Vitals360

Improving Efficiency

Actual Size

USER MANUAL

World's First Mobile Medical Multi-Diagnostic Connected Instrument

Device

GPS,Time, Data Location stamped for each event

Vitals360 Medical Device under FDA 510K

The device was designed, developed and manufactured in accordance with a quality system compliant with ISO13485 standards, which meets the quality requirements of U.S. and international regulatory agencies in the healthcare industry.

Low Energy Bluetooth:
Indicates a connection with other medical devices such as a weight scale.

Wifi Connection:
Indicates a connection has been established to a public or private WIFI network.

4GLTE Connection:
Utilizing redundant,private connections between the wireless carriers and the Vital360 platform.

Connect seamlessly across 550+ carriers,180+ countries,and 2G/3G/4G/LTE/CAT-M technologies.

Security:

1.Automatic device fire-walling and advanced session authentication.

2.Vitals360 transmits data using 256-bit Advanced Encryption Standard and HTTPS for sending information securely using the internet.

3.4GLTE Cellular connectivity is inherently more secure than public WIFI for transmitting data. Instead of receiving a signal from an Internet Service Provider, it receives and sends data through the cellular company the same way it receives a mobile phone connection.

4G LTE SIM Card

Vitals360 User Manual

HIPAA compliant storage & interoperability cloud

The Vitals360 Platform offers a complete wireless healthcare solution that can elegantly and reliably capture and deliver data from the “point-of-care” and deliver it to other clinical information systems such as Electronic Health Records utilizing a secure, HIPAA compliant cloud solution.

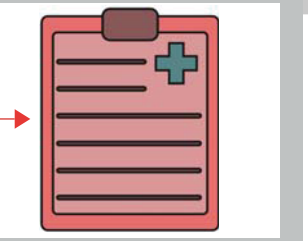
How Does the Vitals360 Platform Work?

Data Acquisition: The patient’s physiological measurements are obtained directly from the Vitals360 device hub combo, which is a cellular-enabled device gateway that enables data transfer from the device directly to the Vitals360 Platforms data center.

Data Transmission: Once the data is acquired from the Vitals360 device, it is transmitted securely via WIFI or 4GLTE technology utilizing secure private connections between the wireless carriers and the Vitals360 Platforms data center.

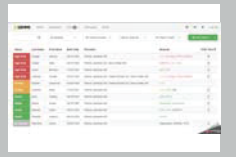
Data Storage/Access: After the Vitals360 Platform has received the patient data, it can immediately be transmitted to other clinical information systems utilizing APIs or HL7 messaging or accessed by way of the Vitals360 Platform provider and patient portals. The tools in our SOC 2 data center proactively monitor and manage the network to insure a high degree of security and reliability. FDA listed as a Class 1 Medical Device Data System (MDDS).

Platform



Chronic Disease Management Portals offered by GEMMS

Provider Portal



Patient Portal

Secure and Robust

- AES encryption of data in transmission and rest.
- Transmission via SSL/https.
- Private Cellular Carrier Network(Private APN).Data
- centers compliant for PCI DSS and HIPAA security Rule.
- Off-site backup network operation centers designed for a high degree of security.
- Planned Disaster Recovery Geo Separation.

The Vitals360 is the WORLD FIRST device that can be used in both Point-of-Care and Remote Patient Monitoring settings.

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The Vitals360 is the WORLD FIRST professional grade mobile medical device with ALL the features listed below:

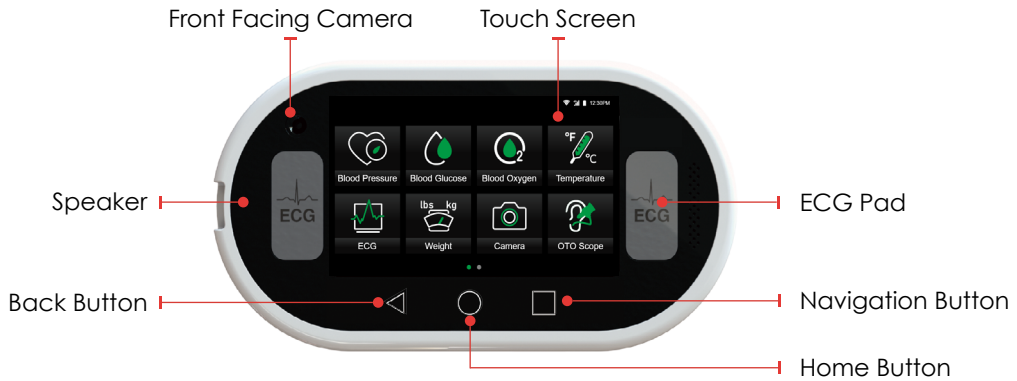
1. Measures: Blood Pressure, Blood Oxygen, Blood Glucose, Temperature, ECG, Heart Rate, Pulse;
2. Bluetooth-enabled: to pair with other peripherals to measure other physiologicparameters;
3. Acts as its own hub: and automatically uploads data to the Vitals360 Cloud via 4GLTE cellular and WiFi connectivity;
4. Utilizes GPS location services to help with medical audits and to reduce fraud;
5. Operates on Android OS and exclusively utilizes the Qualcomm Gobi chip which enables the Vitals360® to connect with most wireless carriers.

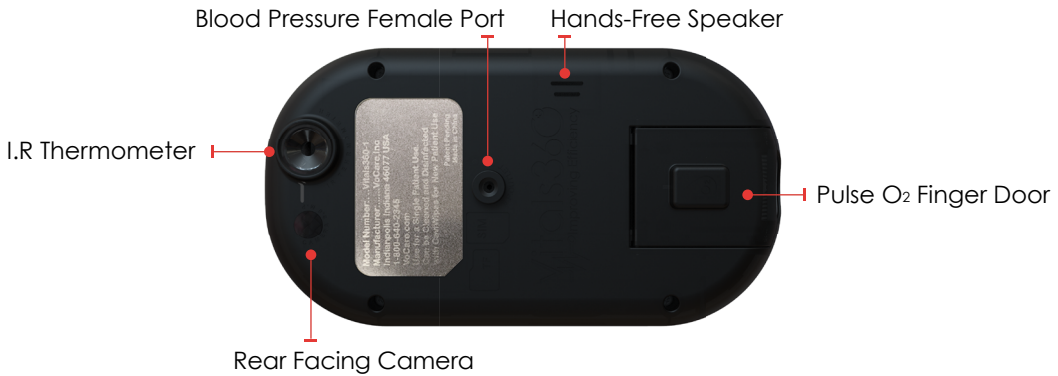
Vitals360® has the lowest cost of deployment and is the easiest for clinicians and patients to use.

Patents Pending.

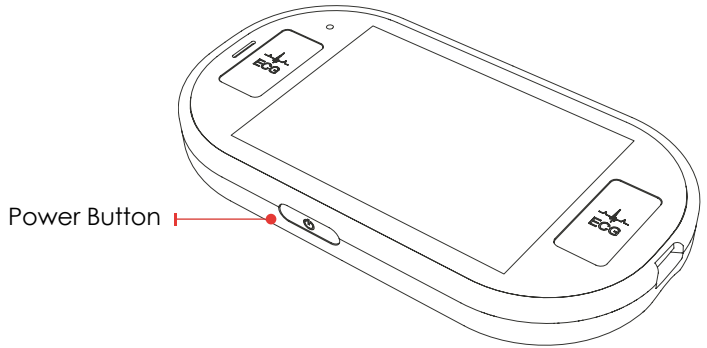
1 Vitals360 Overview

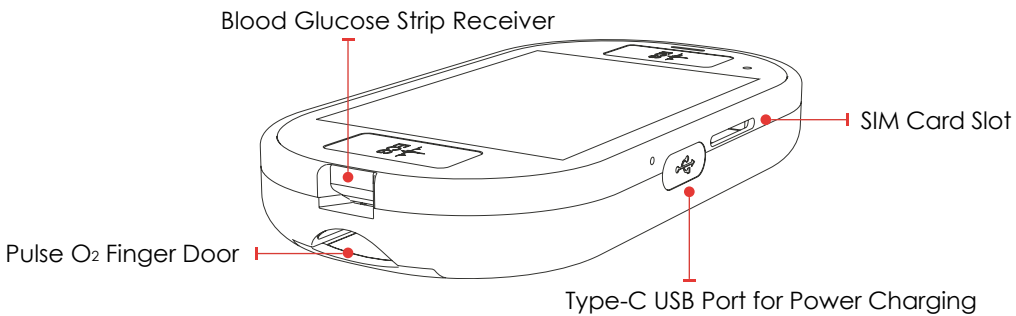
1.1 Device Overview





Vitals360 Improving Efficiency





1.2 Tech Specs

Volume	Approximately 145mm*80mm*25mm
CPU	Qualcomm MSM8909
GPU	Adlreno 306
RAM	1G
ROM	8G
Working Frequency Rate	US FDD:Band 2,4,5,12,13,17 WCDMA:Band 1,2,4,5 SA WCDMA:Band 1,2,5,8 EU WCDMA:Band 1,2,5,8 CN WCDMA:Band 1,2,5,8

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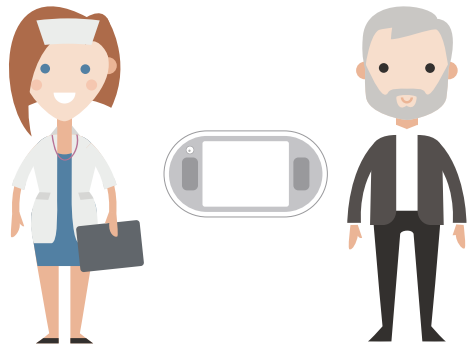
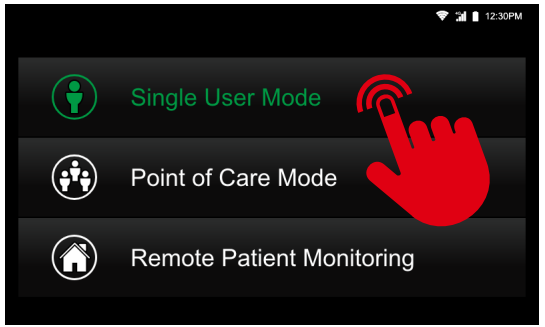
Screen Resolution	800*480 IPS
Wi-Fi	802.11 b/g/n (2.4G Support)
Bluetooth	BT4.0
Battery	1500mAh Li-ion Battery
Front Camera	2MP
Back Camera	5MP
USB Port	Type-C
SIM(Optional)	Nano SIM
GPS	Yes
MIC	Yes
Speaker	Yes

2 Diagnostic Overview

2.1 Modes of Operation

Single User Mode





This mode mimics standard medical devices. The Vital360 can be used without patient registration, as a convenient multi-diagnostic device for spot checking patient vital signs.

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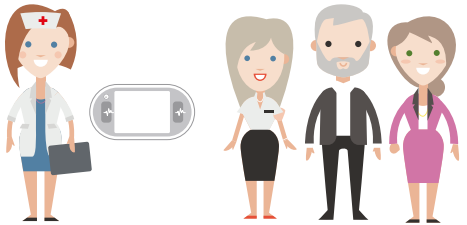
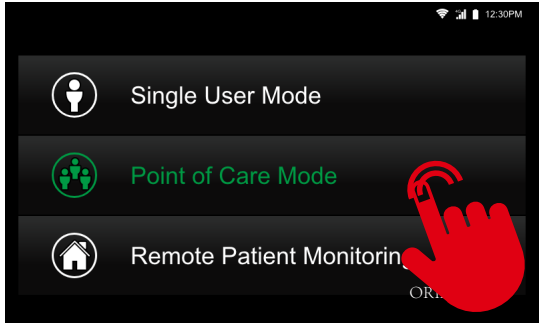
Point of Care Mode





The highly efficient mobile point-of-care mode allows nurses and other healthcare professionals to document patient vital signs directly into other clinical information systems by way of the Vitals360 Cloud.

This mode can be used by a mobile healthcare provider workforce caring for multiple patients. The Vitals360 can replace multiple medical devices, making it ideal for care both inside or outside a healthcare facility.

Other medical devices require the manual entry of data, but when utilizing the Vitals 360 device and the Vitals360 Cloud, patient information can seamlessly flow to any clinical information system that can receive the information.

Additionally, the Vitals360 has GPS location and time-stamping which provides a detailed audit log that can be used should a Medicare audit occur.

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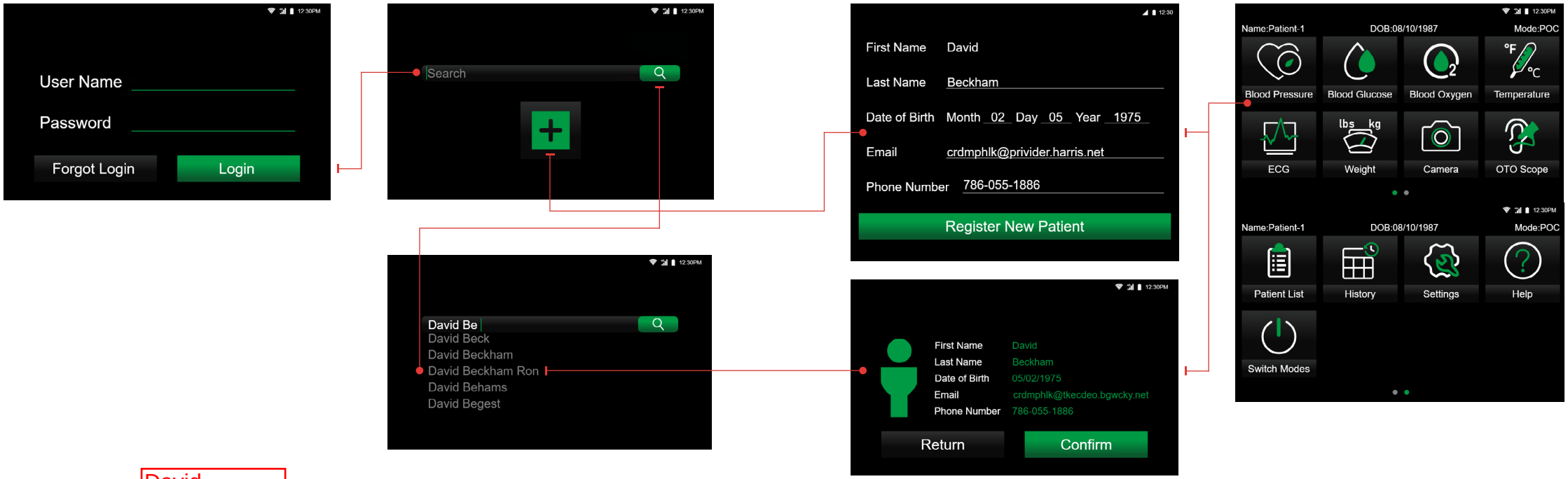
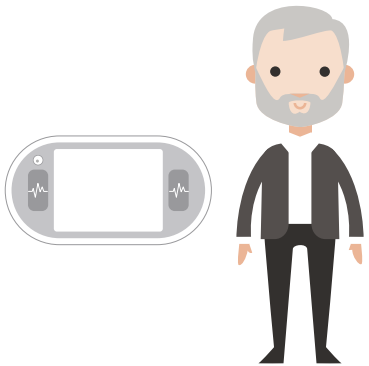
Point of Care Mode (cont)



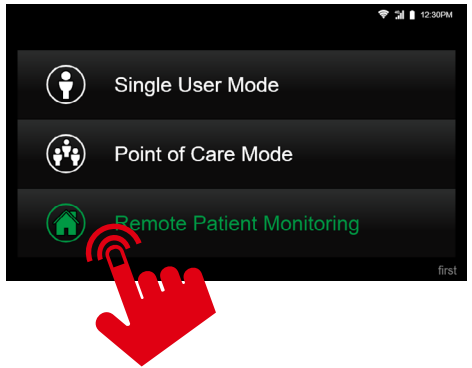
David beckham

After logging into Point of Care mode, you can search for the patient that you are seeing. Once the correct patient is selected,you can view their demographic details by selecting “Details” or register new patients and then go to the test selection screen.

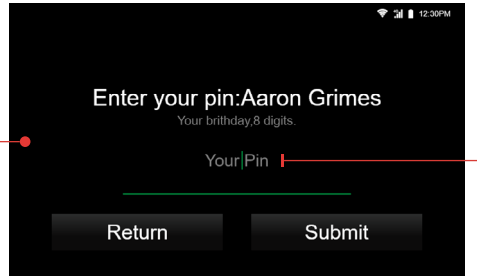
Remote Patient Monitoring

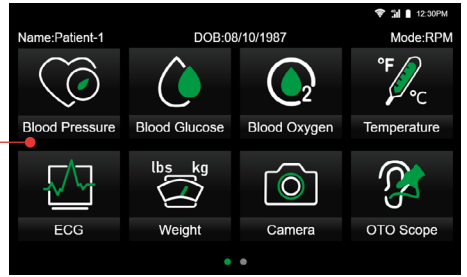


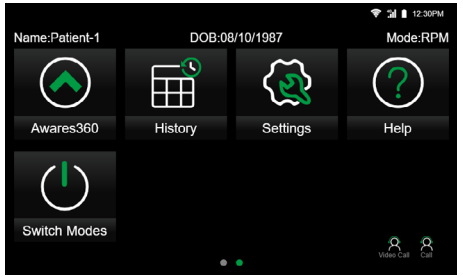
This mode is a daily remote monitoring tool for a single patient. The Vitals360 is easy for any patient to use and remotely provides a picture of a patient's overall health. Patients no longer need to keep track of multiple devices, nor do they have to perform cumbersome manual logging of their vital information.



This highly efficient mobile Remote Patient Monitoring m(RPM) diagnostic device has the lowest cost of deployment when compared to other mRPM solutions. Moreover, it easily integrates with a variety of today's best remote patient monitoring solutions and clinical information systems by way of the Vitals360 Cloud.



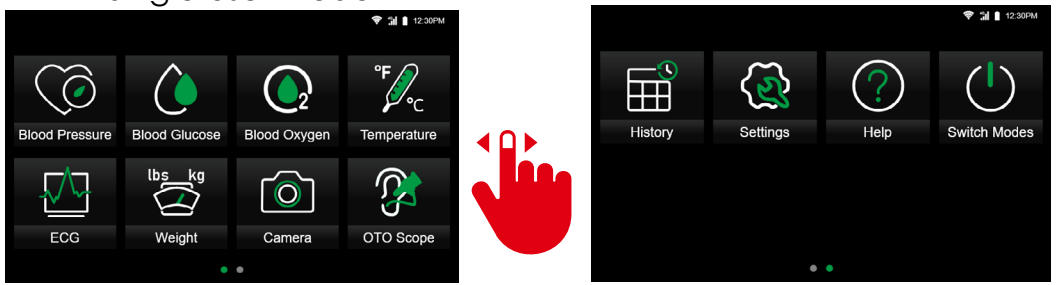




After logging intoRemote Patient Monitoring mode,you can go directly to the testselection screen.

3.1 Menus

Single User Mode



Main Functions

- Blood Pressure
- Blood Glucose
- Blood Oxygen
- Temperature
- Heart Rate
- ECG
- Weight
- Camera
- OTO Scope

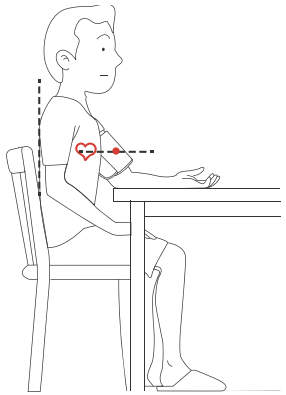
Device Navigation

- Home
- Back
- Setting
- History
- Help
- Settings
- Swith Modes

Blood Pressure 4.1

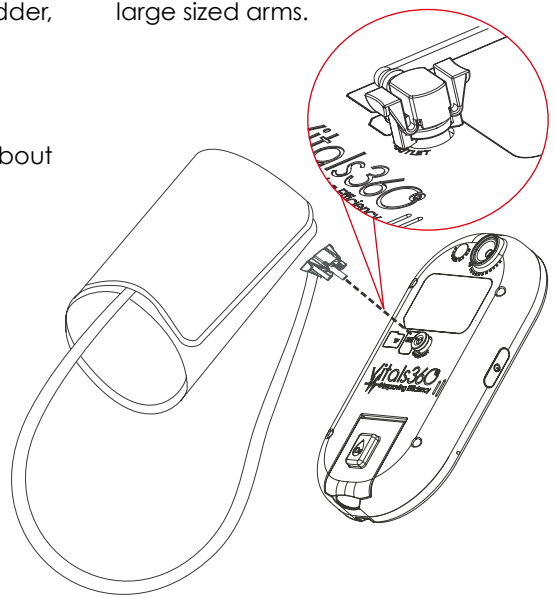
Certain conditions can cause blood pressure to spike temporarily. To get an accurate measurement, you should avoid these conditions before taking your blood pressure. Factors that can affect blood pressure include: stress, smoking, exercise, cold temperatures, a full stomach, a full bladder, caffeine, and some medications.

Sit in a chair next to a table.
Rest your left forearm on the table.
Position your left arm so that it rests at about heart level.
Keep the palm of your hand facing up.



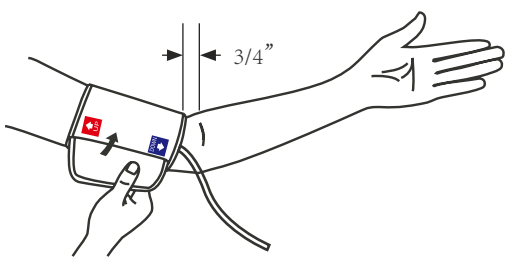
Connect your blood pressure cuff to your Vitals360 device as showen below.

The pre-formed arm cuff expands to fitboth regular and large sized arms.

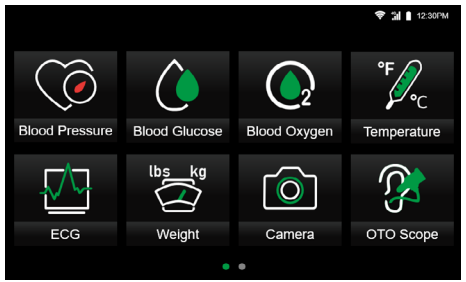


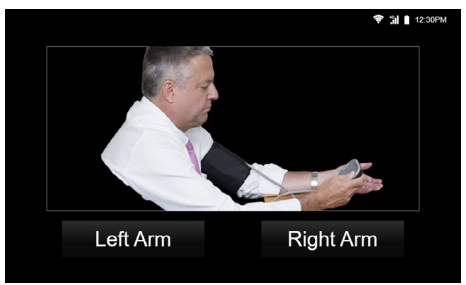
Blood Pressure (cont)

1.Stay relaxed and rest at least 5 minutes before your blood pressure measurement. Remove clothing from your arm or wear thin clothing when measuring your blood pressure.
2.Connect the blood pressure cuff to the Vitals360 device. Next, place the cuff onto your arm making sure that the bottom edge of the cuff is 3/4 inches above the elbow; loosen or tighten the cuff until it is comfortable.
3. Sit with your back straight and supported, your feet flat on the floor, and your legs should not be crossed. Stay still and place the measuring arm on a table, palm-side up and relax so that the middle of the cuff is at the same level as your heart.



4. Select the Blood Pressure icon on your device screen and then select whether you are taking you blood pressure using you right or left arm.





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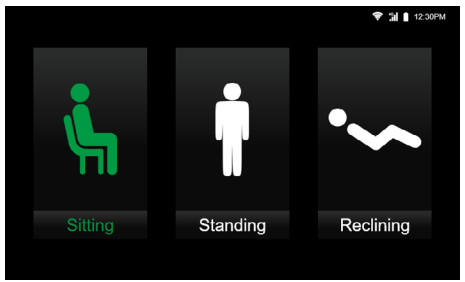
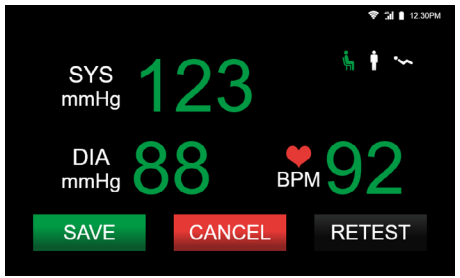
5. On the next screen choose the icon that best matches the position you will be in while taking your blood pressure.



6. On the next screen select “Start” to begin measurement. Keep relaxed while your blood pressure is being measured.

7. Select “Save” to keep the results or “Cancel” to restart the test. Take off the cuff when you’re finished.



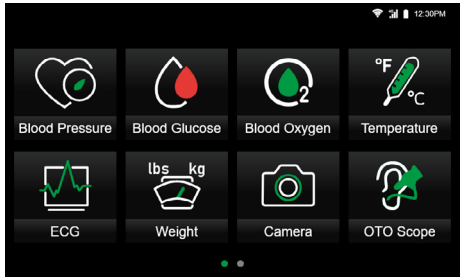
图表美观

Troubleshooting

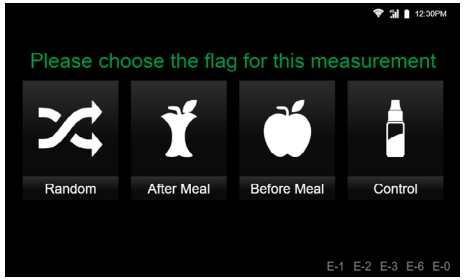
Problem	Possible Cause	Solution
Abnormal result (too low value)	Incorrect cuff position or body posture. Speaking or moving during test.	Review position, posture and repeat test remaining relaxed.
Unable to inflate	Cuff leakage or incorrect device placement	Review device position, replace cuff if damaged (contact manufacturer)
Unable to test	Incorrect device placement or low battery	Check if monitor is placed correctly and check battery.

Blood Glucose (cont)

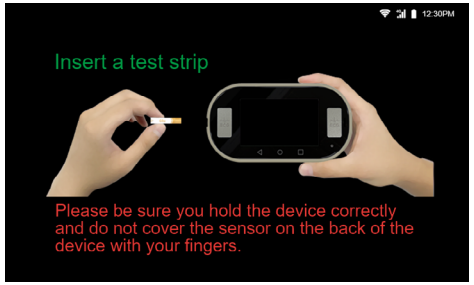
Wash your hands with soap and water before touching test strips and lancing device



1. Select Blood Glucose from the Vitals360 main menu.

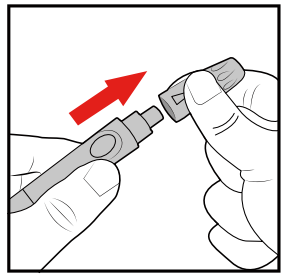


2. Select whether you are testing your glucose before or after a meal.

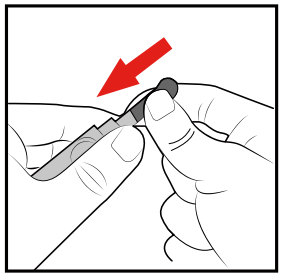


3. Insert the test strip (sold separately) into the strip receiver (see page 5 to locate).

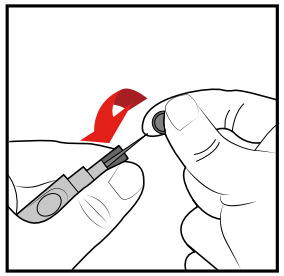
4. Prepare the lancing device:



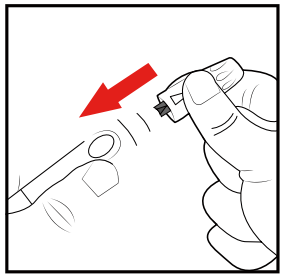
Pull off the cap of the lancing device.



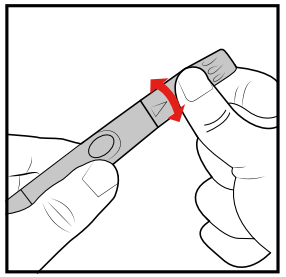
Insert a lancet and push down until it's secured.



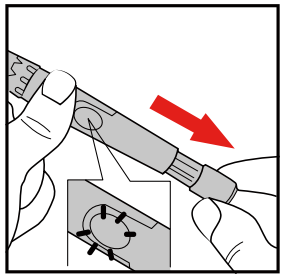
Twist the protective disk of the lancet.



Replace the cap by aligning the arrow with the release button.



Select the depth of penetration by turning the adjustable tip.



Pull the cocking control back until it clicks. You will see a color change in side the release button when it's ready.

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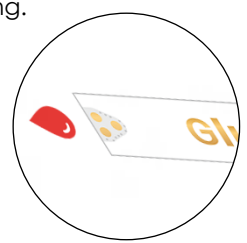
IMPORTANT: Apply sample only to the sample tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.

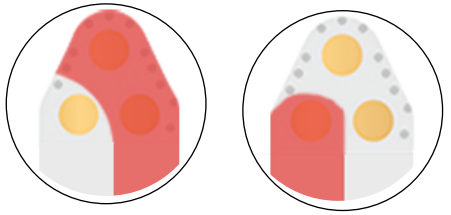


Correct

Incorrect

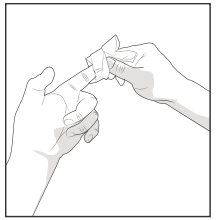
Hold the blood drop to the sample tip of the test strip until the check window is completely full and until the meter begins to count down.If the check window dose not fill, do not add more blood to the test strip. You may get an E-5 message or an countdown but check window does not fill, discard the strip and begin the test again with a fresh test strip.

Correct

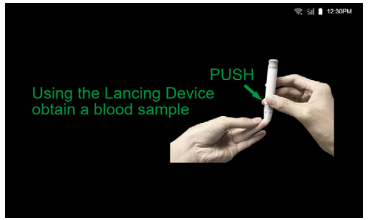


Incorrect

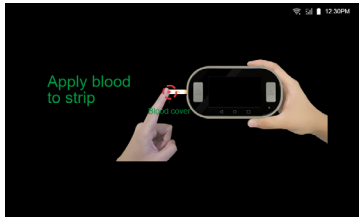
5. Test your blood glucose



Clean your finger.

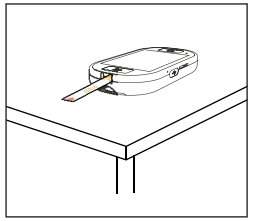


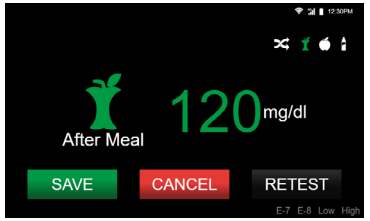
Hold the lancing device firmly against the finger and press the release button.



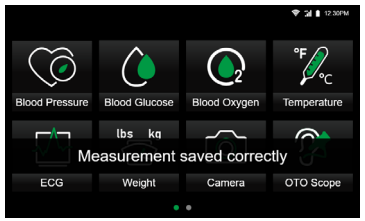
Touch the test strip with he drop of blood until the window is filled.

CAUTION: Please flatwise the device on the table and screen on top when blood glucose measuring to get best measurement result.





6. Select “Save” to keep the results or “Cancel” to restart the test.



7. Select YES to re-test or NO to return to the main menu.

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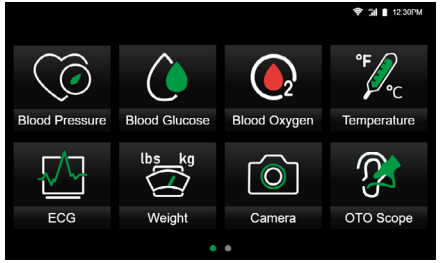
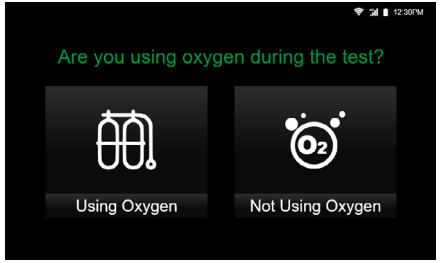
Blood Oxygen and Pulse 4.3

The pulse oximeter function measures your blood oxygen content (SpO2) and pulse rate.

SpO2 is a measurement of how much oxygen the red blood cells in the body's arteries are carrying.



1. Select Blood Oxygen on the main menu.



2. If you are using oxygen atthe time of the test choose button of“Using Oxygen”, If you are not usingoxygen at the time of the test choosebutton of “Not Using Oxygen”