICATION

4.1 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 VSP Transmitter 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 VSP Transmitter. Do not place the Gateway under a metal frame bed.

4.2 VSP Screen

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

4.3 Gateway Application Functions

The Gateway application displays the following information:

- Full screen displaying medical signals (ECG or respiration)
- Display of the HW/SW version on the About screen
- Display Main screen with alerts

4.4 Displaying the Medical Signals

To display medical signals

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



Figure 2 – Medical signal display

To choose display of ECG or respiration

1. Select the vital sign signal viewer from the display.
2. The raw signal data is displayed.

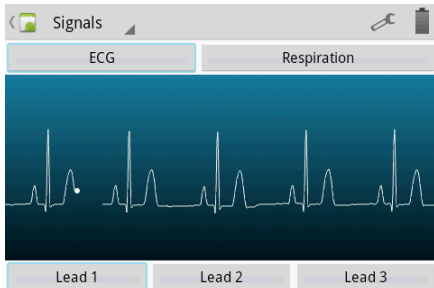
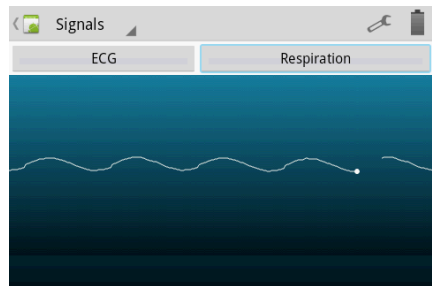


Figure 3 – ECG

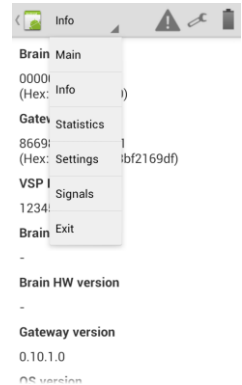


Respiration

4.4.1 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 **Info**. The Info screen is displayed with the hardware, software and Gateway application versions.



4.4.2 Displaying Alerts

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

4.4.2.1 VSP Transmitter Error Alerts

- VSP system initiates 1-3 beeps (1 sec beep)
- Gateway screen displays the error

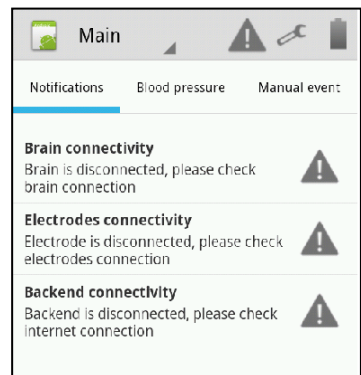
4.4.2.2 Gateway Error Alerts

A Gateway error triggers the following alerts:

- VSP Transmitter 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 CLEANING AND MAINTENANCE

5.1 Conditions of Use

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

5.2 Caring for your VSP Gateway

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

5.3 Cleaning

A trained and certified technician is responsible for maintaining and cleaning the reusable parts of the VSP System. The VSP Gateway should be cleaned prior to transferring to another patient.

5.4 Environment

- Keep the VSP Gateway 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 Gateway in a place where it will be continuously exposed to moisture or steam. Extended exposure to moisture may cause malfunction.



The battery and electronics of the VSP Gateway 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.

2 TROUBLESHOOTING

Problem	Possible Cause(s)	Solution
VSP system displays failure or an inaccurate reading.	Patch is 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 not transmitted to the Gateway.	Disconnected RF channel between VSP Transmitter and Gateway.	1) Verify the Gateway is set for communication and the VSP system is listed as a paired device. 2) Move the VSP Transmitter 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 VSP Transmitter. If the critical error is not resolved, contact LifeWatch Customer Service.

3 SPECIFICATIONS

Basic Parameters	
LCD Parameter	4.3 inch 480*800 Pixels (WVGA)
Touch Lens	Yes (Capacitive Touch screen)
Processor	Dual-core, Cortex A9, 1GHz
Memory	4GB Flash + 1GB RAM
Android OS	Android 4.1.2, Jelly Bean
Storage Card	Micro-SD, up to 32GB
Battery Capacity	1480 mAh LI-IO, BAK512880P
Cellular Communication	
WCDMA Bands	850/1900/2100MHz
HSPA Data rates	Down link 7.2 Mbps; Up link 5.76 Mbps
GSM Bands	850/900/1800/1900MHz
Short Range Communication	
Wi-Fi(WLAN)	IEEE 802.11b/g/n
RF module (Nordic)	2.4 GHz
Bluetooth revision	Ver. 3.0
Main Camera	
Pixel	8MP
Camera technology	CMOS
Auto Focus	Yes
Picture Size	Max 3264×2448
Zoom	Digital zoom 4X

Front Camera	
Pixel	0.3MP
Camera technology	CMOS
Picture Size	Max 640*480
Physical	
Dimensions (H*W*D)	132*71*13 mm
Weight	157 gram
Environmental	
Operating temperature	+10°C to +40°C <i>Note: Body temperature measurement should be performed within an ambient temperature range of 22-26°C</i>
Humidity	10% to 95%, non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Transportation and Storage Conditions	*Temperature range of -25°C to +75 °C *Humidity range of 0 to 95% *Atmospheric pressure range of 70 kPa to 106 kPa

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 the limited use or non-use 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



Due to the risk of ignition or fire, the *VSP system* 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 system* or accessories if you have a known allergy to nickel, silver or other metals.

The *VSP system* is not defibrillation-proof. Exposure to defibrillation (including ICDs) may damage the *VSP*.

The lay user of the *VSP system* 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.

Do not operate the *VSP system* 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 any part of the system. 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.



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.

Warning - Specific Absorption Rate (SAR) information

SAR tests are conducted using standard operating positions accepted by the FCC with the phone transmitting at its highest certified power level in all tested frequency bands, although the SAR is determined at the highest certified power level, the actual SAR level of the phone while operating can be well below the maximum value, in general, the closer you are to a wireless base station antenna, the lower the power output.

Before a new model phone is available for sale to the public, it must be tested and certified to the FCC that it does not exceed the exposure limit established by the FCC, Tests for each phone are performed in positions and locations (e.g. at the ear and worn on the body) as required by the FCC.

For body worn operation, this model phone has been tested and meets the FCC RF exposure guidelines when used with an accessory designated for this product or when used with an accessory that contains no metal and that positions the handset a minimum of 1.0 cm from the body.

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. Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

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 (Model number FGL-00005, FCC ID: SMTLWVGW) 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.

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 VSP Transmitter 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 0.40 inch (1.0 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 a 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.

NOTICE POLICY AND MEDICAL WASTE DISCLAIMER

BY USING THE DEVICE, SOFTWARE, WEBSITE AND/OR WEBSITE SERVICES YOU HEREBY AGREE TO BE BOUND BY THE FOLLOWING NOTICE POLICY AND MEDICAL WASTE DISCLAIMER. IF YOU DO NOT AGREE WITH THE NOTICE POLICY AND/OR MEDICAL WASTE DISCLAIMER, YOU SHOULD DISCONTINUE USE OF THE DEVICE, SOFTWARE, AND/OR OTHER SERVICES.

MEDICAL WASTE DISCLAIMER

In no event shall LifeWatch be liable for personal injury, or any incidental, special, indirect or consequential damages whatsoever that result from the disposal of any medical waste.

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