

Dear *LifeWatch V* owner:

Thank you for selecting the *LifeWatch V* mobile medical phone.

This user manual includes information and instructions for using your new *LifeWatch V* device and should be read carefully before starting to use the device.

If you have any questions about your *LifeWatch V*, please contact your representative:



Illustrations included in this manual are general representations only and are not meant to comply with specific regulatory requirements.

By default, your device is provided with pre-set applications.

Installation of new applications may affect the performance of your device and is the sole responsibility of the user.



Before using the *LifeWatch V*, medical functions please read the Warnings and Precautions, Appendix A, thoroughly.

This User Guide is for the enhanced *LifeWatch V* mobile medical device, also known as the *LifeWatch V+* device. For the sake of brevity, we will refer to the device as the *LifeWatch V* device due to the five main medical functions included in the device:

- | | | |
|--------------|--------------------------------------|-----------------|
| ◆ ECG | ◆ Temperature | ◆ Blood glucose |
| ◆ Heart Rate | ◆ Pulse oximeter (SpO ₂) | |

Copyright © 2013 LifeWatch Technologies Ltd.® All rights reserved.

LifeWatch Technologies Ltd., LifeWatch Inc., LifeWatch Inc. logo, and *LifeWatch V* are trademarks or registered trademarks of LifeWatch AG®.

All other brand names and product names used in this document are trade names, service marks, trademarks, or registered trademarks of their respective owners.

The information and screens provided in this manual are subject to change without notice.

Android™ is a trademark of Google Inc.

LIFEWATCH TECHNOLOGIES LTD. SHALL NOT BE LIABLE FOR TECHNICAL OR EDITORIAL ERRORS OR OMISSIONS CONTAINED HEREIN; NOR FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE FURNISHING, PERFORMANCE, OR USE OF THIS MATERIAL.

Authorized representatives:

Europe



Obelis s.a
Boulevard Général
Wahis 53
1030 Brussels, BELGIUM
Tel: + (32) 2. 732.59.54
Fax: + (32) 2.732.60.03
E-mail: mail@obelis.net

USA

Lifewatch, Inc.
O'Hare International Center
10255 West Higgins Road
Suite 120
Rosemont, IL 60018
Tel: 847-720-2295
Fax: 847-720-1995
Toll Free: 800-633-3361
Fax: 800-954-2375
Email: webmaster@lifewatch.com

Israel



LifeWatch
Technologies Ltd. ®
2 Pekeris St.
Rehovot 7670202
Israel
Tel: 972 8 9484000
Fax: 972 8 9484044
Email: users@lifewatch.com

CE 1313

LifeWatch V Packaging Contents

- ◆ LifeWatch V
- ◆ Charger
- ◆ Earphones
- ◆ User manual
- ◆ Quick user guide
- ◆ USB cable

Optional – LifeWatch V Gluco Accessories Kit Contents

- ◆ Lancing device
- ◆ 10 lancets
- ◆ Gluco strip vial
- ◆ Control solution
- ◆ 10 Alcohol pads
- ◆ Gluco strip Quick user guide
- ◆ Lancer Quick user guide

Indications for Use

The LifeWatch V is a mobile health and wellness device designed for self-testing in order to measure and display blood saturation, blood glucose, ECG (1 lead), heart rate and body temperature. The LifeWatch V is able to transmit the test results by wireless communication to a remote server for storage.

The LifeWatch V blood glucose monitoring system is intended to be used by a single person and should not be shared.

The blood glucose monitoring system is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, and the upper-arm. The blood glucose monitoring system is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program.

Contraindications for Use:

- The LifeWatch V is not intended for use by persons with external defibrillators.
- The LifeWatch V is not intended for the treatment or alleviation of disease.
- The LifeWatch V is not to be used in a magnetic resonance imaging (MRI) environment.
- The blood glucose monitoring system is not intended for the diagnosis of, or screening for, diabetes mellitus.
- Do not place the thermometer probe on scarred tissue or tissue compromised by skin disorders; patients in trauma; patients treated with certain drug therapies.
- Do not place the thermometer probe on skin exposed to direct sunlight, fireplace heat, cold compress therapies, air conditioner flow, and other similar scenarios that may interfere with IR skin Body temperature determinations.

Warnings:

- Do not expose the unit to rain or immerse in water.
- Servicing of the device shall be done by qualified personnel only.
- The user of the LifeWatch V should not take any actions of a medical or clinical nature based on his/her understanding or interpretation of test results without consulting a healthcare professional.
- Classifications of test results obtained for medical applications into categories such as “Low”, “Normal”, “Average”, etc. are based on well-established and widely accepted clinical references; as other classifications may exist, the test results should not constitute the sole basis for diagnosis or for deciding on the appropriate course of medical treatment or therapy.
- The Blood Glucose monitoring system is not for use on patients who are dehydrated, hypotensive, in

shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.

- Not for use by critically ill patients.
- Users whose vision is impaired to the extent that their sight does not enable them to operate the device should not use the Blood Glucose monitoring system.
- The blood glucose monitoring system and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the glucose kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

Symbols on Equipment and Labeling

The following section contains a description of symbols that may be located either on the LifeWatch V device or in documentation accompanying the device in order to draw attention to safety items and other important information.

Label	Description
-------	-------------

Label	Description
	Warning, consult the accompanying text or documents
	Precaution; consult the accompanying text or documents
	Warning, potential biohazard
	Notes, indicates important general information for using the system successfully.
	Consult instructions for use
 XXXX	Manufacturer and date of Manufacture
	Type BF Applied Part

Label	Description
	In vitro device
	Store at specified temperatures; location of thermometer
	WEEE Directive for disposal of Electrical and Electronic Equipment
	Symbol for no alarms
	Symbol indicating a USB connector
	Symbol indicating location of glucose meter

Table of Contents

LifeWatch V Basic Operation	19
For Your General Safety (Precautions)	19
Getting Started	21
Overview	21
Starting up.....	24
Charging the Battery	25
Getting Around Your Device	27
Touch Control	27
Home Screen	28
LifeWatch V Health and Medical Functions	30
Getting Started with the <i>LifeWatch V</i> Medical and Wellness Applications	30
License Agreement	30

First Time Launch	31
Login Screen.....	32
Guest Login	32
Test Application	34
Test General Description	34
Test Screens Description.....	35
History.....	40
Performing Medical Tests	42
Blood Glucose Monitoring System	42
Glucose Test Troubleshooting.....	48
Alternative Site Testing (AST)	49
Control Solution Test	51
Control Solution Troubleshooting	55

ECG/HR/BFA/SpO ₂ /Stress Level Analyzer Tests	56
Body Temperature Test	60
Blood Pressure Test	62
LifeWatch V Application Settings	64
My Profile	65
Sharing Permissions	66
Test Settings	66
Measurement Units	66
Sounds	66
Calendar Application	67
Drug Reminder	68
How to login	71
Heart Rate Calculation Method	71
Introduction	71

Method of Calculation	71
Maintenance	72
Conditions of Use.....	72
Caring for your <i>LifeWatch V</i>	72
Cleaning and Disinfecting	73
Environment.....	74
Preventive Maintenance	75
Troubleshooting.....	76
Specifications.....	79
Basic Parameters	79
Declaration of RoHS Compliance	85
Disposal of Your Device	85
Appendix A Warnings and Precautions	86

Warnings.....	89
Radio Frequency (RF) Exposure (Precautions).....	93
General Statement on RF Energy	93
EMI Considerations.....	93
Body Worn Operation	94
Limiting Exposure to Radio Frequency (RF) Fields (Precautions)	94
Distraction	95
Driving (Precautions)	95
Operating Machinery (Precautions)	95
Product Handling (Precautions).....	95
General Statement on Handling and Use	95
Children.....	96
Demagnetization	96

Electrostatic Discharge (ESD)	96
Antenna.....	96
Normal Use Position	96
Air Bags	96
Seizures/Blackouts	96
Repetitive Strain Injuries.....	96
Emergency Calls.....	97
Loud Noise.....	97
Phone Heating	97
Electrical Safety (Precautions).....	97
Accessories	97
Connection to a Car	97
Faulty and Damaged Products	97
General Statement on Interference	98
Pacemakers	98

Hearing Aids	98
Use of <i>LifeWatch V</i> with other Medical Devices	98
Hospitals	98
Aircraft.....	98
Interference in Cars	98
Explosive Environments (Precautions)	99
Petrol Stations and Explosive Atmospheres.....	99
Blasting Caps and Areas	99
Index.....	100

WARNINGS

- Use the device only for the purposes described in the Instructions for Use.
- To prevent fire, do not expose the device to moisture 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.

WARNING

The device is not suitable for use in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

WARNING

- For optimal use of the *LifeWatch V*, it should be connected to the Internet.
- By default, your device is provided with pre-set applications.
- Installation of new applications may affect the performance of your device and is the sole responsibility of the user.

WARNING

The user of the LifeWatch V should not take any actions of a medical or clinical nature based on his/her diagnosis or interpretation of the test results, without consulting a healthcare professional.

Intended Use

The LifeWatch V is a mobile health and communication device designed for self-testing in order to measure and display blood oxygen saturation (SpO₂), blood glucose levels, ECG (1 lead), heart rate and body temperature. The *LifeWatch V* is intended for use by or on the following population groups:

- Adults
- Pediatrics as defined below

The following applications of the *LifeWatch V* as described in this User Manual and as intended for use by the manufacturer, are not within the scope of the Medical Device Directive 93/42/EEC and are therefore not considered as medical devices, nor are they covered by the this Directive:

- Stress Level Analyzer
- Diet Management (if subscribed)
- Drug Management
- Body Fat Analysis

Test	Age Group
Blood Oxygen Saturation	Adults, 21 years and older
Blood Glucose Monitoring System	By adults and on pediatrics aged 12 years and above. Pediatrics below the age of 12 years: under adult supervision only Excluding neonates and infants less than one year
1 Lead ECG	Adults and pediatrics above 12 years of age
Heart Rate	Adults and pediatrics above 12 years of age
Stress Level Analyzer	Adults, 21 years and older
Body Fat Analyzer	Adults, 21 years and older
Thermometer	Adults and pediatrics above 12 years Pediatrics below the age of 12 years: under adult supervision only Excluding neonates and infants less than one year

Device Definition

The *LifeWatch V* is a state-of-the-art mobile device (smartphone) with medical and non-medical capabilities designed for the maximum convenience of its users. The *LifeWatch V* includes the following modules and applications:

- Pulse oximeter/SpO2 (oxygen saturation)
- Blood Glucose Monitoring System (glucose accessories to be purchased separately)
- 1 Lead ECG (ECG results for subscription users only)
- Heart Rate
- Thermometer
- Body Fat Analyzer
- Stress Level Analyzer
- Blood Pressure (w/external device)
- Diet Management (for subscribed users only)
- Drug Management

NOTE: The *LifeWatch V* can be used as a stand-alone device or via a subscription plan which offers different levels of functionality to service plan subscribers (see section “Offered Service Plans”).

LifeWatch V Basic Operation

For Your General Safety (Precautions)

As the *LifeWatch V* device is a medical device that can be used both as a regular cell phone and as a medical device, this manual includes both warnings and precautions relating to the use of the *LifeWatch V* as a cell phone, AND warnings and precautions concerning the use of the *LifeWatch V* as a medical device.

	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.

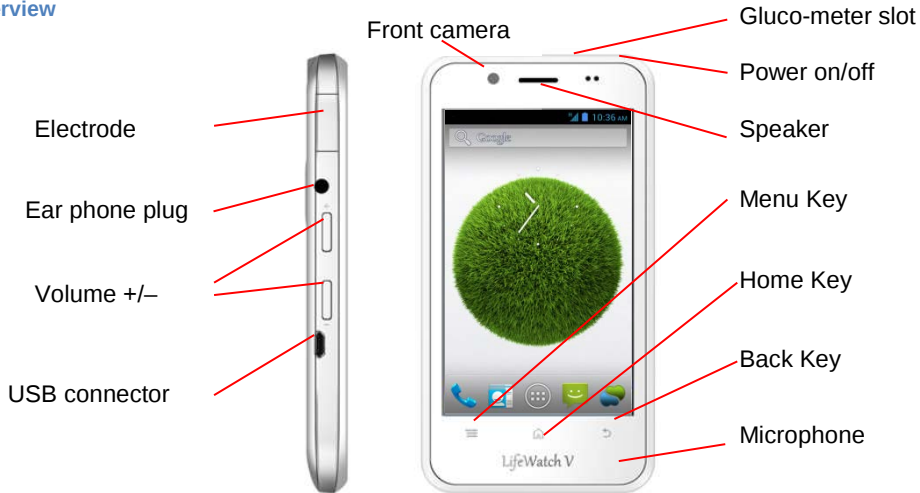
	Don't dispose of your device in fire.		Don't take your device apart.
	Your device can produce a loud sound.		Switch your device off when near explosive materials or liquids.
	Avoid contact with anything magnetic.		Only use approved accessories.
	Don't rely on your device for emergency communications.		

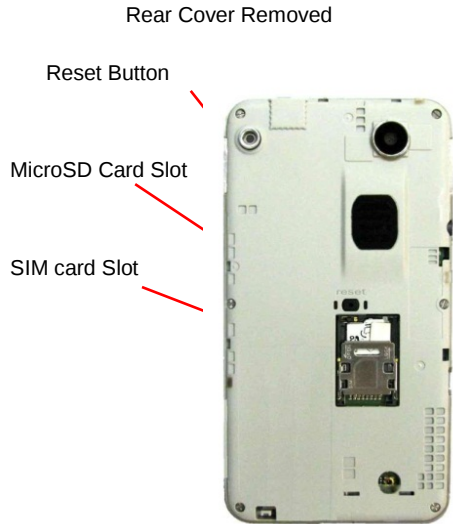
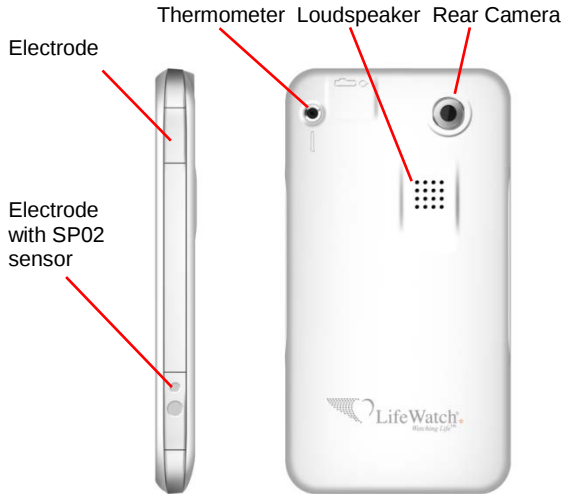


Before using the *LifeWatch V* medical functions please read Appendix A Warnings and Precautions thoroughly.

Getting Started

Overview





Icons



LifeWatch V icon



Call icon



Contacts icon



Messages icon



Applications icon



Starting up

Installing the SIM/microSD Card

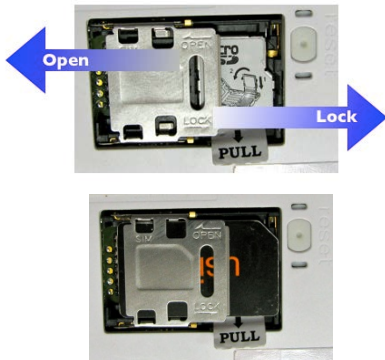
Switch off your device before installing SIM, or memory card.

3. Open the SIM card holder by sliding it in the direction of the OPEN arrow
4. Hold the SIM card by the cut corner and slip it into the card holder.
5. Pull the microSD cover tag
6. Hold your microSD card with the metal contacts facing down and slide it in
7. Press the microSD cover down
8. 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: microSD logo  is a trademark of the SD Card Association.



Charging the Battery

1. Connect the supplied USB plug to the USB/adaptor jack. Ensure that the plug is inserted 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 with the *PA1005-050UIB070*

Input is 100 to 240 V, ~50 to 60 Hz, 0.3A;

Output is 5 V, 0.7A, 3.5 W maximum

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.

If the device is on, the charging icon is located on the status bar. When fully charged, the icon  appears on the status bar.

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.

Setting Up Your Device for the First Time

When you first turn on your device after you purchase it or after resetting it to factory settings, the following should be performed:

1. If the default language needs to be changed, tap Change language and select the desired language.
2. Tap the Android™ icon on the screen.
3. Configure the date and time options, and then tap Next.

Switching to Sleep Mode

To save battery power, Sleep Mode suspends your device setting it to a low-power-consumption state while the display is off. Your device also goes into Sleep Mode by itself when the display is automatically turned off after a certain amount of time. You can define the period of time in **Settings > Display > Screen timeout**. Press Power to switch to Sleep Mode.

Waking Up Your Device

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

NOTE: If you have set an unlock pattern, PIN or password for your device you'll need to draw the pattern or enter the PIN/password to unlock your screen.

Getting Around Your Device

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.

Home Screen

You can modify your *Home* Screen.

Set your own wallpaper, add the widgets or application shortcuts you need, or remove them as you like.

Extended Home Screen

The *Home* Screen extends beyond the screen width, giving you lots more space to add more stuff. Simply slide your finger to the left or right to see the extended *Home* Screen.

Changing Your Wallpaper

1. Tap **Home** to return to the *Home* Screen.
2. Tap **Menu** and select **Wallpaper**.
3. Tap **Gallery**, **Live wallpaper**, Video Wallpaper or **Wallpaper** and choose the image or animation you want to use as the wallpaper. Some cropping may be needed for **Gallery** images.
4. Tap **Set wallpaper**.



Adding Items to Your Home Screen

1. Tap **Application**  to explore the application screen.
2. Tap and hold the desired app until it added to the home screen.

Removing Items from Your Home Screen

1. Tap and hold the item you want to delete until the “Remove” is shown on the screen.
2. Drag the item to the “Remove”area.

LifeWatch V Health and Medical Functions

Getting Started with the LifeWatch V Medical and Wellness Applications

Press the *LifeWatch V* icon on the desktop. This activates the application and opens the license agreement.

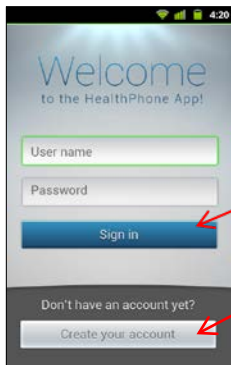


License Agreement

Please read the license agreement. The login screen appears after accepting the terms.

First Time Launch

The first time you open the application the registration screens are displayed.



For registered user - enter your user name and password and tap on the "**Sign In**" button.

For new user - tap on "**Create Account**" in order to start the registration process.

Quick access code

Create your Quick access code by selecting four numbers.

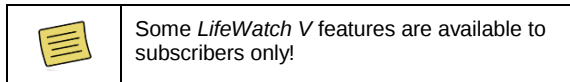
Quick access code confirmation

Re-enter your selected quick access code.

Login Screen

This is the log-in screen for *LifeWatch V* medical applications.
Use the keypad to enter your quick access code.

The *Start* screen appears.



Guest Login

Select **Guest Login** to start **Guest Mode**.

The guest-login allows non-subscribed users to perform certain tests.

The tests are not saved, there is no connection to the remote server and the guest has a limited amount of tests that can be performed per month.



Guest log-in

Start Screen

Select the required application to start.

Application	Icon
Test	
Diet	
Drug	
Calendar	
Information	



Test Application

Test General Description

The *LifeWatch V* performs the following tests:

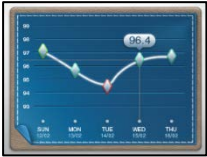
- ◆ **ECG** - The graphical recording of your heart activity, to be used whenever you are concerned about your heart rhythm (history of Arrhythmias) or if you experience the following symptoms of abnormal heart rhythms:
 - ◆ Skipped Beats
 - ◆ Pounding Heart (Palpitations)
 - ◆ Heart Racing or Irregular Pulse
 - ◆ Lightheadedness or Faintness
- ◆ **HR** – Measures the pulse rate (minimum, maximum and average rate that your heart beats)
- ◆ **Stress Level Analyzer** – Analyze the pulse rate to determine the level of mental and physiological stress
- ◆ **BFA (Body Fat Analyzer)** – BFA uses bioelectrical impedance analysis (BIA) to determine the body fat percentage
- ◆ **Gluko-Meter** – Measures the blood glucose level
- ◆ **Body Temperature** – To determine the body temperature via the forehead
- ◆ **Blood Oxygen Saturation** – To determine the oxygen level in the blood
- ◆ **Blood Pressure** – Connect to an external Blood Pressure device and collect results.

Test Screens Description

	Wheel	Use to cycle between tests and select the relevant test
	Information Icon	Press to open the relevant information about the selected test type
	Test Type	Displays test type
	Start Button	Press to start testing
	History Button	Press to display test history (3 last tests)
	Reminder Icon	Press to display the calendar
	Calendar	Displays the current week's reminders with the test type icon

Note: a green outline to a button means it is selected.

Press a button to change the display on the *Start* screen.

Press	To display
Reminder 	 NOTE: Tapping  opens the <i>Reminder Creation</i> window for the current type of test.
History 	 Note: Tapping the graph opens History, see page 40.

Test Wheel Icons

Blood Glucose



BFA (body fat analysis)



Temperature



ECG
(electrocardiogram)



HR (heart rate)



Stress Level
Analyzer



Blood Oxygen
Saturation (SPO2)



Blood Pressure



NOTE:

For tests involving the use of electrodes it is important to:

- Clean electrodes with a lint free dry cloth
- Wash your fingers with soap and dry them
- Do not press too hard on the electrodes
- Sit comfortably for maximum relaxation during the test

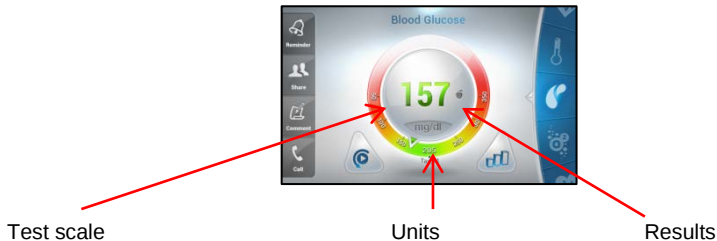


Before starting a test please **disconnect the earphones/USB cable.**

Test Results

After a test has been performed the screen displays the results and provides extra functions.

Example



Each test type has its own units and scale values



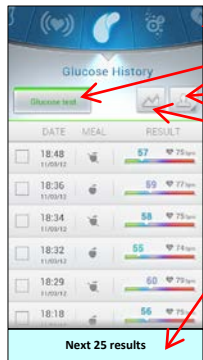
Warning - The user of the LifeWatch V should not take any actions of a medical or clinical nature based on his/her diagnosis or interpretation of the test results, without consulting a healthcare professional.

Test Results Icons

	Reminder - Opens the <i>Reminder</i> window
	Share - Opens the <i>Sharing Selection</i> popup, share the results via Email or SMS
	Comment - Pop-up <i>Notepad</i> for commenting on results. Auto sharing results are sent without the comments
	Call - Initiate a call to the Call Center (Premium Users)
	Crossed-out apple means before meal
	Apple means after meal
	Retake test
	History

History

The screen default is to show the last test type chosen. Scroll using the wheel to change test type.



The screenshot shows the 'Glucose History' screen. At the top, there is a 'Wheel' with icons for different test types. Below the wheel, there are two buttons: 'Glucose test' and 'Other Users'. The main area displays a list of test results with columns for DATE, MEAL, and RESULT. At the bottom, there is a button labeled 'Next 25 results'.

Wheel – scroll to change test type

All Tests – show all tests (all types)

Other Users – displays the test results of other users that you “follow”

Graph – display the test results graph

Next 25 results – displays the next 25 test results

History displays the following for each test:



Share box

Test type

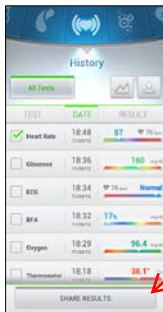
Date & time

Result and threshold

Select a test to share.



Once selected a Share button is added to the end of the test list.



Share Results– select to open **Sending** (SMS/email) option.

A dialog box titled 'Select share type' with two options: 'Email' and 'SMS'.

Select share type
Email
SMS

Performing Medical Tests

The screen automatically goes to the last test type. Use the scroll-wheel to cycle between the various tests.

NOTE: see section Disinfection for cleaning instructions.

Blood Glucose Monitoring System

Be sure to read carefully this section, the test strip insert and the lancing device insert found in the Gluco kit before testing. Make sure you have all items needed to test:

LifeWatch V, Test Strips, Lancing Device and sterile Lancet

Wash and dry your hands before testing.



Use only the glucose strips and control solution provided with the *LifeWatch V* device or authorized for use with the device.

1. To start the glucose test press **Start**.

The screen rotates to the horizontal mode, please hold the *LifeWatch V* horizontally.



The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!



2. A new screen opens, select **Before** or **After** meal.



3. Please insert a new glucose strip into the glucose slot when instructed

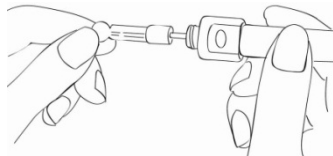


Glucose strips are for single use only; dispose of used strips as per the instructions included with the strips.

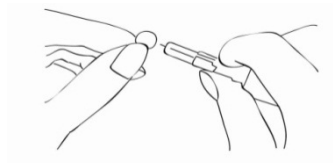


4. Prepare the lancing device:

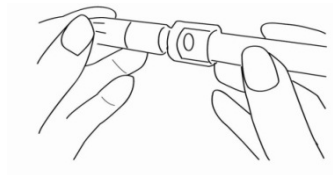
Screw off the cap of Lancing Device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



Twist the protective disk until it separates from the lancet.



Replace the lancet device cap. Turn the cap until it is snug but not too tight.



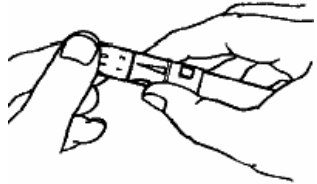
The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip in either direction until the number lines up with the Arrow:

1-2 for soft or thin skin,

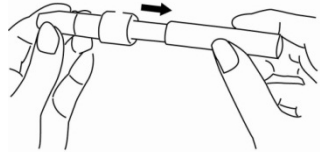
3-4 for average skin,

5 for thick or calloused skin.

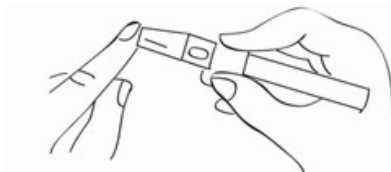
Please select the most suitable depth for you to avoid unnecessary pain.



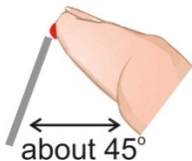
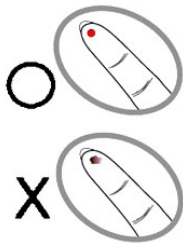
Slide the ejection/cocking control back until it clicks. If it does not click the device may have been cocked when the lancet was inserted.



5. Take a blood sample using the lancing device (see supplied lancing device instructions).



6. Place the finger with the acquired drop of blood at the tip of the glucose strip, as shown on the screen and below.



7. The *Processing* screen appears, after a few seconds the results screen appears.



8. When the test is completed the results screen appears.
Remove the used test strip and lancet; dispose of them.

After 5-10sec of delay – it'll be possible to:

- ◆ Retake the test by pressing the Retest button
- ◆ Use the Scroll Wheel to scroll to another test
- ◆ Display test History
- ◆ Use the available options on the left bar



Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.



Important Information

Severe dehydration resulting from excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

Test results below 70 mg/dL (3.9 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 200 mg/dL (11 mmol/L) mean high blood glucose (hyperglycemia). If you get results below 70 mg/dL or above 200 mg/dL, and do not have symptoms, repeat the test once. If you have symptoms or continue to get results that fall below 70 mg/dL or above 200 mg/dL, follow the treatment advice of your healthcare professional.

If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all the instructions described in the *LifeWatch V* User Manual, call your healthcare professional.

A red blood cell count (hematocrit) that is either very high (above 55%) or very low (below 30%) can cause false results.

Glucose Test Troubleshooting

Problem	Possible Cause(s)	Solution
Blood glucose results are inconsistent.	1. Not enough blood is placed on the Test Strip. 2. Test Strips have passed their expiration date. 3. Deteriorated Test Strip caused by heat or humidity. 4. Device, and/or Test Strip were not at room temperature when used.	1. Rerun test with a new Test Strip and apply a sufficient blood to fill the Test Strip tip. 2. Obtain new Test Strips have not yet exceeded their expiration date. 3. Run a Control Solution Test using a new Test Strip. If the results are still out of range, replace the Test Strip package. See package for proper storage instructions. 4. Allow time for the Device, Control Solution and/or Test Strips to come to room temperature before use.

Alternative Site Testing (AST)

Important: There are limitations for doing AST.

Do Not Use AST for continuous glucose monitoring (CGM) calibration and insulin dose calculations.

Please consult your healthcare professional before you do AST.

What is AST?

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels.

This system provides the capability of testing also on the palm, forearm and upper arm, with the equivalent results to fingertip testing.

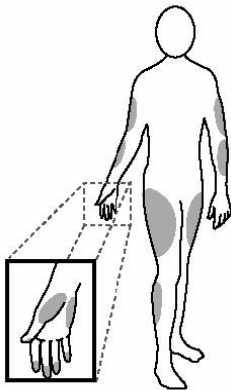
What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings were not so condensed, you will not feel as much pain as at the fingertip.

When to use AST?

Note: Food, medication, illness, stress and exercise can affect blood glucose levels.

Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other event, take blood samples from your finger only.



We strongly recommend that you perform AST ONLY in the following intervals:

- ◆ In a pre-meal or fasting state (more than 2 hours since the last meal).
- ◆ Two hours or more after taking insulin.
- ◆ Two hours or more after exercise.

Do NOT use AST if:

- ◆ You think your blood glucose is low.
- ◆ You are unaware of hypoglycemia.
- ◆ Your AST results do not match the way you feel.
- ◆ You are testing for hyperglycemia.
- ◆ Your routine glucose results are often fluctuating.

How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed (20 seconds) prior to blood extraction, the difference was significantly reduced.

Control Solution Test

Why Use the Control Solution?

Ensure that your *LifeWatch V* and *LifeWatch V* Test Strips are working together properly.

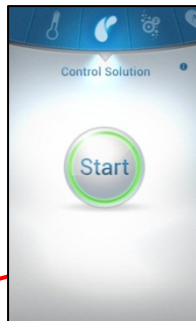
Practice testing without having to use your own blood.

Perform Control solution tests when:

- ◆ First receive your *LifeWatch V*.
- ◆ You feel your *LifeWatch V* or test strips are not working properly.
- ◆ You feel your test results are not accurate.
- ◆ After dropping or damaging your *LifeWatch V*.
- ◆ Your healthcare professional advises you perform the test.

	Avoid exposing the LifeWatch V Blood Glucose Monitoring System to liquids. If exposed to liquids do not use for glucose testing; call our customer service phone number for help."
	Perform control solution tests for any new vial or if "abnormal" results are shown.

1. Select the Control Solution test from the options menu.
2. The following screen appears. To start the test press **Start**.



3. The screen rotates to the horizontal mode, please hold the *LifeWatch V* horizontally.
4. Insert the new glucose strip into the glucose slot when instructed.



Glucose strips are for single use only; dispose of used strips as per the instructions included with the strips.



5. Place the Control Solution:
 - ◆ Shake the control solution vial.
 - ◆ Place the first drop of control solution in a disposable container.
 - ◆ Clean the bottle tip using a tissue or paper towel.
 - ◆ Place a second drop at the tip of the control solution cap.



6. Place the drop of control solution on the strip in the *LifeWatch V* as shown. The drop is drawn into the test strip. Move the cap away when the strip window is filled



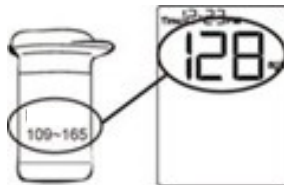
7. The *Processing* screen appears, after a few seconds the results screen appears.



8. When the test is completed the results screen appears.
9. Remove the used test strip and dispose of it.
10. Compare the result of your control solution test to the range printed on your *LifeWatch V* Blood Glucose Test Strip vial label for the control solution level that you used.

Your control solution result should fall within this range.

If your control solution test results are out of the range, repeat the test and refer to *Control Solution Troubleshooting* of this guide to see potential causes of error.



Control Solution Troubleshooting

Problem	Possible Cause(s)	Solution
Control solution test results are inconsistent, or control solution test results are not within the specified range.	1. Not enough control solution is placed on the Test Strip. 2. Test Strips or control solution have passed their expiration date. 3. Deteriorated Test Strip caused by heat or humidity. 4. Device, Control Solution and/or Test Strip are not at room temperature when used.	1. Rerun the test with a new Test Strip and apply sufficient control solution to fill Test Strip tip. 2. Obtain new Test Strips and/or Control Solution that has not yet exceeded their expiration date. 3. If the results are still out of range, replace the package of Test Strips. See package for proper storage instructions. 4. Allow time for the Device, Control Solution and/or Test Strips to come to room temperature before use.

ECG/HR/BFA/SpO₂/Stress Level Analyzer Tests

Recommended Preparations - Wash and dry your hands.

If your fingers are too dry or are extremely cool, accurate measurements may not be possible.

Condition	Actions
Hands are dry.	Slightly moisten hands with a wet towel, then measure.
Your hands are cold	Warm your hands by immersing in warm water or staying in a warm room. Start the measurement again.

Special Instructions for BFA Test

The following physical conditions change the water content in the body, the measured body fat percentage may differ significantly from the real number.

- ◆ Right after vigorous exercise
- ◆ Right after taking bath or sauna
- ◆ When drinking large amounts of alcohol
- ◆ When drinking a large amount of water or after a meal

Exceptions for BFA Test

The measured body fat percentage may differ from the actual body fat percentage of people with changing amounts of water and tissue density within their bodies.

- ◆ Children of growing stage
- ◆ Elderly people and women after menopause
- ◆ Having osteoporosis (very low bone density)
- ◆ People with a fever or swelling
- ◆ Bodybuilders or professional athletes
- ◆ Patients undergoing dialysis
- ◆ Pregnant women



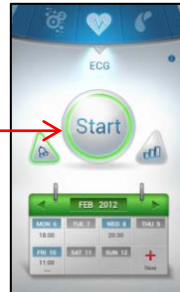
IR emitted from this product. Do not stare at operating lamp.

Start the Test

Use the scroll wheel to cycle between the various tests.

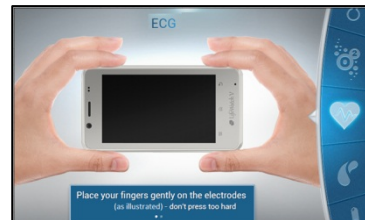
1. To start the test press **Start**.

The screen rotates to the horizontal mode, please hold the *LifeWatch V* horizontally.



NOTE: The ECG test is shown as an example.

2. Place your two index fingers on the sensors located on the upper side of the device and place your left thumb on the lower side sensor and the right thumb on the lower side for support, as shown in the illustration.
 - Make sure you fully cover the three sensors with your fingers
 - Hold the device gently without pressing too hard on the sensors
 - Relax your fingers and make sure you are relaxed and steady.



Location of Sensors



Right side, top in horizontal position

Left side, bottom in horizontal position

3. When the test is completed the results are presented on the “Result Screen”



It is now possible to:

- ◆ Retake the test by pressing the Retest button
- ◆ Use the Scroll Wheel to scroll to another test
- ◆ Display test History
- ◆ Use the available options on the left bar



The ECG test is sent to the backend for analyzing. Results will be presented within seconds. If analysis takes longer than expected, you will be notified when the analysis is completed.

Body Temperature Test

Scroll to the **Thermometer** icon on the wheel.

The following screen is displayed.

1. To start the test press **Start**.

	A high fever or low body temperature requires you to seek immediate medical attention
	In order to achieve the intended accuracy, body temperature measurement should be performed within an ambient temperature range of 22-26°C

2. The screen rotates to the horizontal mode, please hold the *LifeWatch V* horizontally.
3. Follow the screen instructions and place the thermometer on your forehead when instructed.



Please remove glasses and hair from forehead before taking the test



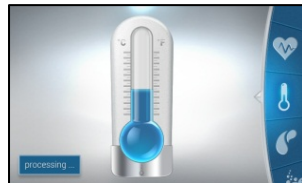
Please allow the device to rest for about two minutes between each temperature test



4. When the counter reaches 0 the test starts followed by beeps. Move the device from left to right, until the beeping stops (about 5 seconds).



5. The processing screen appears while you are moving the device on your forehead, the test ends when the beeping stops.



6. When the test is completed the results screen appears. It is now possible to:

- ◆ Retake the test by pressing the Retest button
- ◆ Use the Scroll Wheel to scroll to another test
- ◆ Display test History
- ◆ Use the available options on the left bar



Blood Pressure Test



Blood pressure test is based on an external blood pressure device with Bluetooth capabilities. A list of compatible devices is available through the settings menu. Please follow the Blood Pressure device manufacturer's instructions for initial setup and pairing procedures.

Scroll to the **Blood Pressure** icon on the wheel. The following screen is displayed.

1. To start the test press **Start**.



	A high or low blood pressure requires you to seek immediate medical attention.
	In order to achieve the intended accuracy, the blood pressure measurement should be performed at rest.

2. The screen rotates to the horizontal mode, please hold the *LifeWatch Phone* horizontally.
3. Your LifeWatch phone will instruct you to sit down, install the inflatable cuff of your blood pressure device around your left arm and to turn on the blood pressure device.



4. Your LifeWatch phone will display an animation until the completion of the test.

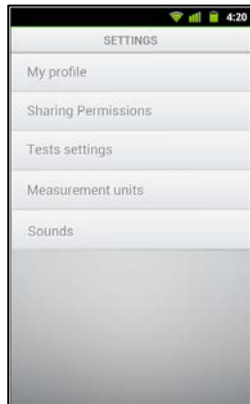


5. When the test is completed the result screen appears. It is now possible to:
- ◆ Retake the test by pressing the Retest button
 - ◆ Use the Scroll Wheel to scroll to another test
 - ◆ Display test History
 - ◆ Use the available options on the left bar



LifeWatch V Application Settings

The *LifeWatch V* application settings are divided into categories:



My Profile

Sharing Permissions

Test Settings

Measurement units

Sounds

My Profile

Press **My Profile** to open the profile details. The details that have been entered during the registration process are displayed.

To change a detail, select it by pressing it and then either enter the new details in the field or if there is a pop-up box, change the setting.

Pop-up Example

Gender



A dark-themed pop-up dialog for selecting gender. It features a title bar with 'Gender:' and a close button. Below the title, there are two radio button options: 'Male' (selected, indicated by a green dot) and 'Female'. At the bottom, there is an 'OK' button.



A screenshot of a mobile application's 'My Profile' settings screen. The screen has a dark background with white text. At the top, there's a 'SETTINGS' header. Below it, a 'My profile' section contains a profile picture placeholder and an 'EDIT' button. The profile details listed are: Gender (Female), Birth date, Height (185 cm), Weight (56 kg), Activity level (Very active), and Stride (80 cm). At the bottom, there are two more sections: 'Sharing Permissions' and 'Tests settings'.

Sharing Permissions

Select **Sharing Permissions** to display the list of people already assigned for sharing and to add new sharing contacts.

Test Settings

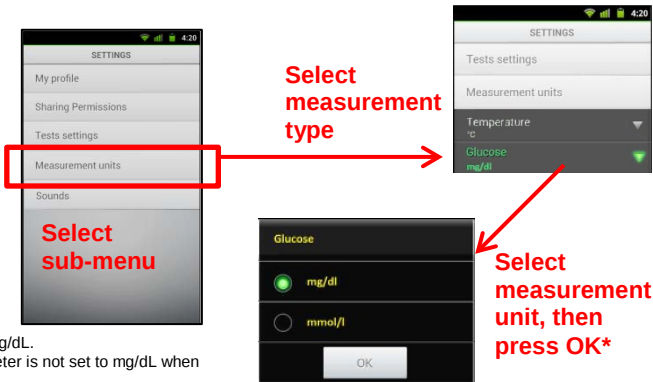
Press on **Test Settings** to open the tests options screen. It is possible to set the desired test goal for each test.

Measurement Units

Select to open the sub menu, tap on the unit type you want to change.

Sounds

Select Sounds options.

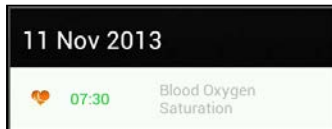


- * The correct glucose units in the U.S. are mg/dL. Please contact customer support if your meter is not set to mg/dL when you purchase it.

Calendar Application

The *Calendar* application displays the set test times and medication use in a calendar format.

You can select to display only tests or only medications. The details are presented when you click on a date with active reminders.



Drug Reminder

Using the *Drug Reminder* application to create reminders for the medications that you are taking, including usage monitoring.

The dosage, time periods, length of use and any special instructions may be added.

It is possible to check the *Reminder* details, freeze (pause) the *Reminder* or delete the *Reminder*.



Offered Service Plans

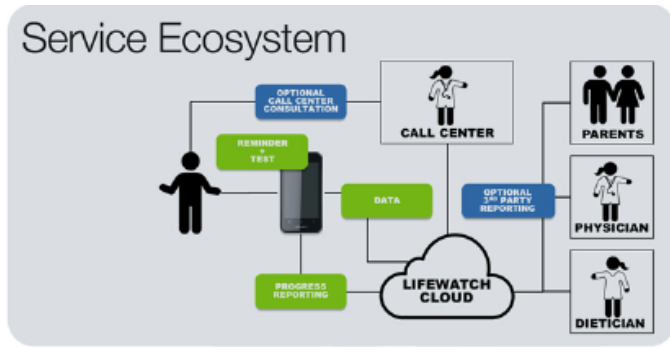
Basic plan - this entry-level package consists of automatic on-line medical measurement analysis & indications.

Premium Plan - in addition to the basic health features, this plan offers a professional human diagnostic interpretation of the measurements taken by the users, powered by a 24/7 call center staffed accordingly.

Feature	Basic	Premium
Health measurement	✓	✓
ECG analysis	✓	✓
Share specific test	✓	✓
Data trending and	✓	✓
Share multiple test	✓	✓
Access to user portal	✓	✓
Meal planning		✓
Exercise planning		✓
Follow family		✓
24/7 call center		✓

LifeWatch V Ecosystem

The LW V handset includes a service enablement platform, to support the transmission of data to be analyzed, evaluated and communicated to health professionals and call center personnel. This platform is cloud-based, making it simple to offer a wide range of high-value services such as automatic reply and self-analysis of ECG measurements, information storage, history and statistics presentation, sharing the information with authorized third parties (doctors, parents etc.).



Web Portal

You will be able to take measurements via the *LifeWatch V* device and manage your health via either the device or the web.

You can manage your health, track and trend your measurements, print reports, share your data with your physician, set-up reminders, access your diet plan (if subscribed) and log your medication intake.

How to login

Access the website www.lifewatchv.com, select your region and click on login (in the right top corner of the webpage).

Insert your username and password.

Heart Rate Calculation Method

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).

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, 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.

Maintenance

Conditions of Use

Your *LifeWatch V* conforms to international regulations insofar as it is used under normal conditions and in accordance with the instructions detailed in this manual.



Wash your hands thoroughly before testing, cleaning or disinfecting the device.

Caring for your *LifeWatch V*

- ◆ Do not open or attempt to repair your *LifeWatch V* yourself; do not tamper or attempt to remove the battery. Only authorized service personnel may repair the device. Incorrect replacement by inadequately trained personnel would result in an unacceptable RISK
- ◆ Do not drop your *LifeWatch V* or subject it to severe impact. Do not use extreme force when pressing the display or keys.
- ◆ Take care to dispose of the device, including the battery and electronic components, as per local/national environmental regulations

Cleaning and Disinfecting

Clean and disinfect the LifeWatch V after each time you are using the glucose meter function and whenever blood and organic debris are visible on the surface.

Step 1- Cleaning:

Dispense a fresh towelette. Wipe the entire device surface thoroughly.
Continue until you remove any visible organic load, debris, dirt etc.
Discard used towelette.

Step 2 – Disinfecting:

Repeat the procedure above with a second, fresh towelette.
Wipe the device surface thoroughly, applying the solution evenly across the entire surface.
Discard used towelette.
After wiping, let the surface **air-dry for at least 3 minutes**;
Important: do not rinse or wipe the surface with a dry cloth.

Cleaning and disinfection of the LifeWatch V are performed using EPA registered germicidal disposable wipes (CaviWipes™ by Metrex (EPA Reg. No. 46781-8)) , available in local pharmacies.

- ◆ Do not use water
- ◆ Do not use organic solvents to clean the device

Environment

- ◆ Keep the device 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
- ◆ As the device is not waterproof, do not use it or store it where liquids such as water, juice, coffee, etc. can splash on it
- ◆ Keep accessories that might be swallowed, away from children
- ◆ Do not store the device in the following ambient conditions:
 - o Locations subject to direct sunlight , high temperatures and high humidity
 - o Dusty locations or near fires or open flames
 - o Locations exposed to strong vibrations
 - o Locations exposed to strong electromagnetic fields

Preventive Maintenance

The following simple preventive maintenance tasks should be performed weekly to ensure the continued maximum capacity performance of the device, and to reduce the possibility of failure:

- ◆ **Mechanical Inspection** - Check for splits, cracks or imperfections in the case. If you have any questions or doubts, call your service provider.

NOTE:

- ◆ Clean the thermometer with a dry, lint free cloth.
- ◆ Do not allow any liquid to enter the case, and avoid pouring water or other liquids on the device while cleaning.
- ◆ Never use abrasives such as wire wool or metal polish.
- ◆ During cleaning, make sure you do not expose the device to temperatures in excess of 45°C (113°F).

Troubleshooting

Low/critical battery Message	Recharge the device for at least one hour	
Failure of medical test	Exceeding device temperature	Device temperature is too high or low, device temperature should be 10 to 40 °C
	Device battery is low	Charge the device
	USB cable or earphone is connected to the device	Disconnect USB cable or earphone before use
	Poor contact with electrodes (ECG, Heart rate, Blood Saturation, Body Fat Percentage, Stress Analysis)	a. Fully cover the three electrodes b. Wash fingers with soap and water and clean electrodes c. Hold the device gently and do not press too hard on the electrodes d. Relax your fingers and make sure you are steady and stable
	Inaccurate Body temperature	Make sure the thermometer lens is placed properly (full surface contact) on your forehead while testing a. Please remove glasses b. Please pull aside any hair on forehead
No device communication during tests	The test function has disabled the phone communication	By the end of the test the communication will be restored

No charging animation	Check if the adapter is properly connected; if the phone battery was completely drained it may take up to one hour until the charging animation appears.
No historical records/can not receive ECG analysis from the server	Make sure the internet connection is available and that your <i>LifeWatch V</i> service plan is active
Phone is frozen, a black screen is shown	Click on the restart button located under the device rear cover
Calls are being dropped	When you are in areas with weak signals or poor reception, you may lose your connection to the network. Move to another area and try again
The touch screen responds slowly or improperly	a. Ensure that your hands are clean and dry when tapping the touch screen. b. Restart your device to clear any temporary software bugs c. Ensure that your device software is upgraded to the latest version. d. If the touch screen is scratched or damaged, take it to your local Service Centre
Others cannot hear you speaking on a call	a. Ensure that you are not covering the built-in microphone b. Ensure that the microphone is close to your mouth c. If using a headset, ensure that it is properly connected
Audio quality is poor	a. Ensure that you are not blocking the device's internal antenna. b. When you are in areas with weak signals or poor reception you may lose reception. Move to another area and try again

Your device is hot to the touch	When you use applications that require more power or use applications on your device for an extended period of time, your device may feel hot to the touch. This is normal and should not affect your device's lifespan or performance
A connection is not established when you connect the device to a PC	a. Ensure that the PC data cable you are using is compatible with your device b. Ensure that you have the proper drivers installed and updated on your PC
Your device displays network or service error messages	a. When you are in areas with weak signals or poor reception, you may lose reception. Move to another area and try again. b. You cannot access some of the options without a subscription. Contact your service provider for more details
Glucose test results not in range of test strip vial values	If you continue to have test results fall outside the range printed on the test strip vial, the device and strips may not be working properly. Do NOT test your blood. Contact the local customer service or place of purchase for help.

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	JB 4.1.2
Storage Card	Micro-SD, up to 32GB
FM Radio	Yes
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
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

Medical Sensors Specifications

ECG

ECG sample rate transmission	250 samples /sec
------------------------------	------------------

Sample resolution	12 bits
-------------------	---------

Heart Rate

HR measurement range	40 to 240 bpm
----------------------	---------------

HR accuracy	± 5 bpm or 10% whichever is greater
-------------	---

R-R interval measured range	225 to 2000 msec
-----------------------------	------------------

R-R interval measured resolution	± 2 msec
----------------------------------	--------------

R-R interval accuracy –	4 msec
-------------------------	--------

QRS detection sensitivity	> 98 %
---------------------------	--------

QRS detection predictability	> 98 %
------------------------------	--------

Stress level analyzer (HRV)

Number of R-R intervals which have to be measured is variable	≥40
SPO2	
Oxygen saturation range:	70 to 100 %
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
SPO2 Accuracy	Root Mean Square (RMS) error: 3.5%
Body Fat Analysis	
Body fat accuracy percentage	15 % relative to Caliper measurement
IR Thermometer	
Body temperature	34 to 41 °C
Ambient temperature	Body temperature measurement should be performed within an ambient temperature range of 22-26°C
Measurement accuracy (vs. black body)	± 0.2 °C

Blood Glucose Monitoring System	
Enzyme Type	GDH-FAD
Sample Size	0.7 μ L
Reaction Time	7 seconds
Haematocrit Range	20-60% (35-55)
Blood Detect	No Blood Detect mechanism
AST - Alternative Site Testing	Yes AST
Applicable Sample Type	Capillary
Code Type	No code
Precision	$\pm 5\%$
Accuracy	$\pm 15\text{mg/dL}$ if $\geq 75\text{mg/dL}$; $\pm 20\%$ if $> 75\text{mg/dL}$
Measuring Range	20 ~ 600mg/dL (1.1 ~ 33.3mmol/L)

Declaration of RoHS Compliance

To minimize the environmental impacts and take more responsibilities to the earth we live on, this document shall serve as a formal declaration that the *LifeWatch V* manufactured by LifeWatch Technologies Ltd. complies with Directive 2011/65 /EC of the European Parliament - RoHS (Restriction of Hazardous Substances) - with respect to the following substances:

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

Disposal of Your Device



The *LifeWatch V* device is covered by the European Directive 2012/19/EC.

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.



The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.

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.

This model phone has been tested and meets the FCC RF exposure guidelines. For body worn operation, 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.

FCC Statement

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.

Appendix A Warnings and Precautions



WARNING Potential Biohazard

Healthcare professionals or persons using the *LifeWatch V* device on multiple patients should be aware of the following and should follow the infection control procedure approved by their facility.

All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

Follow your healthcare provider's recommendations for disposal of used lancets and test strips.

Warnings

Warning



- The *LifeWatch V* 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, such as ventricular tachycardia and ventricular fibrillation.
- The *LifeWatch V* 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 *LifeWatch V* is not intended for use in a hyperbaric chamber, within an oxygen tent or in the presence of flammable anesthetics / medical gases.
- To prevent fire or shock hazard, do not expose the *LifeWatch V* to moisture, liquids or condensation.
- To prevent an allergic reaction, do not use the *LifeWatch V* or accessories if you have a known allergy to nickel, silver or other metals.
- The *LifeWatch V* is not defibrillation-proof. Exposure to defibrillation may damage the *LifeWatch V*, or the *LifeWatch V* may interfere with the operation of the defibrillator.
- The user of the *LifeWatch V* should not take any actions of a medical or clinical nature based on his/her diagnosis or interpretation of the test results, without consulting a healthcare professional.
- If you experience symptoms that are not consistent with any of your test results, you should consult your healthcare provider, doctor or other appropriate medical professional.
- If you are taking medications you should consult with your healthcare professional concerning the possible effect of the medications on the test results. Seek immediate medical attention in the event of a high fever or low body temperature.
- IR emitted from this product. Do not stare at operating lamp.
- Due to the possible seriousness of the abnormal heart rhythms that can be associated with the following conditions, persons with these conditions should consult their physician before using this device:
 - Coronary heart disease

Warning



- Valvular heart disease
 - Heart transplant
 - Heart failure
 - The *LifeWatch V* device should not be used to monitor chest pain and it cannot predict or diagnose a heart attack (myocardial infarction).
 - Do not operate the *LifeWatch V* 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.
- Contraindications Glucose Model use:**
- The Blood Glucose function is not intended for the diagnosis of, or screening for, diabetes
 - The Blood Glucose function should not be used by users whose vision is impaired to the extent that their sight does not enable them to operate the device, nor by neonates or infants less than one year.
 - This system is intended to be used by a single person and should not be shared.

Precaution



- No modification of this equipment is allowed.
- The *LifeWatch V* 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 *LifeWatch V* employs cellular technology. The location of the *LifeWatch V* 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. Incorrect replacement by inadequately trained personnel would result in an unacceptable RISK.
- To avoid damage to the system, the system and accessories should be kept away from extreme heat, including placement of the *LifeWatch V* 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.
- The device is not waterproof. Do not use it or store it where liquids such as water, juice, coffee can splash.

SP02 Test

- Poor peripheral blood circulation may reduce the arterial pulsation, making it difficult to pick up a signal.

Examples: hypovolemia (state of decreased blood volume); cold; cardiac failure; arrhythmias; peripheral vascular disease; and the position of a noninvasive blood pressure cuff.

- There is no SP02 or pulse rate alarm.
- Invalid signal will generate an alarm message.
- In cases of smoke inhalation the blood absorbs COHb* having similar wavelengths of light as oxyhaemoglobin; therefore COHb* will lead to an overestimation of the actual oxygen saturation.

* Carboxyhaemoglobin (COHb)

Precaution



SP02 Test conditions

The SP02 test is sensitive to strong ambient light as well as movement. It should be performed under the following conditions:

- In the home environment or outdoors, but not in direct sunlight
- Without movement
- By day (excluding direct sunlight) or night

ECG

- The ECG waveform displayed on your device is for illustrative purposes and should not be interpreted by you as an indication of your actual clinical condition; do not take any actions of a medical nature based on the display of the ECG waveform.

Glucose Test

- Use only the supplied or recommended glucose strips.
- Glucose strips are for single use only; dispose of used strips as per glucose strip instructions.
- Perform control-solution tests for any new vial or if “abnormal” results are shown.

Perform disinfection after using the *LifeWatch V* glucose meter following the instructions on the Cleaning & Disinfecting section.

ECG/HR/BFA/Stress Level test

- ECG signal analysis is only performed to service subscribers.
- Fingers in contact with electrodes must be clean and free from obstructions in order to have proper contact.
-

	Thermometer • Clean thermometer to allow proper readings. • Clean the thermometer lens with a lint free dry cloth. • Do not use the thermometer shortly after exercising, bathing or coming indoors. • Do not use the thermometer on children under 1 year of age. • Do not rely only on the temperature reading of children if there are health concerns; in such cases parents should seek medical advice. • Consult your healthcare provider, doctor or other appropriate medical professional if or when using drug therapies that may raise the forehead temperature
	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.

Radio Frequency (RF) Exposure (Precautions)

General Statement on RF Energy

Your phone contains a transmitter and a receiver. When it is ON, it receives and transmits RF energy. When you communicate with your phone, the system handling your call controls the power level at which your phone transmits.

EMI Considerations

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

Limiting Exposure to Radio Frequency (RF) Fields (Precautions)

For individuals concerned with limiting their exposure to RF fields, the World Health Organization (WHO) provides the following advice:

Precautionary measures: Present scientific information does not indicate the need for any special precautions for the use of mobile phones. If individuals are concerned, they might choose to limit their own or their children's RF exposure by limiting the length of calls, or using 'hands-free' devices to keep mobile phones away from the head and body when using the *LifeWatch V* device as a cell phone.

Further information on this subject can be obtained from the WHO home page <http://www.who.int/peh-emf> (WHO Fact sheet 193: June 2011).

NOTE: During medical tests the RF function is turned off.

Distraction

Driving (Precautions)

Using the device as a phone or medical device while driving (even with a hands free kit) can cause distraction and lead to an accident. You must comply with local laws and regulations restricting the use of wireless devices while driving.

Operating Machinery (Precautions)

Full attention must be given to operating machinery in order to reduce the risk of an accident.

Product Handling (Precautions)

General Statement on Handling and Use

Please switch the device off whenever the use of a phone is prohibited. Use of your phone is subject to safety measures designed to protect users and their environment.

- ◆ Always treat your device and its accessories with care and keep it in a clean and dust-free place.
- ◆ Do not expose your device or its accessories to open flames or lit tobacco products.
- ◆ Do not expose your device or its accessories to liquid, moisture or high humidity.
- ◆ Do not drop, throw or try to bend your device or its accessories.
- ◆ Do not use harsh chemicals, cleaning solvents, or aerosols to clean the device or its accessories.
- ◆ Do not paint your phone or its accessories.
- ◆ Do not attempt to disassemble your phone or its accessories, only authorized personnel can do so.
- ◆ Do not expose your device or its accessories to extreme temperatures.
- ◆ Please check local regulations for disposal of electronic products.
- ◆ Do not carry your device in your back pocket as it could break when you sit down.

Children

Do not leave your device and its accessories within the reach of small children or allow them to play with it. They can hurt themselves or others, or they can accidentally damage the device.

Your device contains small parts with sharp edges that can cause an injury or may become detached and create a choking hazard.

Demagnetization

To avoid the risk of demagnetization, do not allow electronic devices or magnetic media close to your device for a long period of time.

Electrostatic Discharge (ESD)

Do not touch the metal connectors of the SIM card.

Antenna

Do not touch the internal antenna.

Normal Use Position

When placing or receiving a phone call, hold your phone to your ear, with the bottom towards your mouth.

Air Bags

Do not place a phone in the area over an air bag or in the air bag deployment area as an airbag inflates with great force and serious injury could result.

Store the phone safely before driving your vehicle.

Seizures/Blackouts

The phone can produce a bright or flashing light. A small percentage of people may be susceptible to blackouts or seizures (even if they have never had one before) when exposed to flashing lights or light patterns such as when playing games or watching video. If you have experienced seizures or blackouts or have a family history of such occurrences, please consult a physician.

Repetitive Strain Injuries

To minimize the risk of Repetitive Strain Injury (RSI) when texting or playing games with your device:

- ◆ Do not grip the device too tightly.
- ◆ Press the buttons lightly.
- ◆ Use the special features which are designed to minimize the times of pressing buttons, such as Message Templates and Predictive Text.
- ◆ Take occasional breaks to stretch and relax.

Emergency Calls

This phone, like any wireless phone, operates using radio signals, which cannot guarantee connection under all conditions; therefore, you must never rely solely on any wireless phone for emergency communications.

Loud Noise

This phone is capable of producing loud noises, which may damage your hearing. Turn down the volume before using headphones, Bluetooth stereo headsets or other audio devices.

Phone Heating

Your phone may become warm during charging and during normal use.

Electrical Safety (Precautions)

Accessories

Use only approved accessories. Do not connect with incompatible products or accessories. Take care not to touch or allow metal objects, such as coins or key rings, to contact or short-circuit in the battery terminals.

Connection to a Car

Seek professional advice when connecting a phone interface to the vehicle electrical system.

Faulty and Damaged Products

Do not attempt to disassemble the phone or its accessories.

Only qualified personnel are allowed to service or repair the device or its accessories. If your device or its accessories were submerged in water, punctured, or subjected to a severe fall, then do not use the device or its accessories until they have been checked at an authorized service center.

General Statement on Interference

The precautions listed below must be taken when using the phone in close proximity to personal medical devices, such as pacemakers and hearing aids.

Pacemakers

Pacemaker manufacturers recommend that a minimum separation of 15 cm be maintained between a mobile phone and a pacemaker to avoid potential interference with the pacemaker. To achieve this, use the phone on the opposite ear to your pacemaker and do not carry it in a breast pocket.

Hearing Aids

People with hearing aids or other cochlear implants may experience interfering noises when using wireless devices or when one is nearby.

The level of interference will depend on the type of hearing device and the distance from the source of interference, increasing the separation between them may reduce the interference. You may also consult your hearing aid manufacturer to discuss alternatives.

Use of LifeWatch V with other Medical Devices

Please consult your doctor and the device manufacturer to determine if the operation of your phone may interfere with the operation of your medical device.

Hospitals

Switch off your wireless device when requested to do so in hospitals, clinics or health care facilities. These requests are designed to prevent possible interference with sensitive medical equipment.

Aircraft

Switch off your wireless device whenever you are instructed to do so by airport or airline staff. Consult the airline staff about the use of wireless devices on board the aircraft. If your device offers a 'flight mode', this must be enabled prior to boarding an aircraft.

Interference in Cars

Please note that because of possible interference with electronic equipment, some vehicle manufacturers forbid the use of mobile phones in their vehicles unless a hands-free kit with an external antenna is included in the installation.

Explosive Environments (Precautions)

Petrol Stations and Explosive Atmospheres

In locations with potentially explosive atmospheres, obey all posted signs instructing to turn off wireless devices such as your phone or other radio equipment.

Areas with potentially explosive atmospheres include fuelling areas, below decks on boats, fuel or chemical transfer or storage facilities, areas where the air contains chemicals or particles, such as grain, dust, or metal powders.

Blasting Caps and Areas

Power off your mobile phone when in a blasting area or in areas posted power off “two-way radios” or “electronic devices” to avoid interfering with blasting operations.

Index

Basic Operation.....	19	Getting Started with the LifeWatch V	
Blood Glucose Test.....	42	Medical and Health Applications	30
Charging the Battery	25	Gluco Troubleshooting	48, 55
Control Solution Test.....	51	Health and Medical Functions	30
Device Definition	18	History	40
ECG Test	56	Home Screen.....	28
Electrical Safety	97	Icons.....	23
Explosive Environments.....	99	Important Symbols.....	5
Extended Home Screen	28	LifeWatch V Kit Contents.....	3
First Time Launch	31	Limiting Exposure to Radio Frequency....	94
General Safety	19	Product Handling	95
Getting Around Your Phone	27	Quick Connect Login Screen.....	32
Getting Started.....	21	Radio Frequency (RF) Exposure	93
		Start Screen.....	33

Starting up	24
Switching Your Phone On/Off.....	26
Test Results	38
Test Results Icons.....	39

Test Screens Description.....	35
Test Wheel Icons	37
Touch Control	27